



# IMPORTANT MESSAGE

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Immunization Branch  
Vaccines for Children (VFC) Program  
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[www.vfcca.org](http://www.vfcca.org)

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## VACCINE RECALL – PedvaxHIB and COMVAX

Merck & Co., Inc. ("Merck") has initiated a voluntary recall in the United States for ten lots of PedvaxHIB<sup>®</sup> [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] and two lots of COMVAX<sup>®</sup> [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 <sup>®</sup>	0677U	11 January 2010
PedvaxHIB <sup>®</sup>	0820U	12 January 2010
PedvaxHIB <sup>®</sup>	0995U	16 January 2010
PedvaxHIB <sup>®</sup>	1164U	18 January 2010
PedvaxHIB <sup>®</sup>	0259U	17 October 2009
PedvaxHIB <sup>®</sup>	0435U	18 October 2009
PedvaxHIB <sup>®</sup>	0436U	19 October 2009
PedvaxHIB <sup>®</sup>	0437U	19 October 2009
PedvaxHIB <sup>®</sup>	0819U	09 January 2010
PedvaxHIB <sup>®</sup>	1167U	10 January 2010
PedvaxHIB <sup>®</sup>	J2438	24 October 2009
COMVAX <sup>®</sup>	0376U	05 January 2010
COMVAX <sup>®</sup>	0377U	08 January 2010

The company is taking this voluntary action due to the fact that they cannot assure sterility for these specific vaccine lots. 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<sup>®</sup> or COMVAX<sup>®</sup> 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.

Vaccine lots are routinely tested prior to release. No contaminated vaccine has been identified and the recall is voluntary and precautionary.

If you are in possession of vaccine with any of these lot numbers you should discontinue use immediately. The VFC Program will communicate return procedures as soon as possible. Please note that the recall **only** applies to the lot numbers listed above.

Additional information will soon be available at [www.vfcca.org](http://www.vfcca.org).

For any questions, please call (877) 243-8832.