



Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

Florida Vaccines for Children (VFC) Program

IMPORTANT MESSAGE

Important: Temporary Suspension of Rotarix Vaccine

Dear VFC Program Participants:

The Food and Drug Administration (FDA) recommends that healthcare practitioners temporarily suspend use of the Rotarix vaccine for rotavirus immunization in the United States while the agency learns more about components of an extraneous virus detected in the vaccine. There is no evidence at this time that this finding poses a safety risk.

Routine testing of Rotarix vaccine by an independent U.S. academic research team detected PCV1 genetic material (Porcine Circovirus 1) in the vaccine. PCV1 is not known to cause illness in humans or other animals. Rotarix has been studied extensively and found to have an excellent safety record. Because available evidence supports the safety of Rotarix, no medical follow-up is needed for patients who have been vaccinated with Rotarix.

This temporary suspension will enable further evaluation of the vaccine by the FDA and CDC while not losing its efficacy.

Vaccine Storage and Handling:

- Isolate the Rotarix vaccine while maintaining the proper cold chain in anticipation of the cancellation of the suspension.
- Do not return or discard the vaccine.

It is important to note:

- The vaccine is effective.
- Children who completed the 2 dose series are considered protected.
- There is no need to re-administer any Rotarix doses.

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- If the Rotarix vaccine series has not been completed, complete the series with 2 doses of RotaTeq at the appropriate intervals.
- There is no need to test children who received the vaccine.

The FDA press release is available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm205625.htm>. The FDA has established a website with information regarding the rotavirus vaccine at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm205585.htm#hcpFDA>. This website will provide updates as more information becomes available from the FDA.

VFC Program providers are advised to keep all Rotarix vaccine inventory as viable vaccine.

- **Do not return** any Rotarix vaccine to McKesson Specialty.
- Rotarix vaccine must be kept refrigerated and separated from VFC Program vaccine.

VFC Program providers will be able to order RotaTeq vaccine to use in place of Rotarix inventory. Use the attached *RotaTeq Vaccine Order Form* to indicate current levels of inventory for Rotarix and RotaTeq vaccines. Rotarix inventory will be supplemented with RotaTeq vaccine.

VFC Program providers who use only RotaTeq vaccine are not affected by this direction and are advised to continue using RotaTeq.

Please note that, until notified, orders for rotavirus vaccine will be filled with RotaTeq vaccine.

The Bureau will send out any updates as they become available.

This important announcement is sent on behalf of Charles H. Alexander, Chief, Bureau of Immunization.

Susan Lincicome, M.S.
Director, Florida SHOTS



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Vaccines for Children (VFC) Program RotaTeq® Vaccine Order Form

PIN Number:	
Provider Name:	
Shipping Address:	
Telephone Number:	
Contact Person:	
Fax Number:	

Use this form to request RotaTeq vaccine to supplement your current Rotarix inventory.

For VFC Use Only Doses Approved	Name of the Vaccine	Packaging/ Presentation	Number of Doses Currently In Stock
	RotaTeq® (Merck)	10 single-dose tubes per package	
n/a	Rotarix® (GSK)	10 single-dose tubes per package	

***NOTE:** The VFC Program will make every effort to accommodate your request, given the availability of the vaccine.

VFC Contact Information:

Telephone: (800) 483-2543; Fax: (850) 245-4734

Email: FloridaVFC@doh.state.fl.us

Website: <http://www.ImmunizeFlorida.org/vfc/index.html>

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