



North Carolina Department of Health and Human Services
Division of Public Health – Women’s & Children’s Health Section
1917 Mail Service Center • Raleigh, North Carolina 27699-1917
Tel 919-707-5550 • Fax 919-870-4824

Beverly Eaves Perdue, Governor

Lanier M. Cansler, Secretary

December 15, 2009

TO: 2009 H1N1 Vaccine Providers Who Received Recalled Vaccine

FROM: Beth Rowe-West, R.N., B.S.N., Head
Immunization Branch

RE: Non-Safety-Related Voluntary Recall of Certain Lots of H1N1 Vaccine

If you are receiving this letter, your office has received vaccine from the lots that are being voluntarily recalled by their manufacturer, Sanofi Pasteur, Inc.

Sanofi Pasteur notified CDC and FDA that the potency in four lots of pediatric syringes was found to have dropped below a pre-specified limit required for potency.

Vaccine doses with the following lot numbers are included in the recall:

0.25 ml pre-filled syringes, 10-packs (NDC # 49281-650-25, sometimes coded as 49281-0650-25):
UT023DA
UT028DA
UT028CB

0.25 ml pre-filled syringes, 25-packs (NDC # 49281-650-70, sometimes coded as 49281-0650-70):
UT030CA

Sanofi Pasteur will send providers directions for returning any unused vaccine from these lots. If you transferred vaccine to another provider in your community, please share this information with them. Also be sure to pass along Sanofi Pasteur’s directions for returning unused vaccine.

North Carolina received 17,900 doses of the approximately 800,000 doses impacted by this recall. Those doses were distributed to 132 providers across the state.

The CDC and the FDA are in agreement that revaccination is not needed for those who received vaccine from these lots. However, as is recommended for all 2009 H1N1 vaccines, all children less than 10 years old should receive the two doses of H1N1 vaccine approximately a month apart for the optimal immune response.

cc: SMT
Regional Immunization Staff
Central Office Staff

