

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-P, Capt Paul J. Toth, DSN 343-7445)

CLASS I RECALLS: None.

CLASS II RECALLS:

**6515 NS
MDC 10847**

Circulatory Assist Units, Ventricular

ABIOMED(R) BVS 5000 and BVS 5000i BI-Ventricular Support System, a mechanical circulatory system for use in patients suffering reversible ventricular function. Recall #Z-351/352-0.

Serial Numbers: 1359-1396 and 1552-1738.

CODE
MANUFACTURER
RECALLED BY

Abiomed, Inc., Danvers, Massachusetts.

Manufacturer, by fax on January 26, 2000. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.

223 units.

Consoles will not switch into weaning mode when activated.

None Present

Action Taken _____

**6515 NS
MDC 12636**

Monitor Systems, Physiologic

Pilot Model 9200 Vital Signs Monitor, used to measure blood pressure and heart rate non-invasively. Recall #Z-370-0.

Serial Numbers 000031 through 000077.

CODE
MANUFACTURER
RECALLED BY

Calin Corporation, Hayashi, Komaki City, Japan.

Colin Medical Instruments Corporation, San Antonio, Texas, by telephone beginning November 5, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide, Italy, Colombia, Japan.

46 units were distributed in the United States.

Leakage from a capacitor in the power supply would cause the power supply to fall.

None Present

Action Taken _____

**6530 NS
MDC 13746**

Sterilizers, Steam

Joslyn Steam Sterilizer/Steam Modernization Kit, Model 1626 and 2038. Recall #Z-354/355-0.

Various serial numbers.

CODE
MANUFACTURER
RECALLED BY

Joslyn Sterilizer Corporation, Farmington, New York.

Steris Corporation, Mentor, Ohio, by letter dated January 31,

DISTRIBUTION
QUANTITY
REASON

2000. Firm-initiated recall ongoing.
Alabama, Colorado, Connecticut, Idaho, Illinois, Massachusetts,
Michigan, New York, Ohio, Pennsylvania, Utah, Washington state.
60 units,
Retention bolts may fail due to fatigue.

None Present
 Action Taken _____

6530 NS
MDC 16437
PRODUCT

Chairs, Examination/Treatment

Medical Tilt and Recline Chairs, allows patients to sit
comfortably, includes tilt and recline features and has various
accessories available including trays and headrests:
Model Numbers: HTR3000, HTR3500, HTR5000, and HTR5500.
Recall #Z-364/367-0.

CODE
MANUFACTURER
RECALLED BY

All Serial Numbers beginning with 96H through 99E, inclusive.
Invacare Corporation - Canada, Mississauga, Ontario, Canada.
Invacare Corporation, Elyria, Ohio, by letter on February 3,
2000. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
6,246 units.
Injury to patient's fingers may result when returning chair to
upright position.

None Present
 Action Taken _____

6630NS
MDC 15551
PRODUCT

Clinical Chemistry Analyzers

Chiron Diagnostics Automated Chemiluminescence System, Model
ADVIA:CENTAUR for the quantitative determination of various in
vitro diagnostic assays using direct chemiluminescent technology.
Recall #Z-358/359-0.

CODE
MANUFACTURER
RECALLED BY

Catalog Numbers: 114564, 572561, 572562, 572563, 572564,
and 572566. All ADVIA:Centaur Immunoassay Analyzers with
software versions 2.01 and 2.11.
Bayer Corporation, Oberlin, Ohio.
Manufacturer, by customer bulletin on December 22, 1999.
Firm-initiated field correction ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
660 units.
Software may incorrectly link previous assay results to a
different patient ID.

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 **5 MAY 00** for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DSCP 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	Zen Liquid (1,4-Butanediol), in 35-fluid ounce bottles, OTC intended to be used as a sleep aid. Recall #D-219-0.
CODE	All Lot Numbers.
MANUFACTURER	Science Enhancement Systems, Inc., Delray Beach, Florida.
RECALLED BY	Manufacturer, by letter on January 11, 2000. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	Approximately 5,400 bottles were distributed.
REASON	Product is an unapproved new drug.

[] None Present
 [] Action Taken _____

CLASS II RECALLS:

NSN	6505 Nonstandard
PRODUCT	Extra Strength Panadol PM Caplets, (500 mg Acetaminophen, 25 mg Diphenhydramine HCL), OTC, in bottles of 36 and 50 caplets and dispenser cartons of two caplets per pack. Recall #D-215-0.
CODE	Lot Numbers: PA033SH1 PA033SH2 PA027SJ2 PA083SH1 PA034SH1 PA035SH1 PA098SH1 PA036SH1 PA032SH1 PA027SJ4

MANUFACTURER
RECALLED BY

PA028SJ1. EXP date for all lots: 07/2001.
SmithKline Beecham, Dungarvan Ltd., Count Waterford, Ireland.
SmithKline Beecham, Consumer Health, Parsippany, New Jersey, by
hand delivered letter beginning on January 27, 2000. Firm-
initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Puerto Rico.
171,850 caplets were distributed.
Glass particles were found in bulk diphenhydramine used in
manufacturing.

None Present
 Action Taken _____

NSN
PRODUCT

6505 Nonstandard
a) Solu-Medrol Methylprednisolone sodium succinate for injection,
USP, 500 mg, single dose vial, 4 mL, sterile powder, b) Solu-
Cortef Hydrocortisone sodium succinate for injection, USP, 100
mg, 2mL, Single dose vial, sterile powder,
c) Solu-Cortef Hydrocortisone sodium succinate for injection,
USP, 500 mg, 4 mL, Single dose vial, sterile powder,
Recall #D-216/218-0.

CODE

a) NDC 0009-0765-02. Lots 02DAF and 23DAM EXP 3/31/01.
b) NDC 0009-0900-20. Lot 29DAM EXP 3/31/04
NDC 0009-0900-13. Lot 48DCU EXP 6/30/04
NDC 0009-0912-05. Lots 51DCU and 52DCU EXP 6/30/04
c) NDC 0009-0912-05. Lots 51DCU and 52DCU EXP 6/30/04.

MANUFACTURER
RECALLED BY

Pharmacia & Upjohn, Kalamazoo, Michigan.
Manufacturer, by letter dated January 27, 2000. Firm-
initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide, Bahamas, Cayman Islands, Colombia, Japan.
261,258 vials were distributed.
Lack of assurance of sterility.

None Present
 Action Taken _____

NSN
PRODUCT

6505 Nonstandard
ADCON-L, ANTI-ADHESION CONTROL IN A BARRIER GEL, packaged in
a 5-gram aluminum tube, placed in a tyvek pouch, used by surgeons
only during single-level, posterior, lumbar laminectomy, or
laminotomy procedures, where roots are exposed to inhibit post-
surgical peridural fibrosis. Recall #Z-335-0.

CODE

Catalog #G0001, Lot Numbers: A8069N1, A8106N1, A8138N1, A8145N1,
A8153N1, A8180N1, A8187N1, A8201N1, A8208N1, A8216N1, A8236N1,
and A8243N1.

MANUFACTURER
RECALLED BY

Gliatech, Inc., Cleveland, Ohio.
Manufacturer, by letter dated April 29, 1999. Firm-initiated
recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide.
13,800 units.
The sterility of the device cannot be assured due to a packaging
defect.

None Present
 Action Taken _____

NSN
PRODUCT
CODE
MANUFACTURER
RECALLED BY

6510 Nonstandard
Silon(tm) Transparent Wound Dressing. Recall #Z-356-0.
Lot Numbers: K1023, T2926-S264, T2930-S264, and T2931-S264.
Bio Med Sciences, Inc., Bethelhem, Pennsylvania.
Manufacturer, by telephone starting December 15, 1999 through
December 21, 1999, followed by letter on December 22, 1999.
Firm-initiated recall ongoing.

DISTRIBUTION

Alaska, Alabama, Arkansas, California, Florida, Georgia,
Illinois, Indiana, Massachusetts, North Carolina, Oregon,
Pennsylvania, South Carolina, Tennessee, Texas, Virginia,
Washington state, France.

QUANTITY
REASON

378 units.
Product's sterility may be compromised due to some of the pouches
being inappropriately sealed.

None Present
 Action Taken _____

NSN
PRODUCT
CODE
MANUFACTURER
RECALLED BY

6515 Nonstandard
Tap, 7mm Bioscrew, Catalog #C8657. Recall #Z-353-0.
A60528, A60529, SA60819, SA60820, SA73981, SA86826, SB74552,
SB74553, SB74554, SB74555, SB74556, SB74802, SB74803, SB99534,
SC76127, SC76128, SD64343, SE84417, SE84418, SF66001, SH68532,
SH68533, SJ69944, SJ69946, SJ69947, SJ73064, SK61267, SK61268,
SK61269, SM62496, SM62497, SM62498, SM62504, EM62505, SM75666,
SRB60070, SRB81696, SRB81697, SRB81698, SRB81699, SRB81700,
SRF71142, SRF83000, SRK71511, SRL60388, SRM60390, SRM71588.
Linvatec Corporation, Largo, Florida.
Manufacturer, by letter on December 20, 1999. Firm-initiated
recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
537 units.
Screw may break at weld.

None Present
 Action Taken _____

NSN
PRODUCT
CODE
MANUFACTURER
RECALLED BY

6515 Nonstandard
Fourex Natural Skin Condoms. Recall #Z-374-0.
443, 443P, 444, 444R, 446, 451, 451R, 452, 452C, 452R, 462, 463.
London International Group, PLC, Norcross, Georgia.
Manufacturer, by letter on December 13, 1999. Firm-initiated
recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide.
1,016,146 units.
Products may exhibit objectionable odor, dried out or become

brittle and unusable.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard

STIC-KIT, needle/sharps containment system, packaged as 6 units/card and shrink-wrapped, used primarily by Para-Medical Services, including EMTs, as part of their First Response Kit. Recall #Z-378-0.

CODE

Catalog #EM82691. All Lots manufactured and distributed since October 26, 1998 beginning with '10 28 98'.

MANUFACTURER
RECALLED BY

Kohlbrat & Bunz Corporation, Mooresville, North Carolina. E.M. Innovations, Inc., Kent, Ohio, by fax on January 28, 2000. Firm-initiated recall ongoing.

DISTRIBUTION

Ohio, Missouri, Florida, New Hampshire, Arizona, Wisconsin, California, South Carolina, Oregon, New York, Alaska.

QUANTITY
REASON

244 units.

Needles/sharps may penetrate through container wall and stick healthcare worker.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard

Allograft Heart Valves Model PVOO and Model AVOO. Recall #Z-379/380-0.

CODE Model Number PV00 - Serial Number 3874818
Model Number AV00 - Serial Number 3874826
Model Number AV00 - Serial Number 6094996
Model Number PV00 - Serial Number 6095003.
MANUFACTURER Cryolife, Inc., Kennesaw, Georgia.
RECALLED BY Manufacturer, by letter on February 7, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Michigan, Pennsylvania, California.
QUANTITY 4 valves.
REASON Donors did not meet current guidelines regarding serodilution of plasma.

None Present
 Action Taken _____

NSN **6550 Nonstandard**
PRODUCT IMx Glycated Hemoglobin Ion Capture Component Set, list 1A86-88, 100 test kit; an ion capture assay for the quantitative measurement of percent glycated hemoglobin in human anticoagulated whole blood on the IMx Analyzer.
Recall #Z-407-0.

CODE List # 1A86-88. Set Lot Numbers: 56566M200, 56568M200, 57411M200, 58079M100, 58157M400, 58332M200, 59545M200, 60274M300, 60275M300, 60276M300, 60277M300, 60278M300.

MANUFACTURER Abbott Laboratories, Inc., North Chicago, Illinois.
RECALLED BY Abbott Laboratories, Inc., Abbott Park, Illinois, by letter dated February 10, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.
QUANTITY 27,444 sets were distributed.
REASON The kits may not quantitate the %GHb or give imprecise results.

None Present
 Action Taken _____

NSN **6550 Nonstandard**
PRODUCT IMx Glycated Hemoglobin Ion Capture Component Set, list 1A86-88, 100 test kit; an ion capture assay for the quantitative measurement of percent glycated hemoglobin in human anticoagulated whole blood on the IMx Analyzer.
Recall #Z-407-0.

CODE List # 1A86-88. Set Lot Numbers: 56566M200, 56568M200, 57411M200, 58079M100, 58157M400, 58332M200, 59545M200, 60274M300, 60275M300, 60276M300, 60277M300, 60278M300.

MANUFACTURER Abbott Laboratories, Inc., North Chicago, Illinois.
RECALLED BY Abbott Laboratories, Inc., Abbott Park, Illinois, by letter dated February 10, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.
QUANTITY 27,444 sets were distributed.

REASON

The kits may not quantitate the %GHb or give imprecise results.

None Present

Action Taken _____

CLASS III RECALLS:

NSN

PRODUCT

6505 Nonstandard

Procanbid(tm) Extended-Release Tablets (Procainamide HCL), 500 mg, in 60 tablet bottles, Rx for use as an anti-arrhythmic. Recall #D-211-0.

CODE

Product Code: N0071-0562-20, Lot #40697D EXP 7/00.

MANUFACTURER

Warner Lambert Company, Morris Plains, New Jersey.

RECALLED BY

The Parke Davis, Division of Warner Lambert Company, Morris Plains, New Jersey, by letter on December 23, 1999. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide.

QUANTITY

21,251 bottles were distributed.

REASON

Dissolution failure (2 hour time point).

None Present

Action Taken _____

NSN

PRODUCT

6505 Nonstandard

Q-V Tussin Elixir (Hydrocodone Bitartrate, Pseudoephedrine HCL and Chlorpheniramine Maleate), in 1-pint bottles, under the Qualitest and Vintage labels. Recall #D-220-0.

CODE

NDC #	Lot #	EXP
0603-1609-58	038D8A	04/00
0603-1609-58	035F8A	05/00
0254-9403-58	035F8B	05/00
0603-1609-58	004G8A	06/00
0603-1609-58	005G8A	06/00
0603-1609-58	006G8A	06/00
0603-1609-58	034M8A	11/00.

MANUFACTURER

Vintage Pharmaceuticals, Inc., Huntsville, Alabama.

RECALLED BY

Manufacturer, by letter dated January 28, 2000. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide.

QUANTITY

7,928 of lot 038D8A
2,856 of lot 035F8A
5,052 of lot 035F8B
7,745 of lot 004G8A
7,773 of lot 005G8A
7,861 of lot 006G8A
7,942 of lot 034M8A.

REASON Lack of assurance chlorpheniramine maleate will maintain potency throughout labeled shelf life.

None Present
 Action Taken _____

NSN **6515 Nonstandard**
PRODUCT a) Bard Biopty-Cut Biopsy Needle; b) Bard Biopty-Cut Needle with Spacer. Recall #Z-348/349-0.
CODE Lot Numbers: a) 22JJ1105, 22JJ1135; 22IJ0925.
MANUFACTURER Bard Reynosa, S.S. de C.V., Reynosa, Mexico.
RECALLED BY Bard Peropheral Technologies, C.R. Bard, Inc., Covington, Georgia, by telephone and letter on September 29, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Arkansas, California, Florida, Illinois, Indiana, Kentucky, Mississippi, Missouri, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, Utah, Virginia, West Virginia, Wisconsin, Australia, Belgium.
QUANTITY Firm estimated that 1,052 units remained on market at time of recall initiation.
REASON Product is labeled as a Bard Biopty-Cut Needle, 18 gauge x 16cm long but contains a Bard Biopty-Cut Needle, 18 gauge x 20 cm long.

None Present
 Action Taken _____

NSN **6515 Nonstandard**
PRODUCT LOFRICÆ CATH-Kit, a urinary catheter intended for intermittent urinary catheterization. Recall #Z-368-0.
CODE Product #92084; Lot #3418 EXP 12/02.
MANUFACTURER Astra Tech AB, Molndale, Sweden.
RECALLED BY Astra Tech, Inc., Lexington, Massachusetts, by letter on February 2, 2000. Firm-initiated recall ongoing.
DISTRIBUTION California, Washington state.
QUANTITY 560 units were distributed.
REASON Catheter has no holes for drainage.

None Present
 Action Taken _____

NSN **6520 Nonstandard**
PRODUCT Endontic File. Recall #Z-408-0.
CODE Part #259446, Lot Numbers: 100799, 110199, 121899 and 051199.
MANUFACTURER Maillefer Instruments SA, Ballaigues, Switzerland.
RECALLED BY Den-Tal-EZ, Inc., Lancaster, Pennsylvania, by letter on January 28, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Pennsylvania, Georgia, Texas, Florida, Indiana, New York, Illinois, Minnesota, Washington state, Japan.
QUANTITY 94 units were distributed.

REASON Mislabeled - The wrong size Endostar Files were packaged in part number 259446.

None Present
 Action Taken _____

NSN **6550 Nonstandard**
PRODUCT Corning Calcium pH analyzer 634, intended for the measurement of pH and ionized calcium in whole blood. Recall #Z-350-0.
CODE Model 634 Reagent Pack, Part #478548.
MANUFACTURER Lot Numbers: 9F001 EXP 4/30/01, 9G010 EXP 5/31/01.
RECALLED BY Bayer Diagnostics, Sudbury, Suffolk, England.
Manufacturer by telephone beginning on December 24, 1999.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 127 packs of lot #9F001. 204 packs of lot #9G10 at 4 bottles per pack.
REASON Pseudomonas aeruginosa contamination causing increase in quality control values of pH.

None Present
 Action Taken _____

NSN **6550 Nonstandard**
PRODUCT Premier Giardia Diagnostic Test Kits, an enzyme immunoassay (EIA) for the detection of Giardia lamblia antigens in human stool.
Recall #Z-357-0.
CODE Lot #614096.012 EXP 5/2/2000.
MANUFACTURER Meridian Diagnostics, Inc., Cincinnati, Ohio.
RECALLED BY Manufacturer, by letter on January 7, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Germany and Italy.
478 kits were distributed.
REASON Kits do not meet manufacturer's specifications due to design failure.

None Present
 Action Taken _____

NSN **6550 Nonstandard**
PRODUCT Abbott Vision Cholesterol TestPack, List #1415-10, 10 tests per package, Enzymatic Esterase - Oxidase, Cholesterol test pack used in the Abbott Vision System for the quantitative determination of cholesterol in anticoagulated whole blood, plasma or serum and are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
Recall #Z-363-0.
CODE
Lot Numbers: 54166M200, 54476M300, 54477M300, 55603M100,

55604M100, 55857M300, 55858M300, 56015M300, 57226M100, 57227M100, 57228M100, 57761M100, 58048M100, 58049M100, 58641M200, 58642M200, 58741M400, 58742M400, 59365M300.

MANUFACTURER RECALLED BY Abbott Laboratories, Inc., North Chicago, Illinois.
Abbott Laboratories Inc., Abbott Park, Illinois by letter dated January 31, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Australia, Taiwan, Singapore, Japan, Italy and Germany.

QUANTITY 46,034 ten-packs were distributed.

REASON ENDPOINT NOT REACHED error messages.

None Present
 Action Taken _____

NSN **6550 Nonstandard**
PRODUCT IMx Reaction Cells, list 8397-05; an accessory device for use with the IMx Select Analyzer for MEIA assays; 100 cells per carton. Recall #Z-369-0.

CODE Lot #54034M400.

MANUFACTURER RECALLED BY Abbott Laboratories, Inc., Abbott Park, Illinois.
Manufacturer, by letter dated February 4, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 5,490 boxes were distributed.

REASON Manufacturing defect may result in inadequate flow of the reagents through the reaction cell.

None Present
 Action Taken _____

NSN **6550 Nonstandard**
PRODUCT Triage Cardiac Test Panel, Part #97000, an in-vitro diagnostic test kit intended to be used in a medical setting. Recall #Z-373-0.

CODE Lot #W-17837B.

MANUFACTURER RECALLED BY Biosite Diagnostics, Inc., San Diego, California.
Manufacturer, by telephone on December 7 & 8, 1999. Firm-initiated recall ongoing.

DISTRIBUTION Arkansas, Arizona, California, Florida, Georgia, Idaho, Illinois, Kentucky, Maine, Nebraska, New Jersey, Nevada, New York, South Carolina, Tennessee, Texas, Wisconsin.

QUANTITY 112 kits were distributed.

REASON The reagents were inadvertently switched between the test troughs, resulting in irreproducible and inconsistent test results.

None Present
 Action Taken _____
