

**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 17116  
PRODUCT Defibrillators, Automated, External  
Heartstart Battery Charger, Catalog #902850, intended to charge the following batteries:  
90 11 00 Heartstart Battery  
90 43 00 Heartstart Battery  
90 11-90 Heartstart 3000 Training Battery  
90 41 00 Heartstart 1000 Training Battery. Recall #Z-802-7.  
CODE Lot Nos. 97182A, 97212A.  
MANUFACTURER Ault, Inc., Minneapolis, Minnesota (battery supplier/responsible firm).  
RECALLED BY Laerdal Medical Corp., Wappingers Falls, New York, by letter dated June 27, 1997. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 301 battery charges are affected.  
REASON The two lots of battery chargers were missing a resistor that controls the lights and charging activity in the battery charger.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6525NS  
MDC 12425  
PRODUCT X-Ray Rad Units, Mammographic  
Contour Mammography System, Model M-CTR-1 and M-CTR-2 dedicated for mammographic imaging using X-ray. Recall #Z-859/860-7.  
CODE Units w/ Serial Numbers in 29000 series are Contour 2 models and all others are Contour 1  
(425 Serial #s):  
BMC-27503, BMC-27504, BMC-27505, BMC-27506, BMC-27509, BMC-27510, BMC-27512, BMC-27513, BMC-27514, BMC-27516, BMC-27520, BMC-27522, BMC-27523, BMC-27524, BMC-27526, BMC-27527, BMC-27528, BMC-27578, BMC-27579, BMC-27580, BMC-27581, BMC-27582, BMC-27583, BMC-27584, BMC-27586, BMC-27587, BMC-27596, BMC-27597, BMC-27598, BMC-27599, BMC-27600, BMC-27602, BMC-27603, BMC-27604, BMC-27605, BMC-27606, BMC-27607, BMC-27608, BMC-27609, BMC-27610, BMC-27611, BMC-27612, BMC-27613, BMC-27614, BMC-27615, BMC-27634, BMC-27635, BMC-27636, BMC-27637, BMC-27638, BMC-27639, BMC-27641, BMC-27642, BMC-27643, BMC-27644, BMC-27646, BMC-27647, BMC-27648, BMC-27649, BMC-27650, BMC-27652, BMC-27654, BMC-27655, BMC-27656, BMC-27658, BMC-27701, BMC-27702, BMC-27703, BMC-27705, BMC-27706, BMC-27707, BMC-27708,

BMC-27710, BMC-27711, BMC-27712, BMC-27713, BMC-27714, BMC-27715, BMC-27716, BMC-27717, BMC-27718, BMC-27719, BMC-27720, BMC-27721, BMC-27722, BMC-27723, BMC-27724, BMC-27725, BMC-27726, BMC-27727, BMC-27729, BMC-27730, BMC-27731, BMC-27732, BMC-27733, BMC-27734, BMC-27735, BMC-27737, BMC-27738, BMC-27739, BMC-27740, BMC-27741, BMC-27742, BMC-27743, BMC-27745, BMC-27746, BMC-27753, BMC-27754, BMC-27755, BMC-27756, BMC-27757, BMC-27758, BMC-27759, BMC-27760, BMC-27761, BMC-27762, BMC-27763, BMC-27764, BMC-27765, BMC-27766, BMC-27767, BMC-27768, BMC-27770, BMC-27771, BMC-27772, BMC-27773, BMC-27774, BMC-27775, BMC-27777, BMC-27778, BMC-27779, BMC-27780, BMC-27780, BMC-27781, BMC-27783, BMC-27784, BMC-27801, BMC-27802, BMC-27803, BMC-27804, BMC-27805, BMC-27806, BMC-27807, BMC-27808, BMC-27809, BMC-27812, BMC-27813, BMC-27814, BMC-27815, BMC-27816, BMC-27817, BMC-27818, BMC-27820, BMC-27821, BMC-27822, BMC-27823, BMC-27824, BMC-27828, BMC-27829, BMC-27831, BMC-27832, BMC-27833, BMC-27834, BMC-27835, BMC-27836, BMC-27837, BMC-27838, BMC-27840, BMC-7841, BMC-27842, BMC-27844, BMC-27845, BMC-27846, BMC-27848, BMC-27849, BMC-27850, BMC-27851, BMC-27852, BMC-27853, BMC-27855, BMC-27858, BMC-27859, BMC-27860, BMC-27861, BMC-27865, BMC-27866, BMC-27867, BMC-27868, BMC-27869, BMC-27870, BMC-27871, BMC-27872, BMC-27873, BMC-27874, BMC-27875, BMC-27876, BMC-27877, BMC-27888, BMC-27889, BMC-27890, BMC-27891, BMC-27892, BMC-27893, BMC-27895, BMC-27896, BMC-27897, BMC-27898, BMC-27900, BMC-27901, BMC-27902, BMC-27903, BMC-27904, BMC-27905, BMC-27906, BMC-27907, BMC-27908, BMC-27909, BMC-27910, BMC-27911, BMC-27912, BMC-27913, BMC-27914, BMC-27915, BMC-27916, BMC-27919, BMC-27920, BMC-27922, BMC-27923, BMC-27924, BMC-27925, BMC-27926, BMC-27927, BMC-27928, BMC-27929, BMC-27930, BMC-27931, BMC-27932, BMC-27935, BMC-27936, BMC-27938, BMC-27939, BMC-27940, BMC-27942, BMC-27943, BMC-27945, BMC-27946, BMC-27956, BMC-27957, BMC-27959, BMC-27960, BMC-27961, BMC-27962, BMC-27965, BMC-27966, BMC-27968, BMC-27969, BMC-27971, BMC-27972, BMC-27973, BMC-27974, BMC-27975, BMC-27976, BMC-27979, BMC-27981, BMC-27982, BMC-27985, BMC-27986, BMC-27989, BMC-27990, BMC-27993, BMC-27994, BMC-27995, BMC-27997, BMC-27998, BMC-27999, BMC-28001, BMC-28002, BMC-28003, BMC-28004, BMC-28005, BMC-28015, BMC-28016, BMC-28017, BMC-28018, BMC-28019, BMC-28020, BMC-28021, BMC-28022, BMC-28024, BMC-28025, BMC-28026, BMC-28027, BMC-28032, BMC-28043, BMC-28044, BMC-28045, BMC-28047, BMC-28048, BMC-28050, BMC-28052, BMC-28053, BMC-28054, BMC-28056, BMC-28057, BMC-28059, BMC-28061, BMC-28062, BMC-28063, BMC-28064, BMC-28065, BMC-28066, BMC-28067, BMC-28069, BMC-28071, BMC-28072, BMC-28074, BMC-28075, BMC-28076, BMC-28096, BMC-28097, BMC-28098, BMC-28099, BMC-28103, BMC-28104, BMC-28105, BMC-28109, BMC-28110, BMC-28111, BMC-28112, BMC-28113, BMC-28114, BMC-28116, BMC-28117, BMC-28118, BMC-28119, BMC-28120, BMC-28122, BMC-28125, BMC-28126, BMC-28127, BMC-28128, BMC-28129, BMC-28130, BMC-28133, BMC-28134, BMC-28135, BMC-28136, BMC-28139, BMC-28140, BMC-28141, BMC-28142, BMC-28143, BMC-28144, BMC-28151, BMC-28152, BMC-28154, BMC-28155, BMC-28157, BMC-28158, BMC-28167, BMC-28168, BMC-28171, BMC-28174, BMC-28175, BMC-28176, BMC-28182, BMC-28183, BMC-28185, BMC-28186, BMC-28187, BMC-28188, BMC-28195, BMC-28217, BMC-28219, BMC-28223, BMC-28224, BMC-28225, BMC-28230, BMC-28252, BMC-28253, BMC-28257, BMC-29000, BMC-29001, BMC-29002, BMC-29003, BMC-29004, BMC-29005, BMC-29006, BMC-29007, BMC-29008, BMC-29009, BMC-29010, BMC-29014, BMC-29015, BMC-29016, BMC-29017,

BMC-29022, BMC-29023, BMC-29024, BMC-29026, BMC-29027, BMC-29028, BMC-29045, BMC-29046, BMC-29047, BMC-29048, BMC-29049, BMC-29051, BMC-29052, BMC-29053, BMC-29054, BMC-29055, BMC-29056, BMC-29057, BMC-29059, BMC-29060, BMC-29061, BMC-29062, BMC-29063, BMC-29066, BMC-29068, BMC-29069, BMC-29072, BMC-29073 & BMC-29076.

The following serial numbers are for the 58 units which the firm had shipped retrofit kits between 9/95 and 2/97: (Bennett still needs to verify that these retrofits were performed by dealers' servicemen):

BMC-27830, BMC-29129, BMC-29196, BMC-29081, BMC-28042, BMC-29021, BMC-27941, BMC-29019, BMC-27856, BMC-29177, BMC-28051, BMC-27616, BMC-27610, BMC-27944, BMC-27987, BMC-27996, BMC-27517, BMC-29168, BMC-29067, BMC-27970, BMC-27967, BMC-27769, BMC-28023, BMC-27937, BMC-27525, BMC-27507, BMC-28172, BMC-27508, BMC-29011, BMC-29013, BMC-29020, BMC-27827, BMC-27988, BMC-29287, BMC-29018, BMC-28026, BMC-27847, BMC-29025, BMC-29139, BMC-27843, BMC-29112, BMC-27826, BMC-27958, BMC-28046, BMC-28156, BMC-29249, BMC-29121, BMC-29003, BMC-28058, BMC-27744, BMC-27501, BMC-27653, BMC-29012, BMC-27857, BMC-28121, BMC-27640, BMC-29074 and BMC-27977.

MANUFACTURER Bennett X-Ray Technologies, subsidiary of Trex Medical Corporation, Copiague, NY.  
RECALLED BY Manufacturer, by letter dated March 5, 1997. Firm-initiated field correction ongoing.  
DISTRIBUTION Nationwide and international.  
QUANTITY 483 units subject to retrofit.  
REASON This diagnostic x-ray device was found to be in non-compliance with the Federal Performance Standard for Diagnostic X-ray Systems and their Major Components. The 150 watt bulb may cause overheating in the collimator gears.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6515NS  
MDC 17445  
PRODUCT Multiple Medical Gas Monitors, Respired/Anesthetic  
Multigas Analyzer, simultaneously monitors gas concentrations and alerts clinical personnel when the concentration of anesthetic agents, oxygen, carbon dioxide or nitrous oxide falls outside the defined limits. Recall #Z-862-7.  
CODE Serial Number Range 518-000001 through 518-000551 (non inclusive), Software Versions less than 1.00.26  
MANUFACTURER Spacelabs Medical, Inc., Redmond, Washington.  
RECALLED BY Manufacturer, by letter on May 15, 1997. Firm-initiated field correction ongoing.  
DISTRIBUTION Nationwide and international.  
QUANTITY 303 devices were distributed.  
REASON The multigas analyzer may display an incorrect agent identification.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

6515NS  
MDC 10134  
PRODUCT Anesthesia Units  
Narkomed Anesthesia Machines, intended to deliver anesthetic gases and oxygen and may be used to ventilate patients. Recall #Z-863-7.

CODE Product Manufactured Between December 5, 1996, and March 21, 1997.  
MANUFACTURER North American Drager, Telford, Pennsylvania.  
RECALLED BY Manufacturer, by letter dated June 6, 1997. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide and international.  
QUANTITY 281 units were distributed.  
REASON The oxygen flush button on some of these machines may stick in the open position.

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 10 OCT 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: None**

**CLASS II RECALLS:**

NSN 6505 Nonstandard  
PRODUCT Sea-Clens Wound Cleanser, (Sodium Chloride),

in 6 fluid ounce bottles. (Note: The product is labeled with the company name of Sween Corporation, N. Mankato, Minnesota.) Recall #D-249-7.

CODE Lot #1G6AB EXP 7/98.  
MANUFACTURER Coloplast Corporation, North Mankato, Minnesota.  
RECALLED BY Manufacturer, by letter on August 12, 1997.  
Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 740 cases (6 bottles per case) were distributed; firm estimated that 10 percent of product remained on market at time of recall initiated.  
REASON Pseudomonas Aeruginosa contamination.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6505 Nonstandard  
PRODUCT: Clindamycin Hydrochloride Capsules Recall#D-252-7.  
CODE: lot# 20847, 20848, 28125, 28126, 28127.  
MANUFACTURER: EVA Pharmaceuticals USA, Inc., Sellersville, Pennsylvania.  
RECALLED BY: Manufacturer, on or about July 15, 1997. Firm-initiated recall ongoing.  
DISTRIBUTION: Nationwide.  
QUANTITY: 1,597 X 100 bottles were distributed.  
REASON: labeling: Incorrect expiration date.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6505 Nonstandard  
PRODUCT a) Red Blood Cells; b) Red Blood Cells, Leukocytes Removed; c) Platelets; d) Cryoprecipitate; e) Fresh Frozen Plasma; f) Recovered Plasma. Recall #B-1212/1217-7.  
CODE a) 19037-1569 19034-6451 19039-2788  
19035-9984 19033-9393 19033-1129  
19032-5963 19038-5359 19029-0570  
19027-4568 19029-5428 19026-8142  
b) 19031-7300  
c) 19029-0570 19028-5359  
d) 19026-8142 19031-7300 19039-2788  
19035-9984  
e) 19037-1569  
f) 19026-8142 19031-7300 19035-9984  
19039-2788 19034-6451 19029-0570  
19027-4568 19029-5428 19033-1129

19032-5963 19028-5359.  
MANUFACTURER United Blood Services, Reno, Nevada.  
RECALLED BY Blood Systems Inc., Scottsdale, Arizona, by  
letter on February 18, 1997. Firm-initiated  
recall ongoing.  
DISTRIBUTION Alabama, California, Florida, Louisiana, North  
Carolina, Nevada, South Dakota, Tennessee,  
Texas, Switzerland.  
QUANTITY a) 12 units; b) 1 unit; c) 2 units; d) 4  
units; e) 1 unit; f) 11 units were  
distributed.  
REASON Blood products tested negative for the  
antibody to the human immunodeficiency virus  
type 1 (anti-HIV-1), but were collected from a  
donor who previously tested repeatedly  
reactive for anti-HIV-1, Western blot  
negative.

None Present

Action Taken \_\_\_\_\_

NSN 6505 Nonstandard  
PRODUCT Baxter Gammagard Solvent/Detergent Treated  
Immunoglobulin G (Immune Globulin Intravenous  
(Human): a) Baxter's Gammagard S/D 5G;  
b) Baxter's Gammagard S/D 10G.  
Recall #B-1225/1226-7.  
CODE Lot # 2620M010AB, 2620M011AA, 2620M012AA.  
MANUFACTURER Baxter Healthcare Corporation, Hyland  
Division, Glendale, California.  
RECALLED BY Manufacturer, by letter dated April 24, 1997.  
Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide and international.  
QUANTITY 10,173 vials were distributed.  
REASON Baxter's IGIV solvent/detergent vials are  
misbranded in that they incorrectly list the  
reconstitution volume as 10 ml.

None Present

Action Taken \_\_\_\_\_

NSN 6505 Nonstandard  
PRODUCT a) Red Blood Cells; b) Platelets; c) Fresh  
Frozen Plasma; d) Recovered Plasma.  
Recall #B-1238/1241-7.  
CODE Unit numbers: a) 12415-9782, 12414-7079,  
12412-7323, 12409-7504, 12078-6408,  
12408-2436, 12090-2683, 12088-9992,  
12093-2339, 12080-5112  
b) 12412-7323, 12088-9992, 12090-2683,

12409-7504  
c) 12078-6408, 12415-9782, 2414-7079  
d) 12093-2339, 12408-2436, 12409-7504,  
12412-7323, 12090-2683, 12088-9992,  
12080-5112.

MANUFACTURER United Blood Services, Albuquerque, New Mexico.  
RECALLED BY Blood Systems Inc., Scottsdale, Arizona, by letters on March 11, 1997, and July 7, 1997. Firm-initiated recall ongoing.  
DISTRIBUTION Colorado, North Carolina, New Mexico, Texas, Switzerland.  
QUANTITY a) 10 units; b) 4 units; c) 3 units; d) 7 units were distributed.  
REASON Blood products tested negative for the antibody to the human immunodeficiency virus type 1 (anti-HIV-1), but were collected from a donor who previously tested repeatedly reactive for anti-HIV-1, Western blot negative.

None Present  
 Action Taken \_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT SURGIKOS Latex Surgical Gloves, Sterile.  
Recall #Z-754/761-7.  
CODE Model Numbers Lot Numbers  
6455 95100001 through 97020001  
6460 95100011 through 97030103  
6465 95100103 through 97030209  
6470 95080726 through 97020508  
6475 95081504 through 97031002  
6480 95082296 through 97021603  
6485 95071653 through 97021805  
6490 95071695 through 97021901.  
MANUFACTURER Fime-Darby Latex Products Seramban, Malaysia  
RECALLED BY Johnson & Johnson Medical, Inc., Arlington, Texas, by letter, July 1, 1997. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide and Canada.  
QUANTITY 417,000 pairs were distributed.  
REASON Open seals were found, thereby compromising 288882 the sterility of the medical devices.

None Present  
 Action Taken \_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT Kilit Ampules, are used to monitor steam-under-pressure sterilization cycles,

labeled under the brand names Cotrell Limited and SPS Medical:

- a) Kilit Ampules, Catalog Number 4312018
- b) Kilit Ampules, Catalog Number 4312019
- c) Kilit Ampules, Catalog Number 4399511 (manufactured for Cottrell, Ltd.);
- d) Kilit Ampules, Catalog Number 4399155 (manufactured for SPS Medical).

Recall #Z-764/767-7.

CODE All lots of the above Catalog Numbers are subject to recall.

MANUFACTURER Becton Dickinson Microbiology Systems, Cockeysville, Maryland.

RECALLED BY Becton Dickinson Microbiology Systems, Sparks, Maryland, by letter in May 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY Firm estimates none remains on the market.

REASON Devices do not meet labeled D-values and some are outside the label claim for spore count. This could produce incorrect result when applied to the standard microbiological sterilization cycle.

None Present

Action Taken \_\_\_\_\_

NSN 6515 Nonstandard

PRODUCT Electric Powered Moist Heating Pad with momentary switch:

- a) Roberts Hydro Thero Pad Model 1327-1, Pro-Temp MHP Model 1327-1
- b) Roberts Hydro Thero pad Model 1313-1.

Recall #Z-796/797-7.

CODE a) Control numbers 971247, 971260 through 971324, 971349 through 971362, 971397 through 971431, 971482 through 971561, 970541 through 970660

b) control numbers 970889 through 970911, 970924 through 971025, 971081 through 971200, 971212, 971144 through 971147.

MANUFACTURER Roberts Manufacturing Company, Inc., Baltimore, Maryland.

RECALLED BY Manufacturer, by telephone on May 23, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY a) 315 units; b) 246 units were distributed.

REASON During assembly of the product it was discovered that splitting the electric power cord caused copper wires to become exposed.

None Present

[ ] Action Taken \_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT Heartstart Battery Charger, Catalog #902850,  
intended to charge the following batteries:  
90 11 00 Heartstart Battery  
90 43 00 Heartstart Battery  
90 11-90 Heartstart 3000 Training Battery  
90 41 00 Heartstart 1000 Training Battery.  
Recall #Z-802-7.  
CODE Lot Nos. 97182A, 97212A.  
MANUFACTURER Ault, Inc., Minneapolis, Minnesota (battery  
supplier/responsible firm).  
RECALLED BY Laerdal Medical Corp., Wappingers Falls, New  
York, by letter dated June 27, 1997.  
Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 301 battery charges are affected.  
REASON The two lots of battery chargers were missing  
a resistor that controls the lights and  
charging activity in the battery charger.

[ ] None Present

[ ] Action Taken \_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT Oxygen Pressure Regulator with Constant Flow:  
a) Regulator Model No. L270-020 for the  
following kits: L151JD, L175-010, L175-010D,  
L175-010JD, L175-011D, L175-011JD, L175-014,  
L175-01R, L175-030, L175-030D, L175-030JD,  
L175-03R, L175-140, L444, L444-010, L515,  
L515-010, L515D, L515JD, L520, L520-010, L521,  
L523, L523-100, L524, L525, L526, L541-020,  
L541-040, L542-020, L542-040, L561, L561-010,  
L561-020, L567, L574, L594, L902001, L902002,  
L902003, L520-100  
b) Regulator Model No. L270-050 for the  
following kits: L228 and L228-030.  
Recall #Z-866/867-7.  
CODE All regulators distributed prior to 4/11/97.  
MANUFACTURER Allied Healthcare Products, Inc., St. Louis,  
Missouri.  
RECALLED BY Manufacturer, by letter dated May 20, 1997,  
and by telephone on May 23, 1997.  
Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY Approximately 150,000 regulators were  
distributed.  
REASON The device was involved in fires which

occurred as a result of contamination introduced into the oxygen regulators during maintenance or use.

None Present  
 Action Taken \_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT Consensus Knee Femoral Component, Nonporous CoCr, Size 5 Right, for joint replacement. Recall #Z-868-7.  
CODE Lot No. 230224A.  
MANUFACTURER US Medical Products, Inc., Austin, Texas.  
RECALLED BY Manufacturer, by telephone on May 22, 1997. Firm-initiated recall complete.  
DISTRIBUTION Florida.  
QUANTITY 2 units were distributed.  
REASON The labeling stated product was a right knee component, but the component in the package was a left knee component.

None Present  
 Action Taken \_\_\_\_\_

NSN 6550 Nonstandard  
PRODUCT Abbott HCV EIA 2.0 Diagnostic Kit, Hepatitis C Virus Encoded Antigen. Recall #B-1208-7.  
CODE Lot Number: 29807M100 EXP 29 Oct 97.  
MANUFACTURER Abbott Laboratories, Diagnostics Division, Abbott Park, Illinois.  
RECALLED BY Manufacturer, by telephone on July 25 and 28, 1997, followed by letter dated July 30, 1997. Firm-initiated recall ongoing.  
DISTRIBUTION Florida, Illinois, Michigan, Tennessee, Texas, Washington state.  
QUANTITY 69 - 5000 test kits of HCV EIA were distributed; firm estimated that 20% of the HCV EIA kits remained on the market at time of recall initiation.  
REASON HCV EIA kits may contain a small number of ungrounded coated beads.

None Present  
 Action Taken \_\_\_\_\_

NSN 6550 Nonstandard  
PRODUCT Abbott HIVAG-1 Monoclonal EIA Diagnostic Kit Antibody to Human Immunodeficiency Virus Type

1 (HIV-1). Recall #B-1210-7.  
CODE Lot Number: 28087M201, EXP 17 Sep 97.  
MANUFACTURER Abbott Laboratories, Diagnostics Division,  
Abbott Park, Illinois.  
RECALLED BY Manufacturer, by telephone on July 25 and 28,  
1997, followed by letter dated July 30, 1997.  
Firm-initiated recall ongoing.  
DISTRIBUTION California, Florida, Illinois, Iowa,  
Louisiana, Massachusetts, Michigan, South  
Carolina, Tennessee, Texas.  
QUANTITY 269 - 1000 test kits were distributed, with  
the firm estimating that 3% of the kits  
remain on the market.  
REASON HIVAG-1 EIA kits may contain a small number of  
ungrounded coated beads.

None Present

Action Taken \_\_\_\_\_

NSN 6550 Nonstandard  
PRODUCT Epstein-Barr Virus-Viral Capsid Antigen IgG  
Enzyme-linked Immunosorbent Assay, Product No.  
2325700 (International), 425700 (Domestic),  
Lot No. 2325700-120 (International),  
425700-120 (Domestic), for in-vitro diagnostic  
use. Recall #Z-865-7.  
CODE Lot #120 EXP 11/97.  
MANUFACTURER Trinity Biotech (formerly Clark Laboratories),  
Jamestown, New York.  
RECALLED BY Manufacturer, by letter dated July 25, 1997.  
Firm-initiated recall ongoing.  
DISTRIBUTION New Jersey and international.  
QUANTITY 960 kits were distributed.  
REASON The absorbance of the kit calibrator has  
dropped below the acceptable optical density  
range of 0.250.

None Present

Action Taken \_\_\_\_\_

CLASS III RECALLS:

NSN 6505 Nonstandard  
PRODUCT ACTH (Corticotropin for Injection, USP), 40  
units, in 10 ml vials. Rx, a preparation of  
pituitary adrenocorticotropin hormone derived  
from the anterior lobe of hog pituitary.  
Recall #D-248-7.  
CODE Lot numbers: 01156P, EXP 8/97; 01256P, EXP

9/97; and 01356P, EXP 9/97.  
MANUFACTURER Warner-Lambert Company, Parke-Davis Sterile  
Products Division, Rochester, Michigan.  
RECALLED BY The Parke-Davis Division of Warner-Lambert  
Co., Morris Plains, New Jersey, by letter on  
July 28, 1997. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY The amount of product shipped was as follows:  
34,176 units of lot 01156P between 9/04/96 and  
08/01/96. 800 units of lot 01256P between  
7/31/96 and 5/07/97. 10,323 units of lot  
01356P between 10/31/96 and 5/07/97.  
REASON Variability in assay results (stability).

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6505 Nonstandard  
PRODUCT Vasosulf Ophthalmic Solution (Sulfacetamide  
Sodium 15% phenylephrine Hydrochloride  
0.125%), 5 ml and 15 ml sizes.  
Recall #D-251-7.  
CODE Lot numbers: VE3433 and VE3459.  
MANUFACTURER OMJ Pharmaceuticals, San German, Puerto Rico.  
RECALLED BY CIBA Vision Ophthalmics, Duluth, Georgia, by  
letter August 8, 1997. Firm-initiated recall  
ongoing.  
DISTRIBUTION Nationwide  
QUANTITY 12,552 units for lot VE3433; 6,588 fo lot  
VE3459 were distributed.  
REASON Labeling error -- Phenylephrine HCL content on  
insert reads 25 mg/ml and carton reads 125  
mg/ml. The correct amount is 1.25 mg/ml,  
which is correctly listed on the container and  
carton display panel.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6505 Nonstandard  
PRODUCT: Isocom Capsules Recall #D-256-7.  
CODE: Lot# 48550A, 48550B, 48663, 48779V, 49132,48863.  
MANUFACTURER Glenwood Palisades, Piscataway, New Jersey.  
RECALLED BY: Manufacturer. Firm-initiated recall complete.  
DISTRIBUTION: Nationwide.  
QUANTITY: 31,834 bottles were distributed.  
REASON: Failed dissolution and/or assay.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

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NSN 6505 Nonstandard  
PRODUCT: Nitrostat sublingual tablets. Recall #D-253-7.  
CODE: 063N5F.  
MANUFACTURER: Parke-Davis, Division of Warner Lambert Co.,  
Morris Plains, New Jersey.  
RECALLED BY: Manufacturer, on June 27, 1997 via certified mail.  
Firm-initiated recall ongoing.  
DISTRIBUTION: Nationwide.  
QUANTITY: 48,946 bottles were distributed.  
REASON: Lot may not meet assay specifications through the  
shelf-life of the product.

[ ] None Present  
[ ] Action Taken \_\_\_\_\_

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NSN 6515 Nonstandard  
PRODUCT: Dual Lumen 7Fr. Catheter (DLC-7D), Urodynamics  
Catheterization Trays (TCL-7) that include  
DLC-7D Catheters. Recall #Z-762/763-7.  
CODE Lot numbers: a) 4617701; b) 2617802.  
MANUFACTURER Life-Tech, Inc., Houston, Texas.  
RECALLED BY Manufacturer, by letter, on or about dated June  
30, 1997  
Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide  
QUANTITY 360/30 cartons were distributed.  
REASON The catheters were shipped with a partially  
occluded pressure lumen.

[ ] None Present  
[ ] Action Taken \_\_\_\_\_

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NSN 6515 Nonstandard  
PRODUCT: Sones B Cardiovascular catheter Recall #Z-869-7.  
CODE Lot # 07HG1759.  
MANUFACTURER: USCI Division, C.R. Bard, Inc., Billerica,  
Massachusetts.  
RECALLED BY: Manufacturer, by letter on July 28, 1997. Firm-  
initiated recall ongoing.  
DISTRIBUTION: California, Florida, Georgia, Illinois, Ohio,  
Michigan.  
QUANTITY: 100 units were distributed.  
REASON: Product mislabeled.

[ ] None Present  
[ ] Action Taken \_\_\_\_\_

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NSN 6520 Nonstandard  
PRODUCT: Testoderm with Adhesive Recall #D-254-7.  
CODE: 147831,150889,1508890, 150891.  
MANUFACTURER: Alza Corporation, Vacaville, California.  
RECALLED BY: Manufacturer, on July 31, 1997. Firm-initiated  
recall ongoing.  
DISTRIBUTION: Nationwide.  
QUANTITY: 30 cartons were distributed.  
REASON: out of specifications for the 4 new release rates.

None Present

Action Taken \_\_\_\_\_