

FOR IMMEDIATE RELEASE

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LESS THAN ONE PERCENT OF H1N1 VACCINE AFFECTED BY VOLUNTARY, NON-SAFETY RELATED RECALL

(RICHMOND, Va.)— The Virginia Department of Health stated today that less than one percent of the more than 2 million doses of H1N1 vaccine the state has received is part of the voluntary, non-safety recall by vaccine manufacturer Sanofi Pasteur. The recalled vaccine was used in single-dose vials for children 6 months – 35 months of age.

“Out of 2.4 million doses of vaccine that have been released to Virginia, 23,700 doses, or less than one percent, are part of this voluntary recall,” said State Health Commissioner, Karen Remley, MD, MBA. “It’s important to note that this recall is in no way safety related. All lots that were affected successfully tested for purity and safety,” Dr. Remley stated.

As part of its quality assurance program, the manufacturer, Sanofi Pasteur, performs routine, ongoing stability testing of its influenza A (H1N1) vaccine after the vaccine has been shipped to providers. Stability testing means measuring the strength (also called potency) of a vaccine over time. It is performed because sometimes the strength of a vaccine can go down over time.

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. There is no need to re-administer a dose to those who received vaccine from these lots. However, as is recommended for all 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 H1N1 vaccine.

The Division of Immunization within VDH is working with the local health districts and physicians’ offices to help provide information about the recall. Sanofi Pasteur is notifying all providers who received doses from the lots so that they can return any unused vaccine.

For more information about the H1N1 flu virus, visit www.H1N1GET1.com. Information for the public is also available from the Virginia Department of Health Inquiry Center toll free weekdays from 8 a.m. to 5 p.m. at **1-877-ASK-VDH3** (1-877-275-8343).

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