

**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:

6530NS
MDC 10360 Beds, Orthopedic
PRODUCT Rehabilitation Beds, full electric: a) BCW XL1000 Rehabilitation Bed, full electric, 1,000-lb. capacity, Twin - 39 x 80", 3/4 size 48" x 80" B) BCW XL1000 Rehabilitation Bed, full electric, 1,000-lb. capacity, Double - 54" x 80" c) BCW XL1000 Rehabilitation Bed, full electric, 1,000-lb. capacity, Queen - 60" x 80". Recall #Z-412/414-8.

CODE The following serial numbers are affected by this recall: 105148 105661 105798 105905 105170 105662 105799 105908 105171 105663 105816 105909 105637 105664 105817 105933 105648 105698 105820 106021 105651 105712 105833 106022 105652 105713 105834 106023 105653 105715 105866 106024 105654 105717 105877 106031 105655 105740 105878 106032 105656 105741 105881 106039 105657 105742 105882 106040 105658 105744 105891 105659 105750 105896 105660 105794 105899.

MANUFACTURER Raye's Inc., doing business as Wheelchairs of Kansas, Ellis, Kansas.
RECALLED BY Manufacturer, by letter on March 19, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 58 beds were distributed.
REASON The devices have ground fault problems which could cause shock to the user.

[] None Present
[] Action Taken _____

CLASS III RECALLS:

6515NS
MDC 10396 Biofeedback Systems
PRODUCT Incon Therapy, Recon Rx version 3.01 software for the portable Rx component, a component of a neurological biofeedback monitoring system for the treatment of incontinence. Recall #Z-418-8.

CODE Serial numbers 1600 to 3326.

MANUFACTURER KWM Electronics Corporation, West Jordan, Utah.
RECALLED BY NextEra Medical, L.L.C., Columbus, Ohio, by recall field correction August 1997 and by letter on March 17, 1998. Firm-initiated field correction ongoing.

DISTRIBUTION Indiana, West Virginia, Tennessee, Ohio, North Carolina, New York, Nevada, Kentucky, Illinois, Arizona, Florida.

QUANTITY 1,762 units were distributed.

REASON Rx units were not functioning correctly. Obsolete version 3.01 software had been installed in the units.

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 15 May 98 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
PRODUCT	Bayer, Trasylol (Aprotinin Injection) Sterile Solution, 10,000 K.I.I./mL (1.4 mg/mL), Single Dose Vial, 100ml, NDC 0026-8196-36, 200ml, NDC 0026-8197-63, Rx indicated for prophylactic use to reduce perioperative blood loss and the need for a blood transfusion in patients undergoing cardiopulmonary bypass in the course of repeat coronary artery bypass graft surgery. Recall #D-099-8.
CODE	100ml vials Lot# 7JAB, EXP 6/99 100ml vials Lot# 7LAC, EXP 6/99

200ml vials Lot# 7JFB, EXP 7/99.

MANUFACTURER Bayer AG, Leverkusen, Germany.
 RECALLED BY Bayer Pharmaceutical Division, West Haven, Connecticut (labeler), by letter dated February 26, 1998. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.
 QUANTITY US Lot # 7JAB (Bayer Germany 965863K) 13,980 Vials released 11/21/97.
 US Lot # 7LAC (Bayer Germany 965863K) 15,942 Vials released 1/9/98.
 US Lot # 7JFB (Bayer Germany 967050E) 8,436 Vials released 11/24/97.

REASON Foreign particulate - One vial was found to contain a birch tree seed.

[] None Present
 [] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Propranolol HCL Extended-release Capsules, indicated in the management of hypertension, Rx. Brand name Betachron™, under the following labels: TEVA, URL, Shein, Parmed, Qualitest, Rugby, Geneva, Moore, Major, Zenith Goldline:
 a) Propranolol HCL 60 mg Extended Release (ER) Capsules, 100 count bottles, NDC # 0258-3609-01;
 b) Propranolol HCL 80 mg ER Capsules, 100 count bottles, NDC # 0258-3610-01.
 c) Propranolol HCL 120 mg ER Capsules, 100 count bottles, NDC # 0258-3611-01.
 d) Propranolol HCL 160 mg ER capsules, 100 count bottles, NDC # 0258-3612-01.
 Recall #D-100/103-8.

CODE 60 mg strength: (20 lots)
 6C083 (3/98), 6C085 (3/98), 6C087 (3/98), 6D001 (3/98), 6D003 (3/98), 6D005 (3/98), 6D007 (4/98), 6E004 (5/98), 6E005 (5/98), 6F022 (5/98), 6F023 (5/98), 6G001 (5/98), 6G003 (5/98), 6G004 (5/98), 6G005 (5/98), 6G006 (6/98), 6G019 (6/98), 6G020 (6/98), 6G021 (6/98) & 6G022 (6/98).
 80 mg strength: (6 lots)
 6D068 (3/98), 6E007 (4/98), 6E007A (4/98), 6F005 (7/98), 6F006 (7/98) & 6H011 (7/98).
 120 mg strength: (9 lots)
 6C089 (3/98), 6C090 (3/98), 6D069 (3/98), 6E008 (4/98), 6E008A (4/98), 6F007 (6/98), 6H015 (6/98), 6H016 (6/98) and 6F008 (6/98).
 160 mg strength: (7 lots)
 6C091 (3/98), 6C092 (4/98), 6E009 (4/98), 6E009A (4/98), 6F009 (5/98), 6F010 (7/98), and 6H017 (7/98).

MANUFACTURER Inwood Laboratories, Inc., (a subsidiary of Forest Laboratories, Inc.), Inwood, New York.
RECALLED BY Manufacturer, by letter on March 4, 1998.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Puerto Rico.
QUANTITY 294,016 bottles were distributed as follows:
Total 60 mg bottles distributed : 88,052
Total 80 mg bottles distributed : 90,220
Total 120 mg bottles distributed: 77,755
Total 160 mg bottles distributed: 37,989.
REASON Dissolution failure.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT MGP Hyoscyamine Oral Drops, hyoscyamine sulfate 0.125 mg/mL; Rx oral liquid used as adjunctive therapy in the treatment of peptic ulcers, treatment of infant colic, et al. packaged in 15 mL bottle with 0.25 mL dropper. NDC #60432-103-15. Recall #D-104-8.8
CODE Lot numbers: 21387A, 21400A, 21466A, 21466C.
MANUFACTURER Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois.
RECALLED BY Manufacturer, by letter dated February 24, 1998.
Firm-initiated recall ongoing.
DISTRIBUTION Indiana, Pennsylvania, California, North Carolina, Illinois, Florida, Ohio, Tennessee, Missouri, South Dakota, Utah, Kentucky, New York, Vermont, North Dakota, Michigan.
QUANTITY 21,500 units were distributed; firm estimated that 25 percent of product remained on market at time of recall initiation.
REASON Mislabeling - Labeling indicates each dropperful contains 0.125 mg drug based on a 1 mL dropper, however these lots are packaged with 0.25 mL dropper.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Procainamide Hydrochloride Extended Release Tablets, USP, 500 mg, in 100 tablet bottles, indicated for treatment of documented arrhythmias, under the Schein Pharmaceutical label.
NDC #0364-0716-01. Recall #D-107-8.
CODE Lot #D6A0205 EXP 2/98.
MANUFACTURER Danbury Pharmacal, Inc., a subsidiary of Schein

RECALLED BY Pharmaceutical, Danbury, Connecticut.
Manufacturer, by letter faxed on March 2, 1998.
Firm-initiated recall ongoing.

DISTRIBUTION Alabama, Arizona, California, Georgia, Idaho,
Illinois, Ohio, Massachusetts, Minnesota, New
Mexico, New Jersey, Pennsylvania, Tennessee,
Kentucky, Virginia, Indiana, West Virginia.

QUANTITY 1,955 bottles were distributed.

REASON Dissolution failure at 4th hour interval (24 month
stability test).

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT Tisit Blue Gel Lice Treatment (Pyrethrins
0.3%/Piperonyl Butoxide 3.0%), in 1 ounce tubes,
OTC pediculicide. Recall #D-108-8.

CODE Lot numbers: 50301, 60301, 70302.

MANUFACTURER Pfeiffer Pharmaceuticals, Inc., also known as SSS
Company, Atlanta, Georgia.

RECALLED BY Manufacturer, by letter dated on or about January
12, 1998. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 11,668 tubes were distributed.

REASON Subpotent for Pyrethrins (one of the two active
ingredients).

None Present
 Action Taken _____

NSN 6515 Nonstandard

PRODUCT Hewlett Packard Multifunction Electrode Pads,
used with the HP Codemaster and Codemaster 100
Defibrillator/Monitors, intended as a
multifunction external pad for ECG monitoring:
a) M1749A-Adult U.S. Pads
b) M1749B-Adult IEC Pads
c) M1749B-Pediatric US Pads.
Recall #Z-394/396-8.

CODE Lot numbers: a) 040897, 050897, 020997, 030997
b) 200897; c) 260897.

MANUFACTURER OEM Manufacturer: Cardiotronics Systems, Inc.,
a Division of Ballard Medical Products,
Carlsbad, California.

RECALLED BY Hewlett Packard Company, Medical Products
Group, Andover, Massachusetts, by letter dated
January 16, 1998. Firm-initiated recall
ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 4004 boxes of lot M1749A(10sets/bx); 250 boxes of lot M1749B, and 100 boxes of lot M1749D(sets/box) were distributed.

REASON The conductive gel may deteriorate to a liquid thus making the electrode pads unusable because they will not adhere to a patient and may not provide adequate electrical stimulation.

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard

PRODUCT Lead Aprons and Thyroid Collars, designed to be worn during surgical procedures:

- a) Standard Front, Catalog #101
- b) Surgical Drop, Catalog #103
- c) Two Wing Velcro, Catalog #105
- d) "Buckle Front, Catalog #109
- e) Lumbar Support Cinch Front, Catalog #120
- f) Special Procedure, Catalog #201
- g) Special Procedure Coat with Lumbar Cinch, Catalog 207

The above lead aprons models are followed by the letters L, M, S and P. Also, Model 105 may be preceded by the letter E.

- h) Half Aprons, Catalog #401

The half aprons catalog number is followed by the letters A, C or T.

- i) Thyroid Collar, Catalog #501

The thyroid collars catalog number is followed by the letters A or B. Recall #Z-397/405-8.

CODE See above.

MANUFACTURER Supplier of radioactive lead vinyl sheets:
The Kennedy Company, Scottsboro, Alabama
Supplier of radioactive lead powder:
Taracorp Industries, Granite City, Illinois
Source of radioactive lead:

RECALLED BY Midco Industries, St. Louis, Missouri
Davis Lead Aprons, Inc., Houston, Texas, by letter dated June 13, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Alabama, Arizona, Georgia, Kentucky, Louisiana, North Carolina, Tennessee, Texas.

QUANTITY Quantity Distributed: 179 units--15 model 101, 8 model 103, 13 model 105, 22 model E105, 5 model 109, 21 model 120, 1 model 201, 3 model 207, 9 model 401, and 66 model 501.

REASON The radiation protection devices contain lead contaminated with small amounts of radioactive substances.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Zimmer Versys Cemented Stem Inserter Clamp,
Catalog #00-7896-051-00, used to hold the stem
on the inserter during placement and impaction
into the femoral canal. Recall #Z-407-8.
CODE Lot numbers: 51899100, 51899200, 51899300.
MANUFACTURER Zimmer, Inc., Warsaw, Indiana.
RECALLED BY Manufacturer, by letter dated November 13,
1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 202 units were distributed.
REASON The ball tip of the femoral inserter clamp
broke during, possibly due to usage in an
unintended manner.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT CholestoChek Total Cholesterol Screening Test,
promoted as an over-the-counter Home Screening
Test Kit to determine Total Cholesterol.
Recall #Z-392-8.
CODE All unexpired codes.
MANUFACTURER Technical Chemicals and Products, Inc. (also
known as Health Mark Diagnostics L.L.C.)
Pompano Beach, Florida.
RECALLED BY Manufacturer, by letter on February 3, 1998.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 3,415 kits were distributed.
REASON Lack of 510k for over-the-counter marketing.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Prevpac Triple Therapy (lansopazole capsules 30
mg/Amoxicillin capsules 500 mg/Clarithromycin
tablets 500 mg), Rx, used for the treatment of
duodenal ulcers associated with H. Pylori. NDA

50-757; NDC 0300-3702-01 on commercial box of 14 daily patient packs (blister cards), NDC 0300-3702-10 on professional sample daily patient pack, NDC 0300-3702-11 on commercial single daily patient pack; NDC 0300-3702-00 on professional sample box of 14 daily patient packs; 14 daily patient packs per package, 8 packages per case. Recall #D-105-8.

CODE Lot #35 001 2Z EXP 08/99.

MANUFACTURER Anderson Packaging, Rockford, Illinois (contract packager).

RECALLED BY Tapp Pharmaceuticals, Inc., Deerfield, Illinois, by letters dated January 30, 1998, and February 2, 1998. Firm-initiated recall ongoing.

DISTRIBUTION West Virginia, California, Oregon, Illinois, Tennessee, New York, North Carolina, New Mexico, Missouri, Colorado, Indiana, Texas, Minnesota, Louisiana, Maryland, Massachusetts, Alabama, Idaho, Connecticut, Georgia, Mississippi.

QUANTITY 1,434 cases were distributed

REASON Mislabeling - Some product labeled as "professional samples, not for sale" were released for sale.

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT Triamcinolone Acetonide Lotion USP, 0.1%, in 60 ml bottles, Rx a topical corticosteroid used as anti-inflammatory and antipruritic agents, under the Thames, Zenith Goldline, and Qualitest labels. NDC numbers: 49158-211-32, 0182-1777-68, 0603-7855-49. Recall #D-106-8.

CODE Lot #M283 EXP 2/2002.

MANUFACTURER Thames Pharmacal Company, Inc., Ronkonkoma, New York.

RECALLED BY Manufacturer, by telephone on March 2-3, 1998, followed by letter on March 4, 1998. Firm-initiated recall ongoing.

DISTRIBUTION New York, New Jersey, California, Louisiana Kentucky, Florida, Oregon, Virginia, Alabama.

QUANTITY 2,559 bottles were distributed.

REASON Unapproved raw material source used in product's manufacturing.

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT Elta Swiss Skin Cream in 16 ounce and 28 ounce

CODE plastic containers. Recall #D-109-8.
MANUFACTURER Lot numbers: 7606 (16 oz), 7607 (28 oz).
RECALLED BY Swiss American Products, Inc., Dallas, Texas.
Manufacturer, by letters dated January 12, 1998,
and February 15, 1998. Firm-initiated recall
ongoing.
DISTRIBUTION Nationwide.
QUANTITY 58 16-ounce containers and 168 28-ounce containers
were distributed; firm estimated that 20 16-ounce
and 25 28-ounce containers remained on market at
time of recall initiation.
REASON Short weight fill (lot 7607 only) and unapproved
drug claims. (Note: Both lots bore unapproved
drug claims, labeling issued for correction,
product itself not recalled (lot 7606)).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT API Diphenhist Capsules (Diphenhydramine HCL), 25
mg, in 100 unit bottles, allergy medicine
antihistamine. Recall #D-110-8.
CODE Lot #3600208 EXP 11/99.
MANUFACTURER York Pharmaceuticals, Inc., Kansas City, Kansas.
RECALLED BY Manufacturer, by telephone on March 5, 1998, and
by letter faxed on March 6, 1998. Firm-initiated
recall ongoing.
DISTRIBUTION Tennessee, Texas, New York.
QUANTITY 2,040 bottles were distributed.
REASON Mislabeling - Caplet product labeled as
containing capsules.

None Present
 Action Taken _____
