



**North Carolina Department of Health and Human Services
Division of Public Health – Women’s & Children’s Health Section**

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Beverly Eaves Perdue, Governor

Lanier M. Cansler, Secretary

December 15, 2009

TO: 2009 H1N1 Vaccine Providers
FROM: Beth Rowe-West, R.N., B.S.N., Head
Immunization Branch
RE: Non-Safety-Related Voluntary Recall of Certain Lots of H1N1 Vaccine

As most of you are aware, four lots of H1N1 vaccine have been recalled as part of Sanofi Pasteur’s quality assurance program due to a lower antigen content required for potency levels. Only 0.25 pre-filled syringes were recalled.

The CDC and FDA are in agreement that revaccination is not needed for those who have received vaccine from these lots. The manufacturer will send directions for returning unused vaccine.

Of the approximately 800,000 doses impacted by this recall, 17,900 doses were shipped to 132 providers in North Carolina. Providers in receipt of these lot numbers were notified individually.

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.

cc: SMT
Regional Immunization Staff
Central Office Staff

