

BLASTFAX

Urgent Message Regarding Recall of COMVAX and PedvaxHIB Vaccines

As a result of a recent manufacturer-initiated precautionary vaccine recall, all providers are being asked to identify and follow instructions regarding the Merck vaccines listed below.

The lots that are being recalled are:

Product Description	Lot #	Expiration Date
PedvaxHIB®	0677U	11 January 2010
PedvaxHIB®	0820U	12 January 2010
PedvaxHIB®	0995U	16 January 2010
PedvaxHIB®	1164U	18 January 2010 DISTRIBUTED BY VFC
PedvaxHIB®	0259U	17 October 2009
PedvaxHIB®	0435U	18 October 2009 DISTRIBUTED BY VFC
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

No other lots of PedvaxHIB® or COMVAX® and no other Merck products are affected by this recall.

All inventory matching this description needs to be removed from your refrigerator(s) immediately. There is no need to maintain the cold chain for the recalled lot numbers. For vaccines received from the Georgia VFC Program, place the vaccine in a bag or box and clearly label "Do Not Use" and include a sheet of paper with the following information: VFC ID #, Inventory details (Lot Number(s), Expiration date, and number of doses). Include the word "RECALL" somewhere on the sheet. Immunization Program Consultants (IPC) will be arranging vaccine pick-ups of recalled vaccine. If you choose, you may also send vaccine back to the State warehouse as you would other wasted vaccines.

For affected vaccines that were purchased directly from Merck or a distributor, you will be receiving a Dear Customer letter from Merck with specific instructions for returns. The letter is available at the following link.

<http://www.gaaap.org/Immunization%20page/DearDoctorRecallLetter.pdf>

The recall, initiated by the manufacturer, is precautionary. Children who have been administered vaccine from the affected lots do not need to be revaccinated. The reason for the recall is that the company cannot assure sterility for these specific vaccine lots. The potential contamination in these specific lots was identified as part of Merck's standard evaluation of their manufacturing processes. Sterility tests of the vaccine lots themselves have not found any contamination.

Georgia Chapter

American Academy of Pediatrics

CDC has specifically stated that this recall is **not** in response to a health threat. There have been no findings of any contamination, but potential for contamination exists. Again, this is a precautionary recall.

We realize that this may likely cause a shortage of your Hib vaccine supply. The CDC has assured us that they are working on finding solutions to the vaccine supply issue, and we will provide additional information as soon as it becomes available.

If, after you remove the recalled vaccine, you still have Hib vaccine in stock, please be mindful that children at increased risk for *Haemophilus Influenzae type B* include: children with sickle cell disease, leukemia and malignant neoplasms, HIV and certain other immunocompromising conditions, asplenia, as well as American Indian and Alaska Native children. Vaccinating these children according to the recommended schedule is a high priority.

Remember that vaccination at all age levels should continue – a recall of particular lot numbers of one vaccine should not in any way affect the important day-to-day work of protecting Georgians from vaccine-preventable diseases.

More information on the recall, including Q & A, is available at: <http://www.cdc.gov/vaccines/recs/recalls/hib-recall-faqs-12-12-07.htm>. Please check this site regularly. Please keep yourself and your staff informed so that questions from concerned parents are met with knowledge and compassion.

For questions or concerns regarding this blastfax or any other immunization information, please contact the Chapter's Immunization Coordinator, Mike Chaney at (404) 881-5094 or mchaney@gaaap.org. You may also refer questions to the Georgia Immunization Program at (404) 657-3158.