Ulster County Health Department-Media Advisory: December 18, 2009

Non-Safety-Related Voluntary Recall of Certain Lots of Sanofi Pasteur 2009 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 single-dose, 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.

The Ulster County Health Department is not using any of the recalled lots at our H1N1 Community Clinics.

- 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.
- Children should receive both doses of 2009 H1N1 vaccine from the same type of vaccine (i.e., both doses as inactivated, injectable; or both doses as live, attenuated, nasal spray vaccine).
- 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.

- See http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm for complete details.