

DPHHS HAN

From: DPHHS HAN
Sent: Wednesday, December 23, 2009 10:02 AM
Subject: DPHHS HAN ADVISORY 2009-45: MedImmune Monovalent 2009 (H1N1) Influenza Nasal Spray Vaccine - Shortened Shelf Life of Certain Lots
Attachments: MedImmune Monovalent 2009 H1N1 Influenza Nasal Spray Vaccine - Shortened Shelf Life of Certain Lots.pdf

State of Montana DPHHS HAN ADVISORY

Wednesday, December 23, 2009

Forwarding Instructions:

FORWARD at your discretion to your local HAN contacts

DPHHS Information / Recommendations:

MedImmune Monovalent 2009 (H1N1) Influenza Nasal Spray Vaccine — Shortened Shelf Life of Certain Lots

MedImmune has announced a limited, voluntary, **non-safety**-related recall of remaining unused Monovalent 2009 (H1N1) Influenza Nasal Spray Vaccine of certain lots.

MedImmune has notified CDC and FDA that the potency of 13 lots of 2009 H1N1 nasal spray influenza vaccine were at risk of falling below an acceptable potency level. This slight decrease in potency is not expected to have an impact on the protective response to vaccination. There is no safety concern.

We have determined that only three of the 13 lots were distributed to Montana. These doses were shipped in October and early November. It is believed that most doses were fully potent at the time of administration.

The lots of MedImmune H1N1 nasal spray shipped to Montana were identified as 500756P, 500759P, and 500763P. These lots have an expiration date of 01/25/2010. If you have any of these lots remaining in your inventory, do not administer any more doses of this vaccine, and **remove them from your vaccine refrigerator**. MedImmune will send providers instructions for returning any remaining lots.

People who received vaccine from the recalled lots **do not** need to be revaccinated.

This recall is different than the recalled lots from Sanofi Pasteur earlier this month.

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: MedImmune Monovalent 2009 H1N1 Influenza Nasal Spray Vaccine - Shortened Shelf Life of Certain Lots

This is an official
CDC Health Update

Distributed via Health Alert Network
December 23, 2009, 9:20 EST (9:20 AM EST)
CDCHAN-00304-09-12-23-ADV-N

MedImmune Monovalent 2009 (H1N1) Influenza Nasal Spray Vaccine — Shortened Shelf Life of Certain Lots

MedImmune announces limited, voluntary, non-safety-related recall of remaining unused product

Summary

On December 18 and 21, MedImmune notified CDC and FDA that the potency of 13 lots of monovalent 2009 (H1N1) nasal spray vaccine had decreased below a pre-specified limit or were at risk of falling below that limit in the next week. This slight decrease in vaccine potency is not expected to have an impact on the protective response to vaccination. There are no safety concerns with these lots of 2009 H1N1 vaccine. All lots successfully passed pre-release testing for purity, potency and safety. However, because their potency is now or might soon be below the specified lower limit, MedImmune will send providers directions for returning any unused vaccine from these lots.

Recommendations

The potency of these lots is now or might soon be slightly below the specified range for the product. CDC and FDA are in agreement that the slight decrease in vaccine potency is not expected to have an impact on the protective response to vaccination. For this reason, there is no need to revaccinate persons who have received vaccine from these lots.

People who received vaccine from the recalled lots do not need to take any action. Children and adults aged 10 years and older who received the vaccine do not need any further doses of vaccine. As is recommended for all 2009 H1N1 vaccines, all children younger than 10 years old should get the recommended two doses of 2009 H1N1 vaccine approximately a month apart. Therefore, children younger than 10 years old who have only received one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine. It is best to use the same type of vaccine for the first and second doses.

Background

As part of its quality assurance program, the manufacturer of the nasal spray 2009 H1N1 influenza vaccine, MedImmune, performs routine, ongoing stability testing of the vaccine after it has been shipped to providers. Stability testing means measuring the strength of a vaccine over time.

The 13 lots subject to the recall include approximately 4.7 million doses. These doses were shipped to CDC's contract distributor in October and early November. **Most of the doses are believed to have already been administered while fully potent and within specifications.** However, there are almost certainly some doses that have not yet been used.

The potency issue described here is specific to the 13 lots of nasal spray 2009 H1N1 influenza vaccine listed below. Subsequent lots of the vaccine were produced with a slightly higher initial potency to decrease the chance that the potency would fall "below specification" before their expiration dates. Following its routine practice, the manufacturer will continue to monitor the stability of these subsequent lots.

This recall does not affect 2009 H1N1 vaccine produced by other manufacturers. However, a similar recall was conducted recently, which involved lots from Sanofi Pasteur's pediatric 2009 H1N1 vaccine in 0.25 mL pre-filled syringes. (See

<http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00303>)

Before they were shipped, the lots currently being recalled passed all quality controls and met all specifications for safety, purity, and potency.

MedImmune will send a notification to providers who received doses from any of the 13 lots of vaccine so that they can return any unused vaccine.

Lot Information

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

- 500754P
- 500751P
- 500756P
- 500757P
- 500758P
- 500759P
- 500760P
- 500761P
- 500762P
- 500763P
- 500764P
- 500765P
- 500776P

For More Information:

- For information about the recalled vaccine, see http://www.cdc.gov/h1n1flu/vaccination/sprayrecall_ga.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.
- For manufacturer's information about the recall, see http://www.medimmune.com/pdf/H1N1_Recall_QandA_122209.pdf
- For manufacturer's instructions to providers on actions to be taken, see http://www.medimmune.com/pdf/H1N1_Recall_letter_122209.pdf

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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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