



Pat Quinn, Governor
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TO: Local Health Departments, IDPH Regional Offices, Hospital Administrators and Hospital Infection Control Practitioners

FROM: Karen McMahon
Chief, Immunization Section

DATE: August 17, 2010

RE: Update Re: Sanofi short-dated H1N1 vaccine/ H1N1 Vaccine Recovery

To ensure that its vaccine continues to meet potency standards, Sanofi Pasteur Inc. (the manufacturer) is shortening the expiration period of all its influenza A (H1N1) 2009 monovalent vaccine in multi-dose vials manufactured in 2009 that were distributed in the United States. Sanofi Pasteur Inc., performs routine, ongoing testing of influenza vaccines after the vaccine has been distributed to health care providers as part of its quality assurance program in order to ensure that the vaccine continues to meet required specifications.

In recent testing of its influenza A (H1N1) 2009 monovalent vaccine, sanofi pasteur found that the lots of the vaccine in multi-dose vials may fall below pre-specified limits before the original expiration dates (March 2011 through June 2011). These are the last lots of influenza A (H1N1) 2009 monovalent vaccine remaining to expire.

All lots of influenza A (H1N1) 2009 monovalent vaccine in multi-dose vials manufactured by sanofi pasteur and distributed in the United States should now be administered by September 15, 2010 regardless of the expiration imprinted on the package. The original expiration dates were from March 2011 through June 2011.

There are no safety concerns with these lots of influenza A (H1N1) 2009 monovalent vaccine. People who were immunized with vaccine from the lots with shortened shelf life do not need to take any action. The vaccine currently meets all potency and safety specifications.

This shortened expiration period does not affect any 2010-2011 seasonal influenza vaccine. It applies only to influenza A (H1N1) 2009 monovalent vaccine distributed in the U.S. from CDC via McKesson.

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Approximately 16 million doses in these lots have not been administered. Sanofi has sent notification detailing the change in dating to health care providers who received shipments from the affected lots. As in Phase one of the Central Vaccine Recovery program, providers will receive a mailing label for return of the product. Labels will be mailed in September. The contractor will be working from the same list that was used for distribution of labels in Phase one. H1N1 vaccine MUST be returned by December 1, 2010. Providers who wish to free up storage space do not need to keep their H1N1 vaccine refrigerated until they can return it.

If you have questions, please contact the Immunization Section at 217-785-1455. Thank you.