



For more information contact:
Toby D. Wagoner, Spokesman
Division of Immunization Services
Telephone: (304) 558-6438

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H1N1 Vaccine Recall Was a Quality Assurance Issue Only

State Health officials today said 4,900 doses of Sanofi Pasteur's pre-filled syringe of H1N1 vaccine, for children 6 months to 35 months of age, have been voluntarily recalled after post shipping tests of the vaccine showed antigen levels less than recommended by the Centers for Disease Control and Prevention and the Food and Drug Administration.

Approximately 23 of West Virginia's 54 health departments received 100 to 600 doses of the recalled vaccine. Immunization Services Director Jeff Neccuzi said, "This recall was prompted by voluntary post-shipping antigen tests that indicated antigen content levels were just under those recommended. As a result, the manufacturer chose to recall all 800,000 doses." Neccuzi said parents of children who received one of the vaccines in the four recalled lots have no need for alarm since the recall is not a safety issue. "The H1N1 vaccine is very effective," Neccuzi said. "The CDC and FDA agree that the reduced antigen level is unlikely to result in any significant reduction in immune response in persons who received vaccine from these lots."

H1N1 providers in West Virginia have been instructed on how to return any unused H1N1 vaccine from the recalled lots to the manufacturer. Parents of children less than 10 years of age are encouraged to make sure their child has two doses of H1N1 vaccine. To date, 512,000 doses of H1N1 vaccine have been distributed across West Virginia. More information about H1N1 vaccine is available at www.wvflu.org.