

FDA Revises Recommendations for Rotavirus Vaccines

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 RotaTeg[®].

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.

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>



vis-rotavirus.pdf
(106 KB)

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 my 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>

Please distribute this important update to colleagues, members, coalitions, and partners who provide immunizations or who have an interest in the promotion of vaccines. Please place this information prominently on your website. Contact Laura Rutledge, Robert Griffin, or John Keegan of my staff for questions regarding vaccine recommendations, vaccine orders and vaccine information statements respectively, at 850-245-4342.