From:	Complementary Medicines
To:	[redacted]@ultraviolette.com.au
Subject:	Title: Notice to impose Sunscreen condition of Listing - AUST L 332788 [SEC=OFFICIAL]
Date:	Monday, 31 January 2022 1:48:18 PM
Attachments:	D22-5065273 Notice to impose Sunscreen condition of listing - AUST L 332788.pdf

Dear Sir/Madam

Re: Ultra Violette Lean Screen SPF50+ (AUST L 332788)

In light of the alleged fraudulent scheme involving the reporting of false laboratory test results issued by AMA Laboratories Inc, the TGA has imposed a condition on the listing of all sunscreens on the Australian Register of Therapeutic Goods.

It has come to my attention that since the time you received a Notice imposing such condition of listing on your above sunscreen, you have made change to the product's entry under the Groups Order (known as a 'Grouping' application) or s. 9D of the *Therapeutic Goods Act 1989*. I am therefore issuing you with another Notice to impose the condition of listing (see attached).

Please note that the condition of listing remains unchanged from that previously imposed. Thus, apart from ensuring that your sunscreen remains compliant with the condition of listing, no further action is required on your part.

Kind Regards

Complementary Medicines
Complementary and OTC Medicines Branch

Phone: [redacted]
Email: [redacted]@health.gov.au

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

This information is given to you without prejudice and is not binding on the TGA. It is the responsibility of the sponsor to ensure that all of the legislative requirements are met.

Australian Government
Department of Health
Therapeutic Goods Administration

TGA Reference: D22-5065273

The Managing Director
Grace & Fire Pty Ltd
36 Avondale Street
HAMPTON VIC 3188

By email: s22 [redacted] @ultraviolette.com.au

Dear Sir/Madam

Notice to impose a condition under subsection 28(3) of the *Therapeutic Goods Act 1989*

I am writing to advise you of my decision under subsection 28(3) of the *Therapeutic Goods Act 1989* (**the Act**[1]) to impose a condition of listing for the following listed medicine(s):

- Ultra Violette Lean Screen SPF50+ (AUST L 332788)

This notice includes information about:

A. The purpose and basis of this notice to impose a condition
B. The new condition of listing to be imposed
C. Relevant history
D. The reasons for my decision to impose a new condition
E. Conclusion
F. Review rights

The imposition of the condition will take effect immediately from 27 February 2022.

A. The purpose and basis of this notice to impose a condition

Under subsection 28(3) of the Act, the Secretary of the Department of Health may, by notice in writing given to the person in relation to whom therapeutic goods are registered or listed, impose new conditions on the registration or listing, or vary or remove conditions imposed under subsection (2B) or this subsection.

[1] A copy of the Act can be accessed from http://www.comlaw.gov.au

I am a delegate of the Secretary for the purposes of section 28 of the Act, pursuant to which I may impose a condition of listing on goods listed on the Australian Register of Therapeutic Goods (**ARTG**). This letter is notice that I have decided to impose a condition of listing on the abovementioned goods that are listed on the ARTG for the purpose of subsection 28(3) of the Act. Subsection 28(3A) allows me to exercise this power at my own motion.

Paragraph 28(4)(b) of the Act relevantly permits that the imposition of this condition under subsection 28(3) takes effect on the day specified for the purpose in this notice, being a day not earlier than 28 days after this notice is given to the person.

Please note that a failure to comply with the condition stipulated here in Section B is a ground for a delegate of the Secretary to cancel your medicine from the ARTG under section 30 of the Act.

B. The new condition of listing to be imposed

I have decided to impose a condition of listing on the aforementioned medicine as follows:

The following two conditions apply where testing conducted by AMA Laboratories Inc. is used to substantiate compliance of the product with the Australian and New Zealand Sunscreen Standard AS/NZS 2604 Sunscreen products—Evaluation and classification (the Sunscreen Standard):

a. *The sponsor is required to hold adequate supplementary in-vitro testing data and/or relevant testing data from an independent testing laboratory on a comparable formulation, or other justification acceptable to the Therapeutic Goods Administration (***TGA***), to scientifically justify the validity and accuracy of the SPF, broad spectrum and water resistance claims for the product.*

b. *The sponsor must provide the data, documentation or other justification to the TGA within 10 working days of a request by the TGA, or as deemed reasonable by the delegate upon request.*

C. Relevant history

For therapeutic sunscreens to be eligible for listing on the ARTG, they must comply with the requirements set out under Item 7 of Part 1 of Schedule 4 of the Therapeutic Goods Regulations 1990 (**the Regulations**). This includes that they comply with the Australian and New Zealand Standard *AS/NZS 2604:2012 Sunscreen products - Evaluation and classification* (**the Standard**) in force at the time of listing on the ARTG. Compliance with the Standard requires that sunscreens are tested to verify the sun protection factor (SPF), broad spectrum and water resistance claims.

The sponsors of some sunscreens on the ARTG have in the past, engaged AMA Laboratories to perform SPF testing to substantiate compliance with the Standard. AMA Laboratories is currently being investigated by the United States (US) Department of Justice concerning alleged fraudulent laboratory testing to which AMA Laboratories executives have pleaded guilty.

To address the potential that fraudulent SPF testing data may have been relied upon to support SPF claims of some sunscreens supplied in Australia, the TGA determined that an

interim regulatory measure is needed to safeguard the continued access of Australian consumers to reliable sunscreens.

On 15 June 2020, the TGA published a web statement[2] advising of its concerns regarding the reliability of test data provided by AMA Laboratories. The web statement announced that the TGA would require that sunscreen sponsors provide adequate justification for ongoing supply of their products that have been tested by AMA Laboratories. This could include additional supportive testing data on comparable products in their product line or from product development studies, or other robust scientific justification that substantiates the claimed SPF rating.

On 7 September 2020, the TGA wrote to all sponsors of Australian sunscreens that were listed on the ARTG at the time regarding a proposed condition of listing imposed on all sunscreens as a measure to ensure they are of acceptable efficacy. These sponsors were provided with an opportunity to respond.

The key issues raised in the comments received from sponsors were:

a. Concern that the condition would be operative for sunscreens for which testing data supplied by AMA Laboratories is *not* relied upon;

b. Concerns over possible delays in obtaining additional testing data due to COVID-19 and being afforded sufficient time for sponsors to comply with the proposed condition. October 2020 was suggested as a time *after* which the condition should be applied; and

c. Insufficient detail in the condition to explain what would constitute *'adequate supplementary data'*.

D. The reasons for my decision to impose a new condition

The aim of the condition is to ensure that, until such time as the TGA can have confidence that testing data provided by AMA Laboratories can be relied upon (pending the completion of the US investigation and any measures that may be imposed to address the issues of potential fraud), the SPF, broad spectrum and water resistance efficacy of sunscreens supplied in Australia is acceptable.

I have considered all comments and matters raised in the feedback from sponsors and have taken them into account in informing my decision, as follows:

Imposition of condition on sunscreens not relying on AMA Laboratories

The TGA is imposing the condition of listing on all sunscreens supplied in Australia but the condition would only have material effect on those sunscreens that rely on testing data supplied by AMA Laboratories to support SPF rating, broad spectrum or water resistant claims.

For those sunscreens that do not rely on testing data from AMA Laboratories, the condition will not be operative. Sponsors have the option to obtain testing from AMA Laboratories at any time for their current or future ARTG sunscreen listings.

[2] https://www.tga.gov.au/media-release/sunscreen-spf-testing-ama-laboratories

I am therefore of the view that it remains reasonable to apply the condition of listings to *all* sunscreens.

Delays in testing due to COVID-19

I consider that, since the publication of a web statement in June 2020 advising of the potential to impose an additional condition of listing on sunscreens listed on the ARTG, a substantial period of time has passed. Sponsors have had an opportunity to consider the use of other testing facilities in the interim. Whilst I acknowledge that the COVID-19 pandemic may still pose possible delays in obtaining new testing data, this concern is outweighed by a need to protect the Australian public. I am therefore satisfied that the condition of listing is reasonable in the circumstances, achieving a balance between sufficient time for sponsors to comply and protecting the health of the Australian public.

Meaning of 'adequate supportive data'

To address this concern, the TGA will be providing further guidance to sponsors on the TGA's website on the types of data that may be considered acceptable in meeting the condition of listing. Sponsors should contact the TGA to confirm whether their proposed other justification is adequate. In addition, the feedback has led me to refining the condition from what was previously proposed in order to provide greater clarity. I consider that stipulating broad types of adequate data in the condition of listing coupled with more detailed guidance appropriately balances providing flexibility and clarity for sponsors in how to substantiate the efficacy of their sunscreen.

On the basis of the above, I consider that the concerns raised by sponsors have been adequately addressed and that it remains appropriate to impose the condition of listing in order to ensure Australian consumers access to safe and reliable sunscreens.

I am therefore imposing the condition under subsection 28(3) of the Act on all sunscreens that are listed in the ARTG, to address concerns about the potential impacts of alleged fraudulent testing by AMA Laboratories. This is an interim regulatory measure to ensure that potentially affected products can continue to be supplied in Australia until further SPF testing can be conducted by an independent laboratory.

E. Conclusion

For the reasons outlined in this notice, I am imposing a condition on the listing of Ultra Violette Lean Screen SPF50+ (AUST L 332788) on the ARTG under subsection 28(3) and pursuant to paragraph 28(4)(b) of the Act. This decision will take effect on 27 February 2022.

F. Review rights

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled **"<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and copied to '**decision.review@health.gov.au**'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 40
c/- Parliament House
CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

The TGA will only be emailing a copy of this letter to your company. It is your responsibility to forward this correspondence to any agents or other parties acting on your behalf.

Yours faithfully

Electronically signed and authorised by

s22

Delegate of the Secretary
Complementary and OTC Medicines Branch
Therapeutic Goods Administration

31 January 2022

From: Complementary Medicines
To: s22 @ultraviolette.com.au"
Subject: Notice to impose Sunscreen condition of Listing - AUST L 323071, 384499 [SEC=OFFICIAL]
Date: Friday, 18 March 2022 12:58:00 PM
Attachments: Notice to Impose Condition of Listing - AUST L 323071, 384499 - Ultra Violette SPF 50+ Extreme Screen.pdf
image001.jpg

TGA Ref: E22-537357

Dear Sir/Madam

Please find attached a notice regarding a decision to impose a new condition of listing on sunscreens. Please note that the new condition only effects sunscreens with testing results provided by AMA Laboratories. You are not required to respond to this email or its attachment now, however you may be required to provide relevant details in the future.

It has come to my attention that since the time you received a Notice imposing such condition of listing on your above sunscreens, you have made changes to the products' entry under the Groups Order (known as a 'Grouping' application) or s. 9D of the *Therapeutic Goods Act 1989*. I am therefore issuing you with another Notice to impose the condition of listing (see attached).

The Complementary & OTC Medicines Branch understands that you have included this email address in eBS as a contact point. The TGA will only be sending this letter via email so it is important that you keep your details up-to-date. If you wish to update your contact details with the TGA, please login to your account through TGA Business Services or contact the eBS Helpdesk on 1800 010 624 or ebs@health.gov.au.

Please note, under the Electronic Transaction Act 1999, any notice sent via email is assumed to have been received by the sponsor once it is delivered to the sponsor's email address; not when it is opened by the sponsor.

If you have any questions about this letter, please do not hesitate to contact the Complementary & OTC Medicines branch on s22 or s22 @health.gov.au.

Kind regards

s22
Complementary Medicines
Complementary and OTC Medicines Branch

Phone: s22
Email: s22 @health.gov.au

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

Australian Government
Department of Health
Therapeutic Goods Administration

TGA Reference: D22-5259561

The Managing Director
Grace & Fire Pty Ltd
36 Avondale Street
Hampton VIC 3188

By email: s22 [redacted] **@ultraviolette.com.au**

Dear Sir/Madam

Notice to impose a condition under subsection 28(3)
of the *Therapeutic Goods Act 1989*

I am writing to advise you of my decision under subsection 28(3) of the *Therapeutic Goods Act 1989* (**the Act**[1]) to impose a condition of listing for the following listed medicine(s):

- Ultra Violette SPF 50+ Extreme Screen (AUST L 323071)
- Ultra Violette SPF 50+ Extreme Screen (New Formulation) (AUST L 384499)

This notice includes information about:

A. The purpose and basis of this notice to impose a condition
B. The new condition of listing to be imposed
C. Relevant history
D. The reasons for my decision to impose a new condition
E. Conclusion
F. Review rights

The imposition of the condition will take effect immediately from 13 April 2022.

A. The purpose and basis of this notice to impose a condition

Under subsection 28(3) of the Act, the Secretary of the Department of Health may, by notice in writing given to the person in relation to whom therapeutic goods are registered or listed, impose new conditions on the registration or listing, or vary or remove conditions imposed under subsection (2B) or this subsection.

[1] A copy of the Act can be accessed from http://www.comlaw.gov.au

I am a delegate of the Secretary for the purposes of section 28 of the Act, pursuant to which I may impose a condition of listing on goods listed on the Australian Register of Therapeutic Goods (**ARTG**). This letter is notice that I have decided to impose a condition of listing on the abovementioned goods that are listed on the ARTG for the purpose of subsection 28(3) of the Act. Subsection 28(3A) allows me to exercise this power at my own motion.

Paragraph 28(4)(b) of the Act relevantly permits that the imposition of this condition under subsection 28(3) takes effect on the day specified for the purpose in this notice, being a day not earlier than 28 days after this notice is given to the person.

Please note that a failure to comply with the condition stipulated here in Section B is a ground for a delegate of the Secretary to cancel your medicine from the ARTG under section 30 of the Act.

B. The new condition of listing to be imposed

I have decided to impose a condition of listing on the aforementioned medicine as follows:

The following two conditions apply where testing conducted by AMA Laboratories Inc. is used to substantiate compliance of the product with the Australian and New Zealand Sunscreen Standard AS/NZS 2604 Sunscreen products—Evaluation and classification (the Sunscreen Standard):

a. *The sponsor is required to hold adequate supplementary in-vitro testing data and/or relevant testing data from an independent testing laboratory on a comparable formulation, or other justification acceptable to the Therapeutic Goods Administration (***TGA***), to scientifically justify the validity and accuracy of the SPF, broad spectrum and water resistance claims for the product.*

b. *The sponsor must provide the data, documentation or other justification to the TGA within 10 working days of a request by the TGA, or as deemed reasonable by the delegate upon request.*

C. Relevant history

For therapeutic sunscreens to be eligible for listing on the ARTG, they must comply with the requirements set out under Item 7 of Part 1 of Schedule 4 of the Therapeutic Goods Regulations 1990 (**the Regulations**). This includes that they comply with the Australian and New Zealand Standard *AS/NZS 2604:2012 Sunscreen products - Evaluation and classification* (**the Standard**) in force at the time of listing on the ARTG. Compliance with the Standard requires that sunscreens are tested to verify the sun protection factor (SPF), broad spectrum and water resistance claims.

The sponsors of some sunscreens on the ARTG have in the past, engaged AMA Laboratories to perform SPF testing to substantiate compliance with the Standard. AMA Laboratories is currently being investigated by the United States (US) Department of Justice concerning alleged fraudulent laboratory testing to which AMA Laboratories executives have pleaded guilty.

To address the potential that fraudulent SPF testing data may have been relied upon to support SPF claims of some sunscreens supplied in Australia, the TGA determined that an

interim regulatory measure is needed to safeguard the continued access of Australian consumers to reliable sunscreens.

On 15 June 2020, the TGA published a web statement[2] advising of its concerns regarding the reliability of test data provided by AMA Laboratories. The web statement announced that the TGA would require that sunscreen sponsors provide adequate justification for ongoing supply of their products that have been tested by AMA Laboratories. This could include additional supportive testing data on comparable products in their product line or from product development studies, or other robust scientific justification that substantiates the claimed SPF rating.

On 7 September 2020, the TGA wrote to all sponsors of Australian sunscreens that were listed on the ARTG at the time regarding a proposed condition of listing imposed on all sunscreens as a measure to ensure they are of acceptable efficacy. These sponsors were provided with an opportunity to respond.

The key issues raised in the comments received from sponsors were:

a. Concern that the condition would be operative for sunscreens for which testing data supplied by AMA Laboratories is *not* relied upon;

b. Concerns over possible delays in obtaining additional testing data due to COVID-19 and being afforded sufficient time for sponsors to comply with the proposed condition. October 2020 was suggested as a time *after* which the condition should be applied; and

c. Insufficient detail in the condition to explain what would constitute *'adequate supplementary data'*.

D. The reasons for my decision to impose a new condition

The aim of the condition is to ensure that, until such time as the TGA can have confidence that testing data provided by AMA Laboratories can be relied upon (pending the completion of the US investigation and any measures that may be imposed to address the issues of potential fraud), the SPF, broad spectrum and water resistance efficacy of sunscreens supplied in Australia is acceptable.

I have considered all comments and matters raised in the feedback from sponsors and have taken them into account in informing my decision, as follows:

Imposition of condition on sunscreens not relying on AMA Laboratories

The TGA is imposing the condition of listing on all sunscreens supplied in Australia but the condition would only have material effect on those sunscreens that rely on testing data supplied by AMA Laboratories to support SPF rating, broad spectrum or water resistant claims.

For those sunscreens that do not rely on testing data from AMA Laboratories, the condition will not be operative. Sponsors have the option to obtain testing from AMA Laboratories at any time for their current or future ARTG sunscreen listings.

[2] https://www.tga.gov.au/media-release/sunscreen-spf-testing-ama-laboratories

I am therefore of the view that it remains reasonable to apply the condition of listings to *all* sunscreens.

Delays in testing due to COVID-19

I consider that, since the publication of a web statement in June 2020 advising of the potential to impose an additional condition of listing on sunscreens listed on the ARTG, a substantial period of time has passed. Sponsors have had an opportunity to consider the use of other testing facilities in the interim. Whilst I acknowledge that the COVID-19 pandemic may still pose possible delays in obtaining new testing data, this concern is outweighed by a need to protect the Australian public. I am therefore satisfied that the condition of listing is reasonable in the circumstances, achieving a balance between sufficient time for sponsors to comply and protecting the health of the Australian public.

Meaning of 'adequate supportive data'

To address this concern, the TGA will be providing further guidance to sponsors on the TGA's website on the types of data that may be considered acceptable in meeting the condition of listing. Sponsors should contact the TGA to confirm whether their proposed other justification is adequate. In addition, the feedback has led me to refining the condition from what was previously proposed in order to provide greater clarity. I consider that stipulating broad types of adequate data in the condition of listing coupled with more detailed guidance appropriately balances providing flexibility and clarity for sponsors in how to substantiate the efficacy of their sunscreen.

On the basis of the above, I consider that the concerns raised by sponsors have been adequately addressed and that it remains appropriate to impose the condition of listing in order to ensure Australian consumers access to safe and reliable sunscreens.

I am therefore imposing the condition under subsection 28(3) of the Act on all sunscreens that are listed in the ARTG, to address concerns about the potential impacts of alleged fraudulent testing by AMA Laboratories. This is an interim regulatory measure to ensure that potentially affected products can continue to be supplied in Australia until further SPF testing can be conducted by an independent laboratory.

E. Conclusion

For the reasons outlined in this notice, I am imposing a condition on the listing of Ultra Violette SPF 50+ Extreme Screen (AUST L 323071)

F. Review rights

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

The Minister may either personally undertake a request for reconsideration of an initial decision or delegate to an officer of the Department with the appropriate delegation.

Under section 60(3A) of the Act, the Minister (or the Minister's delegate) is not able to consider any information provided after the notification is made of a request for reconsideration of an initial decision unless the information is provided in response to a request from the Minister (or the Minister's delegate), or it is information that indicates that the quality, safety or efficacy of the relevant therapeutic goods is unacceptable.

Guidelines for requesting reconsideration of an initial decision

A request for reconsideration should be made in writing, signed and dated by the person requesting reconsideration, should be titled **"<insert person/company name> - Request for Reconsideration Under Section 60 of the *Therapeutic Goods Act 1989***" and should include the following:

- a copy of the initial decision notification letter (or other evidence of notification);
- identify, and describe with as much specificity as possible, which component(s) of the initial decision should be reconsidered and set out the reasons why reconsideration is requested;
- any information/documentation in support of the request, clearly labelled to correspond with (any or each of) the reasons why reconsideration is requested; and
- an email address nominated for the purposes of receiving correspondence in relation to the request for reconsideration.

All requests for reconsideration should be given to the Minister by email:

Email: '**minister.hunt.DLO@health.gov.au**' and copied to '**decision.review@health.gov.au**'

Requests for reconsideration that include dossiers (or similar bulk material) that cannot easily be attached to the request given first by email, may then be submitted on a USB drive or CD sent by express post or registered mail to:

Mail: **Minister for Health**
Suite M1 40
c/- Parliament House

CANBERRA ACT 2600

Subject to the *Administrative Appeals Tribunal Act 1975* (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

NOTE: This initial decision remains in effect unless and until it is revoked or revoked and substituted by the Minister (or the Minister's delegate) as a result of a request for reconsideration under section 60 of the Act OR is set aside, varied or remitted by the AAT or is otherwise overturned or stayed.

The TGA will only be emailing a copy of this letter to your company. It is your responsibility to forward this correspondence to any agents or other parties acting on your behalf.

Yours faithfully

Electronically signed and authorised by

s22 [redacted]
Delegate of the Secretary
Complementary and OTC Medicines Branch
Therapeutic Goods Administration

17 March 2022

From: s22 on behalf of Complementary Medicines
To: s22
Subject: 9D(1) application - Listed Medicines - LM-2021-05605-1 - approval letter - Ultra Violette Lean Screen SPF50+ (AUST L 332788). [SEC=OFFICIAL]
Date: Monday, 20 December 2021 9:46:40 AM
Attachments: D21-3440307 LM-2021-05605-1 LM - 9D(1) Approval Letter - AUST L 332788.pdf

Dear s22

Please find attached the outcome of your s.9D(1) application - LM-2021-05605-1 - Ultra Violette Lean Screen SPF50+ (AUST L 332788).

Please note it may take 24-48 hours for this information to appear on the ARTG.

Regards

Complementary Medicines
Complementary and OTC Medicines Branch

Phone: s22
Email: s22 @health.gov.au

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

This information is given to you without prejudice and is not binding on the TGA. It is the responsibility of the sponsor to ensure that all of the legislative requirements are met.

Submission No.: LM-2021-05605-1
Our reference: **D21-3440307**

The Managing Director
Grace & Fire Pty Ltd
36 Avondale Street
Hampton VIC 3188

Attention: s22 [redacted], Regulatory Affairs

Dear Sir/Madam

REQUEST UNDER SUBSECTION 9D(1) FOR VARIATION TO COMPLETE/CORRECT ENTRY IN THE ARTG

I refer to your request under subsection 9D(1) of the *Therapeutic Goods Act 1989* (the Act) dated 7/12/2021 to vary the entry of:

Ultra Violette Lean Screen SPF50+ (AUST L 332788)

('the medicine') in the Australian Register of Therapeutic Goods (ARTG) as follows:

- Excipient Ingredient: ammonium acryloyldimethyltaurate/VP copolymer has been added
- Excipient Ingredient: ammonium acryloyldimethyltaurate/steareth-8 methacrylate copolymer has been deleted

Subsection 9D(1) of the Act can be found online at the following link:
https://www.legislation.gov.au/Series/C2004A03952

Decision

As delegate of the Secretary of the Department of Health, I am:

- under subsection 9D(1) of the Act, varying the entry in the ARTG for the medicine as requested on the basis that the relevant information currently in the entry is incomplete or incorrect and that the variations requested would complete or correct the entry

Request for reconsideration of an initial decision

This decision is a reviewable initial decision under section 60 of the Act. Under section 60, a person whose interests are affected by a 'reviewable' initial decision, can seek reconsideration of the initial decision.

As this document constitutes written notice of the making of an initial decision being given by the Secretary, a request for reconsideration of this initial decision must be given to the Minister within 90 days and be accompanied by any information that you wish to have

considered. A request for reconsideration given to the Minister outside the statutory 90 day reconsideration period cannot be accepted.

Please refer to the TGA website for guidance on requesting reconsideration of this decision, including preparing and submitting the request.

Subject to the Administrative Appeals Tribunal Act 1975 (AAT Act), if you are dissatisfied with the decision upon reconsideration by the Minister (or the Minister's delegate), you can apply to the Administrative Appeals Tribunal (AAT) for a review of that decision upon reconsideration.

If you have any further queries regarding this matter, please contact us via the email below.

Yours faithfully

Signed and authorised by
s22
Delegate of the Secretary
Complementary & OTC Medicines Branch
Email: s22 @health.gov.au

15 December 2021

From: Complementary Medicines
To: [redacted]@ultraviolette.com.au
Subject: RE: Request for information - Sunscreen testing (ref LMP-2019-00192-1) [SEC=OFFICIAL]
Date: Tuesday, 30 June 2020 9:36:27 AM
Attachments: image003.png

Dear [redacted]

Thank you for your email.

We are still ascertaining the impacts of the alleged fraud including whether SPF testing conducted after 2017 may have been impacted. In this context we maintain our request for this information from you.

Regards
Complementary Medicines
Complementary and OTC Medicines Branch

Phone: [redacted]
Email: [redacted]@health.gov.au

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

This information is given to you without prejudice and is not binding on the TGA. It is the responsibility of the sponsor to ensure that all of the legislative requirements are met.

From: [redacted]@ultraviolette.com.au [redacted]@ultraviolette.com.au>
Sent: Tuesday, 16 June 2020 2:55 PM
To: Complementary Medicines [redacted]@health.gov.au>
Subject: RE: Request for information - Sunscreen testing (ref LMP-2019-00192-1) [SEC=OFFICIAL]

Hi [redacted]

I've read through your note and the linked document, and all of my products listed below were registered after 2017 so I am not clear as to why I need to provide the information you requested below?

s22

s22
s22

s22
FUTURE-PROOF YOUR FACE

From: Complementary Medicines s22 @health.gov.au>
Sent: Tuesday, 16 June 2020 2:40 PM
To: s22 @ultraviolette.com.au
Subject: Request for information - Sunscreen testing (ref LMP-2019-00192-1) [SEC=OFFICIAL]

Attention: Grace & Fire Pty Ltd

Dear Sir/Madam

I am writing to you because our records indicate that you are, or represent, the sponsor of one or more sunscreen products that are currently listed in the Australian Register of Therapeutic Goods (ARTG).

This email pertains to the compliance of your sunscreen(s) with the Australian and New Zealand Sunscreen Standard *AS/NZS 2604 Sunscreen products—Evaluation and classification* (the Sunscreen Standard).

Background

The US Department of Justice are currently investigating allegations of a fraud scheme involving the reporting of false laboratory test results issued by AMA Laboratories Inc. According to a press release, dated 9 August 2019 (https://www.justice.gov/usao-sdny/pr/owner-ama-rockland-based-consumer-products-testing-company-arrested-fraud-scheme), members of the AMA Laboratories executive team and supervising laboratory technicians have pleaded guilty to wire fraud resulting from alleged fraudulent laboratory testing. This may have a bearing on your sunscreen product.

The potential of fraudulent testing data being relied upon to support SPF, broad spectrum and water resistance claims for products marketed in Australia, is of concern to the TGA given that such claims constitute the basis for adequately demonstrating the safety and efficacy of sunscreens. At the present time the ongoing US investigation raises doubts about whether test results issued by AMA Laboratories, can be relied upon as satisfactory evidence that products meet the mandatory requirements of the Sunscreen Standard.

The TGA is evaluating the potential impacts of this alleged fraudulent activity on products in Australia to determine what interim regulatory measures are required to ensure that potentially affected products can continue to be supplied in Australia until further SPF testing can be conducted by an independent laboratory.

Request for information

In my capacity as a delegate of the Secretary of the Department of Health for the purposes of section 31 of the *Therapeutic Goods Act 1989* (the Act)[1], I am writing to request the following information about your sunscreens listed below:

307611 - Ultra Violette SPF50+ Supreme Screen
307612 - Ultra Violette SPF50+ Queen Screen
307711 - Ultra Violette SPF30 Clean Screen
323071 - Ultra Violette SPF 50+ Extreme Screen
326834 - Ultra Violette SPF50+ Queen Screen
327019 - Ultra Violette SPF30 Clean Screen
332788 - Ultra Violette Lean Screen SPF50+

- For each sunscreen listed above, can you please provide the following information in relation to SPF, broad spectrum and water resistance testing:
    - Name of the product
    - AUST L number
    - Outline of:
        - what was tested and
        - who performed the testing
        - dates the results were issued, and
        - corresponding certificate number for each test result

Please include the above information in table form if there are four (4) products or more.

Please provide a response by 5 pm **Tuesday 30 June 2020**. Please send your response to s22 [redacted] @health.gov.au.

We will only be emailing this request to your company. It is your responsibility to forward this correspondence to any agents or other parties acting on your behalf.

s22 [redacted]
Listing Compliance Section
Complementary and OTC Medicines Branch

Phone: s22 [redacted]
Email: s22 [redacted] @health.gov.au

Therapeutic Goods Administration
Department of Health

PO Box 100
Woden ACT 2606
www.tga.gov.au

This information is given to you without prejudice and is not binding on the TGA. It is the responsibility of the sponsor to ensure that all of the legislative requirements are met.

[1] A copy of the Act may be accessed from https://www.legislation.gov.au

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[1] A copy of the Act may be accessed from https://www.legislation.gov.au