



Australian Government
Department of Health
 Therapeutic Goods Administration

Akula Foods
 1/65 Eastern Road
 Browns Plains QLD 4118

Our reference: RC-010401

Dear Akula Foods,

Importation and Supply of Unregistered Therapeutic Goods

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health (Department) and is responsible for monitoring, and enforcing where necessary, compliance with the legislation, regulations and rules for therapeutic goods including import, manufacture, advertising and supply.

Therapeutic goods, including traditional and over the counter medicines, must not be imported, supplied or advertised in Australia, unless they are included in the Australian Register of Therapeutic Goods (ARTG) or are otherwise the subject of a relevant exemption, approval or authority under the *Therapeutic Goods Act 1989* (the Act).

Australian Border Force (ABF) has held a parcel, and informed us that you are attempting to import the following therapeutic goods into Australia:

- s47 [REDACTED]
 - [REDACTED] falls within the Australia New Zealand Food Standards Code – Schedule 23 – Prohibited plants and fungi.
 - s47 [REDACTED] is a Schedule 4 Prescription only medicine.

The goods you have attempted to import are *therapeutic goods*, as defined in the *Therapeutic Goods Act 1989* (the Act).

It is an offence under section 19B of the Act to import therapeutic goods without the relevant registration, listing, approval, authority or exemption. In addition, civil penalties can be imposed for the importation of such goods under section 19D of the Act.

The personal importation exemption may apply to allow you to import these products. To be eligible for this exemption, required evidence as specified in Item 1 of Schedule 5 of the *Therapeutic Goods Regulations 1990* must be provided.

However, the Personal Importation Scheme is unlikely to apply in this circumstance as there is a potential that if these goods are received, you may unlawfully supply these goods as the volume is significantly more than a personal supply.

You should be aware that in Australia these products require entry in the Australian Register of Therapeutic Goods (ARTG) prior to import, export, manufacture or supply for human therapeutic use.

Our records indicate that neither you nor your business have not registered these products in the Australian Register of Therapeutic Goods (ARTG).

What you need to do

You are required to provide further information regarding the practices of your company, including:

- If your company believes it should be exempt from the registration process, information on why this is believed to be the case
- Details of the supply process from the initial order and how it is received, through to delivery of the end product for administration
- Any other information that you feel may be relevant to assist us in making a decision regarding if your products should be included on the ARTG or exempt from regulation by the TGA.
- Evidence correspondence of your company cancelling this order.

You are also required to immediately cease all importation, advertising and supply of these products, together with any other unregistered or unlisted product not exempted from this requirement.

You may apply to have your goods listed on the ARTG by following instructions available at <https://www.tga.gov.au/overview-supplying-therapeutic-goods-australia> or by phoning 1800 020 653.

You are to provide written confirmation **by close of business 04 May 2022** of receipt of this letter that you are now complying with legislation relating to the importation, advertising and supply of therapeutic goods.

Any correspondence on this matter should be addressed to myself, s22 and emailed to RC@health.gov.au, or mailed to PO Box 100 Woden ACT 2606. If you need any further assistance or clarification on this matter please do not hesitate to contact me on (02) 6289 1577.

Yours sincerely

s22

Compliance Officer
Regulatory Compliance Section
Therapeutic Goods Administration
20 April 2022

What the law says

In Australia, if you import, manufacture, advertise or supply products with claims for human therapeutic use, they are classified as therapeutic goods under the *Therapeutic Goods Act 1989*.

This requires the goods to be registered on the ARTG prior to import, export, manufacture or supply for human therapeutic use.

It is an offence under section 19B of this Act for a person to import, export, supply, or manufacture therapeutic goods for use in humans unless those goods are listed or registered in the ARTG by the sponsor, or the goods are exempt or are subject of an approval or authority under Sections (18A) (19) or (19A) of the Act.

"Sponsor" includes any person who imports or manufactures therapeutic goods or arranges for their importation or manufacture, for supply to Australians.

Sponsors are subject to the requirements of the Act if they are trading corporations or, in the case of individuals and corporations generally, trade goods between Australia and another country or among States within Australia.

Offences carry a maximum penalty upon conviction of imprisonment for 5 years or a fine of \$840,000 or both for an individual, or a fine of \$4,200,000 for a body corporate in respect of each offence. Offences may also be subject to civil penalties that can attract maximum fines of \$1,050,000 for an individual and \$10,500,000 for a body corporate.

It is also an offence under Section 42DL of the Act for a person to publish or broadcast an advertisement about therapeutic goods, or the supply of those goods, if they are not entered in the ARTG. If convicted by a court for criminal advertising offences (including failure to comply with a direction), it can impose penalties of up to 5 years imprisonment, 4,000 penalty units, or both.

It is an offence under Sections 41MA, 41MD, 41MI, 41MK, and 41MM of the Act, for a person to import, export, supply or manufacture medical devices not included in the register or not complying with essential principles. Offences can carry a maximum penalty upon conviction of 5 years imprisonment or 4,000 penalty units, or both.

Where civil action is pursued, a court can impose maximum penalties of 5,000 penalty units for an individual or 50,000 penalty units for a body corporate. Multiple advertising offences may be pursued.

The value of a penalty unit is currently \$210 as set out in section 4AA of the Crimes Act 1914.

Further information

- Further information regarding advertising and endorsements can be found on the TGA website at <https://www.tga.gov.au/book-page/advertising-and-endorsements>.
- The *Therapeutic Goods Act 1989*, *Therapeutic Goods Regulation 1990* and *Poisons Act* are available at www.legislation.gov.au
- TGA guidance on the Excluded Goods Order is available at <http://www.tga.gov.au/industry/legislation-excluded-goods-order-1101-guidance-4opqr.htm>.



Australian Government
Department of Health
 Therapeutic Goods Administration

Akula Foods
 1/65 Eastern Road
 Browns Plains QLD 4118

Our reference: RC-008537

Dear Akula Foods,

Importation and Supply of Unregistered Therapeutic Goods

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health (Department) and is responsible for monitoring, and enforcing where necessary, compliance with the legislation, regulations and rules for therapeutic goods including import, manufacture, advertising and supply.

Therapeutic goods, including traditional and over the counter medicines, must not be imported, supplied or advertised in Australia, unless they are included in the Australian Register of Therapeutic Goods (ARTG) or are otherwise the subject of a relevant exemption, approval or authority under the *Therapeutic Goods Act 1989* (the Act).

Australian Border Force (ABF) has held a parcel, and informed us that you are attempting to import the following therapeutic goods into Australia:

- [s47](#) [REDACTED]
 [REDACTED] falls within the Australia New Zealand Food Standards Code – Schedule 23 – Prohibited plants and fungi.
 - [s47](#) [REDACTED], is a Schedule 4 Prescription only medicine.

The goods you have attempted to import are *therapeutic goods*, as defined in the *Therapeutic Goods Act 1989* (the Act).

It is an offence under section 19B of the Act to import therapeutic goods without the relevant registration, listing, approval, authority or exemption. In addition, civil penalties can be imposed for the importation of such goods under section 19D of the Act.

The personal importation exemption may apply to allow you to import these products. To be eligible for this exemption, required evidence as specified in Item 1 of Schedule 5 of the *Therapeutic Goods Regulations 1990* must be provided.

However, the Personal Importation Scheme is unlikely to apply in this circumstance as there is a potential that if these goods are received, you may unlawfully supply these goods as the volume is significantly more than a personal supply.

You should be aware that in Australia these products require entry in the Australian Register of Therapeutic Goods (ARTG) prior to import, export, manufacture or supply for human therapeutic use.

Our records indicate that neither you nor your business have not registered these products in the Australian Register of Therapeutic Goods (ARTG).

What you need to do

You are required to provide further information regarding the practices of your company, including:

- If your company believes it should be exempt from the registration process, information on why this is believed to be the case
- Details of the supply process from the initial order and how it is received, through to delivery of the end product for administration
- Any other information that you feel may be relevant to assist us in making a decision regarding if your products should be included on the ARTG or exempt from regulation by the TGA.

You are also required to immediately cease all importation, advertising and supply of these products, together with any other unregistered or unlisted product not exempted from this requirement.

You may apply to have your goods listed on the ARTG by following instructions available at <https://www.tga.gov.au/overview-supplying-therapeutic-goods-australia> or by phoning 1800 020 653.

You are to provide written confirmation **by close of business 03 February 2022** of receipt of this letter that you are now complying with legislation relating to the importation, advertising and supply of therapeutic goods.

Any correspondence on this matter should be addressed to myself, s22 and emailed to RC@health.gov.au, or mailed to PO Box 100 Woden ACT 2606. If you need any further assistance or clarification on this matter please do not hesitate to contact me on (02) 6289 1577.

Yours sincerely

s22

Compliance Officer
Regulatory Compliance Section
Therapeutic Goods Administration
20 January 2022

What the law says

In Australia, if you import, manufacture, advertise or supply products with claims for human therapeutic use, they are classified as therapeutic goods under the *Therapeutic Goods Act 1989*.

This requires the goods to be registered on the ARTG prior to import, export, manufacture or supply for human therapeutic use.

It is an offence under section 19B of this Act for a person to import, export, supply, or manufacture therapeutic goods for use in humans unless those goods are listed or registered in the ARTG by the sponsor, or the goods are exempt or are subject of an approval or authority under Sections (18A) (19) or (19A) of the Act.

"Sponsor" includes any person who imports or manufactures therapeutic goods or arranges for their importation or manufacture, for supply to Australians.

Sponsors are subject to the requirements of the Act if they are trading corporations or, in the case of individuals and corporations generally, trade goods between Australia and another country or among States within Australia.

Offences carry a maximum penalty upon conviction of imprisonment for 5 years or a fine of \$840,000 or both for an individual, or a fine of \$4,200,000 for a body corporate in respect of each offence. Offences may also be subject to civil penalties that can attract maximum fines of \$1,050,000 for an individual and \$10,500,000 for a body corporate.

It is also an offence under Section 42DL of the Act for a person to publish or broadcast an advertisement about therapeutic goods, or the supply of those goods, if they are not entered in the ARTG. If convicted by a court for criminal advertising offences (including failure to comply with a direction), it can impose penalties of up to 5 years imprisonment, 4,000 penalty units, or both.

It is an offence under Sections 41MA, 41MD, 41MI, 41MK, and 41MM of the Act, for a person to import, export, supply or manufacture medical devices not included in the register or not complying with essential principles. Offences can carry a maximum penalty upon conviction of 5 years imprisonment or 4,000 penalty units, or both.

Where civil action is pursued, a court can impose maximum penalties of 5,000 penalty units for an individual or 50,000 penalty units for a body corporate. Multiple advertising offences may be pursued.

The value of a penalty unit is currently \$210 as set out in section 4AA of the Crimes Act 1914.

Further information

- Further information regarding advertising and endorsements can be found on the TGA website at <https://www.tga.gov.au/book-page/advertising-and-endorsements>.
- The *Therapeutic Goods Act 1989*, *Therapeutic Goods Regulation 1990* and *Poisons Act* are available at www.legislation.gov.au
- TGA guidance on the Excluded Goods Order is available at <http://www.tga.gov.au/industry/legislation-excluded-goods-order-1101-guidance-4opqr.htm>.



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

s11C(1)(a)

Akula Foods Pty Ltd
1/64 Eastern Road
Browns Plains QLD 4118

URGENT RESPONSE NEEDED

Our reference: RC-023901

Dear s11C(1)(a)

Importation and Supply of Unregistered Therapeutic Goods

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health (Department) and is responsible for monitoring, and enforcing where necessary, compliance with the legislation, regulations and rules for therapeutic goods including import, manufacture, advertising and supply.

Therapeutic goods, including traditional and over the counter medicines, must not be imported, supplied or advertised in Australia, unless they are included in the Australian Register of Therapeutic Goods (ARTG) or are otherwise the subject of a relevant exemption, approval or authority under the *Therapeutic Goods Act 1989* (the Act).

Australian Border Force (ABF) has held a consignment, and informed us that you are attempting to import the following therapeutic goods into Australia:

Description	Each containing	Category of medicine
s47 Himalaya s47	60 tablets	Not Scheduled. Not considered by committee.
Himalaya	60 capsules	Not Scheduled. Not considered by committee.
Himalaya	60 capsules	Not Scheduled. Not considered by committee.
Himalaya	200ml syrup	Not Scheduled. Not considered by committee.
Himalaya	200ml syrup	Not Scheduled. Not considered by committee.
Himalaya	100 tablets	Not Scheduled. Not considered by committee.

The goods you have attempted to import are *therapeutic goods*, as defined in the *Therapeutic Goods Act 1989* (the Act).

It is an offence under section 19B of the Act to import therapeutic goods without the relevant registration, listing, approval, authority or exemption. In addition, civil penalties can be imposed for the importation of such goods under section 19D of the Act.

The Personal Importation Scheme is unlikely to apply in this circumstance as the importation is addressed to a company and the quantity is in excess of a personal volume.

You should be aware that in Australia these products require entry in the Australian Register of Therapeutic Goods (ARTG) prior to import, export, manufacture or supply for human therapeutic use.

Our records indicate that neither you nor your business have not registered these products in the Australian Register of Therapeutic Goods (ARTG).

You are required to provide further information, including:

- If your company believes it should be exempt from the registration process, information on why this is believed to be the case.
- Any other information that you feel may be relevant to assist us in making a decision regarding if your products should be included on the ARTG or exempt from regulation by the TGA.

Attempted Illegal Importation of Therapeutic Goods

We have been advised by Australian Border Force (ABF) that you are attempting to import **s47** tablets of the substance **Azadirachta indica (Neem)** into Australia.

This substance falls under Schedule 10 of The Poisons Standard (SUSMP), the highest Scheduling category. Schedule 10 substances are classified as having such high risk to public health that their **importation, possession, supply or use** within Australia **is illegal**.

The goods will be seized by the ABF and will be destroyed under section 229 of the Customs Act 1901. You are requested to respond to this letter **by close of business Friday 10 November 2023**, acknowledging the destruction of the goods and agreeing to cease future importation.

Given the risk and illegality of these substances you should be aware that, **should any further illegal importation attempt occur, it can result in prosecution by the Commonwealth.**

This warning letter is to put Akula Foods Pty Ltd on notice of the TGA's concerns in relation to the alleged unlawful importation of unregistered therapeutic goods and to provide the opportunity for Akula Foods Pty Ltd to provide a response for consideration. This is because the delegate is not prevented from considering enforcement action, even if Akula Foods Pty Ltd immediately ceases to engage in non-compliant importations of therapeutic goods.

Akula Foods Pty Ltd has previously come to the attention of the TGA in February 2022, for the alleged importation of unregistered therapeutic goods and the TGA considers you have been appropriately education regarding the requirements outlined by the Act.

You are required to immediately cease all importation and supply of these products, together with any other unregistered or unlisted product not exempted from this requirement.

You may apply to have your goods listed on the ARTG by following instructions available at <https://www.tga.gov.au/overview-supplying-therapeutic-goods-australia> or by phoning 1800 020 653.

You are to provide written confirmation by **close of business Friday 10 November 2023** of receipt of this letter that you are legally authorised to import (and supply) these products, or that you have ceased the import and any supply until such time as the products have been included in the ARTG for human therapeutic use.

Failure to comply with this request to **cease and desist** or continued importation, and any subsequent supply of therapeutic goods may result in the TGA pursuing further enforcement action against you. This may include issuing of infringement notices, commencing legal proceedings against you seeking payment of civil penalties in relation to the alleged unlawful conduct or referring the matter to the Commonwealth Director of Public Prosecutions for criminal prosecution.

Where applicable, the TGA may also raise the matter with, or work in conjunction with, other regulatory agencies, which may have legislative jurisdiction over such matters, such as State or Territory Police and/or State Health Regulators.

Do you need further assistance?

You may wish to seek independent legal advice or the assistance of a regulatory affairs consultant to address non-compliance with your importation, supply and/or online advertising of the goods. You can find a list of organisations that may be able to assist you in finding an adviser or consultant on the TGA website.¹ The TGA does not endorse any of the consultants on our website.

Any correspondence on this matter should be addressed to myself and emailed to RC@health.gov.au, or mailed to PO Box 100 Woden ACT 2606. If you need any further assistance or clarification on this matter, please do not hesitate to contact me on [s22](#)

Yours sincerely

[s22](#)



Compliance Officer
Therapeutic Goods Administration
03 November 2023

¹ See <https://www.tga.gov.au/regulatory-affairs-consultants>

What the law says

In Australia, if you import, manufacture, advertise or supply products with claims for human therapeutic use, they are classified as therapeutic goods under the *Therapeutic Goods Act 1989*.

This requires the goods to be registered on the ARTG prior to import, export, manufacture or supply for human therapeutic use.

It is an offence under section 19B of this Act for a person to import, export, supply, or manufacture therapeutic goods for use in humans unless those goods are listed or registered in the ARTG by the sponsor, or the goods are exempt or are subject of an approval or authority under Sections (18A) (19) or (19A) of the Act.

"Sponsor" includes persons who import or arrange for the importation of therapeutic goods, or who manufacture or arrange for another person to manufacture the goods for supply.

Sponsors are subject to the requirements of the Act if they are trading corporations or, in the case of individuals and corporations generally, trade goods between Australia and another country or among States within Australia.

The maximum penalty upon conviction is Imprisonment for 5 years or a fine of \$1,252,000 or both for an individual.

Please also note that Section 41MIB of the Act, may also subject sponsors of therapeutic goods not included in the Australian Register of Therapeutic Goods to the civil penalties provisions contained in the legislation. Contravention of a civil penalty can attract maximum fines of \$1,565,000 for individuals and \$15,650,000 for a body corporate.

Further information

- Application forms for Listing or Registration of Therapeutic Goods are available from the TGA website: <https://www.tga.gov.au/overview-supplying-therapeutic-goods-australia> or by phoning 1800 020 653
- Further information regarding advertising and endorsements can be found on the TGA website at <https://www.tga.gov.au/book-page/advertising-and-endorsements>.
- The *Therapeutic Goods Act 1989*, *Therapeutic Goods Regulation 1990* and Poisons Act are available at www.legislation.gov.au
- TGA guidance on the Excluded Goods Order is available at <http://www.tga.gov.au/industry/legislation-excluded-goods-order-1101-guidance-4opqr.htm>.

From: s22
To:
Subject: FW: Matter RC-023901 - ASIC On-File Report Current - AKULA FOODS PTY LTD ABN 65 611 490 549 [SEC=OFFICIAL]
Date: Tuesday, 21 November 2023 11:06:54 AM
Attachments: [RC-023901 - ASIC On-File Report Current - AKULA FOODS PTY LTD ABN 65 611 490 549.pdf](#)

From: InfoTrack <helpdesk@infotrack.com.au>
Sent: Tuesday, 21 November 2023 10:48 AM
To: s22 @health.gov.au
Subject: Matter RC-023901 - ASIC On-File Report Current - AKULA FOODS PTY LTD ABN 65 611 490 549

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Orders included in attachment

Reference	Date Ordered	Description	Status
RC-023901	21/11/2023 10:46:52 AM	ASIC: On-File Report Current - AKULA FOODS PTY LTD ABN 65 611 490 549	Complete

S PTY LTD

65 Eastern Rd
Browns Plains, Queensland



Street View & 360°





ARTG Search Visualisation Tool

[Back to tga.gov.au](#)

[Glossary](#)



[Refresh Page](#)

Search by AUST L/R, ARTG ID, Product, Sponsor, Manufacturer of Medical devices and OTGs, Active Ingredient or Excipient

Search Results (0 ARTG entries)

Hover here to see more options (export data, full-page table, etc.) →

ID	Product Name	Sponsor Name	Manufacturer Name (Devices or OTGs)	Public Summary	Product Info	Consumer/ Patient Info	Active Ingredient
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From: s22
To: [REDACTED]
Subject: RTS signed post [SEC=OFFICIAL]
Date: Wednesday, 13 March 2024 12:18:35 PM
Attachments: [SKM-C45824031308490.pdf](#)
[image001.png](#)

Hi s22

Please see hilariously bad scan of an RTS-signed post slip.

s22

s22

Compliance Officer – Product and Import Compliance

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Compliance Branch

Therapeutic Goods Administration
Australian Government Department of Health & Aged Care
T: s22 | E: s22@health.gov.au
Location: 27 Scherger Drive Canberra Airport, ACT 2609
TGA Building Level 2 North
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.



Registered Post



FACT SHEET Therapeutic Goods

Delivery Confirmation – Advice Receipt

Official use RPP44 63700 51000 44436 92602	Sender's Reference RC-023901	AF
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Receipt is acknowledged of the Registered Post item, the number of which appears above.

Sign Here Signature of Addressee* or Agent **s22**

*Registered parcels sent by air to a person must be signed by the addressee only. **s22**

Signature of the Recipient **s22**

Date delivered **11/3/24** **s22**

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- where possible, you keep the medicines or medical devices in their original packaging with any dispensing labels intact
- the goods are not restricted under Australian Border Force controls or quarantine rules and the goods do not contain a controlled substance

You can find out more at www.tga.gov.au/personal-importation-scheme or by calling the TGA on 1800 020 653.

How much can I import under the Personal Importation Scheme?

Under the personal importation scheme, you can import up to 3 months supply of a therapeutic good at any one time and up to a maximum of 15 months supply in a 12 month period. This is calculated according to the maximum daily dose recommended by the manufacturer.

Are imported therapeutic goods safe?

Imported therapeutic goods may be unsafe or may be of poorer quality than those available in Australia. We do not recommend that you buy therapeutic goods online from overseas websites as they can be harmful to your health.

If you still decide to order therapeutic goods (including dietary supplements and herbal preparations) online, you need to know exactly what is in the preparation and ensure you have checked the customs, quarantine and TGA requirements for importation and use in Australia.

You also need to be aware that the TGA has no control over advertising of therapeutic goods on overseas websites, so these have a high chance of:

- being counterfeit (fake)

When importing these goods, you must be prepared to take this risk for yourself and your family.

If we become aware of unsafe goods being available in Australia, we publish safety alerts and issue product recalls, available at www.tga.gov.au/safety-information-consumers

What are the consequences if I import therapeutic goods unlawfully?

If you do not provide evidence that the importation is lawful, your goods will be destroyed.

If you attempt to import therapeutic goods unlawfully you may be subject to criminal prosecution with penalties including jail time and significant financial penalties.

How can I avoid my items being detained in the future?

If you wish to use the Personal Importation Scheme, you can prevent your items being detained by arranging to include a copy of a written authority from an Australian registered medical practitioner (usually, a prescription) in the package with your imported goods.

How can I contact the TGA?

Please contact the Compliance Officer on your letter, or email rc@health.gov.au using the reference number provided about your held parcel.

If you have any general questions, you can contact info@tga.gov.au

You can also contact the Translating and Interpreting Service (TIS) on 131 450 if you would like the assistance of an interpreter.



FACT SHEET Personal Importation of Therapeutic Goods

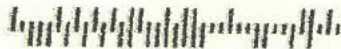
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04.03.24 15M43

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Product and Import Compliance Section
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WODEN ACT 2606



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- the goods are not restricted under Australian Border Force controls or quarantine rules and the goods do not contain a controlled substance

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You also need to be aware that the TGA has no control over advertising of therapeutic goods on overseas websites, so these have a high chance of:

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

MEDIA RELEASE

Akula Foods Pty Ltd fined for allegedly importing unregistered Ayurvedic medicines

XX February 2024

The Therapeutic Goods Administration (TGA) has issued 2 infringement notices totalling \$37,560 to Queensland-based company Akula Foods Pty Ltd for the alleged unlawful import of unregistered complementary medicines.

It is alleged the company attempted to import Himalaya branded Ayurvedic medicines for wholesale supply to retailers.

One of the products, Himalaya branded Neem tablets, contained the ingredient *Azadirachta indica*, commonly known as neem. Neem (except debitterised neem seed oil) is categorised as a Schedule 10 substance in the Poisons Standard. This means it is considered dangerous to human health and is prohibited from supply and use in Australia.

The other product is not included on the [Australian Register of Therapeutic Goods \(ARTG\)](#). Therapeutic goods, including traditional and complementary medicines must be entered in the ARTG before they can be lawfully imported unless an exemption applies. This is an important safeguard to help ensure the safety, quality and performance of products.

The TGA warns those considering importing unregistered therapeutic goods into Australia, including complementary, over the counter and traditional medicines, that they should be aware of, and comply with, the applicable regulatory scheme. Importers who don't follow the requirements risk financial penalties including seizure of the products, fines and other legal action as appropriate.

As supported by [recent court outcomes](#), any business seeking to supply health treatments or services using therapeutic goods must be aware of their obligations under the Therapeutic Goods Act and its regulatory framework. Ignorance is not accepted as a defence for unlawfully importing and supplying products - significant fines or penalties can result from regulatory action.

If you suspect non-compliance in relation to therapeutic goods, you can [report illegal or questionable practices](#) online to the TGA.

Contact for members of the media:

- Email: news@health.gov.au
- Phone: 02 6289 7400

Dear Tracey,

Please see attached briefing for planned enforcement action in relation to Akula Foods Pty Ltd (RC-023901).

We have prepared a media release as we are planning on issuing infringement notices for the alleged import of unregistered therapeutic goods.

Proposed enforcement action

- A delegate in the Regulatory Compliance Branch is planning to give two (2) infringement notices totalling \$37,560 to a Queensland based company, Akula Foods Pty Ltd for allegedly importing unregistered therapeutic goods, being Ayurvedic medicines intended for human consumption.
- The company attempted to import two (2) different Himalaya branded Ayurvedic medicines. The Himalaya branded Neem capsules in this consignment contain neem that is not debitterised neem seed oil. This means that it falls within schedule 10 of the Poisons Standard, and is considered to be a substance of such danger to health as to warrant prohibition of supply and use.
- The remaining Himalaya branded product does not contain any scheduled substances but is considered a therapeutic good as they are labelled as Ayurvedic medicines, and intended for human consumption.
- The company is a wholesale supply and distribution of general groceries and household goods. The company has come to the attention of the TGA on two previous occasions for importing unregistered therapeutic goods. On both occasions the company engaged with Compliance Officers, and as such has been educated about the lawful importation and supply of therapeutic goods.
- ~~While it is open to the delegate to issue one infringement notice for each unregistered product in the consignment,~~ The delegate has elected to issue two infringement notices as a proportionate response to the alleged contraventions (one for the neem product, and another for another large quantity product containing unscheduled ingredients) and a general deterrence for similar companies trading in Ayurvedic and other traditional/complementary medicines.

The delegate is planning to make this decision on **XX** February 2024.

From: s22
To: [REDACTED]
Cc: [REDACTED]
Subject: Akula Foods Pty Ltd Delegate Brief [SEC=OFFICIAL]
Date: Monday, 26 February 2024 11:07:15 AM
Attachments: [image001.png](#)
[image002.png](#)

Ordinarily, by actioning a TRIM workflow approval, I give effect to my decision to issue the infringement notice(s) set out in this brief. As I am working remotely, please use this as my decision to issue the Infringement Notices in [D23-4281253](#). I will complete the TRIM workflow on my return to the office.

Regards,

s22

s22 – Product and Import Compliance

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Compliance Branch

Therapeutic Goods Administration

Australian Government Department of Health and Aged Care

T: s22 | M: s22

E: s22@health.gov.au Protected: s22@protected.health.gov.au

27 Scherger Drive, Canberra Airport, ACT 2609

TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

diversity-logo-combined



Sent from [Workspace ONE Boxer](#)

[SEC=OFFICIAL]

From: [RC](#)
To: [s11C\(1\)\(a\)](#)
Subject: IMPORTANT - Infringement notices given to Akula Foods Pty Ltd in relation to the unlawful importation of therapeutic goods - RC-023901 [SEC=OFFICIAL]
Date: Monday, 26 February 2024 3:03:00 PM
Attachments: [image001.gif](#)
[RC-023901 - AKULA FOODS PTY LTD - Cover Letter.pdf](#)
[TGAIN-RC-023901-2023-1 Infringement Notice - Akula Foods Pty Ltd.pdf](#)
[TGAIN-RC-023901-2023-2 Infringement Notice - Akula Foods Pty Ltd.pdf](#)

Dear [s11C\(1\)\(a\)](#)

Please see **attached** letter to Akula Foods Pty Ltd enclosing two (2) infringement notices requiring your immediate attention. This will also be posted to you.

The payment of the infringement notices are due **by 26 March 2024**.

Please confirm receipt of this email.

Please do not hesitate to contact me if you have any questions.

Regards,

[s22](#)

Product and Import Compliance Section
Regulatory Compliance Branch
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



Important: *This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.*



Australian Government

Department of Health and Aged Care Therapeutic Goods Administration

Akula Foods Pty Ltd
ACN: 611 490 549
[s11C\(1\)\(a\)](#)
1/65 Eastern Road
Browns Plains QLD 4118

By Express Post and by E-mail: [s11C\(1\)\(a\)](#)

Our Reference: TGAIN-RC-023901

Dear [s11C\(1\)\(a\)](#)

Infringement notices given to Akula Foods Pty Ltd in relation to the alleged unlawful importation of therapeutic goods.

Infringement Notice	Amount	Payment Due by
TGAIN-RC-023901/2024-1	\$18,780.00	26 March 2024
TGAIN-RC-023901/2024-2	\$18,780.00	26 March 2024
Total	\$37,560.00	

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (Cth) (the **Act**).

On 26 February 2024 I have decided to give the **enclosed** infringement notices to Akula Foods Pty Ltd (ABN: 65 611 490 549) (the **Company**) under Part 5A-2 of the Act on the basis that I reasonably believe that the Company has contravened 19D of the Act where subsection (1)(a)(i) and (iv) of the Act) applies.

I have decided to issue these infringement notices for alleged contraventions against section 19D(1) of the Act, arising from an importation on or about 16 August 2023 of commercial quantities of therapeutic goods including Himalaya branded Neem (*Azadirachta indica*) capsules, and another unscheduled Himalaya branded therapeutic good.

Based on the products in the most recent importation intercepted by the Australian Border Force (ABF), I have decided to give (2) two infringement notices to the Company.

Of particular concern is the public health risk associated with the Himalaya branded Neem (*Azadirachta indica*) capsules. Neem for ingestion, when not debitterised neem seem oil falls under Schedule 10 of the Poisons Standard (SUSMP), the highest Scheduling category. Schedule 10 substances are classified as having such high risk to public health that their importation, possession, supply or use within Australia is illegal.

I note that prior to this, on or about 15 January 2022, ABF had intercepted and referred to the TGA, an importation of another unregistered therapeutic good. On 20 January 2022 the Company was sent a warning letter and provided education and guidance in relation to the lawful importation and supply of therapeutic goods within Australia. On 31 January 2022, the Company engaged with the TGA confirming that this correspondence had been received, and the importation of unregistered products would cease.

TGA considers the Company has been provided with sufficient guidance and education material to assist with compliance with the regulatory requirements.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804

Phone: 1800 020 653 or 02 6289 4124 Fax: 02 6203 1605

Email: info@tga.gov.au

<https://www.tga.gov.au>

In Australia, therapeutic goods including traditional and over the counter medicines must not be imported, exported, manufactured, supplied (administered to patient/s, sold or given away) or advertised unless they are entered on the Australian Register of Therapeutic Goods (**ARTG**), or an approval or exemption applies. No approval or exemption has been identified in relation to your import.

Only the approved supplier (**Sponsor**), as entered on the ARTG, or their agent can import therapeutic goods into Australia for commercial supply (including use). Any therapeutic good imported for commercial supply must be the version manufactured and approved for the Australian market and not a parallel import. Parallel import occurs when a legitimate version of an overseas product is imported with the intention of being sold in the Australian marketplace. The products must be on the ARTG, under the name of the importer, prior to importation.

As an importer and wholesale supplier of various household goods in Australia, consumers trust that the products they are purchasing comply with Australian safety standards. However, the importation of unregistered therapeutic goods for commercial supply without adhering to the appropriate regulatory framework negates this safe standard of practice. In addition, the TGA does not evaluate unapproved therapeutic goods for quality, safety and efficacy when imported. The use of therapeutic goods that are not entered in the ARTG poses serious risks to consumers.

An infringement notice is an opportunity for the Company to pay an amount as an alternative to having court proceedings brought against them in relation to the alleged contravention described in the relevant notice.

The infringement notices are attached to this letter and include information on how to pay the infringement notice penalty amount, how to request an extension of the compliance period for payment of the infringement notice, how to request that the infringement notices be withdrawn and the actions that the TGA may take in the event of non-payment of the infringement notice.

The ignorance of regulatory requirements when procuring therapeutic goods is not a defence for the alleged unlawful importations of these products for commercial supply. There have been significant Federal Court decisions in which the court has clearly stated that ignorance of, or inexperience with, the therapeutic goods framework is not an excuse.¹ Those who engage in businesses involving therapeutic goods have a responsibility to be aware of the laws that govern those products, and to comply with them from the outset.

It is important that you carefully read the infringement notices and the information contained therein. The amount payable in respect of each notice is \$18,780.00. The due date for payment is **26 March 2024**.

If you have any questions, please contact the case officer, [s22](#), by email at RC@health.gov.au or by phone [s22](#).

Yours sincerely

[s22](#)

[s22](#) Product and Import Compliance
Regulatory Compliance Branch
Therapeutic Goods Administration
Date: 26 February 2024

¹ [Health v Enviro Tech Holdings Pty Ltd](#)



Australian Government

Department of Health and Aged Care Therapeutic Goods Administration

Akula Foods Pty Ltd
ACN: 611 490 549
1/65 Eastern Road
Browns Plains QLD 4118

By Express Post and by Email:
s11C(1)(a)

Infringement Notice Number:

TGAIN-RC-023901/2024-1

Date given: 26 February 2024

Penalty total: \$ 18,780

Payment due: 26 March 2024

Enquiries:

Product Import and Compliance Section

Telephone: 02 6289 2369 or 1800 514 910

Email: rc@health.gov.au

INFRINGEMENT NOTICE GIVEN TO

Akula Foods Pty Ltd

PART A: Infringement Notice given by

s22

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Akula Foods Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Akula Foods Pty Ltd has contravened Section 19D of the Act where subsection (1) applies.

The details of the alleged contravention are that:

- On or about 16 August 2023, in alleged contravention of Section 19D of the Act where subsection (1) applies, Akula Foods Pty Ltd attempted to import into Australia, unregistered therapeutic goods, for use in humans being approximately s47 of Himalaya branded Neem capsules (each containing 60 capsules) said to contain neem (*Azadirachta indica*)

This product was not registered on the Australian Register of Therapeutic Goods (ARTG) in relation to Akula Foods Pty Ltd and was not otherwise subject to an exemption, approval or authority under the Act from the requirement to be registered on the ARTG.

The maximum penalty a court could impose on a company for a single contravention of Section 19D subsection (1)(a)(i) and (iv) of the Act) is 50,000 penalty units. For the above alleged contravention, this amounts to \$15,650,000.¹

The amount payable under this notice is \$18,780. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



CHEQUE

Return **this notice** to
Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601 with your cheque made payable to the Department of Health and Aged Care.
 Please allow 5 business days for payment to be received



CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-RC-023901/2024-1** as reference to identify your payment



ELECTRONIC FUNDS TRANSFER

Account name:

Department of Health and Aged Care
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-RC-023901/2024-1** in the description of your transfer and allow two business days for payment to be received.

Note: The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

¹ A penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313 (section 4AA of the *Crimes Act 1914*).

PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- rc@health.gov.au; or
- PO Box 100; WODEN ACT 2609

Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

How this notice can be withdrawn

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- rc@health.gov.au; or
- PO Box 100; WODEN ACT 2609

Effect of withdrawal of this notice

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

s22

Regulatory Compliance Branch
Therapeutic Goods Administration
PO Box 100; WODEN ACT 2609

Date: 26 February 2024



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Akula Foods Pty Ltd
 ACN: 611 490 549
 1/65 Eastern Road
 Browns Plains QLD 4118

By Express Post and by Email:
 s11C(1)(a)

Infringement Notice Number:

TGAIN-RC-023901/2024-2

Date given: 26 February 2024

Penalty total: \$ 18,780

Payment due: 26 March 2024

Enquiries:

Product Import and Compliance Section

Telephone: 02 6289 2093 or 1800 514 910

Email: rc@health.gov.au

INFRINGEMENT NOTICE GIVEN TO

Akula Foods Pty Ltd

PART A: Infringement Notice given by

s22

Delegate of the Secretary of the Australian Government Department of Health and Aged Care

PART B: Details of alleged contravention

I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under section 42YK of the *Therapeutic Goods Act 1989* (the Act). I have decided to give this Infringement Notice (the notice) to Akula Foods Pty Ltd under Part 5A-2 of the Act on the basis that I reasonably believe that Akula Foods Pty Ltd has contravened Section 19D of the Act where subsection (1) applies.

The details of the alleged contravention are that:

- On or about 16 August 2023, in alleged contravention of Section 19D of the Act where subsection (1) applies, Akula Foods Pty Ltd attempted to import into Australia, unregistered therapeutic goods, for use in humans being approximately s47 of Himalaya branded Triphala capsules (each containing 60 capsules)

The product was not registered on the Australian Register of Therapeutic Goods (ARTG) in relation to Akula Foods Pty Ltd and was not otherwise subject to an exemption, approval or authority under the Act from the requirement to be registered on the ARTG.

The maximum penalty a court could impose on a company for a single contravention of Section 19D subsection (1)(a)(i) and (iv) of the Act) is 50,000 penalty units. For the above alleged contravention, this amounts to \$15,650,000.¹

The amount payable under this notice is \$18,780. The due date for payment of the penalty amount is specified in the red box at the top of this notice.

Please carefully read *Part D: Information about this Infringement Notice*.

PART C: Payment details

Please ensure that you allow time for your payment to be received by the due date.



CHEQUE

Return **this notice** to
Department of Health and Aged Care, Accounts Receivable, GPO Box 9848, Canberra ACT 2601 with your cheque made payable to the Department of Health and Aged Care.
 Please allow 5 business days for payment to be received



CREDIT CARD

Use your credit card to pay your notice by calling the Collector of Relevant Monies directly on **(02) 6289 1095**. Please include the infringement notice number **TGAIN-RC-023901/2024-2** as reference to identify your payment



ELECTRONIC FUNDS TRANSFER

Account name:

Department of Health and Aged Care
BSB: 092 009
Account: 114 071
Bank: Reserve Bank of Australia, London Circuit, Canberra ACT 2601
Swift: RSBKAU2S (if overseas deposits are relevant). Please include the infringement notice number **TGAIN-RC-023901/2024-2** in the description of your transfer and allow two business days for payment to be received.

Note: The Department of Health and Aged Care accepts payment on behalf of the Commonwealth and will issue a tax invoice on receipt of payment.

¹ A penalty unit for a contravention alleged to have occurred on or after 1 July 2023 is \$313 (section 4AA of the *Crimes Act 1914*).

PART D: Information about this Infringement Notice

This information is designed to help you (the person to whom this notice has been given) understand the following:

- the compliance period (the period within which the penalty amount is payable)
- how to apply for an extension of time to pay the penalty amount
- how to make a written representation seeking withdrawal of this notice
- the effect of complying with this notice
- the effect of failing to comply with this notice.

This information is for **general guidance only**. You should obtain independent legal advice if you have specific concerns.

Compliance period

The compliance period for this notice is 28 days beginning on the day after the day that this notice is given to you. The Therapeutic Goods Administration (TGA) is not legally able to accept payment of the notice after it has lapsed.

How to request an extension of time to pay the penalty amount

You may apply to the Secretary of the Australian Government Department of Health and Aged Care (the Secretary) for an extension of the compliance period for this notice, provided your application is made before the end of that period. The Secretary may extend that period in writing before or after the end of that period. You should state in your application why you require an extension and provide supporting documentation such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months. Requests can be made by sending them directly to:

- rc@health.gov.au; or
- PO Box 100; WODEN ACT 2609

Effect of complying with this notice

If you pay the full penalty amount payable under this notice within the compliance period, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act will not be brought against you in relation to the alleged contravention described in this notice (unless this notice is withdrawn).

Your payment of the penalty amount payable under this notice is not an admission of guilt or liability.

The Australian Government Department of Health and Aged Care will, from time to time, make public reference to infringement notices that have been issued to companies or individuals, including in media statements and publications by the TGA containing information about the alleged conduct of a company or an individual and the fact that compliance with the infringement notice does not amount to an admission or finding that the Act has been contravened.

Effect of failing to comply with this notice

An infringement notice is an opportunity for you to pay an amount as an alternative to having court proceedings brought against you in relation to the alleged contravention described in this notice. You may therefore choose not to pay the penalty amount payable under this notice. If you choose not to pay the penalty amount, proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act may be brought against you in relation to the alleged contravention described in this notice.

Effect of the lapsing of the compliance period for the notice

If the compliance period has passed and no payment has been received, the notice is considered to have lapsed. No extension of time can be granted if the application is made after the compliance period has passed and no further payment can be accepted against a lapsed notice. If you pay the penalty amount payable under this notice after the compliance period has lapsed, you will be refunded the amount paid.

Please be aware that once the infringement notice has lapsed, the Secretary may commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

How this notice can be withdrawn

The Secretary may withdraw this notice even if you have already paid the penalty amount payable under this notice. In such a case, you will be refunded the amount paid.

You may make a written representation to the Secretary seeking the withdrawal of this notice. Your representation should explain why this notice should be withdrawn and include supporting documents, such as balance sheets, statements of cash flow, profit and loss statements, and/or bank statements for the last 12 months.

Please ensure that your written representation is addressed to and received by the person who has given you this notice within the compliance period. You can make written representations seeking withdrawal of this infringement notice at any time before the payment due date. However, to allow the Secretary to make a decision in relation to such a request before the payment due date, you should make it no less than seven business days before the payment due date.

Written representations can be made by sending them directly to:

- rc@health.gov.au; or
- PO Box 100; WODEN ACT 2609

Effect of withdrawal of this notice

If this notice is withdrawn, the TGA may nevertheless commence proceedings seeking a pecuniary penalty order under subsection 42Y(2) of the Act against you in relation to the alleged contravention described in this infringement notice.

s22

Regulatory Compliance Branch
Therapeutic Goods Administration
PO Box 100; WODEN ACT 2609

Date: 26 February 2024

From: [RC](#)
To: [Akula Food](#)
Subject: RE: IMPORTANT - Infringement notices given to Akula Foods Pty Ltd in relation to the unlawful importation of therapeutic goods - RC-023901 [SEC=OFFICIAL]
Date: Wednesday, 28 February 2024 3:37:00 PM
Attachments: [image001.gif](#)

H [s11C\(1\)\(a\)](#)

Thank you for your response in relation to the infringement notices given to Akula Foods Pty Ltd. I have read the explanation of your situation and can appreciate your circumstances. I refer you to the heading 'How this notice can be withdrawn' under 'Part D' on the infringement notices, namely the paragraph referring to supporting documentation. If you could please supply any documentation supporting your position to myself by **15 March 2024** at the latest to allow the Secretary sufficient time to make a decision on the matter.

Please let me know if you have any additional questions.

Kind regards,

[s22](#)

Product and Import Compliance Section
Regulatory Compliance Branch
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



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From: Akula Food [s11C\(1\)\(a\)](#)
Sent: Wednesday, February 28, 2024 12:14 PM
To: RC <RC@health.gov.au>
Subject: Re: IMPORTANT - Infringement notices given to Akula Foods Pty Ltd in relation to the unlawful importation of therapeutic goods - RC-023901 [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Sir,

I hope this email finds you well.

Before anything else, thank you for bringing to my notice the recent developments with some of the products that were included in the recent freight. I acknowledge the receipt of the email.

Now, please allow me to quickly explain the situations that have transpired around the concerned products.

We sincerely had no clue that the two products namely 'Himalaya Neem Tablets' and 'Himalaya Triphala Tablets' fall under the banned list. It was an honest mistake to say the least.

We try to the best of our abilities to adhere to all the norms the law dictates. Along with the total respect for the norms, it's against our moral code too to do anything that doesn't fall under the purview of law.

The product mouth freshener that was banned last time, it was only a mouth freshener to the best of our knowledge. Once we were made aware of the restriction, we promptly stopped procuring it. We can offer you the evidence of that if asked.

Now, we have a sincere appeal to make. In lieu of the fact that what happened isn't intentional wrongdoing and also since we've established our innocence, can you please consider waiving the punitive charges? At worst, it was an honest and inadvertent mistake which we will definitely avoid in the future.

We have added the concerned products' names to our list of banned substances. Given an extremely slow recovery of the business from the pandemic, it's an economic necessity that we get a breather. Kindly bail us out in any way possible.

Your help in this regard will be greatly appreciated.

Thank you once again.

In anticipation,

RAM AKULA
AKULA FOODS PTY LTD
1/65 Eastern Road,
Browns Plains, QLD 4118.

s47F



On Mon, Feb 26, 2024 at 2:04 PM RC <RC@health.gov.au> wrote:

|

Dear s11C(1)(a)

Please see **attached** letter to Akula Foods Pty Ltd enclosing two (2) infringement notices requiring your immediate attention. This will also be posted to you.

The payment of the infringement notices are due **by 26 March 2024**.

Please confirm receipt of this email.

Please do not hesitate to contact me if you have any questions.

Regards,

s22

Product and Import Compliance Section
Regulatory Compliance Branch
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



Important: *This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.*

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

From: 47F
To: RC
Subject: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2
Date: Friday, 8 March 2024 12:50:59 PM
Attachments: [Letter to TGA 8.3.24.pdf](#)
[Woolworth's Neem Capsules.pdf](#)
[Packing List.pdf](#)
[Company Tax Return 2022.pdf](#)
[Profit & Loss Statement 2022.pdf](#)

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Attention: s22 (case officer) - Product & Import Compliance Section.

We refer to the above-mentioned matter in which we act on behalf of Akula Foods Pty Ltd.

Please find **attached** our letter of even date together with enclosures for your attention.

Kind Regards,

47F

For and on Behalf of 47F



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au



47F [REDACTED]

Suite 2, Level 3
182-184 Victoria Parade
East Melbourne, Victoria, 3002
Australia
Telephone: (61 3) 9866 5666
Email: info@grossbecroft.com.au
Our Ref: RB:3850

8 March 2024

BY EMAIL: RC@health.gov.au

Attention: s22 (case officer) - Product & Import Compliance Section
Regulatory Compliance Branch, Therapeutic Goods Administration

s22 [REDACTED]
s22 [REDACTED] Product and Import Compliance
Regulatory Compliance Branch
Therapeutic Goods Administration

Dear Madam,

Re: Akula Foods Pty Ltd – Infringement Notices
Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2
TGA Reference: TGAIN-RC-023901

We act as lawyers for Akula Foods Pty Ltd ('Akula').

We refer to your letter to Akula dated 26 February 2024 enclosing two Infringement Notices issued by the TGA against Akula for a total amount of \$37,560.00 in relation to imports of Neem and Triphala tablets.

Akula is a small family-owned business that operates from premises in Browns Plains, Logan south of Brisbane. It has traded approximately 8 years as an importer and distributor of foodstuffs and related products.

We are instructed that Akula was extremely surprised to receive these substantial infringement notices many months after the seizure of the impugned goods on or about 16 August 2023. Whilst appreciating the important regulating function carried out by the TGA, we wish to raise

Visit our Website at www.grossbecroft.com.au

the following matters in support of a request for the withdrawal of the subject infringement notices:

1. We understand from your letter that the principal basis for issuing the infringement notice is the fact that a warning had been given to Akula in connection with the importation of an unregistered therapeutic good in January 2022. The product that was the subject of the warning was a mouth freshener product and bears no relation to the products for which the infringement notices were issued. We consider it unreasonable for the regulator to issue infringement notices in circumstances where there was no previous warning for the same or similar goods noting that the TGA register covers many thousands of therapeutic goods. This is particularly the case where one of the products (Neem) involves a more complex assessment of its constituents and may not be available for TGA registration.
2. We note that both Neem and Triphala tablets are currently sold in Australia by prominent companies such as Nature's Way and Woolworths. In respect of Neem, we understand that under Schedule 10 of the Poisons Standard Neem is a prohibited substance unless it consists of 'de-bitterised neem seed oil' (de-bitterisation being a form of purification as defined by the Poisons Standard). However, a cursory examination of Neem products sold in Australia indicates that there is no evidence that these products fall within this exception. Please see **attached** an example of Neem leaf capsules sold by Woolworths. We also presume that the TGA has tested Akula's products to confirm that they are not derived from de-bitterised neem seed oil. Whilst Akula does take its own regulatory obligations seriously, it contends that the regulatory assessment is not straightforward and does not understand how these Neem products are currently being sold in Australia.
3. The commercial value of the Neem and Triphala tablets was approximately s47 and s47 respectively within a container of products valued at s47. Please see **attached** the packing list for your reference. Akula regrets importing these products and has no intention of ever importing Neem or Triphala tablets in the future when it is importing foodstuffs.
4. The amount of these infringement notices (\$37,560.00) is a prohibitive amount for Akula to pay and it will have a significant negative effect on its business activities given it operates a family business operating on small margins. We **attach** on a **confidential** basis a copy of Akula's 2022 tax return and profit and loss statement that evidences the material impact that these infringement notices will have on its finances.

In the circumstances and based on the matters raised above, we request that you give further consideration to this matter and exercise your discretion to grant a withdrawal of the two infringement notices.

We look forward to your timely reply noting that the due date for payment of the infringement notices is 26 March 2024.

In the meantime, should you have any queries or require any further information please contact our office.

Yours faithfully

s47F



47F

Gross & Becroft Lawyers
Principal

Encl.



Created: 20/04/2023 10:30 PM

AKULA FOODS PTY LTD

1/65 Eastern Road
Browns Plains, QLD 4118

Profit & Loss Statement

s47F

s47G



This report includes Year-End Adjustments.

Created: 20/04/2023 10:30 PM

AKULA FOODS PTY LTD

1/65 Eastern Road
Browns Plains, QLD 4118

Profit & Loss Statement

s47F

s47G



This report includes Year-End Adjustments.

Company Tax Return

2022

s47G

Company Tax Return

2022

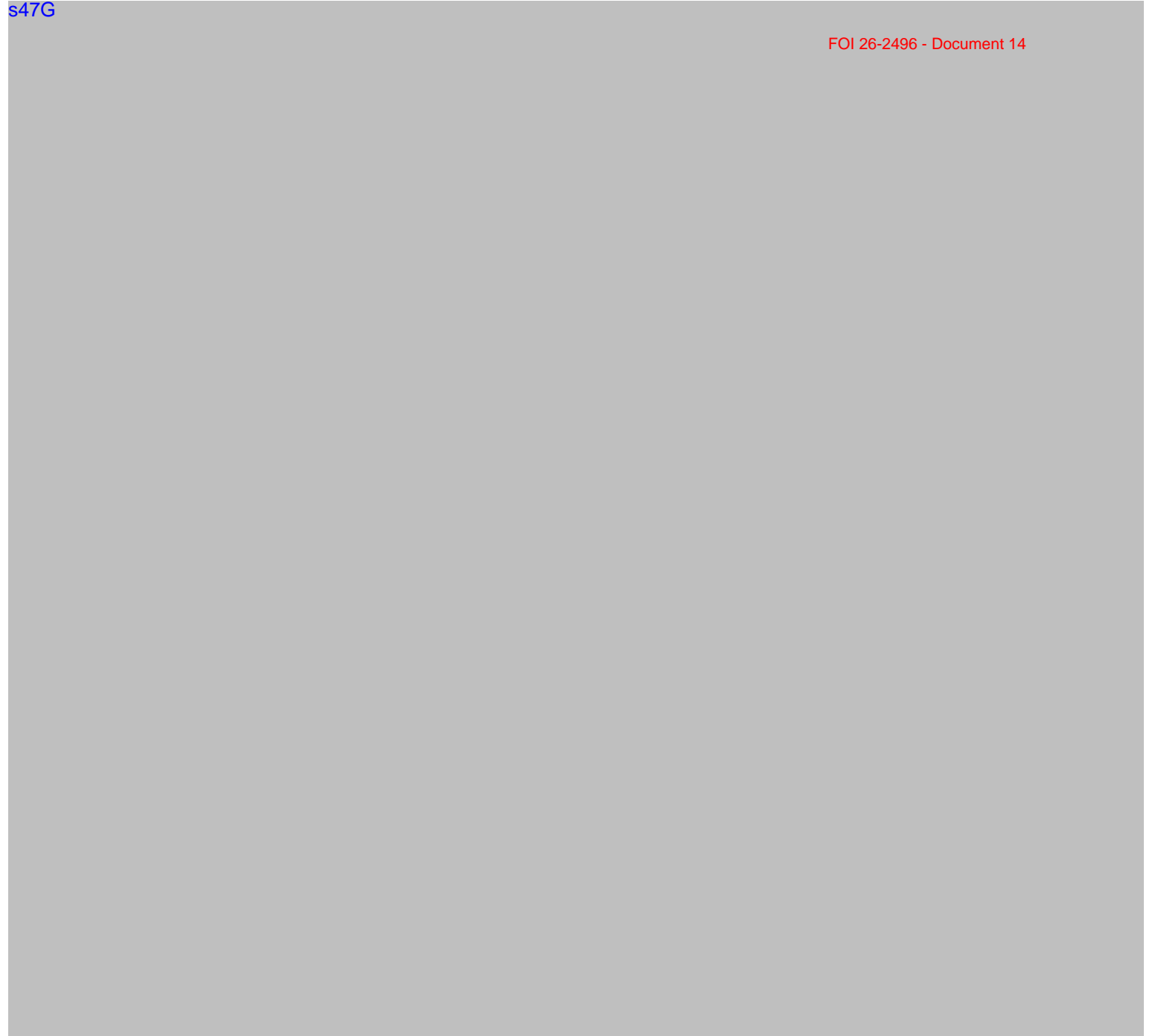
s47G



547G

FOI 26-2496 - Document 14











\$10 off your first Everyday Market order



Code: EMNEW10

FOI 26-2496 - Document 14
Min spend \$100. T&Cs apply.

< Back



Sold & shipped by [Nutra Nourished](#)

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**Nutra Nourished Organic Neem Leaf
Extra Strong Australian Grown for
improved immune system- 60 Vegan
Caps**

Out of stock

Save to list

Add to cart

Product Details

Neem Leaf comes from a flowering plant native to India - the Neem Tree - and in traditional Ayurvedic practices, it has been used for hundreds of years. Nutra Nourished brings you the benefits of this beautiful herb. We have put it in quick-release capsules that provide 330mg of Neem Leaf per serving!

- detoxifying
- helps Destroy Cancerous Cells
- helps Destroy Harmful Bacteria
- improve skin health
- antimalarial effects
- diabetes management
- hair health
- dental and oral health
- aid liver and kidney health

Made in Australia

They are made with naturally dried Australian grown Neem Leaf. Each capsule contains 330mg of Neem Leaf powder with 60 capsules per bottle.

Each capsule contains 330mg of Neem Leaf powder with 60 capsules per bottle. Our capsules are plant-based so are suitable for Vegans

Directions

For general well-being, adults take the suggested dosage of 1-2 tablets per day. It contains 60 capsules in one bottle. Nutra Nourished Neem Capsules are 100% Pure Natural Neem Leaf in Vegan Vegetarian Capsules. They are Neem Leaf Super Food and an Ancient Indian, Tibetan & Nepalese Ayurvedic Herb referred to as Nature's Tree of Life for over 3000 Years.

Free From

sugar, dairy, lactose, gluten, wheat, yeast, starch, soy, nuts, animal products.

No Added

Preservatives, artificial colours and artificial flavours

FOI 26-2496 - Document 14

Warnings

- Always read the label and follow the directions for use.
- Always consult with your Health Professional before taking this Herbal Food.
- Not to be taken when child-bearing or breastfeeding
- Not to be used in children under the age of 18
- This Herbal Food does not replace a Balanced Diet.

Always read the label & follow the directions for use. This food is not a sole source of nutrition and should be consumed in conjunction with a nutritious diet. Avoid this product if you are allergic or sensitive to any of the ingredients.

VITAMIN AND DIETARY SUPPLEMENTS SHOULD NOT REPLACE A BALANCED DIET.

Our Premium Dietary Supplements are not a substitute for good nutrition or a balanced diet. They are not in any way superior to or more beneficial than dietary nutrients.

false

[View less](#)

Disclaimer:

This product is sold and shipped by our Everyday Market Partner who has provided all relevant product information for this listing. Woolworths does not ensure the accuracy or suitability of the information on this page. Product information is intended as a guide only as products may change from time to time. Please always check the product label or enquire with the manufacturer before consuming. Product ratings and reviews are taken from various sources including Bazaarvoice. Woolworths does not represent or warrant the accuracy of any statements, claims or opinions made in product ratings and reviews.

Everyday Market Shipping Fees: If you spend \$50 (incl GST) or more on Everyday Market items, shipping is free for your Everyday Market order. Bulkier, heavier or larger items may incur additional shipping fees. Additional delivery fees and charges may apply to Woolworths groceries, and a shipping fee will apply to an Everyday Market order if that order (excluding Woolworths groceries) does not meet the advertised free shipping threshold. Woolworths reserves the right to vary the terms of this offer at any time without notice.

People Who Bought This Item Also Bought

Special

SAVE \$10.38

\$41.52

~~\$51.90~~ - \$69.20 / 100EA



Nutra Nourished Organic Moringa Leaf Supplement Australian Grown for improved immune system - 60 Vegan Caps

Sold by Nutra Nourished

[Add to cart](#)

[Save to list](#)

Products related to this item



SAVE \$500.01

\$999.99

Will be \$1500.00 - \$10.00 / 100G

Orku 10Kg Organic Chaga Mushroom Powder - Supplement Inonotus Obliquus Health Food

Sold by Aussie Wholesale Store

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Save to list

22% Off Your First App Order

Shop Now

Earn up to \$25 USD in Cashback Rewards

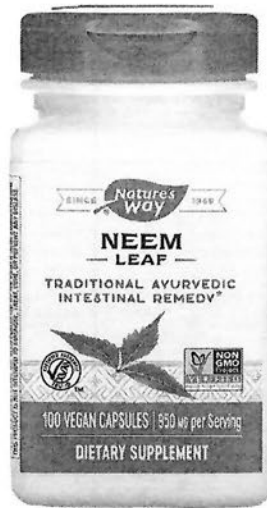
Shop Now

Brands A-Z > Nature's Way
Categories > Herbs > Neem

Nature's Way, Neem Leaf, 950 mg, 100 Vegan Capsules (475 mg per Capsule)

By Nature's Way

☆☆☆☆☆ 4,937 Reviews | 44 Q&A



Roll over image to zoom in



Our Price **AU\$16.25** AU\$0.33/Serving

- 1 +

Add to cart

Price includes GST + FREE shipping over AU\$80.00

Add to lists

In Stock

300+ sold in the last 7 days

- Best By: 12/2028
- First Available: 06/2007
- Shipping Weight: 0.09 kg
- Product Code: NWY-15120
- UPC Code: 033674151204
- Package Quantity: 100 Count
- Dimensions: 11.4 x 6.4 x 6.4 cm , 0.09 kg

Product rank:

- #1 in Neem
- #20 in Ayurveda
- #122 in Herbs

Frequently purchased together



iHerb Rewards - Give 5%, Get 5%

Total: A\$72.65

Add selected to cart

Customers also viewed

<p>Himalaya, Organic Neem, 60 Caplets</p> <p>☆☆☆☆☆ 1,652</p>	<p>Organic India, Neem, 90 Vegetarian Caps</p> <p>☆☆☆☆☆ 636</p> <p>AU\$33.74</p>	<p>Himalaya, Organic Triphala, 60 Caplets</p> <p>☆☆☆☆☆ 1,403</p>	<p>Swanson, Neem Leaf, 500 mg, 100 Capsules</p> <p>☆☆☆☆☆ 93</p> <p>AU\$13.27</p>	<p>NOW Foods, Triphala, 500 mg, 120 Tablets</p> <p>☆☆☆☆☆ 5,549</p>

Product overview

Description

- Since 1969
- Traditional Ayurvedic Intestinal Remedy
- Certified Authentic TRU-ID™
- Non GMO Project Verified
- 950 mg Per Serving
- Dietary Supplement
- Gluten Free
- Vegan
- Quality Global Sourcing

Traditional Ayurvedic Intestinal Remedy

At Nature's Way®, we believe in quality you can trust. So, we start by sourcing botanicals from the places they grow best. Then we use three distinct levels of scientific testing methods to ensure ingredients meet our uncompromising standards. Look for the Tru-ID logo to find products certified for authenticity by independent, third-party testing.

Suggested use

Take 2 capsules three times daily.

Other ingredients

Plant-derived capsule (hypromellose)

Gluten free. No sugar, salt, yeast, wheat, corn, soy, dairy products, or artificial colors, flavors, or preservatives.

Warnings

Not for use in men if attempting to conceive. If pregnant, nursing, or taking any medications, consult a healthcare professional before use.

Keep out of reach of children. Safety sealed with printed inner seal. Do not use if either is broken or missing.

Disclaimer

While iHerb strives to ensure the accuracy of its product images and information, some manufacturing changes to packaging and/or ingredients may be pending update on our site. Although items may occasionally ship with alternate packaging, freshness is always guaranteed. We recommend that you read labels, warnings and directions of all products before use and not rely solely on the information provided by iHerb.

From: 47F
To: RC
Subject: FW: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]
Date: Tuesday, 19 March 2024 12:03:46 PM
Attachments: [FY23 Profit & Loss Statement.pdf](#)
[2023 September AS AkulaFoodsPtyLtd.pdf](#)
[2023 December AS AkulaFoodsPtyLtd - signed.pdf](#)
[9DF228DD-419B-4B65-8B5B-742EA4A200AE.pdf](#)
Importance: High

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22

I refer to your email below in relation to the matter concerning Akula Foods Pty Ltd.

As requested, please find **attached** additional more recent financial information from the 2023 and 2024 Financial Years. Please note that these financial documents are provided to the TGA on a confidential basis solely for the purposes of this matter.

The information comprises:

- Financial Year 2023 Profit and Loss Statement;
- Business Activity Statements for Quarters 1 and 2 for the 2024 Financial Year;
- Business overdraft bank statement for the period 1 October to 31 December 2023.

We note that the Profit and Loss Statement discloses a net profit for FY23 of s47G. Further, the net GST collected as reported in the BASs for Qs 1 and 2 in FY24 disclose that Akula's business expenses s47G. The bank statements disclose that Akula is operating s47G with a current s47G.

We reiterate that the imposition of the two infringement notices totalling \$37,560.00 would have a major financial impact upon our client's business and cause significant financial hardship in circumstances where the business is operating in very difficult trading conditions.

We look forward to your favourable consideration of this matter.

In the meantime, please let us know if you require any further information.

Regards,

47F

Principal



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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From: RC <RC@health.gov.au>
Sent: Thursday, March 14, 2024 10:07 AM
To: 47F <info@grossbecroft.com.au>
Subject: RE: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Attention: 47F – 47F : 3850

Hi 47F

Please note this is not a formal response from the Therapeutic Goods Administration (TGA).

Thank you for your letter and attached documents relating to the request for withdrawal of infringement notices issued to Akula Foods Pty Ltd. The delegate is requesting more financial information as what has been supplied is not sufficiently up to date to make a decision regarding withdrawal. At this point in time the delegate is not considering a withdrawal based on the information that has been supplied.

The delegate is fully aware that company income tax returns are generally not due to the Australian Taxation Office until mid-May each year, so it would not be reasonable to request the 2022/23 financial year return. However any current financial information, ideally from the 2022/23 and 2023/24 financial years, would aid the delegate in making an informed decision regarding the request for withdrawal of the infringement notices issued to Akula Foods Pty Ltd.

Please supply any additional information by **20 March 2024**.

Kind regards,

s22

Product and Import Compliance Section
Regulatory Compliance Branch
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au

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From: 47F <info@grossbecroft.com.au>
Sent: Friday, March 8, 2024 12:51 PM
To: RC <RC@health.gov.au>
Subject: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

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Attention: s22 (case officer) - Product & Import Compliance Section.

We refer to the above-mentioned matter in which we act on behalf of Akula Foods Pty Ltd.

Please find **attached** our letter of even date together with enclosures for your attention.

Kind Regards,

47F

For and on Behalf of 47F



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666

Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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Created: 18/03/2024 12:50 PM

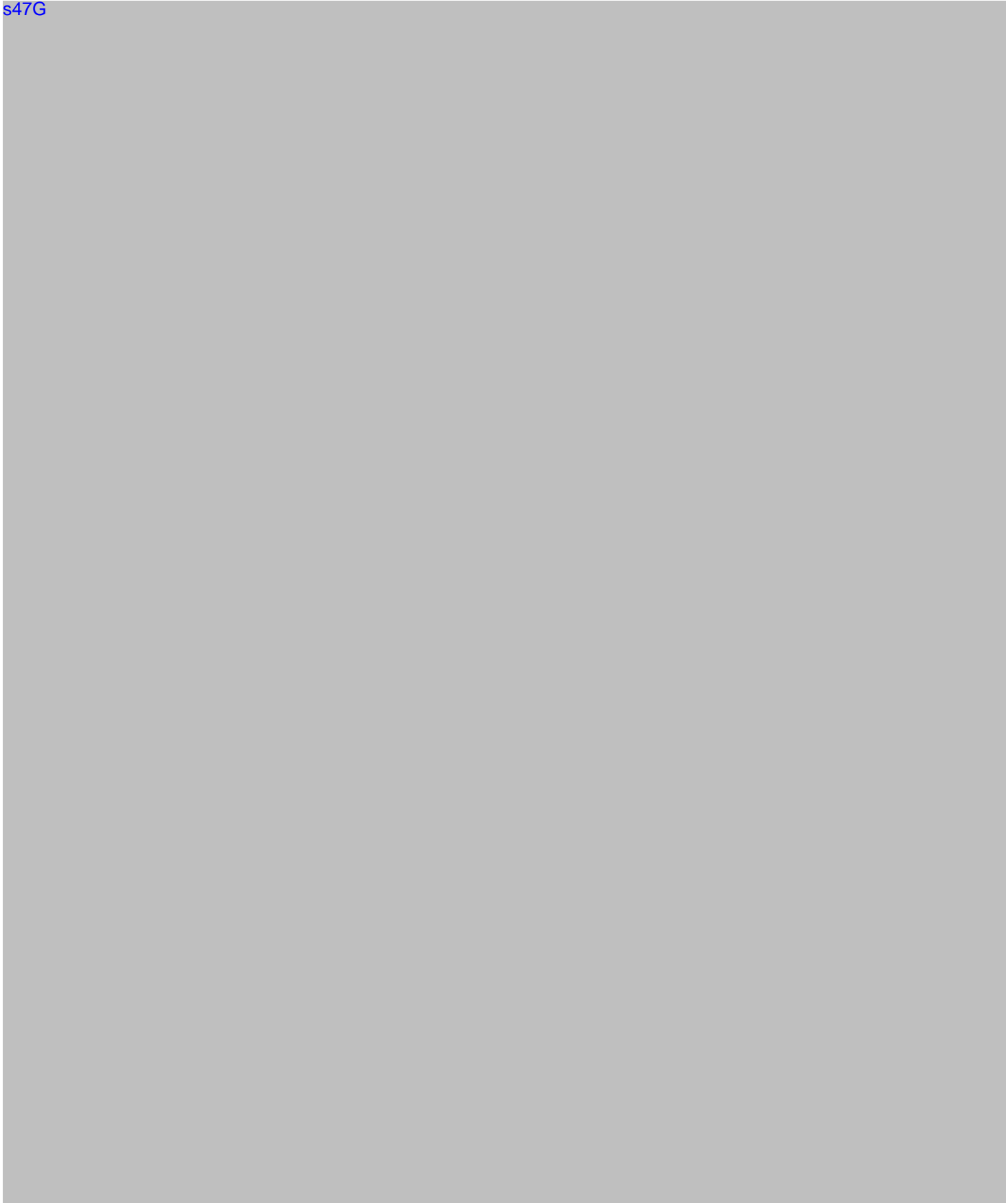
AKULA FOODS PTY LTD

1/65 Eastern Road
Browns Plains QLD 4118

Profit & Loss Statement

s47F

s47G



This report includes Year-End Adjustments.

Created: 18/03/2024 12:50 PM

AKULA FOODS PTY LTD

1/65 Eastern Road
Browns Plains, QLD 4118

Profit & Loss Statement

s47F

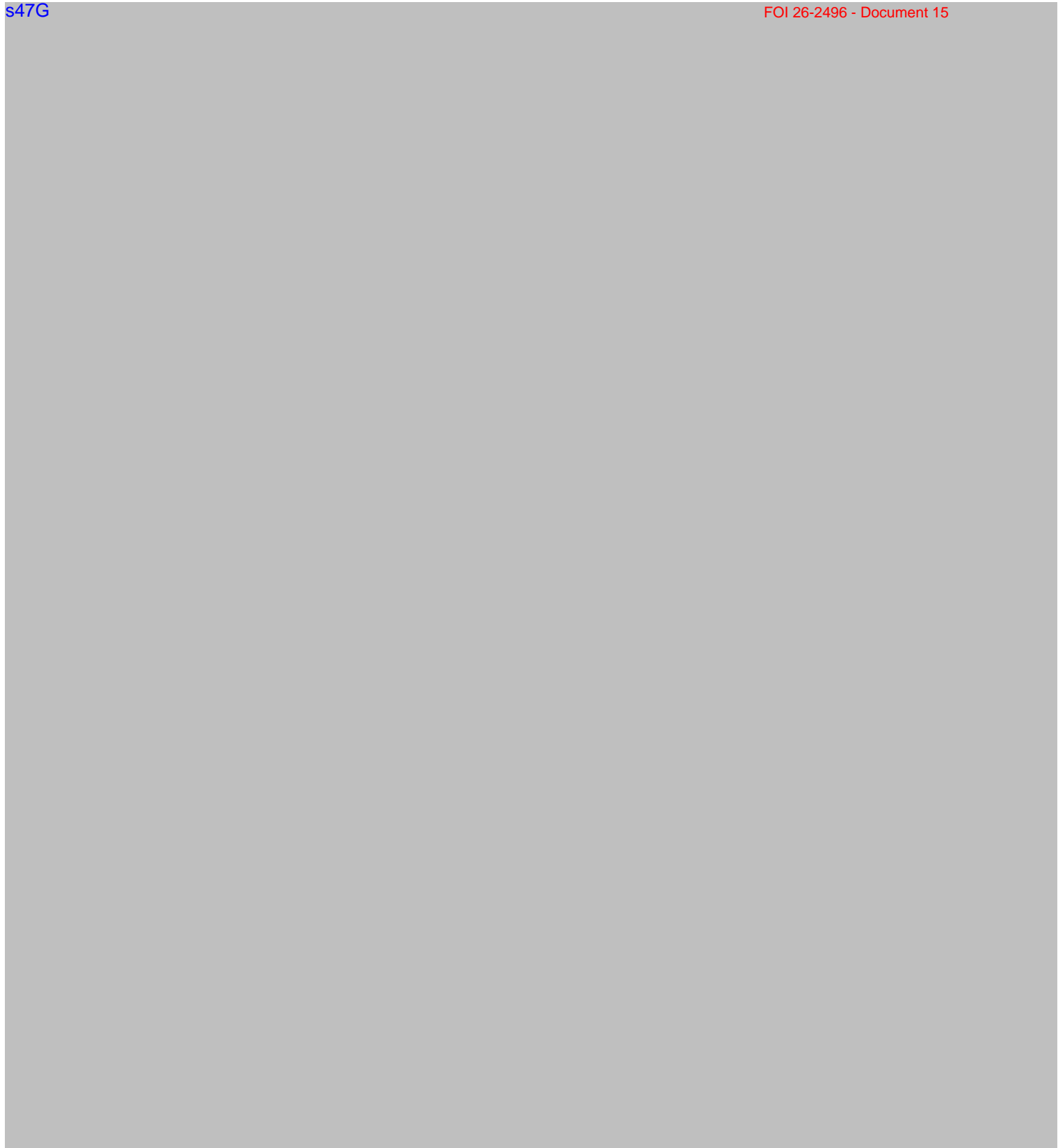
s47G



This report includes Year-End Adjustments.

s47G

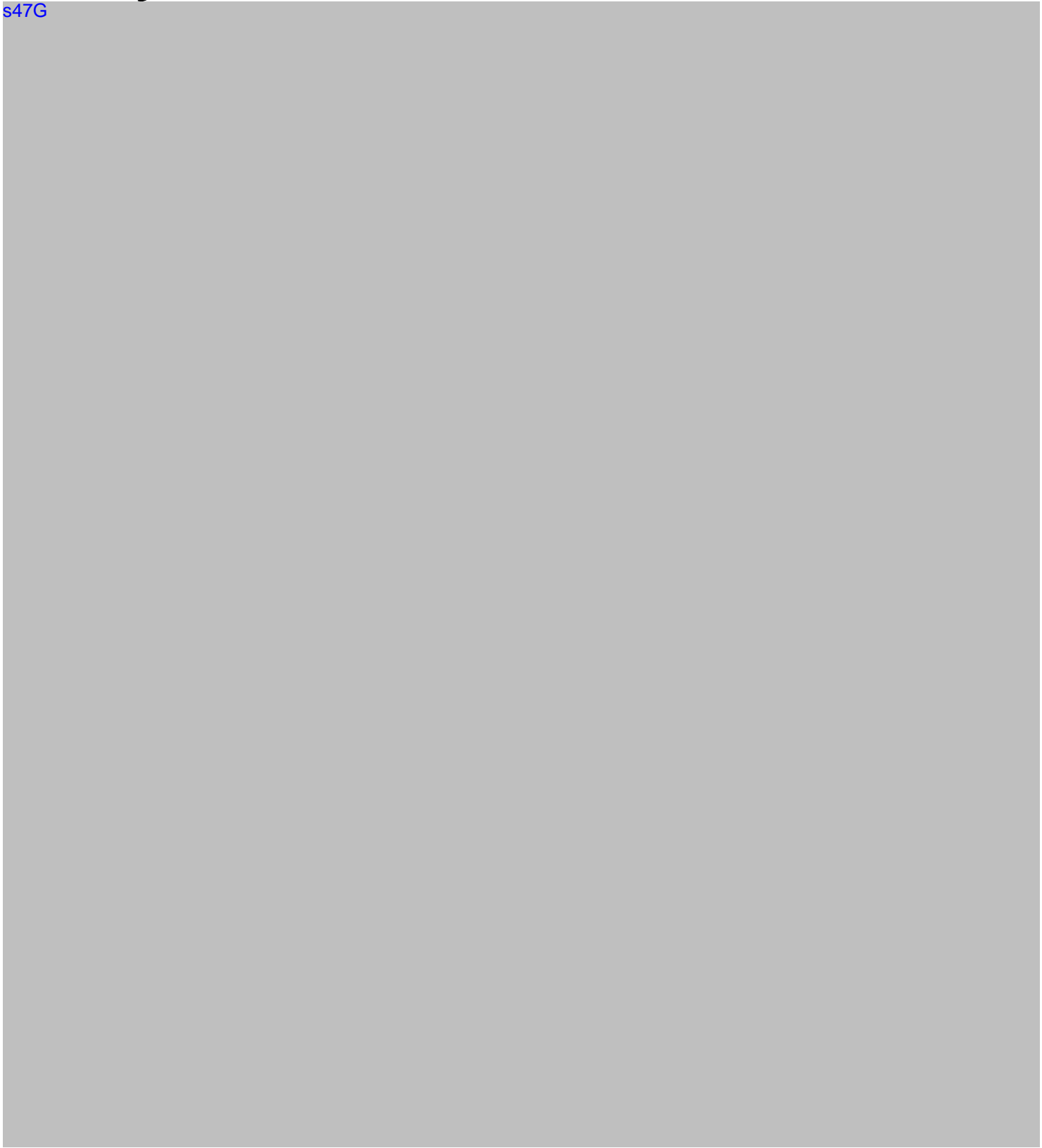
FOI 26-2496 - Document 15



Activity Statement

2023

s47G



Activity Statement

2023

s47G



b47G



s47G



Activity Statement

2023

s47G



Activity Statement

2023

s47G



s47G



From: RC
To: s47F @grossbecroft.com.au; info@grossbecroft.com.au
Subject: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2
Date: Thursday, 4 April 2024 3:21:05 PM
Attachments: [image002.gif](#)
[image003.jpg](#)
[image001.png](#)
[Akula Foods - RC-023901 - DECISION LETTER - Delegate decision to withdraw and extend due date -4 April 2024.pdf](#)
Importance: High

Good afternoon s47F

Thank you for your email on 8 March 2024 and 19 March 2024 to request the withdrawal of two infringement notices given to Akula Foods Pty Ltd.

Please see the **attached** correspondence from the delegate of the Secretary in relation to the decision to withdraw the two infringement notices given to Akula Foods Pty Ltd (TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2).

Please confirm receipt of this email with attached letter.

Sincerely,

s22

Product Import Compliance Section

Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

T: s22 | E: rc@health.gov.au

www.tga.gov.au

27 Scherger Drive, Canberra Airport, ACT 2609

TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s47F @grossbecroft.com.au>

Sent: Tuesday, March 19, 2024 12:04 PM

To: RC <RC@health.gov.au>

Subject: FW: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Importance: High

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22

I refer to your email below in relation to the matter concerning Akula Foods Pty Ltd.

As requested, please find **attached** additional more recent financial information from the 2023 and 2024 Financial Years. Please note that these financial documents are provided to the TGA on a confidential basis solely for the purposes of this matter.

The information comprises:

- Financial Year 2023 Profit and Loss Statement;
- Business Activity Statements for Quarters 1 and 2 for the 2024 Financial Year;
- Business overdraft bank statement for the period 1 October to 31 December 2023.

We note that the Profit and Loss Statement discloses a net profit for FY23 of s47G. Further, the net GST collected as reported in the BASs for Qs 1 and 2 in FY24 disclose that Akula's business expenses are s47G. The bank statements disclose that Akula is operating s47G with a current s47G.

We reiterate that the imposition of the two infringement notices totalling \$37,560.00 would have a major financial impact upon our client's business and cause significant financial hardship in circumstances where the business is operating in very difficult trading conditions.

We look forward to your favourable consideration of this matter.

In the meantime, please let us know if you require any further information.

Regards,

47F

Principal



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666

Email: info@grossbecroft.com.au

www.grossbecroft.com.au

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From: RC <RC@health.gov.au>

Sent: Thursday, March 14, 2024 10:07 AM

To: 47F <info@grossbecroft.com.au>

Subject: RE: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Attention: 47F – 47F 3850

Hi 47F

Please note this is not a formal response from the Therapeutic Goods Administration (TGA).

Thank you for your letter and attached documents relating to the request for withdrawal of infringement notices issued to Akula Foods Pty Ltd. The delegate is requesting more financial information as what has been supplied is not sufficiently up to date to make a decision regarding withdrawal. At this point in time the delegate is not considering a withdrawal based on the information that has been supplied.

The delegate is fully aware that company income tax returns are generally not due to the Australian Taxation Office until mid-May each year, so it would not be reasonable to request the 2022/23 financial year return. However any current financial information, ideally from the 2022/23 and 2023/24 financial years, would aid the delegate in making an informed decision regarding the request for withdrawal of the infringement notices issued to Akula Foods Pty Ltd.

Please supply any additional information by **20 March 2024**.

Kind regards,

s22

Product and Import Compliance Section

Regulatory Compliance Branch

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au



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From: 47F <info@grossbecroft.com.au>
Sent: Friday, March 8, 2024 12:51 PM
To: RC <RC@health.gov.au>
Subject: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Attention: s22 (case officer) - Product & Import Compliance Section.

We refer to the above-mentioned matter in which we act on behalf of Akula Foods Pty Ltd.

Please find **attached** our letter of even date together with enclosures for your attention.

Kind Regards,

s47F

For and on Behalf of s47F



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

The Proper Officer
Akula Foods Pty Ltd
ACN: 611 490 549
1/65 Eastern Road
Browns Plains QLD 4118

Our References:
TGAIN-RC-023901/2024-1 & TGAIN-RC-
023901/2024-2

By Email: s47F@grossbecroft.com.au, info@grossbecroft.com.au

Dear The Proper Officer

**Infringement notices given to Akula Foods Pty Ltd under section 42YK of the
Therapeutic Goods Act 1989: TGAIN-RC-023901/2024-1 & TGAIN-RC-
023901/2024-2**

1. I am a delegate of the Secretary of the Australian Government Department of Health and Aged Care under sections 42YKBA and 42YKC of the *Therapeutic Goods Act 1989 (Cth) (the Act)*. On 26 February 2024, Akula Foods Pty Ltd, (**the company**) was given two infringement notices totalling \$37,560.00.
2. On 8 March 2024, the Therapeutic Goods Administration (**TGA**) received a submission from s47F@grossbecroft.com.au, on behalf of the company, seeking the withdrawal of two infringement notices issued to the company. Additional information with further supporting financial documentation was received by the TGA on 19 March 2024.
3. Please be aware that the amount specified in each infringement notice is determined by the Act and I am unable to reduce the penalty amount of an individual infringement notices.

Decision to withdraw one infringement notice given to Akula Foods Pty Ltd

4. I have considered the submissions made by s47F@grossbecroft.com.au on behalf of the company and supporting evidence and have exercised my discretion under section 42YC(2) of the Act to withdraw one infringement notice (**TGAIN-RC-023901/2024-2**) given to Akula Foods Pty Ltd on 26 February 2024.

Decision not to withdraw one infringement notice given to Akula Foods Pty Ltd

5. As an importer and wholesale supplier of various household goods in Australia, consumers trust that the products they are purchasing comply with Australian safety standards. However, the importation of unregistered therapeutic goods for commercial supply without adhering to the appropriate regulatory framework negates this safe standard of practice. In addition, the TGA does not evaluate

unapproved therapeutic goods for quality, safety and efficacy when imported. The use of therapeutic goods that are not entered in the ARTG poses serious risks to consumers.

6. Having regard to your representations, together with the seriousness of the contravention, under subsection 42YKC of the Act, I have decided not to withdraw one infringement notice (**TGAIN-RC-023901/2024-1**) given to Akula Foods Pty Ltd.

Reasons for decision

7. Under paragraph 42YKC(3)(a) of the Act, I am required, when considering whether to withdraw infringement notices, to take into account your written representations. I understand that your central submissions are:
 - a. Akula Foods Pty Ltd is a small family-owned business that has traded for approximately 8 years as an importer and distributor of foodstuffs and related products
 - b. No prior warning has been given to the company for same or similar goods. Previous TGA correspondence in 2022 concerning the importation of unregistered therapeutic goods bears no relation to the products for which the notices were issued
 - c. Similar Neem and Triphala tablets are currently being sold in Australia by prominent companies and presumably, the TGA has tested Akula's product to confirm that they are not derived from debitterised neem seed oil
 - d. The commercial value of the 2 goods imported was approximately s4 and s47 respectively in a container of products valued at s47; and
 - e. The family business would be significantly affected by the payment of the amount due in the infringement notice.

Your obligations under the TGA's legislative framework

In providing my reasons for my decision not to withdraw infringement notice **TGAIN-RC-023901/2024-1**, I refer to the comments made in my covering letter supporting my decision to give Akula Foods Pty Ltd infringement notices.

8. The product label on the Himalaya branded 'Neem' product references Neem as an ingredient, being a schedule 10 substance and considered to be a substance of such danger to health as to warrant prohibition of supply and use. The label does not refer to the product as being 'debitterised neem seed oil'. A reasonable consumer would therefore be led to believe that the product is in fact Neem.
9. As I outlined in my covering letter, entities engaging in business with therapeutic goods are expected to familiarise themselves with the relevant regulatory framework.
10. Our records indicate that there were multiple instances of engagement with s11C(1) s11C(1)(a) in relation to the prior imports of unregistered therapeutic goods. The

TGA considers the company has been provided with sufficient education and guidance material to assist with the regulatory requirements in relation to the lawful importation and supply of all therapeutic goods within Australia. When previously dealing with the director of the Company with respect to the prior importation of unregistered therapeutic goods, s11C(1)(a) advised that he was now aware of his obligations and that his company would not import again.

11. All Himalaya products imported on this occasion are clearly labelled or represented as medicines with associated therapeutic claims. It is likely that these products will be taken to be therapeutic goods.
12. I have already given consideration to a proportionate response to the alleged non-compliance when I chose to issue two infringement notices, when it was open to me to issue one infringement notice for each alleged contravention (seven, on this occasion).
13. You have identified Similar Neem and Triphala tablets currently being sold and advertised in Australia by prominent companies. I have referred this to the relevant team for consideration. The TGA does not generally release information to the public about specific compliance and enforcement activities, such as current investigations, unless it is necessary or required by the investigative process.

Infringement notices as an alternative to court

14. It is open to the company to elect not to pay the amount specified in the infringement notice and have the matter determined by a court. Please note infringement notices are an alternative to having court proceedings brought against the company in relation to this matter.
15. I note that there have been significant Federal Court decisions in which the Court has clearly stated that ignorance of, or inexperience with, the therapeutic goods framework is not an excuse.¹ Those who engage in businesses involving therapeutic goods have a responsibility to be aware of the laws that govern those products, and to comply with those from the outset.²

Extension of time to pay the notices

16. The due date to pay infringement notice **TGAIN-RC-023901/2024-1** is **26 March 2024**.
17. As per section 42YKBA(1) of the Act, the Secretary may, on the Secretary's own initiative and in writing, extend the period for paying the amount stated in the notice. The Secretary may do so before or after the end of that period.

¹ [Secretary, Department of Health v Enviro Tech Holdings Pty Ltd \[2022\] FCA 865 \(fedcourt.gov.au\)](#) at paragraph [76]

² [Secretary, Department of Health v Oxymed Australia Pty Ltd \[2021\] FCA 1518 \(fedcourt.gov.au\)](#) at paragraph [251].

18. As a delegate of the Secretary, I have decided to extend the due date to pay infringement notice **TGAIN-RC-023901/2024-1 to 26 June 2024**

If you have any questions, please contact the case officer, s22, by email at RC@health.gov.au or by phone (02) 6289 2284

Yours sincerely

s22



s22

Acting Assistant Secretary
Regulatory Compliance Branch
Therapeutic Goods Administration
Date: 4 April 2024

From: s47F
To: RC
Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]
Date: Tuesday, 7 May 2024 1:28:20 PM
Attachments: [image002.jpg](#)
[image004.png](#)
[image005.gif](#)

Hi s22

I refer to the abovementioned matter and note that I have not received a substantive response to our letter of 11 April 2024 concerning payment terms. Could you kindly respond as soon as possible so that I may convey the position to my client.

Regards,

s47F

Principal



Gross & Becroft Lawyers Pty. Ltd.
 Suite 2, Level 3, 182-184 Victoria Parade
 East Melbourne, Victoria 3002
 Tel: 03 9866 5666
 Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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From: RC <RC@health.gov.au>
Sent: Friday, April 19, 2024 11:17 AM
To: s47F @grossbecroft.com.au>
Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Good morning s47

Thank you for your email below. I apologise for the delay in the response as I have been on leave. I will review the correspondence and will be in contact shortly.

Warm regards

s22

Compliance Officer
 Product and Import Compliance Section

Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
 Therapeutic Goods Administration
 Australian Government, Department of Health and Aged Care

T: [s22](#) | E: rc@health.gov.au
www.tga.gov.au
 27 Scherger Drive, Canberra Airport, ACT 2609
 TGA Building Level 2 North
 PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: [s47F](#) <s47F@grossbecroft.com.au>

Sent: Thursday, April 11, 2024 3:38 PM

To: RC <RC@health.gov.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

Dear [s22](#)

Please see correspondence **attached** for your attention in relation to the abovementioned matter.

Regards,

[s47F](#)

Principal



Gross & Becroft Lawyers Pty. Ltd.
 Suite 2, Level 3, 182-184 Victoria Parade
 East Melbourne, Victoria 3002
 Tel: 03 9866 5666

Email: info@grossbecroft.com.au

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From: RC <RC@health.gov.au>

Sent: Thursday, April 4, 2024 3:21 PM

To: [s47F](#) <s47F@grossbecroft.com.au>; [s47F](#) <info@grossbecroft.com.au>

Subject: [SEC=OFFICIAL] TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

Importance: High

Good afternoon [s47F](#)

Thank you for your email on 8 March 2024 and 19 March 2024 to request the withdrawal of two infringement notices given to Akula Foods Pty Ltd.

Please see the **attached** correspondence from the delegate of the Secretary in relation to the decision to withdraw the two infringement notices given to Akula Foods Pty Ltd (TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2).

Please confirm receipt of this email with attached letter.

Sincerely,

s22

Product Import Compliance Section
Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group

Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

T: s22 | E: rc@health.gov.au

www.tga.gov.au

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TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

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From: s47F <s47F@grossbecroft.com.au>

Sent: Tuesday, March 19, 2024 12:04 PM

To: RC <RC@health.gov.au>

Subject: FW: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Importance: High

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22

I refer to your email below in relation to the matter concerning Akula Foods Pty Ltd.

As requested, please find **attached** additional more recent financial information from the 2023 and 2024 Financial Years. Please note that these financial documents are provided to the TGA on a confidential basis solely for the purposes of this matter.

The information comprises:

- Financial Year 2023 Profit and Loss Statement;
- Business Activity Statements for Quarters 1 and 2 for the 2024 Financial Year;
- Business overdraft bank statement for the period 1 October to 31 December 2023.

We note that the Profit and Loss Statement discloses a net profit for FY23 of s47G. Further, the net GST collected as reported in the BASs for Qs 1 and 2 in FY24 disclose that Akula's business expenses are s47G. The bank statements disclose that Akula is operating s47G with a current s47G.

We reiterate that the imposition of the two infringement notices totalling \$37,560.00 would have a major financial impact upon our client's business and cause significant financial hardship in circumstances where the business is operating in very difficult trading conditions.

We look forward to your favourable consideration of this matter.

In the meantime, please let us know if you require any further information.

Regards,

s47F

Principal



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 Suite 2, Level 3, 182-184 Victoria Parade
 East Melbourne, Victoria 3002
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From: RC <RC@health.gov.au>

Sent: Thursday, March 14, 2024 10:07 AM

To: s47F <info@grossbecroft.com.au>

Subject: RE: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Attention: s47F – s47 3850

Hi s47F

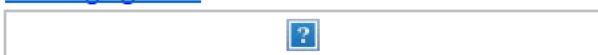
Please note this is not a formal response from the Therapeutic Goods Administration (TGA). Thank you for your letter and attached documents relating to the request for withdrawal of infringement notices issued to Akula Foods Pty Ltd. The delegate is requesting more financial information as what has been supplied is not sufficiently up to date to make a decision regarding withdrawal. At this point in time the delegate is not considering a withdrawal based on the information that has been supplied.

The delegate is fully aware that company income tax returns are generally not due to the Australian Taxation Office until mid-May each year, so it would not be reasonable to request the 2022/23 financial year return. However any current financial information, ideally from the 2022/23 and 2023/24 financial years, would aid the delegate in making an informed decision regarding the request for withdrawal of the infringement notices issued to Akula Foods Pty Ltd. Please supply any additional information by **20 March 2024**.

Kind regards,

s22

Product and Import Compliance Section
 Regulatory Compliance Branch
 Therapeutic Goods Administration
 Department of Health and Aged Care
 PO Box 100
 Woden ACT 2606
www.tga.gov.au



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From: s47F <info@grossbecroft.com.au>

Sent: Friday, March 8, 2024 12:51 PM

To: RC <RC@health.gov.au>

Subject: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Attention: s22 (case officer) - Product & Import Compliance Section.

We refer to the above-mentioned matter in which we act on behalf of Akula Foods Pty Ltd.

Please find **attached** our letter of even date together with enclosures for your attention.

Kind Regards,

s47F

For and on Behalf of s47F



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."



s47F

Suite 2, Level 3
182-184 Victoria Parade
East Melbourne, Victoria, 3002
Australia
Telephone: (61 3) 9866 5666
Email: info@grossbecroft.com.au
Our Ref: RB:3850

'Without Prejudice'

11 April 2024

BY EMAIL: RC@health.gov.au

s22

s22

Product Import Compliance Section
Regulatory Compliance Branch
Therapeutic Goods Administration

Dear s22

Re: **Akula Foods Pty Ltd – Infringement Notices**
Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2
TGA Reference: TGAIN-RC-023901

We refer to your email of 4 April 2024 attaching a copy of the decision and reasons for the withdrawing of infringement notice TGAIN-RC-023901/2024-2 and the maintaining of infringement notice TGAIN-RC-023901/2024-1.

As you are aware, our client is a small family owned business and the payment of a lump sum of \$18,780 would impose a significant financial burden our client, notwithstanding the extension of the payment deadline to 26 June 2024. Accordingly, our client has requested that it be permitted to pay off penalty notice TGAIN-RC-023901/2024-1 in instalments of \$1,000 per month commencing on 26 June 2024. The TGA is already in possession of financial documentation that would support this request and the financial position of our client has been acknowledged in the reasons for the decision.

We look forward to receiving your early response to this request.

Yours faithfully

Visit our Website at www.grossbecroft.com.au

s47F



s47F

Gross & Becroft Lawyers
Principal



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Akula Foods Pty Ltd
 ACN: 611 490 549
 s11C(1)(a)
 1/65 Eastern Road
 Browns Plains QLD 4118

Our References: TGAIN-RC-023901

By Email: s47F grossbecroft.com.au
akulafoods@gmail.com

Dear s11C(1)(a)

Extension of payment due date for the infringement notice given to Akula Foods Pty Ltd under section 42YK of the *Therapeutic Goods Act 1989*: TGAIN- RC-023901/2024-1

1. I am a delegate of the Secretary for the purposes of section 42YKB of the Therapeutic Goods Act 1989 (**the Act**). On 26 February 2024 I decided to give 2 infringement notices (TGAIN- RC-023901/2024-1, TGAIN- RC-023901/2024-2) to Akula Foods Pty Ltd (the company) totaling \$37,560.00 with the original payment due date being 26 March 2024.
2. On 8 March 2024, the Therapeutic Goods Administration (TGA) received a submission from s47F, on behalf of the company, seeking the withdrawal of two infringement notices issued to the company. Additional information with further supporting financial documentation was received by the TGA on 19 March 2024.
3. On 4 April 2024, under subsection 42YC(2) of the Act and having considered the submissions and supporting evidence, I decided to withdraw one infringement notice TGAIN-RC-023901/2024-2 and extend the payment due date for infringement notice TGAIN-RC-023901/2024-1 to 26 June 2024.
4. On 11 April 2024, the TGA received a further request from s47F, on behalf of the company, seeking a payment plan of \$1,000.00 per month, commencing on 26 June 2024. The financial documentation to support this request was already held by the TGA.
5. Under subsection 42YKB(2) of the Act and having considered the request, I agree to extend the payment due date for the infringement notice TGAIN-RC-023901/2024-1 to 1 May 2025.

Infringement notice	Amount	Initial Due Date	Extended Due Date
TGAIN-RC-023901/2024-1	\$18,780.00	26 March 2024	1 May 2025

I have not agreed to an extension to accommodate a payment of \$1,000 per month commencing 26 June 2024 as I do not think that this request is reasonable - it would have extend the compliance period by 20 months. Please refer to proposed dates to facilitate payment in full of TGAIN-RC-023901/2024-1 by the end of the compliance period at **Appendix 1**.

6. Please acknowledge receipt of this correspondence and confirm that you agree with the proposed payment plan, which would facilitate payment in full by the end of the compliance period by close of business on Friday 10 May 2024.
7. I note that should you fail to meet the extended compliance period and associated payment due date, the TGA will consider further enforcement action. An infringement notice is an opportunity for the company to pay an amount as an alternative to having court proceedings brought against them in relation to the alleged contravention described in the relevant notice.

APPENDIX 1 – Extension of time to pay infringement notice given to Akula Foods Pty Ltd

If you elect to pay the infringement notice in instalments, proposed payments may fall due as follows, to conclude payment of \$18,780.00 (total) by the end of the compliance period:

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Yours sincerely

(signed electronically)

s22

s22

Delegate of the Secretary,
Regulatory Compliance Branch
Therapeutic Goods Administration
8 May 2024

[this document has been electronically signed]

From: RC
To: s47F
Subject: Att. 5 - Acceptance of Payment Arrangement - RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]
Date: Friday, 10 May 2024 8:04:45 AM
Attachments: [image001.jpg](#)
[image002.gif](#)
[image003.png](#)

Good morning s22

Thank you for confirming your clients acceptance regarding the infringement notice payment proposal and extension of the due date. The new date for payment is 1 May 2025.

Warm regards

s22

Product Import Compliance Section
Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
 Therapeutic Goods Administration
 Australian Government, Department of Health and Aged Care
 T: s22 | E: rc@health.gov.au
www.tga.gov.au
 27 Scherger Drive, Canberra Airport, ACT 2609
 TGA Building Level 2 North
 PO Box 100, Woden ACT 2606, Australia

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From: s47F <[redacted]@grossbecroft.com.au>
Sent: Thursday, May 9, 2024 2:43 PM
To: RC <RC@health.gov.au>
Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Dear s22

As requested in paragraph 6 of the letter from the TGA received yesterday, I am instructed that Akula Foods has agreed to the proposed repayment plan.

Regards,

s47F

Principal



Gross & Becroft Lawyers Pty. Ltd.
 Suite 2, Level 3, 182-184 Victoria Parade
 East Melbourne, Victoria 3002
 Tel: 03 9866 5666
 Email: info@grossbecroft.com.au
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From: RC <RC@health.gov.au>

Sent: Wednesday, May 8, 2024 3:07 PM

To: s47F [redacted] <s47F@grossbecroft.com.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Good afternoon s47F [redacted]

Thank you for your email.

Please see attached a formal response to your request from the delegate in relation to TGAIN-RC-023901/2024-1.

Kind regards,

s22 [redacted]

Compliance Officer
Product and Import Compliance Section
Regulatory Compliance Branch

Email: rc@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



From: s47F [redacted] <s47F@grossbecroft.com.au>

Sent: Tuesday, May 7, 2024 1:28 PM

To: RC <RC@health.gov.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Hi s22 [redacted]

I refer to the abovementioned matter and note that I have not received a substantive response to our letter of 11 April 2024 concerning payment terms. Could you kindly respond as soon as possible so that I may convey the position to my client.

Regards,

s47F [redacted]

Principal



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From: RC <RC@health.gov.au>

Sent: Friday, April 19, 2024 11:17 AM

To: s47F [redacted] <s47F@grossbecroft.com.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIR-RC-023901/2024-1 and TGAIR-RC-023901/2024-2 [SEC=OFFICIAL]

Good morning s47F [redacted]

Thank you for your email below. I apologise for the delay in the response as I have been on leave. I will review the correspondence and will be in contact shortly.

Warm regards

s22 [redacted]

Compliance Officer

Product and Import Compliance Section

Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group

Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

T: s22 [redacted] | E: rc@health.gov.au

www.tga.gov.au

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PO Box 100, Woden ACT 2606, Australia

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From: s47F [redacted] <s47F@grossbecroft.com.au>

Sent: Thursday, April 11, 2024 3:38 PM

To: RC <RC@health.gov.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIR-RC-023901/2024-1 and TGAIR-RC-023901/2024-2

Dear s22 [redacted]

Please see correspondence **attached** for your attention in relation to the abovementioned matter.

Regards,

s47F

Principal

Gross & Becroft Lawyers Pty. Ltd.
 Suite 2, Level 3, 182-184 Victoria Parade
 East Melbourne, Victoria 3002
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From: RC <RC@health.gov.au>

Sent: Thursday, April 4, 2024 3:21 PM

To: s47F <s47F@grossbecroft.com.au>; s47F <info@grossbecroft.com.au>

Subject: [SEC=OFFICIAL] TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

Importance: High

Good afternoon s47F

Thank you for your email on 8 March 2024 and 19 March 2024 to request the withdrawal of two infringement notices given to Akula Foods Pty Ltd.

Please see the **attached** correspondence from the delegate of the Secretary in relation to the decision to withdraw the two infringement notices given to Akula Foods Pty Ltd (TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2).

Please confirm receipt of this email with attached letter.

Sincerely,

s22

Product Import Compliance Section
Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group

Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

T: s22 | E: rc@health.gov.au

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TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

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From: s47F <s47F@grossbecroft.com.au>

Sent: Tuesday, March 19, 2024 12:04 PM

To: RC <RC@health.gov.au>

Subject: FW: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAİN-RC-023901/2024-1 and TGAİN-RC-023901/2024-2 [SEC=OFFICIAL]

Importance: High

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22

I refer to your email below in relation to the matter concerning Akula Foods Pty Ltd.

As requested, please find **attached** additional more recent financial information from the 2023 and 2024 Financial Years. Please note that these financial documents are provided to the TGA on a confidential basis solely for the purposes of this matter.

The information comprises:

- Financial Year 2023 Profit and Loss Statement;
- Business Activity Statements for Quarters 1 and 2 for the 2024 Financial Year;
- Business overdraft bank statement for the period 1 October to 31 December 2023.

We note that the Profit and Loss Statement discloses a net profit for FY23 of s47G. Further, the net GST collected as reported in the BASs for Qs 1 and 2 in FY24 disclose that Akula's business expenses are s47G. The bank statements disclose that Akula is operating s47G with a current s47G.

We reiterate that the imposition of the two infringement notices totalling \$37,560.00 would have a major financial impact upon our client's business and cause significant financial hardship in circumstances where the business is operating in very difficult trading conditions.

We look forward to your favourable consideration of this matter.

In the meantime, please let us know if you require any further information.

Regards,

s47F

Principal



Gross & Becroft Lawyers Pty. Ltd.

Suite 2, Level 3, 182-184 Victoria Parade

East Melbourne, Victoria 3002

Tel: 03 9866 5666

Email: info@grossbecroft.com.au

www.grossbecroft.com.au

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From: RC <RC@health.gov.au>

Sent: Thursday, March 14, 2024 10:07 AM

To: s47F <info@grossbecroft.com.au>

Subject: RE: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Attention: s47F – s47 F 3850

Hi s47F

Please note this is not a formal response from the Therapeutic Goods Administration (TGA). Thank you for your letter and attached documents relating to the request for withdrawal of infringement notices issued to Akula Foods Pty Ltd. The delegate is requesting more financial information as what has been supplied is not sufficiently up to date to make a decision regarding withdrawal. At this point in time the delegate is not considering a withdrawal based on the information that has been supplied.

The delegate is fully aware that company income tax returns are generally not due to the Australian Taxation Office until mid-May each year, so it would not be reasonable to request the 2022/23 financial year return. However any current financial information, ideally from the 2022/23 and 2023/24 financial years, would aid the delegate in making an informed decision regarding the request for withdrawal of the infringement notices issued to Akula Foods Pty Ltd. Please supply any additional information by **20 March 2024**.

Kind regards,

s22

Product and Import Compliance Section
Regulatory Compliance Branch
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



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From: s47F <info@grossbecroft.com.au>

Sent: Friday, March 8, 2024 12:51 PM

To: RC <RC@health.gov.au>

Subject: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Attention: s22 (case officer) - Product & Import Compliance Section.

We refer to the above-mentioned matter in which we act on behalf of Akula Foods Pty Ltd. Please find **attached** our letter of even date together with enclosures for your attention.

Kind Regards,

s47F

For and on Behalf of s47F



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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Akuka Food Pty Ltd – Payment schedule

TGAIN- RC-023901/2024-1				
Installment	Amount Payable	Due Date	Date Paid	TRIM Ref#
1	\$1,565.00	30 May 2024	25.05.2024	D24-2046053
2	\$1,565.00	30 June 2024		
3	\$1,565.00	30 July 2024		
4	\$1,565.00	30 August 2024		
5	\$1,565.00	30 September 2024		
6	\$1,565.00	30 October 2024		
7	\$1,565.00	30 November 2024		
8	\$1,565.00	30 December 2024		
9	\$1,565.00	30 January 2025		
10	\$1,565.00	28 February 2025		
11	\$1,565.00	30 March 2025		
12	\$1,565.00	30 April 2025		

From: [RC](#)
To: [CRM Health](#)
Subject: UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]
Date: Thursday, 9 May 2024 10:09:26 AM
Attachments: [image002.png](#)

Good morning,

In regards to the expectant monies below, please see the updated information as one infringement notice has been withdrawn.

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Kind regards

[s22](#)

[s22](#)

Product Import Compliance Section

Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

T: [s22](#) | E: rc@health.gov.au

www.tga.gov.au

27 Scherger Drive, Canberra Airport, ACT 2609

TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: RC <RC@health.gov.au>
Sent: Thursday, February 29, 2024 2:21 PM
To: CRM Health <CRM@Health.gov.au>
Subject: Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Hi team,

Please be advised two (2) infringement notices have been issued for Akula Foods Pty Ltd itemised below.

Infringement Notice Reference	Amount Payable	Due Date
TGAIN-RC-023901/2024-1	\$18,780	26 March 2024
TGAIN-RC-023901/2024-2	\$18,780	26 March 2024

Please let me know if there are any questions/issues.

Kind regards,

s22

s22

Product and Import Compliance Section

Regulatory Compliance Branch

Email: s22@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au

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From: s47F
To: RC
Cc: s22
Subject: RE: Final Payment Overdue: Akula Foods Pty Ltd - TGAIN-RC-023901/2024-1 [SEC=OFFICIAL]
Date: Thursday, 8 May 2025 10:06:02 AM
Attachments: [image001.jpg](#)
[image002.png](#)
[image003.png](#)
[image004.gif](#)

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Hi s22

I refer to your email below.

I have been advised by Akula that the final instalment has now been paid.

Regards,

s47F

Principal



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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From: RC

Sent: Thursday, 8 May 2025 8:08 AM

To: s47F

Cc: s22

Subject: Final Payment Overdue: Akula Foods Pty Ltd - TGAIN-RC-023901/2024-1 [SEC=OFFICIAL]

Good morning s47F

I am reaching out to confirm whether your client Akula Foods Pty Ltd intends to pay the final instalment of TGAIN-RC-023901/2024-1 as per the payment proposal agreed on 09 May 2024, noting this payment was due on 30 April 2025 and has yet to be received by the TGA.

I have attached the agreed payment proposal and the payment schedule below for reference.

TGAIN-RC-023901/2024-1

Installment	Amount Payable	Due Date	Date Received
1	\$1,565.00	30 May 2024	25 May 2024
2	\$1,565.00	30 June 2024	25 June 2024
3	\$1,565.00	30 July 2024	24 July 2024
4	\$1,565.00	30 August 2024	26 August 2024
5	\$1,565.00	30 September 2024	25 September 2024
6	\$1,565.00	30 October 2024	28 October 2024
7	\$1,565.00	30 November 2024	21 November 2024
8	\$1,565.00	30 December 2024	23 December 2024
9	\$1,565.00	30 January 2025	23 January 2025
10	\$1,565.00	28 February 2025	26 February 2025
11	\$1,565.00	30 March 2025	20 March 2025
12	\$1,565.00	30 April 2025	Not received

Kind regards,

s22

s22 – Regulatory Compliance Section

Regulatory Practice and Support Division | Health Products Regulation Group
 Regulatory Compliance Branch
 Therapeutic Goods Administration
 Australian Government Department of Health and Aged Care
 27 Scherger Drive, Canberra Airport, ACT 2609
 TGA Building Level 2 North
 PO Box 100, Woden ACT 2606, Australia

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From: RC <RC@health.gov.au>

Sent: Friday, 10 May 2024 8:05 AM

To: s47F <s47F@grossbecroft.com.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Good morning s47F

Thank you for confirming your clients acceptance regarding the infringement notice payment proposal and extension of the due date. The new date for payment is 1 May 2025.

Warm regards

s22

Product Import Compliance Section

Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
 Therapeutic Goods Administration
 Australian Government, Department of Health and Aged Care
 T: s22 | E: rc@health.gov.au
www.tga.gov.au
 27 Scherger Drive, Canberra Airport, ACT 2609
 TGA Building Level 2 North
 PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s47F <[REDACTED]@grossbecroft.com.au>

Sent: Thursday, May 9, 2024 2:43 PM

To: RC <RC@health.gov.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Dear s22

As requested in paragraph 6 of the letter from the TGA received yesterday, I am instructed that Akula Foods has agreed to the proposed repayment plan.

Regards,

s47F

Principal

Gross & Becroft Lawyers Pty. Ltd.
 Suite 2, Level 3, 182-184 Victoria Parade
 East Melbourne, Victoria 3002
 Tel: 03 9866 5666
 Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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From: RC <RC@health.gov.au>

Sent: Wednesday, May 8, 2024 3:07 PM

To: s47F <[REDACTED]@grossbecroft.com.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Good afternoon s47F

Thank you for your email.

Please see attached a formal response to your request from the delegate in relation to TGAIN-RC-023901/2024-1.

Kind regards,

s22

s22

Product and Import Compliance Section
Regulatory Compliance Branch

Email: rc@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



From: s47F <[redacted]@grossbecroft.com.au>

Sent: Tuesday, May 7, 2024 1:28 PM

To: RC <RC@health.gov.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Hi s22

I refer to the abovementioned matter and note that I have not received a substantive response to our letter of 11 April 2024 concerning payment terms. Could you kindly respond as soon as possible so that I may convey the position to my client.

Regards,

s47F

Principal



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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From: RC <RC@health.gov.au>

Sent: Friday, April 19, 2024 11:17 AM

To: [s47F](#) <s47F@grossbecroft.com.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Good morning [s47F](#)

Thank you for your email below. I apologise for the delay in the response as I have been on leave. I will review the correspondence and will be in contact shortly.

Warm regards

[s22](#)

Product and Import Compliance Section

Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
T: [s22](#) | E: rc@health.gov.au
www.tga.gov.au
27 Scherger Drive, Canberra Airport, ACT 2609
TGA Building Level 2 North
PO Box 100, Woden ACT 2606, Australia

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From: [s47F](#) <s47F@grossbecroft.com.au>

Sent: Thursday, April 11, 2024 3:38 PM

To: RC <RC@health.gov.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

Dear [s22](#)

Please see correspondence **attached** for your attention in relation to the abovementioned matter.

Regards,

[s47F](#)

Principal



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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From: RC <RC@health.gov.au>

Sent: Thursday, April 4, 2024 3:21 PM

To: s47F <[REDACTED]@grossbecroft.com.au>; s47F <[REDACTED]@grossbecroft.com.au>

Subject: [SEC=OFFICIAL] TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

Importance: High

Good afternoon s47F

Thank you for your email on 8 March 2024 and 19 March 2024 to request the withdrawal of two infringement notices given to Akula Foods Pty Ltd.

Please see the **attached** correspondence from the delegate of the Secretary in relation to the decision to withdraw the two infringement notices given to Akula Foods Pty Ltd (TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2).

Please confirm receipt of this email with attached letter.

Sincerely,

s22

Product Import Compliance Section

Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group

Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

T: s22 | E: rc@health.gov.au

www.tga.gov.au

27 Scherger Drive, Canberra Airport, ACT 2609

TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

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From: s47F <[REDACTED]@grossbecroft.com.au>

Sent: Tuesday, March 19, 2024 12:04 PM

To: RC <RC@health.gov.au>

Subject: FW: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Importance: High

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22

I refer to your email below in relation to the matter concerning Akula Foods Pty Ltd.

As requested, please find **attached** additional more recent financial information from the 2023 and 2024 Financial Years. Please note that these financial documents are provided to the TGA on a confidential basis solely for the purposes of this matter.

The information comprises:

- Financial Year 2023 Profit and Loss Statement;
- Business Activity Statements for Quarters 1 and 2 for the 2024 Financial Year;

- Business overdraft bank statement for the period 1 October to 31 December 2023.

We note that the Profit and Loss Statement discloses a net profit for FY23 of s47G. Further, the net GST collected as reported in the BASs for Qs 1 and 2 in FY24 disclose that Akula's business expenses s47G. The bank statements disclose that Akula is operating s47G with a current s47G.

We reiterate that the imposition of the two infringement notices totalling \$37,560.00 would have a major financial impact upon our client's business and cause significant financial hardship in circumstances where the business is operating in very difficult trading conditions.

We look forward to your favourable consideration of this matter.

In the meantime, please let us know if you require any further information.

Regards,

s47F

Principal



Gross & Becroft Lawyers Pty. Ltd.

Suite 2, Level 3, 182-184 Victoria Parade

East Melbourne, Victoria 3002

Tel: 03 9866 5666

Email: info@grossbecroft.com.au

www.grossbecroft.com.au

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From: RC <RC@health.gov.au>

Sent: Thursday, March 14, 2024 10:07 AM

To: s47F <info@grossbecroft.com.au>

Subject: RE: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Attention: s47F s47F 3850

Hi s47F

Please note this is not a formal response from the Therapeutic Goods Administration (TGA).

Thank you for your letter and attached documents relating to the request for withdrawal of infringement notices issued to Akula Foods Pty Ltd. The delegate is requesting more financial information as what has been supplied is not sufficiently up to date to make a decision regarding withdrawal. At this point in time the delegate is not considering a withdrawal based on the information that has been supplied.

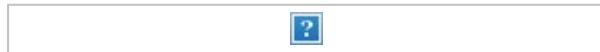
The delegate is fully aware that company income tax returns are generally not due to the Australian Taxation Office until mid-May each year, so it would not be reasonable to request the

2022/23 financial year return. However any current financial information, ideally from the 2022/23 and 2023/24 financial years, would aid the delegate in making an informed decision regarding the request for withdrawal of the infringement notices issued to Akula Foods Pty Ltd. Please supply any additional information by **20 March 2024**.

Kind regards,

s22

Product and Import Compliance Section
Regulatory Compliance Branch
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



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From: s47F <info@grossbecroft.com.au>

Sent: Friday, March 8, 2024 12:51 PM

To: RC <RC@health.gov.au>

Subject: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

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Attention: s22 (case officer) - Product & Import Compliance Section.

We refer to the above-mentioned matter in which we act on behalf of Akula Foods Pty Ltd. Please find **attached** our letter of even date together with enclosures for your attention.

Kind Regards,

s47F

For and on Behalf of s47F



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
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From: s22 on behalf of CRM Health
 To: RC
 Cc: CRM Health
 Subject: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]
 Date: Friday, 9 May 2025 8:07:11 AM
 Attachments: image002.png
 image003.png
 image004.png
 image005.png
 image006.png
 image007.png
 image008.png
 image009.png
 image010.png
 image011.png
 image012.png
 image013.png
 image014.png
 image015.png
 image016.png
 image017.gif
 image001.png

Good morning,
 We received the final payment on 08.05.25.
 TGAIN-RC-023901/2024-12

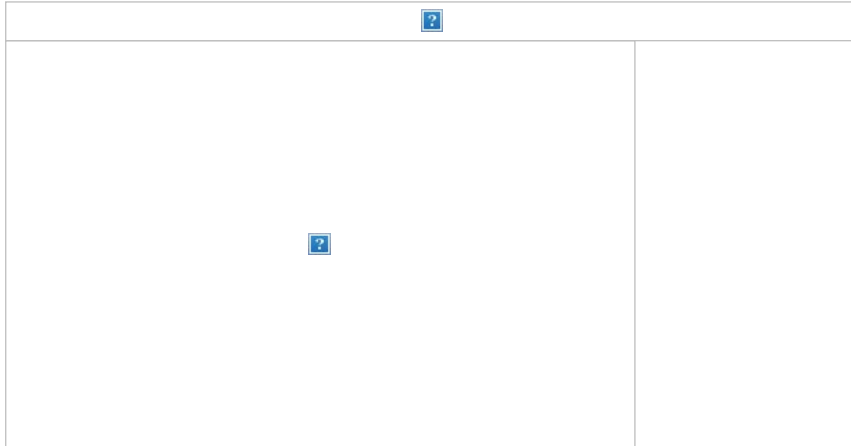
TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2025
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards
 s22
 Financial Management Division | Corporate Operations Group
 Corporate and Financial Strategy and Services (CFSS)
 Australian Government, Department of Health and Aged Care
 T: s22 | E: CRM@health.gov.au
 Location: Level 2 Scarborough House
 GPO Box 9848, Canberra ACT 2601, Australia
 s22
 , please
 call Finance helpdesk on (02) 6289 4900.
 The Department of Health and Aged Care acknowledges the

Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: CRM Health
 Sent: Friday, 21 March 2025 10:00 AM
 To: CRM Health ; RC
 Subject: RE: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

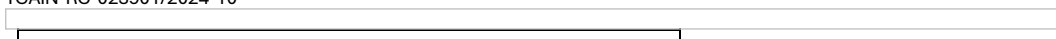
Good morning,
 We received the 11th instalment on 20.03.25.



Regards,
 s22
 Financial Management Division | Corporate Operations Group
 Corporate and Financial Strategy and Services (CFSS)
 Australian Government, Department of Health and Aged Care
 T: s22 | E: s22@health.gov.au
 Location: Level 2 Scarborough House MDP22
 GPO Box 9848, Canberra ACT 2601, Australia
 The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 On Behalf Of CRM Health
 Sent: Thursday, 27 February 2025 10:19 AM
 To: RC
 Cc: CRM Health
 Subject: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,
 We received the 10th instalment on 26.02.25.
 TGAIN-RC-023901/2024-10



Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2025
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards

s22

Financial Management Division | Corporate Operations Group
 Corporate and Financial Strategy and Services (CFSS)
 Australian Government, Department of Health and Aged Care
 T: s22 | E: CRM@health.gov.au
 Location: Level 2 Scarborough House
 GPO Box 9848, Canberra ACT 2601, Australia

s22

, please
 call Finance helpdesk on (02) 6289 4900.
 The Department of Health and Aged Care acknowledges the

Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: CRM Health <CRM@Health.gov.au>

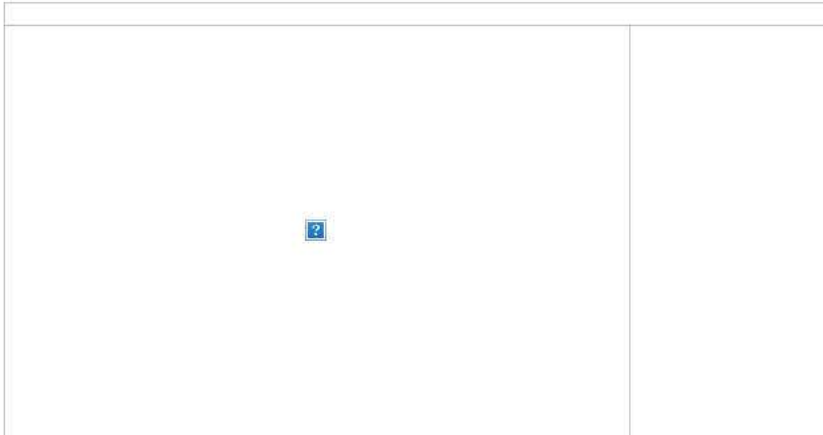
Sent: Friday, 24 January 2025 1:54 PM

To: CRM Health <CRM@Health.gov.au>; RC <RC@health.gov.au>

Subject: RE: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good afternoon,

We received the 9th instalment on 23.01.25.



Regards,

s22

Financial Management Division | Corporate Operations Group
 Corporate and Financial Strategy and Services (CFSS)
 Australian Government, Department of Health and Aged Care
 T: s22 | E: s22@health.gov.au
 Location: Level 2 Scarborough House MDP22
 GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @health.gov.au > On Behalf Of CRM Health

Sent: Tuesday, 24 December 2024 7:20 AM

To: RC <RC@health.gov.au>

Cc: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL] ()

Good morning,

We received the 8th instalment on 23.12.24.

TGAIN-RC-023901/2024-8

Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2025
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards

s22

Financial Management Division | Corporate Operations Group
 Corporate and Financial Strategy and Services (CFSS)
 Australian Government, Department of Health and Aged Care
 T: s22 | E: CRM@health.gov.au
 Location: Level 2 Scarborough House
 GPO Box 9848, Canberra ACT 2601, Australia

s22

, please
 call Finance helpdesk on (02) 6289 4900.
 The Department of Health and Aged Care acknowledges the

Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @health.gov.au > On Behalf Of CRM Health

Sent: Friday, 22 November 2024 11:03 AM

To: RC <RC@health.gov.au>

Cc: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024- s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,

We received the 7th instalment on 21.11.24.

TGAIN-RC-023901/2024-7

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards
s22

Financial Management Division | Corporate Operations Group
Corporate and Financial Strategy and Services (CFSS)
Australian Government, Department of Health and Aged Care
T: s22 | E: CRM@health.gov.au
Location: Level 2 Scarborough House
GPO Box 9848, Canberra ACT 2601, Australia

s22, please
call Finance helpdesk on (02) 6289 4900.
The Department of Health and Aged Care acknowledges the

Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @health.gov.au > On Behalf Of CRM Health

Sent: Monday, 28 October 2024 8:03 AM

To: RC <RC@health.gov.au>

Cc: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL] ()

Good morning,

We received the 6th instalment on 25.10.24.

TGAIN-RC-023901/2024-6

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards
s22

Financial Management Division | Corporate Operations Group
Corporate and Financial Strategy and Services (CFSS)
Australian Government, Department of Health and Aged Care
T: s22 | E: CRM@health.gov.au
Lo 2 Scarborough House
GPO Box 9848, Canberra ACT 2601, Australia

s22, please
call Finance helpdesk on (02) 6289 4900.
The Department of Health and Aged Care acknowledges the

Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @health.gov.au > On Behalf Of CRM Health

Sent: Thursday, 26 September 2024 10:58 AM

To: RC <RC@health.gov.au>

Cc: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,

We received the 5nd instalment on 25.09.24.

TGAIN-RC-023901/2024-5

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards
s22

Financial Management Division | Corporate Operations Group
Corporate and Financial Strategy and Services (CFSS)
Australian Government, Department of Health and Aged Care
T: s22 | E: CRM@health.gov.au
Lo 2 Scarborough House
GPO Box 9848, Canberra ACT 2601, Australia

s22, please call
Finance helpdesk on (02) 6289 4900.
The Department of Health and Aged Care acknowledges the
Traditional Custodians of Australia and their continued

connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @health.gov.au > On Behalf Of CRM Health

Sent: Tuesday, August 27, 2024 8:19 AM

To: RC <RC@health.gov.au>

Cc: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL] ()

Good morning,

We received the 4nd instalment on 26.08.24.

TGAIN-RC-023901/2024-4 – Ram Akula

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024

Regards
s22

Financial Management Division | Corporate Operations Group
Corporate and Financial Strategy and Services (CFSS)
Australian Government, Department of Health and Aged Care
T: s22 | E: CRM@health.gov.au
Location: Level 2 Scarborough House

7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

GPO Box 9848, Canberra ACT 2601, Australia
s22
 , please call
 Finance helpdesk on (02) 6289 4900.
 The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued

connection to land, sea and community. We pay our respects to all Elders past and present.

From: **s22** <s22@health.gov.au> **On Behalf Of** CRM Health

Sent: Wednesday, July 24, 2024 9:33 AM

To: RC <RC@health.gov.au>

Cc: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024-1 **s11C(** UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,

We received the 3nd instalment on 23.07.24.

[Redacted]

TGAIN-RC-023901/2024-1 – Ram Akula

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards
s22
 Financial Management Division | Corporate Operations Group
 Corporate Financial Strategy and Services (CFSS)
 Australian Government Department of Health and Aged Care
 T: **s22** | E: CRM@health.gov.au
 Location: Sirius Building 3.S.545
 GPO Box 9848, Canberra ACT 2601, Australia
s22
 , please call
 Finance helpdesk on (02) 6289 4900.
 The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued

connection to land, sea and community. We pay our respects to all Elders past and present.

From: CRM Health <CRM@Health.gov.au>

Sent: Wednesday, June 26, 2024 8:42 AM

To: CRM Health <CRM@Health.gov.au>; RC <RC@health.gov.au>

Subject: RE: 2000 TGAIN-RC-023901/2024-1 **s11C(1)** UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,

We received the 2nd instalment on 25.06.24.

[Redacted]

Regards,

s22

Financial Management Division | Corporate Operations Group
 Corporate Financial Strategy and Services (CFSS)
 Australian Government Department of Health and Aged Care
 T: **s22** | E: CRM@health.gov.au
 Location: Sirius Building 3.S.548
 GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: CRM Health <CRM@Health.gov.au>

Sent: Tuesday, May 28, 2024 8:29 AM

To: RC <RC@health.gov.au>; CRM Health <CRM@Health.gov.au>

Subject: RE: 2000 TGAIN-RC-023901/2024-1 UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning **s2**,

We received the first instalment of \$1,565.00 on 25.05.24.

[Redacted]

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Paid 25.05.24.
s22
 Financial Management Division | Corporate Operations Group
 Corporate and Financial Strategy and Services (CFSS)
 Australian Government, Department of Health and Aged Care
 T: **s22** | E: **s22** <s22@health.gov.au>
 Location: Sirius Building 3.S.545
 GPO Box 9848, Canberra ACT 2601, Australia
 The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.
From: RC <RC@health.gov.au>

Sent: Thursday, May 9, 2024 10:09 AM

To: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024-1 UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,

In regards to the expectant monies below, please see the updated information as one infringement notice has been withdrawn.

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024

Paid 25.05.24.
 Kind regards
s22

4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

s22

Product Import Compliance Section
Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

T: s22 | E: rc@health.gov.au

www.tga.gov.au

27 Scherger Drive, Canberra Airport, ACT 2609

TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: RC <rc@health.gov.au>

Sent: Thursday, February 29, 2024 2:21 PM

To: CRM Health <CRM@Health.gov.au>

Subject: Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Hi team,

Please be advised two (2) infringement notices have been issued for Akula Foods Pty Ltd itemised below.

Infringement Notice Reference	Amount Payable	Due Date
TGAIN-RC-023901/2024-1	\$18,780	26 March 2024
TGAIN-RC-023901/2024-2	\$18,780	26 March 2024

Please let me know if there are any questions/issues.

Kind regards,

s22

Product and Import Compliance Section

Regulatory Compliance Branch

Email: s22@health.gov.au

Therap

dministration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au



Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

From: s22
 To: [Redacted]
 Cc: [Redacted]
 Subject: Final Payment Not Received: 2000 TGAIN-RC-023901/2024-12 Akula Foods Pty Ltd [SEC=OFFICIAL]
 Date: Tuesday, 6 May 2025 3:58:00 PM
 Attachments: [image004.png](#)
[image018.png](#)
[image019.png](#)
[image020.png](#)
[image021.png](#)
[image022.png](#)
[image023.png](#)
[image024.png](#)
[image025.png](#)
[image026.png](#)
[image027.png](#)
[image028.png](#)
[image029.png](#)
[image030.png](#)
[image031.png](#)
[image032.png](#)
[image033.gif](#)
 Importance: High

Hi s22

The 12th and final payment of \$1565 for TGAIN-RC-023901/2024-1 has not been made by s11C(1) (AKULA) the due date of 30 April 2025, with the extended compliance period expiring on 01 May 2025 – Payment Schedule at the bottom of this email for reference. I have confirmed with Financial Management Division today (06 May 2025) that they have no record of the payment being made (see below email chain).

Throughout the payment arrangement AKULA has repeatedly made payments before the scheduled due dates, so missing this payment is inconsistent with his expected behaviour. Giving AKULA the benefit of the doubt, I believe he thought the 11th instalment was the final payment.

Next Steps:

We may still be in a position to extend the time to pay as per section 42YBA of the *Therapeutic Goods Act 1989* (see below) which allows the Secretary to grant an extension of time to pay an infringement notice by their own initiative either before or **after** the end of that period. However I note that we will need to seek advice from RLSB to confirm this approach before proceeding.

42YKBA - Extension of time to pay amount—extension by Secretary on own initiative

- (1) If the Secretary gives a person an infringement notice, the Secretary may, on the Secretary’s own initiative and in writing, extend the period for paying the amount stated in the notice. The Secretary may do so before or after the end of that period.
Note: The period for paying the amount may be the 28-day period referred to in paragraph 42YKA(1)(h) or an extended period under section 42YKB or this section.
- (2) For the purposes of this Part, if the Secretary extends that period, the period within which the amount stated in the notice is to be paid is the extended period.
- (3) The Secretary must give the person notice of the Secretary’s decision.
- (4) The Secretary may give more than one extension under this section in relation to the infringement notice.

TGAIN- RC-023901/2024-1 Payment Schedule			
Instalment	Amount Payable	Due Date	Date Paid
1	\$1,565.00	30-May-24	25-May-24
2	\$1,565.00	30-Jun-24	25-Jun-24
3	\$1,565.00	30-Jul-24	24-Jul-24
4	\$1,565.00	30-Aug-24	26-Aug-24
5	\$1,565.00	30-Sep-24	25-Sep-24
6	\$1,565.00	30-Oct-24	28-Oct-24
7	\$1,565.00	30-Nov-24	21-Nov-24
8	\$1,565.00	30-Dec-24	23-Dec-24
9	\$1,565.00	30-Jan-24	23-Jan-25
10	\$1,565.00	28-Feb-25	26-Feb-25
11	\$1,565.00	30-Mar-25	20-Mar-25
12	\$1,565.00	30-Apr-25	Overdue

s22
 s22 – Regulatory Compliance Section

Regulatory Practice and Support Division | Health Products Regulation Group
 Regulatory Compliance Branch
 Therapeutic Goods Administration
 Australian Government Department of Health and Aged Care

T: s22
 E: s22@health.gov.au
 27 Scherger Drive, Canberra Airport, ACT 2609
 TGA Building Level 2 North
 PO Box 100, Woden ACT 2606, Australia

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From: CRM Health
 Sent: Tuesday, 6 May 2025 1:33 PM
 To: RC ; CRM Health
 Subject: RE: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Hi s22

We have no record of receiving this payment.

Regards,

s22

Financial Management Division | Corporate Operations Group
Corporate and Financial Strategy and Services (CFSS)
Australian Government, Department of Health and Aged Care
T: s22 | E: s22@health.gov.au
Location: Level 2 Scarborough House MDP22
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: RC <RC@health.gov.au>

Sent: Tuesday, 6 May 2025 8:23 AM

To: CRM Health <CRM@Health.gov.au>

Subject: RE: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning team,

Can you confirm if the final payment of \$1565 for 30 April 2025 has been received?

Kind regards,

s22

– Regulatory Compliance Section

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Compliance Branch
Therapeutic Goods Administration
Australian Government Department of Health and Aged Care

T: s22

E: s22@health.gov.au

27 Scherger Drive, Canberra Airport, ACT 2609

TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

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From: CRM Health <CRM@Health.gov.au>

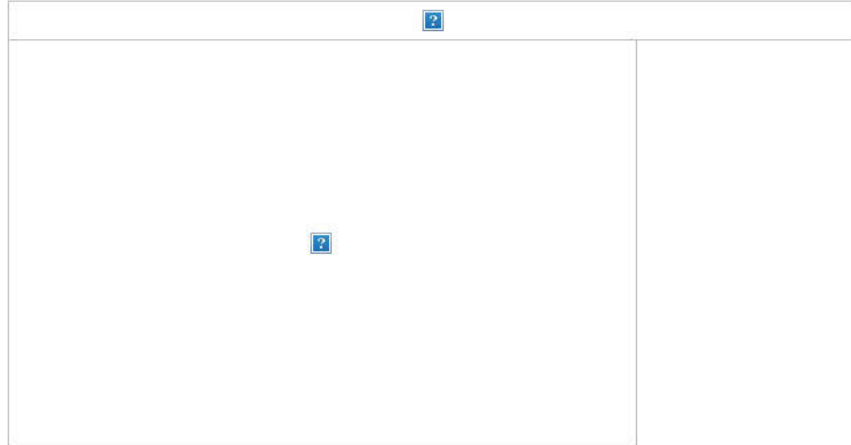
Sent: Friday, 21 March 2025 10:00 AM

To: CRM Health <CRM@Health.gov.au>; RC <RC@health.gov.au>

Subject: RE: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,

We received the 11th instalment on 20.03.25.



Regards,

s22

Financial Management Division | Corporate Operations Group
Corporate and Financial Strategy and Services (CFSS)
Australian Government, Department of Health and Aged Care
T: s22 | E: s22@health.gov.au
Location: Level 2 Scarborough House MDP22
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 On Behalf Of CRM Health

Sent: Thursday, 27 February 2025 10:19 AM

To: RC

Cc: CRM Health

Subject: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL] ()

Good morning,

We received the 10th instalment on 26.02.25.

TGAIN-RC-023901/2024-10

TGAIN-RC-023901/2024-1			Regards s22
Installment	Amount Payable	Due Date	

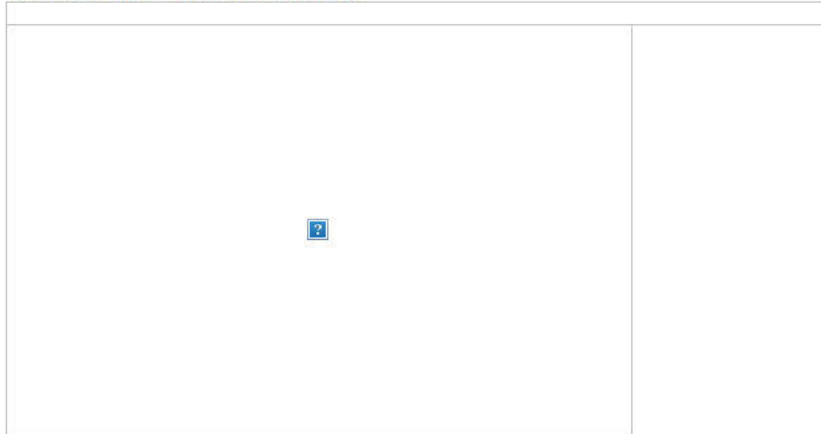
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2025
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

s22
 Financial Management Division | Corporate Operations Group
 Corporate and Financial Strategy and Services (CFSS)
 Australian Government, Department of Health and Aged Care
 T: s22 | E: CRM@health.gov.au
 Location: Level 2 Scarborough House
 GPO Box 9848, Canberra ACT 2601, Australia
 s22
 , please
 call Finance helpdesk on (02) 6289 4900.
 The Department of Health and Aged Care acknowledges the
 Traditional Custodians of Australia and their continued

connection to land, sea and community. We pay our respects to all Elders past and present.

From: CRM Health <CRM@Health.gov.au>
Sent: Friday, 24 January 2025 1:54 PM
To: CRM Health <CRM@Health.gov.au>; RC <RC@health.gov.au>
Subject: RE: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good afternoon,
 We received the 9th instalment on 23.01.25.



Regards,
 s22
 Financial Management Division | Corporate Operations Group
 Corporate and Financial Strategy and Services (CFSS)
 Australian Government, Department of Health and Aged Care
 T: s22 | E: s22@health.gov.au
 Location: Level 2 Scarborough House MDP22
 GPO Box 9848, Canberra ACT 2601, Australia
 The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @health.gov.au > On Behalf Of CRM Health
Sent: Tuesday, 24 December 2024 7:20 AM
To: RC <RC@health.gov.au>
Cc: CRM Health <CRM@Health.gov.au>
Subject: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,
 We received the 8th instalment on 23.12.24.
 TGAIN-RC-023901/2024-8

TGAIN- RC-023901/2024-1		
Instalment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2025
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards
 s22
 Financial Management Division | Corporate Operations Group
 Corporate and Financial Strategy and Services (CFSS)
 Australian Government, Department of Health and Aged Care
 T: s22 | E: CRM@health.gov.au
 Location: Level 2 Scarborough House
 GPO Box 9848, Canberra ACT 2601, Australia
 s22
 , please
 call Finance helpdesk on (02) 6289 4900.
 The Department of Health and Aged Care acknowledges the
 Traditional Custodians of Australia and their continued

connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @health.gov.au > On Behalf Of CRM Health
Sent: Friday, 22 November 2024 11:03 AM
To: RC <RC@health.gov.au>
Cc: CRM Health <CRM@Health.gov.au>
Subject: 2000 TGAIN-RC-023901/2024-1 s11C(1) UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,
 We received the 7th instalment on 21.11.24.

TGAIN-RC-023901/2024-7

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards
s22
Financial Management Division | Corporate Operations Group
Corporate and Financial Strategy and Services (CFSS)
Australian Government, Department of Health and Aged Care
T: s22 | E: CRM@health.gov.au
Loc: 2 Scarborough House
GPO Box 9848, Canberra ACT 2601, Australia
s22
, please
call Finance helpdesk on (02) 6289 4900.
The Department of Health and Aged Care acknowledges the
Traditional Custodians of Australia and their continued

connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @health.gov.au > On Behalf Of CRM Health

Sent: Monday, 28 October 2024 8:03 AM

To: RC <RC@health.gov.au>

Cc: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024-1 s11C(1) IPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL] ()

Good morning,

We received the 6th instalment on 25.10.24.

TGAIN-RC-023901/2024-6

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards
s22
ations Group
Corporate and Financial Strategy and Services (CFSS)
Australian Government, Department of Health and Aged Care
T: s22 | E: CRM@health.gov.au
Lo: 2 Scarborough House
GPO Box 9848, Canberra ACT 2601, Australia
s22
, please
call Finance helpdesk on (02) 6289 4900.
The Department of Health and Aged Care acknowledges the
Traditional Custodians of Australia and their continued

connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @health.gov.au > On Behalf Of CRM Health

Sent: Thursday, 26 September 2024 10:58 AM

To: RC <RC@health.gov.au>

Cc: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024-1 s11C(1) IPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL] ()

Good morning,

We received the 5nd instalment on 25.09.24.

TGAIN-RC-023901/2024-5

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards
s22
Financial Management Division | Corporate Operations Group
Corporate and Financial Strategy and Services (CFSS)
Australian Government, Department of Health and Aged Care
T: s22 | E: CRM@health.gov.au
Location: Level 2 Scarborough House
GPO Box 9848, Canberra ACT 2601, Australia
s22
, please call
Finance helpdesk on (02) 6289 4900.
The Department of Health and Aged Care acknowledges the
Traditional Custodians of Australia and their continued

connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @health.gov.au > On Behalf Of CRM Health

Sent: Tuesday, August 27, 2024 8:19 AM

To: RC <RC@health.gov.au>

Cc: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024- s11C(1) IPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL] ()

Good morning,

We received the 4nd instalment on 26.08.24.

TGAIN-RC-023901/2024-4 – Ram Akula

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024

Regards
s22
Financial Management Division | Corporate Operations Group
Corporate and Financial Strategy and Services (CFSS)
Australian Government, Department of Health and Aged Care
T: s22 | E: CRM@health.gov.au

6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Location: Level 2 Scarborough House
 GPO Box 9848, Canberra ACT 2601, Australia
 s22
 , please call
 Finance helpdesk on (02) 6289 4900.
 The Department of Health and Aged Care acknowledges the
 Traditional Custodians of Australia and their continued

connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @health.gov.au > On Behalf Of CRM Health

Sent: Wednesday, July 24, 2024 9:33 AM

To: RC <RC@health.gov.au>

Cc: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024-1 s11C() UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,

We received the 3rd instalment on 23.07.24.

TGAIN-RC-023901/2024-1 – Ram Akula

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Regards
 s22
 Financial Management Division | Corporate Operations Group
 Corporate Financial Strategy and Services (CFSS)
 Australian Government Department of Health and Aged Care
 T: s22 | E: CRM@health.gov.au
 Location: Sirius Building 3.S.545
 GPO Box 9848, Canberra ACT 2601, Australia
 s22
 , please call
 Finance helpdesk on (02) 6289 4900.
 The Department of Health and Aged Care acknowledges the
 Traditional Custodians of Australia and their continued

connection to land, sea and community. We pay our respects to all Elders past and present.

From: CRM Health <CRM@Health.gov.au>

Sent: Wednesday, June 26, 2024 8:42 AM

To: CRM Health <CRM@Health.gov.au>; RC <RC@health.gov.au>

Subject: RE: 2000 TGAIN-RC-023901/2024- s11C(1) PDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,

We received the 2nd instalment on 25.06.24.

Regards

s22

Financial Management Division | Corporate Operations Group
 Corporate Financial Strategy and Services (CFSS)
 Australian Government Department of Health and Aged Care
 T: s22 | E: CRM@health.gov.au
 Location: Sirius Building 3.S.548
 GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: CRM Health <CRM@Health.gov.au>

Sent: Tuesday, May 28, 2024 8:29 AM

To: RC <RC@health.gov.au>; CRM Health <CRM@Health.gov.au>

Subject: RE: 2000 TGAIN-RC-023901/2024-1 UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning s22

We received the first instalment of \$1,565.00 on 25.05.24.

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024
3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

Paid 25.05.24.
 s22
 Financial Management Division | Corporate Operations Group
 Corporate and Financial Strategy and Services (CFSS)
 Australian Government Department of Health and Aged Care
 T: s22 | E: s22 @health.gov.au
 Location: Sirius Building 3.S.548
 GPO Box 9848, Canberra ACT 2601, Australia
 The Department of Health and Aged Care acknowledges the
 Traditional Custodians of Australia and their continued
 connection to land, sea and community. We pay our respects to
 all Elders past and present.

From: RC <RC@health.gov.au>

Sent: Thursday, May 9, 2024 10:09 AM

To: CRM Health <CRM@Health.gov.au>

Subject: 2000 TGAIN-RC-023901/2024-1 UPDATED EXPECTANT MONIES INFORMATION - RC-023901 - Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning,

In regards to the expectant monies below, please see the updated information as one infringement notice has been withdrawn.

TGAIN- RC-023901/2024-1		
Installment	Amount Payable	Due Date
1	\$1,565.00	30 May 2024
2	\$1,565.00	30 June 2024

Paid 25.05.24.

Kind regards

s22

3	\$1,565.00	30 July 2024
4	\$1,565.00	30 August 2024
5	\$1,565.00	30 September 2024
6	\$1,565.00	30 October 2024
7	\$1,565.00	30 November 2024
8	\$1,565.00	30 December 2024
9	\$1,565.00	30 January 2024
10	\$1,565.00	28 February 2025
11	\$1,565.00	30 March 2025
12	\$1,565.00	30 April 2025

s22

Compliance Section
Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
T: s22 | E: rc@health.gov.au
www.tga.gov.au
27 Scherger Drive, Canberra Airport, ACT 2609
TGA Building Level 2 North
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: RC <RC@health.gov.au>

Sent: Thursday, February 29, 2024 2:21 PM

To: CRM Health <CRM@Health.gov.au>

Subject: Infringement Notices Issued for Akula Foods Pty Ltd [SEC=OFFICIAL]

Hi team,

Please be advised two (2) infringement notices have been issued for Akula Foods Pty Ltd itemised below.

Infringement Notice Reference	Amount Payable	Due Date
TGAIN-RC-023901/2024-1	\$18,780	26 March 2024
TGAIN-RC-023901/2024-2	\$18,780	26 March 2024

Please let me know if there are any questions/issues.

Kind regards,

s22

Product and Import Compliance Section
Regulatory Compliance Branch

Email: s22@health.gov.au

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au

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From: RC
To: s47F
Cc:
Subject: Delegate Decision to Extend Due Date for Payment - Akula Foods Pty Ltd - TGAIN-RC-023901/2024-1 [SEC=OFFICIAL]
Date: Tuesday, 17 June 2025 8:40:00 AM
Attachments: [TGAIN-RC-023901-2024-1 Delegate decision to extend due date.pdf](#)
[image002.png](#)
[image005.jpg](#)
[image006.png](#)
[image007.gif](#)

Good morning s47F

On 13 June 2025, as per section 42YKBA(1) of the *Therapeutic Goods Act 1989*, the Delegate decided to extend the due date to pay infringement notice **TGAIN-RC-023901/2024-1** to 20 June 2025 and accepts the final instalment of \$1565 paid by Akula Foods Pty Ltd on 8 May 2025.

Please find attached delegate decision letter and confirm receipt of this correspondence.

Kind regards,

s22

— Regulatory Compliance Section

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Compliance Branch

Therapeutic Goods Administration
Australian Government Department of Health, Disability and Ageing

27 Scherger Drive, Canberra Airport, ACT 2609
TGA Building Level 2 North
PO Box 100, Woden ACT 2606, Australia

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From: s47F @grossbecroft.com.au>
Sent: Thursday, 8 May 2025 10:06 AM
To: RC <RC@health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Final Payment Overdue: Akula Foods Pty Ltd - TGAIN-RC-023901/2024-1 [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

I refer to your email below.

I have been advised by Akula that the final instalment has now been paid.

Regards,

s47F

Principal



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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From: RC <RC@health.gov.au>

Sent: Thursday, 8 May 2025 8:08 AM

To: s47F <s47F@grossbecroft.com.au>

Cc: s22 <s22@health.gov.au>; s22 <s22@health.gov.au>

Subject: Final Payment Overdue: Akula Foods Pty Ltd - TGAIN-RC-023901/2024-1 [SEC=OFFICIAL]

Good morning s47F

I am reaching out to confirm whether your client Akula Foods Pty Ltd intends to pay the final instalment of TGAIN-RC-023901/2024-1 as per the payment proposal agreed on 09 May 2024, noting this payment was due on 30 April 2025 and has yet to be received by the TGA.

I have attached the agreed payment proposal and the payment schedule below for reference.

TGAIN-RC-023901/2024-1			
Installment	Amount Payable	Due Date	Date Received
1	\$1,565.00	30 May 2024	25 May 2024
2	\$1,565.00	30 June 2024	25 June 2024
3	\$1,565.00	30 July 2024	24 July 2024
4	\$1,565.00	30 August 2024	26 August 2024
5	\$1,565.00	30 September 2024	25 September 2024
6	\$1,565.00	30 October 2024	28 October 2024
7	\$1,565.00	30 November 2024	21 November 2024
8	\$1,565.00	30 December 2024	23 December 2024
9	\$1,565.00	30 January 2025	23 January 2025
10	\$1,565.00	28 February 2025	26 February 2025
11	\$1,565.00	30 March 2025	20 March 2025
12	\$1,565.00	30 April 2025	Not received

Kind regards,

s22

Regulatory Compliance Section

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Compliance Branch

Therapeutic Goods Administration
Australian Government Department of Health and Aged Care

27 Scherger Drive, Canberra Airport, ACT 2609
TGA Building Level 2 North
PO Box 100, Woden ACT 2606, Australia

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From: RC <RC@health.gov.au>

Sent: Friday, 10 May 2024 8:05 AM

To: s47F [redacted] <s47F@grossbecroft.com.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGA-RC-023901/2024-1 and TGA-RC-023901/2024-2 [SEC=OFFICIAL]

Good morning s47F [redacted]

Thank you for confirming your clients acceptance regarding the infringement notice payment proposal and extension of the due date. The new date for payment is 1 May 2025.

Warm regards

s22 [redacted]

Product Import Compliance Section

Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

T: s22 [redacted] | E: rc@health.gov.au

www.tga.gov.au

27 Scherger Drive, Canberra Airport, ACT 2609

TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s47F [redacted] <s47F@grossbecroft.com.au>

Sent: Thursday, May 9, 2024 2:43 PM

To: RC <RC@health.gov.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGA-RC-023901/2024-1 and TGA-RC-023901/2024-2 [SEC=OFFICIAL]

Dear s22 [redacted]

As requested in paragraph 6 of the letter from the TGA received yesterday, I am instructed that Akula Foods has agreed to the proposed repayment plan.

Regards,

s47F [redacted]

Principal



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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From: RC <RC@health.gov.au>
Sent: Wednesday, May 8, 2024 3:07 PM
To: s47F@grossbecroft.com.au
Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGA-RC-023901/2024-1 and TGA-RC-023901/2024-2 [SEC=OFFICIAL]

Good afternoon s47F

Thank you for your email.

Please see attached a formal response to your request from the delegate in relation to TGA-RC-023901/2024-1.

Kind regards,

s22

Product and Import Compliance Section
Regulatory Compliance Branch

Email: rc@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



From: s47F [redacted] <[redacted]@grossbecroft.com.au>
Sent: Tuesday, May 7, 2024 1:28 PM
To: RC <RC@health.gov.au>
Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Hi s22 [redacted]

I refer to the abovementioned matter and note that I have not received a substantive response to our letter of 11 April 2024 concerning payment terms. Could you kindly respond as soon as possible so that I may convey the position to my client.

Regards,

s47F [redacted]

Principal



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au

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From: RC <RC@health.gov.au>
Sent: Friday, April 19, 2024 11:17 AM
To: s47F [redacted] <[redacted]@grossbecroft.com.au>
Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Good morning s47 [redacted]

Thank you for your email below. I apologise for the delay in the response as I have been on leave. I will review the correspondence and will be in contact shortly.

Warm regards

s22

Product and Import Compliance Section

Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

T: s22 | E: rc@health.gov.au

www.tga.gov.au

27 Scherger Drive, Canberra Airport, ACT 2609

TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s47F <s47F@grossbecroft.com.au>

Sent: Thursday, April 11, 2024 3:38 PM

To: RC <RC@health.gov.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGA-RC-023901/2024-1 and TGA-RC-023901/2024-2

Dear s22

Please see correspondence **attached** for your attention in relation to the abovementioned matter.

Regards,

s47F

Principal



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002

Tel: 03 9866 5666

Email: info@grossbecroft.com.au

www.grossbecroft.com.au

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From: RC <RC@health.gov.au>

Sent: Thursday, April 4, 2024 3:21 PM

To: s47F [redacted] <s47F@grossbecroft.com.au>; s47F [redacted] <info@grossbecroft.com.au>

Subject: [SEC=OFFICIAL] TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

Importance: High

Good afternoon s47F [redacted]

Thank you for your email on 8 March 2024 and 19 March 2024 to request the withdrawal of two infringement notices given to Akula Foods Pty Ltd.

Please see the **attached** correspondence from the delegate of the Secretary in relation to the decision to withdraw the two infringement notices given to Akula Foods Pty Ltd (TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2).

Please confirm receipt of this email with attached letter.

Sincerely,

s22 [redacted]

Product Import Compliance Section

Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

T: s22 [redacted] | E: rc@health.gov.au

www.tga.gov.au

27 Scherger Drive, Canberra Airport, ACT 2609

TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

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From: s47F [redacted] <[redacted]@grossbecroft.com.au>
Sent: Tuesday, March 19, 2024 12:04 PM
To: RC <RC@health.gov.au>
Subject: FW: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]
Importance: High

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22 [redacted]

I refer to your email below in relation to the matter concerning Akula Foods Pty Ltd.

As requested, please find **attached** additional more recent financial information from the 2023 and 2024 Financial Years. Please note that these financial documents are provided to the TGA on a confidential basis solely for the purposes of this matter.

The information comprises:

- Financial Year 2023 Profit and Loss Statement;
- Business Activity Statements for Quarters 1 and 2 for the 2024 Financial Year;
- Business overdraft bank statement for the period 1 October to 31 December 2023.

We note that the Profit and Loss Statement discloses a net profit for FY23 of s47G [redacted]. Further, the net GST collected as reported in the BASs for Qs 1 and 2 in FY24 disclose that Akula's business expenses s47G [redacted]. The bank statements disclose that Akula is operating s47G [redacted] with a current s47G [redacted].

We reiterate that the imposition of the two infringement notices totalling \$37,560.00 would have a major financial impact upon our client's business and cause significant financial hardship in circumstances where the business is operating in very difficult trading conditions.

We look forward to your favourable consideration of this matter.

In the meantime, please let us know if you require any further information.

Regards,

s47F [redacted]

Principal



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Email: info@grossbecroft.com.au
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From: RC <RC@health.gov.au>
Sent: Thursday, March 14, 2024 10:07 AM
To: s47F <info@grossbecroft.com.au>
Subject: RE: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Attention: s47F – s4 3850
7E

Hi s47F

Please note this is not a formal response from the Therapeutic Goods Administration (TGA).

Thank you for your letter and attached documents relating to the request for withdrawal of infringement notices issued to Akula Foods Pty Ltd. The delegate is requesting more financial information as what has been supplied is not sufficiently up to date to make a decision regarding withdrawal. At this point in time the delegate is not considering a withdrawal based on the information that has been supplied.

The delegate is fully aware that company income tax returns are generally not due to the Australian Taxation Office until mid-May each year, so it would not be reasonable to request the 2022/23 financial year return. However any current financial information, ideally from the 2022/23 and 2023/24 financial years, would aid the delegate in making an informed decision regarding the request for withdrawal of the infringement notices issued to Akula Foods Pty Ltd.

Please supply any additional information by **20 March 2024**.

Kind regards,

s22

Product and Import Compliance Section
Regulatory Compliance Branch
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



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From: s47F <info@grossbecroft.com.au>
Sent: Friday, March 8, 2024 12:51 PM
To: RC <RC@health.gov.au>
Subject: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Attention: s22 (case officer) - Product & Import Compliance Section.

We refer to the above-mentioned matter in which we act on behalf of Akula Foods Pty Ltd.

Please find **attached** our letter of even date together with enclosures for your attention.

Kind Regards,

s47F

For and on Behalf of s47F



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
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Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

The Proper Officer
Akula Foods Pty Ltd
ACN: 611 490 549
1/65 Eastern Road
Browns Plains QLD 4118

Our Reference:
TGAIN-RC-023901/2024-1

By Email: s47F@grossbecroft.com.au, info@grossbecroft.com.au

Dear The Proper Officer

Infringement notices given to Akula Foods Pty Ltd under section 42YK of the *Therapeutic Goods Act 1989*: TGAIN-RC-023901/2024-1 & TGAIN-RC-023901/2024-2

1. I am a delegate of the Secretary of the Australian Government Department of Health, Disability and Ageing under sections 42YKBA and 42YKC of the *Therapeutic Goods Act 1989 (Cth) (the Act)*. On 26 February 2024, Akula Foods Pty Ltd, (**the company**) was given two infringement notices totalling \$37,560.00.
2. On 8 March 2024, the Therapeutic Goods Administration (**TGA**) received a submission from [s47F](#), on behalf of the company, seeking the withdrawal of two infringement notices issued to the company. Additional information with further supporting financial documentation was received by the TGA on 19 March 2024.

Prior decision to withdraw one infringement notice given to Akula Foods Pty Ltd

3. On 4 April 2024 I considered the submissions made by [s47F](#) on behalf of the company and supporting evidence and exercised my discretion under section 42YC(2) of the Act to withdraw one infringement notice (**TGAIN-RC-023901/2024-2**) given to the company on 26 February 2024.
4. **TGAIN-RC-023901/2024-1** was not withdrawn for the reasons outlined in the letter issued to the company on 4 April 2024.

Prior decisions to extend the due date for payment of one infringement notice by instalments given to Akula Foods Pty Ltd

5. On 4 April 2024 I extended the payment period for **TGAIN-RC-023901/2024-1** until 26 June 2024. On 8 May 2024, I granted a further extension for payment of the infringement notice by instalments to 1 May 2025. This was granted in response to a request by [s47F](#) on behalf of the company under subsection 42YKB(2) of the Act.

6. [s47F](#), on behalf of the company, accepted the proposed payment plan of 12 monthly payments of \$1,565 on 9 May 2024.

Extension of due date for payment and acceptance of final instalment paid

7. The company paid 11 of the 12 instalments within the compliance period. However, the final instalment, due 30 April 2025, was made by the company after the expiry of compliance period ending 1 May 2025. No application for an extension of the payment period was received by the TGA from the company.
8. The Department of Health, Disability and Ageing received this final payment of \$1,565 for **TGAIN-RC-023901/2024-1** on 8 May 2025.
9. As per section 42YKBA(1) of the Act, the Secretary may, on the Secretary's own initiative and in writing, extend the period for paying the amount stated in the notice. The Secretary may do so before or after the end of that period. The payment made on 8 May 2025 was held pending a decision under section 42YKBA.
10. As a delegate of the Secretary, I have decided to extend the due date to pay infringement notice **TGAIN-RC-023901/2024-1** to **20 June 2025**. This correspondence forms notice of this decision as per section 42YKBA(3). I will also accept the final instalment of \$1,565 paid on 8 May 2025, within the extended due date.

Discharge of liability

11. The effect of the accepting the instalment paid on 8 May 2025 is that your liability has been fully discharged, and no court action with respect to the alleged breach set out in **TGAIN-RC-023901/2024-1** can be taken against you.
12. Please be aware that any future contravention of the *Therapeutic Goods Act 1989*, may result in the TGA taking further enforcement action. I advise that the investigation into this matter is now closed and thank you for your cooperation.

If you have any questions, please contact the case officer, [s22](#), by email at RC@health.gov.au or by phone (02) 5132 2231.

Yours sincerely

[s22](#)

[s22](#)

Regulatory Compliance Section
Therapeutic Goods Administration
Date: 13 June 2025

From: RC
To: s47F_grossbecroft.com.au
Subject: FW: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]
Date: Tuesday, 24 December 2024 10:51:00 AM
Attachments: [image001.jpg](#)
[image002.gif](#)
[image003.png](#)
[image004.png](#)

Good afternoon:

I am writing to confirm that we have received payment for instalment number 8.

TGAIN- RC-023901/2024-1			
Installment	Amount Payable	Due Date	Payment received
1	\$1,565.00	30 May 2024	25 May 2024
2	\$1,565.00	30 June 2024	25 June 2024
3	\$1,565.00	30 July 2024	23 July 2024
4	\$1,565.00	30 August 2024	26 August 2024
5	\$1,565.00	30 September 2024	25 September 2024
6	\$1,565.00	30 October 2024	25 October 2024
7	\$1,565.00	30 November 2024	21 November 2024
8	\$1,565.00	30 December 2024	23 December 2024
9	\$1,565.00	30 January 2025	
10	\$1,565.00	28 February 2025	
11	\$1,565.00	30 March 2025	
12	\$1,565.00	30 April 2025	

Regards,

s22

Product Import Compliance

Regulatory Practice and Support Division | Health Products Regulation Group

Regulatory Compliance Branch

Therapeutic Goods Administration

Australian Government Department of Health and Aged Care

T: s22

E: rc@health.gov.au

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: RC

Sent: Friday, 10 May 2024 8:05 AM

To: s47F

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Good morning s47

Thank you for confirming your clients acceptance regarding the infringement notice payment proposal and extension of the due date. The new date for payment is 1 May 2025.

Warm regards

s22

**Product Import Compliance Section
Regulatory Compliance Branch**

Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
T: s22 | E: rc@health.gov.au
www.tga.gov.au
27 Scherger Drive, Canberra Airport, ACT 2609
TGA Building Level 2 North
PO Box 100, Woden ACT 2606, Australia

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From: s47F <s47F@grossbecroft.com.au>

Sent: Thursday, May 9, 2024 2:43 PM

To: RC <RC@health.gov.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAİN-RC-023901/2024-1 and TGAİN-RC-023901/2024-2 [SEC=OFFICIAL]

Dear s22

As requested in paragraph 6 of the letter from the TGA received yesterday, I am instructed that Akula Foods has agreed to the proposed repayment plan.

Regards,

s47F

Principal



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
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From: RC <RC@health.gov.au>

Sent: Wednesday, May 8, 2024 3:07 PM

To: s47F <s47F@grossbecroft.com.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices

-Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Good afternoon s47F

Thank you for your email.

Please see attached a formal response to your request from the delegate in relation to TGAIN-RC-023901/2024-1.



Kind regards,

s22

Product and Import Compliance Section
Regulatory Compliance Branch

Email: rc@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: s47F <s47F@grossbecroft.com.au>

Sent: Tuesday, May 7, 2024 1:28 PM

To: RC <RC@health.gov.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Hi s22

I refer to the abovementioned matter and note that I have not received a substantive response to our letter of 11 April 2024 concerning payment terms. Could you kindly respond as soon as possible so that I may convey the position to my client.

Regards,

s47F

Principal

Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
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From: RC <RC@health.gov.au>

Sent: Friday, April 19, 2024 11:17 AM

To: [s47F](#) <s47F@grossbecroft.com.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Good morning [s47F](#)

Thank you for your email below. I apologise for the delay in the response as I have been on leave. I will review the correspondence and will be in contact shortly.

Warm regards

[s22](#)

Product and Import Compliance Section

Regulatory Compliance Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Therapeutic Goods Administration
Australian Government, Department of Health and Aged Care
T: [s22](#) | E: rc@health.gov.au
www.tga.gov.au

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PO Box 100, Woden ACT 2606, Australia

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From: [s47F](#) <s47F@grossbecroft.com.au>

Sent: Thursday, April 11, 2024 3:38 PM

To: RC <RC@health.gov.au>

Subject: RE: TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

Dear [s22](#)

Please see correspondence **attached** for your attention in relation to the abovementioned matter.

Regards,

[s47F](#)

Principal



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Suite 2, Level 3, 182-184 Victoria Parade
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From: RC <RC@health.gov.au>

Sent: Thursday, April 4, 2024 3:21 PM

To: s47F <[REDACTED]@grossbecroft.com.au>; s47F <[REDACTED]@grossbecroft.com.au>

Subject: [SEC=OFFICIAL] TGA Letter regarding Akula Foods Pty Ltd request to withdraw Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

Importance: High

Good afternoon s47F

Thank you for your email on 8 March 2024 and 19 March 2024 to request the withdrawal of two infringement notices given to Akula Foods Pty Ltd.

Please see the **attached** correspondence from the delegate of the Secretary in relation to the decision to withdraw the two infringement notices given to Akula Foods Pty Ltd (TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2).

Please confirm receipt of this email with attached letter.

Sincerely,

s22

**Product Import Compliance Section
Regulatory Compliance Branch**

Regulatory Practice and Support Division | Health Products Regulation Group

Therapeutic Goods Administration

Australian Government, Department of Health and Aged Care

T: s22 [REDACTED] | E: rc@health.gov.au

www.tga.gov.au

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TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

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From: s47F <[REDACTED]@grossbecroft.com.au>

Sent: Tuesday, March 19, 2024 12:04 PM

To: RC <RC@health.gov.au>

Subject: FW: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Importance: High

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22

I refer to your email below in relation to the matter concerning Akula Foods Pty Ltd.

As requested, please find **attached** additional more recent financial information from the 2023 and 2024 Financial Years. Please note that these financial documents are provided to the TGA on a confidential basis solely for the purposes of this matter.

The information comprises:

- Financial Year 2023 Profit and Loss Statement;

- Business Activity Statements for Quarters 1 and 2 for the 2024 Financial Year;
- Business overdraft bank statement for the period 1 October to 31 December 2023.

We note that the Profit and Loss Statement discloses a net profit for FY23 of s47G. Further, the net GST collected as reported in the BASs for Qs 1 and 2 in FY24 disclose that Akula's business expenses are s47G. The bank statements disclose that Akula is operating s47G with a current s47G.

We reiterate that the imposition of the two infringement notices totalling \$37,560.00 would have a major financial impact upon our client's business and cause significant financial hardship in circumstances where the business is operating in very difficult trading conditions.

We look forward to your favourable consideration of this matter.

In the meantime, please let us know if you require any further information.

Regards,

s47F

Principal



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From: RC <RC@health.gov.au>

Sent: Thursday, March 14, 2024 10:07 AM

To: s47F <info@grossbecroft.com.au>

Subject: RE: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL]

Attention: s47F – s4 3850
 Hi s47F 7F

Please note this is not a formal response from the Therapeutic Goods Administration (TGA). Thank you for your letter and attached documents relating to the request for withdrawal of infringement notices issued to Akula Foods Pty Ltd. The delegate is requesting more financial information as what has been supplied is not sufficiently up to date to make a decision regarding withdrawal. At this point in time the delegate is not considering a withdrawal based on the information that has been supplied.

The delegate is fully aware that company income tax returns are generally not due to the

Australian Taxation Office until mid-May each year, so it would not be reasonable to request the 2022/23 financial year return. However any current financial information, ideally from the 2022/23 and 2023/24 financial years, would aid the delegate in making an informed decision regarding the request for withdrawal of the infringement notices issued to Akula Foods Pty Ltd. Please supply any additional information by **20 March 2024**.

Kind regards,

s22

Product and Import Compliance Section
Regulatory Compliance Branch
Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606
www.tga.gov.au



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From: s47F <info@grossbecroft.com.au>

Sent: Friday, March 8, 2024 12:51 PM

To: RC <RC@health.gov.au>

Subject: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Attention: s22 (case officer) - Product & Import Compliance Section.

We refer to the above-mentioned matter in which we act on behalf of Akula Foods Pty Ltd.

Please find **attached** our letter of even date together with enclosures for your attention.

Kind Regards,

s47F

For and on Behalf of s47F



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From: s22
To: [REDACTED]
Subject: FW: For Review: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL:Sensitive]
Date: Friday, 8 March 2024 2:08:57 PM
Attachments: [image001.jpg](#)
[Letter to TGA 8.3.24.pdf](#)
[Woolworth's Neem Capsules.pdf](#)
[Packing List.pdf](#)
[Company Tax Return 2022.pdf](#)
[Profit & Loss Statement 2022.pdf](#)
[image002.gif](#)

On review of the material attached there are a couple of points I have been able to take away.

1. The letter references the previous import/supply warning letter issued to Akula Foods Pty Ltd and how the product associated with that warning letter bears no relation to the products on which they were infringed. I don't believe the particulars of the product are relevant as the warning is in relation to the importation and supply of unregistered therapeutic goods.

2. s11C(1)(b)

3. The point that the importer will not import specifically Neem or Triphala tablets in the future indicates that they may not actually understand **why** they have been infringed, being the importation and supply of unregistered therapeutic goods.
4. The inclusion of the 2022 Company ITR (income tax return) and P & L, while useful in providing an idea of the income/profit of the business, are only a snapshot in time of the business' overall activity. Given the 2023 Company ITR is not due until 15 May 2024 we do not have a picture of current business activity, nor a trend of the how the business has performed over the last 8 years (as referenced in the 'Letter to TGA' attachment).

Kind regards,

s22

Product and Import Compliance Section
Regulatory Compliance Branch

Email: s22@health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606

www.tga.gov.au



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From: RC

Sent: Friday, March 8, 2024 1:14 PM

To: s22@health.gov.au

Subject: For Review: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1

and TGAIN-RC-023901/2024-2 [SEC=OFFICIAL:Sensitive]

Hi s22

Please see below email and attached documents from Gross and Becroft Lawyers requesting withdrawal of the infringement notices issued to Akula Foods Pty Ltd for your review.

Kind regards,

s22

Product and Import Compliance Section
Regulatory Compliance Branch

Email: s22 @health.gov.au

Therapeutic Goods Administration
Department of Health and Aged Care
PO Box 100
Woden ACT 2606

www.tga.gov.au



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From: s47F <info@grossbecroft.com.au>

Sent: Friday, March 8, 2024 12:51 PM

To: RC <RC@health.gov.au>

Subject: Akula Foods Pty Ltd – Infringement Notices -Nos. TGAIN-RC-023901/2024-1 and TGAIN-RC-023901/2024-2

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Attention: s22 (case officer) - Product & Import Compliance Section.

We refer to the above-mentioned matter in which we act on behalf of Akula Foods Pty Ltd.

Please find **attached** our letter of even date together with enclosures for your attention.

Kind Regards,

s47F

For and on Behalf of s47F



Gross & Becroft Lawyers Pty. Ltd.
Suite 2, Level 3, 182-184 Victoria Parade
East Melbourne, Victoria 3002
Tel: 03 9866 5666
Email: info@grossbecroft.com.au
www.grossbecroft.com.au

s22

From: s22
Sent: Thursday, 20 January 2022 4:35 PM
To: s22
Subject: RE: REDLINE ABF to TGA Detection Referral Email - s47
 - AKULA FOODS (RC-008537) [SEC=OFFICIAL]

Tracking:	Recipient	Recall
	s22	Succeeded: 20/01/2022 4:29 PM
		Succeeded: 20/01/2022 4:36 PM
		Succeeded: 20/01/2022 4:36 PM

Thanks s22 - s47 is S4 so the determination isn't going to make an impact on this one.

s22 – can you please request an exam. If it is a s47 product we'll need to look at the product and packaging to affirm that it is a therapeutic good. Then, an import/supply warning letter. In this instance we'll need to include more information in the warning letter to outline *why* it is a TG, so we can go through it together.

Cheers,

s22

From: s22
Sent: Thursday, 20 January 2022 4:21 PM
To: s22
Cc:
Subject: REDLINE ABF to TGA Detection Referral Email - s47
 AKULA FOODS (RC-008537) [SEC=OFFICIAL]
Importance: High

Good afternoon s22

For your information, PICS have received the below ABF Redline referral for what appears to be a commercial importation of s47 going to a business, Akula Foods.

Noting the recent changes to the permissible ingredients determination:

- The Therapeutic Goods (Permissible Ingredients) Determination No. 1 of 2022 has been signed by the Delegate. The determination removes the ingredient *Areca catechu* (the plant which produces betel nut) due to the risk of genotoxic carcinogenicity associated with its use.

This matter has been allocated to s22 for assessment and action.

Kind regards s22

s22

Regulatory Practice & Support Division | Product & Import Compliance
 Regulatory Compliance Branch
 Australian Government Department of Health
 T: s22 | E: s22 @health.gov.au
 Location: Symonston, ACT GA
 GPO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 @Health.gov.au>
Sent: Thursday, 20 January 2022 2:39 PM
To: s22 @health.gov.au>
Subject: FW: GR-220007804 - ABF to TGA Detection Referral Email - - AKULA FOODS [SEC=OFFICIAL]

Hi s22

Please see referral below 😊

Cheers,

s22

Compliance Assessment and Monitoring Section
 Regulatory Compliance Branch

Email: s22 @health.gov.au

Therapeutic Goods Administration
 Department of Health
 PO Box 100
 Woden ACT 2606
www.tga.gov.au

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The Department of Health acknowledges the Traditional Custodians of Australia, and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22
Sent: Thursday, 20 January 2022 2:35 PM
To: s22 @abf.gov.au | s22 @abf.gov.au>
Subject: RE: GR-220007804 - ABF to TGA Detection Referral Email - - AKULA FOODS [SEC=OFFICIAL]

Hi Team,

Thank you for the referral below.

This is a further import of prescription only medicine for this consignee. Therefore could you please hold this consignment until further notice while we make enquires with the importer.

TGA Reference: RC-008537

Kind regards,

s22

Compliance Assessment and Monitoring Section
Regulatory Compliance Branch

Email: ECT@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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The Department of Health acknowledges the Traditional Custodians of Australia, and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 <s22@abf.gov.au>
Sent: Wednesday, 19 January 2022 6:47 AM
To: ECT <ECT@health.gov.au>; s22 <s22@abf.gov.au>
Subject: RE: GR-220007804 - ABF to TGA Detection Referral Email - - AKULA FOODS [SEC=UNOFFICIAL]

UNOFFICIAL

Good Morning

I'm following up on this ABF referral regarding the detained goods currently being held at our s47E(d) in Brisbane. Our officers are seek an urgent reply to this referral action as the balance of parcel needs to be return to the depot before storage fees and charges start to accumulate.

Your response to this matter regarding seizure action is urgently required.

Happy to discuss further.

s22

Maritime Operations
Operations QLD | North & Immigration Detention Command
Ph: s22 | Em: s22 <s22@abf.gov.au>

UNOFFICIAL

From: Goods Management [s22](#) t@abf.gov.au>
Sent: Saturday, 15 January 2022 10:30 AM
To: ECT@health.gov.au; [s22](#) @abf.gov.au>
Cc: [s22](#) @abf.gov.au>
Subject: GR-220007804 - ABF to TGA Detection Referral Email - - AKULA FOODS [SEC=OFFICIAL:Sensitive]

OFFICIAL:Sensitive

On 15/01/2022 the ABF detected the following goods in the Cargo stream by the Maritime Operations QLD :

- [s47](#) 

The goods were consigned to, or imported by, the following entity:

AKULA FOODS
1/65 EASTERN ROAD BROWNS PLAINS QLD4118 AUSTRALIA

Phone: [s11C\(1\)\(a\)](#)
Email:

FID/SAC Number: AENW7CJYW

Please review the details and advise whether the goods should be seized or released by email.

Name of referring officer: [s22](#)
Group email address: [s22](#) @abf.gov.au

Regards,

Australian Border Force

s47





OFFICIAL:Sensitive

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Any review, retransmission, dissemination or other use of this information by persons or entities other than the intended recipient is prohibited. The Department of Home Affairs and ABF respect your privacy and have obligations under the Privacy Act 1988.

Unsolicited commercial emails MUST NOT be sent to the originator of this email.

From: [Akula Food](#)
To: [RC](#)
Subject: [s22](#)
Date: Wednesday, 9 February 2022 1:20:46 PM

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear [s22](#),
As per Phone discussion with [s22](#) we have been advised that goods will be dispose by Australian customs and we will not be notified about it.

Kind Regards,

[s11C\(1\)\(a\)](#)

AKULA FOODS PTY LTD

1/65 Eastern Road, BROWNS PLAINS, QLD 4118.

[s11C\(1\)\(a\)](#)

From: [Akula Food](#)
To: [RC](#)
Subject: [s22](#)
Date: Monday, 31 January 2022 3:00:20 PM

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear [s22](#),

As per Phone discussion, we have been advised that goods will be dispose by Australian customs and we will not be notified about it.

Kind Regards,

[s11C\(1\)\(a\)](#)

AKULA FOODS PTY LTD

1/65 Eastern Road, BROWNS PLAINS, QLD 4118.

[s11C\(1\)\(a\)](#)

s22

From: RC
Sent: Tuesday, 1 February 2022 11:53 AM
To: s22@abf.gov.au
Cc: s22; s22@ABF.gov.au
Subject: RE: GR-220007804 - ABF to TGA Detection Referral Email - - AKULA FOODS [SEC=OFFICIAL]
Attachments: 20220131023952_S19b S56A Certificate.docx
Importance: High

Good morning,

Please find attached the Application of the Customs Act 1901 to the importation of therapeutic goods and the Therapeutic Goods Act 1989, Section 56A certificate of evidence of certain matters:

- TGA reference: **RC-008537**, ABF reference: **GMS GR-220007804**

Kind regards,

s22

TGA Officer
 Product and Import Compliance Section
 Regulatory Compliance Branch

Phone: s22
 Email: RC@health.gov.au

Therapeutic Goods Administration
 Department of Health
 PO Box 100
 Woden ACT 2606
www.tga.gov.au

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From: s22
Sent: Thursday, 20 January 2022 2:35 PM
To: s22@abf.gov.au
Subject: RE: GR-220007804 - ABF to TGA Detection Referral Email - - AKULA FOODS [SEC=OFFICIAL]

Hi Team,

Thank you for the referral below.

This is a further import of prescription only medicine for this consignee. Therefore could you please hold this consignment until further notice while we make enquires with the importer.

TGA Reference: RC-008537

Kind regards,

s22

Compliance Assessment and Monitoring Section
Regulatory Compliance Branch

Email: ECT@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

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The Department of Health acknowledges the Traditional Custodians of Australia, and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: s22 <[REDACTED]@ABF.GOV.AU>
Sent: Wednesday, 19 January 2022 6:47 AM
To: ECT <ECT@health.gov.au>; s22 <[REDACTED]@abf.gov.au>
Subject: RE: GR-220007804 - ABF to TGA Detection Referral Email - - AKULA FOODS [SEC=UNOFFICIAL]

UNOFFICIAL

Good Morning

I'm following up on this ABF referral regarding the detained goods currently being held at s47E(d) [REDACTED] in Brisbane. Our officers are seek an urgent reply to this referral action as the balance of parcel needs to be return to the depot before storage fees and charges start to accumulate.

Your response to this matter regarding seizure action is urgently required.

Happy to discuss further.

s22

Maritime Operations
Operations QLD | North & Immigration Detention Command
Ph: s22 [REDACTED] | Em: s22 [REDACTED] <[\[REDACTED\]@abf.gov.au](mailto:[REDACTED]@abf.gov.au)>

UNOFFICIAL

From: Goods Management [s22](#) [@abf.gov.au](mailto:s22@abf.gov.au)>
Sent: Saturday, 15 January 2022 10:30 AM
To: ECT@health.gov.au; [s22](#) [@abf.gov.au](mailto:s22@abf.gov.au)>
Cc: [s22](#) [@abf.gov.au](mailto:s22@abf.gov.au)>
Subject: GR-220007804 - ABF to TGA Detection Referral Email - - AKULA FOODS [SEC=OFFICIAL:Sensitive]

OFFICIAL:Sensitive

On 15/01/2022 the ABF detected the following goods in the Cargo stream by the Maritime Operations QLD :

- [s47](#) 

The goods were consigned to, or imported by, the following entity:

AKULA FOODS
1/65 EASTERN ROAD BROWNS PLAINS QLD4118 AUSTRALIA

Phone: [s11C\(1\)\(a\)](#)

Email:

FID/SAC Number: AENW7CJYW

Please review the details and advise whether the goods should be seized or released by email.

Name of referring officer: [s22](#)

Group email address: [s22](#) [@abf.gov.au](mailto:s22@abf.gov.au)

Regards,

Australian Border Force



OFFICIAL:Sensitive

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Australian Government
Department of Health
Therapeutic Goods Administration

Trade and Goods Operational Policy
Customs Compliance Branch
Australian Border Force
Allara House, 48 Allara Street
Canberra ACT 2600

Dear Comptroller General,

Notification regarding application of the *Customs Act 1901* to the unlawful importation of therapeutic goods (unregistered therapeutic goods)

As a delegate of the Secretary, I am notifying you under subsection 19B (7) of the Therapeutic Goods Act 1989 (the Act) that the Secretary wishes the Customs Act 1901 (Customs Act) to apply to the following importations of therapeutic goods for use in humans:

Our Reference: **RC-008537**, Your reference: **GMS GR-220007804**

We advised the above importer that the goods may be seized and destroyed by the Australian Border Force if the importer did not provide evidence of the required approvals or exemptions within 28 days.

The importer has not provided evidence of the necessary registration, listing, exemption, approval or authority under the Act in order for these goods to be lawfully imported.

Specifically, I am satisfied that the goods are therapeutic goods being imported into Australia for use in humans and as set out in the attached Certificate of Evidence, the goods:

- a) Are not registered goods or listed goods
- b) Are not exempt goods
- c) Are not exempt under section 18A of the Act
- d) Are not subject of an approval or authority under section 19 of the Act
- e) Are not the subject of an approval under section 19A of the Act

I therefore consider that the importation of these goods is an offence under subsection 19B (4A) of the Act.

Accordingly, by virtue of this notification under subsection 19B(7) of the Act, the Customs Act has effect as if the goods included in the importation were goods described as forfeited to the Crown under section 229 of the Customs Act because they were prohibited imports within the meaning of that Act.

If you would like to discuss this matter further, please contact the Enforcement Coordination Team at RC@health.gov.au.

Yours sincerely

s22

Delegate of the Secretary
Regulatory Compliance Section
Therapeutic Goods Administration
31 January 2022

[This document is electronically signed]



Australian Government
Department of Health
Therapeutic Goods Administration

GMS GR-220007804

Certificate No: RC-008537

THERAPEUTIC GOODS ACT 1989, SECTION 56A
CERTIFICATE OF EVIDENCE OF CERTAIN MATTERS

I, [s22](#) delegate of the Secretary to the Department of Health for the purposes of Section 56A of the Therapeutic Goods Act 1989 (“the Act”), **HEREBY CERTIFY:**

in relation to the following particular person/s (“the person/s”):

Importer(s)

- Akula Foods of 1/65 Easter road Browns Plains QLD 4118 Australia

in respect of the following particular therapeutic goods or particular class of therapeutic goods (“the goods”):

Description	Each containing	Total amount	Category of medicine
s47			(S4) Prescription Only Medicine

THAT: Between 17 October 2021 and 15 January 2022:

- 56A (1)(a) there was no exemption in effect under section 18 or 18A in relation to the goods; and
- 56A (1)(b) there was no approval or authority under section 19 granted to the person/s in relation to the goods; and
- 56A (1)(c) there was no approval under section 19A granted to the person/s in relation to the goods; and
- 56A (1)(d) the goods were not included in the Register as registered goods; and
- 56A (1)(e) the goods were not included in the Register as listed goods; and

DATE: 31 January 2022

Yours sincerely

[s22](#)

Delegate of the Secretary
Regulatory Compliance Section
Therapeutic Goods Administration
[This document is electronically signed]

From: [RC](#)
To: [s22](#) [@abf.gov.au](#)
Cc: [s22](#)
Subject: RE: ABF to TGA Detection Referral Email - AKULA FOODS - GR-220021581 [SEC=OFFICIAL:Sensitive]
Date: Wednesday, 25 May 2022 12:58:28 PM
Attachments: [S56a - GR-220021581 - Rc-0101401_S19b_S56A Certificate.docx](#)
[image001.gif](#)

Good afternoon,

Please find attached the Application of the Customs Act 1901 to the importation of therapeutic goods and the Therapeutic Goods Act 1989, Section 56A certificate of evidence of certain matters:

- TGA reference: RC-010401, ABF reference: GR-220021581

Kind regards,

[s22](#)

TGA Officer
Product and Import Compliance Section
[Regulatory Compliance Branch](#)

Phone: [s22](#)

Email: RC@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au



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From: Goods Management
Sent: Monday, 7 February 2022 1:51 PM
To: ECT, [s22](#) [@abf.gov.au](#)
Cc: [s22](#) [abf.gov.au](#)
Subject: ABF to TGA Detection Referral Email - - AKULA FOODS - GR-220021581
[SEC=OFFICIAL:Sensitive]
OFFICIAL:Sensitive

On 07/02/2022 the ABF detected the following goods in the Cargo stream by the Maritime Operations QLD :

[s47](#)

A large grey rectangular redaction box covering the majority of the text in this section.

The goods were consigned to, or imported by, the following entity:

AKULA FOODS
1/65 EASTERN ROAD BROWNS PLAINS QLD4118 AUSTRALIA

FID/SAC Number: AEN7G7HTN

s47G

Please review the details and advise whether the goods should be seized or released by email.

Name of referring officer: s22
Group email address: s22 @abf.gov.au

Regards,

s22
Border Force Officer
Maritime Operations
Operations QLD | North & Immigration Detention Command
Australian Border Force
☎ s22 ✉ s22 @abf.gov.au

OFFICIAL:Sensitive

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Any review, retransmission, dissemination or other use of this information by persons or entities other than the intended recipient is prohibited. The Department of Home Affairs and ABF respect your privacy and have obligations under the Privacy Act 1988.

Unsolicited commercial emails MUST NOT be sent to the originator of this email.



Australian Government
Department of Health
Therapeutic Goods Administration

Trade and Goods Operational Policy
Customs Compliance Branch
Australian Border Force
Allara House, 48 Allara Street
Canberra ACT 2600

Dear Comptroller General,

Notification regarding application of the *Customs Act 1901* to the unlawful importation of therapeutic goods (unregistered therapeutic goods)

As a delegate of the Secretary, I am notifying you under subsection 19B (7) of the Therapeutic Goods Act 1989 (the Act) that the Secretary wishes the Customs Act 1901 (Customs Act) to apply to the following importations of therapeutic goods for use in humans:

Our Reference: **RC-010401**, Your reference: **GR-220021581**

We advised the above importer that the goods may be seized and destroyed by the Australian Border Force if the importer did not provide evidence of the required approvals or exemptions within 28 days.

The importer has not provided evidence of the necessary registration, listing, exemption, approval or authority under the Act in order for these goods to be lawfully imported.

Specifically, I am satisfied that the goods are therapeutic goods being imported into Australia for use in humans and as set out in the attached Certificate of Evidence, the goods:

- a) Are not registered goods or listed goods
- b) Are not exempt goods
- c) Are not exempt under section 18A of the Act
- d) Are not subject of an approval or authority under section 19 of the Act
- e) Are not the subject of an approval under section 19A of the Act

I therefore consider that the importation of these goods is an offence under subsection 19B (4A) of the Act.

Accordingly, by virtue of this notification under subsection 19B(7) of the Act, the Customs Act has effect as if the goods included in the importation were goods described as forfeited to the Crown under section 229 of the Customs Act because they were prohibited imports within the meaning of that Act.

If you would like to discuss this matter further, please contact the Enforcement Coordination Team at RC@health.gov.au.

Yours sincerely

s22

Delegate of the Secretary
Regulatory Compliance Section
Therapeutic Goods Administration
24 May 2022

[This document is electronically signed]



Australian Government
Department of Health
Therapeutic Goods Administration

GR-220021581

Certificate No: RC-010401

THERAPEUTIC GOODS ACT 1989, SECTION 56A
CERTIFICATE OF EVIDENCE OF CERTAIN MATTERS

I, [s22](#) delegate of the Secretary to the Department of Health for the purposes of Section 56A of the Therapeutic Goods Act 1989 (“the Act”), **HEREBY CERTIFY:**

in relation to the following particular person/s (“the person/s”):

Importer(s)

- Akula Foods of 1/65 Easter road Browns Plains QLD 4118 Australia

in respect of the following particular therapeutic goods or particular class of therapeutic goods (“the goods”):

Description	Each containing	Total amount	Category of medicine
s47			(S4) Prescription Only Medicine

THAT: Between 09 November 2021 and 07 February 2022:

- 56A (1)(a) there was no exemption in effect under section 18 or 18A in relation to the goods; and
- 56A (1)(b) there was no approval or authority under section 19 granted to the person/s in relation to the goods; and
- 56A (1)(c) there was no approval under section 19A granted to the person/s in relation to the goods; and
- 56A (1)(d) the goods were not included in the Register as registered goods; and
- 56A (1)(e) the goods were not included in the Register as listed goods; and

DATE: 24 May 2022

Yours sincerely

[s22](#)

Delegate of the Secretary
Regulatory Compliance Section
Therapeutic Goods Administration
[This document is electronically signed]

From: s22
To: RC
Cc: s22
Subject: RE: ABF to TGA Detection Referral Email - - AKULA FOODS - GR-220021581 [SEC=OFFICIAL:Sensitive]
Date: Tuesday, 1 March 2022 10:52:18 AM
Attachments: [image001.png](#)
[GR-220021581 AKULA FOODS - s47 REFERRAL TO TGA.pdf](#)
[GR-220021581 AKULA FOODS - FCL EXAMINATION PHOTOGRAPHS.PDF](#)

OFFICIAL: Sensitive

Good Morning s22

Please find attached a copy of the Full Import Declaration (FID) that was lodged in ICS for this consignment. I have also attached a copy of the examination photographs. Please let us know if you require further information.

Kind Regards

s22

Leading Border Force Officer
Maritime Operations
Operations QLD|North & Immigration Detention Command
Australian Border Force
P: s22
E: s22@abf.gov.au

OFFICIAL: Sensitive

From: RC
Sent: Monday, 28 February 2022 10:13 AM
To: s22
Cc: s22
Subject: RE: ABF to TGA Detection Referral Email - - AKULA FOODS - GR-220021581 [SEC=OFFICIAL:Sensitive]

Good afternoon ABF,

Could you please provide any images of the shipping labels or the consignment documents for this shipment please?

Kind regards,

s22

TGA Officer
Product and Import Compliance Section
Regulatory Compliance Branch

Phone: s22

Email: RC@health.gov.au

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www.tga.gov.au

From: Goods Management [s22](#) [@abf.gov.au](#)>
Sent: Monday, 7 February 2022 1:51 PM
To: ECT <ECT@health.gov.au>, [s22](#) [@abf.gov.au](#)
Cc: [s22](#) [@abf.gov.au](#)
Subject: ABF to TGA Detection Referral Email - - AKULA FOODS - GR-220021581
[SEC=OFFICIAL:Sensitive]
OFFICIAL:Sensitive

On 07/02/2022 the ABF detected the following goods in the Cargo stream by the Maritime Operations QLD :

[s47](#)

The goods were consigned to, or imported by, the following entity:

AKULA FOODS
1/65 EASTERN ROAD BROWNS PLAINS QLD4118 AUSTRALIA

FID/SAC Number: AEN7G7HTN



[s47G](#)

Please review the details and advise whether the goods should be seized or released by email.

Name of referring officer: [s22](#)
Group email address: [s22](#) [@abf.gov.au](#)

Regards,

[s22](#)

Border Force Officer
Maritime Operations
Operations QLD | North & Immigration Detention Command
Australian Border Force
 [s22](#) |  [s22](#) [@abf.gov.au](#)

OFFICIAL:Sensitive

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Sea Cargo Report View

Version 1

s47



Report



Import Declaration (N10) Tariff Line Summary View

s47





Import Declaration (N10) Duty, Taxes & Charges



s47



Importer / Supplier History

s47



s47



s47



s47



s47



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s47



s47



s47



s47



S47



s47



s47



s47



s47



From: Cargo Operations QLD
 To: Cargo Operations QLD; RedlineQld; ECT
 Cc: s22
 Subject: Team CHARLIE - EXAM # 3212632 - AKULA FOODS PTY LTD - TGA Referral [SEC=OFFICIAL]
 Date: Monday, 11 September 2023 2:01:27 PM
 Attachments: Team Charlie - EXAM # 3212632 - OBOL - OOLU2722034540 - AKULA FOODS PTY LTD - TGA Referral.pdf

OFFICIAL

Please see details for a detection of TGA goods at Interport today. ICS notes added transferred to Air Cargo Temporary Storage Facility. Exams completed. Part shipment. Balance of consignment remains at Interport.

Depot	Date of Detection	Country of Origin	Exam type s47E(d)	Detection	Quantity	Unit of Measure (Unit, Millilitres, Litre, Grams, Kilograms, Sticks, Vials)	Comments
Interport	11SEP2023	India	s47E(d)	Various TGA goods.		GRAMS	Declared as:

OBOL – OOLU2722034540
 EXAMS - 3212632
 B390 - 178599
 Seal – 0049485 – 0049494 and 0049505 - 0049514
 GMS – GR-230120811
 Consignee: AKULA FOODS PTY LTD. 1/64 EASTERN ROAD, BROWNS PLAINS QLD 4118 AUSTRALIA
 Consignor: s47

Exam Details

Air Cargo Team Charlie attended Interport bond today to action Exam 3212632.
 On arrival consignment had been removed from the container and placed in the bonded area.
 Examination of the consignment located products to be referred to TGA.

s47

s47E(d)

No further TGA or prohibited items located.
 TGA goods held on B390 and transported to s47E(d) or follow up action. Remainder of consignment remains at Interport bond.

OFFICIAL

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s47



S47



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s47



s47



From: [TGA Info](#)
To: [ECT](#)
Subject: Call back request [SEC=OFFICIAL] CCEMS:01870003232
Date: Wednesday, 6 September 2023 10:41:35 AM

Dear Team

Please find below details of a call back request for your follow up and response.

Name	s11C(1)(a)
Type of caller (if known)	
Client ID/Company Name (if known)	
ARTG ID/Product name (if known)	
Contact details	Mobile: s11C(1)(a) Telephone:
Enquiry details	Calling to see what is happening with his goods, is an importer and has been told by someone from biosecurity that his goods are being held pending TGA investigation. Does not have a border force or TGA reference number, entry number is AEY446Y7W. The container contains ayurvedic medicines

I have informed the caller that their call will be returned within 2 working days, as per the [TGA customer service standards](#).

Kind regards

s22

TGA Contact Centre

Regulatory Assistance Section
 Regulatory Engagement Branch

Phone: 1800 020 653 Fax: 02 6203 1605

Email: info@tga.gov.au

Therapeutic Goods Administration
 Department of Health and Aged Care
 PO Box 100
 Woden ACT 2606

www.tga.gov.au



This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.

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From: RC
 To: Cargo Operations QLD
 Cc: s22@abf.gov.au
 Subject: RC-023901 - s56A Certificate of Evidence - Team CHARLIE - EXAM # 3212632 - AKULA FOODS PTY LTD - TGA Referral [SEC=OFFICIAL]
 Date: Friday, 16 February 2024 11:44:00 AM
 Attachments: RC-023901_s19h_s56A_Certificate.pdf
 image001.gif

Good morning,

The Therapeutic Goods Administration (TGA) has determined that the following goods referred are not within the jurisdiction of the TGA and are subsequently referred back to the ABF for relevant action:

s47


For the remainder of the consignment, please find attached the Application of the *Customs Act 1901* to the importation of therapeutic goods and *Therapeutic Goods Act 1989*, section 56A Certificate of Evidence of Certain Matters:

1. TGA reference: RC-023901
2. ABF reference: EXAM # 3212632

Regards,

s22
 Product and Import Compliance Section
 Regulatory Compliance Branch
 Email: s22@health.gov.au
 Therapeutic Goods Administration
 Department of Health and Aged Care
 PO Box 100
 Woden ACT 2606
www.tga.gov.au

Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.

From: Cargo Operations QLD <cargooperationsqld@abf.gov.au>
 Sent: Monday, September 11, 2023 2:00 PM
 To: Cargo Operations QLD <cargooperationsqld@abf.gov.au>; RedlineQLD <redlineqld@abf.gov.au>; ECT <ECT@health.gov.au>
 Cc: s22@abf.gov.au; s22@ABF.GOV.AU
 Subject: Team CHARLIE - EXAM # 3212632 - AKULA FOODS PTY LTD - TGA Referral [SEC=OFFICIAL]

OFFICIAL

Please see details for a detection of TGA goods at Interport today. ICS notes added transferred to Air Cargo Temporary Storage Facility. Exams completed. Part shipment. Balance of consignment remains at Interport.

Depot	Date of Detection	Country of Origin	Exam type s47E(d)	Detection	Quantity	Unit of Measure (Unit, Millilitres, Litre, Grams, Kilograms, Sticks, Vials)	Comments
Interport	11SEP2023	India	s47E(d)	Various TGA goods.		GRAMS	Declared as:

OBOL – OOLU2722034540

EXAMS - 3212632

B390 - 178599

Seal – 0049485 – 0049494 and 0049505 - 0049514

GMS – GR-230120811

Consignee: AKULA FOODS PTY LTD. 1/64 EASTERN ROAD, BROWNS PLAINS QLD 4118 AUSTRALIA

Consignor: s47

Exam Details

Air Cargo Team Charlie attended Interport bond today to action Exam 3212632.

On arrival consignment had been removed from the container and placed in the bonded area.

Examination of the consignment located products to be referred to TGA.

s47

Redline Qld indicated TGA reference RC-023901 is of interest as part of their programmed exam email.

No further TGA or prohibited items located.

TGA goods held on B390 and transported to s47E(d) or follow up action. Remainder of consignment remains at Interport bond.

OFFICIAL

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Trade and Goods Operational Policy
Customs Compliance Branch
Australian Border Force
Allara House, 48 Allara Street
Canberra ACT 2600

Dear Comptroller General,

Notification regarding application of the *Customs Act 1901* to the unlawful importation of therapeutic goods (unregistered therapeutic goods)

As a delegate of the Secretary, I am notifying you under subsection 19B (7) of the *Therapeutic Goods Act 1989* (the Act) that the Secretary wishes the *Customs Act 1901* (Customs Act) to apply to the following importations of therapeutic goods for use in humans:

Our Reference: **RC-023901**, Your reference: **GR-230120811**

We advised the above importer that the goods may be seized and destroyed by the Australian Border Force if the importer did not provide evidence of the required approvals or exemptions.

The importer has not provided evidence of the necessary registration, listing, exemption, approval or authority under the Act in order for these goods to be lawfully imported.

Specifically, I am satisfied that the goods are therapeutic goods being imported into Australia for use in humans and as set out in the attached Certificate of Evidence, the goods:

- a) Are not registered goods or listed goods
- b) Are not exempt goods
- c) Are not exempt under section 18A of the Act
- d) Are not subject of an approval or authority under section 19 of the Act
- e) Are not the subject of an approval under section 19A of the Act

I therefore consider that the importation of these goods is an offence under subsection 19B(4A) of the Act.

Accordingly, by virtue of this notification under subsection 19B(7) of the Act, the Customs Act has effect as if the goods included in the importation were goods described as forfeited to the Crown under section 229 of the Customs Act because they were prohibited imports within the meaning of that Act.

If you would like to discuss this matter further, please contact the Enforcement Coordination Team at RC@health.gov.au.

Yours sincerely

s22

Delegate of the Secretary
Regulatory Compliance Branch
Therapeutic Goods Administration
05 February 2024

[This document is electronically signed]



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

GR-230120811

Certificate No: RC-023901

THERAPEUTIC GOODS ACT 1989, SECTION 56A
CERTIFICATE OF EVIDENCE OF CERTAIN MATTERS

I, s22 delegate of the Secretary to the Department of Health and Aged Care for the purposes of Section 56A of the Therapeutic Goods Act 1989 ("the Act"), HEREBY CERTIFY:

in relation to the following particular person/s ("the person/s"):

Importer(s)

- Akula Foods of 1/65 Eastern Road Browns Plains QLD 4118 Australia
s11C(1)(a)

in respect of the following particular therapeutic goods or particular class of therapeutic goods ("the goods"):

Table with 4 columns: Description, Each containing, Total amount, Category of medicine. Row 1: s47, [Redacted], [Redacted], Not scheduled. Not considered by committee. Row 2: [Redacted], [Redacted], [Redacted], (S10) Schedule 10 Substance.

THAT: Between 13 June 2023 and 11 September 2023:

- 56A (1)(a) there was no exemption in effect under section 18 or 18A in relation to the goods; and
56A (1)(b) there was no approval or authority under section 19 granted to the person/s in relation to the goods; and
56A (1)(c) there was no approval under section 19A granted to the person/s in relation to the goods; and
56A (1)(d) the goods were not included in the Register as registered goods; and
56A (1)(e) the goods were not included in the Register as listed goods; and
56A (1)(h) there was no declaration under Section 7 of the Act which applied to the goods; and
56A (1)(ha) there was no determination under Section 7AA which applied to the goods

DATE: 05 February 2024

Yours sincerely

s22 [Redacted Signature]

Delegate of the Secretary
Regulatory Compliance Branch
Therapeutic Goods Administration

[This document is electronically signed]

From: s22
To: LUTTON, Tracey
Cc: s22 Advertising Education; s22
Subject: RE: For clearance: Draft media release - Infringement notices given to Akula Foods Pty Ltd [SEC=OFFICIAL]
Date: Monday, 26 February 2024 4:41:01 PM
Attachments: image003.png
 image006.png
 image007.png
 image008.png
 image009.png

Hi Tracey,
 Web publication requests have been submitted for both of these, please see WEB-1168 and WEB-1169.
 Thanks,

s22

**Compliance Education
 Advertising and Compliance Education and Policy Section (ACEPS)**

Regulatory Practice and Support Division | Health Products Regulation Group
 Regulatory Compliance Branch | Australian Government, Department of Health and Aged Care
 T: s22 | E: s22@health.gov.au
 Location: Level 2 North, Gulgana building, Fairbairn, ACT
 PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22
Sent: Monday, February 26, 2024 4:12 PM
To: s22 LUTTON, Tracey ; s22
Cc: s22 ; Advertising Education
Subject: RE: For clearance: Draft media release - Infringement notices given to Akula Foods Pty Ltd [SEC=OFFICIAL]

Good afternoon all
 Both IN packages have been issued.
 Thanks

s22
 s22 – Product and Import Compliance

Regulatory Practice and Support Division | Health Products Regulation Group
 Regulatory Compliance Branch
 Therapeutic Goods Administration
 Australian Government Department of Health and Aged Care
 T: s22 | E: s22@health.gov.au
 27 Scherger Drive, Canberra Airport, ACT 2609
 TGA Building Level 2 North
 PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.



From: s22@Health.gov.au>

Sent: Monday, February 26, 2024 10:23 AM

To: s22 @health.gov.au>; s22
s22 @health.gov.au>

Cc: s22 @health.gov.au>; Advertising Education
<advertising.education@tga.gov.au>

Subject: RE: For clearance: Draft media release - Infringement notices given to Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning s22 and s22

Could you please let me know when the INs have been issued for these two (Akula Foods and s22) for timing of the two MR?

Thanks

s22

Compliance Education

Advertising and Compliance Education and Policy Section (ACEPS)

Regulatory Practice and Support Division | Health Products Regulation Group
Regulatory Compliance Branch | Australian Government, Department of Health and Aged Care

T: s22 | E: s22 @health.gov.au

Location: Level 2 North, Gulgana building, Fairbairn, ACT
PO Box 100, Woden ACT 2606, Australia

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From: LUTTON, Tracey <Tracey.Lutton@health.gov.au>

Sent: Monday, February 26, 2024 8:05 AM

To: s22 @health.gov.au>; s22
s22 @health.gov.au>; s22 @Health.gov.au>;
s22 @Health.gov.au>

Cc: s22 @health.gov.au>; s22
s22 @Health.gov.au>; s22 @Health.gov.au>; s22
s22 @Health.gov.au>

Subject: FW: For clearance: Draft media release - Infringement notices given to Akula Foods Pty Ltd [SEC=OFFICIAL]

Hello @s22

The MR and action for **both** INs has been approved by FAS and Dep Sec and we are good to go issuing the INs.

Following the issuing of the INs @s22 and @s22 can you please action both MRs.

@s22 – can you please document the process – as this was the quickest and easiest and didn't involve TRIM or workflows – so lets do them this way going forward.

FYI – Chris has sent on to the MO – and they have acknowledge this morning.

Thanks all

Tracey

From: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>

Sent: Sunday, February 25, 2024 6:40 PM

To: BEDFORD, Chris <Chris.Bedford@health.gov.au>

Cc: s22 @health.gov.au>; LUTTON, Tracey
<Tracey.Lutton@health.gov.au>; s22 @health.gov.au>; s22
s22 @Health.gov.au>; s22 @health.gov.au>

Subject: RE: For clearance: Draft media release - Infringement notices given to Akula Foods Pty Ltd [SEC=OFFICIAL]

Thanks Chris

Media release looks good, and I am happy for you and the team to give s22 and the MO the heads up.

Well done.

Regards

T

From: BEDFORD, Chris <Chris.Bedford@health.gov.au>

Sent: Thursday, February 22, 2024 11:48 AM

To: LAWLER, Tony <Anthony.LAWLER@Health.gov.au>

Cc: s22 <[REDACTED]@health.gov.au>; LUTTON, Tracey

<Tracey.Lutton@health.gov.au>; s22 <[REDACTED]@health.gov.au>; s22 <[REDACTED]

<[REDACTED]@Health.gov.au>; s22 <[REDACTED]@health.gov.au>

Subject: For clearance: Draft media release - Infringement notices given to Akula Foods Pty Ltd [SEC=OFFICIAL]

Hi Tony

The Product and Import Compliance Section has been investigating the alleged import and advertisement of unapproved complementary medicines.

A media release has been developed and is attached for approval to publish. The draft media release has been reviewed by the Regulatory Education Section.

Seeking your approval for the media release attached have to assist with decision making please find below the case synopsis.

Proposed enforcement action:

- A delegate in the Regulatory Compliance Branch is planning to give two (2) infringement notices totalling \$37,560 to a Queensland based company Akula Foods Pty Ltd for allegedly importing unregistered therapeutic goods.

The infringement notices are detailed below:

- One infringement notice for the alleged import of an unregistered ayurvedic medicine that contains a Schedule 10 substance, in contravention of section 19D(1a) of the Act
- One infringement notice for the alleged import of an unregistered ayurvedic medicine, also in contravention of section 19D(1a) of the Act

Case synopsis:

- In Australia, Ayurvedic medicines (sometimes known as traditional medicine) are a type of complementary medicine that are generally required to meet the same standards of quality and safety as other medicines. Ayurvedic medicines must not contain dangerous substances or heavy metals at levels that pose an unacceptable risk to the health and safety of Australian consumers.
- The company attempted to import a number of different unregistered Himalaya branded Ayurvedic medicines. These included Himalaya branded Neem capsules for internal use, containing neem that is not debitterised neem seed oil. This means that it falls within schedule 10 of the Poisons Standard, and is considered to be a substance of such danger to health as to warrant prohibition of supply and use.
- The remaining Himalaya branded products do not contain any scheduled substances but are considered to be a therapeutic good as they are labelled as Ayurvedic medicines with associated therapeutic claims, and intended for human/oral consumption.
- While the company wholesales and distributes general groceries and household goods, the company has come to the attention of the TGA on two previous occasions for importing unregistered therapeutic goods. On both occasions the company engaged with Compliance Officers – they have been educated about the lawful importation and supply of therapeutic goods in Australia.

- While it is open to the delegate to issue more than 2 infringement notices, they have decided on two as a proportionate response to the alleged contraventions (one for the neem product, and another for another large quantity product containing unscheduled ingredients) and a general deterrence for similar companies trading in Ayurvedic and other traditional/complementary medicines.

The TGA has previously issued safety advisories relating to unregistered Ayurvedic medicines in [2020](#), [2021](#) and [2022](#), including references to neem in this presentation being a prohibited Schedule 10 substance.

A briefing for the MO is below for forwarding (or for the team to forward) to the MO.

Happy to discuss.

Chris

#####

Good morning/afternoon s22 and s22

For your awareness, the Regulatory Compliance Branch is planning to issue two (2) infringement notices totalling \$37,560 to a Queensland based company Akula Foods Pty Ltd for alleged contraventions of the *Therapeutic Goods Act 1989* relating to the import of unregistered complementary medicines.

Background

- In 2023, a consignment containing a commercial quantity of unregistered Ayurvedic medicines was held by the Australian Border Force. Therapeutic goods, including traditional and complementary medicines must be entered in the ARTG before they can be lawfully imported unless an exception applies
- The Sponsor, Akula Foods Pty Ltd had previously been warned by the TGA for importing unregistered complementary medicines with the intent to distribute on a wholesale basis to retailers without the relevant approval or authority, in alleged contravention of the Act.
- One of these Ayurvedic medicines contained neem for internal use that is not debitterised neem seed oil. This means that it falls within schedule 10 of the Poisons Standard, and is considered to be a substance of such danger to health as to warrant prohibition of supply and use.
- While the remainder of the unregistered complementary medicines did not contain scheduled substances and were largely low risk, the import and supply of unregistered therapeutic goods by retail outlets poses a risk to consumer health. Infringement notices in this circumstance act as both a specific and general deterrence.

We will be publishing a media release (as attached) early next week following the issue of the infringement notices.

If further information is required please let us know.

Chris Bedford

Acting First Assistant Secretary

Regulatory Practice and Support Division

Australian Government Department of Health and Aged Care

T: 02 6289 5327 | M: s22 | E: chris.bedford@health.gov.au

Location: Gulgana Building, Fairbairn, Canberra

GPO Box 9848, Canberra ACT 2601, Australia

Executive Assistant | s22

T: s22 | E: s22@health.gov.au

Executive Officer | s22

T: s22 | E: s22@health.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.



From: s22
To: s22
Cc: s22 Advertising Education
Subject: RE: For clearance: Draft media release - Infringement notices given to Akula Foods Pty Ltd [SEC=OFFICIAL]
Date: Monday, 26 February 2024 3:01:46 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)

Hi s22

Both Infringement notices, Akula Foods and s22 are being issued this afternoon

Warm regards

s22

From: s22
Sent: Monday, February 26, 2024 10:23 AM
To: s22
Cc: s22 Advertising Education
Subject: RE: For clearance: Draft media release - Infringement notices given to Akula Foods Pty Ltd [SEC=OFFICIAL]

Good morning s22 and s22

Could you please let me know when the INs have been issued for these two (Akula Foods and s22) for timing of the two MR?

Thanks

s22

[he/him]

A/g Assistant Director – Compliance Education
Advertising and Compliance Education and Policy Section (ACEPS)

Regulatory Practice and Support Division | Health Products Regulation Group
 Regulatory Compliance Branch | Australian Government, Department of Health and Aged Care
 T: s22 | E s22 @health.gov.au
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From: LUTTON, Tracey <Tracey.Lutton@health.gov.au>

Sent: Monday, February 26, 2024 8:05 AM

To: s22 @health.gov.au>, s22 @health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>

Cc: s22 @health.gov.au>, s22 @Health.gov.au>; s22 @Health.gov.au>; s22 @Health.gov.au>

Subject: FW: For clearance: Draft media release - Infringement notices given to Akula Foods Pty Ltd [SEC=OFFICIAL]

Hello @s22

The MR and action for **both** INs has been approved by FAS and Dep Sec and we are good to go issuing the INs.

Following the issuing of the INs @s22 and @s22 can you please action both MRs.

@s22 – can you please document the process – as this was the quickest and easiest and didn't involve TRIM or workflows – so lets do them this way going forward.

FYI – Chris has sent on to the MO – and they have acknowledge this morning.

Thanks all

Tracey

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Cc: s22 <[REDACTED]@health.gov.au>; LUTTON, Tracey <Tracey.Lutton@health.gov.au>; s22 <[REDACTED]@health.gov.au>; s22 <[REDACTED]@Health.gov.au>; s22 <[REDACTED]@health.gov.au>
Subject: For clearance: Draft media release - Infringement notices given to Akula Foods Pty Ltd [SEC=OFFICIAL]

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The infringement notices are detailed below:

- One infringement notice for the alleged import of an unregistered ayurvedic medicine that contains a Schedule 10 substance, in contravention of section 19D(1a) of the Act
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Case synopsis:

- In Australia, Ayurvedic medicines (sometimes known as traditional medicine) are a type of complementary medicine that are generally required to meet the same standards of quality and safety as other medicines. Ayurvedic medicines must not contain dangerous substances or heavy metals at levels that pose an unacceptable risk to the health and safety of Australian consumers.
- The company attempted to import a number of different unregistered Himalaya branded Ayurvedic medicines. These included Himalaya branded Neem capsules for internal use,

containing neem that is not debitterised neem seed oil. This means that it falls within schedule 10 of the Poisons Standard, and is considered to be a substance of such danger to health as to warrant prohibition of supply and use.

- The remaining Himalaya branded products do not contain any scheduled substances but are considered to be a therapeutic good as they are labelled as Ayurvedic medicines with associated therapeutic claims, and intended for human/oral consumption.
- While the company wholesales and distributes general groceries and household goods, the company has come to the attention of the TGA on two previous occasions for importing unregistered therapeutic goods. On both occasions the company engaged with Compliance Officers – they have been educated about the lawful importation and supply of therapeutic goods in Australia.
- While it is open to the delegate to issue more than 2 infringement notices, they have decided on two as a proportionate response to the alleged contraventions (one for the neem product, and another for another large quantity product containing unscheduled ingredients) and a general deterrence for similar companies trading in Ayurvedic and other traditional/complementary medicines.

The TGA has previously issued safety advisories relating to unregistered Ayurvedic medicines in [2020](#), [2021](#) and [2022](#), including references to neem in this presentation being a prohibited Schedule 10 substance.

A briefing for the MO is below for forwarding (or for the team to forward) to the MO.

Happy to discuss.

Chris

#####

Good morning/afternoon s22 and s22

For your awareness, the Regulatory Compliance Branch is planning to issue two (2) infringement notices totalling \$37,560 to a Queensland based company Akula Foods Pty Ltd for alleged contraventions of the *Therapeutic Goods Act 1989* relating to the import of unregistered complementary medicines.

Background

- In 2023, a consignment containing a commercial quantity of unregistered Ayurvedic medicines was held by the Australian Border Force. Therapeutic goods, including traditional and complementary medicines must be entered in the ARTG before they can be lawfully imported unless an exception applies
- The Sponsor, Akula Foods Pty Ltd had previously been warned by the TGA for importing unregistered complementary medicines with the intent to distribute on a wholesale basis to retailers without the relevant approval or authority, in alleged contravention of the Act.
- One of these Ayurvedic medicines contained neem for internal use that is not debitterised neem seed oil. This means that it falls within schedule 10 of the Poisons Standard, and is considered to be a substance of such danger to health as to warrant prohibition of supply and use.
- While the remainder of the unregistered complementary medicines did not contain scheduled substances and were largely low risk, the import and supply of unregistered therapeutic goods by retail outlets poses a risk to consumer health. Infringement notices in this circumstance act as both a specific and general deterrence.

We will be publishing a media release (as attached) early next week following the issue of the infringement notices.

If further information is required please let us know.

Chris Bedford

Acting First Assistant Secretary

Regulatory Practice and Support Division

Australian Government Department of Health and Aged Care

T: 02 6289 5327 | M: s22 | E: chris.bedford@health.gov.au

Location: Gulgana Building, Fairbairn, Canberra

GPO Box 9848, Canberra ACT 2601, Australia

Executive Assistant | s22

T: s22 | E: s22@health.gov.au

Executive Officer | s22

T: s22 | E: s22@health.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.



From: s22
To: [REDACTED]
Cc: s22
Subject: RE: Media release - Akula Foods Pty Ltd - For Clearance: Media Release TGAIN-RC-023901-2023 [SEC=OFFICIAL]
Date: Wednesday, 10 January 2024 3:27:35 PM
Attachments: [image001.png](#)
[image002.gif](#)
[image003.png](#)
[image004.png](#)

Thanks s22

I have reviewed with minor changes and completed the workflow.

The INs are currently with s22 . s22 or I will reach out once we have the date of issue.

Kind regards

s22

s22 – Product and Import Compliance

Regulatory Practice and Support Division | Health Products Regulation Group
 Regulatory Compliance Branch

Therapeutic Goods Administration

Australian Government Department of Health and Aged Care

T: s22 | E: s22 @health.gov.au

27 Scherger Drive, Canberra Airport, ACT 2609

TGA Building Level 2 North

PO Box 100, Woden ACT 2606, Australia

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diversity-logo-combined



From: s22

Sent: Wednesday, 10 January 2024 1:33 PM

To: s22

Cc: s22 ; Advertising Education

Subject: Media release - Akula Foods Pty Ltd - For Clearance: Media Release TGAIN-RC-023901-2023 [SEC=OFFICIAL]

Dear PICS

Akula Foods media release is ready for line area clearance [D23-4467196](#) so I have workflowed it to s22 . Minor changes by REB.

Next steps:

- Line area review
- ACEPS review
- REB review
- EL2 clearance
- AS clearance
- Publishing request

Once cleared, and the INs issued – when is that again? – we can submit a publishing request.

Kind regards

s22

From: s22 <[redacted]@Health.gov.au> **On Behalf Of** TGA Education
Sent: Tuesday, 9 January 2024 4:02 PM
To: s22 <[redacted]@health.gov.au>; s22 <[redacted]@Health.gov.au>
Cc: s22 <[redacted]@Health.gov.au>
Subject: FW: Review Media release - Akula Foods Pty Ltd - For Clearance: Media Release TGAIN-RC-023901-2023 [SEC=OFFICIAL]

Hi team

Sorry for the delay in getting back to you. Fairly minor changes and a comment about the changes – i.e. we separated that product with the schedule 10 ingredient from the other products so that it doesn't imply that a product with schedule 10 ingredients would be approved for listing on the ARTG. Hope that makes sense!

Cheers

s22

From: s22 <[redacted]@health.gov.au>
Sent: Monday, 8 January 2024 11:45 AM
To: s22 <[redacted]@Health.gov.au>; s22 <[redacted]@health.gov.au>; s22 <[redacted]@health.gov.au>; TGA Education <tga.education@tga.gov.au>
Cc: s22 <[redacted]@Health.gov.au>; Advertising Education <advertising.education@tga.gov.au>; s22 <[redacted]@Health.gov.au>
Subject: Review Media release - Akula Foods Pty Ltd - For Clearance: Media Release TGAIN-RC-023901-2023 [SEC=OFFICIAL]

Dear **REB**

We would appreciate your review of this Media release.

Whoever ends up doing the review, could I ask you to please add in a 'Review' TRIM workflow and complete it before return. Thank you

Next steps:

- Line area review
- ACEPS review
- **REB review**
- EL2 clearance
- AS clearance
- Publishing request

Dear s22 and s22 (and s22)

I have made an addition to the MR and edited a couple of bits – have a look of you want to. As above, I have also sent this off to REB for their review as well.

When the MRs are intended to be issued?

What is the Act breach code? 19B?

Kind regards

s22

Compliance Education

Advertising and Compliance Education and Policy Section (ACEPS)

Health and Safety Representative (HSR) (HPRG Admin)

[HPRG representative for National Work Health and Safety Committee \(NWHSC\)](#)

Regulatory Practice and Support Division | Health Products Regulation Group

Regulatory Compliance Branch | Australian Government, Department of Health and Aged Care

T: s22 | E: s22 @health.gov.au

Location: Level 2 North, Gulgana building, Fairbairn, ACT

PO Box 100, Woden ACT 2606, Australia

Typical location: Office: Tuesday and Thursday, WFH M/W/F

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders

both past and present.

From: s22 [redacted] <[redacted]@Health.gov.au>

Sent: Monday, 8 January 2024 10:25 AM

To: s22 [redacted] <[redacted]@health.gov.au>

Subject: FW: For Clearance: Media Release TGAIN-RC-023901-2023 [SEC=OFFICIAL]

This is the MR I mentioned.

Happy to deal with it myself but if you wanted something easy to get the ball rolling so to speak just let me know

s22 [redacted]

– Compliance Education

Advertising and Compliance Education and Policy Section (ACEPS)

Regulatory Practice and Support Division | Health Products Regulation Group

Regulatory Compliance Branch | Australian Government, Department of Health and Aged Care

T s22 [redacted] | E: s22 [redacted] <[redacted]@health.gov.au>

Location: Level 2 North, Gulgana building, Fairbairn, ACT

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: s22 [redacted] <[redacted]@Health.gov.au>

Sent: Friday, 5 January 2024 3:59 PM

To: s22 [redacted] <[redacted]@Health.gov.au>

Subject: For Clearance: Media Release TGAIN-RC-023901-2023 [SEC=OFFICIAL]

H s22 [redacted]

PICS has a media release ready to progress through the clearance process. Please see attached TRIM reference for media release for TGAIN-RC-023901-2023. s22 [redacted] has cleared this one.

Please let me know if you have any questions.

Cheers,

s22 [redacted]

Product and Import Compliance Section

Regulatory Compliance Branch

Email: s22 [redacted] <[redacted]@health.gov.au>

Therapeutic Goods Administration

Department of Health and Aged Care

PO Box 100

Woden ACT 2606

www.tga.gov.au



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From: [Microsoft Power Apps and Power Automate](#)
To: s22
Cc:
Subject: Your web publishing request has been received - Job number is WEB-1168
Date: Monday, 26 February 2024 4:35:18 PM

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Please do not reply to this automated email as we will not receive it.

Hi s22

Thank you for your web publishing request. An email has been sent to the nominated Approver.

Your job number is WEB-1168.

You can [check the status of your web publishing request](#) at any time.

APPROVER DETAILS

Approver: LUTTON, Tracey

Section 61: Yes

Message to Approver: Hi Tracey, please see below web publication requests for the Akula Foods Pty Ltd IN MR, PICS confirmed the INs have been issued already this afternoon.
Thanks, s22

JOB DETAILS

Title:
MR for IN package to Akula Foods Pty Ltd

Priority:
Standard

Requested publication date (if provided):

Job type:
Page update, Media release

TRIM links:

[D23-4467196](#)

Pages to be updated (if relevant):

Media release publication.
a. <https://www.tga.gov.au/news/media-releases>

b. [https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/news-and-information - Complementary medicines > 2024](https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/news-and-information-Complementary-medicines-2024)

please also create a new entry in the IN register page using the same link to the MR

c. [https://www.tga.gov.au/infringement-notices - Status: Infringement notices issued - Alleged contraventions: section 19D of the Act](https://www.tga.gov.au/infringement-notices-Status-Infringement-notices-issued-2024)

Job description:

Media release publication. a. <https://www.tga.gov.au/news/media-releases> b.

[https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/news-and-information - Complementary medicines > 2024](https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub/news-and-information-Complementary-medicines-2024) please also create a new entry in the IN register

page using the same link to the MR c. [https://www.tga.gov.au/infringement-notices - Status: Infringement notices issued - Alleged contraventions: sections 19D of the Act](https://www.tga.gov.au/infringement-notices-Status-Infringement-notices-issued-2024)

ADDITIONAL REQUESTS

If you have indicated that a social media post or news item may be required then the Regulatory Education team has been notified and they may be in touch.

Social media:

Yes

News item:

Yes

Topic tags:

Complementary medicines, Import/Export, Medicines safety, Regulatory compliance, Unapproved therapeutic goods

Audience tags:

Advertisers, Consumer, Health Professional, Sponsor

Collection (if relevant):

You will receive an email notification when this publishing request has been approved or rejected.

Once your web request has been actioned you will receive an email with any new or updated web page links.

Please note, if you would like to cancel this publishing job, you will need to ask your approver to reject the job.

Kind regards

Publishing Team

s22



s22

E: tga.website@tga.gov.au

Web Experience Section
HPRG Transformation Branch

Regulatory Practice and Support Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
27 Scherger Drive, Level 2 , Fairbairn Business Park
FAIRBAIRN, ACT 2600

Regulatory Engagement Branch [Service Gateway](#)
Direct access to our services and resources

Need help writing guidance? Check out the [Regulatory Guidance Toolkit](#)

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