

FOOD AND DRUG ADMINISTRATION (FDA)
RECALLS/ALERT NOTICES

1. FDA MEDICAL EQUIPMENT RECALLS AND ALERTS. The following recalls are reported in accordance with AFMLL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMLL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items. (FOM, Capt David Zemkosky, DSN 343-4028)

CLASS I RECALLS: None

CLASS II RECALLS:

6525NS

MDC 15975 X-Ray Tube Assys (Stands & Suspension)
 PRODUCT Acoma Overhead Tube Support Model A90000-9, a fully counter-balanced heavy-duty radiographic x-ray tube suspension system. Recall #Z-240-7.
 CODE Serial numbers 05010194001 through 05010895018; All units shipped between 1/26/94 and 9/30/95.
 MANUFACTURER Acoma Medical Imaging, Inc., Wheeling, Illinois.
 RECALLED BY Manufacturer, by sending Equipment Field Modification Bulletin No. 97-01-OTS-001, Acoma Recall #1451001-1996-00001, on January 21, 1997. Firm-initiated field correction ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 136 units were distributed.
 REASON Screw heads may come off and allow the plate at the end of the bridge to fall off.

None Present
 Action Taken _____

6525NS

MDC 13271 X-Ray Rad Units, Fixed
 PRODUCT Diagnostic X-Ray System - SuperStand, general purpose radiography:
 (a) Model No. WWS0004 SuperStand;
 (b) Model No. WWS0005 SuperStand;
 (c) Model No. WWS0007 SuperStand;
 (d) Model No. WWS0008 SuperStand.
 Recall #Z-270/273-7.
 CODE All units.
 MANUFACTURER Wuestec Medical, Inc., Mobile, Alabama.
 RECALLED BY Manufacturer. FDA approved the firm's corrective action plan on February 18, 1997. Firm-initiated field correction ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY All units produced.

REASON The diagnostic x-ray devices were found noncompliant with 21 CFR 1010.2 and 1010.3 of the Federal Performance Standard for Diagnostic X-Ray System and Their Major Components. Some of the devices were improperly identified and certified to the diagnostic x-ray standard.

None Present
 Action Taken _____

MDC N0001 Nonmedical
PRODUCT All promotional material for ElectroMedia Air Cleaners, Model numbers 50C, 100C, and 35F, a medical recirculating air cleaner which can be used in industrial settings, but is also used by medical facilities. Recall #Z-282-7.

CODE Promotional material is for all codes for model numbers 35F, 50C, and 100C.

MANUFACTURER It's All About Clean Air, Inc., Glasgow, Kentucky.

RECALLED BY Manufacturer, by letter on January 27, 1997. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide.

QUANTITY Approximately 1,500 to 2,000 pieces of literature and/or brochures were distributed.

REASON The firm's advertisements/promotional material contain medical claims for which the firm does not have an approved 510(k).

None Present
 Action Taken _____

CLASS III RECALLS:

6515NS

MDC 11969 Heart-Lung Bypass Unit
PRODUCT BVS Blood Pump, used with the Abiomed BVS 5000 Bi-Ventricular Support Systems. Recall #Z-222-7.

CODE Control numbers beginning with G96, H96, I96, J96, D96 (Only part of D96 is affected: Pumps with control numbers ending in P48, P50, P51, P52, P54, P55, and P56) and E96, F96.

MANUFACTURER Abiomed, Inc., Danvers, Massachusetts.

RECALLED BY Manufacturer, by letter on November 7, 1996, and by fax on January 30, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Japan, Netherlands, Switzerland.

QUANTITY 321 units were distributed.

REASON The pump is subject to leakage which occurs at the outflow connector (bottom of the pump).

None Present
 Action Taken _____

6540NS

MDC 11479 Electronystagmographs
 PRODUCT Chartr ENG System, a computer based electronystagmograph used as a
 diagnostic tool. Recall #Z-252-7.
 CODE All units shipped prior to 11/22/96.
 MANUFACTURER ICS Medical Corporation, Schaumburg, Illinois.
 RECALLED BY Manufacturer, by letter dated November 22, 1996. Firm-initiated recall
 ongoing.
 DISTRIBUTION Nationwide, Egypt, Wales, Portugal, England, Canada.
 QUANTITY 32 units were distributed.
 REASON The keyboard will lock up if a certain sequence of keys is entered.

[] None Present
 [] Action Taken _____

MEDICAL EQUIPMENT SAFETY ALERTS: None

2. DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

CLASS I: A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

CLASS II: A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CLASS III: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.
 Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of these items on hand will immediately suspend the materiel from issue and use. CONUS activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. OVERSEAS activities will report quantities suspended to AFMLO/FOM-P no later than 25 APR 97 for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DPSC purchase order number, contract number, and stock record account number (SRAN). (FOM-P), Bonnie Phillips, DSN (343-4170)

CLASS I RECALLS: None

CLASS II RECALLS:

NSN 6505 Nonstandard and Numerous NSN's
 PRODUCT Doxycycline Hyclate, 100 mg Capsules, USP, in
 bottles of 50 and 500, Rx, a broad spectrum

antibiotic. Recall #D-118-7.

CODE Various labels and lot numbers as follows:

(a) Aligen Doxycycline Hyclate 100 mg capsules, USP in bottles of 50 capsules distributed by Aligen Independent

Laboratories, Inc., Jackson Hole, Wyoming
Lots: 55301M3 EXP 10/98 and 55310M3 EXP 10/98

(b) Aligen Doxycycline Hyclate 100 mg capsules, USP in bottles of 500 capsules distributed by Aligen Independent

Laboratories, Inc., Jackson Hole, Wyoming
Lots: 55304H3 EXP 08/98 and 55303M3 EXP 10/98

(c) Doxychel Doxycycline Hyclate 100 mg Capsules in bottles of 50 capsules, Rachelle Laboratories, Inc., Culver, Indiana, Lot:

55303R3 EXP 11/98

(d) Doxychel Doxycycline Hyclate 100 mg Capsules in bottles of 500 capsules, Rachelle Laboratories, Inc., Culver, Indiana,

Lots: 55302M3 EXP 10/98, 55305M3 EXP 10/98, 55306M3 EXP 10/98, 55308M3 EXP 10/98, 55309M3 EXP 10/98, and 55308R3 EXP 11/98

(e) Geneva Doxycycline Hyclate 100 mg capsules, USP in bottles of 50 capsules distributed by Geneva Pharmaceuticals, Inc., Broomfield, Colorado, Lots: 55310M3 EXP 10/98 and 55306R3 EXP 11/98

(f) Geneva Doxycycline Hyclate 100 mg capsules, USP in bottles of 500 capsules distributed by Geneva Pharmaceuticals, Inc., Broomfield, Colorado, Lots: 55307H3 EXP 08/98 and 55303R3 EXP 11/98

(g) Halsey Doxycycline Hyclate 100 mg capsules, USP in bottles of 50 capsules, Halsey Drug Co., Inc., Brooklyn, New York
Lots: 55306H3 EXP 08/98, 55310M3 EXP 10/98, 55303R3 EXP 11/98, and 55306R3 EXP 11/98

(h) Halsey Doxycycline Hyclate 100 mg capsules, USP in bottles of 500 capsules, Halsey Drug Co., Inc., Brooklyn, New York
Lots: 55306H3 EXP 08/98, 55304H3 EXP 08/98, 55307H3 EXP 08/98, 55308H3 EXP 08/98, 55301K3 EXP 09/98 and 55307A4 EXP 11/98

(i) Major Doxycycline Hyclate 100 mg capsules, USP in bottles of 50 capsules, Major Pharmaceutical Corp., Chicago, Illinois, and labeled "Manufactured by Halsey Drug Co., Inc., Brooklyn, N.Y." Lots: 55306H3 EXP

08/98, 55309H3 EXP 08/98, 55310M3 EXP
10/98 and 55306R3 EXP 11/98

(j) Major Doxycycline Hyclate 100 mg capsules,
USP in bottles of 500 capsules distributed by
Major Pharmaceutical Corp., Chicago, Illinois
and labeled "Manufactured by Halsey Drug Co.,
Inc., Brooklyn, N.Y." Lots: 55307H3 EXP
08/98, 55308H3 EXP 08/98, 55302M3 EXP 10/98
and 55306R3 EXP 11/98

(k) Mason Doxycycline Hyclate 100 mg capsules,
USP in bottles of 500 capsules distributed by
Mason Distributors, Inc., Hialeah, Florida,
and labeled "Mfd. by Halsey Drug Co., Inc.,
Brooklyn, N.Y." Lots: 55303M3 EXP 10/98 and
55301R3 EXP 11/98

(l) Moore Doxycycline Hyclate 100 mg capsules,
USP in bottles of 50 capsules distributed by
h.l. Moore Drug Exchange, New Britain,
Connecticut, and labeled "Mfg. by Halsey Drug
Co., Inc., Brooklyn, N.Y." Lots: 55306H3 EXP
08/98, 55309H3 EXP 08/98, 55310M3 EXP 10/98
and 55306R3 EXP 11/98

(m) Moore Doxycycline Hyclate 100 mg capsules,
USP in bottles of 500 capsules distributed by
h.l. Moore Drug Exchange, New Britain,
Connecticut, and labeled "Mfg. by Halsey Drug
Co., Inc., Brooklyn, N.Y." Lots: 55304H3 EXP
08/98, 55308H3 EXP 08/98, 55301K3 EXP 09/98,
55302M3 EXP 10/98

(n) Parmed Doxycycline Hyclate 100 mg
capsules, USP in bottles of 50 capsules
distributed by Parmed Pharmaceuticals, Inc.,
Niagara Falls, New York, and labeled "Mfg. by:
Halsey Drug Co., Inc., Brooklyn, N.Y."
Lot: 55310M3 EXP 10/98

(o) Parmed Doxycycline Hyclate 100 mg
capsules, USP in bottles of 500 capsules
distributed by Parmed Pharmaceuticals, Inc.,
Niagara Falls, New York, and labeled "Mfg. by:
Halsey Drug Co., Inc., Brooklyn, N.Y."
Lot: 55302M3 EXP 10/98

(p) Qualitest Doxycycline Hyclate 100 mg
capsules, USP in bottles of 50 capsules and
labeled "Mfg. for: Qualitest Products, Inc.,
Huntsville, Alabama. Mfg. by: Halsey Drug
Co, Inc., Brooklyn, N.Y." Lots: 55309H3 EXP
08/98, 55310M3 EXP 10/98 and 55306R3 EXP 11/98

(q) Qualitest Doxycycline Hyclate 100 mg
capsules, USP in bottles of 500 capsules and

labeled "Mfg. for: Qualitest Products, Inc.,
Huntsville, Alabama. Mfg. by: Halsey Drug Co.,
Inc., Brooklyn, N.Y." Lots: 55306H3 EXP
08-98, 55303M3 EXP 10/98, 55301R3 EXP 11/98,
55303R3 EXP 11/98 and 55306R3 EXP 11/98
(r) URL Doxycycline Hyclate 100 mg capsules,
USP in bottles of 50 capsules and labeled
"Manufactured for United Research
Laboratories, Inc., Bensalem, Pennsylvania
Mfd. By Halsey Drug Co., Inc., Brooklyn, N.Y."
Lots: 55306H3 EXP 08/98 and 55309H3 EXP 08/98
(s) URL Doxycycline Hyclate 100 mg capsules,
USP in bottles of 500 capsules and labeled
"Manufactured for United Research
Laboratories, Inc., Bensalem, Pennsylvania
Mfd. By Halsey Drug Co., Inc., Brooklyn, N.Y."
Lots: 55308H3 EXP 08/98 and 55301K3 EXP 09/98
(t) Warner Chilcott Doxycycline Hyclate 100 mg
capsules, USP in bottles of 50 capsules and
labeled "Manufactured for: Warner Chilcott
Labs, Div of Warner-Lambert Co., Morris
Plains, New Jersey By: Halsey Drug Co., Inc.,
Brooklyn, NY" Lots: 94953W EXP 08/98 and
55301M3 EXP 10/98
(U) Warner Chilcott Doxycycline Hyclate 100 mg
capsules, USP in bottles of 500 capsules and
labeled "Manufactured for: Warner Chilcott
Labs, Div of Warner-Lambert Co., Morris
Plains, New Jersey By: Halsey Drug Co., Inc.,
Brooklyn, NY" Lots: 92183W EXP 08/98, 55304M3
EXP 10/98 and 55311R3 EXP 11/98.

MANUFACTURER Houba, Inc., a subsidiary of Halsey Drug
Company, Inc., Culver, Indiana.

RECALLED BY Manufacturer, by letter dated January 3,
1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 12 million capsules were distributed.

REASON Stability is not assured through expiration
date (capsules may be excessively brittle).
See Q. A. message's 7066-0005 and 7069-0006.

None Present
 Action Taken _____

NSN 6515 Nonstandard

PRODUCT Leep Foot Pedal Accessory, Part Number 6032,
used with the Leep System 1000 Generator. The

Leep procedure is indicated in the diagnosis and treatment of some Cervical Intraepithelial Neoplasia (CIN) in patients. Recall #Z-253-7.

CODE Serial Numbers of Generator Units:
9512F300 - 9512F324, 9601F325 - 9601F374,
9605F375 - 9005F449.

MANUFACTURER Alsa Apparacchi, Bologna, Italy (foot pedal).

RECALLED BY Cooper Surgical, Shelton, Connecticut, by
letter on November 11, 1996. Firm-initiated
recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 132 units were distributed.

REASON The foot pedal air bladder may crack and
prevent activation of the Leep device.

None Present
 Action Taken _____

NSN 6515 Nonstandard

PRODUCT 72" Adult Heated Wire Breathing Circuits, used
to provide heat to the humidified air passing
to the patient's trachea through a breathing
tube attached to a ventilator.
Recall #Z-285-7.

CODE	Product Code	Lot Number
	1570240	97544
	1572347	97241
		97508
	157606	97144
		97552
		97980
	1576073	97178
		97723
	157610	96749
		97177
		97707
	1576139	97398
	157615	96892
		97855
	1576162	96750
		97145
		97249
	157617	97724
		97982
	157620	96940
		97553
	1576214	96941

97250
97399
97726
1576380 97245
157657 97121
1576689 96935
97720
97977
1576712 96576
542031 96741
97246
97550
97848.

MANUFACTURER Marquest Medical Products, Inc., Englewood,
Colorado

RECALLED BY Manufacturer, by letter on November 1, 1996.
Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 1,001 units were distributed.

REASON A manufacturing process error in which the
electrical insulation of the wire was scored
during assembly, exposing the metallic
conductor to the environment within the
breathing circuit.

None Present
 Action Taken _____

NSN 6515 Nonstandard

PRODUCT Adult Arterial Filters, indicated for use in
cardiopulmonary bypass procedures for removal
of particulate and gaseous micro emboli:
(a) Model No. 20; (b) Model No. M-220;
(c) Model No. M-40; (d) Model No. M-440;
(e) Model No. CBM-20; (f) Model No. CBM-40.
Recall #Z-287/292-7.

CODE Lot Numbers: 0132407-1 and 032406-501.

MANUFACTURER Medtronic Cardiopulmonary, Anaheim,
California.

RECALLED BY Manufacturer, by letter dated October 25,
1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 90,000 units were distributed.

REASON Breakage at the arterial outlet port.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Z-274/281-7, Royal Flush Plug Angiographic
Catheters with Beacon Enhanced Radiopaque
Tips, which appeared in the February 26, 1997,
Enforcement Report should read:
MANUFACTURER: Cook, Inc., Bloomington,
Indiana.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Neomycin (1.75 mg/ml) and Polymyxin B Sulfates
(10,000 units/ml) and Gramicidin (0.025 mg/ml,
Ophthalmic Solution, USP, Rx sterile, 10 ml,
under the following labels: Akorn - AK-SPOR,
Alba - ALBA-3 OPHTHALMIC SOLUTION, Carisle,
Geneva, Goldline, IDE-Interstate - TRIBIOTIC,
Rugby, Steris, URL, Aligen, Generics of Puerto
Rico - TRIPLE ANTIBIOTIC OPHTHALMIC, Major -
NEOCIDIN OPHTHALMIC SOLUTION, E. Fougera,
Schein. Recall #D-101-7.

CODE All lots within expiration date.
MANUFACTURER Steris Laboratories, Inc., Phoenix, Arizona.
RECALLED BY Manufacturer, by letter dated March 18, 1996.
Firm-initiated recall complete.
DISTRIBUTION Nationwide and Puerto Rico.
QUANTITY Approximately 1,668,000 units of all lots were
distributed.
REASON Product lacks stability (i.e. Gramicidin fails
potency assay at 18-month stability timepoint
-- 80%; SPEC is 90-110%).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT B-C-12-1000 (B Complex with C and B12),
Lyophilized), for Injection, in 10 ml

multidose vials, under the following labels:
Carlisle, Clint Pharmaceuticals, Inc. -
"VITA-PLEX", Germiphene, Gil Pharmaceutical -
"VITAJECT", Goldline, Hyrex - "KEY-PLEX
UNIVIAL", IDE - Interstate, International
Ethical Lab - "NEUROFORTE-SIX", Jaapharm
Canada Inc., Keene Pharmaceuticals - "VICAM
(IV)", Key Co., Lambda Pharmacal - "NEURO B12
FORTE", Llorens Pharm Corp., McGuff Co.,
Medical Products Panamericana - "NEURODEP",
Merit, Moore, OTC Pharmaceutical Products -
"NEUROBION", R.W. Enterprise (USA), Rugby,
Schein, Seyer - "SUPERVITE", Sorter - "NEURIN
- BC", Steris, United Research Labs.
Recall #D-102-7.

CODE All lots within expiration date.
MANUFACTURER Steris Laboratories, Inc., Phoenix, Arizona.
RECALLED BY Manufacturer, by letters dated April 17, 1996,
and June 13, 1996. Firm-initiated recall
complete.
DISTRIBUTION Nationwide and Japan.
QUANTITY Approximately 388,000 units were distributed.
REASON Product lacks stability (i.e., Dexpanthenol
fails potency assay as early as the 12-month
stability timepoint -- 89%; SPEC is 90-110%).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Morphine Sulfate Injection, Rx, USP, (a) 1
mg/ml and (b) 0.5 mg/ml, in 10 ml single dose
vials. Recall #D-103/104-7.
CODE Lot numbers: (a) 94K200, 94M050, 95E380,
95H610; (b) 94L120, 94L700, 95A010.
MANUFACTURER Steris Laboratories, Inc, Phoenix, Arizona.
RECALLED BY Manufacturer, by letter dated April 26, 1996.
Firm-initiated recall complete.
DISTRIBUTION Nationwide.
QUANTITY (a) Approximately 36,000 vials; (b)
Approximately 53,000 vials were distributed.
REASON Presence of particulate matter.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Chorionic Gonadotropin for Injection, Rx, USP,
10,000 units/10 ml multiple dose vial,
distributed under the following labels:
Steris, Schein, Carlisle, Goldline, Hyrex -
Chorex-10, R.W. Enterprises (USA) - Ovulatone.
Recall #D-105-7.
CODE All product within expiration date.
MANUFACTURER Steris Laboratories, Inc., Phoenix, Arizona.
RECALLED BY Manufacturer, by letter dated May 17, 1996.
Firm-initiated recall complete.
DISTRIBUTION Nationwide.
QUANTITY Approximately 147,000 vials were distributed.
REASON presence of particulate matter.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Multivitamins for Infusion, Rx, in 10 ml
single dose vials, under the following labels:
Schein, Steris, Faulding (Canada).
Recall #D-106-7.
CODE All lots within expiration date.
MANUFACTURER Steris Laboratories, Inc., Phoenix, Arizona.
RECALLED BY Manufacturer, by letter dated April 19, 1996.
Firm-initiated recall complete.
DISTRIBUTION Nationwide and Canada.
QUANTITY Approximately 3 million vials were
distributed.
REASON Presence of particulate matter.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Heparin Sodium Injection, USP, Rx, used for
used for anti-coagulant prophylaxis and
treatment, under the following labels -
Steris, Schein, Biogen:
(a) 1,000 units/ml in 10 ml vials;
(b) 20,000 units/ml, in 1 ml and 2 ml vials;
(c) 40,000 units/ml, in 1 ml, 2 ml, and 5 ml
vials. Recall #D-107/109-7.

CODE Lot numbers: (a) 95F780; (b) 96C390 (1 ml),
94E850, 95D740, 95F910 (2 ml); (c) 95K080 (1
ml), 95B190 (2 ml), 95A040, 95B191, 95K081,
95A040 (5 ml).
MANUFACTURER Steris Laboratories, Inc., Phoenix, Arizona.
RECALLED BY Manufacturer, by letter dated November 4,
1996. Firm-initiated recall complete.
DISTRIBUTION Nationwide and Ukraine.
QUANTITY Approximately 34,000 vials of all sizes were
distributed.
REASON Presence of particulate matter.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Prochlorperazine Edisylate Injection, USP, 10
mg/2 ml, Rx, used for used for the treatment
of severe nausea and vomiting, and for the
management of the manifestations of psychotic
disorders. Recall #D-110-7.
CODE Lot numbers: 94F910, 94G570, 94H280, 94H320,
94J400 (All lots within expiration date).
MANUFACTURER Steris Laboratories, Inc., Phoenix, Arizona.
RECALLED BY Manufacturer, by letters dated January 18,
1996, and February 8, 1996. Firm-initiated
recall complete.
DISTRIBUTION Nationwide.
QUANTITY Approximately 18,500 vials were distributed.
REASON Product lacks stability (fails potency assay
at the end of expiry).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT GoJo brand Hand Medic Antiseptic Skin
Treatment, OTC, in 500 ml cartridges.
Recall #D-111-7.
CODE Batch numbers: 049671, 049672, 049673,
049674.
MANUFACTURER Gojo Industries, Inc., Cuyahoga Falls, Ohio.
RECALLED BY Manufacturer, by fax sent on January 28-30,
1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide (to industrial users only).

QUANTITY The following amounts of product identified with the referenced stock numbers were distributed: Stock No. 8242-512-R1: 8,184 cartridges; Stock No. 1302-01: 5,760 cases; and Stock No. 8242-06: 220 cases.

REASON Subpotent -- Recalled lots do not contain the sole active ingredient, benzalkonium chloride.

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT Martec brand Piroxicam Capsules, USP, 10 mg, in bottles of 100, Rx indicated for use in arthritis. Recall #D-112-7.

CODE 96556-1 EXP 03/01.

MANUFACTURER Martec Pharmaceutical, Inc., Kansas City, Missouri.

RECALLED BY Manufacturer, by letter dated January 24, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 1,347 bottles were distributed between 7/11/97 - 1/23/97.

REASON Unit label may lack the prescription legend; insert is correctly labeled.

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT Ethex brand Hydrocodone Bitartrate and Guaifenesin Liquid, in 16 fluid ounce bottles, Rx for the temporary relief of dry, nonproductive cough associated with upper and lower respiratory tract congestion. Recall #D-116-7.

CODE Lot numbers: L8693 and L8696.

MANUFACTURER KV Pharmaceutical Company, St. Louis, Missouri.

RECALLED BY Ethex Corporation, St. Louis, Missouri, by letter dated January 24, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 14,136 bottles of lot L8693 were distributed between 12/23-30/96 and 7,307 bottles of lot

L8696 were distributed between January 13-16, 1997.

REASON Presence of precipitate (guaifenesin is precipitating due to exposure to low temperatures while warehoused and shipped.

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT Alcoholado Alcanformentol 70, OTC alcohol 70% (topical liquid), in 12 fluid ounce bottles.
Recall #D-117-7.

CODE Lot #G07-0794 EXP 11/27/99.

MANUFACTURER Specialties Chemical, Inc., Ponce Puerto Rico.

RECALLED BY Manufacturer, by visit on January 27, 1997.
Firm-initiated recall ongoing.

DISTRIBUTION Puerto Rico.

QUANTITY 192 bottles were distributed.

REASON Incorrect product formulation -- isopropyl alcohol used instead of ethyl alcohol.

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT RX Guiatuss with Codeine Syrup, in 1 gallon, 16 ounce, 8 ounce, and 4 ounce bottles, an expectorant, cough suppressant, under the following labels: Barre, Rugby, Schein, and H.L. Moore.
Recall #D-120-7.

CODE Lot numbers: RB6059, RA6016, RS5841, RP5742, RP5743, RN5652, RL5568, RK5512, RJ5429, RB5089, RA5028, RA5027.

MANUFACTURER Alpharma (Barre-National), Baltimore, Maryland.

RECALLED BY Manufacturer, by letter on January 14, 1997.
Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 1,563,288 units were distributed.

REASON Product lacks stability (i.e. codeine phosphate analysis results showed decreasing potency).

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT Sodium Acetate Injection, USP, 100 mEq, (2 mEq/ml), Preservative Free, in 50 ml single dose vials, for IV use only after dilution, as a source of sodium for addition to large volume IV fluids to prevent or correct hyponatremia in patients with restricted or no oral intake. Recall #D-121-7.

CODE Lot numbers: 150681 EXP 5/97, 160634 EXP 4/98.

MANUFACTURER Fujisawa USA, Inc., Melrose Park, Illinois.

RECALLED BY Fujisawa USA, Inc., Deerfield, Illinois, by letter dated February 11, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 29,375 vials were distributed; firm estimated that 25 percent of the product remained on market at time of recall initiation.

REASON Label error on declared strength (i.e. label incorrectly states "Each ml contains 272.16 mg sodium acetate" (anhydrous), it should read, "Each ml contains 164 mg sodium acetate (anhydrous).

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT Nitrostat Sublingual Tablets, 0.4 mg (Nitroglycerin Tablets USP), in bottles of 25, Rx indicated for the acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease. Recall #D-119-7.

CODE Lot #01385F EXP 7/97.

MANUFACTURER Warner Lambert Company, Fajardo, Puerto Rico.

RECALLED BY Parke-Davis, Division of Warner Lambert Company, Morris Plains, New Jersey, by letter on January 28, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 23,750 bottles were distributed.

REASON Product lacks stability (failed content assay

at the 15-month stability timepoint -- 86.6%;
SPEC is 90-110%).

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Branemark System Sterile Mk II 5 x 13 mm wide
Platform Fixture, Catalog #SDCA 668, a self-
tapping endosseous implant fixture.
Recall #Z-250-7.
CODE Lot #530423.
MANUFACTURER Nobel Biocare AB, Gothenburg, Sweden.
RECALLED BY Nobel Biocare USA, Inc., Westmont, Illinois,
by telephone on December 20, 1996. Firm-
initiated recall ongoing.
DISTRIBUTION California, New York, Florida, Pennsylvania,
Texas, New Mexico, Illinois.
QUANTITY 22 fixtures were distributed.
REASON The vials labeled as containing a 5 x 13 mm
wide platform fixture actually contain a 3.3 x
15 mm narrow platform fixture.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Branemark System Sterile carbon steel drills,
single use drills, countersinks and pilot
drills used to prepare the bone for endosseous
implant fixtures:
(a) Catalog #SDIB 001 - Drill Kit, 7-10 mm
(b) Catalog #SDIB 004 - Drill Kit, 7-15 mm
(c) Catalog #SDIB 133 - Drill Kit, Long Shaft,
L 7-15 mm
(d) Catalog #SDIB 091 - Twist Drill, d 2.0 mm,
L 7-15 mm
(e) Catalog #SDIB 092 - Twist Drill, d 2.0 mm,
L 13-20 mm
(f) Catalog #SDIB 003 - Twist Drill, d 3.0 mm,
L 7-10 mm
(g) Catalog #SDIB 081 - Twist Drill, d 3.0 mm,
L 7-15 mm
(h) Catalog #SDIB 086 - Twist Drill, d 3.0 mm,
L 13-20 mm

- (i) Catalog #SDIB 135 - Twist Drill, d 3.0 mm, L 7-15 mm Long Shaft
- (j) Catalog #SDIB 268 - Twist Drill, d 3.15 mm, L 7-15 mm
- (k) Catalog #SDIB 269 - Twist Drill, d 3.15 mm, L 13-20 mm
- (l) Catalog #SDIB 274 - Twist Drill, d 4.3 mm, L 6-12 mm
- (m) Catalog #SDIB 021 - Countersink, Short
- (n) Catalog #SDIB 005 - Countersink, Long
- (o) Catalog #SDIB 136 - Countersink, Long Shaft
- (p) Catalog #SDIB 291 - Pilot Drill, d 4.3/3 mm. Recall #Z-254/269-7.

CODE All carbon-steel drills, lots 522558 through 524432.

MANUFACTURER Nobel Biocare AB, fka Nobelpharma AB, Gothenburg, Sweden.

RECALLED BY Nobel Biocare USA, Inc., fka Nobelpharma USA, Westmont, Illinois, by letter dated May 17, 1996. Firm-initiated recall compete.

DISTRIBUTION Nationwide.

QUANTITY 9,689 units were distributed.

REASON The carbon steel surface of the devices may have oxidized.

None Present
 Action Taken _____
