

From: Health Alert Network (CDC)
Sent: Wednesday, December 23, 2009 10:05 AM
To: Haugen, Valerie A. (CMS/CMM)
Subject: MedImmune Monovalent 2009 (H1N1) Influenza Nasal Spray Vaccine - Shortened Shelf Life of Certain Lots

 Department of Health and Human Services Centers for Disease Control and Prevention	
This is a message from the HAN	
Alert Id:	CDCHAN-000304-2009-12-23-UPD-N
Alert Title	MedImmune Monovalent 2009 (H1N1) Influenza Nasal Spray Vaccine - Shortened Shelf Life of Certain Lots
Program type	UPDATE
Status Type	Actual
Severity	Unknown
Acknowledgement Required?	YES
Sensitive?	NO
Message Expiration	UNDETERMINED
Urgency	The Urgency is not known.
Delivery Time	Within 15 Minutes

The text of the message follows:

This is an official
CDC Health Update

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 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

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.

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