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 12575	**Monitors, Apnea**
PRODUCT	Corometrics Infant (Apnea) Monitors: Models: 500, 500E, 500EXL, 501, 502, 510, 511. Recall #Z-623/633-9.
CODE	Catalog Number and Serial Number: Z-623-9 Catalog Number: 0500CAH Serial Numbers: 13000072 through 13000079 Z-624-9 Catalog Number: 0500CEH Serial Numbers: 13000727 through 13000735 Z-625-9 Catalog Number: 0500EAA Serial Numbers: 01008733, 01313153, 01413992, 02008925, 02401891, 03313332, 0382141, 04009140, 04906080, 05414166, 06009449, 06414255, 07313548, 0782589, 0782643, 08111351, 08313729, 08313748, 08401467, 08414373, 08414377, 0882788, 0882825, 0882915, 09212832, 09414386, 09414418, 0983105, 0983125, 10212900, 10313792, 10414489, 11212995, 1183710, 11907344, 12010360, 12010412, 12111764, 12111770, 12111778 Z-626-9 Catalog Number: 0500FAA Serial Numbers: 13000520, 13000521, 13000523, 13000524, 13000527,13000528 Z-627-9 Catalog Number:0500FEH Serial Numbers: 13000215 through 13000226, 13000230, 13000231 13000233 through 13000237 Z-628-9 Catalog Number: 0501AAY Serial Number: 13000027 Z-629-9 Catalog Number: 0502AAA Serial Numbers: 06901691, 13000258 through 13000263 Z-630-9 Catalog Number: 0502ALH Serial Numbers: 13000140,13000145,13000146 Z-631-9 Catalog Number: 051OAAT Serial Number: 13000022 Z-632-9 Catalog Number: 0511BAT Serial Numbers: 13000373 through 13000381, 13000384, 13000386, 13000387 Z-633-9 Catalog Number: 0511BDT Serial Number: 13000054,13000055,13000056.
MANUFACTURER	Corometrics Medical Systems, Inc., Wallingford, Connecticut.
RECALLED BY	Manufacturer, by telephone on January 18, 1999, and by letter on January 21, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	California, Connecticut, Florida, Georgia, Louisiana, Massachusetts, Maryland, Minnesota, Mississippi, Kansas, Nebraska, New York, Ohio, Tennessee, Texas, Virginia, Washington, international.

QUANTITY	106 units were distributed.
REASON	The audio alarm may fail to sound.
	[ ] None Present [ ] Action Taken _____ _____

6515 NS

MDC 16228	**Lithotripters**
PRODUCT	Lithotripsy System Software EPROMS: a) Software Version LSH V 3.0; b) Software Version V 1.2. Recall #Z-680/681.
CODE	Model: LithoTron System, software versions LSH V 3.0 and LITHO V 1.2 for operation of the following LithoTron instruments: S/N 002, 004, 012, 014, 020, 021, 022, 026, 028, 030, 031, 034, 0045, 046, 047, 048, 050.
MANUFACTURER	HMT High Medical Technologies AG, CH-8280 Kreuzlingen, Switzerland.
RECALLED BY	HealthTronics, Marietta, Georgia, by software upgrade on November 24, 1998, and by letter dated January 13, 1999. Firm-initiated field correction ongoing.
DISTRIBUTION	Nebraska, Missouri, Texas, Washington state, Indiana, Pennsylvania, Florida, Connecticut, California, Tennessee, Georgia.
QUANTITY	17 LithoTran systems were distributed.
REASON	Software upgrade yielding error messages and complete lock-up of instrument.
	[ ] None Present [ ] Action Taken _____ _____

6515 NS

MDC 14360	**Compressor Compact, Ventilator**
PRODUCT	Alreco 40400. Recall #Z-595-9.
CODE	Compressor Compact Reorder #6150440 with serial number 20481 and lower except 20463.
MANUFACTURER	Allen Rehnstrom AB, Osterbagen, Sweden.
RECALLED BY	Siemens Medical Systems, Inc., Danvers, Massachusetts, by letter dated February 17, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	379 units were distributed.
REASON	Failure of secondary fuse F3 on Siemens Compressor compact stops gas delivery.
	[ ] None Present [ ] Action Taken _____ _____

6525 NS

MDC 15944	**Camera, Gamma**
PRODUCT	Model 3000 Nuclear Cameras: a) Model Prism 3000XP; b) Model Prism 3000 S'. Recall #Z-641/642-9.
CODE	All serial numbers.
MANUFACTURER	Picker International, Inc., Highland Heights, Ohio.
RECALLED BY	Manufacturer, by Mandatory Service Letter #403, dated November 18, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.

QUANTITY	325 units were distributed.
REASON	Unintended motion of gantry during set up.
	[ ] None Present [ ] Action Taken _____ _____

6525 NS

MDC 15944	**Cameras, Gamma**
PRODUCT	Prism XPVT Nuclear Medicine Imaging System: a) AXIS Catalog # 210714; b) AXIS Catalog # 210880; c) AXIS Catalog # 211037; d) AXIS Catalog # 211039; e) IRIX Catalog # 210857; f) IRIX Catalog # 210881; g) IRIX Catalog # 211036; h) IRIX Catalog # 211040. Recall #Z-643/650-9.
CODE	Serial numbers: a) 101 - 171, 173 - 175, 177, 180; b) 101 - 171, 173 - 175, 177; c) 172, 176, 181 - 245, 252, 253, 255; d) 172, 176, 181 - 245, 252, 253, 255; e) 101 - 171, 173 - 175, 177 - 180; f) 101 - 171, 173 - 175, 177 - 180; g) 172, 176, 181 - 234, 252, 253, 255; h) 172, 176, 181 - 245, 252, 253, 255.
MANUFACTURER	Picker International., Inc., Highland Heights, Ohio.
RECALLED BY	Manufacturer, by letter dated December 15, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	63 units were distributed.
REASON	Unexpected camera movement which requires the operator to power down and reboot with delay in diagnosis.
	[ ] None Present [ ] Action Taken _____ _____

6525 NS

MDC 15944	**Cameras, Gamma**
PRODUCT	Nuclear Medical Imaging Systems: a) Prism 1000; b) Prism 1500; c) Prism 2000; d) Prism 3000. Recall #Z-651/654-9.
CODE	Serial Numbers: a) Prism 1000s - All Prism 1000XP - All up to and including S/N 973; b) Prism 1500XP - All up to and including S/N 135; c) Prism 2000S - All Prism 2000XP - All up to and including S/N 973; d) Prism 3000XP, systems S/N 273-424.
MANUFACTURER	Picker International., Inc., Highland Heights, Ohio.
RECALLED BY	Manufacturer, by Mandatory Service Letter #384, dated May 12, 1997. Firm-initiated field correction ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	158 units were distributed.
REASON	Software error may result in loss of data requiring patient re-scan and possible delay in diagnosis.
	[ ] None Present [ ] Action Taken _____ _____

6525 NS
MDC 15944 **Cameras, Gamma**

PRODUCT	Nuclear Medical Imaging Systems w/FX and FX 800 Series Computers and Version 8.3.11 software. Recall #Z-655/656-9.
CODE	All serial numbers.
MANUFACTURER	Picker International, Inc., Highland Heights, Ohio.
RECALLED BY	Manufacturer, by Mandatory Service Letter #404, dated November 17, 1998. Firm-initiated field correction ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	70 units were distributed.
REASON	Software error may result in patient misdiagnosis.

[ ] None Present
[ ] Action Taken _____
_____

6525 NS
MDC 16389 **Collimator Cart**

PRODUCT	Collimator Cart of the Millennium Mg Computed Emission Tomography System. Recall #Z-618-9.
CODE	Collimator Cart Model #2173498. Affected units were distributed prior to May 1998.
MANUFACTURER	GE Medical Systems, Waukesha, Wisconsin. ELGEMS, Ltd Advanced Technology, CenterHaifa, Israel.
RECALLED BY	GE Medical Systems, Waukesha, Wisconsin by field modification instruction #40598 on January 20, 1999. Firm-initiated field correction ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	77 carts were distributed.
REASON	Casters in the wheel assemblies of the collimator cart can fall off, allowing the collimator cart to tip over.

[ ] None Present
[ ] Action Taken _____
_____

6525 NS
MDC 16260 **Array Coil, Magnetic Resanance Imagers**

PRODUCT	Edge System Pelvic Array Coil, an accessory to the MRI. Recall #Z-660-9.
CODE	All serial numbers.
MANUFACTURER	Picker International, Inc., Highland Heights, Ohio.
RECALLED BY	Manufacturer, by Mandatory Service Letter #388, dated October 20, 1997. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.

[ ] None Present
[ ] Action Taken _____
_____

6530 NS
MDC 13037 **Phototherapy Units**

PRODUCT	Olympic Mini Bili-lite, Models 77 & 78. Recall #Z-683/684-9.
CODE	Catalog Numbers: 51477 and 51478, Serial Numbers 1191, 1192, 10052 though 10188 (non-continuous).

MANUFACTURER	Olympic Medical Corp., Seattle, Washington.
RECALLED BY	Manufacturer, by fax on November 19, 1998.
DISTRIBUTION	Nationwide and international.
QUANTITY	138 units were distributed.
REASON	Support springs in Bili-Lites may break causing arm to fall.

[ ] None Present
[ ] Action Taken _____
_____

6630 NS

MDC 115551	**Clinical Chemistry Analyzer**
PRODUCT	Abbott Alcyon(tm) 300 Analyzer (without Ise Module) and 3001, an automated chemistry analyzer for in vitro diagnostic use. Recall #Z-617-9.
CODE	List numbers: 4D66-02, 4D67-02, 4D68-02, 4D69-02.
MANUFACTURER	Abbott Laboratories, Irving, Texas.
RECALLED BY	Abbott Laboratories, Abbott Park, Illinois, by telephone on January 29, 1999, and by letter dated February 1, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	631 units were distributed.
REASON	Possible mixup of patient sample results.

[ ] None Present
[ ] Action Taken _____
_____

MEDICAL DEVICE SAFETY ALERTS:

6515 NS

MDC 11128	**Defibrillator/Monitors**
PRODUCT	Hewlett Packard M2475B Codemaster 100 Defibrillator/Monitor powered by the Nickel Cadmium (NiCd) Rechargeable Batteries. Safety Alert #N-004-9.
CODE	HP Part No. M2476B-2.5 Amp-hr and M2477B-4-.0 Amp-hr.
MANUFACTURER	Hewlett Packard Company, Andover, Massachusetts.
ALERTED BY	Manufacturer, by medical device safety alert on December 12, 1998.
DISTRIBUTION	Nationwide and international.
QUANTITY	3,815 units were distributed.
REASON	Rechargable NiCad batteries used beyond shelf-life of 2 years may not function.

[ ] 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 **14 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	6520 Nonstandard
PRODUCT	Rx Dental anesthetics in blister packed cartridges, under the following labels: Novocol, Henry Schein, or Carlisle: a) Lidocaine Hydrochloride 2% and Epinephrine Injection, USP 1:50,000; b) Lidocaine Hydrochloride 3% and Epinephrine Injection, USP 1:100,000; c) Mepivacaine Hydrochloride Injection, USP 3%; d) Mepivacaine Hydrochloride 2% and Levonordefrin Injection, USP. 1:20,000. Recall #D-119/122-9.
CODE	Lot numbers: a) 7412B, 7412C, 8081, 8207, 8159, 8161B; b) 7102, 7182, 7284, 7270A, 7309, 8157, 8162A, 8162, 8163, 8164, 8249; c) 7157; d) 7412A, 8160.
MANUFACTURER	Novocol Pharmaceutical of Canada, Inc., Cambridge, Ontario, Canada.
RECALLED BY	Novocol Pharmaceutical of Canada, Inc., New castle, Delaware, by letter on January 14-15, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	Undetermined.
REASON	Microbial contamination.
	[ ] None Present [ ] Action Taken _____ _____

CLASS II RECALLS:

NSN	6505 Nonstandard
PRODUCT	Triprolidine Hydrochloride and Pseudoephedrine Hydrochloride Syrup USP (1.25mg/5mL and 30mg/5mL) in 4 fluid ounce bottles, OTC oral liquid nasal decongestant/antihistamine, under the Morton Grove Pharmaceuticals (MGP)

	(NDC #60431-600-04) and Goldline, (NDC #0182-1609-37) labels. Recall #D-124-9.
CODE	Lot numbers: 21377A, 21377C, 21377E, 21377F EXP 07/99.
MANUFACTURER	Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois.
RECALLED BY	Manufacturer, by letter dated February 2, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	14,430 bottles were distributed; firm estimated that little, if any, product remained on market at time of recall initiation.
REASON	Potency failure (triprolidine HCL) during stability testing.
	[ ] None Present [ ] Action Taken _____

NSN	6505 Nonstandard
PRODUCT	Generic pre-filled syringes aseptically manufactured and distributed by Medefil: a) 0.9% Sodium Chloride Injection, USP, Preservative Free 2ml fill in 3 ml syringe - NDC #64253-777-12; 5 ml fill in 6 ml syringe - NDC #64253-777-25; 10 ml fill in 12 ml syringe - NDC #64253-777-30; 5 ml fill in 12 ml syringe - NDC #64253-777-35; b) Heparin Sodium 10 units/ml in 0.9% Sodium Chloride Injection, USP, 5 ml fill in 12 ml syringe - NDC #64253-666-35; c) Heparin Sodium 100 units/ml in 0.9% Sodium Chloride Injection USP 3ml fill in 6 ml syringe - NDC #64253-555-23; 5 ml fill in 6 ml syringe - NDC #64253-555-25; 10 ml fill in 12 ml syringe - NDC #64253-555-30; 5 ml fill in 12 ml syringe - NDC #64253-555-35. Recall #D-126/128-9.
CODE	All lots: S00005, S00006, S00007, S00008, S00009, S00010, S00011, S00012, S00013, S00014, S00015, S00017, S00018, S00019, S00020, S00021, S00022, S00023, S00024, S00025, H00005, H100005, H100006, H100007, H100008, H100009.
MANUFACTURER	Medefil, Inc., Schaumburg, Illinois.
RECALLED BY	Manufacturer, by letter dated February 8, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Ohio.
QUANTITY	a) 1,532 cases; b) 25 cases; c) 262 cases were distributed between 12/18/98 and 1/28/99; firm estimated that 50% of the product remained on the market at time of recall initiation.
REASON	Products were marketed without approved (NDA/ANDA) and numerous deviations from current good manufacturing practices (GCMP's) related to sterile drug production.
	[ ] None Present [ ] Action Taken _____

NSN	6505 Nonstandard
PRODUCT	Oxygen, USP, Rx, compressed, in high pressure cylinders, E, D, and A size; Oxygen, USP, Rx, liquefied, in GP-4500 and GP-5500 vessels; Medical Air, USP, Rx, compressed, in high pressure cylinders, Size 233. Recall #D-129/131-9.

CODE	Medical Air USP: 18L981 18L982 01M981 02M981 Medical Oxygen USP: 05L981 05L982 05L983 06L981 18L981 18L982 01M981 02M981 02M982 04M981 04M982 07M981 07M982 07M983 07M984 07M985 07M986 08M981 08M982.
MANUFACTURER	Red Ball Oxygen Co., Inc., Shreveport, Louisiana.
RECALLED BY	Manufacturer, by fax followed by letter dated December 18, 1998, and telephone. Firm-initiated recall ongoing.
DISTRIBUTION	Arkansas, Louisiana, Texas.
QUANTITY	a) 1,008 cylinders; b) 6 cylinders; c) 2 cylinders were distributed.
REASON	Current good manufacturing practice deviations including but not limited to: Lack of documented assay results for purity and identity and Lack of equipment calibration records.
	[ ] None Present [ ] Action Taken _____ _____

	6505 Nonstandard
PRODUCT	Sodium Hyaluronate FB, a sterile visco-elastic material that is injected into the eye during certain ophthalmic surgeries: a) Amvisc Product No. 780 (Sodium Hyaluronate FB); b) Amvisc Plus Product No. 850 (Sodium Hyaluronate FB); c) Amvisc Plus Product No. 880 (Sodium Hyaluronate FB). Recall #Z-667/669-9.
CODE	All serial numbers.
MANUFACTURER	Lifecore Biomedical, Inc., Chaska, Minnesota.
RECALLED BY	World Optics, Agoura, California, by fax on January 18, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Arkansas, California, Idaho, Florida, Minnesota, Pennsylvania, Texas, Utah.
QUANTITY	4,872 units were distributed.
REASON	The devices were marketed without an approval PMA.
	[ ] None Present [ ] Action Taken _____ _____

NSN	6515 Nonstandard
PRODUCT	Disposable Administration Set for Peritoneal Dialysis, a sterile, single use only fluid pathway for use with the Home Care Automated PD System only. Recall #Z-639-9.
CODE	Catalog #5C4469, Lot numbers: H98J26529, H98J26537, H98J27527, H98K30537, H98L02526, H98J27535, H98J28525, H98J28533, H98K30545, H98L02583, H98J28541, H98J29523, H98J30588, H98L01528, H98L03581, H98K02585, H98K03583, H98K04581, H98L01536, H98L04589.
MANUFACTURER	Baxter Healthcare Corporation, Mountain Home, Arkansas.
RECALLED BY	Baxter Healthcare Corporation, Deerfield, Illinois, by letter dated February 4 and 5, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	93,720 sets were distributed.

REASON	The sets may restrict fluid delivery due to an obstruction in the cassette, which may result in alarm situations that will not allow patients to proceed with therapy. [ ] None Present [ ] Action Taken _____

NSN	6515 Nonstandard
PRODUCT	PERM-CATH Catheters: a) 36cm Catheter Insertion Tray Part #88-17680-001; b) 40cm Catheter Insertion Tray Part #88-17681-001; c) 36cm Catheter Kit Part #88-17748-001; d) 40cm Catheter Kit Part #88-17749-001; e) 45cm Catheter Kit Part #88-31692-001. The kits contain a limited amount of surgical products, the trays contain all surgical products needed for surgery. Recall #Z-634/638-9.
CODE	Lot numbers: a) 802453, 802712; b) 802454, 802575, 802482; c) 802455, 802456, 802457, 802576; d) lots 802458, 802577; e) lots 802278, 802591.
MANUFACTURER	The Kendall Company, Bothell, Washington.
RECALLED BY	Manufacturer, by letter sent on or about February 10-11, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	Approximately 9,536 Percaths were distributed: a) 757 trays; b) 3,764 trays; c) 3,630 kits; d) 820 kits; e) 565 kits.
REASON	The introducer sheath would not separate as intended upon completion of catheter insertion procedure. [ ] None Present [ ] Action Taken _____

NSN	6515 Nonstandard
PRODUCT	Port-A-Cath P.A.S. Port II Implantable Venous Access, used for the delivery of drugs, fluids, and nutritional solutions by infusion or syringe. Recall #Z-682-9.
CODE	All lots.
MANUFACTURER	Sims Deltec, Inc., St. Paul, Minnesota.
RECALLED BY	Manufacturer, by letter on February 16, 1999. Firm-initiated field correction ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	13,235 units were distributed.
REASON	The portal housings of some of the devices became cracked and some of the septums in the devices became dislodged. [ ] None Present [ ] Action Taken _____

NSN	6515 Nonstandard
PRODUCT	Bubble Suction Tubing. Recall #Z-685-9.
CODE	Lot #41AJCM16 EXP 2004-01.
MANUFACTURER	ConMed Corporation, El Paso, Texas.
RECALLED BY	Manufacturer, by fax on February 19, 1999, and by letter dated February 22, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	North Carolina and Florida.

QUANTITY	12 cases (50 units per case) were distributed.
REASON	Non-sterility.
	[ ] None Present [ ] Action Taken _____ _____

NSN	6515 Nonstandard
PRODUCT	8mm Straight Ratchet Clips, indicated for surgical clamping during cardiovascular peripheral vascular, and general surgery: a) Model No. G-8050; b) Model No. AVD-8000. Recall Z-687/688-9.
CODE	Lot numbers: a) 96B067, 98B118, C8E032, C8F003; b) E5N013, 96A007, 96C182, 96B065, 96E130 - 96E132, 96G316, 96H446, 97F286, 97K067, 97M206, 98B052, 98C074, C8E012.
MANUFACTURER	Applied Medical Resources, Laguna Hills, California.
RECALLED BY	Manufacturer, by telephone or fax beginning August 6, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	411 units were distributed.
REASON	A non-radiused corner on the ratchet clip could perforate the pouches, thereby, compromising the sterility of the devices.
	[ ] None Present [ ] Action Taken _____ _____

NSN	6515 Nonstandard
PRODUCT	Kendall Sher-I-Bronch Endobronchial Tubes and VHA Plus Sher-I-Bronch Endobronchial Tubes, Left and Right Sided, intended for use in thoracic surgery, bronchospirometry, administration of endobronchial anesthesia, etc. The tube is indicated for main stem brochus intubation and allows for selective inflation or deflation of either lung. Model: Kendall Sher-I-Bronch -10 Catalog Numbers; VHA Plus Sher-I-Bronch- 4 Catalog Numbers. See Code Information. Recall #Z-699/712-9.
CODE	Kendall's Sher-I-Bronch Endobronchial: CATALOG LOT NO. Description 5-16028 067903 Left Sided, 28 Fr O68551 069429 5-16035 067691 Left Sided, 35 Fr 068385 069422 069431 069865 070339 070749 5-16037 067625 Left Sided, 37 Fr 067685 067688 068387 068555 068586 069003 069005

069860
069861
069867
070341
070869
5-16039 067168 Left Sided, 39 Fr
067174
067684
067687
068548
068553
069423
069424
069862
070338
070340
070343
5-16041 067622 Left Sided, 41 Fr
068550
069006
069859
070346
070867
5-16128 067904 Right Sided, 28 Fr
068386
069194
069426
5-16135 067692 Right Sided, 35 Fr
068388
069425
069431
5-16137 067172 Right Sided, 37 Fr
069004
069427
069433
5-16139 067173 Right Sided, 39 Fr
069863
5-16141 067621 Right Sided, 41 Fr
069428
070345
VHA Plus Label:
V5-16035 069421 Left Sided, 35 Fr
V5-16037 069002 Left Sided, 37 Fr
070342
070870
V5-16039 067686 Left Sided, 39 Fr
070344
V5-16041 068549 Left Sided, 41 Fr
070868.

MANUFACTURER Kendall Company, Argyle, New York.

RECALLED BY Kendall Healthcare, Mansfield, Massachusetts, by letter on February 5, 1999. Firm-initiated recall ongoing.

DISTRIBUTION	Nationwide and international.
QUANTITY	15,731 Kendall units and 895 VHA Plus units were distributed.
REASON	Improper assembly (gap in bonding) of endobronchial tubes may cause leaking of air/gas.
	[ ] None Present [ ] Action Taken _____

NSN	6515 Nonstandard
PRODUCT	CaverMap Surgical Aid Disposables Kit (Sterile). Part No. 8300. The UroMed CaverMap Surgical is indicated for use in the stimulation of the cavernosal nerves, during open prostatectomy surgical procedures. The kit contains: probe tip, return lead, and tumescence sensor. Model: CaverMap Surgical Aid Disposables Kit (sterile). Recall #Z-716-9.
CODE	Part #8300, Lot #JBH9014, EXP 7/14/99.
MANUFACTURER	Uromed Corporation, Norwood, Massachusetts.
RECALLED BY	Manufacturer, by fax on February 11, 1999, followed by telephone on February 12, 15, 16, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	California, Colorado, New York, Florida, Illinois, Missouri, Washington state, Tennessee, Canada.
QUANTITY	123 units were distributed.
REASON	Sterility of device is compromised due to tears in the Mylar Pouch.
	[ ] None Present [ ] Action Taken _____

NSN	6550 Nonstandard
PRODUCT	a) Precitrol-A Control Serum and Diluent, Catalog No. 620211/917211,; b) Precitrol-N Control Serum and Diluent, Catalog No. 620212/917212; c) Precical Calibrator Serum and Diluent, Catalog No. 620213/917213, d) Bilirubin, Total and Direct, Catalog No. 123919. Recall #Z-672/675-9.
CODE	Lot Numbers: a) 121033, EXP 09/23/99; b) 121034 EXP 07/25/99; c) 108615 EXP 02/28/99; 121035 EXP 07/11/99; 253410 EXP 02/06/00; 298017, EXP 05/21/00; 750001, EXP 11/20/00; and 75002, EXP 12/01/00; d)679951, EXP 5/99; and 693365, EXP 8/00.
MANUFACTURER	Roche Diagnostics/Boehringer Mannheim Corporation, Indianapolis, Indiana; Boehringer Mannheim GmbH, Mannheim, Germany (Catalog #123919 only).
RECALLED BY	Roche Diagnostics/Boehringer Mannheim Corporation, Indianapolis, Indiana, by letter on December 7, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	Approximately 233,000 kits.
REASON	The method for calibration of total bilirubin/DPD results in a +16% analytical bias compared to the Doumas method.
	[ ] None Present [ ] Action Taken _____

CLASS III RECALLS:

NSN	6505 Nonstandard
PRODUCT	Isoniazid Tablets, USP, 300 mg, in 30, 100, and 1,000 tablet bottles, Rx intended for all forms of tuberculosis in which organisms are susceptible, under the following labels: Barr, Schein, Rugby, UDL. NDC numbers: 0555-0071-01, 0555-0071-02, 0555-0071-05. Recall #D-123-9.
CODE	Lot numbers: 5L071AL, 6A071AL, 6A071AM, 6B071CO, 6C071AT, 6D071AB, 6D071AZ, 6D071BA, 6E071CB, 6E071CC, and 6E071AE EXP 5/99.
MANUFACTURER	Barr Laboratories, Inc., Northvale, New Jersey.
RECALLED BY	Barr Laboratories, Inc., Pomona, New York, by letter beginning on January 8, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	288,549 containers were distributed.
REASON	Dissolution failure (stability).
	[ ] None Present [ ] Action Taken _____ _____

NSN	6505 Nonstandard
PRODUCT	Nalex DH, Rx antitussive and decongestant, (Hydrocodone Bitartrate 1.67 mg/5mL/Phenylephrine Hydrochloride 5 mg/5mL), in 16 fluid ounce bottles, distributed by Blansett Pharmacal Co., Inc., (BPCI). NDC #51674-0005-7. Recall #D-125-9.
CODE	Lot #91638 EXP 10/2000.
MANUFACTURER	Great Southern Laboratories (GSL), Houston, Texas.
RECALLED BY	Manufacturer, by letter dated February 2, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	6,506 bottles were distributed.
REASON	Mislabeling - Some bottles have the incorrect (Nalex A) insert attached.
	[ ] None Present [ ] Action Taken _____ _____

NSN	6515 Nonstandard
PRODUCT	Scimed Owens Lo-Profile Balloon Dilatation Catheters: a) Model H74926140; b) Model H74926150; c) H74926160; d) H74926170. Recall #Z-619/622-9.
CODE	Lot numbers: a) 1875484, 1984517, and 2051216; b) 1875485, 1890301, 1999830, and 2032596; c) 1850364 and 1929297; d) 1819312, 1860969, 1921073, and 1965812.
MANUFACTURER	Scimed Life Systems, Inc., Maple Grove, Minnesota.
RECALLED BY	Manufacturer, by letter sent on February 5, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	170 units were distributed.
REASON	Improper assembly of the devices makes them unusable.
	[ ] None Present [ ] Action Taken _____ _____

NSN	6550 Nonstandard
PRODUCT	Sicklequik, an in-vitro diagnostic used as a differential solubility test for Hemoglobin S for diagnosis of sickle cell anemia. Recall #Z-670-9.
CODE	Lot numbers: 5732 and 5738.
MANUFACTURER	Biopool International, Westchester, Pennsylvania.
RECALLED BY	Organon Teknika Corporation, Durham, North Carolina, by letter on September 18, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide, The Netherlands, Canada.
QUANTITY	271 kits containing 25 vials or 100 vials were released for distribution.
REASON	The test interpretations with these products have proven to be difficult.

[ ] None Present
[ ] Action Taken _____
_____

NSN	6550 Nonstandard
PRODUCT	ICON Fx hCG Serum-Urine and Urine Test Kits, designed to detect human chorionic gonadotropin (hCG) in urine or serum, as an aid in the early detection of pregnancy: a) Product No. 40005, ICON Fx hCG Serum-Urine - 5 Tests; b) Product No. 40025, ICON Fx hCG Serum-Urine - 25 Tests; c) Product No. 40050, ICON Fx hCG Serum-Urine - 50 Tests; d) Product No. 41025, ICON Fx hCG Urine - 25 Tests. Recall #Z-676/679-9.
CODE	All lots of the above test kits.
MANUFACTURER	Beckman Coulter, Inc., (formerly Smith Kline Diagnostics), Palo Alto, California.
RECALLED BY	Beckman Coulter, Inc., Brea, California, by letter on January 27, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and Puerto Rico.
QUANTITY	8,338 kits were distributed.
REASON	Device gives false negative results in urine samples.

[ ] None Present
[ ] Action Taken _____
_____

NSN	6550 Nonstandard
PRODUCT	Aeroset System Reagent Application Sheet for Urine/CSF Protein Reagent, used for the quantitation of total protein in human urine or cerebrospinal fluid (CSF). Recall #Z-596-9.
CODE	List #07D79-01.
MANUFACTURER	Abbott Laboratories, Irving, Texas.
RECALLED BY	Abbott Laboratories, Abbott Park, Illinois, by telephone on January 25, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	176 units were distributed.
REASON	Depressed protein concentrations in the range between 200 and 600 mg/dL.

[ ] None Present
[ ] Action Taken _____
_____

NSN	6550 Nonstandard
PRODUCT	Premier C. Difficile, diagnostic test kits, an enzyme immunoassay for the detection of C. difficile Toxin A in stool specimen. This test kit is intended for use as an aid in the diagnosis of C. difficile-associated disease. Recall #Z-640-9.
CODE	LOT #601096.155.
MANUFACTURER	Meridian Diagnostics, Inc., Cincinnati, Ohio.
RECALLED BY	Manufacturer, by letter on February 15, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	2,158 kits were distributed.
REASON	Bacterial contamination of sample diluent, which may affect test results.
	[ ] None Present [ ] Action Taken _____ _____

ALERT NOTIFICATIONS:

Subject: Q.A Message 9088-0002
Advance Alert-Pharmaceutical Cotton Coil

1. This is advance notification to alert you about a problem which has been identified with cotton supplied by Personna Medical/Div of American Safety Razor Company.
2. Certain lots of cotton coil received by Personna during 1998 from their producer were double treated with hydrogen peroxide leaving various levels of hydrogen peroxide residue. Many manufacturers used this cotton for packaging, including drug manufacturers who used the cotton to fill drug bottle headspace.
3. While it is too early to tell the extent of the problem, Personna has advised FDA that they have received complaints from several pharmaceutical manufacturers. These complaints range from thyroid tablets showing a color change and testing sub-potent, enteric coated aspirin tablets showing a color change and exhibiting an off-odor, morphine tablets showing a color change, and an amino acid product showing impurity/stability problems.
4. While we do not know at this time the exact companies involved we are advising that if you should find the above problems or other problems which might be caused by this, that you submit A SF380 to DSCP with a information copy to AFMLO/FOM-P, ATTN: Bonnie Phillips.
5. The FDA is conducting an investigation of a large number of manufacturers who have been identified as receiving cotton from Personna. We will provide additional information as soon as we know what companies are involved.
6. POC at AFMLO/FOM-P is Bonnie Phillips, DSN 343-4170.
7. This information will be published in AFMLL 04-99.
8. For MAJCOMS and NGB - This message has been transmitted to all designated subordinate Medical Activities IAW AFMAN 23-110, VOL 5, Chap 19.