

Blastfax

Non-Safety Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes

Summary:

As part of its quality assurance program, Sanofi Pasteur, Inc., performs additional routine, ongoing testing of influenza vaccines after the vaccine has been distributed to health care providers to ensure that vaccines continue to meet required specifications. **In recent testing of the amount of antigen in its influenza A (H1N1) monovalent vaccine, Sanofi Pasteur found four distributed lots of singledose, pre-filled syringe pediatric (0.25 mL.) vaccine with antigen content lower than required potency levels.** The manufacturer is conducting a non-safety related voluntary recall of these affected lots of vaccine.

Recommendations

There is no need to revaccinate persons who have received vaccine from these lots. Providers are being asked to return any vaccine to the manufacturer in the following lots that remains unused to the manufacturer:

- 0.25 mL pre-filled syringes, 10-packs (NDC # 49281-650-25, sometimes coded as 49281- 0650-25):
UT023DA, UT028DA, UT028CB
- 0.25 mL pre-filled syringes, 25-packs (NDC # 49281-650-70, sometimes coded as 49281-0650-70):
UT030CA

These lots were shipped in November and are intended for **children 6 months through 35 months of age**. Sanofi Pasteur will send directions for returning unused vaccine from these lots to providers. The affected vaccine met all specifications at the time of release. CDC and FDA have determined that there are no safety concerns for children who have received this vaccine. Sanofi Pasteur has discontinued distribution of the 0.25 mL syringes of H1N1 pediatric vaccines.

The drop in antigen content below the required specification that is described here is specific to Sanofi Pasteur's pediatric H1N1 monovalent vaccine in 0.25 mL pre-filled syringes. The same vaccine packaged in other forms, such as 0.5 mL pre-filled syringes for older children and adults and multidose vials, continue to meet specifications.

The antigen content in the affected lots of vaccine is only slightly below the specification limit. The slightly reduced concentration of vaccine antigen found in retesting these lots is still expected to be effective in stimulating a protective response. There is no need to re-administer a dose to those who received vaccine from these lots. However, as is recommended for all 2009 H1N1 vaccines, all children less than 10 years old should get the recommended two doses of H1N1 vaccine approximately a month apart for the optimal immune response. So, children less than 10 years old who have only received one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.

For children 6 months of age and older, vaccine is available in multidose vials. The vaccine in multidose vials is safe and effective vaccine for children. One difference between vaccine in pre-filled syringes and the multidose vials is that the multidose vials contain a preservative (thimerosal) to prevent potential contamination after the vial is opened. The standard dose for this preparation for administration to infants 6-35 months old is the same as for the pre-filled syringes, 0.25 mL. For healthy children at least 2 years of age, the nasal spray (live, attenuated influenza vaccine) is also an option. The nasal spray vaccine is produced in single units that do not contain thimerosal.

For Questions and Answers related to the withdrawn vaccine see http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm

For questions or concerns regarding this blastfax or any other immunization information, please contact the Chapter's Immunization Coordinator, Mike Chaney at (404) 881-5094 or mchaney@gaaap.org.