

DPHHS HAN

From: DPHHS HAN
Sent: Tuesday, December 15, 2009 1:37 PM
Subject: DPHHS HAN ADVISORY 2009-44: Non-Safety Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes
Attachments: CDC UPDATE _Non-Safety Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric Vaccine in Pre-Filled Syringes.pdf

State of Montana DPHHS HAN ADVISORY

Tuesday, December 15, 2009

Forwarding Instructions:

FORWARD at your discretion to your local HAN contacts

DPHHS Information / Recommendations:

DPHHS is forwarding the attached CDC HAN concerning a H1N1 vaccine recall. The recall is based on a concern that the vaccine may not have a high enough antigen content to provide protection. This is NOT a safety recall.

Sanofi Pasteur found four distributed lots of single dose, pre-filled syringe pediatric (0.25mL.) vaccine with antigen content lower than required potency levels. The manufacturer is conducting a non-safety related voluntary recall of these affected lots. While the antigen content of these lots is now below the specification limit for the product, CDC and FDA 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. For this reason, **there is no need to revaccinate persons who have received vaccine from these lots.**

According to shipping logs, it appears that Montana has only received a 1,000 doses of the effected Sanofi Pasteur vaccine lot number UT030CA . Lot number UT030CA was a direct shipment to four counties during the week of 11/30/09. These counties have been notified by phone this morning and all vaccine from this lot number is accounted for and none had been administered.

Below are the lot numbers effected by this recall. Sanofi Pasteur has discontinued distribution of the 0.25mL. syringes of the H1N1 pediatric vaccine. Sanofi Pasteur will be sending out directions for returning unused vaccine from these lots. Although we do not have a record of receiving any other vaccine from the recalled lots, we are requesting that each jurisdiction review their stock for the following lot numbers: UT028DA, UT028CB, UT030CA, UT023DA.

If you are in possession of any of the recalled lots contact the Immunization Program at 444-5580.

DPHHS Subject Matter Expert (SME) Contact:

For more information contact the DPHHS Immunization Program at (406) 444-5580

Distributed by the Department of Public Health and Human Services Health Alert Network (HAN) System

DPHHS Health Alert Hotline: 1-800-701-5769

DPHHS HAN Website: www.han.mt.gov

You have received this message based upon the information contained within our emergency notification data base. If you have a different e-mail or fax address that you would like us to use please notify us as soon as possible by e-mail at hhshan@mt.gov.

The goal of Montana's Health Alert Network is to transmit information to local public health authorities as quickly as possible, and assign a suitable priority to the message. For questions or comments about Montana's HAN system you may contact the DPHHS HAN Coordinator, Gerry Wheat at gwheat@mt.gov.

Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

Subject: Non-Safety Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes

**This is an official
CDC Health Update**

Distributed via Health Alert Network
December 15, 2009, 10:04 EST (10:04 AM EST)
CDCHAN-00303-09-12-15-ADV-N

Non-Safety Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes

Summary: As part of its quality assurance program, Sanofi Pasteur, Inc., performs additional routine, ongoing testing of influenza vaccines after the vaccine has been distributed to health care providers to ensure that vaccines continue to meet required specifications. In recent testing of the amount of antigen in its influenza A (H1N1) monovalent vaccine, Sanofi Pasteur found four distributed lots of single-dose, pre-filled syringe pediatric (0.25 mL) vaccine with antigen content lower than required potency levels. The manufacturer is conducting a non-safety related voluntary recall of these affected lots of vaccine.

Background

After performing these tests, Sanofi Pasteur notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that the antigen content in one lot of pediatric syringes that had been distributed to providers 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 had fallen below pre-specified limits. This means that doses from these four vaccine lots no longer meet the specifications for antigen content.

Recommendations

While the antigen content of these lots is now below the specification limit for the product, CDC and FDA 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. For this reason, there is no need to revaccinate persons who have received vaccine from these lots.

Providers are being asked to return any vaccine to the manufacturer in the following lots that remains unused to the manufacturer:

- 0.25 mL pre-filled syringes, 10-packs (NDC # 49281-650-25, sometimes coded as 49281-0650-25):
UT023DA
UT028DA
UT028CB
- 0.25 mL pre-filled syringes, 25-packs (NDC # 49281-650-70, sometimes coded as 49281-0650-70):
UT030CA

These lots were shipped in November and are intended for children 6 months through 35 months of age. Sanofi Pasteur will send directions for returning unused vaccine from these lots to providers.

All vaccines are thoroughly tested prior to release and shipping to determine that they meet all manufacturer and FDA standards for purity, potency and safety. The affected vaccine met all specifications at the time of release. CDC and FDA have determined that there are no safety concerns for children who have received this vaccine. Sanofi Pasteur has discontinued distribution of the 0.25 mL syringes of H1N1 pediatric vaccines.

The drop in antigen content below the required specification that is described here is specific to Sanofi Pasteur's pediatric H1N1 monovalent vaccine in 0.25 mL pre-filled syringes. The same vaccine packaged in other forms, such as 0.5 mL pre-filled syringes for older children and adults and multi-dose vials, continue to meet specifications.

The antigen content in the affected lots of vaccine is only slightly below the specification limit. The slightly reduced concentration of vaccine antigen found in retesting these lots is still expected to be effective in stimulating a protective response. There is no need to re-administer a dose to those who received vaccine from these lots. However, as is recommended for all 2009 H1N1 vaccines, all children less than 10 years old should get the recommended two doses of H1N1 vaccine approximately a month apart for the optimal immune response. So, children less than 10 years old who have only received one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.

For children 6 months of age and older, vaccine is available in multidose vials. The vaccine in multidose vials is safe and effective vaccine for children. One difference between vaccine in pre-filled syringes and the multidose vials is that the multidose vials contain a preservative (thimerosal) to prevent potential contamination after the vial is opened. The standard dose for this preparation for administration to infants 6-35 months old is the same as for the pre-filled syringes, 0.25 mL. For healthy children at least 2 years of age, the nasal spray (live, attenuated influenza vaccine) is also an option. The nasal spray vaccine is produced in single units that do not contain thimerosal.

For More Information:

- For Questions and Answers related to the withdrawn vaccine see http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm
- Call CDC's toll-free information line, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, which is available 24 hours a day, every day.

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##This Message was distributed to **State and Local Health Officers, Public Information Officers, Epidemiologists and HAN Coordinators as well as Clinician organizations##**

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You have received this message based upon the information contained within our emergency notification data base. If you have a different or additional e-mail or fax address that you would like us to use please contact your State-based Health Alert Network program at your State or local health department.
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