



State of New Jersey

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December 13, 2007

TO: All New Jersey Providers
FROM: Angela Sorrells-Washington, Program Manager
Vaccine Preventable Disease Program

Barbara Giudici, Coordinator
Vaccines For Children Program

SUBJECT: Merck Vaccine Recall

The NJDHSS Vaccine Preventable Disease Program has just been notified late yesterday that Merck & Co. has initiated a voluntary recall for ten lots of Pedvax HIB® (Haemophilus b Conjugate Vaccine) and two lots of COMVAX® (Haemophilus b Conjugate and Hepatitis B (Recombinant vaccine). About 1 million doses of vaccine are being recalled as a precautionary measure by Merck due to the fact that they cannot assure sterility for these vaccine lots. The potential contamination in these specific lots was identified as part of the standard evaluation of their manufacturing process.

The following lots being recalled:

Table with 3 columns: PRODUCT DESCRIPTION, LOT #, EXP. DATE. Rows include PedvaxHIB® and COMVAX® with their respective lot numbers and expiration dates.

Providers should immediately discontinue use of any of the affected lots and follow Merck's instruction for returning recalled vaccine (both VFC and non-VFC). Providers should identify VFC vaccine separate from non-VFC vaccine. A letter from Merck, which is being sent out today, will explain the reason for the recall, identify the contaminated lots and contain instructions on how to return the affected vaccine. The

Sanofi Pasteur product ActHib® should be used in place of the affected lots shown above.

Children who received Hib vaccine from the affected lots do not need to be revaccinated. No potency concerns have been identified for these vaccine lots. Merck has not received any reports of illnesses or reactions in children who have received these affected vaccines.

Providers with shortages of vaccine may defer the booster (12-15 month old) dose of Hib containing vaccine in fully immunized children who are not otherwise at increased risk of invasive Hib disease. Providers who are completely out of Hib vaccine can contact Sanofi Pasteur regarding the availability of Hib vaccine to meet immediate short term needs. As we receive any new information we will share it with you.

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

Thank you for your continued excellence in the care of New Jersey's children.