



Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

December 14, 2007

Dear Vaccines for Children (VFC) Program Participants:

Important notice: Hib recall of eleven lot numbers

There have been many questions regarding yesterday's breaking news concerning Merck's recall of a number of Hib vaccine lot numbers. 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 listed below.

Product Description	Lot #	Expiration Date	Supplied By
PedvaxHIB®	0677U	11 January 2010	Merck/non-VFC
PedvaxHIB®	0820U	12 January 2010	Merck/non-VFC
PedvaxHIB®	0995U	16 January 2010	VFC
PedvaxHIB®	1164U	18 January 2010	Merck/non-VFC
PedvaxHIB®	0259U	17 October 2009	Merck/non-VFC
PedvaxHIB®	0435U	18 October 2009	Merck/non-VFC
PedvaxHIB®	0436U	19 October 2009	VFC
PedvaxHIB®	0437U	19 October 2009	Merck/non-VFC
PedvaxHIB®	0819U	09 January 2010	VFC
PedvaxHIB®	1167U	10 January 2010	Merck/non-VFC
PedvaxHIB®	J2438	24 October 2009	Merck/non-VFC
COMVAX®	0376U	05 January 2010	Merck/non-VFC
COMVAX®	0377U	08 January 2010	VFC

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

Please note:

- Merck has not identified potency concerns for these vaccine lots.
- Children who received vaccine from the affected lots **do not need to be revaccinated**.

Providers should immediately discontinue use of any of the affected lots and follow Merck's instructions for returning recalled vaccine (both VFC and non-VFC vaccine) to the manufacturer.

Merck is working closely with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) 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 Merck according to the procedure described below. If you did not purchase the vaccine 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 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.

VFC have submitted a list of VFC providers who received the recalled vaccines to Merck and they will be mailing the Business Reply Card and Packing Slip as indicated above.

We recommend all providers to check the FDA website at <http://www.fda.gov/> for future updates.

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For replacement purposes of VFC vaccine, fax a copy of the Vaccine Return Form (enclosed) to the VFC Program at (850) 245-4734. Please indicate the name of the vaccine and the number of doses returned to Merck. *Do not send any of these vaccines to the Department of Health Central Pharmacy.*

The following links also detail information about the recall:
<http://www.cdc.gov/vaccines/recs/recalls/hib-recall-faqs-12-12-07.htm>, and
<http://www.cdc.gov/vaccines/recs/recalls/hib-recall-faqs-12-12-07.htm>.

Please widely distribute this information to all staff, colleagues, members, coalitions, and partners with an interest in immunizations.

If you have any questions or comments concerning the revised guidelines, please contact Phyllis Yambor, R.N., Bureau of Immunization, at (850) 245-4342. For information regarding the VFC Program vaccine supply, please contact Robert Griffin or your VFC Program Representative at (800) 483-2543.

Sincerely,



Charles H. Alexander
Chief, Bureau of Immunization
Division of Disease Control
Department of Health

CHA/rg/ir
Enclosure

cc: Robert Griffin, VFC Program Coordinator, Bureau of Immunization
Bureau of Immunization Field Staff



VACCINE RETURN FORM

Florida Vaccines for Children Program

PIN # _____

- Return expired and/or unserviceable vaccine to:
DOH Central Pharmacy
2818 – B Mahan Drive
Tallahassee, FL 32308-5410
- Include this completed form with the vaccines being returned
- Do not send any documentation other than the VFC return form.
- **Do not return opened vials!** Dispose of them safely

Incident Date	Vaccine Name	Manufacturer	Lot Number	Number of Doses	Expiration Date	Reason

Name of County Health Department contact person:
Date: Telephone ()

Provide a written narration detailing the following in the space below.

1. Circumstances surrounding the loss
2. Remedial action to prevent recurrence

Please Note: This form may be typed or handwritten