TEXAS DEPARTMENT OF STATE HEALTH SERVICES

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KIRK COLE
INTERIM COMMISSIONER

April 24, 2015

Dear Texas Immunization Provider,

This is to inform you of a voluntary product recall of:

2014-2015 FLUZONE® QUADRIVALENT (INFLUENZA VACCINE) MULTI DOSE VIALS

All remaining doses of three lots of the 2014-2015 Fluzone Quadrivalent vaccine supplied in multidose vials are being recalled due to the antigen content declining below the stability specification limit of two strains (– A/Texas H3N2 and B/Brisbane (Victoria lineage)). The Texas Vaccines for Children (TVFC) Program distributed vaccines from one of the lots affected (U1190AC). The vaccine recall is not a result of any identified safety concerns and re-immunization is not necessary.

Please read the attached letter from Sanofi Pasteur for additional information and affected lot numbers. This recall does not affect any other lots of Fluzone Quadrivalent vaccine or any other presentations of Sanofi Pasteur's Fluzone vaccines.

All remaining doses from the lots of Fluzone Quadrivalent vaccine listed should not be used. Sanofi Pasteur will be contacting providers who received any of the affected lots in order to communicate the recall information and instructions directly to them.

For questions about the recall, please contact Sanofi Pasteur at 1-800-VACCINE (1-800-822-2463), Monday – Friday, 8:30 AM - 6:00 PM.

Sincerely,

Monica Gamez,
Director, Infectious Disease Control Unit

Enclosure: Sanofi Pasteur Vaccine Recall Notice

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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