

**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, Mr. Dave Baker, DSN 343-7487)

CLASS I RECALLS: None.

CLASS II RECALLS:

NSN 6515
MDC 16272
PRODUCT Hewlett Packard Image Point Ultrasound System, Model 2410A used with the Model M21359A 7.5 MHZ Linear Transducer, used in ultrasound imaging to determine stenosis of the carotid artery. Recall #Z-160-8.

CODE All systems with Software Rev. A.0.0., A.0.1, A.0.2.

MANUFACTURER Hewlett Packard Company, Medical Products Group, Andover, Massachusetts.

RECALLED BY Manufacturer, by letter dated July 20, 1997. Firm-initiated field correction complete.

DISTRIBUTION Nationwide and international.

QUANTITY 441 units were distributed.

REASON Software overestimates peak blood velocity by 15-25% in some Doppler examinations with the Model 2135A transducer.

None Present
 Action Taken _____

NSN 6515
MDC 13215
PRODUCT Board Assembly, PCB ASSY #1 + 2, Part No. 71-04-01-142S, utilized with the Flo-Gard 8200 Volumetric Infusion Pump, product code 2M8023, an electronic component for the Flo-Gard 8200 Volumetric Infusion Pump, composed of two printed circuit boards connected by ribbon cables. This board assembly contains the operational software for the infusion pump. Recall #Z-777-8.

CODE There are no lot numbers. Units affected were shipped between 2/20/98 and 6/15/98 for self service repairs.

MANUFACTURER Nera Electronics Pte. Ltd., Singapore.

RECALLED BY Baxter Healthcare Corporation, IV Systems Division, Round Lake, Illinois, by telephone on July 27-31, 1998, followed by letter on August 4, 1998. Firm-initiated recall ongoing.

DISTRIBUTION California, North Carolina, New Jersey, Illinois, Texas, Pennsylvania, South Carolina, Georgia and Puerto Rico.

QUANTITY 13 board assemblies were distributed.

REASON

The board assemblies had the wrong software version installed on them. The boards have version 2.09 instead of version 2.13.

None Present

Action Taken _____

NSN 6530
MDC 14101 or 14106
PRODUCT

"DRS SYSTEM", a spinal traction device used to provide patient static traction, intermittent traction as well as numerous other claimed intended uses such as: Low back pain relief, degenerated disc, facet disease, herniated disc, sciatica, joint mobilization, myofascial release and ligamentous stretch, etc. NOTE: The device itself is NOT UNDER RECALL, rather the instruction manual and certain promotional material containing unapproved therapeutic claims is under recall. Recall #Z-782-8. All units.

CODE
MANUFACTURER
RECALLED BY

Professional Distribution Systems, Inc.,(PDS), Boca Raton, FL. Manufacturer, by fax and letter mailed on June 25, 1998. Firm-initiated field correction ongoing.

DISTRIBUTION

Indiana, South Carolina, Illinois, Utah, New Jersey, Florida, Missouri, North Carolina, Georgia, Pennsylvania, Connecticut, Alabama, District of Columbia, California, Tennessee, Maryland, Nicaragua, Canada.

QUANTITY
REASON

33 units were distributed.

The earlier versions of the devices Operator's Manual and Sales Brochures contain terminology and claims that are unacceptable for the approved 510K now and was originally violative because the firm had not approved 510K when the devices were originally distributed.

None Present

Action Taken _____

NSN 6525
MDC 13272
PRODUCT

300MS Portable Mobile Stand, for use with MinXray's H500 Portable X-Ray Unit, X903G Portable Veterinary X-Ray Unit, and HF80 and HF100 High Frequency Portable Veterinary X-Ray Units. A stand used with portable x-ray units to allow positioning of the x-ray head over the center of a hospital bed. The stand has casters to allow mobility, a tube arm that raises and lowers via hand crank and the head swivels both left and right, easily disassembling for transport. Recall #Z-784-8.

CODE
MANUFACTURER
RECALLED BY

Stands distributed between 11/2/92 and 3/25/93.

Kaufman Products Chicago, Illinois.

MinXray Inc., Northbrook, Illinois, by telephone on March 30, 1998 through April 2, 1993, and by letters dated April 6 and 12, 1993, followed by letter and telephone on June 21, 1995. Firm-initiated field correction complete.

DISTRIBUTION

Kentucky, Florida, Ohio, Illinois, Texas, Oklahoma, Utah and Minnesota, for further distribution to end user locations.

QUANTITY

22 stands were distributed.

REASON The lock nut on the handle holding assembly could come loose, allowing the x-ray head to fall on the patient.

None Present
 Action Taken _____

NSN 6640
MDC 15551
PRODUCT

Software Versions 3.22 and 3.23, Catalog #81500, a medical device used for in-vitro quantitative determinations of various clinical chemistries in serum. Recall #Z-786/787-8.

CODE
MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

All analyzers with software versions 3.22 and 3.23 Catalog #81500. Beckman Coulter, Inc., Brea, California. Manufacturer, by letter on June 24, 1998. Firm-initiated recall ongoing. Nationwide and international. Approximately 1,296 units were distributed. Software anomaly in these versions may allow test results to be posted to a different patient sample number.

None Present
 Action Taken _____

NSN 6530
MDC 12330
PRODUCT

Power Lifts marketed under the trade name AReliant Power Lift@. Recall # Z-779/781-8.

CODE

80 FSA Models: RPA450, RPL450, and RPA600. All serial numbers above referenced Model Numbers of the Reliant Power Lifts manufactured between November, 1996 and January 1998, are subject to recall.

MANUFACTURER
RECALLED BY

Invacare Corporation, Elyria, Ohio. Manufacturer, by telephone, fax, Fed X, on July 28, 1998. Firm-initiated recall on-going.

DISTRIBUTION
QUANTITY
REASON

Nationwide. 722 patient power lifts are currently in distribution. The linear actuator shaft may break while in use, resulting in a patient falling from the lift.

None Present
 Action Taken _____

NSN 6530
MDC 13814
PRODUCT
CODE
MANUFACTURER
RECALLED BY

Midmark Surgical Lounge Stretch, Model 547. Recall #Z-783-8. TFW001000 through TFW001059.

DISTRIBUTION
QUANTITY
REASON

Midmark Corporation, Versailles, Ohio. Manufacturer, by telephone on July 28-30, 1998 and by letter dated July 30, 1998. Florida, Hawaii, Texas, New York, Connecticut. 22 Stretchers. There is a potential for the weld between the side rail and the spur gear to fail

causing the side rail to drop without warning.

[] None Present
[] Action Taken _____

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 **16 October 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	Oxygen, USP, in high pressure aluminum cylinders, used for respiratory therapy and emergency oxygen. Recall #D-223-8.
CODE	All lots.
MANUFACTURER	Cambria Medical Company (formerly Altoona Medox Ent, Inc.), Altoona, Pennsylvania.
RECALLED BY	Manufacturer, by visit to be accomplished by the end of May 5, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Pennsylvania.
QUANTITY	Undetermined.
REASON	Good manufacturing practice deviations.

[] None Present
[] Action Taken _____

NSN	6505 Nonstandard
PRODUCT	Nitrostat Sublingual Tablets (Nitroglycerin), 0.4 mg (1/150 gr) in bottles of 25, indicated for the acute relief of an attack

orprophylaxis of angina pectoris due to coronary artery disease.
 Recall #D-225-8.
 Lot numbers: 11906F EXP 10/98, 01417F EXP 12/98.
 Warner Lambert Company, Fajardo, Puerto Rico.
 Parke-Davis, Division of Warner Lambert Company, Morris Plain,
 New Jersey, by letter on June 30, 1998. Firm-initiated recall
 ongoing.

CODE
 MANUFACTURER
 RECALLED BY

DISTRIBUTION
 QUANTITY

REASON

Nationwide.
 25,657 bottles of lot 11906F and 24,353 bottles of lot 01417F
 were distributed.
 Subpotent at 15 and 18 month stability test stations.

None Present
 Action Taken _____

6505 Nonstandard
 a)Red Blood Cells, b)Platelets, c)Fresh Frozen Plasma,
 d)Cryoprecipitated AHF, e) Plasma, f)Recovered Plasma, g) Red
 Blood Cells, for further manufacturing. Recall #B-1506/B-1513-8.
 Unit# 42X95806
 American Red Cross Blood Services, Cleveland, Ohio.
 Manufacturer, by letters on March 28, 1997 and April 13, 1998.
 Firm-initiated recall on-going.

NSN
 PRODUCT

CODE
 MANUFACTURER
 RECALLED BY

DISTRIBUTION
 QUANTITY

REASON

Ohio, California, New York, Florida, Massachusetts and Switzerland.
 a)130 units, b)67 units c)3 units d)2 units e) 20 units f)108 units g)7
 units.
 Blood products, which tested negative for antibody to the human
 immunodeficiency virus type 1 (anti-HIV-1), but were collected from
 donors who previously tested repeatedly reactive for anti-HIV-1 and
 were improperly reentered, were distributed.

None Present
 Action Taken _____

6505 Nonstandard
 Recall #D-100/103-8, Propranolol HCL (Inwood Laboratories),
 Which appeared in the March 25, 1998, April 1 and 15, 1998, and
 July 29, 1998 Enforcement Reports has been extended as follows:
 Propranolol HCL, 60 mg, Extended Release (ER) Capsules, 100
 Count bottles, 1 additional lot 7J032.

NSN
 UPDATE

None Present
 Action Taken _____

6515 Nonstandard
 Board Assembly, PCB ASSY #1 + 2, Part No. 71-04-01-142S,
 Utilized with the Flo-Gard 8200 Volumetric Infusion Pump, product
 Code 2M8023, an electronic component for the Flo-Gard 8200
 Volumetric Infusion Pump, composed of two printed circuit boards
 Connected by ribbon cables. This board assembly contains the

NSN
 PRODUCT

Operational software for the infusion pump. Recall #Z-777-8.
 There are no lot numbers. Units affected were shipped between 2/20/98 and 6/15/98 for self service repairs.

CODE
 MANUFACTURER
 RECALLED BY
 DISTRIBUTION
 QUANTITY
 REASON

Nera Electronics Pte. Ltd., Singapore.
 Baxter Healthcare Corporation, IV Systems Division, Round Lake, Illinois, by telephone on July 27-31, 1998, followed by letter on August 4, 1998. Firm-initiated recall ongoing.
 California, North Carolina, New Jersey, Illinois, Texas, Pennsylvania, South Carolina, Georgia and Puerto Rico.
 13 board assemblies were distributed.
 The board assemblies had the wrong software version installed on them. The boards have version 2.09 instead of version 2.13.

None Present
 Action Taken _____

NSN
 PRODUCT
 CODE
 MANUFACTURER
 RECALLED BY
 DISTRIBUTION
 QUANTITY
 REASON

6515 Nonstandard
 CoaguChek PT Test Strip, sold for professional use in conjunction with the CoaguChek System, for quantitative prothrombin time testing in fresh capillary or venous whole blood.
 Recall #Z-785-8.
 Lot 090 EXP 12/31/99.
 Roche Diagnostics/Boehringer Mannheim Corporation, Indianapolis, Indiana.
 Manufacturer, by letter sent on June 29, 1998. Firm-initiated recall ongoing.
 Nationwide.
 1,607 test kits were distributed between June 8 and June 24, 1998.
 The firm's quality assurance testing found that some of the packages have an incomplete seal in the foil wrap and that could lead to strip degradation and potentially erroneous test results.

None Present
 Action Taken _____

NSN
 PRODUCT
 CODE

6520 Nonstandard
 Titanium plasma sprayed (TPS) cylindrical Endosseous Dental Implants and Hydroxylapatite (HA) coated cylindrical Endosseous Dental Implants. Recall #Z-804/819-8.
 CATALOG NUMBER LOT NUMBER
 HH315 48240
 HP410 47452
 HP413 48241
 HP415 43413
 HP415 43975
 TH310 39751
 TH310 44851
 TH310 48292
 TH313 40047
 TH313 40570

TH313	43184
TH313	47451
TH315	38149
TH315	43183
TP485	39750
TP485	43182
TP410	38147
"	39752
"	41240
"	44002
"	44850
"	46213
"	46928
"	47950
TP413	40568
"	42111
"	47301
"	43763
"	45023
TP415	38148
"	38150
"	39208
"	40567
"	43185
"	46841
TP418	44853
TP418	47949
TP585	48367
TP510	37978
"	39491
"	39745
"	47951
"	40571
"	43414
"	43976
TP513	37334
"	37979
"	39492
"	39746
"	40569
"	44852
"	47952
TP610	34192
"	38151
"	40566
"	47953
"	47954

MANUFACTURER
RECALLED BY

DISTRIBUTION
QUANTITY

REASON

Implant Innovations, Palm Beach Gardens, FL.
Manufacturer, by telephone on June 9, 1998. Firm-initiated recall on-going.
Nationwide and International
3,914 implants were shipped.
The Sterile Barrier packaging may have a hole in the outer pouch.

None Present
 Action Taken _____

NSN 6530 Nonstandard
PRODUCT "DRS SYSTEM", a spinal traction device used to provide patient static traction, intermittent traction as well as numerous other claimed intended uses such as: Low back pain relief, degenerated disc, facet disease, herniated disc, sciatica, joint mobilization, myofascial release and ligamentous stretch, etc.
NOTE: The device itself is NOT UNDER RECALL, rather the instruction manual and certain promotional material containing unapproved therapeutic claims is under recall.
Recall #Z-782-8.
CODE All units.
MANUFACTURER Professional Distribution Systems, Inc.,(PDS), Boca Raton, FL.
RECALLED BY Manufacturer, by fax and letter mailed on June 25, 1998.
DISTRIBUTION Firm-initiated field correction ongoing.
Indiana, South Carolina, Illinois, Utah, New Jersey, Florida, Missouri, North Carolina, Georgia, Pennsylvania, Connecticut, Alabama, District of Columbia, California, Tennessee, Maryland, Nicaragua, Canada.
QUANTITY 33 units were distributed.
REASON The earlier versions of the devices Operator's Manual and Sales Brochures contain terminology and claims that are unacceptable for the approved 510K now and was originally violative because the firm had not approved 510K when the devices were originally distributed.

[] None Present
[] Action Taken _____

NSN 6530 Nonstandard
PRODUCT Midmark Surgical Lounge Stretch, Model 547. Recall #Z-783-8.
CODE TFW001000 through TFW001059.
MANUFACTURER Midmark Corporation, Versailles, Ohio.
RECALLED BY Manufacturer, by telephone on July 28-30, 1998 and by letter dated July 30, 1998.
DISTRIBUTION Florida, Hawaii, Texas, New York, Connecticut.
QUANTITY 22 Stretchers.
REASON There is a potential for the weld between the side rail and the spur gear to fail causing the side rail to drop without warning.
PRODUCT Promotional Material on Coronary Stent System. Recall # Z-788-8.
CODE Not applicable.
MANUFACTURER Guidant ACS/DVI, Temecula, CA.
RECALLED BY Manufacturer, by letter on June 12 and June 30, 1998. Firm-initiated recall on-going.
DISTRIBUTION Nationwide.
QUANTITY 211 physicians.
REASON Unauthorized newsletters were sent containing inappropriate use of the device.

[] None Present
[] Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Casanthranol and Docusate Sodium Capsules, 30/100 mg, in 60 and 100 capsule bottles, OTC laxative and stool softener, under the Good Neighbor Pharmacy and Brite-Life labels. Recall #D-224-8.
CODE Good Neighbor 60s, NDC 24385-495-72, BBC # 792-242, Lots: F032 (exp. date 2/2000), F047 (2/2000), F055 (3/2000), F088 (5/2000), F107 (4/2000), F138A (6/2000). Good Neighbor 100s, NDC 24385-495-78, BBC # 897-074, Lots: E288 (12/1999), F088A (5/2000). Brite Life 60s, NDC 24385-495-72, BBC # 791-988, Lots: F032 (2/2000), F047 (2/2000), F066 (3/2000), F107 (4/2000), F138 (6/2000). Brite Life 100s, NDC 24385-495-78, BBC # 897-363, Lots: E289 A (5/2000).
MANUFACTURER RP Scherer North America, St. Petersburg, Florida.
RECALLED BY PL Developments, Inc., Farmingdale, New York, by telephone on July 22, 1998, followed by letter on July 29, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Michigan and California.
QUANTITY 50,277 bottles of all lots and sizes were distributed.
REASON Immediate container label lacks directions for use/dosage instructions.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT OTC Calcium Supplements, 1.8 gm, in 16 fluid ounce (pint) bottles: a) Calciquid, Calcium Supplement (Calcium Glubionate Syrup, USP, Econolab brand NDC 55053-690-16; Breckenridge brand NDC #51991-495-16; b) Calcionate, Calcium Supplement (Calcium Glubionate Syrup, USP), Rugby brand, NDC # 0536-2770-85. Recall #D-226/227-8.
CODE Only Lot Number "80416" Expiration of "3-01".
MANUFACTURER Pegasus Laboratories, Inc., Pensacola, Florida.
RECALLED BY Manufacturer, by letter on June 25, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Texas, Arizona, Illinois, Maryland, New York, New Jersey, California, Pennsylvania, Missouri, Kentucky, Indiana, Georgia, Iowa.
QUANTITY 2,360 pints were distributed.
REASON Mislabeling - Some of the bottles contain a different product-Crantex Liquid (phenylpropanolamine HCL 20 mg/guaifenesin 100 mg/alcohol 5% in each 5 ml).

None Present
 Action Taken _____

NSN 6505 Nonstandard
 Amway brand "FORMUCARE" Triple Antibiotic Ointment (Bacitracin-Neomycin Sulfate-Polymyxin B Sulfate), net wt. 28.35 g (1 oz.). An OTC topical antibiotic used for first aid. Manufactured for Amway Corporation, Ada, MI. Recall #D-230-8.

CODE Lot M255, expiration date 1/2000 Lot M211, expiration date 12/1999
 Amway product codes: Triple antibiotic ointment A-5600; Antifungal Cream A-5569.

MANUFACTURER Thames Pharmacal Co., Inc., Ronkonkoma, New York.
 RECALLED BY anufacturer, by verbal direction to distributor on May 18, 1998 and by letter August 3, 1998. Firm-initiated recall on-going.

DISTRIBUTION Amway Coporation, East Ada, Michigan.
 QUANTITY 1,308.5 cases were distributed.

REASON Mispackaging - some tubes of Amway brand "FORMUCARE" Antifungal Cream were packaged into cartons labeled "Formucare" Triple Antibiotic Ointment and distributed.

[] None Present
 [] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Piryryl Shampoo in 2, 4 and 8 oz containers used in the treatment of head, pubic and body lice. Recall #D-231-8.

CODE Lot No. NDC No. Size Exp Date Label

RK7600	11822-1583-4	4 oz	11/99	Rite Aid
RK7600	211158394	4 oz	11/99	Rite Aid
RL7708	0472-1583-94	4 oz	11/99	Alpharma
RL7708	0904-2528-20	4 oz	11/99	Major
RK7711	41163-1583-4	4 oz	10/99	Albertson's
RK7711	11822-1583-4	4 oz	10/99	Rite Aid
RK7711	0472-1583-94	4 oz	10/99	Alpharma
RN7792	49348-443-34	4 oz	12/99	Valurite
RN7792	41163-1583-4	4 oz	12/99	Rite Aid
RN7792	0904-2528-20	4 oz	12/99	Major
RN7792	11822-1585-4	4 oz	12/99	Rite Aid
RN7792	41131-1583-4	4 oz	12/99	Home Best
RS7972	11822-1583-8	8 oz	01/00	Rite Aid
RS7972	0472-1583-92	2 oz	01/00	Alpharma
RS7972	6021986	2 oz	01/00	Rugby
RP7914	0472-1583-94	4 oz	03/00	Alpharma
RP7914	11822-1583-4	4 oz	03/00	Rite Aid

MANUFACTURER Alpharma, U.S. Pharmaceutical Division, Baltimore, Maryland. Alpharma label and private labels to include: Rite Aid, Major, Albertson's, Valurite, Home Best and Rugby.

RECALLED BY Manufacturer, by letter certified mail on/about 8/14/98. Firm initiated recall on-going.

DISTRIBUTION Nationwide.
 QUANTITY RK7600 - 30,409 units produced/30,384 units distributed. RL7708 - 28,270 units produced/28,224 units distributed. RK7711 - 30,484 units produced/30,348 units distributed. RN7792 - 30,713 units Produced/25,656 units distributed RS7972 - 58,204 units produced/45,348 units distributed RP7914 - 75,648 units produced/5,184 units distributed. A total of 165,144 units were shipped.

REASON

Pyrethrins was calculated incorrectly for the raw material.

None Present

Action Taken _____

NSN

PRODUCT

CODE

MANUFACTURER

RECALLED BY

DISTRIBUTION

QUANTITY

REASON

6505 Nonstandard

Doxorubicin Hydrochloride for injection. Recall #D-232-8.

Lot No. 22102

Ben Venue Laboratories, Bedford, Ohio.

Manufacturer, by letter on August 13, 1998.

Nationwide, Puerto Rico

13,920 vials

Product exceeds shelf life moisture.

None Present

Action Taken _____