CSL Biotherapies

# Press Release

**For immediate release**

September 29, 2011

## CSL Biotherapies Response to News Reports on FDA Inspections

CSL Biotherapies wishes to clarify that it has not received any new letters or warnings from the US Food and Drug Authority (FDA) or the Australian Therapeutic Goods Administration (TGA) concerning its compliance with current Good Manufacturing Practice (cGMP).

The Australian newspaper has today made reference to FDA inspection reports issued to CSL Biotherapies at the completion of scheduled inspections of its influenza vaccine manufacturing site in April 2010 and March 2011.

The FDA and the TGA conduct regular inspections of all manufacturers whose products they licence. These inspections are a normal part of the regulatory process and ensure companies continuously improve their compliance with cGMP.

Inspection reports – known as Form 483's – contain observations only and are not a final determination of a manufacturers' compliance with cGMP. The final determination of compliance is made after manufacturers have had the opportunity to respond to the observations and discuss them with the FDA.

The observations recorded during the inspection of CSL Biotherapies' influenza vaccine operations in April 2010 were addressed to the satisfaction of the FDA within that same year.

Many of the observations from the March 2011 inspection have also been satisfactorily addressed. Those requiring further attention were contained in the FDA Warning Letter issued to CSL Biotherapies in June 2011. This was covered extensively by the media at that time.

These remaining compliance issues are in the process of resolution and CSL Biotherapies is working closely with the FDA and the TGA to close-out the issues as agreed with the regulators.

Ongoing monitoring by CSL and regulatory agencies continues to support the safety profile of CSL's influenza vaccine in the recommended age groups. Our influenza vaccine is currently being distributed in the United States for the 2011/2012 influenza season as approved by the FDA.

CSL Biotherapies takes the safety and quality of its medicines very seriously and is fully committed to resolving all outstanding cGMP issues to the full satisfaction of the FDA and the TGA as quickly as possible.

***For more information about CSL Limited, visit www.csl.com.au***

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