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Press Release

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State responds to non-safety related recall of some 2009 H1N1 vaccine

Vaccine safety not in question, no need to re-immunize

(Anchorage, AK) — The Alaska Department of Health and Social Services is notifying providers who received pediatric H1N1 vaccine that was voluntarily recalled today by the manufacturer, Sanofi Pasteur.

According to the federal Centers for Disease Control and Prevention (CDC), Sanofi Pasteur discovered four lots of single-dose, prefilled-syringe pediatric (0.25 mL) vaccine for children ages 6 months–35 months with antigen content that had fallen slightly lower than the required potency levels. The federal Food and Drug Administration (FDA) and CDC are in agreement that the small decrease in antigen content is unlikely to result in a clinically significant reduction in immune response among persons who have received the vaccine.

The manufacturer is conducting a non-safety related voluntary recall of these identified lots of vaccine. Alaska received 1,900 doses of the vaccine from the identified lots and distributed them to medical providers statewide.

“There are no safety concerns with these recalled lots of 2009 H1N1 vaccine,” said Laurel Wood, immunization program manager for the state Division of Public Health. “Both the CDC and the Food and Drug Administration agree that the small decrease in antigen content found in these lots of vaccine is unlikely to have caused the vaccine to be ineffective. Parents of children who received vaccine from the recalled lots do not need to take any action, other than to complete the two-dose immunization series if not already completed. Remember, children age 9 and under are recommended to receive two doses of H1N1 vaccine.”

Wood added, “We’ll be contacting each provider who received this vaccine individually. In the meantime, we are asking providers who still have the vaccine on hand to set it aside until we hear from the CDC how they want to proceed. Most Alaska providers still have a comparable vaccine in multi-dose vials that is also safe and effective for use in children of this age.”

For more information, go to: www.pandemicflu.alaska.gov or call the Pan Flu Hotline at 1-888-9PANFLU.

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