

**December 16, 2009**

**Non-Safety-Related Voluntary Recall of Certain Lots of H1N1 Pediatric Vaccine**

Recalled Product:

**Sanofi Pasteur**

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

These lots were shipped in November and December and are intended for children 6 months through 35 months of age.

Providers should check to determine if they have any of the product remaining. If so, they should immediately discontinue administering product from these lots, set the product aside, and label it clearly to assure that the product is not used.

Providers may use other lots of Sanofi Pasteur .25 pre-filled syringes (if available) or vaccine in other formulations that are licensed for use in this age group.

DSHS will contact providers with instructions about what to do with recalled vaccine as soon as we have that information from the manufacturer, and to determine if any additional vaccine supplies are needed.

- There are no safety concerns with these recalled lots of 2009 H1N1 vaccine. All lots successfully passed pre-release testing for purity, potency and safety.
- Only specified lots of the 2009 H1N1 pediatric vaccine for children 6-35 months in pre-filled syringes are affected.
- There is no need to re-administer a dose to those who received vaccine from these lots. The vaccine potency is only slightly below the "specified" range. The vaccine in these lots is still expected to be effective in stimulating a protective response despite this slight reduction in the concentration of antigen.
- 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. Therefore, 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.
- Parents of children who received vaccine from the recalled lots do not need to take any action, other than to complete the two-dose immunization series if not already completed.
- All vaccines are routinely tested for purity, potency and safety prior to release. The four lots of vaccine met all required specifications at the time of release and shipment to distribution centers. The vaccine provided in multi-dose vials and the single-dose, 0.5 mL pre-filled syringes for persons 36 months and older continues to meet all specifications.