



IMPORTANT MESSAGE

California Department of Public Health
Immunization Branch
Vaccines for Children (VFC) Program
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FDA determines it is appropriate to resume the use of Rotarix[®] vaccine in children

Dear VFC Provider,

On March 23, 2010, the Vaccines for Children (VFC) Program notified all providers of a precautionary temporary suspension issued by Food and Drug Administration (FDA) for the administration of GSK's rotavirus vaccine, Rotarix[®]. This came as a result of the findings of an independent research laboratory that detected fragments of Porcine Circovirus (PCV), type 1, in this vaccine.

Providers were instructed to temporarily quarantine the vaccine in their refrigerator for a period of 4-6 weeks, until FDA could evaluate the laboratory findings and findings generated by vaccine manufacturers and FDA's own laboratories. Data was reviewed in concert with a thorough review of the scientific literature and input from scientific and public health experts during a convened meeting on May 7, 2010.

FDA Revised Recommendations

Based on the information presented, FDA found no evidence that PCV1 or PCV2 posed a safety risk in humans and determined that **it is appropriate to resume the use of Rotarix[®] vaccine and continue the use of RotaTeq[®]**. Both rotavirus vaccines have strong safety records and provide substantial benefits, including the prevention of thousands of hospitalizations as a result of serious rotavirus disease. You may find a copy of a VFC Provider notification at www.eziz.org.

Rotarix[®] Vaccine Supply

- Providers with quarantined doses of Rotarix[®] in their refrigerator may go ahead add these doses to their vaccine inventory for routine use.
- 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.
- Ordering of Rotarix[®] vaccine has been resumed through VFC. An updated copy of the VFC Order Form is available at VFC's Website, www.eziz.org.

If you have any questions about this process, please call VFC's Customer Service at 1-877-243-8832.

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