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Voluntary Recall of Certain Lots of PedvaxHIB® [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] and COMVAX® [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine] / NDC 0006-4897-00 and 0006-4898-00

December 11, 2007

Dear Customer, Doctor, Healthcare Provider:

Merck & Co., Inc. ("Merck") has initiated a voluntary recall in the United States for ten lots of PedvaxHIB® [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] and two lots of COMVAX® [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine]. This letter is being written to inform you of this recall, and to advise you not to administer any vaccine from the vaccine lots being recalled. The lots that are being recalled are:

PRODUCT DESCRIPTION	LOT #	EXP. DATE
PedvaxHIB®	0677U	11 January 2010
PedvaxHIB®	0820U	12 January 2010
PedvaxHIB®	0995U	16 January 2010
PedvaxHIB®	1164U	18 January 2010
PedvaxHIB®	0259U	17 October 2009
PedvaxHIB®	0435U	18 October 2009
PedvaxHIB®	0436U	19 October 2009
PedvaxHIB®	0437U	19 October 2009
PedvaxHIB®	0819U	09 January 2010
PedvaxHIB®	1167U	10 January 2010
COMVAX®	0376U	05 January 2010
COMVAX®	0377U	08 January 2010

The affected doses were distributed starting in April 2007. No other lots of PedvaxHIB® or COMVAX® and no other Merck products are affected by this recall.

The company is taking this voluntary action due to the fact that we cannot assure sterility for these specific vaccine lots. The potential contamination in these specific lots was identified as part of our standard evaluation of our manufacturing processes. In routine testing of the vaccine manufacturing equipment used to produce PedvaxHIB® and COMVAX®, Merck identified an issue that creates the potential for microorganisms to survive the sterilization process. Specifically, during this evaluation, Merck identified the presence of *Bacillus cereus*. Sterility tests of the vaccine lots themselves have not found any contamination. The potential for contamination of any individual vaccine is low, and, if present, the level of contamination would be low. However, because we cannot guarantee the sterility of these specific lots of vaccine, we are conducting this recall.

Based on this information, Merck recommends that you immediately discontinue use of any of the affected lots. If an individual was vaccinated with a vial of PedvaxHIB® or COMVAX® that contained *B. cereus* or other microorganisms, there is a risk that they could develop localized or disseminated infections. By analogy to other *B. cereus* infections, immunocompromised individuals may be at the greatest risk for these infections.

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No potency concerns have been identified for these vaccine lots. Individuals who received vaccine from these lots should complete their immunization series with a Haemophilus b conjugate-containing vaccine not affected by this recall, but do not need to be revaccinated to replace a dose they received from a recalled lot.

Merck is working closely with the Food and Drug Administration and the Centers for Disease Control and Prevention to inform affected customers of this recall action. If you have purchased any of these affected lots directly from Merck, please return the vaccine to us according to the procedure described below; if you did not purchase directly from Merck, please return the vaccine to your distributor. In addition, if you have further distributed these lots of PedvaxHIB® and COMVAX® to other health care providers or offices, please contact them to ensure that all affected product is returned.

In order to ensure an effective recall and return process, it is important that you do the following for product purchased directly from Merck:

1. Please complete the enclosed Business Reply Card and the Packing Slip labeled "Non-VFC Vaccine" including entry of number of vials returned.
2. Mail the postage paid Business Reply Card even if you do not have any of the product identified above to ensure accountability.
3. Return all of the product identified above and the Packing Slip using the prepaid Shipping Labels to:

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

Credit for product will be issued at the price in effect for purchase directly from Merck at the time of purchase.

For any Vaccines for Children (VFC) vaccine from the affected lots, please do the following:

1. Please complete the Business Reply Card and the Packing Slip labeled "VFC Vaccine" including entry of number of vials returned.
2. Mail the postage paid Business Reply Card even if you do not have any of the product identified above to ensure accountability.
3. Return all of the product identified above and the Packing Slip using the prepaid Shipping Labels to:

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

If you have both non-VFC and VFC vaccine to return, you may ship them together in the same shipping container as long as you have accounted for the vials separately using the appropriate forms outlined above.

Please report any potentially vaccine-related adverse experiences to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 (or at www.vaers.hhs.gov), and to Merck at 1-800-672-6372. If you have any questions concerning medical or other issues, please contact the Merck National Service Center at 1-800-672-6372. The Prescribing Information for

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PedvaxHIB and COMVAX is available from the Merck National Service Center or at www.merckvaccines.com.

We appreciate your immediate attention to this recall and sincerely regret any difficulty caused by this action. Merck is committed to resolving this issue as quickly as possible and to ensure that our full line of vaccines is available to our customers as soon as possible.

Sincerely,

Mark Feinberg, MD, PhD, FACP
Vice President
Medical Affairs and Policy
Merck Vaccines and Infectious Diseases
Merck & Co., Inc.