



Findlay City Health Department

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FOR IMMEDIATE RELEASE

DECEMBER 16, 2009

The Findlay City and Hancock County Health Departments are submitting this release to update the community on the CDC's Non-Safety-Related Voluntary Recall of Certain Lots of Sanofi Pasteur 2009 H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes.

As part of its quality assurance program, Sanofi Pasteur, Inc., performs additional routine, ongoing testing of Influenza vaccines after the vaccine has been distributed to health care providers to ensure that vaccines continue to meet required specifications.

After performing these tests, Sanofi Pasteur notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that the antigen content in several lots of pediatric syringes that had been distributed to providers was later found to have dropped below a pre-specified limit.

(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.

The lot numbers listed below are those that have been recalled:

0.25 mL Pre-filled syringe 10-pack: UT023DA; UT028DA; UT028CB

0.25 mL Pre-filled syringe 25-pack: UT030CA

PLEASE NOTE: FINDLAY CITY AND HANCOCK COUNTY HEALTH DEPARTMENTS DID NOT RECEIVE ANY DOSES WITH THESE LOT NUMBERS.