

New York State Department of Health

**Notice of Voluntary Non-Safety Related Recall of Influenza A (H1N1) 2009 Monovalent Vaccine**  
**(2/1/10)**

The U.S. Centers for Disease Control and Prevention have announced a **Non-safety Related Voluntary Recall** of certain lots of H1N1 Vaccine. Sanofi Pasteur found five distributed lots of single-dose, pre-filled syringe pediatric (0.25mL) vaccine and one distributed lot of single-dose pre-filled syringe for older children and adults (0.5mL) vaccine that had potency below pre-specified limits.

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 vaccine 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.
- 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).
- All vaccines are routinely tested for purity, potency, and safety prior to release. These lots of vaccine meet all the required specification at the time of release and shipment to distribution centers.

**Affected Lot Numbers**

<b>Lot Number</b>	<b>NDC#</b>	<b>Description</b>
UT023AA	49281-650-25 (which also may be recorded as NDC # 49281-0650-25)	0.25mL syringes in 10-packs
UT023BA	49281-650-25 (which also may be recorded as NDC # 49281-0650-25)	0.25mL syringes in 10-packs
UT023CA	49281-650-25 (which also may be recorded as NDC # 49281-0650-25)	0.25mL syringes in 10-packs
UT023EA	49281-650-25 (which also may be recorded as NDC # 49281-0650-25)	0.25mL syringes in 10-packs
UT023FA	49281-650-25 (which also may be recorded as NDC # 49281-0650-25)	0.25mL syringes in 10-packs
UT037AA	49281-650-90 (which also may be recorded as NDC # 49281-0650-90)	0.5mL syringes in 25-packs

### **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/>

# This is an official **CDC HEALTH UPDATE**

Distributed via Health Alert Network

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## **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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**Categories of Health Alert Messages:**

<b>Health Alert</b>	Conveys the highest level of importance; warrants immediate action or attention.
<b>Health Advisory</b>	Provides important information for a specific incident or situation; may not require immediate action.
<b>Health Update</b>	Provides updated information regarding an incident or situation; unlikely to require immediate action.

##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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