

**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:

6515NS
MDC 10142 Anesthesia Unit, Gas Scavenger
PRODUCT AirCare Source Control Airator. Recall #Z-910-7.
CODE Serial numbers 000085 through 000298.
MANUFACTURER Industrial Molding Corporation, Lubbock, Texas.
RECALLED BY Apotheus Laboratories, Ltd., Lubbock, Texas, by telephone on July 21, 1997, by fax on July 22, 1997, followed by letter dated July 23, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Florida, Illinois, Louisiana, Kentucky, Kansas, Pennsylvania, Texas.
QUANTITY 213 units were distributed.
REASON Seven units were found to have Primary Inspiratory Relief (PIR) Valves that stuck; two of the devices were also found to have stuck Inspiratory Negative Pressure Relief Valves.

[] None Present
[] Action Taken _____

6640NS
MDC 17740 Hematology Analyzer
PRODUCT Cell-Dyn 3500 Software, Revision G or H used in Cell-Dyn 3500 CS Hematology Analyzer and Cell-Dyn 3500SL Hematology Analyzer. Recall #Z-021/022-8.
CODE List Nos: 03H69-01, 04H41-01, 91340-01, 91340-03, 91350-01, 91350-03.
MANUFACTURER Abbott Diagnostics Division, Santa Clara, California.
RECALLED BY Manufacturer, by letter sent beginning September 29, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.
QUANTITY 3,938 kits were distributed.
REASON When using the Cell-Dyn 3500 Software, Revision G or H, specimens run in the Auxiliary Mode can recover white blood cells (WBC) results higher than expected.

[] None Present
[] Action Taken _____

6515NS
MDC 10024 Defibrillator
PRODUCT Cardiolife Defibrillator, used to restore normal heart rhythms:
a) Model TEC-8250A;
b) Model TEC-8251A. Recall #Z-023/024-8.

CODE a) Units shipped from 7/21/92 - 8/18/94;
b) Units shipped from 6/22/92 -3/13/96.

MANUFACTURER Nihon Kohden Corporation, Ohsato-Gun, Saitama- Ken, Japan.

RECALLED BY Nihon Kohden American, Inc., Irvine, California, by telephone followed by letter on August 12, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and Canada.

QUANTITY 134 units were distributed.

REASON If the battery is used beyond the recommended life cycle, the battery may develop an internal short circuit, thereby creating an excessive current flow in the charging circuit of the defibrillator which could render the defibrillator inoperable until appropriate repairs can be made.

None Present
 Action Taken _____

6515NS
MDC 17678
PRODUCT Vital Signs Monitor
Vigilance brand Continuous Cardiac Output/Oximetry (CCO/SvO2) Monitor, with drug calculation mode to calculate infusion rates, Product Code 74 DYG. Recall Z-031-8.

CODE Various serial numbers.

MANUFACTURER Baxter Healthcare Corporation, Cardio Vascular Group (CVG), Irvine, California.

RECALLED BY Manufacturer, by letter dated September 5, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and Japan.

QUANTITY 312 units were distributed.

REASON An inherent software coding error, when combined with a data entry of the patients weight in pounds, will result in an infusion rate 2.2 times greater than the correct calculation.

None Present
 Action Taken _____

CLASS III RECALLS: None

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 12 DEC 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:

NSN 6505 Nonstandard
PRODUCT Epi EZ Pen Auto-Injector (Epinephrine Injection 1:1000), 0.3 mg, Rx for allergic emergencies, distributed by Dey Laboratories, Napa, California. Recall #D-012-8.
CODE Lot #6SA145 EXP 9/98.
MANUFACTURER Meridian Medical Technologies, Inc., St. Louis, Missouri.
RECALLED BY Manufacturer, by press release on September 22, 1997, and by letter on September 23, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 30,348 units were distributed.
REASON Premature/spontaneous activation.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Amicar Syrup, 25%, in 16 ounce bottles, useful in enhancing hemostasis when fibrinolysis contributes to bleeding. Recall #D-017-8.
CODE Lot numbers: 445-578 EXP MAR00 and 446-877 EXP APR00.
MANUFACTURER Lederle/Wyeth Ayerst Pharmaceuticals, Pearl River, New York.
CALLED BY Immunex Corporation, Seattle, Washington, by

fax on September 17, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 2,215 bottles of lot 445-578 and 133 bottles of lot 446-877 were distributed.

REASON Product is contaminated with Candida parapsilosis (yeast).

None Present

Action Taken _____

CLASS II RECALLS:

NSN 6505 Nonstandard

PRODUCT Ultane (Sevoflurane) Inhalation Anesthetic, Rx halogenated general inhalation anesthetic drug. Recall #D-011-8.

CODE Lot numbers 21-272-DK, 13-326-DK, 14-686-DK, 15-321-DK, 17-292-DK, 18-612-DK, 18-621-DK, 19-316-DK, 19-317-DK, 19-318-DK, 19-331-DK, 20-021-DK, 20-022-DK, 20-024-DK, 21-271-DK, 21-313-DK, 22-006-DK, 22-007-DK, 22-510-DK, 22-511-DK, 23-100-DK, 23-277-DK, 25-334-DK.

MANUFACTURER Central Glass, Ube City, Japan.

RECALLED BY Abbott Laboratories, Hospital Products Division, Abbott Park, Illinois, by letter dated October 1, 1997.

Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Curacao, Aruba, Nasha.

QUANTITY 240,000 bottles were distributed; firm estimated that 10,000 bottles remained on market at time of recall initiation.

REASON Product fails acidic level specification which may result in one or more of the following: degradation, pungent odor, cloudiness, and/or crystal formation.

None Present

Action Taken _____

NSN 6505 Nonstandard

PRODUCT Prostaglandin E-1 in powder form, packaged in 10 mg vials. Recall #D-013-8.

CODE Lot numbers 4554, 5456, and 5540.

MANUFACTURER B&B Pharmaceuticals, Inc. Aurora, Colorado (relabeler/distributor).

RECALLED BY B&B Pharmaceuticals, Inc., Aurora, Colorado,
by telephone beginning August 13, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION California, Colorado, Florida, Idaho,
Maryland, North Carolina, Texas, Washington
state.
QUANTITY 40 vials were distributed.
REASON Unapproved drug substance.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Belladonna Alkaloids with Phenobarbital
Tablets, (Phenobarbital USP 16.2 mg/Hyoscyamine
Sulfate USP 0.1037 mg/Atropine
Sulfate USP 0.0194/Scopolamine Hydrochloride
USP 0.0065 mg), in bottles of 100 and 1,000.
Product is sold as Bellatal and Rexatal under
the Richwood label and as Hyosophen under the
Rugby label. The drug provides peripheral
anticholinergic/antispasmodic action and mild
sedation is prescribed for use in the
treatment of irritable bowel syndrome and
acute enterocolitis. Recall #D-020-8.
CODE Lot numbers: B3899 EXP 10/97, B3916 EXP 1/98,
B3917 EXP 1/98, 61008 EXP 10/98, 61009 EXP
10/98, 61204 EXP 12/98, 70107 EXP 1/99, 70301
EXP 3/99, 70302 EXP 4/99, 70407 EXP 4/99,
70616 EXP 7/99, 70702 EXP 7/99.
MANUFACTURER Richwood Pharmaceuticals Company, Inc., doing
business as Manufacturing Chemists Company,
Indianapolis, Indiana.
RECALLED BY Richwood Pharmaceuticals Company, Inc.,
Florence, Kentucky, by letter faxed on
October 8, 1997, followed by mail. Firm-
initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 29,123,000 tablets were distributed.
REASON Product failed content uniformity testing for
Belladonna Alkaloids.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Claforan Sterile (cefotaxime sodium) equiv. to

1 g cefotaxime IM/IV, in cartons of 25 vials,
a broad spectrum antibiotic. Recall #D-021-8.
CODE Lot #97H3W (cartons), 97H3W1 and 97H3W2
(vials).
MANUFACTURER Hoechst Marion Roussel, Frankfort, Germany
(bulk powder).
RECALLED BY Hoechst Marion Roussel, Kansas City, Missouri,
by letter dated September 2, 1997, followed by
telephone on September 3, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 99,550 vials were distributed.
REASON Glass particles in vials.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) Red Blood Cells; b) Platelets; c) Fresh
Frozen Plasma; d) Recovered Plasma.
Recall #B-1362/1365-7.
CODE Contact FDA, Center for Biologics Evaluation
and Research, Office of Compliance (301) 827-6220
for individual unit numbers recalled.
MANUFACTURER Topeka Blood Bank, Inc., doing business as
Kansas Blood Services, Topeka, Kansas.
RECALLED BY Manufacturer, by telephone and letter on June
23, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Arkansas, California, Florida, Georgia,
Kansas, Missouri.
QUANTITY a) 285 units; b) 41 units; c) 110 units; d)
159 units were distributed.
REASON Blood products were collected from donors in
which infectious disease testing (HIV antigen,
anti-HIV 1/2) was performed improperly.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Red Blood Cells. Recall #B-055-8.
CODE Unit #4799158.
MANUFACTURER BloodCare, Dallas, Texas.
RECALLED BY Manufacturer, by telephone on April 10, 1997,
followed by letter dated May 12, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Texas.

QUANTITY 1 unit was distributed.
REASON Blood product was collected from a donor who traveled to an area considered endemic for malaria.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Medi-Ject Needle-free Syringe Kit for use with the Medi-Jector Choice Needle Free Insulin Injector, Adult Model 300037-001 and Pediatric Model 300040-001. Recall #Z-011-8.
CODE All Medi-Ject Needle-free Syringe Kits distributed prior to September 10, 1997.
MANUFACTURER Medi-Ject Corporation, Minneapolis, Minnesota.
RECALLED BY Manufacturer, by letter on September 25, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.
QUANTITY 4,244 kits were distributed.
REASON Some of the disposable adapters in the kits fit too tightly to the Needle-free Syringe and may result in the unintended removal or partial removal of the Needle-free Syringe from the power pack after filling. The second problem is that the Needle-free Syringes in the kits may crack during use resulting in a reduced dose of insulin to the patient.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Emjoi Electro-Acupuncture Stimulator. Recall #Z-013-8.
CODE All codes.
MANUFACTURER Tactica International, Inc., New York, New York.
RECALLED BY Manufacturer, by telephone beginning May 1997, followed by letter on September 30, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Minnesota, Virginia, New Hampshire, California.
QUANTITY 1,500 units were distributed.
REASON Firm distributed device into commerce without an approved 510(k).

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT ProSpect Clostridium difficile Microplate Assay is an immunoassay, intended for the qualitative detection of Clostridium difficile Toxin A in human fecal specimens as an aid in the diagnosis of Clostridium difficile-associated disease. Recall #Z-014-8.
CODE Alexon Lot No:
970511 970146 970006 960955 960761A
960761 960760.
Bartel's lot numbers that cover the above:
Specimen Treatment Buffer Lot Nos:
6J379 6K196 6M209 7A478 7E433.
HRP-Goat anti-Rabbit Conjugate Lot Nos:
6K124 6K200 6M214 7A473-2 7E435-2.
MANUFACTURER Bartels, Inc., The Diagnostics Division of Intracel Corporation, Issaquah, Washington.
RECALLED BY Alexon Trent, Inc., Sunnyvale, California, by fax and mail on August 27-28, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Florida, Wisconsin, Idaho, Colorado, Georgia, California, Washington state, Michigan, international.
QUANTITY 348 kits were distributed.
REASON Cross-reactivity between the specimen treatment buffer and the conjugate used in the manufacture of the kit. Bartel's results showed that specific samples, but not all samples, showed both high indeterminate and low level positive results.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Metamucil Powder, Orange Flavored, Natural Psyllium Fiber, in 12 gram (0.43 ounce) professional sample packets, 2 packets per card, 40 cards per carton, OTC fiber therapy for the treatment of irregularity (cathartic).

Recall #D-010-8.
 CODE Lot #7104XD12 EXP 2/00.
 MANUFACTURER The Procter & Gamble Company, Phoenix,
 Arizona.
 RECALLED BY The Procter & Gamble Company, Cincinnati,
 Ohio, by E-mail on August 27, 1997.
 Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 182 cartons were distributed; firm estimated
 that 35 cartons remained on market at time of
 recall initiation.
 REASON Misbranding - Product labeled to contain
 aspartame but actually contains sucrose sugar.

[] None Present

[] Action Taken _____

NSN 6505 Nonstandard
 UPDATE Recall #D-171-7, Granutec, Inc., Wilson, North
 Carolina, (OTC) Regular Strength, Enteric
 Coated Aspirin Tablets, 325 mg, packaged in
 100, 250, and 500 count bottles, which
 appeared in the May 14, 1997, Enforcement
 Report has been extended to include the
 following lot numbers:

6058819	6069698	6015599
6058968	6047666	6026171
6114426	5113597	6036992
6125692	5124047	6047855
6125337	6014882	6048100
6125693	6070457	6058558
6047685	6081231	6058760
6058557	6081465	6058835
6070179	6058535	6059049
6124825	6125438	6069175
6125690	6058822	6069606
6069234	6070180	6069625
6069695	6081384	6070336
6070181	6125437	6070743
6070429	6037379	6081025
6081548	6081546	6081129
6102918	6092501	6081377
6125335	6114174	6124822
7016839	7016193	6125334
6070096	6125336	7015963
6081547	6058823	7016391
6125338	6069699	7016602
6047667	6092303	7027513
6047668	6125689	7027564

6069697 5123936 6015422.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Hytone (Hydrocortisone) 2-1/2% Cream, packaged
 in tubes of 3.5 g (professional sample size),
 Rx topical cream used for the treatment of
 inflammatory and pruritic manifestations of
 corticosteroid responsive dermatoses.
 Recall #D-278-7.
CODE Lot #MN0969 EXP 6/30/98.
MANUFACTURER Rhone-Poulenc Rorer Puerto Rico, Inc., Manati,
 Puerto Rico.
RECALLED BY Dermik Laboratories, Inc., (a Rhone Poulenc
 Rorer Co.) Collegeville, Pennsylvania, by
 letter July 14, 1997. Firm-initiated recall
 ongoing.
DISTRIBUTION Nationwide.
QUANTITY Firm estimates little if any product remained
 on market at time of recall initiation.
REASON Out of specification assay (high) and
 incorrect expiration dating; product labeled
 with 48 months in contrast to correct 24
 months after manufacturing.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Barre brand Dihistine DH Elixir, Cough
 Suppressant/Nasal Decongestant /Antihistamine
 (Codeine Phosphate/Pseudoephedrine
 Hydrochloride/Chlorpheniramine maleate), in 4,
 8, 16, and 164 (1 gallon) containers, Rx for
 the temporary relief of cough.
 Recall #D-014-8.
CODE Lot numbers: RD6219, RF6266, RF6305, RF6306,
 RF6307, RJ6419, RJ6476, RJ6477, RJ6478,
 RK6524, RK6525, RK6526, RK6527, RL6621,
 RL6622, RN6710, VS5831, RL6817, RL6818.
MANUFACTURER Alparma, U.S. Pharmaceuticals Division,
 Baltimore, Maryland.
RECALLED BY Manufacturer, by letter dated September 9,
 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.

QUANTITY Firm estimated that 24,412 units remained in
commerce at time of recall initiation.
REASON Subpotent for codeine phosphate at 18 month
stability test point.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT OTC vitamin/amino acids/mineral products: a)
Plex in 20 ounce containers; b) Kids Plex Jr,
in 16 ounce containers.
Recall #D-015/016-8.

CODE Lot numbers: a) 97144; b) 97419, 97148,
97128, 97077.

MANUFACTURER Natureade, Inc., Paramount, California.
RECALLED BY Performance Nutrition, Division of Naturade,
Inc., Dallas, Texas, by letter September 30,
1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and Canada.

QUANTITY a) 2,205 units; b) 16,749 units were
distributed.

REASON Product insert makes unapproved drug claims
related to attention deficit hyperactivity
disorder.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Nitrostat Sublingual Tablets (Nitroglycerin,
USP), 0.3 mg, in bottles of 100, indicated for
the acute relief of an attack or prophylaxis
of angina pectoris due to coronary artery
disease. Recall #D-018-8.

CODE Lot #04446F EXP 3/98.

MANUFACTURER Warner Lambert Company, Fajardo, Puerto Rico.
RECALLED BY Parke-Davis, Division of Warner Lambert
Company, Morris Plains, New Jersey, by letter
on September 18, 1997. Firm-initiated recall
ongoing.

DISTRIBUTION Nationwide.

QUANTITY 24,846 bottles were distributed.

REASON Assay failure at 15 month stability test.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Orudis KT Caplets (Ketoprofen), 12.5 mg in bottles of 30 Caplets and Siderack/Floorstand Displays containing 4 dozen 30's, OTC product, indicated for the temporary relief of minor aches and pains. Recall #D-022-8.
CODE Lot 6XG288 (bottles) and 2716, 3016 (case for lot 6XG288).
MANUFACTURER Whitehall Robins Laboratories, Guayama, Puerto Rico.
RECALLED BY Whitehall-Robins Healthcare, Madison, New Jersey, by letter on September 19, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 43,740 bottles were distributed; firm estimated that 4,000 bottles remained on market at time of recall initiation.
REASON Content uniformity failure.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Oxygen USP, in aluminum "D" size high pressure cylinders. Recall #D-023-8.
CODE All lots remaining in expiry date.
MANUFACTURER Valley Medical Equipment and Supply, Inc., Star City, West Virginia.
RECALLED BY Manufacturer, by visit. Firm-initiated recall ongoing.
DISTRIBUTION West Virginia and Pennsylvania.
QUANTITY Approximately 20 cylinders were distributed.
REASON Current good manufacturing practice deviations. Failure to document assay results.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT AMS Sphincter 800/Securo-T Urinary Prosthesis Accessory Kit, Part Number 72401685, used to treat urinary incontinence caused by intrinsic sphincter deficiency (ISD). Recall #Z-019-8.

CODE The lot number of the recalled accessory kits begins with DE157, and is followed by three additional digits which vary and indicate the number of each unit.

MANUFACTURER American Medical Systems, Inc., Pfizer Medical Technology Group, Minnetonka, Minnesota.

RECALLED BY Manufacturer, by letter on October 9, 1997. Firm-initiated field correction ongoing.

DISTRIBUTION California, Massachusetts, Minnesota, Missouri, North Carolina, Pennsylvania, Texas, and Utah.

QUANTITY
REASON

18 units were distributed.
A package insert for another product was put
in the product packages.

- None Present
 - Action Taken _____
-