

DEPARTMENT OF
PUBLIC HEALTH AND HUMAN SERVICES



Brian Schweitzer
GOVERNOR

Anna Whiting Sorrell
DIRECTOR

STATE OF MONTANA

www.dphhs.mt.gov

PO BOX 4210
HELENA, MT 59604-4210
(406) 444-5622
FAX (406) 444-1970

State of Montana
DPHHS HAN ADVISORY

Forwarding Instructions:

FORWARD to your local HAN contacts that may have Sanofi Pasteur H1N1 Vaccine

DPHHS Information / Recommendations:

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

Please review the enclosed CDC Info Service Message on H1N1 vaccine shortened shelf life.

DPHHS Subject Matter Expert (SME) Contact:

For more Information regarding the returning of expired vaccine to McKesson: Contact the Montana DPHHS Immunization Program at (406) 444-5580.

**Distributed by the Department of Public Health and Human Services
Health Alert Network (HAN) System**

DPHHS Health Alert Hotline: 1-800-701-5769

DPHHS HAN Website: www.han.mt.gov

You have received this message based upon the information contained within our emergency notification data base. If you have a different e-mail or fax address that you would like us to use please notify us as soon as possible by e-mail at hhshan@mt.gov.

The goal of Montana's Health Alert Network is to transmit information to local public health authorities as quickly as possible, and assign a suitable priority to the message. For questions or comments about Montana's HAN system you may contact the DPHHS HAN Coordinator, Gerry Wheat at gwheat@mt.gov.

Categories of Health Alert Messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

DPHHS HAN

From: Health Alert Network Info Services (CDC) [healthalertnetwork@cdc.gov]
Sent: Thursday, August 05, 2010 3:29 PM
To: Health Alert Network (CDC)
Subject: CDC HAN Info Service 00317: Sanofi Pasteur Influenza A (H1N1) 2009 Monovalent Vaccine in Multi-dose Vials -Shortened Shelf Life
Attachments: Sanofi Pasteur Monovalent 2009 HAN_INFO_SVC.pdf

This is an official CDC HAN Info Service Message

Distributed via the Health Alert Network
August 5, 2010, 17:00 EST (5:00 PM EDT)
HANINFO-00317-2010-08-05-N

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>.

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##This Message was distributed to State and Local Health Officers, Public Information Officers, Epidemiologists and HAN Coordinators as well as Clinician organizations##

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<<Sanofi Pasteur Monovalent 2009 HAN_INFO_SVC.pdf>>