

Ocean County Health Department  
PO Box 2191  
Toms River, NJ 08754-2191  
**FOR IMMEDIATE RELEASE**

Contact: Leslie Terjesen  
Public Information Officer  
732-341-9700, ext. 7224  
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## **VOLUNTARY RECALL OF LIMITED NUMBER OF H1N1 VACCINE LOTS DOES NOT WARRANT HEALTH OR SAFETY CONCERNS**

It was announced this week that Sanofi Pasteur, one of the pharmaceutical companies that manufactures H1N1 influenza vaccine, is recalling four vaccine lots of pediatric pre-filled syringes. The recall is a result of routine, ongoing stability testing of its H1N1 vaccine after the vaccine has been shipped to providers. This testing measures the strength or potency of a vaccine over time because sometimes the strength of the vaccine can go down. On December 7<sup>th</sup>, Sanofi Pasteur notified the Centers for Disease Control and Prevention and the Food and Drug Administration that the potency in one lot was found to have dropped below a pre-specified limit. Due to this finding, additional lots were tested and it was discovered that three other lots that had been distributed also had an antigen (active ingredient) content that, while properly filled at the time of manufacturing, was later measured to be below pre-specified limits. Potency (or strength) is determined by the measurement of the concentration of the active ingredient in the H1N1 vaccine. This means that doses from these four vaccine lots no longer meet the manufacturer's specifications for potency. Approximately 800,000 doses of vaccine in these lots were distributed to providers throughout the United States.

“The Ocean County Health Department did receive four hundred doses of one of the lot numbers and used a small number of pre-filled syringes from one of these lots at one of our recent clinics”, said Daniel Regenye, Assistant Public Health Coordinator. Regenye continued, “The Ocean County Health Department wants parents to know that there are no safety concerns with these lots of H1N1 vaccine. All lots successfully passed pre-release testing for purity, potency and safety. **Infants and children who received vaccines from these lots do not need to repeat the first vaccination. 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. The vaccine potency in the mentioned lots was 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 the antigen.**

Leslie Terjesen, Ocean County Health Department Public Information Officer, stated, “Although there is no need to re-administer a dose to those who received vaccine from these lots, it 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. 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.”

(prH1N1recall/pg)

There are additional types of H1N1 vaccine for children 6 months of age and older. You can visit the Centers for Disease Control and Prevention website regarding the recall and vaccine information at [www.cdc.gov/h1n1flu/vaccination/syringes\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm).

A listing of H1N1 vaccination clinics is posted on the Ocean County Health Department website at [www.ochd.org](http://www.ochd.org). It is recommended that the second dose of H1N1 vaccine for children under 10 years of age wait at least 30 days for the second dose. If there are questions regarding H1N1 vaccine or this recall, please call the New Jersey Department of Health and Senior Services H1N1 Hotline at 1-866-321-9751 or the Ocean County Health Department at 732-341-9700, ext. 7791.

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