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Florida Vaccines for Children (VFC) Program

IMPORTANT MESSAGE

Important: FDA Revises Recommendations for Rotavirus Vaccines

Dear VFC Program Participants:

The Bureau of Immunization is pleased to bring to your attention this important updated information concerning licensed vaccines against rotavirus, released by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention.

On May 14, 2010, the FDA revised its recommendations for rotavirus vaccines for the prevention of the disease in infants and has determined that it is appropriate for clinicians and healthcare 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.

The FDA also considered the following in its decision:

- Both vaccines have strong safety records, including clinical trials involving tens of thousands of patients as well as clinical experience with millions of vaccine recipients.
- The FDA has no evidence that PCV1 or PCV2 pose a safety risk in humans, and neither is known to cause infection or illness in humans.
- The benefits of the vaccines are substantial, and include prevention of death in some parts of the world and hospitalization for severe rotavirus disease in the United States. These benefits outweigh the risk, which is theoretical.

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Information for parents and caregivers is available on the FDA website at:
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205547.htm>

Information for healthcare providers is available on the FDA website at:
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205548.htm>

Centers for Disease Control and Prevention's website and links regarding vaccines against rotavirus:
<http://www.cdc.gov/vaccines/vpd-vac/rotavirus/default.htm#FDA>

CDC has posted a revised Rotavirus VIS at:
<http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-rotavirus.pdf>

Healthcare providers should periodically access the VIS electronically and print out a supply for routine distribution. If necessary, bureau staff can FAX copies to providers without internet access. Please contact VFC staff using the information below.

Links to the latest vaccine information statements should be bookmarked from:

- Bureau of Immunization website: <http://www.immunizeFlorida.org/community/vis.htm>
- Centers for Disease Control and Prevention website:
<http://www.cdc.gov/vaccines/pubs/vis/default.htm>
- Immunization Action Coalition (primary source for translated VIS) website:
<http://www.immunize.org/vis/#index>

Rotarix is now available for ordering through the VFC Program. Providers who have viable Rotarix inventory can use the vaccine. For questions regarding vaccine orders please contact your VFC representative at (800) 483-2543.

If you have questions regarding recommendations on the use of rotavirus vaccines, please contact Laura Rutledge at (850) 245-4342.

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