Australian Government
Department of Health
Therapeutic Goods Administration

Filenote

Product name: N/A
Company: Wild Child Laboratories, Malaga WA
Sub ID: N/A
TRIM File: PH21/4113
E-File: D22-5659212
Prepared by: s22
Date: 04th July 2022

Inspection Review & Details

Background

This is a notification that Inspector, s22 attended the Opening and Closing meetings of an FDA 'For Cause' on-site Inspection (FEI 3006210769) of Wild Child Laboratories Pty Ltd, located in Malaga, Western Australia on the 13th and 17th June 2022 respectively conducted by s22 (Lead) & s22 (Laboratory expert).

The inspector was invited to join the opening meeting virtually, held at 09:00am (WA local time) on Monday the 13th June stated the reason for the inspection being in regard to the FDA dissatisfaction to the companies response of the previous FDA inspection. General introductions on the reason for the inspection and pleasantries were undertaken, completing at 09:45am approx. (WA local Time).

The inspection was held and undertaken by the FDA with no TGA involvement.

The inspector was then invited to join the closing meeting virtually, held on Friday the 17th June at 16:00pm (WA local time). The FDA inspectors after thanking the company detailed Non-significant Issues as follows:

s22 : s37

s22 : s37

The FDA then issued a 7 item FDA 483 form and require a 15 calendar response for the following:

s37

s37

The company is required to respond within 15 days on the response to the above FDA483.

s37

Regards,

s22

04th July 2022

Australian Government
Department of Health
Therapeutic Goods Administration

Manufacturing
Quality Branch

MQB Form			
FORM 10.2a	Assessor Briefing Form		
Comes under	SOP 10.1 – Signal Assessment Procedure, and SOP 10.2 – Compliance Signal Investigation Procedure		
SOP 10.2 – Compliance Signal Investigation Procedure	Director, Licensing and Compliance Strategy Section	Authorised by	Quality Manager
Process Owner	18 December 2020	Version #	3.0

This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <http://www.tga.gov.au/about/tga-information-to.htm>.

This Assessor Briefing Form is to be used for:

- **External Non-Compliant Intelligence Signals ;**
- **Internal TGA Non-Compliant Intelligence Signals**

Section 1: Initial Assessment – LCSS to complete

s37

[redacted]

s37 [redacted]

s37 [redacted]

s37 [redacted]

Summary of the review and information to be requested from sponsors/manufacturer (specify):	
Comments:	

s37 [redacted]

Section 1 completed by:	s22 [redacted]	Date:	5/07/2023	☑ e-signed in TRIM
Section 1 Peer Reviewed by:	s22 [redacted]	Date:	18/09/2023	☑ e-signed in TRIM

Proceed to Section 2.

Section 2: Assessment of Risk– LCSS to complete

2.1 Request for Information, Questionnaire and Risk Assessments (P12)

Sponsor	Date Request Sent	TRIM Reference

2.2 Manufacturer (MNF) Information

Evidence	TRIM Reference	Note
Inspection Report associated with the signal Agency: Inspection Date:		
GMP Non-Compliance Report and/or GMP Certificate for the associated signal		
MNF Response and CAPAs		
Site Master File		
Summary of assessment:	[include assessment of all information provided for this site. Identify key concerns, deficiencies and determine whether CAPAs address the root cause]	

2.3 Sponsor Specific Information

Duplicate table below for each Sponsor as required.

Name of sponsor:		TRIM Reference
Send letter to sponsor	Date:	
Response provided and is complete?	☐Yes ☐ No	
Completed GMP Compliance Supply Questionnaire Form?	☐Yes ☐ No	
Risk Assessment provided?	☐Yes ☐ No	
Are there products currently supplied or intended to be supplied to Australia?	☐Yes ☐ No	
Critical product from this sponsor? Confirmed with Medicines Shortages?	☐Yes ☐ No ☐Yes ☐ No	
Addition Evidence (specify):		
Summary of assessment:	[consider the risk assessment and supply information in conjunction with the manufacturer's information in relation to the nature of the signal]	

2.4 Medicine Shortages (P13)

Are any of the products (ARTG Listings) on the Medicines Watch List - https://www.tga.gov.au/book/export/html/872589	☐Yes – confirm with Medicine Shortages	☐No

Email sent to Medicines Shortages for advice:	
Date: Click here to enter a date.	TRIM:
Advice from Medicines Shortages:	
Date: Click here to enter a date.	TRIM:
Critical Products: [Include detail and/or TRIM Reference]	

2.5 Overall Assessment Summary

Overall Assessment and recommendations:

2.6 Completion of Section 2

Advice from other areas of the TGA required?	☐ Yes	☐ No	
Inspectorate advice requested (Section 3)	☐ Yes	☐ No	☐ N/A
Other Actions Required:	TRIM Reference / Comment		
Advice required from Labs? ☐ Yes ☐ No ☐ N/A			
Advice required from PSAB? ☐ Yes ☐ No ☐ N/A			
Advice required from PCS? ☐ Yes ☐ No ☐ N/A			
Advice required from Recalls? ☐ Yes ☐ No ☐ N/A			
Advice required from COMB/OTC? ☐ Yes ☐ No ☐ N/A			
Referral to ECT? ☐ Yes ☐ No ☐ N/A			
Other actions required: ☐ Yes ☐ No ☐ N/A (specify other actions required or refer to another section of this report or TRIM link)			

Additional Comment:	

Section 2 completed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM
Section 2 Peer Reviewed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM

Section 3: Advice from Inspectorate – Inspectorate to complete

Where there are questions over the seriousness of the deficiencies, the risk assessment provided or there are other questions around information provided by the sponsor/manufacturer, send form to inspectorate for advice.

In the table below, include the relevant information and specific questions for the inspectors. Refer to R16/252445 for the listing of inspector subject matter experts. Copy of email notification is to be sent (CC) to Inspection Director, LCSS Director, and Inspection Team Leader.

Date email sent to the inspectorate:	Click here to enter a date.
Advice due by: (2 weeks)	Click here to enter a date.

3.1 GMP Compliance summary and recommendations on compliance signal

3.2 Inspectorate comments on the recommendations compliance signal

Agree / Not Agree with the recommendations proposed [delete as appropriate]	
Rationale for decision	
If disagree, please provide alternative recommendations and supporting rationale:	
If an inspection is recommended to be conducted, has Section 3.3 below been reviewed and completed?	☐Yes ☐No

3.3 Inspection requirements

Where it is determined that a TGA inspection is required, include the relevant information below. Inspection duration to be determined as per WI 5.1.4 – Inspection duration and team composition (R13/964735). Ensure a comment is provided where a recommendation differs to WI 5.1.4.

Parameter	Recommendation by Compliance	Inspectorate comment and rationale (Note - where the inspection duration differs from WI 5.1.4 please ensure justification is provided)
Reason inspection is required:		
Scope of products to be inspected (e.g. sterile only):		
Number of Inspectors:		
Total number of inspection days:		
Expertise required (e.g. sterile inspector, Labs expert):		
Unannounced or announced:		

Timeframe required for inspection to be conducted Specify month & year		

Inspectorate to complete

Section 3 completed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM
Section 3 Peer Reviewed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM

3.4 Inspection raised in MIS – LCSS to complete

Inspection application number:	
OMQ scheduling notified:	Click here to enter a date.
Completed by:	Choose an item.
Date:	Click here to enter a date.

3.5 Inspection outcome – LCSS to complete (post inspection)

Number of deficiencies [Refer to post inspection letter]	Critical: Major: Minor:
Inspection Rating: [Refer to post inspection letter]	☐ Yes (A1, A2, or A3) ☐ No (unacceptable)
Completed by:	Choose an item.
Date:	Click here to enter a date.

3.6 Referral to ERB – LCSS to complete

If inspection rating is unacceptable and/or regulatory actions are recommended from the Inspectorate and/or Review Panel, refer signal to ERB for further advice:	☐ Referred to ERB (Section 5) ☐ Referral Not Required ☐ N/A

Compliance Team to complete

Section 3 completed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM
Section 3 Peer Reviewed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM

Section 4: Proposed Regulatory Actions

LCSS to complete

4.1 Recommended Actions

Recommendation for further regulatory actions by MQB:	☐ Yes ☐ No [If a regulatory action is recommended, please provide description of the action below and include detail of relevant inspection, licence or clearances, ARTGs and/or TRIM reference]
Regulatory Area	Summary of Recommended Actions [and/or TRIM Reference]
Inspection ☐ Yes ☐ No ☐ N/A [If 'Yes', please also complete Sections 3.4 to 3.6]	
Licence ☐ Yes ☐ No ☐ N/A	
Clearance Applications ☐ Yes ☐ No ☐ N/A	
Issued Clearances ☐ Yes ☐ No ☐ N/A	
ARTG ☐ Yes ☐ No ☐ N/A	
Compliance Enforcement Section (Referral) ☐ Yes ☐ No ☐ N/A If 'Yes', please include TRIM reference to the referral correspondence	
Are there any other Regulatory Actions required?	☐Yes ☐No If 'Yes', what are they:
Referral to Executive Review Board (ERB)?	☐ Yes ☐ No ☐ N/A If 'Yes", please complete Section 5: Executive Review Board (ERB
Additional Comment:	
Site to remain on GMP Watch List:	☐ Yes ☐ No

Section 4 completed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM
Section 4 Peer Reviewed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM

Section 5: Executive Review Board (ERB)

Where it is recommended that actions should be taken or imposed against the sponsor/manufacturer, the Executive Review Board should be ratified (see WI 10.3 - D20-766572).

Actions to be considered include:

- Laboratory testing
- Regulatory actions against products (condition, suspend, recall) (s28, 29, 30EA)
- Regulatory actions against licences (condition, curtail, recall) (s41)
- Enforceable undertakings (s42YL)
- Civil Penalties for counterfeit medicines (s42EA)

Documents to be provided to ERB: (Document Title and TRIM links)	
Summary of issues and proposed actions:	
Date ERB convened:	Click here to enter a date.
ERB Minutes: [TRIM Reference]	

Proposed Regulatory Action	Summary of ERB Outcome / Decision
1.	
2.	

All Recommendations Endorsed by the ERB?
☐ Yes – All actions endorsed – progress with actions and close out
☐ No – Return to Section 2 and add addendum to the recommendation

Section 5 completed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM
Section 5 Peer Reviewed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM

Section 6: Close out

LCSS to complete

All internal recommendations have been completed and acknowledged by the relevant section e.g. inspection, clearance, etc.	☐ Yes ☐ No ☐ N/A
All sponsors have been advised of the final outcome of the compliance investigation?	☐ Yes ☐ No [include TRIM References]
All required actions have been completed:	☐ Yes ☐ No ☐ N/A
This compliance signal investigation case can be closed? (* - see Note)	☐ Yes ☐ No If not, please include detail in the 'Comments' section below
Comments:	
Has this signal been fully resolved?	☐ Yes ☐ No
If not fully resolved, the site is flagged 'yes' on watch list (signal 'active')	☐ Yes ☐ No
Specify additional evidence required to fully resolve this signal (where applicable)	
Comments:	

*__Note__: A signal that has not been resolved continues to be flagged as 'active' signal on the watch list (marked as 'Yes' on the watch list). Once the signal has been fully resolved, the signal is no longer active and the site can be removed from the watch list (marked as 'No' on the watch list). A compliance case may be closed without the signal being fully resolved, as long as it has been determined that the measures put in place (e.g. risk assessments, proposed corrective actions and regulatory actions) adequately manage the risks such that no further compliance actions are required unless a new signal is raised.

Section 6 completed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM
Section 6 Peer Reviewed by:	Choose an item.	Date:	Click here to enter a date.	☐ e-signed in TRIM

Version history

Version	Description of change	Author/s	Effective date
V1.0	New Form	s22 [redacted]	22 January 2019
V2.0	Re-designed based on updated compliance signal process	s22 [redacted]	19 November 2019
V2.1	Updating of the document format to: o streamline of the briefing form and triaging process (No process change)_ o addition of information to be requested o remove duplication and redundant information. o Include addition information in relation to the inspection recommendation.	s22 [redacted]	18 December 2020

From: s22
To: s22
Subject: RE: Wild Child WA Pty Ltd [SEC=OFFICIAL]
Date: Wednesday, 2 November 2022 4:17:38 PM
Attachments: image001.png
[D22-5659212] Inspection Filenote_FDA Wild Child Inspection Notes June 2022.DOCX

Dear s22

Please find a debrief of the closing meeting I attended that may help you with the discussion.

Regards,

s22

From: s22 @Health.gov.au>
Sent: Wednesday, 2 November 2022 2:39 PM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: Wild Child WA Pty Ltd [SEC=OFFICIAL]

Good Afternoon All,

Wild Child WA have been issued an Import Alert and have been found Unacceptable following a US FDA Inspection in June 2022.

Could you please confirm if there was an inspector present at the US inspection, and if there is any further information regarding the US FDA inspection and the sites non-compliance. Compliance will be contacting the FDA to request a copy of the 483/EIR as per our standard process, however this will take some time to be provided to the TGA.

Thank you and kind regards,

s22
Compliance Officer
Manufacturing Quality Branch
Medical Devices and Product Qualty Division | Health Products Regulatory Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Fairbairn Scherger 2N
PO Box 100, Canberra ACT 2601, Australia

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Australian Government
Department of Health
Therapeutic Goods Administration

Filenote

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04th July 2022

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To: s22
Subject: Wild Child WA Pty Ltd [SEC=OFFICIAL]
Date: Wednesday, 2 November 2022 2:39:20 PM
Attachments: image001.png
Wild Child Import Alert 66-40.PNG
Wild Child WA Pty Ltd FACTS.PNG

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Compliance Officer
Manufacturing Quality Branch
Medical Devices and Product Qualty Division | Health Products Regulatory Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
Location: Fairbairn Scherger 2N
PO Box 100, Canberra ACT 2601, Australia

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s33

From: InternationalGMP
To: GMP Compliance
Cc: s22
Subject: FW: [EXTERNAL] Wild Child WA Pty Ltd [SEC=OFFICIAL]
Date: Wednesday, 9 November 2022 10:58:01 AM
Attachments: image001.png
image004.png
image005.png
image007.png

Good Morning s22

Please see the response below from s22 of the US FDA in regards to your query of Wild Child WA Pty Ltd.

Warm regards,
s22

s22
s22 – Licensing and Compliance Strategy Section
Manufacturing Quality Branch

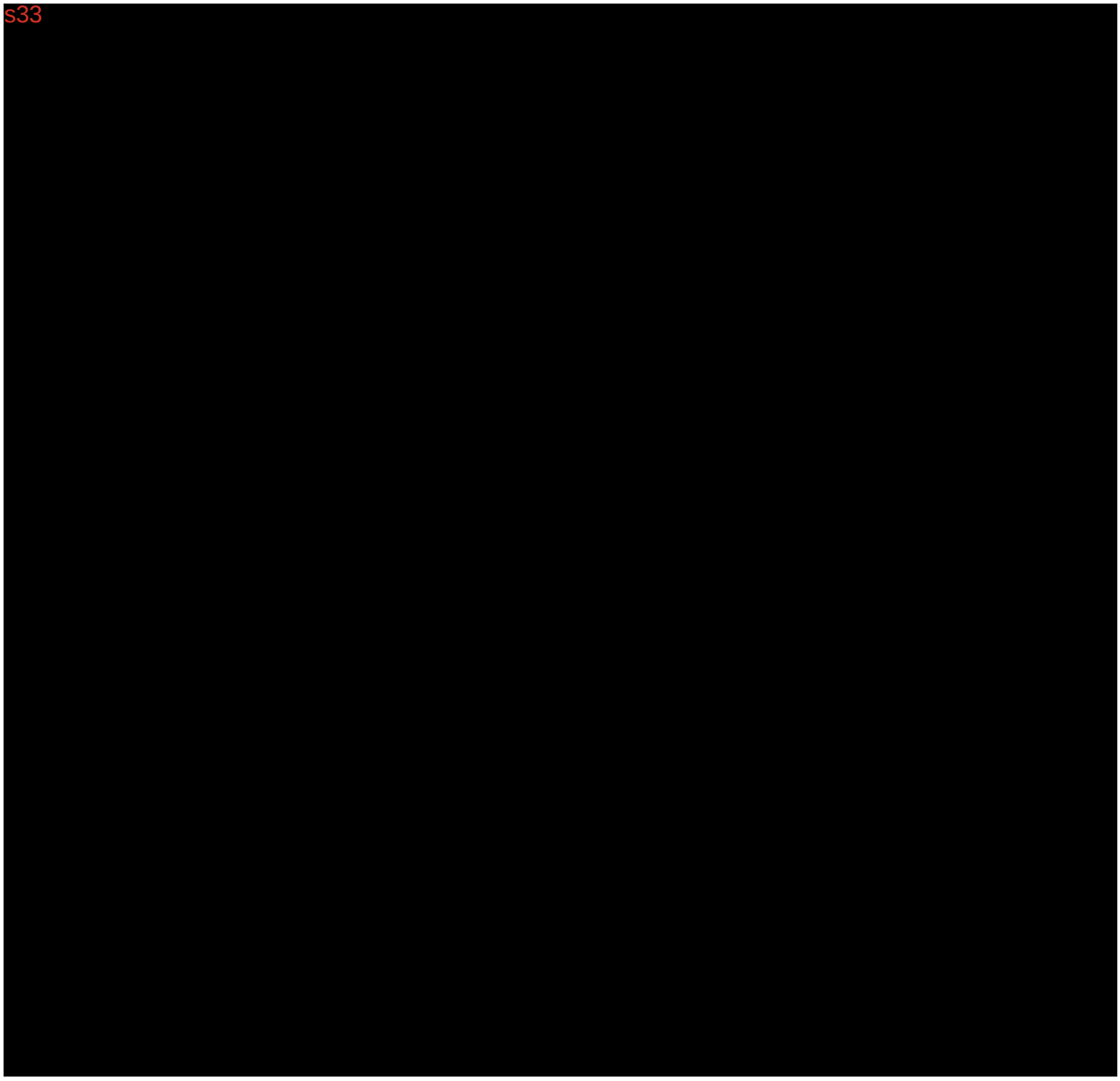
Medical Devices and Product Quality Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as 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.

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.

s33


s33


s33


s33

From: InternationalGMP
To: GMP Compliance
Cc: s22
Subject: FW: Confidential FDA Records Request under 20.89 for Wild Child WA Pty Ltd FEI 3006210769 [SEC=OFFICIAL]
Date: Monday, 5 December 2022 9:53:39 AM
Attachments: image001.png
image004.png
image005.png
image007.png
rev_FDA 483 - Wild Child WA Pty Ltd - June 13 -17 2022.pdf

Good Morning s22

Please see the response from the US FDA regarding your enquiry of Wild Child WA Pty Ltd.

Please note: "The document is being shared with the Australian Therapeutic Goods Agency, (TGA) in confidence, and **should not be disclosed to the public or persons outside your organization**. FDA considers it critical that you maintain the confidentiality of this information and abide by the obligations contained in the Confidentiality Commitment referenced above."

Warm regards,
s22

s22
s22 – Licensing and Compliance Strategy Section
Manufacturing Quality Branch

Medical Devices and Product Quality Division | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: s22 | E: s22 @health.gov.au
PO Box 100, Woden ACT 2606, Australia

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s33

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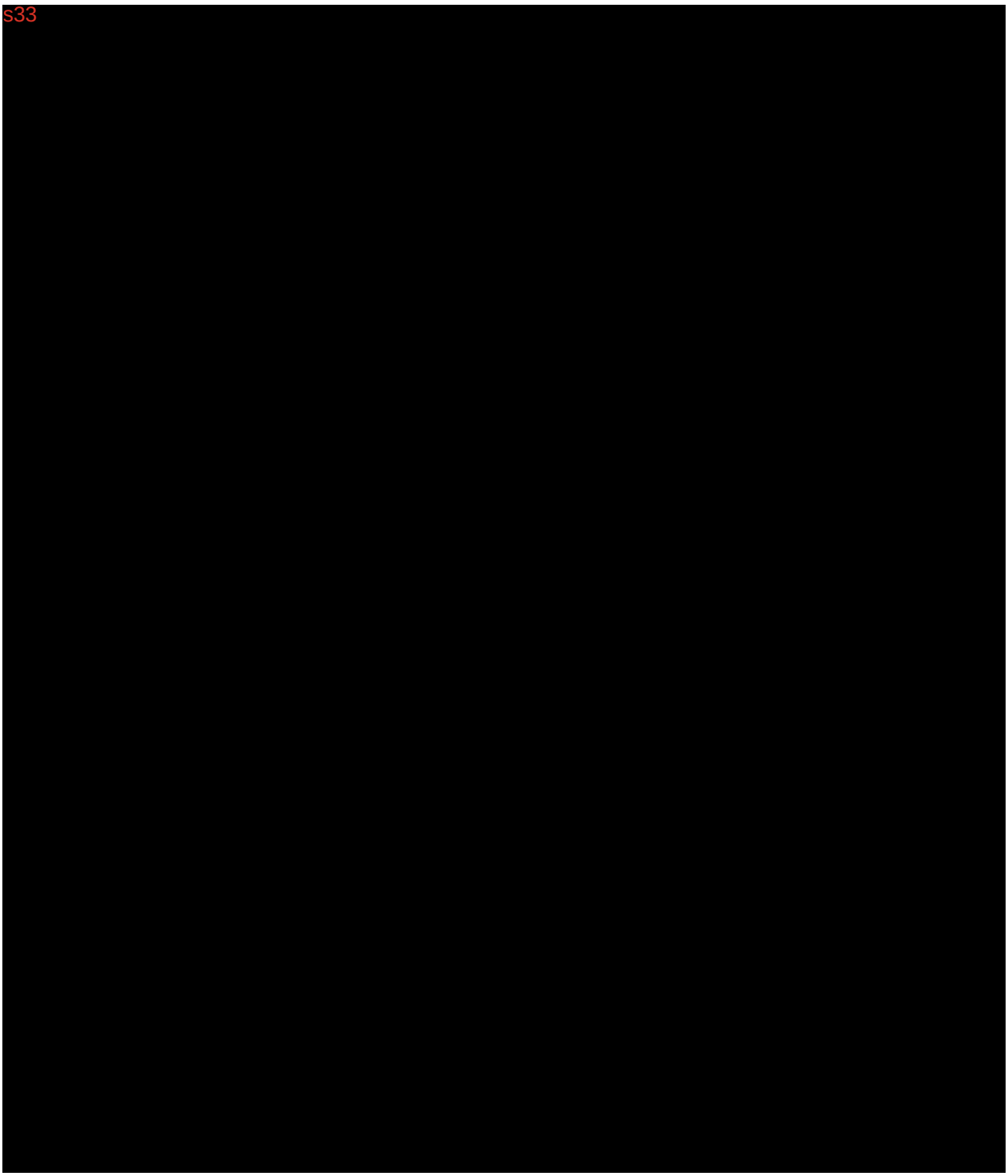

s33

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[redacted]

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Document 7

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Document 7

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Document 7

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Document 7

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Document 7

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Document 7

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

OFFICIAL

Note for file

Date and time	27/11/2025 3.25pm
Type of event (e.g. meeting/ telephone conversation)	File note related in response to FOI 26-2398
Topic	File note related in response to FOI 26-2398
Participants	NA

Key points	
Decision	Information sought as per FOI 26-2398 Part 6 of the request. • *whether any FDA-originated safety signals or warnings concerning Australian listed or licensed manufacturers were received between 1 January 2021 and the present;* TGA Response: Yes • *the number of such instances;* TGA Response: 2 • *the general nature of the issues (e.g., GMP, quality failures, inspection findings).* TGA Response: General GMP non-compliant observations. *No manufacturer names are required.*
Author details	Signed: s22 27/11/2025 3.30pm