



Charlie Crist
Governor

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

March 6, 2009

Dear Vaccines for Children (VFC) Program Participants:

Important Pediatric Hepatitis B Vaccine Supply Update

The Florida Department of Health (DOH), Bureau of Immunization is providing the following important update from the Centers for Disease Control and Prevention (CDC) concerning the supply of pediatric hepatitis B vaccine.

In February 2009, the CDC received notice from both *Merck & Co.* and *GlaxoSmithKline* that the vaccine manufacturers experienced an inability to fill orders for pediatric hepatitis B vaccine, resulting in backorders.

The CDC and the vaccine manufacturers have discussed the United States' pediatric hepatitis B vaccine supply. Based upon these discussions, the CDC has released monovalent hepatitis B vaccine doses from its pediatric vaccine stockpiles, which contain both the pediatric formulations of Recombivax® (*Merck & Co.*) and Engerix-B® (*GlaxoSmithKline*). The CDC has provided these doses to the respective manufacturers to fill public and private sector orders through March 2009.

- *Merck & Co.* expects its supply of the pediatric formulation of Recombivax® to be limited throughout the remainder of 2009, and does not expect to return to a full supply until some time in 2010.
- *Merck & Co.* may be able to produce some additional doses of the pediatric formulation of Recombivax®, available for distribution during the second quarter of 2009. *Merck & Co.* will communicate with customers and public health authorities as additional information becomes available.
- *GlaxoSmithKline* expects to be able to meet the United States' market demand for monovalent hepatitis B vaccine through the end of May 2009 with its pediatric formulation of Engerix-B®
- *GlaxoSmithKline* is working closely with the CDC to determine how much additional monovalent pediatric hepatitis B vaccine can be supplied to the United States' market during the second half of 2009.
- *GlaxoSmithKline* also produces the hepatitis B-containing combination vaccine Pediarix® (DTaP-Hep B-IPV), which is in good supply.

You can find updates on vaccine shortages and delays on the CDC's website at:
<http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm>.

You can find additional information regarding regulatory issues related to vaccine supply on the United States Food and Drug Administration (FDA) website at:
<http://www.fda.gov/cber/shortage/shortage.htm>.

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Please note that the CDC's recommended immunization schedule for pediatric hepatitis B vaccine has not changed. You can find the recommended immunization schedule on the CDC's website at: <http://www.cdc.gov/vaccines/recs/schedules/default.htm>.

The VFC Program's Current Pediatric Hepatitis B Vaccine Supply

As of March 4, 2009, the VFC Program has experienced backorders of the syringe presentation of the pediatric formulation of Engerix-B®. However, the program has not experienced backorders of the vial presentation of the pediatric formulations of Engerix-B® and Recombivax®.

The Bureau of Immunization will provide updates on the pediatric hepatitis B vaccine supply as more information becomes available.

Please widely distribute this information to all staff, colleagues, members, coalitions, and partners with an interest in the provision of pediatric hepatitis B vaccine. Please contact Robert Griffin, VFC Program Coordinator, at (800) 483-2543 if you have any questions regarding the VFC Program's vaccine supply. For questions regarding the CDC's recommendations for the use of vaccines, please contact Phyllis Yambor, R.N., Bureau of Immunization, at (850) 245-4342.

Sincerely,

Signature on file

Charles H. Alexander, Chief
Bureau of Immunization
Division of Disease Control

CHA/rg/sdh

cc: Phyllis Yambor, R.N., Executive Community Health Nursing Director,
Bureau of Immunization
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