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IMPORTANT PRESCRIBING INFORMATION

**SUBJECT: DOSAGE AND ADMINISTRATION CHANGE FOR HIBERIX®
[HAEMOPHILUS B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE)]**

December 16, 2010

Dear Healthcare Professional:

GlaxoSmithKline (GSK) Biologicals would like to inform you of a change to the Dosage and Administration section of the Prescribing Information for Hiberix® [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)]. HIBERIX is a vaccine indicated for active immunization as a booster dose for the prevention of invasive disease caused by *Haemophilus influenzae* type b. HIBERIX is approved for use in children 15 months through 4 years of age (prior to the fifth birthday).

HIBERIX is supplied in a vial of lyophilized vaccine to be reconstituted with an accompanying saline diluent that is provided in a prefilled syringe. GSK received inquiries from healthcare professionals as to whether they should use the prefilled syringe provided or switch to a new, graduated syringe to administer HIBERIX following reconstitution. GSK has identified the basis for this question to be the diagram in the Dosage and Administration section of the Prescribing Information, which illustrates the withdrawal of 0.5 mL of reconstituted vaccine from the vial back into the syringe, which is not graduated.

In order to clarify that after reconstitution the entire contents of the vial (approximately 0.5 mL) should be withdrawn back into the non-graduated syringe, the Prescribing Information has been revised as follows:

2 DOSAGE AND ADMINISTRATION

2.1 Reconstitution Instructions

HIBERIX is to be reconstituted only with the accompanying saline diluent. The reconstituted vaccine should be a clear and colorless solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

(*continued on reverse*)

Figure 1. Cleanse vial stopper. Attach appropriate needle to accompanying prefilled syringe of saline diluent and insert into vial.

Figure 2. Transfer entire contents of prefilled syringe into vial. With needle still inserted, vigorously shake the vial.

Figure 3. After reconstitution, withdraw entire contents of vial (approximately 0.5 mL) and administer by intramuscular injection.

After reconstitution, Hiberix® [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)] should be administered promptly or stored refrigerated between 2° and 8°C and administered within 24 hours. If the vaccine is not administered promptly, shake the solution vigorously again before injection.

Previously Vaccinated Children

Children previously vaccinated with HIBERIX in accordance with the Indications and Usage and the diagram in the Dosage and Administration sections in the prior Prescribing Information should not be revaccinated.

The updated Prescribing Information can be found online at http://www.gsksource.com/gskprm/htdocs/documents/HIBERIX.PDF.

In order for GSK to continue to monitor the safety of HIBERIX, we encourage healthcare professionals to report suspected adverse events to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 (www.vaers.hhs.gov), or GSK at 1-888-825-5249. If you have any questions concerning medical or other issues, please contact the GSK Response Center at 1-888-825-5249.

FDA has reviewed this letter and agrees with the letter's contents.

We appreciate your immediate attention to this change in the Dosage and Administration section of the Prescribing Information for HIBERIX and regret any inconvenience caused by this action.

Sincerely,

Leonard R. Friedland, MD

Leonard Friedland, MD
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