

BLASTFAX

Recommendation to Temporarily Suspend Usage of Rotarix[®] Vaccine

The U.S. Food and Drug Administration (FDA) is recommending that clinicians and public health professionals in the United States temporarily suspend the use of Rotarix[®]. The FDA has learned that DNA from porcine circovirus type 1 (PCV1), a virus not known to cause disease in humans, is present in the Rotarix[®] vaccine. All available evidence indicates that there has been no increased risk to patients who have received this vaccine. PCV1 is not known to cause any disease in animals or humans; therefore, it has not been routinely tested for in vaccine development. Rotarix[®] has been extensively studied, before and after approval, and found to have an excellent safety record (i.e., no unusual adverse events). However, FDA is recommending that healthcare practitioners temporarily suspend usage of the Rotarix[®] vaccine for rotavirus immunization in the United States while further studies are conducted. This recommendation applies to **all lots** of the Rotarix[®] vaccine. RotaTeq[®] vaccine is available for rotavirus immunization during this period. For children who have received one dose of Rotarix[®], CDC advises that clinicians complete the series with RotaTeq[®] for the next two doses. Within the next four to six weeks, FDA will convene an advisory committee to review the available data and make recommendations on the licensed rotavirus vaccines. The agency anticipates that following the advisory committee meeting, based on expert input and additional review, FDA will make further recommendations on the use of the two licensed rotavirus vaccines in the United States. Clinicians are requested to report any suspected adverse events following Rotarix[®] vaccination to the Vaccine Adverse Event Reporting System (VAERS) via phone 800-822-7967 or on-line: <http://vaers.hhs.gov>.

Please see the following links for FDA's guidance for Healthcare Providers and Parents/Caregivers:

Additional Information for Healthcare Providers and Public Health Professionals

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205548.htm>

Information for Parents and Caregivers

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205547.htm>

The Georgia VFC Program routinely uses Rotarix[®], and will switch to RotaTeq[®] at least temporarily. Providers that have VFC Rotarix in stock should store the vaccine at the correct temperature until further notice.

For questions or concerns regarding this blastfax or any other immunization information, please contact the Chapter's EPIC Immunization Program Director, Jill Ray, at (404)881-5081 or jray@gaaap.org or the Chapter's Immunization Coordinator, Mike Chaney at (404) 881-5094 or mchaney@gaaap.org.