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Office of Public Affairs

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Voluntary Recall of H1N1 Vaccine Involves 18,000 Doses in North Carolina

RALEIGH – The North Carolina Division of Public Health is in the process of contacting 132 health care providers who received H1N1 pediatric vaccine from four lots that were voluntarily recalled today by the manufacturer, Sanofi Pasteur, Inc. North Carolina received 17,900 doses of the about 800,000 doses impacted by this recall. These vaccinations were intended for children ages 6 months to 35 months of age.

“There are no safety concerns with these lots of H1N1 vaccine,” State Epidemiologist Megan Davies said. “The concern is that the recalled vaccine may not be strong enough to provide full immunity. However, children in this age group should have adequate protection because we already recommend that they receive two doses of the vaccine.”

North Carolina has received sufficient vaccine to meet the needs of this age group as well as the general population. Everyone is encouraged to get immunized against H1N1.

The vaccine is being voluntarily recalled because the manufacturer determined the antigen content, which is the component in the vaccine that causes immunity to a virus, is slightly below the specified range. The Centers for Disease Control and Prevention (CDC) says the vaccine in these lots still offers protection against H1N1 influenza. The CDC does not recommend doctors re-administer flu shots to those who received vaccine from these lots.

Vaccine from these lots was distributed to providers across the state. Providers who received the recalled vaccine should return unused doses to the manufacturer. Sanofi Pasteur plans to send directions to affected providers for returning unused vaccine from these lots.

More information on this voluntary recall can be found online at:

www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm

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Location: 101 Blair Drive • Adams Building • Raleigh, N.C. 27603

www.ncdhhs.gov

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