



Mendocino County Health and Human Services Agency

Healthy People, Healthy Communities

Press Release

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FOR IMMEDIATE RELEASE

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H1N1 VACCINE RECALL

Ukiah - The Center for Disease Control (CDC) has declared a non-safety recall for the single dose injectable H1N1 vaccine designed for children 6 to 35 months, manufactured by Sanofi-Pasteur.

The problem is not a safety issue. As part of its quality assurance program, the manufacturer, Sanofi Pasteur, performs routine, ongoing stability testing of its influenza A (H1N1) vaccine after the vaccine has been shipped to providers. Stability testing means measuring the strength (also called potency) of a vaccine over time. It is performed because sometimes the strength of a vaccine can go down over time. On December 7, Sanofi Pasteur notified the CDC and Federal Drug Administration that the potency in one batch (called a "lot") of the vaccine in pediatric syringes that had been distributed was later found to have dropped below a pre-specified limit. As a result of this finding, Sanofi Pasteur tested additional lots and found that three other lots that had been distributed also had an antigen content that, while at the proper potency at the time of manufacturing, was later measured to be below pre-specified limits. This means that doses from these four vaccine lots no longer meet the manufacturer's specifications for potency.

The recall is for vaccine produced by Sanofi Pasteur only. Vaccine produced in other forms and by other manufacturers is not affected. Sanofi Pasteur is investigating to determine what caused the problem.

“Parents don’t need to be concerned about the safety of the vaccine,” said Dr. Marvin Trotter, Mendocino County Public Health Officer. “There is nothing harmful in the vaccine. It passed all tests for purity and safety prior to its release.”

In California, there are approximately 159 providers affected and 47,800 doses. “Community Health Services did not receive any of the recalled vaccine, but we are contacting local providers and asking if they have received any,” Commented Dr. Trotter.

Parents are reminded that children between 6 months and 9 years of age need two doses of H1N1 vaccine to be fully protected against the disease.

Parents whose children may have received vaccine from one of the recalled lots do not have to take any action, other than to complete the two dose immunization series if not already completed.

For more information and questions on the recall including lot numbers go to http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm

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