

## Health Update:

### 2009 H1N1 Influenza Update 17: Non-Safety-Related Recall of Specific Lots of H1N1 Influenza Nasal Spray Vaccine

December 23, 2009

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**Health Alerts** convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies or the public.

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**Health Guidances** contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

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Health Update  
December 23, 2009

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DIRECTOR

**SUBJECT:** 2009 H1N1 Influenza Update 17: Non-Safety-Related Recall of Specific Lots of H1N1 Influenza Nasal Spray Vaccine

On December 23, 2009, the Centers for Disease Control and Prevention (CDC) issued the following Health Update.

#### 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\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/sprayrecall_qa.htm).

Call CDC’s toll-free information line, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, available 24/7.

For manufacturer’s information about the recall, see

[http://www.medimmune.com/pdf/H1N1\\_Recall\\_QandA\\_122209.pdf](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](http://www.medimmune.com/pdf/H1N1_Recall_letter_122209.pdf)

Links to comprehensive information and guidance for medical professionals on 2009 H1N1 influenza are available at [http://www.dhss.mo.gov/BT\\_Response/MedProfs.html](http://www.dhss.mo.gov/BT_Response/MedProfs.html). Links to comprehensive information and guidance on seasonal influenza are found at <http://www.dhss.mo.gov/PandemicInfluenza/MedSeasonalFlu.html>.

Missourians, including Missouri medical professionals, now have access to a toll-free H1N1 influenza information line. Named the **H1N1 InfoLine**, and sponsored by DHSS, it can provide information and guidance on 2009 H1N1 influenza and H1N1 vaccine to both the public and medical providers. This service is available 24 hours a day, seven days a week at 1-877-FLU-4141 (1-877-358-4141).

