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MERCK
Manufacturing Division

March 14, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To Whom It May Concern:

Docket Number 98N-1109
Mercury Compounds in Drugs and Food

Merck & Co., Inc. has reformulated Hepatitis B Vaccine (Recombinant), STN 101066, to remove the mercury compound, thimerosal. This product is distributed under the tradename RECOMBIVAX HB®. Merck was approved by the Food and Drug Administration to manufacture and market thimerosal-free versions of the product: pediatric/adolescent, 5 µg/0.5 mL, adult, 10 µg/mL, and dialysis, 40 µg/mL.

In the United States, Merck has discontinued marketing of thimerosal-containing RECOMBIVAX HB® and sells only the thimerosal-free version of the product. As a result, this letter is to request that Merck's RECOMBIVAX HB® vaccine be removed from the list of Mercury in Drug and Biologic Products according to the procedure indicated in the Federal Register Docket Number 98N-1109.

I would appreciate receiving confirmation of the FDA's intention to remove thimerosal-containing RECOMBIVAX HB® from the list of Mercury in Drug and Biologic Products. If you have any questions, please contact Dr. Roberta L. McKee at (215) 652-5603, or me at (215) 652-5336.

Sincerely,

Mark Rosolowsky, Ph.D.

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aud:jmg
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