



North Carolina Department of Health and Human Services
Division of Public Health – Women’s & Children’s Health Section
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Michael F. Easley, Governor

Dempsey Benton, Secretary

November 20, 2008

MEMORANDUM

TO: Universal Childhood Vaccine Distribution Program Participants

FROM: Beth Rowe-West, RN, BSN, Head
Immunization Branch

SUBJECT: Update on Shortage *Haemophilus influenzae* type b (Hib) Vaccine

The purpose of this memo is to update providers on the status of the nationwide shortage of *Haemophilus influenzae* type b (Hib) vaccine. On October 17, 2008, Merck & Company, manufacturer of PedvaxHIB[®], recalled in December, 2007, released a public statement announcing that **they will not return to the Hib vaccine market until mid-2009** due to additional manufacturing changes that require regulatory filings with the Food and Drug Administration (FDA).

At this time, Centers for Disease Control and Prevention (CDC) recommendations for Hib vaccine are unchanged. The recommendation to withhold the booster dose of Hib vaccine remains in effect. CDC will closely monitor Hib vaccine supply levels and will make appropriate changes to the recommendations if the need arises.

Supplies of ActHIB[™], Pentacel[™], and PedvaxHIB[®] are allocated to states by the CDC. We expect this shortage to continue for at least the next eight months. During this time, we expect allocations of ActHIB[™] to decline. It is impossible for most North Carolina providers to vaccinate their patients against Hib disease using only single-antigen Hib vaccine. Therefore we will continue to fill Hib orders with both ActHIB[™] and Pentacel[™] without prior notification. Until supplies of Hib vaccine return to normal levels, **providers must utilize all Hib-containing vaccines available to protect their patients from Hib disease.**

The attached table provides guidance for substituting Pentacel[™] for other products. For the complete guidance on use of Pentacel[™], go to: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5739a4.htm?s_cid=mm5739a4_e

The DTaP/IPV and ActHIB[™] components of Pentacel[™] should be **clearly labeled and stored in close proximity** in your refrigerator. Immunization errors have occurred because staff have given only the DTaP/IPV component and forgotten to use this as the diluent for the ActHIB[™] component. This type of error results in wasted doses of ActHIB[™] and may result in children not being adequately protected.

If you need additional information or assistance please contact your Regional Immunization Nurse Consultant or the Customer Service Staff at 1-877-873-6247.

Attachment

cc:	SMT	Regional Immunization Staff	Vaccine Manufacturers
	Central Office Staff	Joy Reed	Maelyn Powell
	Steve Shore	Peter Graber	Greg Griggs

Integrating Pentacel into your vaccine schedule during the continued Hib shortage & deferral of the 15-18 month dose of Hib for healthy children—these are examples only

Example 1: Schedule for Hep B, Hib, IPV and DTaP for children who have already received Pediarix at 2 months only

	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B			Hep B		
Hib	Hib			DTaP	DTaP
IPV					IPV
Pentacel†		Pentacel†			

OR

Example 2: Schedule for Hep B, Hib, IPV and DTaP for children who have already received Pediarix at 2 and 4 months

	2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
Hep B			Hep B		
Hib	Hib	Hib			
IPV				DTaP	DTaP
Pentacel†		Pentacel†			

† Pentacel contains DTaP; Hep B, and IPV
 ‡ Pentacel contains DTaP; Hib; and IPV

The lot numbers of the Pentacel™ components are linked so that the lot number of one component will identify the lot number of the other component. If Pentacel™ is used as supplied there is no need to record both numbers, the carton lot number or tear-off lot number label on the hib (which are identical) is adequate and identifies all components. However, if the DTaP-IPV component is used to reconstitute a vial of ActHIB™ that is supplied as Pentacel™, both numbers should be recorded.

Supplies are sufficient to reintroduce the booster dose of Hib at 15-18 months of age for all children the schedule could look like this for Hib, IPV and DTaP—these are examples only

Rule for Hep B, Hib, IPV and Dtap for children who have already received Pediarix at 2 months only

2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
3		Hep B		
	Hib			DTaP
	Pediarix*			
		Pentacel†	Pentacel†	

Rule for Hep B, Hib, IPV and Dtap for children who have already received Pediarix at 2 and 4 months

2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
3		Hep B		
	Hib			DTaP
	Pediarix*			
		Pentacel†	Pentacel†	

Rule for Hep B, Hib, IPV and Dtap for children receiving only Pentacel

2 mos.	4 mos.	6 mos.	15-18 mos.	4-6 years
3		Hep B		
				DTaP
	Pentacel†	Pentacel†	Pentacel†	

*Pediarix contains DTaP; Hep B, and IPV
 †Pentacel contains DTaP; Hib; and IPV