

Q & A ABOUT THE RECENT 2009 H1N1 VACCINE RECALL
As of December 16, 2009

Background:

Sanofi Pasteur, Inc. has notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that routine testing of its pediatric Influenza A (H1N1)2009 Monovalent Vaccine in 0.25mL syringes has identified four distributed lots with lower antigen content than the specification limit. These lots were shipped in November and are intended for children 6 through 35 months of age. Providers are being asked to return any vaccine that remains unused to the manufacturer from the specified lots

➤ **How do we know this vaccine is safe?**

There are no safety concerns with these recalled lots of 2009 H1N1 vaccine. All lots successfully passed pre-release testing for purity, potency and safety. The FDA and the CDC have determined that there are no safety concerns with any of these lots.

➤ **Which vaccine is affected?**

Only specified lots of the 2009 H1N1 pediatric vaccine for children 6-35 months in pre-filled syringes are affected.

➤ **How do we know the other types of vaccines are good and should not be recalled?**

All vaccines are routinely tested for purity, potency and safety prior to release. The four lots of vaccine met all required specifications at the time of release and shipment to distribution centers. The vaccine provided in multi-dose vials and the single-dose, 0.5 mL pre-filled syringes for persons 36 months and older continues to meet all specifications.

➤ **Did Dutchess County receive such vaccine? Did we give these vaccines out?**

Dutchess County Department of Health (DCDOH) did receive some of this vaccine; DCDOH did not redistribute any of these vaccines to local area providers. DCDOH has removed these vaccines from its inventory. DCDOH's records indicate that 20 children received this particular vaccine from us at our clinic held on Saturday December 12, 2009, at Vail Farm Elementary school in Lagranville. We are in the process of notifying the parents of these children.

➤ **I want to know if my child got this particular vaccine and what I should do.**

Parents of children who received vaccine from the recalled lots do not need to take any action, other than to complete the two-dose immunization series if not already completed.

➤ **Should my child be re-vaccinated?**

There is no need to re-administer a dose to those who received vaccine from these lots. The vaccine potency is only slightly below the “specified” range. The vaccine in these lots is still expected to be effective in stimulating a protective response despite this slight reduction in the concentration of antigen. There is no indication that the vaccine would be ineffective even if it is under the limits. There is still antigen in the vaccine, just not as much. For this reason, there is no need to revaccinate persons who have received vaccine from these lots.

➤ **If my child received one dose should he/she get the second recommended dose?**

All children less than 10 years old should get the recommended two doses of H1N1 vaccine approximately a month apart for the optimal immune response. Therefore, children less than 10 years old who have only received one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.

Children who have received one dose of the vaccine that has been recalled should receive the recommended second dose of Influenza A (H1N1) 2009 Monovalent Vaccine.

➤ **I want more info. Where can I get more information about this recall?**

- For Questions and Answers related to the withdrawn vaccine see http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm
- Call CDC’s toll-free information line, which is available 24 hours a day, every day. 800-CDC-INFO (800-232-4636) or TTY: (888) 232-6348.

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