

**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 15757 Lasers, Surgical
PRODUCT Model Chromos 694 Ruby Laser System, used in dermatology (hair removal). Recall #Z-630-8.
CODE Model Chromos 694.
MANUFACTURER Mehl/Biophile International (SLS Biophile in Wales is the actual manufacturer, owned by Mehl).
RECALLED BY Mehl/Biophile International Corporation, Gainesville, Florida. FDA approved the firm's corrective action plan June 5, 1998. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide.
QUANTITY 51 units were distributed.
REASON The device failed to comply with 21 CFR 1040.10(f)(2)(iii) in that it lacked a fail-safe fiber interlock, lacked certain labels per 1010.2, 1040.10(g)(4) and (g)(6), and the operators manual lacked calibration procedures per 1040.11(a)(2).

None Present
 Action Taken _____

CLASS III RECALLS: None

MEDICAL EQUIPMENT SAFETY ALERTS:

6515NS
MDC 11218 Hemodialysis Units
PRODUCT Hemodialysis Machine, Model 2008H, used in clinics to treat patients with kidney deficiency. Safety Alert #N-006-8.
CODE All serial numbers.
MANUFACTURER Fresenius Medical Care, Walnut Creek, California.
ALERTED BY Manufacturer, by letter dated April 27, 1998.
DISTRIBUTION Nationwide, Canada, Mexico, Caribbean.
QUANTITY 23,000 units were distributed.
REASON On rare occasions the machine may spontaneously shut down during mid-treatment without an audible alarm.

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 7 Aug 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:

NSN	6505 Nonstandard
PRODUCT	a) Epi Pen, Auto Injector (Epinephrine Injection 1:1000), 0.3mL, 0.3 mg, 1 EpiPen per box, 12 units per carton or tray, RX, labeled under three different responsible firm names: (1) Dey Pharma label (NDC #49502-500-01) (2) Center label (NDC #0268-0301-01) and (3) Center label (NDC #0268-0301-01) b) EpiPen Jr., Auto-Injector 0.15 mg (Epinephrine Injection 1:2000), 0.3mL, 0.15 mg, for allergic emergencies (anaphylaxis), RX, labeled under three different responsible firm names: (1) Dey Pharma label - NDC #49502-501-01; (2) Center label - NDC #0268-0302-01; and (3) Center label - NDC #0268-0302-01. Recall #D-150/151-8.
CODE	Lot numbers: 7SX208, 7SX209, 7SX216, 7SX217, 7SX194, 7RX204, 7RX223, 7SR247, 7SR265, 7SR286, 7SR292, 7SR293, 7SR317, 7SR318, 7SR321, 7SR342, 7SR355, 7SR356, 7SR358, 7SR370, 7SR371, 7SR378, 7JR242, 7JR243, 7JR289, 7JR290, 7JR323, 7JR361, 7JR362, 7JR374, 7JR375, 8SR004, 8SS077, 8SS078, 7C6214, 7C6279, 7C8277, 7C8381, 7F7221, 7F7262, 7F7380, 7C5238, 7C5376, 7F8391, 7F8220, 7F8263, 7CA382.
MANUFACTURER RECALLED BY	Meridian Medical Technologies, Inc., St. Louis, Missouri. Manufacturer, by press release on May 8, 1998, and by letter dated May 8, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	Approximately 1,000,000 auto-injectors were distributed.
REASON	Subpotency.

None Present
 Action Taken _____

CLASS II RECALLS:

NSN 6505 Nonstandard
PRODUCT Anzemet(R) Injection (Dolasetron Mesylate), 12.5 mg (20mg/mL), in 0.625 mL ampuls, Rx anti-nauseant and anti-emetic agent. NDC #0088-1208-65.
Recall #D-169-8.
CODE Lot #73007091 EXP 5/99.
MANUFACTURER Ben Venue Laboratories, Bedford, Ohio. Contract Manufacture
RECALLED BY Hoechst Marion Roussel, Inc., Cincinnati, Ohio, by letter on May 14, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 31,506 ampules were distributed; firm estimated that 30 percent of product (9,452 ampules) remained on market at time of recall initiation.
REASON Precipitate formation (dolasetron sulfate crystals) due to inadequate ampule washing.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) Cyclomydril (cyclopentolate hydrochloride, phenylephrine hydrochloride) a prescription Sterile Ophthalmic Solution packaged in 2 ml and 5 ml plastic DROP-TAINER dispensers. Indications and Usage: Production of mydriasis (dilation of the pupil of the eye). NDC 0065-0359-02 (2 ml), NDC 0065-0359-05 (5 ml) b) Epinal 1% (epinephryl borate) a prescription Sterile Ophthalmic Solution in 7.5 ml glass bottles with sterile dropper assembly. Indications and Usage: Control of simple (open angle) glaucoma; may be used in combination with miotics, beta blockers, hyperosmotic agents, or carbonic anhydrase. NDC 0065-0264-07, c) Mydrfrin 2.5% (Phenylephrine Hydrochloride Ophthalmic Solution) in 3 ml plastic DROP-TAINER dispensers Indications and Usage: Recommended as a vasoconstrictor, decongestant, and mydriatic in a variety of ophthalmic conditions and procedures. NDC 0065-0342-03.
Recall #D-177/179-8

CODE Lot Code Expiration Date
Cyclomydril AAFP 8/31/98
(National) ACFT 11/30/98
ADL7 4/30/99
AFDH 5/31/99
AFZA 9/30/99
AHYA 11/30/99
AHWX 12/31/99
AKAP 2/28/2000
AKWM 4/30/2000
Cyclomydril AAMA
(International) ADHP
AHYAA
AKWMA

Epinal 1% AH87 1/31/99
 Mydrfrin 2.5% 6FXA 5/31/98
 6FXF 5/31/98
 AAFL 8/31/98
 AAYA 9/30/98
 ACZ3 12/31/98
 ACZ9 1/31/99
 AC75 2/28/99
 ADL3 3/31/99
 AFC5 5/31/99
 AFMU 7/31/99
 AFY9 8/31/99
 AHCY 8/31/99
 AHCZ 10/31/99
 AHC1 11/30/99
 AHWP 11/30/99
 AHWN 1/31/2000
 AHWW 1/31/2000
 AKAU 3/31/2000
 10913F 4/30/2000.

MANUFACTURER RECALLED BY Alcon Laboratories, Inc., Fort Worth, Texas.
 Manufacturer, by letter on May 22, 1998.
 Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY a) Nationwide and international; b&c) Nationwide.
 a) 238,758 units; b) 3,838 units; c) 840,756 units were distributed.

REASON Contamination - Some units could contain microscopic particles from the lining (glass) of the manufacturing vessel.

None Present
 Action Taken _____

NSN PRODUCT 6515 Nonstandard
 LeukoNet Pre-Storage Leukoreduction Filtration System (Leukocyte Reduction Filter w/Attached Storage Bag for Red Blood Cells).
 Recall #B-1077-8.

CODE Lot # 72461-73511's, Product Mfg. from 9/3/97-12/17/97.

MANUFACTURER RECALLED BY HemaSure, Inc., Marlborough, Massachusetts.
 Manufacturer, by fax or by telephone on January 6, 1998, and by letter on April 20, 1998.
 Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY Nationwide and international.
 60,796 filters were distributed.

REASON LeukoNet, leukocyte reduction filters have been implicated with numerous reports of adverse transfusion reactions.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Tincoben(R) Topical Protective Tincture (Benzoin, Aloe, Tolu Balsam and Storax), in 4 fluid ounce bottles, OTC, indicated for use as a topical protective. NDC #0496-0542-04.
Recall #D-168-6.
CODE Lot #57-035 EXP 2/99.
MANUFACTURER Ferndale Laboratories, Inc., Ferndale, Michigan.
RECALLED BY Manufacturer, by letter on April 23, 1998.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 13,313 bottles were distributed.
REASON Stability failure (below specification) for non-volatile residue.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT BullFrog Quick Gel SPF 18 Sunblock, in 4 ounce bottles. Recall #D-170-8.
CODE Lot #97K2.
MANUFACTURER Chattem, Inc., Chattanooga, Tennessee.
RECALLED BY Manufacturer, by letter dated May 8, 1998.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 20,697 units were distributed.
REASON Mislabeling - The back panel label incorrectly declares the product as SPF36.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT SUPAC Analgesic Tablets (Acetaminophen 160 mg/Aspirin 230 mg/caffeine 33 mg), in 100 and 1,000 tablet bottles. Recall #D-171-8.
CODE Lot numbers: 5F03, 5H01, 5L06.
MANUFACTURER Mission Pharmacal Company, Boerne, Texas.
RECALLED BY Manufacturer.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 2533/100 tablets and 1133/1000 Tablets bottles were distributed.
REASON Stability - Data does not support labeled expiration date (salicylic acid value).

None Present

Action Taken _____

NSN 6505 Nonstandard
PRODUCT Generic and private label forms of over-the-counter liquid medications: a) Milk of Magnesia (Magnesium Hydroxide 400 mg), in 12 fluid ounce bottles; b) Tussin DM (Guaifenesin, USP 100 mg/Dextromethorphan Hydrobromide, USP 10 mg), in 4 fluid ounce bottles; c) Nite Time Adult (Acetaminophen, USP 1000 mg/Dextromethorphan Hydrobromide, USP 30 mg/Pseudoephedrine Hydrochloride, USP 12.5 mg), in 6 fluid ounce bottles; d) Pink Bismuth (Bismuth Subsalicylate 262 mg per 30 ml), in 12 fluid ounce bottles; e) Antacid Liquid with Simethicone (Magnesium Hydroxide 200 mg Aluminum Hydroxide 200 mg/Simethicone 20 mg), in 12 fluid ounce bottles; f) Antacid Liquid (Magnesium Hydroxide/Aluminum Hydroxide), in 12 fluid ounce bottles. Recall #D-161/163 & 165/168-8.

CODE All lot numbers.
MANUFACTURER OTC Technologies, Inc., Atlanta, Georgia.
RECALLED BY Manufacturer, by letter on May 1, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Michigan, California, Mississippi, North Carolina, Florida.
QUANTITY Approximately 14,214 cases (12 units per case) were distributed.
REASON Good manufacturing practice and formulation deviations (reduced or lack of active ingredients).

None Present

Action Taken _____

NSN 6505 Nonstandard
PRODUCT Oxygen Medical, USP, Compressed, Rx, in M6, D, E, M, and H steel and aluminum cylinders and in 30L and 40L cryogenic vessels. Recall #D-173-8.

CODE All lot numbers prior to 5/20/98.
MANUFACTURER Home Health Care, Inc., doing business as Commonwealth Home Health Care, Inc. , Danville, Virginia.
RECALLED BY Manufacturer, by telephone on May 20, 1998, followed by visit Firm-initiated recall ongoing.
DISTRIBUTION Virginia and North Carolina.
QUANTITY Firm estimates 1,500 cylinders of all sizes and 30 cryogenic vessels remain in commerce.
REASON Good manufacturing practice deviations.

None Present

Action Taken _____

NSN 6505 Nonstandard
PRODUCT Health Care brand Pink Bismuth (Bismuth Subsalicylate) in 6 fluid ounce clear plastic bottles, OTC for relief of indigestion, upset stomach, heartburn, diarrhea, and nausea. NDC #062091-805-06. Recall #D-174-8

CODE All lots.
MANUFACTURER South Atlantic Industries, Greenville, South Carolina.

RECALLED BY Great Lakes Wholesale, Wyoming, Michigan, by letter dated August 21, 1997.
Firm-initiated recall complete.
DISTRIBUTION Nationwide, Canada, Granada, West Indies, Puerto Rico.
QUANTITY 18,348 bottles were distributed.
REASON Formulation problems - Clumps due to excess methylcellulose.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Oxygen Medical, USP, Compressed, Rx, in B, C, D, E, M, and N-60 cylinders.
Recall #D-175-8.
CODE All lot numbers prior to 5/11/98.
MANUFACTURER Advanced Health Care Services, Inc., Pulaski, Virginia.
RECALLED BY Manufacturer, by visit on May 11, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Virginia and North Carolina.
QUANTITY 100 of all types of cylinders remain in commerce.
REASON Good manufacturing deviations.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Schein Pharmaceutical Potassium Chloride for Oral Solution, USP, 20 mEq,
Orange Flavor, in 1.5 gram packets of 30 per carton, Rx for therapeutic use
in patients with hypokalemia with or without metabolic alkalosis, in digitalis
intoxication, and in patients with hypokalemic familial periodic paralysis;
and for the prevention of potassium depletion. NDC #0364-7378-30.
Recall #D-176-8.
CODE Lot numbers: KC60209-5, KC70203-1, KC60709-1, KC70203-5, KC60710-1,
KC70713-4, KC60901-3, KC70819-7, KC60901-4, KC70819-6, KC61122-1,
KC71125-6, KC61122-2, KC71125-4.
MANUFACTURER Bajamar Chemical Company Inc., St. Louis, Missouri repacker/responsible firm).
RECALLED BY Repacker, by letter dated April 16, 1998. Firm-initiated recall ongoing.
DISTRIBUTION New York and Arizona.
QUANTITY 27,024 30-packet cartons were distributed.
REASON Mislabeling - Exterior cartons incorrectly declare 2.5 grams of potassium chloride.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT ZOLL Radiolucent StatPadz Electrodes, intended for
use in defibrillation, non invasive pacing,
cardioversion and ECG monitoring in conjunction
with ZOLL defibrillator/pacer equipment.
Recall #Z-587-8.
CODE Lot #1198 EXP 14 SEP 98.
MANUFACTURER Bio-Detek Inc., Pawtucket, Rhode Island.
RECALLED BY Manufacturer, by letter on April 30, 1998.

DISTRIBUTION
QUANTITY
REASON

Firm-initiated recall ongoing.
Nationwide and Uruguay.
600 pairs were distributed.
Electrode pads were unable to conduct
defibrillation.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
Tempest Orthopedic Pump Tube Set, Accessory to Orthopedic Pump, which
is used to deliver saline solution to distend joints, knee and shoulder to facilitate
Arthroscopic surgery. Recall #Z-601-8.

CODE

Part Number: 350-200-000; Affected lot Numbers: 98030682, 98040822,
98040782, 98050962, 98040802.

MANUFACTURER
RECALLED BY

Stryker Puerto Rico, Arroyo, Puerto Rico.
Stryker Endoscopy, Santa Clara, California, by letter sent on June 5, 1998.
Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and China.
1,518 units were distributed.
A minute crack in the blister pack may compromise the sterility of the device.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
Hu-Friedy Dental Hand Instruments with, Advantouch Resin Handles,
dental hand instruments including scalers, curettes, explorers, probes, mirror
handles and operative instruments used for the manual removal of plaque and
calculus from teeth, examination of teeth for caries detection, screening for
periodontal disease states, holding mirror heads and cavity preparation and
restorations. Recall #Z-603-8.

CODE

All instruments with the cream color Advantouch resin handles (306 catalog
numbers).

MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

Hu-Friedy Manufacturing Company, Inc., Chicago, Illinois.
Manufacturer, by letters dated May 20 and 28, 1998. Firm-initiated recall ongoing.
Nationwide.
756,387 devices were distributed.
The device handle may snap or break during use.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
Pelorus brand Stereotatic Surgical Kits: a) Skull Mount Kit, Catalog #744A1330;
b) Biopsy Kit Catalog #744A1335; c) MRI Skull Mount Kit, Catalog #744A1486,
single use, sterile devices used to perform neurological surgeries on the brain,
under the Ohio Medical Instrument label. Recall #Z-620/622-8.

CODE

All codes.

MANUFACTURER

Ohio Medical Instrument Company, Cincinnati, Ohio.

RECALLED BY
DISTRIBUTION
QUANTITY
REASON

Manufacturer, by letter on May 29, 1998. Firm-initiated recall ongoing.
Nationwide and Puerto Rico.
453 kits were distributed.
Sterilization of the device has not been adequately validated.

None Present
 Action Taken _____

NSN
PRODUCT

6550 Nonstandard
Richard-Allan Scientific brand Bouins Fluid Specimen Management System
for fixation of pathological specimens in 1 gallon containers, Reorder Number
57211, Allegiance catalog number C4340-3. The product is a general fixative
for histology. Recall #Z-624-8.

CODE

Lots numbers: 97A17, EXP 01/99; 97C12, EXP 03/99; 97F20, EXP 06/99;
97H07, EXP 08/99; 97K20, EXP 10/99 and 97M19, EXP 12/99. All lots
produced since January 1997.

MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

Richard-Allan Scientific, Kalamazoo, Michigan.
Manufacturer, by letter on April 30, 1998. Firm-initiated recall ongoing.
Nationwide.
797 gallons were distributed.
The amount of formaldehyde in the formula was decreased in error from 23% to
2%.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
Medi-trace 1210H Combination Defibrillation, Pacing and ECG Electrodes, part
#31177721, intended for use in defibrillation and pacing procedures.
Recall #Z-632-8.

CODE

HC0001	HC80006	HC80011
HC80002	HC80007	HC80013
HC80003	HC80008	HC80015
HC80004	HC80009	HC80016
HC80005	HC80010.	

MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

Graphic Controls Canada, Ltd., Ganonoque, Ontario, Canada.
Graphic Controls Corporation, Buffalo, New York, by letter dated May 20, 1998,
and by fax on May 22 & 26, 1998. Firm-initiated recall ongoing.
Nationwide, Canada, Spain, Australia, Brazil.
908.5 cases were distributed.
The lead wire of the electrode may become detached from the electrode body
upon opening the electrode pouch.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
Molteno brand, Sterile, Double Plate and Dual Chamber Plate Glaucoma
Shunt Implants, used to reduce the intraocular pressure in severe and
complex cases of glaucoma where conventional drainage procedures have

CODE failed or offer little prospect of success. Recall #Z-608-8.
MANUFACTURER Lots R21005, R22005, L21003 & L22003.
RECALLED BY Molteno Ophthalmic, Dunedin, New Zealand.
Innovative Ophthalmic Products, Inc. (IOP), Costa Mesa, California, by
telephone, and by letters dated from March 20, 1998 to April 10, 1998.
Firm-initiated recall ongoing.
DISTRIBUTION California, Connecticut, Florida, Indiana, Massachusetts, Michigan, Minnesota,
Missouri, New York, Ohio, Pennsylvania, South Carolina, Texas, Vermont,
Washington state, Wisconsin, Puerto Rico, Canada.
QUANTITY 146 units were distributed.
REASON Tube is curved instead of straight.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Richard-Allan Scientific brand Bouins Fluid Specimen Management System
for fixation of pathological specimens in 1 gallon containers, Reorder Number
57211, Allegiance catalog number C4340-3. The product is a general fixative
for histology. Recall #Z-624-8.
CODE Lots numbers: 97A17, EXP 01/99; 97C12, EXP 03/99; 97F20, EXP 06/99;
97H07, EXP 08/99; 97K20, EXP 10/99 and 97M19, EXP 12/99. All lots
produced since January 1997.
MANUFACTURER Richard-Allan Scientific, Kalamazoo, Michigan.
RECALLED BY Manufacturer, by letter on April 30, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 797 gallons were distributed.
REASON The amount of formaldehyde in the formula was decreased in error from 23% to
2%.

None Present
 Action Taken _____
