



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

JAN 10 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 Winkenwerder

William Winkenwerder, Jr., MD

Attachments:
As stated

cc:

Surgeon General of the Army

Surgeon General of the Navy

Surgeon General of the Air 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 (One or both doses from an indicated lot)	Yes 4 weeks after vaccination	Positive	0
		Negative	2*
1 (Dose from an indicated lot)	No	Not applicable	2*

* 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
			0745J	10-Mar-02
			1407J	10-Mar-02
			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
			0692K	29-Mar-03
			0852K	2-Apr-03
			1200K	31-May-03
			0714L	2-Jun-03
			1178K	3-Jun-03
			0715L	20-Sep-03
			0716L	20-Sep-03

URGENT: DRUG RECALL



December 10, 2001
Event ID:

<p>PRODUCT</p>	<p>Product: VAQTA® (Hepatitis A Vaccine, Inactivated)</p> <p>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)</p> <p>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: 1761H (11/02/01), 1937H (11/16/01), 0159J (12/8/01), (Expiration Date): 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)</p> <p>Manufactured By: Merck & Co., Inc. West Point, USA</p>
<p>REASON</p>	<p>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.</p>
<p>ACTION</p>	<ol style="list-style-type: none"> 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
<p>RECALL INSTRUCTIONS</p>	<p>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</p>

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.

BUSINESS REPLY CARD

Merck & Co., Inc.

VAQTA® (Hepatitis A Vaccine, Inactivated)

IDC 0006-4844-00 50U/1 mL of hepatitis A virus protein

LOT #	EXP. DATE	SYRINGES ON HAND	LOT #	EXP. DATE	SYRINGES ON HAND	LOT #	EXP. DATE	SYRINGES ON HAND	LOT #	EXP. DATE	SYRINGES ON HAND
0460L	30-Oct-03		0031L	5-Nov-03		0031LSA1	5-Nov-03		0525L	18-Feb-04	

NDC 0006-4844-38 50U/1 mL of hepatitis A virus protein

0030L	29-Oct-03		0523L	15-Feb-04		0507L	17-Feb-04		0524L	18-Feb-04	
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IDC 0006-4845-00 25U/0.5 mL of hepatitis A virus protein

0115K	17-Feb-02		0952J	13-Apr-02		0430L	25-Aug-03		1628K	25-Aug-03	
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IDC 0006-4845-38 25U/0.5 mL of hepatitis A virus protein

1761H	2-Nov-01		1937H	16-Nov-01		0159J	8-Dec-01		0158J	11-Jan-02	
0580J	19-Feb-02		0746J	4-Mar-02		0745J	10-Mar-02		1407J	10-Mar-02	
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		0692K	29-Mar-03		0852K	2-Apr-03		1200K	31-May-03	
0714L	2-Jun-03		1178K	3-Jun-03		0715L	20-Sep-03		0716L	20-Sep-03	

our timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card within five (5) business days, even if you do not have the recalled product. Thank you.

ave read the Recall Instructions, quarantined product as defined, and have notified our accounts in _____ (include date) via _____ (include method of notification).

Signature: _____ Title: _____

Printed Name: _____ Phone: _____

PACKING SLIP

Merck & Co., Inc.

VAQTA® (Hepatitis A Vaccine, Inactivated)

IDC 0006-4844-00 50U/1 mL of hepatitis A virus protein

LOT #	EXP. DATE	SYRINGES ON HAND	LOT #	EXP. DATE	SYRINGES ON HAND	LOT #	EXP. DATE	SYRINGES ON HAND	LOT #	EXP. DATE	SYRINGES ON HAND
0460L	30-Oct-03		0031L	5-Nov-03		0031LSA1	5-Nov-03		0525L	18-Feb-04	

NDC 0006-4844-38 50U/1 mL of hepatitis A virus protein

0030L	29-Oct-03		0523L	15-Feb-04		0507L	17-Feb-04		0524L	18-Feb-04	
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IDC 0006-4845-00 25U/0.5 mL of hepatitis A virus protein

0115K	17-Feb-02		0952J	13-Apr-02		0430L	25-Aug-03		1628K	25-Aug-03	
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IDC 0006-4845-38 25U/0.5 mL of hepatitis A virus protein

1761H	2-Nov-01		1937H	16-Nov-01		0159J	8-Dec-01		0158J	11-Jan-02	
0580J	19-Feb-02		0746J	4-Mar-02		0745J	10-Mar-02		1407J	10-Mar-02	
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		0692K	29-Mar-03		0852K	2-Apr-03		1200K	31-May-03	
0714L	2-Jun-03		1178K	3-Jun-03		0715L	20-Sep-03		0716L	20-Sep-03	

The following information is required to assure proper crediting: Debit Memo: _____

Direct Purchase: Account # Name and address

Direct Purchase: Name and address of distributor

THIS PRODUCT IS NOT FOR RESALE

ARS



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)



PATIENT DATA

Please Print- Last Name of Patient (or I.D.#)

First Name of Patient

M.I. of Patient

Male Female

Patient I.D.

Accession No.

Ordering Physician

Date of Birth (MM DD YYYY)

Soc. Sec. Number

Check box if Patient is:

Fasting Non-fasting

Comments

DUPLICATE REPORT TO:

QUEST DIAGNOSTICS ACCT. # (IF KNOWN)

PHYSICIAN NAME

STREET

CITY

STATE

ZIP CODE

WRITE PHYSICIAN'S NAME AND ADDRESS HERE:

ATTENTION SPECIMEN PROCESSING ENTER INTO HOUSE / ORPHAN ACCOUNT FOR SUPERVISOR REVIEW.

X 10155(F) MERCK HAV AB

NO OTHER TESTS MAY BE ORDERED ON THIS REQUISITION

IF YOU HAVE A QUEST DIAGNOSTICS ACCOUNT, USE YOUR QUEST DIAGNOSTICS REQUISITION AND ORDER 10155(F)

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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.

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
0159J	E-DATE: 12/08/01	0158J	E-DATE: 01/11/02
0115K	E-DATE: 02/17/02	0580J	E-DATE: 02/19/02
0746J	E-DATE: 03/04/02	1407J	E-DATE: 03/10/02
0745J	E-DATE: 03/10/02	0952J	E-DATE: 04/13/02
1915J	E-DATE: 04/13/02	1751J	E-DATE: 05/16/02
0117K	E-DATE: 05/17/02	1750J	E-DATE: 05/18/02
1871J	E-DATE: 10/18/02	1802JSA2	E-DATE: 10/24/02
1802J	E-DATE: 10/24/02	0118K	E-DATE: 12/22/02
0309K	E-DATE: 12/22/02	0330K	E-DATE: 12/22/02
0547K	E-DATE: 12/23/02	0680K	E-DATE: 02/09/03
0548K	E-DATE: 02/10/03	0692K	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

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):

1761H	E-DATE: 11/02/01	1937H	E-DATE: 11/16/01
0159J	E-DATE: 12/08/01	0158J	E-DATE: 01/11/02
0115K	E-DATE: 02/17/02	0580J	E-DATE: 02/19/02
0746J	E-DATE: 03/04/02	1407J	E-DATE: 03/10/02
0745J	E-DATE: 03/10/02	0952J	E-DATE: 04/13/02
1915J	E-DATE: 04/13/02	1751J	E-DATE: 05/16/02
0117K	E-DATE: 05/17/02	1750J	E-DATE: 05/18/02
1871J	E-DATE: 10/18/02	1802JSA2	E-DATE: 10/24/02
1802J	E-DATE: 10/24/02	0118K	E-DATE: 12/22/02
0309K	E-DATE: 12/22/02	0330K	E-DATE: 12/22/02
0547K	E-DATE: 12/23/02	0680K	E-DATE: 02/09/03
0548K	E-DATE: 02/10/03	0692K	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
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

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 MAJCS
OMS
& 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

Q011396.txt

01 182050Z 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-01-1396
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
0159J	E-DATE: 12/08/01	0158J	E-DATE: 01/11/02
0115K	E-DATE: 02/17/02	0580J	E-DATE: 02/19/02
0746J	E-DATE: 03/04/02	1407J	E-DATE: 03/10/02
0745J	E-DATE: 03/10/02	0952J	E-DATE: 04/13/02

Q011396.txt

1915J	E-DATE: 04/13/02	1751J	E-DATE: 05/16/02
0117K	E-DATE: 05/17/02	1750J	E-DATE: 05/18/02
1871J	E-DATE: 10/18/02	1802JSA2	E-DATE: 10/24/02
1802J	E-DATE: 10/24/02	0118K	E-DATE: 12/22/02
0309K	E-DATE: 12/22/02	0330K	E-DATE: 12/22/02
0547K	E-DATE: 12/23/02	0680K	E-DATE: 02/09/03
0548K	E-DATE: 02/10/03	0692K	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

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):

1761H	E-DATE: 11/02/01	1937H	E-DATE: 11/16/01
0159J	E-DATE: 12/08/01	0158J	E-DATE: 01/11/02
0115K	E-DATE: 02/17/02	0580J	E-DATE: 02/19/02
0746J	E-DATE: 03/04/02	1407J	E-DATE: 03/10/02
0745J	E-DATE: 03/10/02	0952J	E-DATE: 04/13/02
1915J	E-DATE: 04/13/02	1751J	E-DATE: 05/16/02
0117K	E-DATE: 05/17/02	1750J	E-DATE: 05/18/02
1871J	E-DATE: 10/18/02	1802JSA2	E-DATE: 10/24/02
1802J	E-DATE: 10/24/02	0118K	E-DATE: 12/22/02
0309K	E-DATE: 12/22/02	0330K	E-DATE: 12/22/02
0547K	E-DATE: 12/23/02	0680K	E-DATE: 02/09/03
0548K	E-DATE: 02/10/03	0692K	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
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

04. REASON AND DISPOSITION AS ABOVE.

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

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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

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.

6. MERCK PRE-FILLED SYRINGES ARE ON INDEFINITE BACKORDER STATUS; ONLY VIALS WILL BE AVAILABLE FOR THE FORESEEABLE 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 (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, EA

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

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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 MAJ
COMS
& NGB--THIS MSG HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MED
ICAL
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,
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