NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Mary T. Bassett, MD, MPH
Commissioner

Jane R. Zucker, MD, MSc
Assistant Commissioner
Bureau of Immunization

42-09 28th Street, CN21
Queens, NY 11101-4132

April 28, 2015

Dear Colleague:

The New York City Department of Health and Mental Hygiene Bureau of Immunization has been informed that Sanofi Pasteur has recalled three lots of its 2014-15 Fluzone Quadrivalent vaccine in multi-dose vials. As detailed in the attached letter, during routine ongoing monitoring of the stability of its influenza vaccines, Sanofi found that there was a decline in the stability specification limit for the A/Texas H3N2 and B/Brisbane (Victoria lineage) strains. There are no safety concerns related to the recalled vaccine, nor is revaccination recommended.

The lot below was distributed through the New York City Vaccines for Children (VFC) program:

Lot Number	Expiration Date	Carton NDC	Vial NDC	Presentation
UI190AC	30JUN2015	49281-621-15	49281-621-78	10-dose vials

If you purchased vaccine outside of the VFC program, for adult or privately insured pediatric patients, you may have also received vaccine from the above lot. In addition, there are two more lots of vaccine involved in the recall that were distributed, listed below:

Lot Number	Expiration Date	Carton NDC	Vial NDC	Presentation
UI196AA	30JUN2015	49281-621-15	49281-621-78	10-dose vials
UI190AD	30JUN2015	49281-621-15	49281-621-78	10-dose vials

Please check your vaccine inventory to determine if you have any of the affected lots. If you do, separate and label the vaccine to ensure that you do not use it. You will be contacted by Sanofi with instructions for how to return the vaccine.

For VFC vaccine only, once you have determined how many doses of the affected influenza lot you will be returning, go to the Online Registry, click on the VFC icon, then click on the VFC Vaccine Returns/Wastage tab. Scroll down to the VFC Vaccine Returns/Wastage form and select "Other wastage (non-returnable)" (last choice) for the Vaccine Return/Wastage Reason. Complete the rest of the form's columns, then click on "Add Event."

For questions about the recalled lots, please contact Sanofi at 800-VACCINE. For questions related to vaccine supply or the VFC program, please email us at nycimmunize@health.nyc.gov or call 347-396-2405. Thank you for your efforts in protecting New Yorkers from vaccine-preventable illnesses.

Sincerely,

Jane R. Zucker, MD, MSc
Assistant Commissioner

SANOFI PASTEUR

IMPORTANT INFORMATION REGARDING THREE LOTS OF SANOFI PASTEUR'S 2014-2015 FLUZONE® QUADRIVALENT (INFLUENZA VACCINE) SUPPLIED IN MULTIDOSE VIALS

April 21, 2015

Dear Health Care Professional:

Sanofi Pasteur is committed to providing our customers with quality vaccines. As part of ongoing monitoring of the stability of all of our influenza vaccines, we have found that the antigen content of 3 lots of the 2014-2015 Fluzone Quadrivalent vaccine supplied in multidose vials has declined below the stability specification limit for 2 strains – A/Texas H3N2 and B/Brisbane (Victoria lineage). Stability tests for the A/California H1N1 and B/Massachusetts (Yamagata lineage) strains in these lots have remained within specification. You are receiving this communication because we have identified that you were shipped doses from 1 or more of these 3 lots.

There are no safety concerns related to these 3 lots and re-immunization is not necessary.

However, in response to the stability testing results, Sanofi Pasteur is initiating a voluntary recall of the remaining doses of 3 lots of Fluzone Quadrivalent vaccine:

Lot Number:	Expiration Date:	Carton NDC[a]:	Vial NDC:	Presentation:
UI196AA	30JUN15	49281-621-15	49281-621-78	10-dose vials
UI190AC	30JUN15	49281-621-15	49281-621-78	10-dose vials
UI190AD	30JUN15	49281-621-15	49281-621-78	10-dose vials

This action does not impact any other lot of Fluzone Quadrivalent vaccine or any other presentations of Sanofi Pasteur's Fluzone vaccines.

These lots passed all quality controls and met all licensed specifications required by the US Food and Drug Administration (FDA) at the time of shipping.

If you have any remaining doses from the above lots of Fluzone Quadrivalent vaccine, please do not use them and return the vaccine as outlined in the attached instructions.

We appreciate your attention to this matter.

Sincerely,

David Greenberg

David P. Greenberg, MD
Vice President, Scientific & Medical Affairs and Chief Medical Officer

[a] NDC = National Drug Code.

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