

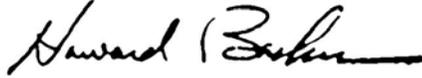


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DATE: December 5, 2007 IZB-FY0708-05
 TO: Public and Private Sector Vaccines for Children (VFC) Providers
 FROM: Howard Backer, M.D., M.P.H., Chief Immunization Branch 
 SUBJECT: Haemophilus Influenzae, type B (Hib) Shortage

Merck & Co., Inc. has reported that PedvaxHIB[®] is unavailable for shipment. Merck expects PedvaxHIB[®] to be available sometime in the first quarter of 2008; however, the exact timing is dependent upon resolution of a manufacturing issue. There are currently adequate amounts of ComVax[®] (Hib/Hepatitis B) to meet historical demand, but not to meet additional demand.

The VFC Program has stopped accepting orders for PedvaxHIB[®]. Orders received by the VFC Program requesting PedvaxHIB[®], will be substituted with Sanofi Pasteur's ActHIB[®]. A revised order form that shows PedvaxHIB[®] as unavailable is included with this mailing.

The recommended schedule for Hib vaccine includes 3 or 4 doses by two years of age, and is dependent upon on the specific Hib vaccine product used. The primary series of PRP-OMP (PedvaxHIB[®]) is two doses; whereas PRP-T (ActHIB[®]) requires a three dose primary series (see Table 1).

Table 1. Primary and Booster Hib Vaccination Schedule

| Vaccine | 2 Months | 4 Months | 6 Months | 12-15 Months |
|--|----------|----------|----------|--------------|
| PRP-T (ActHIB [®]) | Dose 1 | Dose 2 | Dose 3 | Booster |
| PRP-OMP (PedvaxHIB [®] or ComVax [®]) | Dose 1 | Dose 2 | | Booster |

When it becomes necessary to complete a series with ActHIB[®] that was started with PedvaxHIB[®] or ComVax[®], the following guidelines should be followed:

- If the first two doses of PedvaxHIB[®] or Comvax[®] were administered as the primary series, ActHIB[®] should be administered for the booster dose at age 12-15 months.

- If only one dose of PedvaxHIB[®] or Comvax[®] has been administered, the primary series should be completed with two additional doses of ActHIB[®] followed by a booster dose at age 12-15 months.

The minimum interval between Hib vaccine doses in the primary series is 4 weeks; the recommended interval between the primary series and the final dose is 8 weeks. The minimum age for the booster dose is 12 months. Please consult the Catch-Up Immunization Schedule (found on page 3 of the 2007 Recommended Immunization Schedule for the timing of doses for children who start late or are behind:

<http://www.cdc.gov/vaccines/recs/schedules/downloads/child/2007/child-schedule-color-print.pdf>

Please note that ActHIB[®] vaccine is a lyophilized powder which requires reconstitution with the saline diluent supplied with the vaccine before administration:

- It is very important to use the vaccine diluent supplied by the manufacturer, which is a 0.4% sodium chloride solution, not sterile water. If a sterile water diluent is used by mistake, the Centers for Disease Control and Prevention (CDC) recommends repeating the affected vaccine dose(s).
- The ActHib[®] vial presents a challenge when attempting to retrieve all the reconstituted vaccine. It requires that the needle be inserted carefully and straight into the middle of the vial stopper (Figure 1). If the needle is inserted at an angle, it touches the edge of the stopper and retrieving all of the reconstituted vaccine is difficult (Figure 2).



Figure 1. Correct



Figure 2. Incorrect

We understand and regret the inconvenience involved in switching to a different product with a different schedule. We will notify you as soon as PedvaxHIB[®] becomes available again.

For a listing of additional products that are currently unavailable through VFC, please visit the VFC program's website at www.vfcca.org.

QUESTIONS?

If you have any questions, please contact VFC Customer Service at 1-877-243-8832 (1-877-2GET-VFC).

Enclosures: VFC Vaccine Order Form, CDPH 8501 (11/07)

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