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Public Information Release

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MEDIMMUNE FLU MIST RECALL

December 23, 2009

Today, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) announce that they were notified by Medimmune, the makers of the H1N1 FluMist, of a slight decrease in potency of certain lots of the FluMist vaccine. The Miami County Health District checked its records and found out that it received and used 800 doses of the vaccine. The doses were received on October 14, 2009, and were all used by November 8, 2009.

Medimmune periodically tests its vaccine in storage to see if it has lost potency. In recent tests, some of its stored vaccine was approaching its predetermined potency level, or was approaching that level. This involves vaccine that in storage. Most of the lots of vaccine have already been given and if so, were fully potent. The purpose of the recall is to have local doctor's offices and public health agencies look into their current inventory and return any of the affected vaccines that are still in storage.

At the Miami County Health District, it is our practice to use vaccines first that expire first. We use no expired vaccine. All of the doses of this particular vaccine were administered by November 8th. Therefore, nobody needs to be revaccinated and they should be fully protected. We have no leftover vaccine in storage, so there is nothing to return to the manufacturer.

Specifically, this particular lot of FluMist was given to health care workers on October 26th, and to priority individuals on November 2nd and November 8th.

There is no issue of safety. The issue was potency of the vaccine that was in storage. To summarize, people who already received the vaccine are fully protected and do not need to be revaccinated.

For a full list of questions and answers, please see the attachment.

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VOLUNTARY NON-SAFETY-RELATED RECALL OF SPECIFIC LOTS OF NASAL SPRAY VACCINE FOR 2009 H1N1 INFLUENZA

Questions and Answers

Why are some lots of the nasal spray 2009 H1N1 flu vaccine being recalled from the market?

As part of its quality assurance program, the manufacturer of the nasal spray monovalent 2009 H1N1 flu vaccine, MedImmune, performs routine, ongoing stability testing of the vaccine. Stability testing means measuring the strength (also called potency) of the vaccine over time to make sure it does not go below a pre-specified limit during the vaccine's "shelf life". On December 18 and 21, the manufacturer notified CDC and FDA that the potency in 13 batches (called "lots") of nasal spray vaccine had decreased below the pre-specified limit or were at risk of falling below that limit within the upcoming week. The vaccine was within the specified range at the time the vaccine was distributed. The slight decrease in potency should not affect how the vaccine works. However, the manufacturer will send providers directions for returning any unused vaccine from these lots.

What does potency mean for the nasal spray 2009 H1N1 vaccine?

Potency (or strength) is determined by the measurement of the concentration of the active component in the 2009 H1N1 vaccine.

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

No. There are no safety concerns with these lots of 2009 H1N1 vaccine. All lots successfully passed pre-release testing for safety, purity and potency.

Should people who received vaccines from these lots be revaccinated?

No. The vaccine potency is or will soon be only slightly below the limit. In addition, much of this vaccine has already been administered while fully potent and within specifications. The vaccine in these lots is 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.

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

Persons who received vaccine from the recalled lots do not need to take any special actions. 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 for the optimal immune response. Therefore, children younger than 10 years old who have only received one dose of the nasal spray 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 dose.



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What are the affected lot numbers?

The affected lot numbers are:

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

How many doses are in these lots?

There were approximately 4.7 million doses in these lots that were distributed to providers. Most of the doses were shipped to vaccine providers in October and early November, during a time when the vaccine potency was still at or above the recommended level. The manufacturer is recalling any doses from these lots that may still be unused.

Is the potency issue related to this recall isolated to just the 13 lots of nasal spray vaccine?

The voluntary recall described here is specific to the 13 lots of nasal spray 2009 H1N1 flu vaccine noted above. Subsequent lots of the vaccine were produced with a slightly higher potency to decrease the chance that they would fall "below specification" before their expiration dates. As per their routine practice, the manufacturer will continue to monitor the potency of those lots, and will notify healthcare providers if the shelf life of any additional lots is shorter than expected.

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

What testing was performed on these lots of vaccine before they were released?

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

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

The manufacturer 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.

Where were the affected lots of vaccine distributed?

Vaccine from these 13 lots was distributed throughout the United States.