NEWS RELEASE
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Recalled H1N1 influenza vaccine lots being returned

FOR IMMEDIATE RELEASE

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The Alabama Department of Public Health is returning 5,200 doses of H1N1 influenza vaccine because of a voluntary recall from the manufacturer. The recall was issued for reasons unrelated to vaccine safety. These lots of vaccine were manufactured for infants and children 6 to 35 months of age, so this recall does not affect the nasal mist vaccine now being used in school clinics or injected doses administered to older children and adults.

Doses of H1N1 vaccine for infants 6 months to 35 months of age were recalled because the potency in one batch (called a “lot”) of pediatric syringes that had been distributed was later found to have dropped below a pre-specified limit.

The vaccine potency is only slightly below the “specified” range. Further testing found three additional lots that had dropped below the pre-specified limit. 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. According to the Centers for Disease Control and Prevention, there is no need to re-administer a dose to those who received vaccine from these lots and there is no safety concern. As is recommended for all 2009 H1N1 vaccine, children less than 10 years old should receive a second dose of vaccine about a month after the first in order to achieve optimal protection.

The vaccine being recalled was manufactured by Sanofi Pasteur, Inc. The company performs ongoing testing of vaccine after it has been distributed to ensure that vaccine continues to meet required specifications.

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