

DEPARTMENT OF THE ARMY OFFICE OF THE SURGEON GENERAL 5109 LEESBURG PIKE FALLS CHURCH VA 22041-3258



DASG-PPM-NC 14 February 2002

MEMORANDUM FOR

COMMANDERS, REGIONAL MEDICAL COMMANDS COMMANDER, 18TH MEDICAL COMMAND, UNIT 15281, APO AP 96205-0054

SUBJECT: Recall of VAQTA in Pre-filled Syringes

1. This memorandum provides guidance to Army medical treatment facilities (MTFs), immunization clinics, and health care providers on procedures for hepatitis A vaccine (VAQTA) recall and how to manage beneficiaries who received vaccine from affected lots. Ensure widest dissemination of and compliance with this guidance.

2. References.

- a. Memorandum, Office of the Assistant Secretary of Defense for Health Affairs, ASD(HA), 10 Jan 02, subject: Recall of VAQTA in Pre-filled Syringes (encl).
- b. DOD-MMQC-01-1392, VAQTA (hepatitis A vaccine, inactivated) / immediate suspension, 131900ZDec01.
- c. DOD-MMQC-01-1396, VAQTA (hepatitis A vaccine, inactivated) pre-filled syringes / urgent drug recall, 182050Dec01.
- 3. Merck & Co., Inc. recently recalled certain lots of its single-dose, pre-filled syringe form of hepatitis A vaccine (VAQTA) because of reduced potency in a portion of the doses. References 2b and 2c direct DOD activities to discontinue use of affected lots and to follow specified recall procedures.
- 4. Vaccine Logistics.
- a. <u>Unused Vaccine</u>. MTFs will inspect stock and return unused doses to place of purchase for credit per instructions in reference 2c.
- b. <u>Administered Vaccine</u>. MTFs will review logistic, pharmacy, clinic, and medical records to determine the number of affected doses that were administered to beneficiaries. USAMMA will provide guidance to MTFs in a forth-coming medical materiel quality control (MMQC) message on procedures to apply for credit or replacement of these doses.

SUBJECT: Recall of VAQTA in Pre-filled Syringes

5. Management of beneficiaries.

- a. Identify and notify beneficiaries who may have been immunized with recalled lots of VAQTA. Give priority to deployed military/civilian personnel, other active duty personnel, and beneficiaries residing in areas where hepatitis A poses a high risk.
- (1) Review medical records of all military personnel during in-processing, annual birthmonth reviews, or readiness processing to identify individuals who may have received doses from affected lots. Complete this review NLT 31 January 2003. Alternatively, local databases may be used to identify personnel in defined groups if these databases contain complete hepatitis A vaccination histories for all currently assigned personnel.
- (2) To identify other beneficiaries who may have received affected vaccine, initiate public information campaigns to announce the recall and procedures to seek medical evaluation. Concurrently, health care providers should review health records during clinical encounters to determine whether or not an individual received or may have received a dose of hepatitis A vaccine from an affected lot.
- b. Adult pre-filled syringe doses released before 30 May 2001 and pediatric pre-filled syringe doses released before 9 June 1999 did not originate from affected lots. Make every reasonable effort to determine whether beneficiaries received vaccine from affected lots during the periods indicated above. Use all forms of documentation available, including local databases, immunization logs and health records. If documentation available does not permit ascertainment of lot used for immunization, assume that the dose came from an affected lot according to the following time periods:
 - (1) Any adult dose administered between 01 June 2001 and 15 December 2001.
 - (2) Any pediatric dose administered between 11 June 1999 and 15 December 2001.
- c. Inform all beneficiaries who received vaccine from an affected lot that the vaccine has been recalled and that they may require screening or revaccination, as outlined below. Assure that all beneficiaries are informed of the following information.
 - The vaccine dose they received, regardless of the lot number, is SAFE. The reason for the vaccine recall concerns possibly lowered potency of the vaccine.
 - Most likely, the dose of the vaccine that they received was adequate and they are immune to hepatitis A. However, there is some chance that the vaccine they received did not provide complete protection against hepatitis A.
 - For some beneficiaries, the best approach may be to simply revaccinate. For others, a blood test may be appropriate to determine if they need additional vaccine.

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SUBJECT: Recall of VAQTA in Pre-filled Syringes

- d. For individuals who have received only a single dose of hepatitis A vaccine and that dose was from an affected lot, revaccinate with a primary series of hepatitis A vaccine.
- e. For individuals who received two doses of hepatitis A vaccine, of which one or both doses were from an affected lot, offer screening and/or revaccinate according to the following guidelines.
- (1) Revaccinate (with one or two doses, as appropriate) all active duty and DA civilian employee personnel who are currently deployed in support of CINC-supported operations.
- (2) For other active duty personnel, serologically screen (and then revaccinate if needed) or simply revaccinate (with one or two doses, as appropriate). Local determination will be made on which strategy to adopt.
- (3) For other beneficiaries, evaluate whether protection against hepatitis A is still needed. If protection is still needed, serologically screen (and then revaccinate if needed) or simply revaccinate (with one or two doses, as appropriate). Local determination will be made on which strategy to adopt.
- f. If serological screening is performed for beneficiaries in categories 2 and 3 above, specific guidance is included in reference 2a. The vaccine manufacturer has offered to support required screening tests. Call 1-800-439-4958 for current details of manufacturer-contracted testing of blood samples. If local MTFs decide to use testing services provided through the manufacturer, assure that test results are received, reviewed and filed in the beneficiary's health record. If serological tests confirm lack of immunity to hepatitis A, repeat a full vaccination series (ie, two doses according to the usual schedule).
- g. Document all patient evaluations, serologic testing and results (if performed), and whether re-immunization occurred on Standard Form 600 in the beneficiary's health record.
 - h. Document all immunizations for active duty personnel in MEDPROS.
- 6. The point of contact for this action is COL Jeffrey Gunzenhauser, OTSG Preventive Medicine Staff Officer, DSN 761-3160, Commercial (703) 681-3160, or e-mail Jeffrey.Gunzenhauser@otsg.amedd.army.mil.

Encl

Memo, ASD(HA), 10 Jan 02

JAMES B. PEAKE

Lieutenant General

Commanding

DASG-PPM-NC

SUBJECT: Recall of VAQTA in Pre-filled Syringes

CF:

- Surgeon, U.S. Army Europe, APO, AE 09014 (w/encl)
- Surgeon, National Guard Bureau, 111 South George Mason Drive, Arlington, VA 22204-1382 (w/encl)
- Surgeon, U.S. Army Reserve Command, 1401 Deshler Street, SW, Fort McPherson, GA 30330-2000 (w/encl)
- Surgeon, U.S. Army Material Command, 5001 Eisenhower Avenue, Alexandria, VA 22333-0001 (w/encl)
- Surgeon, U.S. Army Training and Doctrine Command, 7 Fenwick Road, Fort Monroe, VA 23651-5000 (w/encl)
- Surgeon, U.S. Army Forces Command, 1777 Hardee Avenue, SW, Fort McPherson, GA 30330-6000 (w/encl)
- Surgeon, U.S. Army Special Operations Command, Fort Bragg, NC 28307-5200 (w/encl)
- Surgeon, U.S. Army South, P.O. Box 34000, Fort Buchanan, Puerto Rico 00934-3400 (w/encl)
- Surgeon, U.S. Army Forces Central Command, 1881 Hardee Avenue, SW, Fort McPherson, GA 30330-1064 (w/encl)
- Surgeon, U.S. Army Pacific, Fort Shafter, HI 96858-5100 (w/encl)
- Commander, AMEDD Center and School, 2250 Stanley Road, Fort Sam Houston, TX 78234-6100 (w/encl)
- Commander, U.S. Medical Research and Materiel Command, 504 Scott Street, Fort Detrick, MD 21702-5012 (w/encl)
- Commander, U.S. Army Center for Health Promotion and Preventive Medicine, 5158 Blackhawk Road, Aberdeen Proving Ground, MD 21010-5403 (w/encl)

THE ASSISTANT SECRETARY OF DEFENSE



WASHINGTON, D. C. 20301-1200

"JAN 1 0 2002

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (SAF/MR)
DIRECTOR, MEDICAL READINESS DIVISION, J4
DIRECTOR, TRICARE MANAGEMENT ACTIVITY

SUBJECT: Recall of VAQTA in Pre-filled Syringes

Merck recently recalled single dose, prefilled syringes of their inactivated hepatitis A vaccine product (VAQTA) because of variable antigen contents in some syringes in the recalled lots. There are no issues with safety. Only specific lots of adult and pediatric formulations were recalled, and information concerning the recall is contained in the attached information sheets provided by Merck (Attachments 1-5). Merck has been the exclusive supplier to DoD for the last few years. Preliminary estimates using US Air Force data indicate that about 7% of adults and 11% of children vaccinated with VAQTA since May 29, 2001 and August 9, 1999 respectively were vaccinated using recalled prefilled syringes.

Per attached DoD Medical Materiel Quality Control (MMQC) messages (Attachments 6-7), DoD activities/organizations in possession of lots of recalled vaccine were directed to immediately discontinue their use and follow Merck's and the MMQC recall procedures.

The following additional guidance is provided from this office:

- Services shall provide the FDA-approved Merck information sheets along with
 Service guidance to medical treatment facilities, immunization clinics, and health care
 providers (military, DoD employed, and DoD contracted). Service guidance will
 include procedures for return and replacement of unused vaccine, identification and
 recall of beneficiaries who were immunized with recalled vaccine, procedures for
 determining the need for testing and revaccination, and procedures for obtaining
 Merck-supported antibody titer testing and replacement vaccine.
- Recall and revaccination procedures may take several months. Priority should be given to identifying and discontinuing unused recalled syringes, and identifying and evaluating beneficiaries who have received immunization from recalled lots and have the highest risk of exposure to hepatitis A virus (including but not limited to military personnel and beneficiaries deployed to, or residing in, high threat areas).
- Please provide copies of any Service memoranda or instructions concerning the recall to this office.

My point of contact for this action is COL Benedict M. Diniega (703) 681-1711.

Bill Winherverder

William Winkenwerder, Jr., MD

Attachments: As stated

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Nier Force
US Coast Guard, Director of Health and Safety
Assistant Secretary of Defense (Reserve Affairs)
OSD Public Affairs
Defense Supply Center Philadelphia
US Army Medical Materiel Agency

Important Information on VAQTA® (Hepatitis A Vaccine, Inactivated) in prefilled syringes

Dear Doctor/Health Care Provider,

Re-tests of VAQTA® [Hepatitis A Vaccine, Inactivated] in prefilled syringes have revealed a decreased antigen content in some syringes below the established minimum specification. As a result, a possibility exists that **persons vaccinated with VAQTA®** in **prefilled syringes** from the indicated lots may be insufficiently protected against hepatitis A.

Merck & Co., Inc. is voluntarily recalling the indicated lots [See Attachment I for all indicated lots] of VAQTA® in prefilled syringes. Patients who may have received doses from the indicated lots would have been vaccinated after May 29, 2001 with the adult formulation, (50U/1 mL), and after August 9, 1999 with the pediatric/adolescent formulation, (25U/0.5 mL).

The indicated lots should no longer be used. You are kindly requested to return any stock of the recalled VAQTA® in prefilled syringes to Merck according to the enclosed instructions or, if not purchased directly from Merck, to your distributor. Cold chain transport is not necessary.

The following are not affected by this recall:

- All VAQTA® packaged in vials, and
- Lots of VAQTA® packaged in syringes not on the attached list.

If you have questions with respect to returns please contact the Merck Order Management Center at 1 - 800 - 637 - 2579.

For Individuals Vaccinated with Prefilled Syringes from Indicated Lots:

It is suggested that you review the records of patients who may have been vaccinated after the following dates with VAQTA® in prefilled syringes, to see if the indicated lots were used in such vaccination:

- Adult formulation (50U/1 mL): May 29, 2001
- Pediatric/adolescent formulation (25U/0.5 mL): August 9, 1999.

If in your clinical assessment, revaccination against hepatitis A and/or antibody testing is indicated for these patients, you may consider the following guideline:

Total number of doses of hepatitis A vaccine patient received	Antibody testing recommended	Result	Number of further doses for revaccination	
2	Yes	Positive	0	
(One or both doses from an indicated lot)	4 weeks after vaccination	Negative	2*	
1	No	Not applicable	2*	
(Dose from an indicated lot)				

* For time interval, please see the enclosed full Prescribing Information for VAQTA®. For some vaccinees it may be preferable to test antibody status after a single revaccination dose. Antibody testing may be done at the earliest 4 weeks after the first dose of revaccination. Vaccinees will be eligible for receipt of the second dose depending on the results of the antibody test

In order to determine the immunogenicity of the indicated lots of vaccine administered to your patient, Merck & Co., Inc. is negotiating a contract with a testing laboratory to determine the hepatitis A antibody concentration in these patients. If you choose to do antibody testing, the service by this laboratory will be free. Please contact Merck & Co., Inc. via telephone for a complete set of instructions.

Telephone no.: 1-800-439-4958

If revaccination doses are necessary, contact Merck & Co., Inc. via fax regarding re-supply of vaccine free of charge. Please send your written request to the following fax number, indicating the number of revaccination doses used and identifying your source of supply.

Fax-no.: 215-652-6700

For medical questions please call the Merck National Service Center at 1-800 – 672 - 6372.

Before prescribing, please read the enclosed Prescribing Information for VAQTA® [Hepatitis A Vaccine, Inactivated].

We do hope that you will understand these necessary measures.

Kind regards,

Thomas M. Vernon, M. D. VP Policy, Public Health & Medical Affairs

The following table summarizes phone and fax numbers:

Questions with respect to returns	Telephone:	1 - 800 - 637 - 2579
Request of instructions for antibody testing	Telephone:	1 – 800 – 439 - 4958
Request of hepatitis A vaccine	FAX:	215 – 652 - 6700
Medical questions	Telephone:	1- 800 - 672- 6372

Attachment 1

NDC #	STRENGTH	PRODUCT DESCRIPTION	LOT#	EXP. DATE
0006-4844-00	50U/1 mL of hepatitis A virus protein	VAQTA®	0460L	30-Oct-03
			0031L	5-Nov-03
			0031LSA1	5-Nov-03
			0525L	18-Feb-04
0006-4844-38	50U/1 mL of hepatitis A virus protein	VAQTA®	0030L	29-Oct-03
			0523L	15-Feb-04
			0507L	17-Feb-04
			0524L	18-Feb-04
0006-4845-00	25U/0.5 mL of hepatitis A virus protein	VAQTA®	0115K	17-Feb-02
			0952J	13-Apr-02
			0430L	25-Aug-03
			1628K	25-Aug-03
0006-4845-38	25U/0.5 mL of hepatitis A virus protein	VAQTA®	1761H	2-Nov-01
			1937H	16-Nov-01
			0159J	8-Dec-01
			0158J	11-Jan-02
			0580J	19-Feb-02
			0746J	4-Mar-02
	ļ		0745J	10-Mar-02
			1407J	10-Mar-02
	ļ		1915J	13-Apr-02
			1751J	16-May-02
			0117K	17-May-02
			1750J	18-May-02
			1871J	18-Oct-02
			1802J	24-Oct-02
			1802JSA2	24-Oct-02
			0118K	22-Dec-02
			0309K	22-Dec-02
	-		0330K	22-Dec-02
			0547K	23-Dec-02
			0680K	9-Feb-03
			0548K	10-Feb-03
	<u> </u>		0692K	29-Mar-03
			0852K	2-Apr-03
			1200K	31-May-03
	 		0714L	2-Jun-03
			1178K	3-Jun-03
-	 		0715L	20-Sep-03
<u> </u>	L	l	0716L	20-Sep-03

URGENT: DRUG RECALL



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 0030L (10/29/03), 0460L (10/30/03), 0031L (11/05/03), (Expiration Date): 0031LSA1 (11/05/03), 0507L (02/17/04), 0525L (2/18/04), 0524L (2/18/04), 0523L (2/15/04)	
	NDC: Strength: 25U/0.5 mL of Hepatitis A virus protein Package Size: 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	 Stop distributing, and quarantine the indicated lots of product. 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. Mail the postage paid Business Reply Card even if you do not have the recalled product. 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.

PRODUCT FOR RETURN - Vaccines

RETURNED PRODUCT IS TO BE SENT DIRECTLY TO:

ATTN: NNC Dept.

Merck Order Fulfillment Center
1645 Satellite Blvd.
Duluth, GA 30097

To ensure the issuance of proper credit and for the protection of our customers, acceptance of returned product will be subject to the following conditions:

- The enclosed packing list must accompany the returned product.
- The shipping carton must bear the name and address of the sender.

Merck & Co., Inc. will compensate customers affected by a product recall as follows:

- Credit for product will be issued at the direct price in effect at the time of purchase.
- Customers will be reimbursed for reasonable and customary administrative and handling costs as determined by Merck.
- Merck & Co., Inc. will pay actual transportation charges for product returned as a result of a recall.



Dear Health Care Provider,

Thank you for contacting the Merck Vaccine Product Assistance Line. The following information is being faxed in response to your request for instructions related to obtaining serology testing for your patients vaccinated with VAQTA® (Hepatitis A Vaccine, Inactivated) prefilled syringes which are subject to the recall notice recently sent to you.

If you believe it is appropriate to have a patient who received VAQTA® from the recalled lots tested for Hepatitis A immune status, Merck will pay for serology testing provided by Quest Diagnostics. The cost of serology testing performed by any other laboratory will not be reimbursed or otherwise covered by Merck. Instructions for patient testing are as follows:

If you are a Current Client of Quest Diagnostics:

Order

- ➤ Order the Merck HAV Ab test using test code 10155 (F) on a Quest Diagnostics requisitions from your existing supply (NOTE PLEASE DISREGARD ATTACHED REQUISITION IT IS FOR NON CLIENTS ONLY). Use of this test code will assure that neither you nor your patient will be charged for this test and that your patient's results will be reported back to you.
- > Do not submit any orders for any additional tests on this requisition; please order any other testing for your patient using a separate requisition.

Specimen Requirements

> 1 mL serum. Collect specimen in a serum separator tube. Separate serum from cells and transport to laboratory at room temperature.

Transport of Specimen

- ➤ If you draw blood in the office, your regular Quest Diagnostics courier will pick up the specimen and deliver it to the laboratory.
- ➤ If you do not draw blood in your office and would like to send the patient to a Quest Diagnostics Patient Service Center (PSC), the most convenient location can be identified by either looking on the Quest Diagnostics web site at www.questdiagnostics.com or by calling the PSC Locator at 1-800-377-8448.

If you are Not a Current Client of Quest Diagnostics:

Order

> Use the attached Quest Diagnostics requisition to order the Merck HAV Ab test. If you need additional requisitions, please feel free to photocopy the attached requisition. Note – information regarding physician name, address, and telephone number on the requisition must be fully completed in order to insure that the patient's test results are returned to your office. Use the attached requisition only

for the Merck HAV Ab test. **DO NOT ORDER ANY ADDITIONAL TESTS ON THIS REQUISITION.**

Specimen Requirement

> 1 mL serum. Collect specimen in a serum separator tube. Separate serum from cells and transport to laboratory at room temperature

Transport of Specimen

> If you draw blood in the office, Federal Express the specimen along with the completed attached requisition to:

Quest Diagnostics Incorporated Attn: Specimen Accessioning 1 Malcolm Avenue Teterboro, NJ 07608

Please note the following related to this shipment:

- □ Ship via Federal Express at room temperature using standard specimen over pack
- □ Designate 2-day air shipment
- □ Use Federal Express account number 2641-8449-5 for this specific shipment
- ➤ If you do not draw blood in your office, send the patient along with the completed custom requisition to the most convenient PSC location, which may be identified by either looking on the Quest Diagnostics web site at www.questdiagnostics.com or by calling the PSC Locator at 1-800-377-8448.

If you have questions with respect to vaccine returns

If you have questions with respect to vaccine returns, please contact the Merck Order Management Center at 1-800-637-2579.

If revaccination doses are necessary

If revaccination doses are necessary, contact Merck & Co. via fax. Please send your written request to the following fax number, indicating the number of revaccination doses used and identifying your source of supply: 215-652-6700

If you have medical questions

If you have medical questions, please call the Merck National Service Center at 1-800-672-6372.

Merck & Co., Inc. regrets any inconvenience this recall may have caused. We value your trust and appreciate your patience and cooperation during this process.

		Customized Requisition			
CLIENT	INFORMATION	Name Merck HAV Address Telephone 800-631-1390 Account Number Date Collected (Month-Day-Year) Time Collected (Use 24 Hr. Clock) Time Collected (Use 24 Hr. Clock)			
PATIENT DATA		Please Print- Last Name of Patient (or I.D.#) Patient I.D. Accession No. Ordering Physician Date of Birth (MM DD YYYY) Soc. Sec. Number Comments Comments M.I. of Patient Male Female Check box if Patient is: Non- Fasting fasting			
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Q011392.TXT 01 131900Z Dec 01 PP PP UUUU AA ZYUW FROM QUAD SERVICE MMQC FT DETRICK MD//USAMMA/AFMLO/NMLC// TO 11370 488 7485 7486 7487 7488 7783 9344 9345 **UNCLAS** SUBJ: DOD-MMQC-01-1392 VAQTA (HEPATITIS A VACCINE, INACTIVATED)/IMMEDIATE SUSPENSION 01. THE FOLLOWING MEDICAL MATERIEL IS SUSPENDED. REASON: THE LOTS IDENTIFIED BELOW WERE FOUND TO BE SUB-POTENT AND MUST BE REMOVED FROM USE. DISPOSITION: INSPECT STOCK FOR MATERIEL. IF FOUND, SEGREGATE STOCK, SUSPEND FROM USE, AND AWAIT FORTHCOMING INSTRUCTIONS ON VACCINE DISPOSITION AND CLINICAL RECOMMENDATIONS. 6505-01-432-0418 NSN: UI: EA NOM: HEPATITIS A VIRUS VACCINE INACTIVATED 25UN/0.5ML SYR PEDIATRIC NDC: F00006484500 MFR: MERCK LOT/SERIAL NUMBER(S): E-DATE: 11/02/01 E-DATE: 12/08/01 1761H 1937H E-DATE: 11/16/01 01593 01583 E-DATE: 01/11/02 E-DATE: 02/17/02 E-DATE: 02/19/02 0115K 0580J 07461 E-DATE: 03/04/02 E-DATE: 03/10/02 14071 0745J E-DATE: 03/10/02 09523 E-DATE: 04/13/02 1915J E-DATE: 04/13/02 E-DATE: 05/16/02 1751J E-DATE: 05/17/02 0117K **1750**J E-DATE: 05/18/02 E-DATE: 10/18/02 E-DATE: 10/24/02 E-DATE: 12/22/02 E-DATE: 12/23/02 1871J 1802JSA2 E-DATE: 10/24/02 E-DATE: 12/22/02 E-DATE: 12/22/02 1802J 0118K 0309K 0330K E-DATE: 02/09/03 0547K 0680K E-DATE: 02/10/03 0548K 0692K E-DATE: 03/29/03 E-DATE: 05/31/03 0852K E-DATE: 04/02/03 1200K 0714L E-DATE: 06/02/03 1178ĸ E-DATE: 06/03/03 E-DATE: 08/25/03 0430L 1628K E-DATE: 08/25/03 E-DATE: 09/20/03 0715L 0716L E-DATE: 09/20/03 02. REASON AND DISPOSITION AS ABOVE. 6505-01-432-0416 UI: PG NSN: NOM: HEPATITIS A VIRUS VACCINE INACTIVATED 25UN/0.5ML SYRINGE 5/PG F00006484538 NDC: MFR: **MERCK** LOT/SERIAL NUMBER(S): E-DATE: 11/02/01 1937H 1761H E-DATE: 11/16/01 0159J E-DATE: 12/08/01 0158J E-DATE: 01/11/02

Page 1

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0548K	E-DATE: 02/10/03	0692κ	E-DATE: 03/29/03
0852K	E-DATE: 04/02/03	1200K	E-DATE: 05/31/03
0714L	E-DATE: 06/02/03	1178K	E-DATE: 06/03/03
0430L	E-DATE: 08/25/03	1628K	E-DATE: 08/25/03
0715L	E-DATE: 09/20/03	0716L	E-DATE: 09/20/03

03. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-01-432-0378 UI: PG

NOM: HEPATITIS A VIRUS VACCINE INACTIVATED 50UN/1ML 1ML SYRINGE 5/PG

NDC: F00006484438

MFR: MERCK

LOT/SERIAL NUMBER(S):

0030L E-DATE: 10/29/03 0460L E-DATE: 10/30/03 E-DATE: 11/05/03 0031L E-DATE: 11/05/03 0031LSA1 0507L E-DATE: 02/17/04 0525L E-DATE: 02/18/04 0524L E-DATE: 02/18/04 0523L E-DATE: 02/15/04

04. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-01-432-0376 UI: EA

NOM: HEPATITIS A VIRUS VACCINE INACTIVATED 50UN/1ML ADULT 1ML SYRINGE

NDC: F00006484400

MFR: MERCK

LOT/SERIAL NUMBER(S):

 0030L
 E-DATE: 10/29/03
 0460L
 E-DATE: 10/30/03

 0031L
 E-DATE: 11/05/03
 0031LSA1
 E-DATE: 11/05/03

 0507L
 E-DATE: 02/17/04
 0525L
 E-DATE: 02/18/04

 0524L
 E-DATE: 02/18/04
 0523L
 E-DATE: 02/15/04

- 5. PASS MSG TO MEDICAL LOG OFCRS, CMD CHANNELS, PHARMACY, MED STAFF SECTION, SUPPLY OFCRS, PREVENTIVE MEDICINE/ENVIRONMENTAL SCIENCE OFCRS, AND SUPPORTED ACTYS/CTRS.
- 6. AIR FORCE: SEE AFMAN 23-110, VOL 5, FOR REQUIRED ACTIONS. FOR MAJCOMS & NGB--THIS MSG HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MEDICAL ACTIVITIES IAW AFMAN 23-110, VOL 5, CHAP 19.
- 7. SVC SPECIFIC POCS ARE AS FOLLOWS (FAX NOS. ARE AVAILABLE 24 HRS):

ARMY: PAULA THORN, 301-619-4305/2045, DSN: 343, FAX 2938,

E-MAIL: PAULA.THORN@AMEDD.ARMY.MIL

USAMMCE: HORST WERNER, COM: 011-49-6331-86-7118/7181, DSN: 495-7118, FAX: X6218, E-MAIL: HORST.WERNER@AMEDD.ARMY.MIL

AIR FORCE: CAPT JASON ORTIZ, 301-619-4168, DSN: 343, FAX 6842,

E-MAIL: JASON.ORTIZ@FT-DETRICK.AF.MIL

NAVY: HUGH WIESMAN, 301-619-3088, DSN: 343, FAX 3087,

E-MAIL: HAWIESMAN@US.MED.NAVY.MIL

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01 182050Z Dec 01 PP PP UUUU AA ZYUW FROM QUAD SERVICE MMQC FT DETRICK MD//USAMMA/AFMLO/NMLC//

UNCLAS

9345

SUBJ: DOD-MMQC-01-1396

VAQTA (HEPATITIS A VACCINE, INACTIVATED) PRE-FILLED SYRINGES/URGENT DRUG RECALL

REF: DOD-MMQC-01-1392/VAQTA (HEPATITIS A VACCINE, INACTIVATED)/IMMEDIATE

SUSPENSION

01. MFR HAS RECALLED THE FOLLOWING MEDICAL MATERIEL. REASON: SOME OF THE PRE-FILLED SYRINGES FROM THE LOTS IDENTIFIED BELOW WERE FOUND TO BE SUB-POTENT. DISPOSITION: INSPECT STOCK FOR MATERIEL. IF FOUND, RETURN TO PLACE OF PURCHASE FOR CREDIT. PLACE OF PURCHASE USE FEDERAL EXPRESS (ACCT NO 2641-8449-5) AND RETURN TO: MERCK ORDER FULFILLMENT CENTER, ATTN: NNC DEPT, 1645 SATELLITE BLVD, DULUTH, GA, 30097. CALL 800-637-2579 OR 215-631-5901 FOR ASSISTANCE IF NEEDED.

NSN: 6505-01-432-0418 UI: EA

NOM: HEPATITIS A VIRUS VACCINE INACTIVATED 25UN/0.5ML SYR PEDIATRIC

NDC: F00006484500

MFR: MERCK

LOT/SERIAL NUMBER(S): 1761H E-DATE: 11/02/01 1937H E-DATE: 11/16/01 01591 E-DATE: 12/08/01 0158J E-DATE: 01/11/02 0115K E-DATE: 02/17/02 0580J E-DATE: 02/19/02 E-DATE: 03/04/02 0746J 1407J E-DATE: 03/10/02 E-DATE: 03/10/02 0952J E-DATE: 04/13/02 07453 E-DATE: 04/13/02 **1751**J E-DATE: 05/16/02 1915J E-DATE: 05/17/02 E-DATE: 10/18/02 0117K 1750J E-DATE: 05/18/02 1871) 10/24/02 1802JSA2 E-DATE: E-DATE: 10/24/02 18023 E-DATE: 0118K 12/22/02 12/22/02 0309K E-DATE: 12/22/02 0330K E-DATE: 0547K E-DATE: 12/23/02 0680K E-DATE: 02/09/03 0548K E-DATE: 02/10/03 0692K E-DATE: 03/29/03 E-DATE: 04/02/03 E-DATE: 05/31/03 0852K 1200K E-DATE: 06/03/03 0714L E-DATE: 06/02/03 1178K 0430L E-DATE: 08/25/03 1628ĸ E-DATE: 08/25/03 E-DATE: 09/20/03 0716L E-DATE: 09/20/03 0715L

02. REASON AND DISPOSITION AS ABOVE.

NSN: 6505-01-432-0416 UI: PG

NOM: HEPATITIS A VIRUS VACCINE INACTIVATED 25UN/0.5ML SYRINGE 5/PG

NDC: F00006484538

MFR: MERCK

LOT/SERIAL NUMBER(S):

Q011396.TXT E-DATE: 11/02/01 1937H 1761H E-DATE: 11/16/01 E-DATE: 12/08/01 E-DATE: 02/17/02 E-DATE: 03/04/02 01581 01593 E-DATE: 01/11/02 0115K 0580J E-DATE: 02/19/02 E-DATE: 03/10/02 **1407**J 0746J 0745J E-DATE: 03/10/02 0952J E-DATE: 04/13/02 E-DATE: 04/13/02 1915J 1751J E-DATE: 05/16/02 0117K E-DATE: 05/17/02 **1750**J E-DATE: 05/18/02 E-DATE: 10/18/02 1871J 1802JSA2 E-DATE: 10/24/02 E-DATE: 10/24/02 1802J 0118K E-DATE: 12/22/02 E-DATE: 12/22/02 0309K 0330K E-DATE: 12/22/02 E-DATE: 12/23/02 E-DATE: 02/10/03 E-DATE: 04/02/03 0547K 0680K E-DATE: 02/09/03 0548K 0692K E-DATE: 03/29/03 E-DATE: 05/31/03 1200K 0852K E-DATE: 06/02/03 E-DATE: 06/03/03 1178K 0714L E-DATE: 08/25/03 E-DATE: 08/25/03 0430L 1628ĸ E-DATE: 09/20/03 E-DATE: 09/20/03

03. REASON AND DISPOSITION AS ABOVE.

6505-01-432-0378 UI: PG NSN:

NOM: HEPATITIS A VIRUS VACCINE INACTIVATED 50UN/1ML 1ML SYRINGE 5/PG

0716L

NDC: F00006484438

MFR: MERCK

0715L

LOT/SERIAL NUMBER(S):

E-DATE: 10/30/03 0030L E-DATE: 10/29/03 0460L 0031L E-DATE: 11/05/03 0031LSA1 E-DATE: 11/05/03 E-DATE: 02/17/04 E-DATE: 02/18/04 0507L 0525L E-DATE: 02/18/04 0523L E-DATE: 02/15/04 0524L

04. REASON AND DISPOSITION AS ABOVE.

6505-01-432-0376 UI: EA NSN:

HEPATITIS A VIRUS VACCINE INACTIVATED 50UN/1ML ADULT 1ML SYRINGE NOM:

F00006484400 NDC:

MFR: MERCK

LOT/SERIAL NUMBER(S):

E-DATE: 10/29/03 E-DATE: 11/05/03 E-DATE: 02/17/04 0460L 0030L E-DATE: 10/30/03 E-DATE: 11/05/03 E-DATE: 02/18/04 0031L 0031LSA1 0507L 0525L E-DATE: 02/18/04 E-DATE: 02/15/04 0523L 0524L

NOTE: SUBMIT *ACTUAL* REQUIREMENTS/ORDERS THROUGH REGULAR CHANNELS. MERCK HAS INDICATED THAT THEY HAVE SET-ASIDE DOSES FOR MILITARY USE; PURCHASER SHOULD INDICATE THIS POINT, IF NECESSARY, WHEN ORDERING.

- 5. NOT ALL SYRINGES IN THESE SPECIFIC LOTS, AND NOT ALL LOTS OF HEPATITIS A. WERE EQUALLY AFFECTED, HOWEVER, MERCK IS RECALLING EACH OF THESE LOTS TO ALLEVIATE PATIENT CONCERNS.
- MERCK PRE-FILLED SYRINGES ARE ON INDEFINITE BACKORDER STATUS; ONLY VIALS WILL BE AVAILABLE FOR THE FORSEEABLE FUTURE. THE ALTERNATIVE PRODUCTS FROM MERCK LISTED BELOW SHOULD BE PROCURED. NOTE: MERCK HOLDS AN EXCLUSIVE CONTRACT WITH DSCP FOR HEPATITIS A VACCINE FOR DOD CUSTOMERS. ACTIVITIES MUST EMPLOY VAQTA AS THE PRODUCT OF CHOICE FOR HEPATITIS A VACCINE, WHEN AVAILABLE.
- A. NSN 6505-01-432-0379, NDC 00006-4841-38, HEPATITIS A VIRUS VACCINE (VAQTA), 50 UNITS/ML (ADULT STRENGTH), 1ML SINGLE-DOSE VIALS, 5S
- B. NSN 6505-01-432-0380, NDC 00006-4841-00, HEPATITIS A VIRUS VACCINE (VAQTA), 50 UNITS/ML (ADULT STRENGTH), 1ML SINGLE-DOSE VIAL, EA
- C. NSN 6505-01-432-0421, NDC 00006-4831-38, HEPATITIS A VIRUS VACCINE Page 2

- (VAQTA), 25 UNITS/0.5ML (PEDIATRIC STRENGTH), 0.5ML SINGLE-DOSE VIALS, 5S
- D. NSN 6505-01-432-0424, NDC 00006-4831-00, HEPATITIS A VIRUS VACCINE (VAQTA), 25 UNITS/0.5ML (PEDIATRIC STRENGTH), 0.5ML SINGLE-DOSE VIAL, FA
- E. NSN 6505-NS, NDC 00006-4831-41, HEPATITIS A VIRUS VACCINE (VAQTA), 25 UNITS/0.5ML (PEDIATRIC STRENGTH), 0.5ML SINGLE-DOSE VIALS, 10S
- 7. SHOULD SHORTAGES OCCUR, ACTIVITIES MAY EMPLOY AN ALTERNATIVE HEPATITIS A VACCINE PRODUCT. HAVRIX SHOULD ONLY BE ORDERED IF UNABLE TO PURCHASE VAQTA.
- A. NSN 6505-01-458-4678, NDC 58160-0835-35, HEPATITIS A VIRUS VACCINE (HAVRIX), 1440 ELU/ML (ADULT STRENGTH), 1ML, TIP-LOK, PRE-FILLED SYRINGE, 23 GAUGE/1" NEEDLE, 5S
- B. NSN 6505-01-458-4674, NDC 58160-0835-32, HEPATITIS A VIRUS VACCINE (HAVRIX), 1440 ELU/ML (ADULT STRENGTH), 1ML, TIP-LOK, PRE-FILLED SYRINGE, 23 GAUGE/1" NEEDLE, EA
- C. NSN 6505-01-398-3329, NDC 58160-0835-01, HEPATITIS A VIRUS VACCINE (HAVRIX), 1440 ELU/ML (ADULT STRENGTH), 1ML, SDV, EA
- D. NSN 6505-01-431-9404, NDC 58160-0837-01, HEPATITIS A VIRUS VACCINE (HAVRIX), 720 ELU/0.5 ML (PEDIATRIC), SDV, EA
- E. NSN 6505-01-458-4673, NDC 58160-0837-35, HEPATITIS A VIRUS VACCINE (HAVRIX), 720 ELU/0.5ML (PEDIATRIC), TIP LOK PRE-FILLED SYRINGE, 25 GAUGE/5/8" NEEDLE, 5S
- F. NSN 6505-NS, NDC 58160-0837-11, HEPATITIS A VIRUS VACCINE (HAVRIX), 720 ELU/0.5ML, SDV, 10S
- G. NSN 6505-NS, NDC 58160-0837-26, HEPATITIS A VIRUS VACCINE (HAVRIX), 720 ELU/0.5ML, TIP-LOK PREFILLED SYRINGE, 25 GAUGE/5/8" NEEDLE, 25S
- H. NSN 6505-NS, NDC 58160-0837-58, HEPATITIS A VIRUS VACCINE (HAVRIX), 720 ELU/0.5ML, PREFILLED SAFETY TIP-LOK SYRINGE WITH BD SAFETYGLIDE 23 GAUGE/1" NEEDLE, 25S
- 8. THE VAQTA POTENCY ISSUE DOES NOT CREATE A PATIENT SAFETY CONCERN BUT SOME IMMUNIZATIONS MAY NOT PROVIDE ADEQUATE PROTECTION AGAINST HEPATITIS A. CLINICAL ISSUES FOR THOSE PERSONNEL WHO RECEIVED THE AFFECTED LOTS WILL BE DISCUSSED IN FORTHCOMING SERVICE GUIDANCE.
- 9. RETURN PRODUCT TO DESTINATION INDICATED IN DISPOSITION INSTRUCTIONS (PARA 1). DO NOT RETURN PRODUCT TO DLA DEPOT.
- 10. PASS MSG TO MEDICAL LOG OFCRS, CMD CHANNELS, PHARMACY, MED STAFF SECTION, SUPPLY OFCRS, PREVENTIVE MEDICINE/ENVIRONMENTAL SCIENCE OFCRS, AND SUPPORTED ACTYS/CTRS.
- 11. AIR FORCE: SEE AFMAN 23-110, VOL 5, FOR REQUIRED ACTIONS. FOR MAJCOMS & NGB--THIS MSG HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MEDICAL ACTIVITIES IAW AFMAN 23-110, VOL 5, CHAP 19.
- 12. SVC SPECIFIC POCS ARE AS FOLLOWS (FAX NOS. ARE AVAILABLE 24 HRS):

ARMY: PAULA THORN, 301-619-4305/2045, DSN: 343, FAX 2938, E-MAIL: PAULA.THORN@AMEDD.ARMY.MIL

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AIR FORCE: CAPT JASON ORTIZ, 301-619-4168, DSN: 343, FAX 6842, E-MAIL: JASON.ORTIZ@FT-DETRICK.AF.MIL

NAVY: HUGH WIESMAN, 301-619-3088, DSN: 343, FAX 3087, E-MAIL: HAWIESMAN@US.MED.NAVY.MIL