URGENT: DRUG RECALL

MERCK

December 10, 2001
Event ID:

PRODUCT	Product: **VAQTA® (Hepatitis A Vaccine, Inactivated)** NDC: 0006-4844-00 / 0006-4844-38 Strength: 50U/1 mL of Hepatitis A virus protein Package Size: 1 mL single-dose or package of 5 prefilled syringe(s) Lot Number (Expiration Date): 0030L (10/29/03), 0460L (10/30/03), 0031L (11/05/03), 0031LSA1 (11/05/03), 0507L (02/17/04), 0525L (2/18/04), 0524L (2/18/04), 0523L (2/15/04) NDC: 0006-4845-00 / 0006-4845-38 Strength: 25U/0.5 mL of Hepatitis A virus protein Package Size: 0.5 mL single-dose or package of 5 prefilled syringe(s) Lot Number (Expiration Date): 1761H (11/02/01), 1937H (11/16/01), 0159J (12/8/01), 0158J (1/11/02), 0115K (2/17/02), 0580J (2/19/02), 0746J (3/4/02), 1407J (3/10/02), 0745J (3/10/02) 0952J (4/13/02), 1915J (4/13/02), 1751J (5/16/02), 0117K (5/17/02), 1750J (5/18/02), 1871J (10/18/02), 1802JSA2 (10/24/02), 1802J (10/24/02), 0118K (12/22/02), 0309K (12/22/02), 0330K (12/22/02), 0547K (12/23/02), 0680K (2/9/03), 0548K (2/10/03), 0692K (3/29/03), 0852K (4/2/03), 1200K (5/31/03), 0714L (6/2/03), 1178K (6/3/03), 0430L (8/25/03), 1628K (8/25/03), 0715L (9/20/03), 0716L (9/20/03) Manufactured By: Merck & Co., Inc. West Point, USA
REASON	Recent investigation indicates that some syringes within the above mentioned lots may have antigen levels below the product specification limit. Persons vaccinated with VAQTA® in prefilled syringes from the indicated lots may be insufficiently protected against hepatitis A.
ACTION	1. Stop distributing, and quarantine the indicated lots of product. 2. Please carry out a physical count and record this data on the Business Reply Card and the Packing Slip, which are included with this letter. 3. Mail the postage paid Business Reply Card **even if you do not have the recalled product.** 4. Return the recalled product and Packing Slip using the prepaid Shipping Labels to: ATTN: NNC Dept. Merck Order Fulfillment Center 1645 Satellite Blvd. Duluth, GA 30097
RECALL INSTRUCTIONS	This recall is being conducted to the user level. If product has been further distributed you must contact all of your accounts to the Physician/Health Care Professional level. If your customers are not physicians/health care professionals, please instruct your customers that they need to notify their

	customers to the physician/health care professional level also. The attached Dear Doctor Letter should be provided to physician/health care providers for further guidance with regard to patient care. No other lots, packages, or formulations are being recalled. For medical questions, contact Merck's National Service Center at 800-672-6372. For shipping assistance please contact Merck's Order Management Center at 800-637-2579. For questions about the recall process, contact NNC at 800-668-4391. This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.