



Important Information from the San Antonio Metropolitan Health District (SAMHD)

March 23, 2010

FDA Recommends Clinicians Temporarily Suspend Use of Rotarix[®] Vaccine

The Food and Drug Administration (FDA) is recommending that healthcare practitioners temporarily suspend use of Rotarix[®] (GlaxoSmithKline-GSK) vaccine as a precaution for rotavirus immunization in the United States while the agency learns more about components of an extraneous virus detected in the vaccine. FDA has learned that DNA from porcine circovirus type 1 (PCV1) is present in the Rotarix[®] vaccine. This finding was reported to FDA by GlaxoSmithKline on March 15th, 2010 based on work originally performed by an academic research team using a novel technique to look for viruses. GlaxoSmithKline then conducted additional studies and confirmed that PCV1 DNA was present in the finished Rotarix[®] vaccine. There is no evidence at this time that this finding poses a safety risk, as PCV1 is not known to cause disease in humans. The FDA does not believe medical follow-up or revaccination is warranted for children whom have been vaccinated with Rotarix[®] since all available evidence supports the safety and effectiveness of this vaccine.

This temporary suspension applies to all lots of the Rotarix[®] vaccine. Because new recommendations are expected in 4-6 weeks, healthcare providers are asked to keep Rotarix[®] in their offices for possible future use. In the meantime, RotaTeq[®] vaccine (Merck and Company) is available for rotavirus immunization during this period. RotaTeq[®] is made using different materials from Rotarix[®]. FDA has no evidence that PCV1 is present in RotaTeq[®] vaccine. If children in your practice received one dose of Rotarix[®], the CDC advises that they complete their series with RotaTeq[®] for the next two doses.

SAMHD Vaccine Management staff will be contacting Vaccines for Children (VFC) provider offices by phone that currently order Rotarix[®] vaccine from our program to provide additional guidance. Please use the following link to obtain additional information and frequent updates from the FDA on this situation: www.fda.gov.

SAMHD thanks you for your continued efforts to protect our community.