

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

PRODUCT

Circulatory Assist Units, Ventricular

BVS 5000i Bi-Ventricular Support System, intended for use as a mechanical circulatory support system. Recall #Z-944-9.

Serial Numbers: 1693, 1697, 1701, 1716, 1722-1725.

CODE

MANUFACTURER

Abiomed, Inc., Danvers, Massachusetts.

RECALLED BY

Manufacturer, by fax on April 30, 1999. Firm-initiated field correction ongoing.

DISTRIBUTION

California, District of Columbia, Florida, Pennsylvania, New York, Tennessee, Texas, Washington state.

QUANTITY

8 units were distributed.

REASON

Solenoid valves do not provide adequate flow to the blood pump.

None Present

Action Taken _____

6515, 6530, 6540 NS

MDC 15757. 16944

PRODUCT

Laser (General)

Lasers and Laser Pointers:

a) Model No. LCM-T Lasers;

b) Model No. LP-1M Laser Pointers;

c) Model No. LP-2M Laser Pointers;

d) Model No. GP-2 (Pulsed) Laser Pointers.

Recall #Z-950/953-9.

CODE

a) Model No. LCM-T Lasers;

b) Model No. LP-1M Laser Pointers;

c) Model No. LP-2M Laser Pointers;

d) Model No. GP-2 (Pulsed) Laser Pointers.

MANUFACTURER

Power Technology, Inc., Mabelvale, Arkansas.

RECALLED BY

Manufacturer. FDA approved the firm's corrective action plan on May 21, 1999. Firm-initiated field correction ongoing.

DISTRIBUTION

Nationwide.

QUANTITY

59 units were distributed.

REASON

The LCM-T lasers were introduced into commerce uncertified and did not comply with the performance standard (Section 538 of the Federal Food and Drug and Cosmetic Act and 21 CFR 1010.2) The LP-1M and the GP-2 (pulsed) laser pointers exceeded the Class IIIa and Class II single pulse energy limits of the laser standard (21 CFRE 1040.10(c)(1). The LP-2M laser pointer failed to have a remote interlock connector, an adequate beam attenuator and the correct text on the warning logotype label (21 CFR 1040.10(g)(2)(iii).

None Present

Action Taken _____

6525 NS

MDC 10822

PRODUCT

X-Ray Rad Units, Chest

IiRAD DR1000C Digital Chest System, general purpose x-ray device.

Recall #Z-949-9.

CODE

Model IiRAD DR1000C.

MANUFACTURER
RECALLED BY

Fischer Imaging Corporation, Denver, Colorado.
Manufacturer. FDA approved the firm's corrective action plan
June 1999. Firm-initiated field correction ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide.
2 units were distributed.
The units are defective under 21 CFR 1003.2 in that they do not
assure certification to field sizing specifications are met
because the system intermittently opens wide open in the vertical
direction when the exposure button is depressed. This can result
in the patient receiving excess exposure where no useful
diagnostic imaging can occur.
 None Present
 Action Taken _____

6525 NS
MDC 10822
PRODUCT

X-Ray Rad Units, Chest

Acoma X1000 Hydraulic Stand, Item #SSB-T0959-6, part of the Trans
X-1000 Fully Automatic Chest X-ray system, intended for use in
general radiographic applications. The Trans X-1000 is a fully
automatic chest film changer. It provides a direct film
transport mechanism between the film supply magazine and the film
processor, a fully automatic chest film changer. Recall #Z-942-
9.

CODE
MANUFACTURER
RECALLED BY

Serial numbers: 300002, 300007, 300010, 300011, 300012.
Canon, Inc., Tokyo, Japan.
Canon USA, Inc., Lake Success, New York, by letter on January 19,
1999. Firm-initiated field correction complete.

DISTRIBUTION
QUANTITY
REASON

Missouri, Ohio, Florida, New York, Pennsylvania, Illinois.
6 units were distributed.
The arm support mechanism (handle) can break.
 None Present
 Action Taken _____

6530 NS
MDC 15757
UPDATE

Lasers, Surgical

Model CVX CVX-300 Excimer Laser, Recall #Z-934-9, which appeared
in the June 2, 1999 Enforcement Report should read: CODE
Serial numbers: 1468 thru 1502, 79600 79601 79602 79603
79605 79606 79610 thru 79631, 79805, 79806, 79807, 79808.

DISTRIBUTION
QUANTITY

Nationwide, Argentina, Canada,
Europe.
67 units were distributed.
 None Present
 Action Taken _____

CLASS III RECALLS:

6515 NS
MDC 14775
PRODUCT

Stimulators, Neuromuscular

Minnova Pelvic Floor Stimulation System; and InnoSense Pelvic
Floor Stimulation and Electromyography System. Both systems use
mild electrical stimulation to help control urinary incontinence.
Recall #Z-865/866-9.

CODE

Affected Minnova serial numbers:
82004**, with the ** equal to 52, 53, 57, 59, 63-65, 67, 68, 70,
71, 73, 75, 76, 81-85, 87, 92, 93, 99
82005**, with the ** equal to 10, 12-29, 31, 35-38, 41-50, 52-54,
58, 59, 64, 66, 68-74, 77-79, 81-84, 88, 89, 92, 95, 96, 98, 99

82006**, with the ** equal to 03, 04, 06-10, 12-15, 17, 19, 21-23, 42, 68, 73-77, 83, 95-99

8200700

The affected InnoSense serial numbers are:

8000499

80005**, with the ** equal to 00-11, 13-20, 24, 93

8000602

80506**, with the ** equal to 51-71

80507**, with the ** equal to 49-58, 60-62, 71-74, 76-86.

MANUFACTURER
RECALLED BY

EMPI, Inc., St. Paul, Minnesota.

Manufacturer, by letter dated March 6, 1999. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide and international.

QUANTITY

126 Minnova devices and 73 InnoSense devices were distributed.

REASON

An oversized dimension of an electrical pin connector in a socket in each device will result in an incorrect electrical connection between the patient electrode and the device.

[] 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 **30 Jul 99** 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

Rejuvamin PM Capsules (Gammadeoxytetrone Acid), OTC in packets of 4 units. Recall #D-231-9.

CODE

All lot numbers

MANUFACTURER

Tishcon Corporation, Westbury, New York (contract Manufacturer).

RECALLED BY

Biocentrics, A Division of Unique Products Company, Brentwood, Tennessee, by letter dated April 20, 1999. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide.

QUANTITY

Approximately 150 cases (each case containing 24 boxes with 30 packets inside the box) were manufactured. All of the product was distributed except 5 boxes (150 packets).

REASON

Product is an unapproved new drug.

[] None Present

[] Action Taken _____

NSN 6550 Nonstandard
 PRODUCT Get Smart Be Prepared, 207 piece Emergency First Aid Kit.
 Recall #Z-954-9.
 CODE Not coded -- Only the kits with a red cross on the label are
 subject to recall.
 MANUFACTURER Total Resources International, Inc., Walnut, California.
 RECALLED BY Manufacturer, by letter dated April 22, 1999. Firm-initiated
 recall ongoing.
 DISTRIBUTION` Pennsylvania, Maryland, Mississippi, Missouri, Arkansas,
 Louisiana, Texas.
 QUANTITY 5,000 first aid kits were distributed.
 REASON The Povidone Iodine pads in the kits are contaminated with
 microorganisms such as Pseudomonas putida, Salmonella spp., Poly
 D, and Aeromonas sorbia.
 None Present
 Action Taken _____

CLASS II RECALLS:

NSN 6505 Nonstandard
 PRODUCT Indomethacin Extended Release Capsules, USP, 75 mg, packaged in
 7, 10, 14, 20 and 30 capsule unit containers, Rx non-steroidal
 anti-inflammatory drug used for the treatment of osteoarthritis,
 ankylosing spondylitis and rheumatoid arthritis, NDC #0258-3607-
 01 Recall #D-237-9.
 CODE Product #1518-0: lots 8230204, 8201099, 8161047, 8154080,
 9048138, 9034225, 8266102, 8247110, 9076111, 9070061, 9050087
 Product #1518-1: lots 8166183, 8154081, 8258129, 8239032,
 8253084, 8209090, 9006096, 8336136, 8335170, 8316110, 9096140,
 9091075, 9084013, 9049091
 Product #1518-2: 8303074, 8259121, 8247043, 8142062, 9085035,
 9070002, 8355066, 8328097
 Product #1518-3: 8237077, 8233057, 8230127, 8210077, 8341203,
 8335171, 8327166, 8237157
 Product #1518-6: lots 9068141, 9067119, 9039184, 8362154,
 8308179, 8307158, 8280168, 8160142, 8147139.
 MANUFACTURER Inwood Laboratories, Inc., Inwood, New York.
 RECALLED BY Allscripts, Inc., Libertyville, Illinois (repacker), by letter
 dated April 28, 1999. Firm-initiated recall ongoing.
 DISTRIBUTION Indiana, Illinois, California, Missouri, Pennsylvania, Wyoming,
 Iowa, Maine, Nevada, Ohio, Colorado, Washington state, Florida,
 Tennessee, Michigan, Connecticut.
 QUANTITY 62 bottles of 30, 300 bottles of 7, 280 bottles of 14, 91 bottles
 of 20 and 124 bottles of 10 capsules were distributed. Firm
 estimates that less than 25% of the product remained on the
 market at time of recall initiation.
 REASON Dissolution failure.
 None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Bromocriptine Mesylate, USP, Rx used to reduce tumor size prior
 to performing surgeries: a) Bromocriptine Mesylate Tablets 2.5
 mg, in 30 and 100 count bottles, under the Rosemont and Mylan
 labels; b) Bromocriptine Mesylate Capsules 5 mg, in 30 and 100
 count bottles under the Rosemont label. Recall #D-245/246-9.
 CODE All lots within expiration date.
 MANUFACTURER Lek Pharmaceutical and Chemical Company, Ljubijana, Slovenia.
 RECALLED BY Lek, USA Englewood Cliffs, New Jersey, by telephone and fax on

DISTRIBUTION
QUANTITY
REASON

March 9, 1999, and by letter dated April 1, 1999. Firm-initiated recall ongoing.
Colorado.
a) 6,678,000 bottles; b) 881,000 bottles were distributed.
Lack of assurance of bioequivalence.
 None Present
 Action Taken _____

NSN
PRODUCT

6505 Nonstandard
Heparin Sodium 100 units/mL in 0.9% Sodium Chloride 5 mL fill in a 12 mL syringe. The pre-filled heparin syringe is not intended to provide any therapeutic value.
Recall #D-264-9.

CODE
MANUFACTURER
RECALLED BY

Lot numbers: 990202A and 990202B.
E.M.T.-Rx, Raleigh, North Carolina.
Manufacturer, by telephone on May 26, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide.
10,440 units were distributed.
Mislabeling - Label states heparin concentration at 100 unit/mL while manufacturing records indicate concentration at 10 units/mL.
 None Present
 Action Taken _____

NSN
PRODUCT

6505 Nonstandard
Forest Levothroid Tablets, Rx indicated as replacement or substitution for diminished or absent thyroid function:
a) LevothroidÆ Tablets, (Levothyroxine Sodium), 25 mcg, in 100 tablet bottles, NDC #0456-0320-01
b) LevothroidÆ Tablets, (Levothyroxine Sodium), 50 mcg, in 100 and 5,000 tablet bottles, NDC #0456-0321-51
c) LevothroidÆ Tablets, (Levothyroxine Sodium), 88 mcg, in 5,000 tablet bottles, NDC #0456-0329-01
d) LevothroidÆ Tablets, (Levothyroxine Sodium), 112 mcg, in 5,000 tablet bottles, NDC #0456-0330-01.
Recall #D-265/268-9.

CODE

Lot Numbers: a) 10981 and 1992; b) 109830, 109832, 109833 and 1995; c) 119829 and 119830; d) 119835 and 12988.

MANUFACTURER
RECALLED BY

Forest Pharmaceuticals, Inc., Cincinnati, Ohio.
Forest Pharmaceuticals, Inc., St. Louis, Missouri, by letter dated April 2, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY

Nationwide.
a) 20,123 100-tablet bottles; b) 7,356 5000-tablet bottles; c) 27,487 100-tablet bottles; d) 14,366 100-tablet bottles were distributed.

REASON

Subpotency.
 None Present
 Action Taken _____

NSN
PRODUCT

6505 Nonstandard
Levothyroxine Sodium Tablets, Rx in bottles of 100 and 1000, used as a replacement or supplemental therapy in patients with hypothyroidism and as a pituitary TSH suppressant in the treatment or prevention of various types of euthyroid goiters:
a) 25 mcg (0.025mg); b) .50 mg (0.05mg);
c) 150 mcg (.15mg); d) 300 mcg (.3mg). Recall #D-256/259-9.

CODE

a) Levothyroxine Sodium 0.025mg Rx Tablets, lot #'s:

004097A, exp. 02/99 (NDC #0254-3911-28)
004097B, exp. 02/99 (NDC #0254-3911-28)
004097C, exp. 02/99 (NDC #0603-4192-32)
047117D, exp. 05/99 (NDC #0603-4192-32)
047117E, exp. 05/99 (NDC #0254-3911-38)
047117G, exp. 05/99 (NDC #0677-1648-01)
047117H, exp. 05/99 (NDC #0677-1648-10)
032127A, exp. 05/99 (NDC #0254-3911-28)
032127B, exp. 05/99 (NDC #0254-3911-38)
032127C, exp. 05/99 (NDC #0254-4192-21)
032127D, exp. 05/99 (NDC #0603-4192-32)
033127B, exp. 05/99 (NDC #0603-4192-21)
033127C, exp. 05/99 (NDC #0603-4192-32)
033127D, exp. 05/99 (NDC #0254-3911-28)
033127E, exp. 05/99 (NDC #0254-3911-38)

b) Levothyroxine Sodium 0.05mg Rx Tablets, lot #'s:

005097A, exp. 02/99 (NDC #0254-3912-38)
005097F, exp. 02/99 (NDC #0254-3912-38)
006097A, exp. 02/99 (NDC #0603-4193-32)
004127A, exp. 05/99 (NDC #0603-4193-21)
004127B, exp. 05/99 (NDC #0254-3912-28)
004127C, exp. 05/99 (NDC #0603-4193-32)

c) Levothyroxine Sodium 0.150mg Tablets, lot #'s:

044087A, exp. 07/99 (NDC #0603-4196-21)
044087B, exp. 07/99 (NDC #0254-3915-28)
044087C, exp. 07/99 (NDC #0677-0992-01)
044087D, exp. 07/99 (NDC #0254-3915-38)
044087E, exp. 07/99 (NDC #0603-4196-32)

d) Levothyroxine Sodium 0.3mg Rx Tablets, lot #'s:

017047C, exp. 03/99 (NDC #0254-3917-28)
017047D, exp. 03/99 (NDC #0254-3917-28)
017047F, exp. 03/99 (NDC #0254-3917-28)
017047G, exp. 03/99 (NDC #0603-4198-21)
017047B, exp. 03/99 (NDC #0603-3917-38).

MANUFACTURER

RECALLED BY

DISTRIBUTION

QUANTITY

Vintage Pharmaceuticals, Inc., Charlotte, North Carolina.
Manufacturer, by letter dated November 11, 1998. Firm-initiated recall ongoing.

Alabama.

4800 bottles of Levothyroxine Sodium 0.025mg, lot #004097A.
6077 bottles of Levothyroxine Sodium 0.025mg, lot #004097B.
954 bottles of Levothyroxine Sodium 0.025mg, lot #004097C.
532 bottles of Levothyroxine Sodium 0.025mg, lot #047117D.
1369 bottles of Levothyroxine Sodium 0.025mg, lot #047117E.
1421 bottles of Levothyroxine Sodium 0.025mg, lot #047117G.
838 bottles of Levothyroxine Sodium 0.025mg, lot #047117H.
4192 bottles of Levothyroxine Sodium 0.025mg, lot #032127A.
1208 bottles of Levothyroxine Sodium 0.025mg, lot #032127B.
2772 bottles of Levothyroxine Sodium 0.025mg, lot #032127C.
984 bottles of Levothyroxine Sodium 0.025mg, lot #032127D.
2592 bottles of Levothyroxine Sodium 0.025mg, lot #033127B.
1800 bottles of Levothyroxine Sodium 0.025mg, lot #033127C.
2527 bottles of Levothyroxine Sodium 0.025mg, lot #033127D.
600 bottles of Levothyroxine Sodium 0.025mg, lot #033127E.
1179 bottles of Levothyroxine Sodium 0.05mg, lot #005097A.
804 bottles of Levothyroxine Sodium 0.05mg, lot #005097F.
3000 bottles of Levothyroxine Sodium 0.05mg, lot #006097A.
3192 bottles of Levothyroxine Sodium 0.05mg, lot #004127A.
9720 bottles of Levothyroxine Sodium 0.05mg, lot #004127B.
1074 bottles of Levothyroxine Sodium 0.05mg, lot #004127C.

652 bottles of Levothyroxine Sodium 0.3mg, lot #017047C.
1792 bottles of Levothyroxine Sodium 0.3mg, lot #017047D.
1440 bottles of Levothyroxine Sodium 0.3mg, lot #017047F.
1200 bottles of Levothyroxine Sodium 0.3mg, lot #017047G.
924 bottles of Levothyroxine Sodium 0.3mg, lot #017047B.
1407 bottles of Levothyroxine Sodium 0.150mg lot #044087A.
1784 bottles of Levothyroxine Sodium 0.150mg lot #044087B.
1195 bottles of Levothyroxine Sodium 0.150mg lot #044087C.
829 bottles of Levothyroxine Sodium 0.150mg lot #044087D.
589 bottles of Levothyroxine Sodium 0.150mg lot #044087E.

REASON
Lack of assurance of potency through expiration date.
[] None Present
[] Action Taken _____

NSN
PRODUCT
CODE
MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

6515 Nonstandard
CryoValve Allograft (heart valve), Model PV00.
Recall #Z-980-9.
Serial number 6553109.
CryoLife, Inc., Kennesaw, Georgia.
Manufacturer, by letter on March 26, 1999. Firm-initiated recall complete.
Utah.
1 unit was distributed and subsequently destroyed.
The donor's final autopsy report, which included a histological exam of the donor's brain, revealed evidence of viral encephalitis.
[] None Present
[] Action Taken _____

NSN
PRODUCT
CODE
MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

6515 Nonstandard
CryoValve Allograft (heart valve), Model PVOO.
Recall #Z-981-9.
Serial #6406157.
CryoLife, Inc., Kennesaw, Georgia.
Manufacturer, by letter on March 29, 1999. Firm-initiated recall complete.
Michigan.
1 unit was distributed.
The donor's final autopsy report revealed undiagnosed Sarcoma (Fibrosarcoma) of the right leg.
[] None Present
[] Action Taken _____

NSN
PRODUCT
CODE
MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

6515 Nonstandard
CryoValve Allograft (heart valve):
a) Model No. AV40, Serial No. 6285082;
b) Model No. AV05, Serial No. 6314988. Recall #Z-982/983-9.
a) Serial No. 6285082; b) Serial No. 6314988.
CryoLife, Inc., Kennesaw, Georgia.
Manufacturer, by letter on April 1, 1999. Firm-initiated recall complete.
a) Maryland; b) Texas.
1 unit of each component was distributed.
The donors do not meet current guidelines regarding serodilution of plasma because of the amount of transfused/infused fluids administered.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Seraflo Q-Set Hemodialysis Tubing Set (common name is "Q-set Bloodlines", Catalog numbers 205-Q01, 205-Q02, 205-Q03, 205-Q04, 205-Q05, 205-Q06, 205-Q07, 205-Q08, 205-Q09, 205-Q10, 205-Q11, 205-Q13 AND 205-Q14. Recall #Z-967/979-9.

CODE All lot numbers and expiration dates.
MANUFACTURER Nissho Nipro Corporation, Sena, Ayuhaya, Thailand.
RECALLED BY Nipro Medical Corporation, Miami, Florida, by letter dated May 6, 1999 and subrecalled by Althin Medical, Miami Lakes, Florida, by letter dated May 7, 1999. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.
QUANTITY 2,122,488 sets were distributed.
REASON The dialysis machines which utilize the Seraflo bloodlines may become contaminated with blood due to blood backing up in the bloodlines.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Shielded Trocar (obturator), Model: GT012, GT011, GT05, GT-05-7, GSNT11. Recall #Z-994/998-9.

CODE All 50 lots of 5 sizes of Trocars manufactured between 1/1/98 and 4/1/99

MANUFACTURER Gibbons Surgical Corporation, Virginia Beach, Virginia.
RECALLED BY Manufacturer, by fax on May 17, 1999, followed by telephone. Firm-initiated recall ongoing.

DISTRIBUTION Alabama, California, Pennsylvania, Texas, Michigan, Massachusetts, Missouri, Austria, Germany.

QUANTITY 51,080 units were distributed.
REASON Gamma sterilization was not validated. Devices were dosed at a different level than that provided for in validation study.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Apex Universal Irrigation Console, pumps intended to provide necessary pressure ranges during arthroscopy from 20 to 150 mmHg. They also provide flow rates of up to 2000ml/min. for proper and safe joint distension and visualization:

CODE a) Model C7100; b) Model C7100A. Recall #Z-1001/1002-9.
Models C7100 or C7100A Apex Irrigation Pumps with screened power supplies.
Serial Numbers: a) 1124, 1144, 1191, 1360, 1370, 1501, 1589, 1621, 1625, 1684, 1702, 1768, 1816, 1845, 1859, 2027, 2120
b) 1006, 1050, 1052, 1056, 1103, 1114, 1137, 1197, 1198, 1249, 1266, 1328, 1355, 1405, 1447, 1449, 1454, 1461, 1505, 1519, 1541, 1543, 1544, 1616, 1628, 1654, 1691, 1693, 1709, 1799, 1802, 1833, 1841, 1842, 1881, 1931, 1985, 2008, 2052, 2066, 2125, 10026, 10036, 10046, 10070, 10088, 10162, 10175, 10188, 10209, 10213, 10231, 10256, 10262, 10263, 10342, 10381, 10384, 10387, 10414, 10418, 10429, 10434, 10436, 10438, 10445-10447, 10455, 10504, 10507, 10512, 10529, 10531, 10536, 10539, 10554, 10560, 10588, 10600, 10647, 10707, 10756, 10763, 10775, 10789, 10799, 10804,

10807, 10838, 10848, 10861, 10872, 10873, 10876, 10880, 10884, 10889, 10895, 10898, 10899, 10900, 10901, 10905-10907, 10909-10912, 10914-10916, 10918, 10919, 10922, 10925, 10927, 10928, 10930, 10933, 10938, 10939, 10941, 10943, 10944, 10949, 10951.
Linivatec Corporation, Largo, Florida.
Manufacturer, by letter on June 2, 1999, followed by visit.
Firm-initiated recall ongoing.
Nationwide and international.
145 units were distributed.
Pump may only operate intermittently.
 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Patil Emergency Cricothyrotomy Catheters:
a) Cook Critical Care Brand Patil Emergency Cricothyrotomy Catheter Set with 6 French Airway Catheter, Reorder No. C-DTJV-6.0-6.0-PATIL;
b) Cook Critical Care Brand Patil Emergency Cricothyrotomy Catheter Set with 9 French Airway Catheter, Reorder No. C-DTJV-9.0-6.0-PATIL. Recall #Z-1009/1010-9.

CODE All Lot Numbers.
MANUFACTURER Cook Incorporated, Bloomington, Indiana.
RECALLED BY Manufacturer, by letter sent on April 29, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 535 units were distributed.
REASON The 6 cc syringe will not connect to the cricothyrotomy catheter, thus not allowing aspiration to verify correct final placement of the catheter within the trachea as per the instructions for use.
 None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT IMMUNOCARD(TM) C. DIFFICILE, diagnostic test kit used for the detection of C. difficile Common Antigen.
Recall #Z-1007-9.

CODE Lot Numbers: #706050.125 EXP 8/9/98; #706050.126, EXP 11/11/99.
Product Number: 706050.
MANUFACTURER Meridian Diagnostics, Inc., Cincinnati, Ohio.
RECALLED BY Manufacturer, by telephone beginning April 27, 1999, or by letter. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Italy, Canada.
QUANTITY A total of 304 kits (161 - lot #706050.125) and (143 - lot #706050.126).
REASON Negative color reactions may result in invalid or false negative test results.
 None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Hemoglobin Reagent. Recall #Z-947-9.
CODE HEC-506, Lot: #801164, Expiration: 1 JAN 2000.
MANUFACTURER EG & G Wallace, Inc., Norton, Ohio.
RECALLED BY EG & G Wallace, Inc., Akron, Ohio, by fax on April 21, 1999.
Firm-initiated recall ongoing.
DISTRIBUTION Tennessee, Virginia, California, Illinois, Massachusetts,

Nebraska, New York, Canada, Brazil.
 QUANTITY 33 sets were distributed.
 REASON Product is packaged with an insert sheet which incorrectly identifies the control as Hb A/S in the heading, instead of the correct control identification of Hb A/F.
 None Present
 Action Taken _____

NSN 6550 Nonstandard
 PRODUCT CMV IgM ELISA Test System, an enzyme-linked immunosorbent assay (ELISA) for the detection of IgM antibodies to cytomegalovirus. Recall #Z-943-9.
 CODE Lot #9VIRO17456, Product #9Z9501M EXP 11/30/99.
 MANUFACTURER Zeus Scientific, Inc., Branchburg, New Jersey.
 RECALLED BY Manufacturer, by letter sent October 29, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide, China, Indonesia.
 QUANTITY 66 kits were distributed.
 REASON The product may produce false positive test results.
 None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
 PRODUCT Trifluoperazine HCl Tablets, USP, a) 1mg, in 100 count bottles; b) 2mg, in 100 count bottles; c) and 5mg, in 100 and 500 count bottles; d) Fluphenazine HCl Tablets, USP, 1 mg, in 100 and 500 count bottles, Rx prescribed for the management of the manifestations of psychotic disorders and non-psychotic anxiety. Recall #D-233/236-9.

CODE

a-c) Strength	Lot No	NDC No.	Size(Tabs)	Exp Date
1 mg	E132L	00378-2401-01	100	10/00
2 mg	E131L	00378-2402-01	100	10/00
5 mg	E128L	00378-2405-01	100	10/00
5 mg	E128L	00378-2405-05	500	10/00
d) 1 mg	E235E	00378-6004-01	100	08/00
		00378-6004-05	500	08/00.

MANUFACTURER Mylan Pharmaceuticals, Inc., Morgantown, West Virginia.
 RECALLED BY Manufacturer, by letters on or about April 12, 1999, and May 6, 1999. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY a-c) Firm estimated that 14,392 bottles of 100 tablets, and 200 bottles of 500 tablets; d) 9,047 bottles of 100 and 960 bottles of 500 tablets remained on market at time of recall initiation.
 REASON Subpotency (at 3 month stability).
 None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Rx oral tablets in unit dose blister packages of 100 tablets, 10 strips of 10 tablets, indicated for the management of psychotic disorders:
 a) Trifluoperazine Hydrochloride Tablets, USP, 1 mg, in unit dose packages of 100 (10 strips of 10 tablets). NDC #51079-572-20
 b) Trifluoperazine Hydrochloride Tablets, USP, 2 mg, in

unit dose packages of 100 (10 strips of 10 tablets). NDC #51079-573-20

c) Trifluoperazine Hydrochloride Tablets, USP, 5mg, in unit dose packages of 100 (10 strips of 10 tablets). NDC #51079-574-20

d) Fluphenazine Hydrochloride Tablets, USP, 1 mg, in unit dose packages of 100 (10 strips of 10 tablets). NDC #51079-485-20. Recall #D-238/241-9.

Lot numbers: a) 9A159; b) 9A160 and 9B358; c) 9A161 and 9C485; d) 8S844.

Mylan Pharmaceuticals, Inc., Morgantown, West Virginia.
UDL Laboratories, Inc., Rockford, Illinois (repacker), by letter dated May 13, 1999. Firm-initiated recall ongoing.

Nationwide.

a) 100; b) 275; c) 374; d) 1,404 unit cartons were distributed; firm estimated that 40% of the products remained on the market at time of recall initiation.

Subpotency (at 3 month stability).
 None Present
 Action Taken _____

NSN
PRODUCT 6505 Nonstandard
Lycall Cold Sore Ointment (Lysine/Camphor/Menthol), in 8 gram jars. Recall #D-242-9.

CODE
MANUFACTURER Lot #1541 EXP 23/01.
RECALLED BY Caleb Laboratories, Inc., Minneapolis, Minnesota.
Manufacturer, by telephone beginning on April 28, 1999, and by letter faxed on April 28, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY Minnesota, Wisconsin, North Dakota, Colorado.
REASON 924 jars were distributed.
Lysine subpotency.
 None Present
 Action Taken _____

NSN
PRODUCT 6505 Nonstandard
Rugby brand Calcium Carbonate Tablets, 10 gr (648 mg), in 1,000 tablet containers. Recall #D-244-9.

CODE
MANUFACTURER Lot #1795-8911 EXP 11/02.
RECALLED BY Tischon Corporation, Salisbury, Maryland.
Tishcon Corporation, Westbury, New York, by fax and certified mail on April 12, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY Georgia.
REASON 1,005 bottles were distributed.
Tablet mix-up - Bottles contain brewer's yeast tablets (light brown).
 None Present
 Action Taken _____

NSN
PRODUCT 6505 Nonstandard
Acyclovir Tablets or Capsules, Rx used as an anti-viral medication for Herpes Simplex I:
a) 200 mg, in 100, 500 and 1,000 capsule bottles
b) 400 mg, Rx in 100, 500, and 1,000 tablet bottles
c) 800 mg, Rx in 100, 500, and 1,000 tablet bottles
Labels and NDC Numbers --
Schein Pharmaceuticals
0365-2692-01 100 capsules/200 mg

0364-2689-01 100 tablets/400 mg
 0364-2689-05 500 tablets/400 mg
 0364-2689-01 100 tablets/800 mg
 Mylan Pharmaceutical Inc.
 0378-1464-01 100 tablets/400 mg
 0378-1468-01 100 tablets/800 mg
 Par Pharmaceutical
 49884-460-05 200 mg 500 capsules
 49884-460-01 100 capsules
 49884-460-10 1000 capsules
 49884-487-01 400 mg 100 tablets
 49884-487-05 500 tablets
 49884-487-10 1000 tablets
 49884-474-01 800 mg 100 tablets
 49884-474-05 500 tablets
 49884-474-10 1000 tablets
 Cimetidine Tablets, used as a stomach acid reducer for patients with stomach ulcers
 d) 200 mg, Rx and OTC, in 6,10, 12,18, 30, 50, 60, 90, and 100 count units
 e) 300 mg, Rx in 100, 500, and 1,000 count bottles
 f) 400 mg, Rx in 60, 100, 500, and 1,000 count bottles
 g) 800 mg, Rx in 30, 100, and 250 count bottles.
 Labels and NDC Numbers--
 Cimetidine 200 mg OTC

Firm Name	NDC#	Packaged Size
Eckerd Drug Company	19458-957-61	6 tablet blister
	19458-957-62	18 tablet blister
	19458-957-63	30 tablet blister
	19458-957-64	60 tablet blister
Albertson's	41163-229-08	30 tablet blister
Equate	50606-229-08	30 tablet blister
Packaged by	50606-229-15	60 tablet blister
BI-MART		12 tablet blister
		30 tablet blister
Western Family Foods, Inc.		12 tablet blister
		30 tablet blister
Kaiser Permanente	00179-1308-30	30 tablet blister
	00179-1308-90	90 tablet blister
Pharmacist Formula		18 tablet blister
Marketed by:		(special 30 tablet blister for above)
Leiner Health Products, Inc.		30 tablet blister
		50 tablet blister
VONS	58828-229-08	30 tablet blister
Safeway Inc.	21130-229-08	30 tablet blister
Bulk shipping label		
LEK Pharmaceutical and Chemical Co., d.d.		
Ljubljana, Slovenia		60x6 coated tablet blister
		60x6 tablets acid reducer
		60x10 tablets acid reducer
		60x10 coated tablets
Cimetidine 200 mg, RX		
Rosemont	0832-0101-00	100 tablet bottles
Brightstone	62939-2111-1	100 tablet bottles
Schein	364-2591-01	100 tablet bottles
	0364-2591-01	100 tablet bottles
Martec	52555-708-01	100 tablet bottles
Qualitest	0603-2890-21	100 tablet bottles
URL	0677-1527-01	100 tablet bottles
Cimetidine 300 mg		

Rosemont 0102-00 100 tablet bottles
0832-0102-50 500 tablet bottles
0832-0102-10 1000 tablet bottles
Brightstone 62939-2121-1 100 tablet bottles
Schein 0364-2592-01 100 tablet bottles
0364-2592-05 500 tablet bottles
Martec 52555-709-01 100 tablet bottles
Apothecon 59772-0229-5 500 tablet bottles
Qualitest 0603-2891-28 500 tablet bottles
URL 0677-1528-01 100 tablet bottles
MOVA 55370-866-07 100 tablet bottles
Cimetidine 400 mg
Rosemont 0832-0103-06 60 tablet bottles
0832-0103-00 100 tablet bottles
0832-0103-50 500 tablet bottles
0832-0103-10 1000 tablet bottles
Brightstone 62939-2131-1 100 tablet bottles
Martec 52555-710-01 100 tablet bottles
Schein 0364-2593-01 100 tablet bottles
0364-2593-05 500 tablet bottles
URL 0677-1529-01 100 tablet bottles
0677-1529-05 500 tablet bottles
Novapharm 55953-436-40 100 tablet bottles
55953-436-70 500 tablet bottles
55953-436-80 1000 tablet bottles
Apothecon 59772-0230-3 100 tablet bottles
59772-0230-7 500 tablet bottles
Qualitest 0603-2892-28 500 tablet bottles
Cimetidine 800 mg
Rosemont 0832-0104-03 30 tablet bottles
0832-0104-00 100 tablet bottles
0832-0104-25 250 tablet bottles
Martec 52555-711-01 100 tablet bottles
Novapharm 55953-516-40 100 tablet bottles
Schein 0364-2594-01 100 tablet bottles
0364-2594-01
Brightstone 62939-2141-1 100 tablet bottles
Qualitest 0603-2893-21 100 tablet bottles
Apothecon 59772-0231-3 100 tablet bottles
59772-0231-4 250 tablet bottles.

Recall #D-247/253-9.

CODE
MANUFACTURER
RECALLED BY

All lots within expiration date.
LEK Pharmaceutical and Chemical Company, Ljubljana, Slovenia.
LEK, USA Englewood Cliffs, New Jersey, by telephone or fax March
7 or 9, 1999, and by letter dated April 1 or 15, 1999. Firm-
initiated recall ongoing.

DISTRIBUTION
QUANTITY

New Jersey, New York, West Virginia.
Acyclovir Tablets -- 37,464 bottles (Par)
430,284 bottles (Schein)
740,000 bottles (Mylan)
Acyclovir Capsules -- 22,110 bottles (Par)
320,378 bottles (Schein)
Cimetidine Tablets --
200 mg OTC 11,026 blisters
200 mg RX 34,866 bottles
400 mg 307,813 bottles
800 mg 130,139 bottles were distributed.

REASON

Lack of assurance of bioequivalence.
[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Astra 4% Citanest Forte with Epinephrine 1:200,000 (Prilocaine and Epinephrine Injection, USP), in 1.8 mL cartons, indicated for the production of local anesthesia in dentistry. NDC #0186-0540-14. Recall #D-255-9.

CODE Lot No. Expiration Date
0540801072 Jul-99
0540801075 Jul-99
0540802017 Aug-99
0540803036 Sep-99
0540803044 Sep-99
0540803053 Sep-99
0540803072 Sep-99
0540803090 Sep-99
0540804018 Oct-99
0540804023 Oct-99
0540804037 Oct-99
0540804049 Oct-99
0540804054 Oct-99
0540804103 Oct-99
0540804107 Oct-99
0540805001 Nov-99

MANUFACTURER Astra Pharmaceuticals, L.P., Westborough, Massachusetts.
RECALLED BY Manufacturer, by letter on May 28, 1999. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 56,252 units were distributed
REASON Epinephrine subpotency (stability).
[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Various Custom Allergenic extract Mixtures and Stock Extracts. Recall #B-863-9.

CODE A total of 637 different lot numbers are subject to recall.
MANUFACTURER Allergy Laboratories of Ohio, Inc., Columbus, Ohio.
RECALLED BY Manufacturer, by letter on either February 17, 1999, March 5, 8, 10, 11, 12, 15, 16, 17, or 18, 1999. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 1,521 vials were distributed.
REASON Allergenic extracts were labeled with extended expiration dates.
[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Miacalcin Nasal Spray (Calcitonin-Salmon), 200 IU/dose, in 2 mL vials, Rx for the treatment for postmenopausal osteoporosis in females greater than five years postmenopause, with low bone mass relative to healthy premenopausal females. NDC 0078-0311-90. Recall #D-254-9.

CODE Lot #355A9473 EXP Date: December 2001
Lot #206Z4722 EXP Date - Aug / 2000
Lot #236Z5438 EXP Date - Oct / 2000
Lot #362B9718 EXP Date - Jan / 2002
Lot #362B9719 EXP Date - Jan / 2002

Lot #362B9971 EXP Date - Jan / 2002
 Lot #200Z4716 EXP Date - Jul / 2000
 Lot #201Z4717 EXP Date - Jul / 2000
 Lot #202Z4718 EXP Date - Aug / 2000
 Lot #203Z4719 EXP Date - Aug / 2000
 Lot #204Z4720 EXP Date - Aug / 2000
 Lot #205Z4721 EXP Date - Aug / 2000
 Lot #207Z4723 EXP Date - Aug / 2000
 Lot #208Z4724 EXP Date - Aug / 2000
 Lot #210Z4725 EXP Date - Aug / 2000
 Lot #213Z4726 EXP Date - Sep / 2000
 Lot #214Z5066 EXP Date - Sep / 2000
 Lot #215Z5067 EXP Date - Sep / 2000
 Lot #216Z5068 EXP Date - Sep / 2000
 Lot #323A6800 EXP Date - May / 2001
 Lot #323A6802 EXP Date - May / 2001
 Lot #323A6804 EXP Date - May / 2001
 Lot #323A6806 EXP Date - May / 2001
 Lot #323A6808 EXP Date - May / 2001
 Lot #323A6810 EXP Date - May / 2001
 Lot #324A6491 EXP Date - May / 2001
 Lot #324A6494 EXP Date - May / 2001
 Lot #324A6496 EXP Date - May / 2001
 Lot #324A6611 EXP Date - May / 2001
 Lot #324A6613 EXP Date - May / 2001

This recall covers all of the firms manufactured product lots from 11/19/97 thru 05/20/99 identified under the same numbers NDC 0078-0311-90), and Lots: (Miacalcin Nasal Spray 200 IU Carton of 1's): Lot #209Z2255 EXP Date - Aug / 2000 Lot #324A6483 EXP Date - May / 2001 -- and all of the firms manufactured product lots identified under NDC 0078-9149-01.

MANUFACTURER RECALLED BY

Novartis Pharmaceuticals Corporation, Basel, Switzerland.
 Novartis Pharmaceuticals Corporation, Suffern, New York, by letter on May 4, 1999. Firm-initiated recall ongoing.

DISTRIBUTION

New Jersey, Tennessee, Indiana, Texas, Washington state, Oregon, California, Massachusetts, Illinois, Missouri, Florida, Puerto Rico, Vermont, North Dakota, New York, Michigan, Kentucky, Pennsylvania, New Mexico.

QUANTITY REASON

131,837 cartons were distributed.
 Discoloration, low pH, and subpotency potential due to embedded ferrous contamination in a portion of glass vials used in production.
 None Present
 Action Taken _____

NSN PRODUCT

6505 Nonstandard
 Fluocinolone Acetonide Topical Solution USP 0.01% in 60 mL bottles, Rx synthetic steroid used as an anti-inflammatory and anti-pruritic agent, under the Zenith Goldline (NDC 0182-1564-68) and H.L. Moore (NDC 0839-6660-84). labels.
 Recall #D-260-9.

CODE MANUFACTURER RECALLED BY

Lot #K722 EXP 01/00.
 Thames Pharmacal Company, Inc., Ronkonkoma, New York. Manufacturer, by letter sent on May 7, 1999. Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY

Ohio, California, Connecticut.
 1,632 bottles were distributed; firm estimated that less than 10 percent of the product remained on the market at time of recall

initiation.
REASON Subpotency (stability).
[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) Hygroton Tablets (chlorthalidone, USP), 50 mg, in 100
tablet bottles, NDC 0075-0020-00; b) Hygroton Tablets
(chlorthalidone, USP), 25 mg, in 100 tablet bottles NDC
0075-0022-00. Products are Rx oral diuretics. Recall
#D-262/263-9.

CODE Lot Numbers: a) MN3117 EXP 6/30/00 and MN2528 EXP
9/30/00; b) MN2523 EXP 8/31/99 and MN2428 EXP 8/31/99.

MANUFACTURER Rhone Poulenc Rorer, Manati, Puerto Rico.
RECALLED BY Rhone Poulenc Rorer, Collegeville, Pennsylvania, by
letter dated April 16, 1999. Firm-initiated recall
ongoing.

DISTRIBUTION Nationwide.
QUANTITY Firm estimated that 3,000 units of the 50 mg tablets and
approximately 3,000 units of the 25 mg tablets remained
on market at time of recall initiation.

REASON Dissolution failure.
[] None Present
[] Action Taken _____
