

New York State Department of Health

Notice of Expiration Date Change of Influenza A (H1N1) 2009 Monovalent Vaccine (1/11/2010)

The U.S. Centers for Disease Control and Prevention have announced an **Expiration Date Change** of the Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal by MedImmune.

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).

Summary

Routine stability testing of Influenza A (H1N1) 2009 Monovalent Live Intranasal 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 12 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 **January 15, 2010** regardless of the expiration date imprinted on the sprayer.

Affected Lot Numbers

Lot Number	Lot Number	Lot Number	Lot Number
500778P	500779P	500780P	500781P
500782P	500783P	500784P	500785P
500796P	500797P	500798P	500799P

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. Within the next few days MedImmune will be sending you a Business Reply Card along with other material.
2. Please complete the Business Reply Card and send back the material per the enclosed instructions using the supplied postage material.
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 contact MedImmune at 1-866-209-9273 and they will provide you with the material discussed above. Additional assistance can be obtained through MedImmune Customer Services at 1-800-949-3789.
2. Please complete the Business Reply Card and send back the material per the enclosed instructions using the supplied postage material.
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/>



MedImmune

Event: 2079

07 January 2010

Dear Distributor/Health Care Professional:

Subject: Important Information Regarding Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal Expiration Dating

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

Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal Expiration Date Update

Product Code (NDC)	Lot Number	Labeled Expiration Date	Re-Assigned Expiration Date
66019-200-01 66019-200-05 66019-200-10	500778P	1/29/2010	1/15/2010
	500779P	2/4/2010	1/15/2010
	500780P	2/6/2010	1/15/2010
	500781P	2/10/2010	1/15/2010
	500782P	2/11/2010	1/15/2010
	500783P	2/12/2010	1/15/2010
	500784P	2/14/2010	1/15/2010
	500785P	2/16/2010	1/15/2010
	500796P	2/17/2010	1/15/2010
	500797P	2/19/2010	1/15/2010
	500798P	2/21/2010	1/15/2010
	500799P	2/22/2010	1/15/2010

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

Please see Prescribing Information for indications and usage, dosage and administration, and safety information. MedImmune is conducting this field correction with the full knowledge of the Food and Drug Administration.

Should you have any questions regarding this information, please contact us at: 1-877-574-5040.

Should you have any medical questions please contact us at: 1-877-633-4411.

Sincerely,

Timothy J. Maines

Vice President, Corporate Quality Assurance, MedImmune, LLC