

HEALTH ALERT
From Durham County Health Department
H1N1 VACCINE: NON-SAFETY Related Voluntary Recall
December 16, 2009

PLEASE SHARE THIS WITH OTHER PROVIDERS IN YOUR PRACTICE

The CDC has issued an alert regarding the **voluntary recall** of certain lots of Sanofi Pasteur H1N1 Pediatric Vaccine (0.25ml, for 6 through 35 month olds) in Pre-filled Syringes.

The recalled vaccine is considered safe and does not pose any additional risk to your patients. However, there may be a decrease in potency of the recalled vaccine.

Recent testing by Sanofi Pasteur has shown a drop in the antigen content of four lots of the Pediatric H1N1 vaccine supplied in 0.25ml pre-filled syringes since distribution. The antigen level in these 4 lots was found to be below the required potency levels.

The Recalled lots are:

Sanofi Pasteur Influenza A H1N1 monovalent vaccine, 0.25ml pre-filled syringes for 6 through 35 months of age

Lot Number: UT023DA

Lot Number: UT028DA

Lot Number: UT028CB

Lot Number: UT030CA

PLEASE CHECK YOUR SUPPLY IMMEDIATELY. If you have any of these lots in your supply, please isolate them from the other vaccine (place in a bag / separate box) and mark them as DO NOT USE. Please continue to store the vaccine in the refrigerator until further instructions are provided.

NOTE: The Durham County Health Department did not receive or administer any of the vaccine included in this recall. If you received shipments of H1N1 vaccine directly through the McKesson System you should inventory your vaccine supply.

Return of Recalled Vaccine:

The NC Immunization Branch is currently working out the details regarding the return of the recalled lots of vaccine. They will be providing guidance directly to providers who are affected by this recall. If you have questions regarding the return of the vaccine please call the **NC Immunization Branch at (919) 707-5550.**

H1N1 Vaccination Options for 6 through 35 month olds:

You may continue to vaccinate children from 6 through 35 months of age using 0.25ml in pre-filled syringes that are not from the above lots or you can draw up 0.25ml of H1N1 vaccine from multi-dose vials of H1N1 vaccine licensed for children under the age of 4 years. Also, healthy children over the age of 2 may be given the live attenuated nasal spray H1N1 vaccine.

Children who are 6 through 35 months of age (as well as all children under 10 years) should get the recommended two doses of H1N1 vaccine about 1 month apart for optimal immune response.

Patients who have received the recalled vaccine:

The CDC and FDA agree that the small decrease in the antigen content is unlikely to result in a significant reduction in immune response among children who have already received this vaccine. Re-vaccination is NOT recommended for those who have received vaccine from these lots.

For Questions and Answers related to the recalled vaccine go to: http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm