

DPHHS HAN

From: DPHHS HAN
Sent: Monday, February 01, 2010 10:40 AM
Subject: DPHHS HAN ADVISORY: 2010-6 Non-Safety-Related Voluntary Recall of Unused Doses from Certain Lots of Sanofi Pasteur H1N1 Vaccine in Pre-Filled Syringes
Attachments: HAN_Health_Update_Sanofi_Recall_2010_01_29.pdf; Ltr_to_Pediatrician_Orgs_2010_01_26.pdf

State of Montana DPHHS HAN ADVISORY

Forwarding Instructions:
FORWARD to your local HAN contacts

DPHHS Information / Recommendations:

Non-Safety-Related Voluntary Recall of Unused Doses from Certain Lots of Sanofi Pasteur H1N1 Vaccine in Pre-Filled Syringes

After performing routine tests, Sanofi Pasteur notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that the potency in five lots of pediatric pre-filled syringes and one lot of adult pre-filled syringes that had been distributed to providers was later found to have dropped below a pre-specified limit.

In recent testing of its influenza A (H1N1) monovalent vaccine, Sanofi Pasteur found five distributed lots of single-dose, pre-filled syringe pediatric (0.25 mL) vaccine and one distributed lot of single-dose pre-filled syringe for older children and adults (0.5 mL) vaccine had potency below pre-specified limits. The manufacturer is conducting a non-safety related voluntary recall of any unused doses of these affected lots of vaccine. Information will be sent by Sanofi Pasteur to providers who received vaccine from the affected lots.

The following recalled lots were shipped to Montana providers:

UT023AA (shipped October 29, 2009), UT023BA (shipped November 5 and 9, 2009) and UT037AA (shipped January 4, 2010).

Please note that this is a non-safety related recall, and those who received the vaccine do not need to be re-vaccinated.

All unused vaccine should be removed from inventory, reported and returned to the DPHHS Immunization Program. Please call (406) 444-0277 for additional instructions related to returning unused vaccine.

For Your Information

Please find attached a letter from the Director of the CDC encouraging health care providers to continue encouraging vaccination in children.

DPHHS Subject Matter Expert (SME) Contact:
Immunization Section – (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.

This is an official **CDC HEALTH UPDATE**

Distributed via Health Alert Network

Friday, January 29, 2010

Non-Safety-Related Voluntary Recall of Unused Doses from Certain Lots of Sanofi Pasteur H1N1 Vaccine in Pre-Filled Syringes

Summary: As part of its quality assurance program, Sanofi Pasteur, Inc., performs routine, ongoing testing of influenza vaccines after the vaccine has been distributed to health care providers to ensure that the vaccine continues to meet required specifications. In recent testing of its influenza A (H1N1) monovalent vaccine, Sanofi Pasteur found five distributed lots of single-dose, pre-filled syringe pediatric (0.25 mL) vaccine and one distributed lot of single-dose pre-filled syringe for older children and adults (0.5 mL) vaccine had potency below pre-specified limits. The manufacturer is conducting a non-safety related voluntary recall of any unused doses of these affected lots of vaccine. Information will be sent by Sanofi Pasteur to providers who received vaccine from the affected lots.

Background

After performing routine tests, Sanofi Pasteur notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that the potency in five lots of pediatric pre-filled syringes and one lot of adult pre-filled syringes that had been distributed to providers was later found to have dropped below a pre-specified limit.

Recommendations

While the potency of these lots is now below the manufacturer's specification 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 will be asked to return any unused vaccine from the affected lots to the manufacturer. The only vaccine affected by this recall is supplied in pre-filled syringes and is identified by the following lot numbers:

UT023AA, UT023BA, UT023CA, UT023EA, UT023FA

(NDC # 49281-650-25, which also may be recorded as # 49281-0650-25), 0.25 mL syringes in 10-packs

UT037AA

(NDC # 49281-650-90, which also may be recorded as # 49281-0650-90), 0.5 mL syringes in 25-packs

These lots were shipped to providers between November 2009 and January 2010. Sanofi Pasteur will send directions for returning unused vaccine from these lots to providers.

All vaccines are thoroughly tested prior to release and shipping for safety, purity, and potency. The affected lots met all required specifications at the time of release. CDC and FDA have determined that there are no safety concerns for people who have received these vaccines.

The potency of the affected lots of vaccine is only slightly below the specification limit. Vaccine doses from these lots are 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.

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. 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.

Sanofi Pasteur has informed the CDC that it will be submitting a field correction to the FDA to request a change for the expiration date of the company's remaining pediatric and adult pre-filled syringes. CDC will share additional information as soon as it is available.

For More Information:

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##

You have received this message based upon the information contained within our emergency notification database. 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



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 26, 2010

Dear Colleague:

As we begin this New Year, I wish to recognize your dedication in promoting the safety of our nation's children by vaccinating them against the 2009 H1N1 influenza, and remind you that children from 6 months through 9 years of age need 2 doses of the vaccine against the 2009 H1N1 influenza to be fully protected.

As medical providers, we understand that children can develop severe complications from influenza infection. Since April 26, 2009, the Centers for Disease Control and Prevention (CDC) has received over 250 reports of laboratory-confirmed influenza-associated deaths among children caused by the 2009 H1N1 flu in the United States, and CDC estimates that over 1,100 deaths among children have probably occurred. Furthermore, children younger than 5 years old have higher rates of hospitalization caused by the 2009 H1N1 influenza than any other age group, and school age children have the highest rates of infection.

Vaccination is the best form of prevention against complications of influenza. Studies indicate that a second (booster) dose given 28 or more days after the first dose is needed to achieve optimal protection in children from 6 months through 9 years old.

The vaccine against the 2009 H1N1 influenza is made the same way as seasonal flu vaccines. CDC and the Food and Drug Administration, working with health care providers and state and local officials, are closely monitoring vaccine safety. Evidence from tens of millions of vaccinations indicates that the safety profile is similar to that of seasonal influenza vaccines, which have a very good safety track record. Side effects reported have been mild and brief, and similar to those experienced following seasonal flu vaccine. These include soreness, redness, or swelling at the injection site, fainting (mainly adolescents), headache, muscle aches, fever, and nausea.

Your support during this 2009-2010 flu season has been instrumental to the success of this unprecedented national vaccination program. We now have plenty of vaccine for every child who needs that second dose, as well as for children who have not yet been vaccinated. Please remind parents and caregivers that children from 6 months through 9 years of age require both doses of the vaccine against the 2009 H1N1 influenza.

I look forward to continuing the partnership with you and your professional medical organizations, and ensuring that children's health remains a top priority of CDC.

Sincerely,

Thomas R. Frieden, M.D., M.P.H.
Director, CDC, and
Administrator, Agency for Toxic
Substances and Disease Registry