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TO: California Vaccines for Children (VFC) Program Providers

FROM: John Talarico, DO, MPH, Chief *Talarico, DO*  
Immunization Branch  
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SUBJECT: FDA Revises Recommendations for Rotarix®

As a precaution, the U.S. Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) recommended in March that providers in the United States temporarily suspend their use of the GSK rotavirus vaccine, Rotarix® while they investigated the detection of DNA from a pig virus (porcine circovirus type 1) in the vaccine. Recently DNA from porcine circovirus types 1 and 2 were also identified in RotaTeq®. The U.S. Food and Drug Administration has carefully reviewed its recommendations for rotavirus vaccines for the prevention of the disease in infants and has determined that it is appropriate for clinicians and health care professionals to resume the use of Rotarix® and to continue the use of RotaTeq®.

The agency reached its decision based on a careful evaluation of information from laboratory results from the manufacturers and the FDA's own laboratories, a thorough review of the scientific literature, and input from scientific and public health experts, including members of the FDA's Vaccines and Related Biological Products Advisory Committee that convened on May 7, 2010 to discuss these vaccines. FDA has no evidence that either PCV1 or PCV2 poses a safety risk in humans, and notes that neither is known to cause infection or illness in humans. In addition, both rotavirus vaccines have strong safety records, including clinical trials involving tens of thousands of patients as well as clinical experience with millions of recipients. Additional information can be found on the FDA website at:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205539.htm>  
mVaccine Ordering

In our initial communication, providers were instructed to mark Rotarix® doses "Do Not Use" and keep them stored properly in the refrigerator to maintain their potency until a decision has been made. Now that the FDA has recommended that providers should resume use of Rotarix®, providers should go ahead and start using these doses now.

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For providers that have both Rotateq® and Rotarix®, we ask that you finish using both products (paying attention to expiration dates) and then again choose which one product you will continue to use in your practice. Please make sure to develop a clear plan if you will be transitioning from one formulation to another. Providers should review ACIP recommended schedules and proper vaccine storage, preparation, administration, and documentation with their staff if they currently have both rotavirus vaccine formulations.

## Questions

If you have any questions, please call your VFC Representative or the VFC Program at 877-243-8832 (877-2GET-VFC). You can also visit our website at [www.eziz.org](http://www.eziz.org).

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