

**Blastfax**

**MedImmune Announces Limited, Voluntary, Non-safety-related Recall of Certain Lots of Unused 2009 H1N1 Product - Shortened Shelf Life**

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.

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.

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.

**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

A total of 330 providers in Georgia received 140,600 affected doses via direct shipment. Each of the providers receiving the affected doses is being contacted by phone by Georgia Immunization Program staff. A message is also being posted on the GRITS announcement page.

Also for reference, a "Question and Answer" document is accessible at the following link:

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

Providers who have received H1N1 vaccine from the lots in question directly from McKesson will receive a packet with instructions from MedImmune. The provider letter from MedImmune is also accessible at the following link:

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

- 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).
- Also you can 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](http://www.medimmune.com/pdf/H1N1_Recall_QandA_122209.pdf)

For questions or concerns regarding this blastfax or any other immunization information, please contact the Chapter's Immunization Coordinator, Mike Chaney at (404) 881-5094 or [mchaney@gaaap.org](mailto:mchaney@gaaap.org).