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TO: North Carolina Immunization Program (NCIP) Participants

FROM: Beth Rowe-West, R.N., B.S.N., Head
Immunization Branch

SUBJECT: *Urgent:* Update on ROTARIX® Vaccine

The purpose of this memo is to alert providers of new information regarding ROTARIX® vaccine, manufactured by Glaxo Smith Kline (GSK). The U.S. Food and Drug Administration (FDA) has learned that DNA from porcine circovirus 1 (PCV1) is present in ROTARIX® vaccine. PCV1 is not known to cause illness in humans or animals, and there is no evidence at this time that this finding poses a safety risk. Children who received ROTARIX® need no additional medical follow-up. While the agency is learning more about the situation, FDA is recommending that clinicians and public health professionals in the United States temporarily suspend the use of ROTARIX®. FDA will keep the public and the clinical community updated as more information becomes available.

For additional background information and Questions and Answers for patients and providers, go to the FDA web site at: http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205539.htm

The NCIP is recommending that providers immediately suspend the use of ROTARIX®, continue to store the vaccine properly, mark it "Do Not Use" and instead administer the other licensed rotavirus vaccine product, RotaTeq®, manufactured by Merck. Providers who do not have RotaTeq® in stock may order it from the NCIP at this time. The Centers for Disease Control and Prevention (CDC) is working with Merck to obtain additional RotaTeq®, as well as having discussions about Merck's ability to supply the overall U.S. market during the temporary suspension of ROTARIX®. We will provide updated supply information as soon as it becomes available.

More information regarding this ROTARIX® issue will be shared with providers when the FDA makes it available.

For additional information, contact the NCIP Help Desk at 1-877-873-6247.

Cc: Jeff Engel, Joy Reed, Megan Davies, Ann Nance, Zack Moore, Maclyn Powell, NCIB, NCIB Field Services, SMT, Jessica Gerdes, Steve Shore, Vaccine Manufacturers, Greg Griggs