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Sanofi Pasteur Influenza A (H1N1) 2009 Monovalent Vaccine in Multi-dose Vials —Shortened Shelf Life

Summary

Sanofi Pasteur has notified CDC and FDA that their influenza A (H1N1) 2009 monovalent vaccine manufactured in 2009 in multi-dose vials will have a shorter expiration period than indicated on the label, and they will provide more specific notification of which lots will be affected and the new expiration date in the very near future. This is to ensure that the vaccine is used while it remains within its potency specification. There are no safety concerns with these lots of 2009 H1N1 vaccine. People who were immunized with Sanofi Pasteur influenza A (H1N1) 2009 monovalent vaccine from multi-dose vials do not need to take any action.

2009 H1N1 viruses, along with influenza A H3N2 viruses and influenza B viruses are circulating internationally. While it cannot be known in advance which influenza viruses will predominate in any given year, the 2009 H1N1 virus, along with influenza A H3N2 viruses and influenza B viruses may circulate in the United States during its upcoming influenza season. The 2010-2011 influenza vaccine will protect against an influenza A H3N2 virus, an influenza B virus and the 2009 H1N1 virus. Initial shipping of the 2010-2011 influenza vaccine has begun.

Background

As part of its quality assurance program, Sanofi Pasteur 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 multi-dose vials subject to this change in expiration date include approximately 16 million doses of vaccine manufactured in 2009 that has not yet been administered, but that has been shipped to providers. Although the vaccine remains potent, it is losing potency more rapidly than expected, and therefore the shelf life will be shortened.

Sanofi Pasteur influenza A (H1N1) 2009 monovalent vaccine in multi-dose vials is the only remaining presentation of monovalent 2009 H1N1 influenza vaccine whose expiration date has not yet passed.

Sanofi Pasteur will send a notification to providers who received this product regarding the specific lot numbers and the new expiration date.

For More Information

For Questions and Answers on Using Monovalent 2009 Influenza A (H1N1) Vaccine Prior to the Availability of Trivalent 2010–11 Seasonal Influenza Vaccine go to:

<http://www.cdc.gov/flu/about/qa/infohealthcare.htm>

Questions about the Federal H1N1 Influenza Vaccine Central Recovery Program should be directed to:

State immunization programs or the HHS Supply Service center (1-800-642-0263, 7:00 am to 7:00 pm EST).

For other inquiries, please contact Sanofi Pasteur Customer Services:

1-800-VACCINE (1-800-822-2463) or visit:

<http://www.vaccineshoppe.com>.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national and international organizations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES