North Carolina Department of Health and Human Services
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Beverly Eaves Perdue, Governor

Lanier M. Cansler, Secretary

February 1, 2010

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
Additional recalled lot number shipped to your practice

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 five lots of pediatric pre-filled syringes and one lot of adult pre-filled syringes that had been distributed to providers was later 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):
UT023AA
UT023BA
UT023CA
UTO23FA

** **Lot number UTO23EA was not included in the first memo and your practice did receive this H1N1 vaccine.**

0.5 mL pre-filled syringes, 25-packs (NDC # 49281-650-90, sometimes coded as 49281-0650-90):
UT037AA

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.These lots were shipped to providers between November 2009 and January 2010.

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