Shortened Expiration Period For Sanofi Pasteur Influenza A (H1N1) 2009 Monovalent Vaccine In Multi-dose Vials Questions & Answers

Why is Sanofi Pasteur changing the expiration dates of 2009 H1N1 vaccine in multi-dose vials?

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.

What is the new expiration date?

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.

What were the original expiration dates on these H1N1 vaccines?

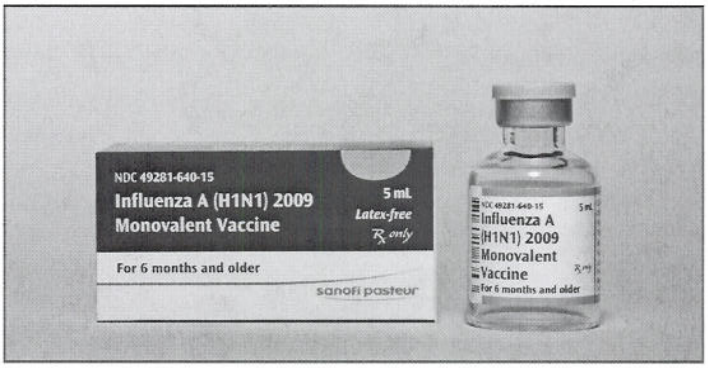
The original expiration dates were from March 2011 through June 2011.

Are there any concerns about the safety of these vaccines?

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.

Will this affect the 2010-2011 seasonal influenza vaccine supply?

No. 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.



How many doses were in these lots?

Approximately 16 million doses in these lots have not been administered.

What is being done to notify health care providers of this change?

The manufacturer has sent notification detailing the change in dating to health care providers who received shipments from the affected lots.

How can healthcare providers that have remaining influenza A (H1N1) 2009 monovalent vaccine dispose of it?

The U.S. Federal Government has a Central H1N1 Influenza Vaccine Recovery Program for collecting unused expiring or expired influenza influenza A (H1N1) 2009 H1N1 monovalent vaccine. Anyone who wishes to use this voluntary service will need a provider identification number (PIN) in order to return vaccine.

In the change in expiry notification letter that Sanofi Pasteur Inc. sent to providers in August 2010, the provider's PIN is printed with the address that appears in the window of the mailing envelope. Any providers who have unused expiring or expired influenza A (H1N1) 2009 monovalent vaccine but who did not receive a notification letter or cannot locate their PIN, should contact the HHS supply service center (1-800-642-0263, 7:00 a.m. – 7:00 p.m. EST).

Additional information on the Central H1N1 Influenza Vaccine Recovery Program for remaining influenza A (H1N1) 2009 monovalent vaccine can be found on the CDC's web site, http://www.cdc.gov/h1n1flu/vaccination/QA_Central_Vacc_Rcvry_Prog.htm.