

New York State Department of Health

Notice of Voluntary Recall of Influenza A (H1N1) 2009 Monovalent Vaccine

The U.S. Centers for Disease Control and Prevention have announced a **Non-safety Related Voluntary Recall** of the Sanofi Pasteur H1N1 Pediatric (0.25mL, for 6-35 month olds) vaccine in pre-filled syringes.

If you have any questions regarding the information below, please contact the New York State Department of Health H1N1 Hotline at 1-800-KID-SHOT (1-800-543-7468).

Summary

It is important to note the following key points about this recall:

- There are **NO safety concerns** with these recalled lots of 2009 H1N1 vaccine. All lots have successfully passed pre-release testing for purity, potency, and safety.
- Only specified lots of the 2009 H1N1 pediatric vaccine for children 6-35 months in pre-filled syringes are affected
- There is **NO NEED TO RE-ADMINISTER A DOSE** to those who received vaccine from these lots. The vaccine potency is only slightly below the “specified range”. The vaccine in these lots is still expected to be effective in stimulating a protective response despite this slight reduction in the concentration of antigen
- 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. Therefore, children under 10 years old who have only received one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.
- 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.
- When possible, children should receive both doses of 2009 H1N1 vaccine from the same type of vaccine (i.e., both doses as inactivated, injectable; or both doses as live, attenuated, nasal spray vaccine). However, providers should not wait to give the second dose and different products can be used.
- All vaccines are routinely tested for purity, potency, and safety prior to release. The four lots of vaccine meet all the required specification at the time of release and shipment to distribution centers. The vaccine provided in multi-dose vials and the single-dose, 0.5mL pre-filled syringes for persons 36 months and older continues to meet all specifications.

Affected Lot Numbers

Lot Number	Expiration Date	NDC#
UT023DA	4/30/2011	49281-650-25 (which also may be recorded as NDC # 49281-0650-25)
UT028CB	4/9/2011	49281-650-25 (which also may be recorded as NDC # 49281-0650-25)
UT028DA	4/9/2011	49281-650-25 (which also may be recorded as NDC # 49281-0650-25)
UT030CA	3/30/2011	49281-650-70 (which also may be recorded as NDC # 49281-0650-70)

Action Required

1. Examine your inventory to determine if you have any remaining stock of the recalled lots.
2. Please stop using the lot numbers immediately and set them aside to prevent the inadvertent administration of these lot numbers.
3. Follow the applicable instructions below to coordinate the return of the vaccine.
4. If necessary, please contact the New York State Department of Health H1N1 Hotline at 1-800-KID-SHOT (1-800-543-7468) to place an order for replacement vaccine. **PLEASE ENSURE THAT YOU ADVISE THE CALL TAKER THAT THIS IS REPLACEMENT VACCINE FOR USE DUE TO THE RECALL.**

Instructions on How to Return Your Vaccine

If you received your vaccine **DIRECTLY FROM McKESSON:**

1. Within the next few days Sanofi Pasteur will be sending you a Business Reply Card along with other material.
2. Please complete the Business Reply Card and send back the material per the enclosed instructions using the supplied postage material.
3. Contact the New York State Department of Health H1N1 Hotline at 1-800-KID-SHOT (1-800-543-7468) to place an order for replacement vaccine. **PLEASE ENSURE THAT YOU ADVISE THE CALL TAKER THAT THIS IS REPLACEMENT VACCINE FOR USE DUE TO THE RECALL.**

If you received your vaccine **THROUGH A REDISTRUBUTION (THROUGH THE LOCAL HEALTH DEPARTMENT OF ANOTHER PROVIDER):**

1. Please contact Sanofi Pasteur at 1-888-241-9288 and they will provide you with the material discussed above. Additional assistance can be obtained through Sanofi Pasteur Customer Services at 1-800-VACCINE (1-800-822-2463).
2. Please complete the Business Reply Card and send back the material per the enclosed instructions using the supplied postage material.
3. Contact the New York State Department of Health H1N1 Hotline at 1-800-KID-SHOT (1-800-543-7468) to place an order for replacement vaccine. **PLEASE ENSURE THAT YOU ADVISE THE CALL TAKER THAT THIS IS REPLACEMENT VACCINE FOR USE DUE TO THE RECALL.**

The detailed recall notice can be found at the end of this document or at the following link:

<http://www.health.state.ny.us/diseases/communicable/influenza/h1n1/>

**IMPORTANT INFORMATION REGARDING FOUR LOTS OF SANOFI PASTEUR'S
PEDIATRIC INFLUENZA A (H1N1) 2009 MONOVALENT VACCINE**

December 16, 2009

Dear Health-care Professional:

Sanofi Pasteur, Inc. has notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that routine testing of its pediatric Influenza A (H1N1) 2009 Monovalent Vaccine in 0.25mL syringes has identified four distributed lots with lower antigen content than the specification limit.

The FDA and the CDC have determined that **there are no safety concerns** with any of these lots.

The CDC first notified grantees last Friday that one lot was impacted. We now know the following four lots are impacted:

UT023DA, UT028CB, UT028DA (NDC # 49281-650-25, which also may be recorded as NDC # 49281-0650-25), 0.25mL syringes in 10 packs.

UT030CA (NDC # 49281-650-70, which also may be recorded as NDC # 49281-0650-70), 0.25mL syringes in 25 packs.

These lots were shipped in November and are intended for children 6 through 35 months of age.

If you have unused doses from these lots, you should return them as outlined in the attached instructions.

The FDA and the CDC do not recommend repeating any doses that children received from these lots. This is because the drop in antigen content is unlikely to result in a clinically significant reduction in immune response. Children who have received one dose should receive the recommended second dose of Influenza A (H1N1) 2009 Monovalent Vaccine.

We appreciate your attention to this matter.

Sincerely,



Michael D. Decker, MD, MPH
Vice President, Scientific & Medical Affairs and Chief Medical Officer

MKT19022

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 Questions & Answers

December 15, 2009, 9:00 AM ET

Why are some lots of pediatric H1N1 vaccine manufactured by Sanofi Pasteur in pre-filled syringes being recalled from the market?

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 CDC and FDA that the potency in one batch (called a “lot”) of 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 properly filled 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. Sanofi Pasteur will send providers directions for returning any unused vaccine from these lots.

What does potency mean for the H1N1 vaccine?

Potency (or strength) is determined by the measurement of the concentration of the active ingredient (also called antigen) in the H1N1 vaccine.

Are there any concerns about safety of vaccines from these lots?

No. There are no safety concerns with these lots of H1N1 vaccine. All lots successfully passed pre-release testing for purity, potency and safety.

Should infants and children who received vaccines from these lots be revaccinated?

No. The vaccine potency is only slightly below the “specified” range. The vaccine in these lots is still expected to be effective in stimulating a protective response despite this slight reduction in the concentration of antigen. 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. Therefore, 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.

What action(s) should parents of children who have received vaccine from the recalled lots take?

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.

What are the lot numbers affected by this recall?

Vaccine doses with the following lot numbers are included in the recall:

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

How many doses of the pediatric H1N1 vaccine are affected by this recall?

Approximately 800,000 doses of vaccine in these lots were distributed to providers.

Is the potency issue related to this recall isolated to just the pediatric H1N1 vaccine for 6-35 month olds?

The potency problem described here is specific to the four lots of Sanofi Pasteur's pediatric H1N1 vaccine in 0.25 mL pre-filled syringes. Sanofi Pasteur is investigating what caused the problem. The same vaccine packaged in other dosing forms, such as pre-filled syringes for older children adults, and multi-dose vials, continues to meet specifications. This recall does not affect H1N1 vaccine produced by other manufacturers.

Were these lots of vaccine shipped after failing a required test?

No. The lots being recalled passed all quality controls and met all specifications before they were shipped.

All vaccines are routinely tested for purity, potency and safety prior to release. The four lots of vaccine met all required specifications at the time of release and shipment to distribution centers. The vaccine provided in multi-dose vials and

the single-dose, 0.5 mL pre-filled syringes for persons 36 months and older continues to meet all specifications.

What is being done to notify providers who received vaccine from the affected lots?

Sanofi Pasteur will send a notification to providers who received doses from any of the four lots of vaccine so that they can return any unused vaccine.

Where were the affected lots of vaccine distributed?

Vaccine from these four lots was distributed throughout the United States.

For U.S. children 6-35 months old, what other options are available currently for vaccination against H1N1 influenza?

For children 6 months of age and older, vaccine is available in multidose vials. The vaccine in multidose vials has not experienced this drop in potency and meets all standards of safety, purity and potency. As with all multidose vials of vaccines, these multidose vials contain a preservative (thimerosal) to prevent potential contamination after the vial is opened. The standard dose for this preparation in the 6-35 month age group 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. This vaccine is produced in single-units that do not contain thimerosal.