



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

December 21, 2007

TO: Universal Childhood Vaccine Distribution Program Participants

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

SUBJECT: Update on PedvaxHIB Recall

This memo is to provide instructions on returning the recalled state-supplied Hib vaccine. The following lot numbers of PedvaxHIB® vaccine should be returned by following the instructions below.

Recalled lot numbers:

0259U 0677U 0819U

Instructions for Returning Recalled Vaccine

1. If you have not received shipping materials, call Stericycle at 1-800-668-4391 to request a VFC Business Reply Card, prepaid shipping labels, and packing slip - (be sure to indicate the number of vials being returned).
2. Return all remaining doses of the product and documentation identified above using the prepaid shipping labels to:

Stericycle, Attn: Merck Returns
2670 Executive Drive, Suite A
Indianapolis, IN 46241

3. Complete and return a Wasted/Expired Vaccine Report to the North Carolina Immunization Branch. Those providers using NCIR can run the report automatically. Those providers not on NCIR can obtain a copy of the form at the following website: <http://www.immunizenc.org/forms.htm>.

This return system has been coordinated by CDC and Merck. Please ensure that you request enough supplies to return all vials of affected vaccine.

Please **do not** return the recalled Hib vaccine to the Immunization Branch. The vaccine **must be** returned using the above system to ensure North Carolina receives credit for all returned doses.

Interim Recommendations for the Use of Hib Conjugate Vaccines

On December 19, 2007, the CDC released an **MMWR Dispatch** containing important information on new interim recommendations for administering Hib vaccine to children.

A copy of this dispatch is attached, and may also be accessed on the web at

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm56d1219a1.htm>. **Please read this information carefully and keep a copy for your reference.** All the necessary information you need to be aware of regarding administration of Hib vaccine is contained in this MMWR Dispatch.

The basic interim recommendations are as follows:

- Defer administering the routine Hib vaccine booster administered at age 12-15 months except for specified high-risk groups.
- Certain children at increased risk for Hib disease, including children with asplenia, sickle cell disease, human immunodeficiency virus infection, and certain other immunodeficiency syndromes, and malignant neoplasms should continue to receive the full routinely recommended schedule including the 12-15 month booster dose.
- American Indian(AI) and Alaska native (AN) children should also continue to receive the full routinely recommended schedule including the 12-15 month booster dose.
- Providers who currently use PRP-OMP-containing Hib vaccines (PedvaxHib and Comvax) to serve predominantly AI/AN children in AI/AN communities should continue to use only PRP-OMP-containing Hib vaccines.
- When a patient receives a combination of the two types of Hib vaccine during the primary series, the primary series automatically becomes a three dose series. Some examples of possible scenarios involving combinations of types of Hib vaccines in the primary series are:

2 mos PedvaxHIB; 4 months Pedvax HIB	primary series complete; no booster during interim unless high-risk.
2 mos Pedvax HIB; 4 months ActHIB	1 more dose of ActHIB at 6 months to complete primary series; no booster during interim unless high risk
All doses ActHIB	2; 4; and 6 months to complete the primary series, no booster during interim

Please read the MMWR Dispatch for further details. Information on Hib vaccine schedules is also found in the CDC Pink Book.

Hib Vaccine Availability

We have received an allocation of the federal vaccine stockpile from the CDC, and for those practices affected directly by this recall, we have begun to process orders of Hib vaccine prioritized by provider need. If you received a call from Branch staff on Thursday, December 13th or Friday, December 14th, there is no need to place an order for the Hib vaccine you were forced to return. For those practices not affected directly by this recall, there may be little or no Hib available for order until February.

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

cc: SMT
Central Office Staff
Steve Shore
Vaccine Manufacturers

Regional Immunization Staff
Joy Reed
Peter Graber

