Australian Government

Department of Health
Therapeutic Goods Administration

[redacted]

RE: GMP INSPECTION of South Eastern Sydney Local Health District

Please find attached the Inspection report for the inspection that took place at your premises Macquarie Street Sydney on 14 – 17 November 2017.

[redacted]

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

[redacted]

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TGA Health Safety Regulation

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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

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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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