

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2011-2012, 19 October 2011

Question: E11-254

OUTCOME 1: Population Health

Topic: FOOD AND DRUG ADMINISTRATION (FDA) AUDIT

Written Question on Notice

Senator Xenophon asked:

Media reports in August and September this year stated that the FDA had expressed serious concerns about the faults in this audit.

- a) Was the TGA aware of these faults?
- b) What action did the TGA take?
- c) Why did it take reports from the FDA to bring attention to this issue?

Answer:

- a) Refer to answer for Question E11-255.
- b) Refer to answer for Question E11-255.
- c) As described in response E11-255 the issues identified by the FDA audit of CSL are of the same underlying type as ones identified by Therapeutic Goods Administration (TGA) but the specific examples reported by FDA have not previously been observed by TGA auditors.

The FDA has a system where it publishes details of its Warning Letters and Untitled Letters. TGA does not currently do this. When put into context of the large number of Warning Letters the FDA has published this year alone (nearly three hundred for products regulated by the TGA), it is evident that the Warning Letter to CSL is part of normal operational business for the FDA.