



MEDIA RELEASE

STATE OF TENNESSEE
DEPARTMENT OF HEALTH

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CONTACT: Andrea Ewin Turner
615.741.3111 (office)
615.708.9384 (cell)

H1N1 FLU VACCINE MANUFACTURER VOLUNTARILY RECALLS DOSES *Non-safety Related Recall of Vaccine Product for Children*

NASHVILLE, Tenn. – The Tennessee Department of Health is working to notify health care providers of a nationwide voluntary non-safety recall of 800,000 doses of H1N1 flu vaccine. Sanofi Pasteur, Inc., is recalling four lots of H1N1 vaccine in 0.25 ml pre-filled syringes designed for use in children ages 6 to 35 months. These lots passed all tests for potency and purity when they were distributed, but routine follow-up tests after distribution found that levels of antigen, the active ingredient, were slightly lower than the level specified on the label. The recall is not related to any safety or effectiveness concerns.

“We want to assure parents whose children may have received this vaccine product that it is safe and effective at preventing H1N1 flu when given as part of the two dose series recommended for all children under age ten,” said Health Commissioner Susan R. Cooper, MSN, RN. “Our recommendations haven’t changed. H1N1 flu is still circulating, and vaccination is the best way to prevent the illness.”

The lot numbers of vaccine included in the recall are: **UT023DA, UT028DA, UT028CB** and **UT030CA**. Some 800,000 doses of H1N1 vaccine are included in these lots. The vaccine met all antigen level and safety specifications at the time it was distributed; routine monthly follow-up testing showed that antigen in these lots fell slightly below the pre-specified level.

Tennessee has distributed only 82,600 total doses of 0.25 ml pre-filled syringes from Sanofi Pasteur since it began providing H1N1 flu vaccine in October, out of a total of 1.85 million H1N1 vaccine doses distributed in Tennessee to date. It is not yet known how many of these doses were from the lot numbers impacted by the recall. The Department of Health is working with the Centers for Disease Control and Prevention to ensure that providers who received affected lots are notified to discontinue use of those vaccine products and to await instructions from Sanofi Pasteur for returning unused doses to the company.

No action is required by parents with children between the ages of 6 to 35 months who may have received H1N1 flu vaccine in the form of a pre-filled syringe from Sanofi Pasteur. The doses are considered safe and effective; revaccination is not recommended. Other H1N1 vaccine products are available for children in this age group, so vaccine will still be available for parents whose young children have not been fully vaccinated. Parents with questions may contact their child’s health provider, or call the Tennessee Flu Information line toll-free at 1-877-252-3432.

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This news release can be accessed online at <http://news.tennesseeanytime.org/taxonomy/term/30>.

**CORDELL HULL BUILDING, 3RD FLOOR
425 FIFTH AVENUE NORTH
NASHVILLE, TN 37243
WWW.TENNESSEE.GOV/HEALTH**