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Date: March 23, 2010
To: Vaccine for Children Program Providers
From: Immunization Program
RE: Temporary Suspension of Rotarix

On March 22, 2010, out of an abundance of caution, the Food and Drug Administration (FDA) called for the temporary suspension of Rotarix (rotavirus vaccine) made by GlaxoSmithKline (GSK). The suspension is not due to an efficacy or safety issue but it is due to the detection of porcine cirovirus type 1 genetic material, in the Rotarix vaccine. Porcine cirovirus type 1 does not cause illness in either people or animals. The full FDA summary and recommendations are available at www.fda.gov/NewsEvents/PublicHealthFocus/ucm205585.htm

Over the next four to six weeks, the FDA will utilize an advisory committee to review data and make recommendations regarding Rotarix vaccine and further recommendations on the use of rotavirus vaccine in the United States. In the interim, the FDA recommends that healthcare professionals in the United States temporarily suspend the use of Rotarix. Healthcare providers should maintain existing inventory of Rotarix vaccine until further information is available from the FDA. Rotarix vaccine must be stored in the refrigerator and maintain a temperature range of 2-8°C or 35-46°F.

Healthcare providers should continue to vaccinate against rotavirus utilizing RotaTeq vaccine, manufactured by Merck. Patients who have received a complete two dose series of Rotarix do not need additional doses of vaccine. Patients who have received one dose of Rotarix should complete the series with two additional doses of RotaTeq given at an interval of at least one month between doses.

Existing orders of Rotarix vaccine submitted to the Iowa Vaccine for Children (VFC) Program will be substituted with RotaTeq vaccine. Healthcare providers should assess their need for rotavirus vaccine and place orders accordingly for RotaTeq. At this time, ordering for Rotarix has been disabled in the Immunization Registry Information System (IRIS).

Additional details will be provided as they become available. If you have further questions please contact the Iowa Department of Public Health, Immunization Program at 1-800-831-6293.