

New York State Department of Health

Notice of Expiration Date Change of Influenza A (H1N1) 2009 Monovalent Vaccine (2/3/2010)

The U.S. Centers for Disease Control and Prevention have announced an **Expiration Date Change** of the Sanofi Influenza A (H1N1) 2009 Monovalent Vaccine in Pre-filled syringes.

If you have any questions regarding the information below, please contact the New York State Department of Health H1N1 Hotline at 1-800-KID-SHOT (1-800-543-7468).

Please note NEW discard instructions at the end of this document

Summary

Routine stability testing of Influenza A (H1N1) 2009 Monovalent Vaccine Lot revealed a slight decrease in potency of the H1N1 component of the vaccine. The vaccine met all required specifications at the time of release and has been monitored in weekly time intervals since that point. The vaccine has consistently met all specifications until the most recent test point. There are 50 Lots that have been affected by this expiration date change. These lots are listed later in this document.

The new expiration date for all of the lot numbers addressed in this change are now **February 15, 2010** regardless of the expiration date imprinted on the sprayer.

Affected Lot Numbers

The following Lot Numbers reference the 0.25mL pre-filled syringes in 10-packs (NDC# 49281-0650-25)

Lot Number	Label Expiration Date	Re-Assigned Expiration Date
UT014AA	March 4, 2011	February 15, 2010
UT014BA	March 4, 2011	February 15, 2010
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

The following Lot Numbers reference the 0.5mL pre-filled syringes in 10-packs (NDC# 49281-0650-50)

Lot Number	Label Expiration Date	Re-Assigned Expiration Date
UP033CA	April 16, 2011	February 15, 2010
UP036CA	April 19, 2011	February 15, 2010
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
UP060CA	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

The following Lot Numbers reference the 0.5mL pre-filled syringes in 25-packs (NDC# 49281-0650-90)

Lot Number	Label Expiration Date	Re-Assigned Expiration Date
UT036DA	April 26, 2011	February 15, 2010
UT040BA	April 28, 2011	February 15, 2010
UT047AA	May 9, 2011	February 15, 2010
UT046BA	May 9, 2011	February 15, 2010
UT046AA	May 4, 2011	February 15, 2010

Action Required

1. Please use the vaccine per existing clinical guidelines, **but not past the revised expiration date.**
2. If you require any replacement vaccine, please contact the NYSDOH H1N1 Hotline at 1-800-KID-SHOT and place an order. The order will be filled as soon as possible.

Instructions on How to Return Your Vaccine

If you received your vaccine **DIRECTLY FROM McKESSON:**

1. Please ensure that all unused, expired product is discarded in an appropriate manner, or
2. You may return the product for destruction to Sanofi Pasteur Inc., c/o Capital Returns at 6101 N. 64th Street, Milwaukee, WI 53218.
3. Contact the New York State Department of Health H1N1 Hotline at 1-800-KID-SHOT (1-800-543-7468) to place an order for replacement vaccine.

If you received your vaccine **THROUGH A REDISTRUBUTION (THROUGH THE LOCAL HEALTH DEPARTMENT OR ANOTHER PROVIDER):**

1. Please ensure that all unused, expired product is discarded in an appropriate manner, or
2. You may return the product for destruction to Sanofi Pasteur Inc., c/o Capital Returns at 6101 N. 64th Street, Milwaukee, WI 53218.
3. Contact the New York State Department of Health H1N1 Hotline at 1-800-KID-SHOT (1-800-543-7468) to place an order for replacement vaccine.

The detailed notice can be found at the end of this document or at the following link:

<http://www.health.state.ny.us/diseases/communicable/influenza/h1n1/>

**IMPORTANT INFORMATION REGARDING SANOFI PASTEUR'S
INFLUENZA A (H1N1) 2009 MONOVALENT VACCINE IN PREFILLED SYRINGES**

February 3, 2010

Dear Health-Care Professional:

This letter is to inform you that some lots of Influenza A (H1N1) 2009 Monovalent Vaccine in pre-filled syringes will have a shorter expiration period than indicated on the label. The following lots are affected by the shorter dating period:

**Influenza A (H1N1) 2009 Monovalent Vaccine in Prefilled Syringes
Expiration Date Change**

Product Code (NDC)	Description	Lot Number	Labeled Expiration Date	Re-Assigned Expiration Date
49281-650-25	0.25mL syringes in 10-packs	UT014AA	March 4, 2011	February 15, 2010
		UT014BA	March 4, 2011	February 15, 2010
		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 syringes in 10-packs	UP033CA	April 16, 2011	February 15, 2010
		UP036CA	April 19, 2011	February 15, 2010
		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 syringes in 25-packs	UT036DA	April 26, 2011	February 15, 2010
		UT040BA	April 28, 2011	February 15, 2010
		UT047AA	May 9, 2011	February 15, 2010
		UT046BA	May 9, 2011	February 15, 2010
		UT046AA	May 4, 2011	February 15, 2010

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

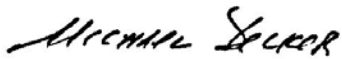
This action applies only to the lots of sanofi pasteur's pandemic vaccine in prefilled syringes listed above. It does not impact any presentations of sanofi pasteur's seasonal influenza vaccine, Fluzone[®], Influenza Virus Vaccine.

You should refer to the Prescribing Information for information on indications and usage, dosage and administration, and safety information. Please ensure that all unused, expired product is 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.

For further information on this action, please visit sanofi pasteur's Web site, www.vaccineshoppe.com.

We appreciate your attention to this matter.

Sincerely,



Michael D. Decker, MD, MPH
Vice President, Scientific & Medical Affairs and Chief Medical Officer

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