



**NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE**
Thomas Farley, MD, MPH
Commissioner

Jane R. Zucker, MD, MSc
Assistant Commissioner
jzucker@health.nyc.gov

Bureau of Immunization
2 Lafayette Street, 19th Fl.
New York, NY 10007

March 22, 2010

Dear Colleague:

Today the Food and Drug Administration (FDA) announced a temporary suspension of the use of the GSK rotavirus vaccine, Rotarix[®]. The suspension is due to a finding of DNA from porcine circovirus type 1 in the vaccine. This virus is not known to cause disease in pigs or humans and is found in other products, including some foods. At this time, it is not known if this is intact virus capable of causing infection or DNA fragments. As a result of these findings, the FDA is taking this step as a precautionary measure. A Health Alert released today by the Centers for Disease Control and Prevention is attached.

The safety profile of Rotarix, including pre-licensure and post-licensure data, has not revealed any safety issues. Rotarix is in widespread use in many other countries. The alternative rotavirus vaccine, Rotateq[®] (Merck), is available and should be used to vaccinate all children at the appropriate ages as recommended.

Since licensure in 2008, 46,280 doses of this vaccine have been distributed by the Vaccines for Children (VFC) Program in New York City. The number of doses ordered through the private sector is not known. As of today, preliminary estimates are that a total of 40,268 doses of Rotarix have been reported to the Citywide Immunization Registry (CIR) as administered to 27,591 patients at 715 facilities. These data include both VFC-distributed and privately purchased vaccine.

Children who have completed the Rotarix series do not need to be revaccinated or to have any follow up testing at this time. Children who have received 1 dose of Rotarix should have the series completed with 2 doses of Rotateq (Merck vaccines). As this is a temporary suspension, providers are being asked to keep and store any Rotarix product they have in their office at appropriate temperatures. Please mark the product "do not use" until further information is available.

Additional information is available at
<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm205585.htm#news>

For questions related to vaccine supply or availability, the CIR, or for professional or technical questions, please call 212-676-2323.

We thank you for your continuing efforts to protect children from vaccine-preventable diseases.

Sincerely,

A handwritten signature in black ink that reads "Jane R. Zucker".

Jane R. Zucker, MD, MSc
Assistant Commissioner
Bureau of Immunization