



AUG 12 1998

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Dear Colleague:

To date, the only licensed combination vaccine containing Haemophilus influenzae type b (Hib) conjugate vaccine and diphtheria and tetanus toxoid and acellular pertussis (DTaP) vaccine is for use in toddlers (age 15-18 months of age). We have become aware that in certain clinical settings, licensed Hib conjugate vaccines and DTaP vaccines are being combined for administration as a single injection in infants 2, 4, and 6 months of age. These vaccines (DTaP/Hib) have not been licensed for combination use in the primary immunization series in infants. Clinical studies in infants conducted under Investigational New Drug Applications (INDs) have demonstrated that using some combination products may induce a suboptimal immune response to the Hib component. Therefore, only products licensed and labeled for use in the primary immunization series should be used in infants.

The following is consistent with the currently approved labeling for Haemophilus influenzae type b (Hib) conjugate vaccines:

For the immunization of children less than 15 months of age:

Any licensed Hib conjugate vaccine may be given concurrently in separate sites with DTaP or Diphtheria and Tetanus Toxoids and Whole Cell Pertussis Vaccine (DTP) vaccine, according to the package insert. Alternatively, any of the licensed combination products containing DTP and Hib conjugate vaccine may be used. Please note that ACIP has a stated preference for products containing an acellular pertussis component.

For the immunization of children 15 months of age or older:

Any licensed Hib conjugate vaccine may be given concurrently in separate sites with DTaP or DTP vaccine. Alternatively, any of the licensed combination products containing DTP and Hib or TriHIBit™ [ActHIB™ (Hib conjugate vaccine) reconstituted with Tripedia™ (DTaP)] may be used. Please note that ACIP has a stated preference for products containing an acellular pertussis component.

In the event that an infant has received an unlicensed DTaP/Hib combination product, please contact the Immunization Hotline at the Centers for Disease Control and Prevention (1-800-232-2522 for English and 1-800-232-0233 for Espanol) as to further immunization actions which may be required.

Sincerely yours,

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