

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.

6515 NS

MDC 12636

PRODUCT

Monitor, Systems

Solar 7000 and Solar 8000 Patient Monitors with Version 5D Software, used to display physiological data from modules which monitor the patient for ECG, blood pressure, cardiac output, respiration, pulse oximetry, etc. Recall #Z-727/728-9. Solar 7000/8000 Patient Monitors with 5D software, which had been updated from Version 5A, B or C software, are affected. New units, which only had 5D software installed at the manufacturing plant, are not affected if they never had an earlier software version. There were, however, some units in stock which were updated at the manufacturer from Version 5C to Version 5D software when this became available on 12/18/98. Some of these new units were distributed. The affected new units were shipped between 12/18/98 and 2/10/99, but do not have consecutive serial numbers. These units, plus units which were updated with 5D software at users, are to be corrected in the field in the firm=s recall action.

CODE

MANUFACTURER

RECALLED BY

Marquette Electronics, Inc., Milwaukee, Wisconsin.

DISTRIBUTION

QUANTITY

Manufacturer, by letters on February 5 and 15, 1999. Firm-initiated field correction ongoing.

Nationwide and international.

REASON

607 new units affected by the problem and 97 Version 5D software update kits were distributed. It is unknown how many of the 97 software update kits have been installed on units which previously had Version 5A, B, or C software.

A software deviation can affect the alarm default settings, which may result in incorrect or missed alarm notification.

None Present

Action Taken _____

CLASS II RECALLS:

6515 NS

MDC 14278

PRODUCT

Scanners, Ultrasonic (Diagnostic

Philips Medical Sonodiagnost 800, intended for endovaginal biopsy for various gynecologic and obstetric procedures including follicular retrieval, endometrial biopsy, and fluid aspiration of any type in a potentially pregnant patient. Recall #Z-772-9.

CODE

All SD800's with Software versions 2.1. and 2.1.1 used with

Endovaginal Transducer EV7014, serial numbers are as follows:

3424A00105 3434A00109 3434A00133 3441A00122 3441A00130

3510A00142 3510A00145 3510A00185 3510A00188 3514A00160

3514A00168 3527A00052 3527A00204 3624A00471 3640A00626

3728A00051 3728A00120 3728A00165 3728A00519 3728A00611

3728A00612 3728A00614 3728A00635 3728A00637 through

3728A00750, 3728A00752 through 3628A00756.

MANUFACTURER

RECALLED BY

Hewlett-Packard Company, Andover, Massachusetts

DISTRIBUTION

QUANTITY

Manufacturer, by letter dated March 5, 1999. Firm-initiated recall ongoing.

REASON

Nationwide.

145 units were distributed.

Software used with Transducer EV7014 incorrectly indicates track of the biopsy needle.

None Present

Action Taken _____

6515 NS
MDC 13449
PRODUCT

Saws, Bone

3M Sarns Sternal Saw II and Saw Protector: a) 3M Sarns Sternal Saw II, Catalog No. 5590, Part No. 98-0702-0597-0, used only in medical sternotomies; b) 3M Sarns Sternal Saw II Protector, Part No. 78-8067-9735-9. Recall #Z-774/775-9. a) Serial Nos. 13176 thru 13365, and any Sarns Sternal Saw II serviced by 3M Health Care from 6/1/98 thru 2/4/99; b) All units.

CODE

MANUFACTURER
RECALLED BY

3M Health Care, Ann Arbor, Michigan.
Manufacturer, by letter dated March 15, 1999. Firm-initiated field correction ongoing.

DISTRIBUTION
QUANTITY

Nationwide and international.
Approximately 225 saws sold or repaired since the change plus 126 replacement protectors.

REASON

The saw blade protector is subject to breakage.

None Present
 Action Taken _____

6515 NS
MDC 16214
PRODUCT

Wheelchairs, Powered

Crow River Models 7684LA & 7684LAFF Vangater Personal Transit Lifts, an electro-mechanical wheelchair lift for American-made, full-sized vans with side doors. Recall #Z-713/714-9.

CODE

The affected units were shipped between 12/14/98 and 2/18/99. The units have serial numbers from 98120005 through 99010255, but not all units in this serial number range are affected.

MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

Crow River Industries, Inc., Brooten, Minnesota.
Manufacturer, by letter on February 5, 1999. Firm-initiated recall ongoing.
Nationwide, Canada, Kuwait, Spain
192 units were distributed.
Weld failure could allow the device platform to free fall or deploy rapidly from the vertical (stowed) position to the horizontal (unstowed) position.

None Present
 Action Taken _____

6515 NS
MDC 11128
PRODUCT

Defibrillators/Monitors

Zoll "M Series" Defibrillator/Pacemaker, used to convert ventricular fibrillation to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats. Recall #Z-731-9.

CODE

M Series Device Corrective Action Serial Number Listing:
T98F00051 T98I00436 T98I00443 T98F00067 T98I00445
T98F00091 T98I00446 T98F00123 T98I00448 T98I00450
T98F00124 T98I00452 T98F00129 T98I00454 T98I00458
T98F00135 T98I00460 T98I00462 T98F00140 T98I00467
T98F00143 T98I00468 T98F00146 T98I00476 T98F00150
T98I00477 T98F00153 T98I00481 T98I00483 T98F00156
T98I00486 T98I00489 T98F00158 T98I00491 T98F00162
T98I00493 T98F00163 T98I00495 T98I00497 T98F00165
T98I00501 T98I00503 T98F00166 T98I00505 T98I00511
T98F00169 T98I00513 T98F00171 T98I00514 T98F00173
T98I00516 T98F00175 T98H00178 T98I00519 T98H00180
T98I00520 T98H00181 T98I00522 T98I00529 T98H00184
T98I00531 T98H00187 T98H00189 T98I00532
T98H00191 T98H00196 T98I00534 T98H00198 T98H00201
T98I00537 T98I00541 T98H00204 T98H00208 T98I00543
T98H00210 T98H00217 T98I00544 T98H00219 T98I00253

T98I00546 T98J00598 T98I00255 T98I00267 T98I00552
T98I00269 T98I00281 T98I00554 T98I00556
T98I00283 T98I00289 T98I00588 T98J00590
T98I00291 T98I00303 T98J00595 T98J00598
T98I00305 T98I00321 T98J00600 T98I00323 T98I00337
T98J00602 T98J00605 T98I00339 T98I00345 T98J00611
T98I00347 T98J00613 T98I00348 T98J00615
T98I00350 T98I00365 T98J00618 T98I00367 T98I00375
T98J00620 T98I00377 T98I00379 T98J00624 T98J00627
T98I00381 T98J00629 T98I00382 T98J00631
T98I00384 T98I00395 T98J00632 T98I00397 T98I00405
T98J00635 T98I00407 T98J00637 T98J00639 T98I00408
T98J00642 T98J00644 T98I00411 T98I00418 T98J00647
T98I00420 T98J00648 T98I00422 T98I00431 T98J00650
T98I00433 T98J00653 T98I00434 T98J00655 T98J00657
T98J00659 T98K00752 T98J00661 T98J00664 T98K00762
T98J00666 T98J00670 T98K00767 T98J00672 T98K00768
T98J00673 T98K00773 T98J00676 T98K00775 T98J00677
T98K00776 T98J00679 T98J00685 T98K00783
T98J00688 T98J00693 T98K00785 T98J00695 T98K00795
T98J00700 T98J00705 T98K00810 T98J00709 T98J00713
T98K00821 T98K00715 T98K00836 T98K00716 T98K00839
T98K00720 T98K00852 T98K00722 T98K00859 T98K00727
T98K00868 T98K00731 T98L00899 T98K00733 T98L00903
T98K00734 T98L00916 T98K00738 T98L00918 T98K00740
T95L00925 T98L00927 T98K00741 T98L00954
T98K00743 T98K00745 T98L00960 T98K00748
T98L01019.

MANUFACTURER
RECALLED BY

Zoll Medical Corporation, Burlington, Massachusetts.
Manufacturer, by letter on February 1 and 2, 1999. Firm-initiated field correction ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
452 units were distributed.
Failure of a memory chip resulted in the failure of the unit to power on when turned to the "on" position.

[] None Present
[] Action Taken _____

6630 NS
MDC
PRODUCT

Clinical Chemistry Analyzers

All Boehringer Mannheim Elecsys 2010 Immunoassay Analyzers with Software Versions (01)-(39), (02)-(13), (02)-(14), (03)-(08), (03)-(09) and (05)-(05)-CLAS connected system a) Boehringer Mannheim Elecsys 2010 Immunoassay Systems Analyzer with Disk System, Catalog No. 1568248; b) Boehringer Mannheim Elecsys 2010 Immunoassay Systems Analyzer with Rack System, Catalog No. 1804014. Recall #Z-729/730-9.

CODE

All Boehringer Mannheim Elecsys 2010 Immunoassay Analyzers with Software Versions (01)-(39), (02)-(13), (02)-(14), (03)-(08), (03)-(09) and (05)-(05)-CLAS connected system.

MANUFACTURER
RECALLED BY

Hitachi, Ltd., Instrument Division (HID), Japan.
Roche Diagnostics Corporation, Indianapolis, Indiana, by letter beginning on January 18, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and Canada.
160 analyzers were distributed.
The test results may be mismatched and reported under the wrong sample number due to a software problem.

[] None Present

[] Action Taken _____

6680 NS
MDC 13366
PRODUCT

Regulators, High Pressures, Gas

Aluminum Oxygen Regulators, for use in portable and fixed oxygen cylinders:

a) Model No. LSP 106; b) Model No. LSP 270; c) Model No. LSP 280; d) Model No. LSP 370; e) Model No. LSP 735; f) All Robertshaw Controls. Recall #Z-693/698-9.

CODE
MANUFACTURER
RECALLED BY

All codes.
Allied Healthcare Products, Inc., St. Louis, Missouri.
Manufacturer, by press release and by letter faxed on February 4, 1999.
Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
Approximately 137,000 units were distributed.
Fires and explosions have been associated with use of aluminum regulators.

[] 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 **28 May 99** 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
PRODUCT

6505 Nonstandard
Blue Nitro Vitality, (2(3H)-Furanone), in 32 fluid ounce bottles. Recall #D-134-9.

CODE
MANUFACTURER
RECALLED BY

All lot numbers.
Alpha Earth, Inc., Fort Lauderdale, Florida.
Manufacturer, by letter on February 5 and 6, 1999. Firm-initiated recall ongoing. See also FDA talk paper T99-5, January 21, 1999.

DISTRIBUTION
QUANTITY
REASON

Georgia and Florida.
Approximately 25,000 bottles were distributed.
Product is an unapproved new drug.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT AAN brand RemForce Oral Liquid (2-(3H)- Furanone dihydro), in 32 fluid ounce bottles, OTC product with night-time sleep aid claims and also represented as a dietary supplement. Recall #D-152-9.
 CODE All lot codes.
 MANUFACTURER Ameri-Kal, Inc./SOE Trading & Management, Auburn, California.
 RECALLED BY Advanced Athletic Nutrition (AAN), Roseville, California, by letter on January 28, 1999. Firm-initiated recall ongoing. See also FDA talk paper T99-5, January 21, 1999.
 DISTRIBUTION Arizona, California, Colorado, Delaware, Florida, Georgia, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New York, Oklahoma, Oregon, Texas.
 QUANTITY Undetermined.
 REASON Product is an unapproved new drug.

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT a) Povidone-Iodine Solution, USP 10%, packaged in 3/4 fluid ounce (22mL) packets, distributed under one brand name - Professional Disposables, Inc., labeled as an antiseptic and germicide; b) Povidone-Iodine Prep Pad, sold in small and medium sizes, saturated with a 10% povidone-iodine solution, labeled as an antiseptic and germicide, distributed under the following brand names: Professional Disposables, Inc., ABCO, Allegiance, Bergen Brunswig, Medline, and Total Resources. Recall #D-154/155-9.

CODE Lot numbers: a) 7006741 EXP 12/00, Item #L57725.

b) Brand	Lot No.	Item No.	EXP
PDI	9700009438,	B40600,	12/2000
	9700009695,	B40600,	12/2000
	9700009939,	B40600,	12/2000
	9700010027,	B40600,	12/2000
	9800000781	B40600,	12/2000
	9800000533	B40600	01/01
	9800001356	B40600	01/01
	9800001493	B40600	01/01
	9800002497	B40600	01/01
	9800003002	B40600	01/01
	9800000161	B40673	12/2000
	9800002312	B40701	01/01)
	ABCO	9700010542	B14200
Allegiance	9700009572	B87500	12/00
	9700010571	B87500	12/00
	9800002492	B87500	01/01
Bergen Brunswig	9800002175	B60600	01/01
Medline	9800000615	B64200	01/00)
	9800002320	B64204	01/01)
Total Resources	9800000069	B08589	12/00).

MANUFACTURER Nice-Pak Products, Inc., Orangeburg, New York.
 RECALLED BY Manufacturer, by letters on February 2 and 19, 1999. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Canada, Ireland, Portugal.
 QUANTITY a) 352 cases (250 packets per case); b) 7,125 cases (1,000 prep pads per case) were distributed.

REASON Microbial contamination with Pseudomonas putida, Salmonella spp. Poly D, and Aeromonas sobria.

None Present
 Action Taken _____

CLASS II RECALLS:

NSN 6505 Nonstandard
PRODUCT Lorazepam Tablets, USP, 2mg, in 100 tablet bottles, Rx antianxiety agent. NDC #52544-242-01. Recall #D-132-9.
CODE Lot #PC-1163.
MANUFACTURER Watson Laboratories, Inc., Subsidiary of Watson Pharmaceuticals, Inc., Miami, Florida.
RECALLED BY Manufacturer, by letter on February 25, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 21,459 bottles were distributed.
REASON Misbranding - Product bears incorrect expiration date of February 2001; exceeding the true date of February 2000.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Aspirin Tablets, USP, Chewable, Orange Flavored, 81 mg (1-1/4 grain), in 100 tablets (10 x 10 blister cards), NDC #62584-645-01, and 750 tablets (25 x 30 blister cards), NDC #62584-645-33. Recall #D-135-9.
CODE Lot numbers: 4363C, 5542B, 6191A, 6192A, 8034B, 8716B, 4363B, 5542A, 6191B, 6192B, 6192C, 8034A, 8276, 8716A, and 9315.
MANUFACTURER LNK International, Inc, Hauppauge, New York.
RECALLED BY AmeriSource Health Services Corporation, doing business as American Health Packaging, Columbus, Ohio (repacker/responsible firm), by letter on March 2, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Texas, Idaho, Kentucky, Florida, Arizona, Massachusetts, New Jersey, Wisconsin, Pennsylvania, Virginia, Indiana, Oklahoma, New York, Illinois.
QUANTITY 881 units of 25 blister cards X 30 tablets, and 27,558 units of 10 blister cards X 10 tablets were distributed; firm estimated that 654 units (25 X 30) and 20,874 units (10 X 10) remained in distribution channels at time of recall initiation.
REASON Stability - Out of specification for percent (%) free salicylic acid.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Naturade Children's Cough Syrup, OTC, (Glyceryl Guaiacolate (Guaiifenesin)) 150 mg/15 ml, in 4 ounce and 8 ounce bottles. Recall #D-144-9.
CODE Lot #I44047 EXP 9/99.
MANUFACTURER Irenda Corporation, Los Angeles, California.
RECALLED BY Naturade, Inc., Paramount, California, by letter dated March 10, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Arizona, California, Colorado, Connecticut, Iowa, Illinois, Indiana, Missouri, New Hampshire, New Jersey, New York, Pennsylvania, Washington state, Wisconsin.
QUANTITY 7,356 4-ounce bottles and 984 8-ounce bottles were distributed.
REASON Mislabeling - The directions for children 2 to under 6 years of age indicate dosage of 1 (one) tablespoon every 4 hours instead of the correct 1 (one) teaspoon every 4 hours.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Mapap Tablets, Regular Strength (Acetaminophen) 325 mg, in 1000 tablet bottles, OTC labeled as an aspirin free pain reliever, distributed by Major Pharmaceuticals. NDC #0904-1982-80. Recall #D-145-9.
CODE Lot #98M422 EXP 12/01.
MANUFACTURER PDK Laboratories, Inc., Hauppauge, New York.
RECALLED BY Manufacturer, by letters faxed on February 18, 1999, and mailed on February 23, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Indiana and California.
QUANTITY 2,797 bottles were distributed; firm estimated that 1,327 bottles remained on market at time of recall initiation.
REASON Tablet mix-up - Some acetaminophen 500 mg tablets were mixed in bottles of 325 mg tablets.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT a) External Ventricular Monitoring Drainage Set; b) Drainage Accessory Kit. Recall #Z-691/692-9.
CODE a) Catalog #910-118A; b) Catalog #910-122.
MANUFACTURER NMT Neurosciences, Duluth, Georgia.
RECALLED BY Manufacturer, by letter on January 12, 1999. Firm-initiated recall ongoing.
DISTRIBUTION California, Colorado, Connecticut, Florida, Georgia, Hawaii, North Carolina, Ohio, Tennessee, Texas, Washington state.
QUANTITY 77 sets were distributed.
REASON The male luer lock fitting is deformed and does not fit the drainage bag therefore is not functioning as intended.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Defibrillation Electrode Pads Model: Catalog # (p/n): 902402 Packed 1 box of 10 pair with Catalog #902400 Packed 1 box of 5 pair with Catalog #902401 Packed 1 box of 2 pair with Catalog #902404. Recall #Z-732-9.
CODE All Lots. Part #/Catalog #: 902402 (electrodes). The following part numbers represent the various packaging configurations which contain the electrodes: 902400, 902401, 902404.
MANUFACTURER Laerdal Medical Corporation, Wappingers Falls, New York.
RECALLED BY Manufacturer, by letter dated February 11, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Canada, Norway.
QUANTITY 36,000 pair of electrodes were distributed.
REASON The conductive gel on individual pads can deteriorate into a liquid. Gel deterioration may occur to the extent the electrode pad becomes unusable because it will not adhere to the patient and will not provide adequate electrical contact.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Omega-21 Slotted Connector, Part No. 1280-08, pectide screw fixation and non-pectide hook and sacroiliac screw fixation of the non-cervical spine. Recall #Z-773-9.
CODE Lot No. 35573.
MANUFACTURER Industrias Quirurgicas De Levante S.L., Valencia, Spain.

RECALLED BY EBI Medical Systems, Inc., Parsippany, New Jersey, by letter March 24, 1999.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 12 units were distributed.
REASON The screw in the connector could not be properly fixed to the connector once the fixing nut was at the end of the threaded tail of the screw.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT AMS 700 Ultrex Plus Penile Prosthesis AMS Ambicore Penile Prosthesis, Prefilled and Preconnected AMS 700 Inflate/Deflate Pump Prefilled Model: AMS 700 U Ultrex Plus Penile Prosthesis, Models 72401463, 72401464, 72401466, and 72401467. AMS 700 Inflate/Deflate Pump Prefilled, Model 72400154 AMS Ambicore Penile Prosthesis, Models 72401450, 72401451, 72401452, 72401454, and 72401455. Recall #Z-735/744-9.

CODE AMS 700 Ultrex Plus Penile Prostheses:
Model Number Lot
72401463 EE451
72401464 EE452
72401466 EE453 and EE785
72401467 EE787
AMS 700 Inflate/Deflate Pump Prefilled:
Model Number Lot
72400154 EE638
EE689
EE639

AMS Ambicore Penile Prostheses:
Model Number Lot
72401450 EE307 and EE310
72401451 ED756
72401452 EE456
72401454 EE846 and ED847
72401455 ED849, ED850, and ED851.

MANUFACTURER American Medical Systems, Inc. Minnetonka, Minnesota.
RECALLED BY Manufacturer, by telephone on March 5, 1999, and by letter dated March 8, 1999.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Australia, Bahrain, Canada, France, Italy, Germany, Spain.
QUANTITY 110 units were distributed.
REASON Sterile packaging of some of the device units was found to be leaking.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Leep Redikit for Gynecological Loop Electrosurgical Excision Procedure, Part #6060. Recall #D-143-9.

CODE Lot Numbers: 711054L 711144L 711184L 711194L 712124L
712164L 712174L 712184L 712314L 801224L 801234L
802184L 802254L 803054L 803124L 803234L 804014L
804024E 804204E 804294E 80810E 81008E 81024E
81027E 81110E 81122E 81125E 90120E 90129E
90201E.

MANUFACTURER Cooper Surgical, Inc., Shelton, Connecticut.
RECALLED BY Manufacturer, by letter on March 1, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 27,622 kits were distributed.

REASON Lack of assurance of sterility for Novocol brand/manufactured Octocaine 100 (Lidocaine HCL 2% and Epinephrine 1:100,000) 1.8 MI Cartridges packaged in each kit.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT BARD 6 F Envision Pigtail Cardiovascular Angiographic Catheters, intravascular diagnostic catheters used to record intracardiac pressures, to sample blood, and to introduce substances into the heart: Catalog Numbers: 061085, 061086, 061088, 061089, 662005, 662009. Recall #Z-766/771-9.

CODE

Item #	Lot #	Mfg. Date
XS Straight/12 sideholes		
Z-766-9	061085	08FI0841 Jun-98
	061085	08FI0842 Jun-98
XS 145 Degree/12 sideholes		
Z-767-9	061086	08FI0850 Jun-98
	061086	08FI0849 Jun-98
	061086	08GI1186 Jul-98
	061086	08GI1185 Jul-98
XS Straight/6 sideholes		
Z-768-9	061088	08EI2365 May-98
	061088	08FI1945 Jul-98
	061088	08FI1944 Jul-98
XS 145 Degree/6 sideholes		
Z-769-9	061089	08EI2453 May-98
	061089	08FI2156 Jun-98
BTO Angiokit		
Z-770-9	662005	08FI1210 Jun-98
BTO Kit		
Z-771-9	662009	08EI1536 May-98
	662009	08FI1211 Jun-98
	662009	08AJ0486 Jan-99
	662009	08LI0622 Dec-98
	662009	08KI0148 Nov-98.

MANUFACTURER C.R. Bard, Inc., Billerica, Massachusetts.
RECALLED BY Manufacturer, by letter dated March 16, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Alabama, Florida, Indiana, Louisiana, Massachusetts, Maryland, Missouri, North Carolina, New York, Pennsylvania, Texas, Virginia, District of Columbia, Ireland.

QUANTITY 3,055 units were distributed.
REASON The tip may detach from catheter.

None Present
 Action Taken _____

NSN 6540 Nonstandard
UPDATE The following statement is issued to clarify the responsibility issues involving recall Z-667/669-9 published in the Enforcement Report for March 3, 1999: The distribution and sale of Amvisc FB in the U.S. was an independent action by World Optics. Neither Lifecore Medical, Inc. nor Bausch & Lomb Surgical, Inc. had any involvement or prior knowledge of the sales of Amvisc FB in the U.S.

None Present
 Action Taken _____

NSN 6550 Nonstandard
 PRODUCT Progesterone Reagent Microparticle Enzyme Immunoassay. Recall #Z-734-9.
 CODE List No. 7A64-20, Lot Nos. 40868M300, EXP 2/21/99; 2623M200, EXP 4/10/99;
 43658M100, EXP 4/24/99; 44002M100, 2/21/99; 44524M200, EXP 5/23/99;
 44870M200, EXP 6/30/99; 45085M100, EXP 8/5/99; 45436M300, EXP 8/19/99;
 45878M200, EXP 2/21/99; and 48729M200, EXP 10/14/99.
 MANUFACTURER Abbott Laboratories, Abbott Park, Illinois.
 RECALLED BY Manufacturer, by letter on January 29, 1999. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY 12,408 packs were distributed.
 REASON Product produces elevated calibrator rates and unacceptable precision.

None Present
 Action Taken _____

NSN 6550 Nonstandard
 PRODUCT Microvasive urology products Protegen Collagen Impregnated Sling
 and VESICA Sling Kits With PROTEGEN:
 a) Catalog No. 820-111, Vesica Drill in Kit with standard size
 ProteGen;
 b) Catalog No. 820-112, Vesica Drill in Kit with large size
 ProteGen;
 c) Catalog No. 820-116, Vesica Drill in Mini Kit with standard
 size ProteGen;
 d) Catalog No. 820-117, Vesica Drill in Mini Kit with large
 ProteGen;
 e) Catalog No. 820-121, ProteGen standard size;
 f) Catalog No. 820-122, ProteGen large size;
 g) Catalog No. 820-131, Vesica Press in Kit with standard size
 ProteGen;
 h) Catalog No. 820-132, Vesica Press in Kit with large size
 ProteGen;
 i) Catalog No. 820-136, Vesica Press in Mini Kit with standard
 size ProteGen;
 j) Catalog No. 820-137, Vesica Press in Mini Kit with large size
 ProteGen. Recall #Z-717/726-9.
 CODE All lots.
 MANUFACTURER Meadox Division, Boston Scientific Corporation Wayne, New Jersey.
 RECALLED BY Boston Scientific Corporation, Microvasive Urology, Natick, Massachusetts, by
 letter on January 22, 1999. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY 16,931 ProteGen Standard Size Slings and 6,466 ProteGen Large Size Slings were
 distributed.
 REASON Use of ProteGen in the treatment of female urinary incontinence is associated
 with higher than expected rate of vaginal erosion and dehiscence, and does not
 appear to function as intended.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
 PRODUCT Nutrilite, for IV use after Dilution, Multi-Electrolyte
 Concentrate-(Electrolytes mEq/20mL: Acetate 40.6; Potassium 40.6; Chloride
 33.6;
 Sodium 25; Magnesium 8; Calcium 5; Gluconate 5) 20 mL single dose vial, Rx
 indicated for use as a supplement to parenteral nutritional solutions containing
 amino acids, dextrose and/or other calorie sources delivered by central venous

or peripheral infusion to facilitate amino acid utilization and maintain electrolyte balance in adults. It is also indicated as a source of replacement electrolytes for the depleted adult during parenteral therapy. NDC #0517-3120-25. Recall #D-151-9.

CODE Lot #8342 EXP 5/00.
MANUFACTURER Luitpold Pharmaceuticals, Inc., also known as American Regent Laboratories, Inc., Shirley, New York.
RECALLED BY Manufacturer, by telephone on February 10, 1999, followed by letter.
DISTRIBUTION Firm-initiated recall ongoing.
QUANTITY Nationwide.
REASON 61,825 vials were distributed.
Particulate matter.

NSN 6505 Nonstandard
PRODUCT Ethyl Chloride USP, in 3.5 fluid ounce glass bottles, a vapocoolant (skin refrigerant) intended for topical application to control localized pain associated with injections, minor surgical procedures (such as lancing boils, incisions, and drainage of small abscesses), and/or athletic injuries. It is also intended for the treatment of restricted motion associated with myofascial pain caused by trigger points. Recall #Z-761-9.

CODE Lot numbers (medium spray): 1850 through 1879. Lot numbers (fine spray): 802 through 828.
MANUFACTURER Gebauer Company, Cleveland, Ohio.
RECALLED BY Manufacturer, by letter on March 6, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 444,627 bottles were distributed.
REASON Product failed the 18 month stability testing for non-volatile residue.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Epinephrine Inhalation Aerosol, USP, 5.5 mg/ml, 1/2 ounce (15 ml), for the temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma disorders, distributed under the Walgreen, Osco, Eckerd, CVS, Menley and James, Marquee, Longs, Select Brands, Drug Guild, Sav-on, American Fare, Major, Quality Choice and Rite Aid labels. Recall #D-140-9.

CODE Lot No. NDC No. Size Exp Date Label
RN7836 11917-003-93 15 ml 04/00 Walgreens
12810-970-99 15 ml 04/00 Osco Drug
19458-5066-1 15 ml 04/00 Eckerd
50428-583-20 15 ml 04/00 CVS
87900-970-99 15 ml 04/00 Menley & James
RN7839 076-00970-15 15 ml 04/00 Marquee
12333-9477-1 15 ml 04/00 Longs
15127-970-15 15 ml 04/00 Select Brands
19458-9001-1 15 ml 04/00 Eckerd
26032-970-15 15 ml 04/00 Drug Guild
37097-970-15 15 ml 04/00 Sav-on
7200-1755-4 15 ml 04/00 American Fare
RN7841 0904-7770-35 15 ml 05/00 Major
11161-970-99 15 ml 05/00 Quality Choice
11822-3479-7 15 ml 05/00 Rite Aid
11917-003-93 15 ml 05/00 Walgreens
12810-970-99 15 ml 05/00 Osco Drug
7200-1755-5 15 ml 05/00 American

Fare.
MANUFACTURER Alpharma, U.S. Pharmaceutical Division, Baltimore, Maryland.
RECALLED BY Manufacturer, by letter on or about January 20, 1999. Firm-initiated recall

DISTRIBUTION
 QUANTITY

ongoing.
 Nationwide.

Lot No.	NDC	SHIPPED
RN7836	11917-003-93	13860
	12810-970-99	5976
	19458-5066-1	9900
	50428-583-20	72
	87900-970-99	22704
RN7839	076-00970-15	2844
	12333-9477-1	3996
	15127-970-15	4356
	19458-9001-1	13212
	26032-970-15	1368
	37097-970-15	2844
	7200-1755-4	12384
RN7841	0904-7770-35	2844
	11161-970-99	2844
	11822-3479-7	10368
	11917-003-93	14796
	12810-970-99	4284
	7200-1755-5	9720.

REASON Failure to meet the USP criteria for unit spray and total doses.

None Present
 Action Taken _____

NSN
 PRODUCT 6505 Nonstandard
 Lithobid - Lithium Carbonate, USP 300 mg Slow-Release Tablets, Rx in 1,000
 tablet bottles, indicated in the treatment of manic episodes of manic depressive
 illness. Recall #D-142-9.

CODE Lot #88406.
 MANUFACTURER Solvay Pharmaceuticals, Inc., Marietta, Georgia.
 RECALLED BY Manufacturer, by letter on February 22, 1999. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 1,378 bottles were distributed.
 REASON Dissolution failure at 18 month stability testing.

None Present
 Action Taken _____

NSN
 PRODUCT 6515 Nonstandard
 E2 Sanitizing Hand Soap (Water, Quaternary ammonium chlorides ...), one (1)
 gallon plastic containers, under the Namico Inc. and U.S. Foodservice Inc.
 labels. Recall #D-133-9.

CODE All production batch codes are subject to recall. All product remaining on the
 market.
 MANUFACTURER Carroll Company, Walbridge, Ohio.
 RECALLED BY Manufacturer, by letter on March 1, 1999. Firm-initiated recall ongoing.
 DISTRIBUTION Pennsylvania, North Carolina, Kentucky, Michigan, Minnesota, Missouri, Illinois,
 Maine, Virginia, Ohio.
 QUANTITY Firm estimated that a maximum of 520 gallons of product remained on market at
 time of recall initiation.
 REASON Lack of current good manufacturing practice compliance.

None Present
 Action Taken _____

NSN	6550 Nonstandard
PRODUCT	Abbott Cell-Dyn 3000 Series Hematology Systems, Cell-Dyn Reticulocyte Reagent, when used in combination with Cell-Dyn 3500 reticulocyte software enables a whole blood specimen to be analyzed for reticulocytes. The Reticulocyte Reagent is intended for in vitro diagnostic use (outside the body). Recall #Z-715-9.
CODE	Lot numbers: 4249512, 424812, 4362312, 4362412, 4362512, 4368312, 4368412, 4484012, 4491712, 4597912, 4598012, 4599712, 459912, 4617712, 4617912, 4729312, 4729512, 4842912.
MANUFACTURER	Abbott Laboratories, Santa Clara, California.
RECALLED BY	Manufacturer, by letter on February 25, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	1,780 kits were distributed.
REASON	These lots may exhibit elevated Reticulocyte results. In some cases, the results may exceed the normal range on normal specimens without a Reticulocyte data flag being observed.

[] None Present
 [] Action Taken _____

MEDICAL INFORMATION/MEDICAL ALERTS:

SUBJECT: Q. A. MESSAGE 9099-0004

MEDICAL INFORMATION:/HEPATITIS A VACCINE, ADULT

1. PER Q. A. MESSAGE 7273-0008, ALL USING ACTIVITIES ORDERING HEPATITIS A VACCINE, ADULT MUST ORDER THROUGH THE APPROVED REQUIREMENTS CONTRACT WITH MERCK HUMAN SERVICES VIA THE PHARMACEUTICAL PRIME VENDOR PROGRAM. THE PRICES ON THE MERCK CONTRACT ARE SIGNIFICANTLY CHEAPER SINCE WE HAVE ENTERED INTO THIS EXCLUSIVE AGREEMENT. THIS PRODUCT IS COMMONLY KNOWN UNDER THE TRADEMARK NAME VAQTA AND IS AVAILABLE IN 3 VARIATIONS. HEP A VAC, SYR, 1S 6505-01-432-0376 NDC 00006-4844-00 HEP A VAC, SYR, 5S 6505-01-432-0378 NDC 00006-4844-38 HEP A VAC, SYR, SGL DS 6505-01-432-0380 NDC 00006-4841-00
2. WE ARE RECEIVING FEEDBACK THAT ORDERS ARE STILL BEING PLACED TO SMITHKLINE BEECHAM FOR HEPATITIS A VACCINE, COMMONLY KNOWN UNDER THE TRADEMARK NAME HAVRIX. MERCK IS THE MANDATORY SOURCE OF SUPPLY FOR HEP A VACCINE. WE SIGNED UP TO A REQUIREMENTS CONTRACT, WENT THROUGH THE BID PROCESS, AND BY LAW MUST AWARD OUR BUSINESS TO THE COMPANY WHO BID THE LOWEST PRICE. COMPETING VENDORS THAT LOWER THEIR PRICE AFTER THE FACT, SHOULD NOT AND CANNOT LEGALLY BE GIVEN THE BUSINESS. IF YOU ARE UNDER THE IMPRESSION THAT SENDING ORDERS TO SMITHKLINE AT THE LOWER PRICE WILL SAVE THE GOVERNMENT MONEY, YOU ARE WRONG. ASIDE FROM JEOPARDIZING THE WHOLE COMMITTED VOLUME CONTRACTING CONCEPT, SUCCESSFUL BIDDERS MAY SEEK RECOURSE FOR MISSED OPPORTUNITIES FOR ORDERS PLACED OUTSIDE THE REQUIREMENTS/COMMITTED VOLUME CONTRACT. YOUR MTF MAY BE HELD RESPONSIBLE FOR PAYING ANY PENALTY ASSOCIATED WITH THE IN APPROPRIATE PURCHASES. IF YOUR FACILITY IS NOT BUYING THE MERCK PLEASE CHANGE YOUR PROCEDURE TO DIRECT ALL FUTURE PURCHASES TO MERCK.
3. GENERALLY OUR ROLE AS LOGISTICIANS IS TO CONTINUALLY LOOK FOR THE LOWEST DELIVERED COST ALTERNATIVES, BUT WE MUST RESPECT OUR WORD TO BID WINNERS WHEN THEY RECEIVE THE REQUIREMENTS CONTRACT AWARD. IF YOU HAVE QUESTIONS REGARDING THIS MATTER, PLEASE CALL CAPT DON FAUST, AFMSA/SGSL, DSN 240-3963 OR BONNIE PHILLIPS, AFMLO/FOM-P, DSN 343-4170.
4. POC AT AFMLO/FOM-P IS BONNIE PHILLIPS, DSN 343-4170.
5. THIS INFORMATION WILL BE PUBLISHED IS AFMLL SUPPLEMENT 04-99.
6. FOR MAJCOMS AND NGB - THIS MESSAGE HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MEDICAL ACTIVITIES IAW AFMAN 23-110, VOL 5, CHAP 19.

SUBJECT: Q. A. MESSAGE 9099-0005

AIR FORCE---REPAIR/REPLACEMENT OF ALL OXYGEN REGULATORS MADE OF ALUMINUM, ALL MANUFACTURERS

PASS TO ALL AIR FORCE ACTIVE DUTY & PEACETIME MEDICAL FACILITIES, TO INCLUDE ALL NATL GUARD RESERVE MEDICAL UNITS, PARA RESCUE, AND FIRE DEPT FACILITIES. ALL AF MAJCOMS PLEASE ENSURE THIS MESSAGE IS FORWARDED TO ALL DEPLOYED MEDICAL UNITS. EXPEDITIOUS ACTION IS REQUIRED TO REPLACE/REPAIR ALL REGULATORS CONTAINING ALUMINUM FROM USING ACTIVITIES (WARDS, PHARMACIES, CLINICS, EMERGENCY ROOM, WRM, ETC.)

1. AIR FORCE ACTIVITIES WILL IMMEDIATELY INSPECT/REPAIR/REPLACE THE FOLLOWING MATERIEL MADE OF ALUMINUM. YOU MAY HAVE THE MATERIEL CATALOGED UNDER OTHER NSNS OTHER THAN THOSE LISTED BELOW:

NSNS: 6515NS

6530NS

6680NS,

6515-01-457-2239

6530-01-449-0132

6680-01-234-6789

6680-00-935-4242

6680-01-174-6276

PRODUCT: OXYGEN, REGULATOR

LOT/SERIAL NO: ALL

MANUFACTURER: ALL

REASON: REPORTS HAVE BEEN RECEIVED OF ALUMINUM REGULATORS USED W/ OXYGEN CYLINDERS BURNING OR EXPLODING, CAUSING SEVERE BURNS.

REF DOD-MMQC 99-1097 MESSAGE, SUBJECT: EXPLOSIONS AND FIRES IN ALUMINUM OXYGEN REGULATORS/ FDA AND NIOSH PUBLIC HEALTH ADVISORY

2. IF YOU ARE PRESENTLY USING OXYGEN REGULATORS WHICH CONTAIN ANY ALUMINUM EXPOSED TO HIGH-PRESSURE OXYGEN, REPLACE WITH REGULATOR MADE OF BRASS. CONSULT THE MANUFACTURER IF YOU DON'T KNOW WHAT MATL IS USED IN YOUR REGULATOR.

3. PLEASE BE ADVISED THAT THE REPLACEMENT WILL BE AT THE COST OF EACH ACTIVITY WITH THE EXCEPTION OF LSP REGULATORS, MFR: ALLIED HEALTHCARE/ROBERT SHAW CONTROLS, REFERENCED IN THE FOLLOWING MESSAGES:

REF A: DOD-MMQC-99-1093 311907Z MAR 99

REF B: DOD MMQC-99-1054 111242Z MAR 99

REF C: DOD MMQC-99-1033 182239Z FEB 99

REF D: DOD MMQC-99-1924 091622Z FEB 99

REF E: R FORCE Q. A. MESSAGE 9049-0001 181823Z FEB 99

4. POC AT AFMO/FOM-P IS BONNIE PHILLIPS, DSN 343-4170.

5. THIS INFORMATION WILL BE PUBLISHED IN AFMLL SUPPLEMENT 04-99.

6. FOR MAJCOMS & NGB - THIS MESSAGE HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MEDICAL ACTIVITIES IAW AFMAN 23-110, VOL 5. CHAP 19.