Voluntary Recall of H1N1 Vaccine 12/2009

As part of its quality assurance program, Sanofi Pasteur performs routine, ongoing stability testing of its influenza A (H1N1) vaccine after the vaccine has been shipped to providers. Stability testing means measuring the potency of a vaccine over time. It is performed because sometimes the strength of a vaccine can go down over time. On December 7, Sanofi Pasteur notified CDC and FDA that the potency in one lot of pediatric syringes that had been distributed was later found to have dropped below a pre-specified limit. As a result of this finding, Sanofi Pasteur tested additional lots and found that three other lots that had been distributed also had an antigen content that, while properly filled at the time of manufacturing, was later measured to be below pre-specified limits. This means that doses from these four vaccine lots no longer meet the manufacturer’s specifications for potency. The manufacturer is conducting a non-safety related voluntary recall of these affected lots of vaccine. Approximately 800,000 doses of vaccine in these lots were distributed to providers.

While the antigen content of these lots is now below the specification limit for the product, CDC and FDA are in agreement that the small decrease in antigen content is unlikely to result in a clinically significant reduction in immune response among persons who have received the vaccine. For this reason, there is no need to revaccinate persons who have received vaccine from these lots.

Providers are being asked to return any vaccine that remains unused to the manufacturer from the specified lots (the lot numbers are posted at:

http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm

Resources for more information:
Non-Safety-Related Voluntary Recall of Certain Lots of Sanofi Pasteur H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes Questions & Answers - posted at:

http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm