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Beverly Eaves Perdue, Governor

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August 12, 2010

TO: 2009 H1N1 Vaccine Providers

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

RE: Non-Safety-Related Shortened Expiration Date of 2009 Sanofi Pasteur H1N1 Vaccine

Sanofi Pasteur notified CDC and FDA that monovalent 2009 (H1N1) influenza vaccine in multidose vials will have a shorter expiration period than indicated on the label. Sanofi Pasteur monovalent 2009 H1N1 influenza vaccine in multidose vials should be used by September 15, 2010, regardless of the expiration imprinted on the package. This is to ensure that the vaccine is used while it remains within its potency specification. There are no safety concerns with these lots of 2009 H1N1 vaccine. People who received vaccine from multidose vials with shortened shelf life do not need to take any action.

Background: As part of its quality assurance program, Sanofi Pasteur performs routine, ongoing stability testing of the vaccine after it has been shipped to providers. Stability testing means measuring the strength of a vaccine over time. Although the vaccine remains potent, it is losing potency more rapidly than expected, and therefore the shelf life is being shortened.

Sanofi Pasteur monovalent 2009 H1N1 influenza vaccine in multidose vials is the only remaining presentation of 2009 H1N1 influenza vaccine whose expiration date has not yet passed. After September 15, 2010, 2009 H1N1 influenza vaccine will no longer be available. All 2009 H1N1 influenza vaccine in multidose vials that has not been used should be discarded in an appropriate manner, which may include returning the product using the Federal H1N1 Influenza Vaccine Central Recovery Program. . http://www.cdc.gov/h1n1flu/vaccination/QA_Central_Vacc_Rcvry_Prog.htm

Sanofi Pasteur will send a notification to all providers who received this product.

cc: SMT
Regional Immunization Staff
Central Office Staff

