

section 42

From: section 22
Sent: Wednesday, 29 May 2019 5:20 PM
To: TGA FOI
Cc: Medicines Scheduling
Subject: RE: For action: ASADA consultation under FOI - Due 30 May 2019 [SEC=OFFICIAL:Sensitive]
Importance: High

Hello,

If the person who submitted the scheduling application is happy for the information to be released under FOI then we have no objections to the release of this information.

However, if that is not the case, any information in the scheduling application that has not already been published on the TGA website as part of the interim or final decision should be exempt from release to the FOI applicant. Potential harm that may arise from its release includes that the TGA has not received permission from the person that submitted the scheduling application to publically release their personal information (or release of part or all of the submission).

Kind regards,

section 22

section 22

section 22 | Scheduling and Committee Support

Regulatory Engagement and Planning Branch | Regulatory Practice and Support Division
Health Products Regulation Group
Australian Government Department of Health

section 22

Location: Symonston

The Department of Health 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: TGA FOI
Sent: Wednesday, 29 May 2019 2:39 PM
To: Medicines Scheduling; TGA FOI; section 22
Cc: section 22
Subject: RE: For action: ASADA consultation under FOI - Due 30 May 2019 [SEC=OFFICIAL:Sensitive]

Hi section 22

Thank you for this information however I think there may be some confusion. Essentially we are only interested in whether any of the content of the attached document should be exempt from release to the applicant. If so we need to outline what potential harm may arise from its release. This will assist the decision maker at ASADA to redact or release information in the document.

Please let me know if you have any questions.

Thank you

section 22

section 22

HPRG Regulatory Information Access

Reporting & Collaboration Services | Regulatory Engagement & Planning
Health Products Regulation Group
Australian Government Department of Health

section 22

TGAFOI@health.gov.au

Location: Symonston, GE26

PO Box 100, Canberra ACT 2601, Australia

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From: Medicines Scheduling
Sent: Wednesday, 29 May 2019 12:50 PM
To: TGA FOI; section 22
Cc: section 22
Subject: RE: For action: ASADA consultation under FOI - Due 30 May 2019 [SEC=OFFICIAL:Sensitive]

Hi section 22

Thank you for your email in relation to a scheduling application submitted for performance and image enhancing drugs (PIEDS). This scheduling proposal was considered by the ACMS#13 in November 2014.

The application (with certain redactions) along with the interim and final decisions have been made publically available on the TGA website. Please see the relevant links below:

- [Interim decision](#) (includes Application details, and details on the pre-meeting public submission)
- [Final decision](#) and [Reasons for Scheduling delegate's final decisions](#) (includes details on public submission on the interim decision)

I have discussed your query with section 22 we are not in a position to give any further access permissions.

Please contact section 22 if you have any questions,

Kind Regards,

section 22

The Chemicals and Medicines Scheduling Secretariat Team

Scheduling & Committee Support

Regulatory Engagement & Planning Branch | Regulatory Practice and Support Division
Health Products Regulation Group
Australian Government Department of Health

section 22 E: chemicals.scheduling@health.gov.au and medicines.scheduling@health.gov.au

From: TGA FOI

Sent: Friday, 24 May 2019 3:05 PM

To: section 22

Cc: section 22

Subject: FW: For action: ASADA consultation under FOI - Due 30 May 2019 [SEC=OFFICIAL:Sensitive]

Dear section 22

Please see below a request from ASADA relating to the application for scheduling of Thymosin. section 22 has asked me to forward the attached document to you, to consider whether there are any sensitivities in ASADA releasing the document.

Let me know if you have any questions.

Thank you

section 22

section 22

section 22 | Reporting and Collaboration Services Section

Regulatory Engagement and Planning Branch | Regulatory Practice & Support Division
Health Products Regulation Group
Australian Government Department of Health

section 22

PO Box 100, Canberra ACT 2601, Australia

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From: TGA FOI
Sent: Friday, 24 May 2019 12:51 PM
To: section 22
Cc: TGA FOI; section 22
Subject: For action: ASADA consultation under FOI - Due 30 May 2019 [SEC=OFFICIAL:Sensitive]

Dear section 22

TGA is being consulted as a third party in relation to an FOI request that ASADA is processing (per the email below).

Could you, or the appropriate person, please review the attached document and advise whether there is any sensitivity in releasing it to the FOI applicant.

We would appreciate your response by **Thursday 30 May 2019** in order to provide the response to ASADA by their deadline.

Kind regards

section 22

section 22

HPRG Regulatory Information Access

Reporting & Collaboration Services | Regulatory Engagement & Planning
Health Products Regulation Group
Australian Government Department of Health

section 22

E: TGAFOI@health.gov.au

Location: Symonston, GE26

PO Box 100, Canberra ACT 2601, Australia

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From: s22 On Behalf Of FOI
Sent: Friday, 24 May 2019 10:09 AM
To: FOI
Subject: Consultation on possible release of documents - ASADA [DLM=For-Official-Use-Only]

Dear Colleagues,

ASADA has received an FOI request for documents relating to an application being made to the Therapeutic Goods Administration (**TGA**) in August of 2015 to have the substance Thymosin Beta 4 scheduled.

The attached document has been captured by the scope of that request. I note that the attached document is a 2014 application by the National Integrity of Sport Unit (**NISU**) to the TGA along similar lines. It has been captured by the scope of the request due to being attached to an email discussing the 2015 application.

I would be grateful for any views the Department of Health may have on the potential release of the attached document under FOI. If the Department identifies any issues with the document being provided to the applicant could you please outline what potential harm may arise from such a course of action.

It at all possible it would be great if any response to be provided by **Friday 31 May 2019** to allow ASADA time to consider it prior to any decision on release being made. If that timeframe is not possible please just let me know as soon as possible so I can negotiate additional time with the applicant.

Please do not hesitate to contact me should you have any questions in relation to the above.

Kind regards,

s2
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Australian Sports Anti-Doping Authority

s22
W www.asada.gov.au

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