

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2010-11, 20 October 2010

Question: E10-244

OUTCOME 1: Population Health

Topic: AUDITS OF CSL

Written Question on Notice

Senator Fierravanti-Wells asked:

- a) Is the TGA aware of any audits undertaken of CSL by any US authority? If so, please advise:
- b) The date of those audits?
- c) What deficiencies were identified during those audits?
- d) The extent of those audits – what was inspected, reviewed etc.
- e) Did any relate to product safety issues?
- f) Any corrective action required to remedy the deficiency?
- g) The corrective action taken to remedy the deficiency?
- h) Any product recall resulting from any deficiency?

Answer:

- a) The Government is aware that officers from the US Food and Drug Administration's centre for Biological Evaluation and Research conducted an inspection of CSL for compliance with current Good Manufacturing Practice (cGMP) Regulations and US market authorisations.

b) 19-28 April 2010.

c – g)

The US FDA has a similar process for the inspection of manufacturing sites to TGA audits and similarly maintains the confidentiality of its establishment inspection reports (see the answer to Question E10-243).

The FDA's April 2010 routine inspection was limited to the manufacture of Afluria® (a seasonal influenza product) and Influenza A® (H1N1 vaccine) presented in vials for supply to the US market.

Some of the GMP violations observed during its routine inspection were released under US Regulations in an *Untitled Letter* dated 28 June 2010 available on the US FDA's Website at:

www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/Enforcement/UntitledLetters/ucm217293.htm.

The US FDA's website states that 'An Untitled Letter is an initial correspondence with regulated industry that cites violations that do not meet the threshold of regulatory significance for a Warning Letter'. The US FDA has subsequently accepted CSL's corrective actions and closed its inspection on 11 August 2010.

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h) No.