

Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2012-2013, 30 & 31 May and 1 June 2012

Question: E12-294

OUTCOME 1: Population Health

Topic: Therapeutic Goods Administration

Type of Question: Written Question on Notice

Number of pages: 1

Senator: Senator Fierravanti-Wells

Question:

What were the results of the TGA's most recent audit of CSL's production facilities?

Answer:

Commonwealth Serum Laboratories (CSL's) flu vaccine manufacturing facility was most recently inspected by the Therapeutic Goods Administration (TGA), in conjunction with the US Food and Drug Administration (FDA), from 16 – 24 April 2012. This inspection found that CSL's investigation of manufacturing deviations was inadequate. The same deficiency was identified in inspections by both the FDA and the TGA in 2011. The deficiency was rated critical because it was a repeated deficiency. At this stage, there is no evidence that product safety has been affected by CSL's inadequate investigations.

TGA reinspected the facility on 23 - 24 May 2012 to reaffirm progress in resolving deficiencies identified in the TGA April 2012 inspection. All manufactured product currently remains under quarantine pending satisfactory resolution of the issues.