



CDC Health Alert Network (HAN) Info Service Message: Sanofi Pasteur Monovalent 2009 (H1N1) Influenza Vaccine in Pre-Filled Syringes – Shortened Shelf Life of Certain Lots

Distributed via Health Alert Network

Tuesday, February 2, 2010, 18:45 ET (6:45 PM EST)

CDCHAN-0309-2010-02-02-UPD-N

Summary

Sanofi Pasteur has notified CDC and FDA that some lots of monovalent 2009 (H1N1) influenza vaccine in prefilled syringes will have a shorter expiration period than indicated on the label. The lots of Sanofi Pasteur monovalent 2009 H1N1 influenza vaccine in prefilled syringes should be used by February 15, 2010, as indicated in the table below regardless of the expiration imprinted on the package. 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 received vaccine from the lots listed below with shortened shelf life do not need to take any action.

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 50 lots subject to this change in expiration date include approximately 12 million doses. These lots were shipped to providers between November 2009 and January 2010. Although these lots remain potent, they are losing their potency more rapidly than expected, and therefore the shelf life is being shortened. While **most of the doses from these lots are believed to have already been administered**, there are almost certainly some doses that have not yet been used.

The change in expiration date described here is specific to the 50 lots of Sanofi Pasteur 2009 H1N1 influenza vaccine in pre-filled syringes listed below. However, a related recall (See <http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00306> (<http://www2a.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00306>)) was conducted recently, which involved lots from Sanofi Pasteur's 2009 H1N1 vaccine in 0.25 mL and 0.5 mL pre-filled syringes. These actions do not affect Sanofi Pasteur's 2009 H1N1 vaccine in multi-dose vials.

Sanofi Pasteur will send a notification to providers who received doses from any of the 50 lots of vaccine described below.

Lot Information

These lots should be used by February 15, 2010, as indicated in the table below regardless of the expiration date imprinted on the package.

All pre-filled syringes that have not been used by February 15, 2010 should be discarded in an appropriate manner, or you may return the product for destruction to Sanofi Pasteur Inc., c/o Capital Returns at 6101 N. 64th Street, Milwaukee, WI 53218

Influenza A (H1N1) 2009 Monovalent Vaccine in Pre-Filled Syringes**Expiration Date Change****Product Code (NDC) Description Lot Number Labeled Expiration Date Re-Assigned Expiration Date**

49281-650-25 0.25mL UT014AA March 4, 2011 February 15, 2010
 syringes in UT014BA March 4, 2011 February 15, 2010
 10-packs UT014CA March 4, 2011 February 15, 2010
 UT014DA March 4, 2011 February 15, 2010
 UT014FA March 27, 2011 February 15, 2010
 UT014EA March 25, 2011 February 15, 2010
 UT029DA April 7, 2011 February 15, 2010
 UT029BA April 6, 2011 February 15, 2010
 UT029CA April 6, 2011 February 15, 2010
 UT029EA April 8, 2011 February 15, 2010
 UT030EA April 10, 2011 February 15, 2010
 UT030FA April 11, 2011 February 15, 2010
 UT033CA April 12, 2011 February 15, 2010
 UT033DA April 12, 2011 February 15, 2010

Product Code (NDC) Description Lot Number Labeled Expiration Date Re-Assigned Expiration Date

49281-650-50 0.5mL UP033CA April 16, 2011 February 15, 2010
 syringes in UP036CA April 19, 2011 February 15, 2010
 10-packs UP034BB April 22, 2011 February 15, 2010
 UP036EA May 3, 2011 February 15, 2010
 UP037CA April 30, 2011 February 15, 2010
 UP037DA May 2, 2011 February 15, 2010
 UP048CA May 6, 2011 February 15, 2010
 UP040CA May 4, 2011 February 15, 2010
 UP048DA May 9, 2011 February 15, 2010
 UP049FA May 16, 2011 February 15, 2010
 UP049CA May 11, 2011 February 15, 2010
 UP049DA May 13, 2011 February 15, 2010
 UP035BA April 15, 2011 February 15, 2010
 UP059DA May 16, 2011 February 15, 2010
 UP060CA May 17, 2011 February 15, 2010
 UP060DA May 19, 2011 February 15, 2010
 UT047BA May 11, 2011 February 15, 2010
 UP033AB April 9, 2011 February 15, 2010
 UP041BA April 30, 2011 February 15, 2010
 UT041AA April 29, 2011 February 15, 2010
 UT034AA April 19, 2011 February 15, 2010
 UT045BA May 5, 2011 February 15, 2010
 UP061DA May 21, 2011 February 15, 2010
 UP061FA May 23, 2011 February 15, 2010
 UP035AA April 12, 2011 February 15, 2010
 UT048BA May 12, 2011 February 15, 2010
 UT058BA May 16, 2011 February 15, 2010
 UT059AA May 18, 2011 February 15, 2010
 UT058AA May 14, 2011 February 15, 2010
 UT061GA May 24, 2011 February 15, 2010
 UP045EA June 9, 2011 February 15, 2010

49281-650-90 0.5mL UT036DA April 26, 2011 February 15, 2010
 syringes in UT040BA April 28, 2011 February 15, 2010
 25-packs UT047AA May 9, 2011 February 15, 2010

UT046BA May 9, 2011 February 15, 2010

UT046AA May 4, 2011 February 15, 2010

For More Information:

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.

Page last reviewed February 1, 2010 12:15 PM ET

Page last updated February 1, 2010 12:15 PM ET

Content source: Centers for Disease Control and Prevention

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800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, 24 Hours/Every Day
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