From: s22 [redacted]
To: s22 [redacted]
Cc: s22 [redacted]
Subject: Inspection Report - SESLHD NTB Sydney NSW 14 - 17 November 2017 [SEC=UNCLASSIFIED]
Date: Wednesday, 4 April 2018 3:59:11 PM
Attachments: Inspection Report - SESLHD NTB Sydney NSW 14 - 17 November 2017.pdf
Review of response 2 T18 3348 TGA Close Out Record - SESLHD- Sydney NSW 14 - 17 November 2017(2).pdf

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Dear [redacted] and [redacted],

Please find attached inspection report for your variation inspection.

As mentioned in the report the issue of the varied license is in progress.

Please let me know if you have any questions or clarifications.

Regards

[redacted]

[redacted]

Inspections Section
Manufacturing Quality Branch | Medical Devices and Product Quality Division
Therapeutic Goods Administration
Australian Government Department of Health
Level 8, 595 Collins Street, Melbourne, Victoria, Australia.
PO Box 100 Woden ACT 2606 Australia

[redacted] health.gov.au

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Complaints and recalls

The manufacturer had a written procedure to manage recalls, "EATB-Q-WI-020". The inspector reviewed the procedure and the arrangements for recalls and found them suitable. There had been a number of recalls (DISC-17/648) and two complaints notifications since last inspections. The inspector reviewed the management of recalls and noted that although the investigations have been very thorough the manufacturer "action plan" had an oversight in that did not address the need for primary input of an experienced and qualified physician in determining and reviewing the causality of the adverse events. (*Deficiency 4)*

There had been a limited number of complaints since the last inspection. The manufacturer managed complaints with the DISC system. The inspector reviewed a sample of complaints and found them managed according to the manufacturer's procedure.

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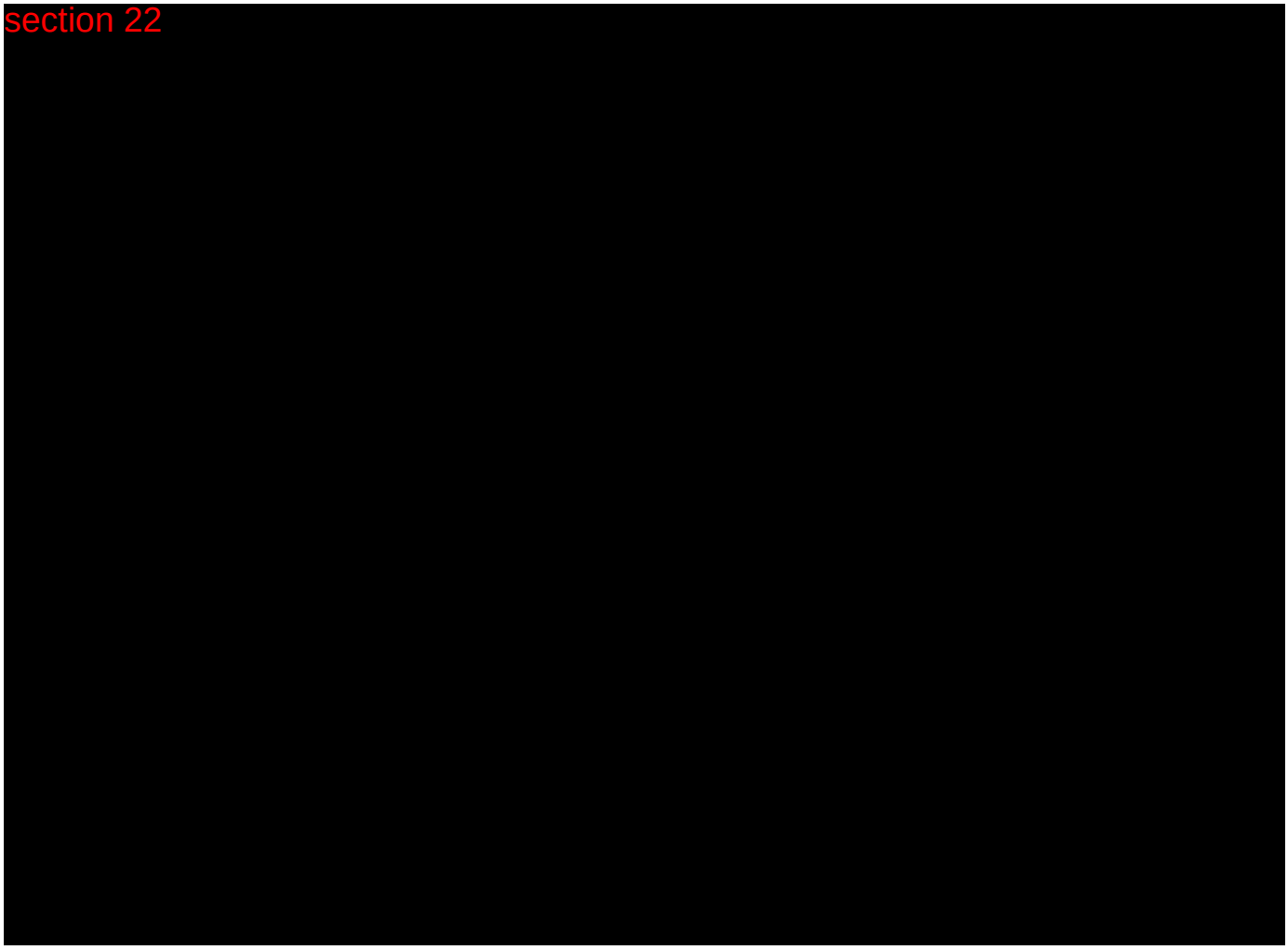

4. The requirements of Clause 107 that corrective or preventive action should be taken to eliminate the cause of nonconformities in order to prevent recurrence or occurrence were not met as the investigation into DISC-17/648 that had been instigated by a number of recalls had as an outcome an "action plan" that did not address the need for primary input of an experienced and qualified physician in determining and reviewing the causality of the adverse events.

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