

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 11218 Hemodialysis Units
PRODUCT Gambro Centrysystem 3 Ultrafiltration (UF) Pump Thermal Fuse.
 Recall #Z-201-7.
CODE All catalog and all serial numbers.
MANUFACTURER Gambro Healthcare (formerly COBE Renal Care), Lakewood,
 Colorado.
RECALLED BY Manufacturer, by letter on October 7-9, 1996. Firm-initiated
 recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 13,064 systems were distributed.
REASON The Ultra Filtration Pump Thermal Fuse can fatigue and shut
 down the UF pump without alarming.

None Present

Action Taken _____

6515NS
MDC 13209 Pumps, Enteral Feeding
PRODUCT Kangaroo Entriflush Enteral Feeding Pump, Rx device used to
 regulate the flow of enteral feedings: (a) Catalog #8884-
 352405 (new); (b) Catalog #8884-352413 (refurbished). Recall
 #Z-208/209-7.
CODE All pumps.
MANUFACTURER Sherwood Davis & Geck, Watertown, New York.
RECALLED BY Sherwood Davis & Geck, St. Louis, Missouri, by letter dated
 December 4, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 1,954 units were distributed.
REASON The pumps may deliver formula at rates up to twice the
 programmed feeding rate.

None Present

Action Taken _____

6515NS
MDC 10846 Circulatory Assist Units

PRODUCT Abiomed (R) BVS 5000i Bi-Ventricular Support System, temporary artificial heart system consoles. Recall #Z-221-7.
 CODE Serial Numbers: 1500-1523.
 MANUFACTURER Abiomed, Inc., Danvers, Massachusetts.
 RECALLED BY Manufacturer, by letter on October 8, 1996. Firm-initiated recall ongoing.
 DISTRIBUTION California, Connecticut, District of Columbia, Florida, Illinois, Kentucky, Massachusetts, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, Texas, West Virginia.
 QUANTITY 24 consoles (2 valves each) were distributed.
 REASON The transducers may malfunction and result in several types of device failures. If the transducer fails during power-up, the BVS System may fail the self-test. If the transducer malfunctions during use, the BVS System may produce erratic or reduced blood flow.

None Present
 Action Taken _____

6515NS
 MDC 11218
 PRODUCT **Hemodialysis Units**
 Fresenius Hemodialysis Delivery Systems: (a) Model 2008H/3008; (b) Model 2008E; (c) Model 2008C/D; (d) Model 2008BSS. Recall #Z-224/227-7.
 CODE All lots.
 MANUFACTURER Fresenius USA, Inc., Walnut Creek, California.
 RECALLED BY Manufacturer, by visit November 22, 1996. Firm-initiated field correction ongoing.
 DISTRIBUTION Nationwide, Canada, Mexico.
 QUANTITY 5,172 modules were distributed.
 REASON Certain solenoids used in the level detector module line clamp contain a rubber bumper that may become gummy, causing the line clamp to stick open after a blood alarm.

None Present
 Action Taken _____

CLASS III RECALLS:

PRODUCT Bio-Tek Software Microplate Readers, in-vitro diagnostic medical device: (a) Product #ELx800; (b) ELx808. Recall #Z-219/220-7.
 CODE All serial numbers.
 MANUFACTURER Bio-Tek Instruments, Inc., Winooski, Vermont.
 RECALLED BY Manufacturer, by letter on November 19, 1996. Firm-initiated field correction ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY 1,328 units were distributed.
 REASON An error in the device's data reduction software could produce erroneous results.

None Present
 Action Taken _____

MEDICAL EQUIPMENT SAFETY ALERTS:

6525NS
MDC 15944 **Cameras, Gamma**
PRODUCT Picker Prism Nuclear Medicine Imaging Systems, used for
 diagnostic purposes for SPECT and body imaging performed in a
 hospital or clinic setting: (a) Model No. 1000S/215003, Model
 No. 1000XP/210337 and Model No. 1500XP/210502; (b) Model Nos.
 2000S/215000, 2000XP/210336; (c) N-006-7 - Model No.
 3000S/210060 and Model No. 3000XP/210335. Safety Alert #N-
 004/006-7.
CODE All models and all serial numbers.
MANUFACTURER Picker International, Inc., Highland Heights, Ohio.
ALERTED BY Manufacturer, by letter dated November 16, 1996.
DISTRIBUTION Nationwide and international.
QUANTITY 1,112 units were distributed.
REASON Objects should not be placed in the path of the equipment.

[] 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 MAR 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 Dilantin Kapseals (Extended Phenytoin Sodium),
USP, 100 mg, antiepileptic drug, in bottles of
1000 and 100. Recall #D-074-7.
CODE Lot numbers: 05785F EXP 7/97 (1000'S); 04885F
EXP 7/97 (100'S); 03075F EXP 7/97 (100'S);
02395F EXP 9/97 (100'S); 01595F EXP 8/97
(100'S); 00666F EXP 5/98 (100'S); 084N5F EXP
11/97 (100'S); 04185F EXP 7/97 (1,000'S);
10055F, 016N5F AND 04356F (100'S); 03385F,
07416F (1000'S).
MANUFACTURER Warner-Lambert Company, Fajardo, Puerto Rico.
RECALLED BY Parke Davis, Division of Warner-Lambert
Company, Morris Plain, New Jersey, by letter
on October 26, 1996. Firm-initiated recall
ongoing.
DISTRIBUTION Nationwide.
QUANTITY

Lot No.	Quantity Shipped
05785F	4,016
04185F	3,973
04885F	39,694
03075F	39,115
02395F	40,176
01595F	38,586
00666F	72
084N5F	41,184
016N5F	40,080
04356F	40,607
03385F	3,936
07416F	3,840
10055F	40,680.

REASON Stability dissolution failure.

[] None Present

[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Loestrin, Fe 1/20 (1 mg Norethindrone Acetate
and 20 mcg Ethinyl Estradiol Tablets, USP, and
Ferrous Fumarate Tablets, 75 mg), 5 dispensers
of 28 tablets per dispenser. Recall #D-077-7.
CODE Lot #001N5F EXP 10/97.
MANUFACTURER Warner-Lambert Company, Fajardo, Puerto Rico.

RECALLED BY Parke-Davis, Division of Warner-Lambert Company, Morris Plain, New Jersey, by letter on August 26, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 47,225 dispensers were distributed.

REASON Product failed potency assay for Ethinyl Estradiol at the three month stability timepoint.

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT Liquid Oxygen, USP, in low pressure , 165 cryogenic vessels. Recall #D-082-7.

CODE Lot numbers: 001L611, 002L612, 002L613, 002L615, 002L618, 003L618, 003L620, 003L621, 004L622, 004L625, 004L627.

MANUFACTURER Haun Welding Supply, Inc., Watertown, New York.

RECALLED BY Haun Welding Supply, Syracuse, New York, verbally and by letter on December 2, 1996. Firm-initiated recall complete.

DISTRIBUTION New York.

QUANTITY None remains in distribution.

REASON Good manufacturing practice deficiencies.

None Present
 Action Taken _____

NSN 6515 Nonstandard

PRODUCT Richard Allen brand Disposable Endoscopic Clip Applier, Reflex-ELC with Titanium Clips, Product No. 530, used in Reflex Brand Cholecystectomy Kit No. 37001. Recall #Z-218-7.

CODE Custom Kit Nos. C37200 and C37201, All lots with Lot No./Expiration Date of 25JAN99 or earlier.

MANUFACTURER Richard-Allan Medical, Richland, Michigan.

RECALLED BY Manufacturer, by sending technical bulletin dated February 21, 1994, and by letter dated March 1, 1994. Firm-initiated recall complete.

DISTRIBUTION Nationwide and international.

QUANTITY Undetermined.

REASON Clip applier jaw are subject to opening too far and not being able to contain an unformed

clip, allowing the clip to fall during use.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Charging units for Sonicare Dental Hygiene Products, battery operated toothbrushes that use sonic frequency brushing to clean teeth: (a) Sonicare Personal, PS-1; (b) Sonicare Plus, PL-1; (c) Sonicare with Quadpacer, QP-1. Recall #Z-205/207-7.
CODE Charging units with lot numbers 19636 through 19644.
MANUFACTURER Optiva Corporation, Bellevue, Washington.
RECALLED BY Manufacturer, by press release on November 6, 1996, and by letters on November 7 and 8, 1996. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY (a) 86,627 units; (b) 41,573 units; (c) 14,805 units were distributed.
REASON The charging units may have been manufactured without electrical insulation (potting compound) potentially exposing the user to electrical shock.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT 3M Electrosurgical Patient Plates, Split with Cord, Catalog No. 1179, a disposable dispersive electrode and is the return electrode for electrical current introduced into the body during surgery by electrosurgical cutting and coagulation procedures. Recall #Z-210-7.
CODE Lot Nos. 1999-10CG, 1999-10CH, 1999-10CP, 1999-10CJ, 1999-10CC.
MANUFACTURER 3M Company Valley Plant, Valley, Nebraska.
RECALLED BY 3M Health Care, 3M Company, St. Paul, Minnesota, by letter sent on December 26, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 146,280 units were distributed.
REASON An intermittent electrical continuity within

the plug terminal on the cord plate may prevent activation of the electrosurgical generator.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Supra-Annular Aortic Carbomedics Prosthetic Heart Valve, Size 21, Model No. S500.
Recall #Z-211-7.
CODE Lot #255857.
MANUFACTURER CarboMedics, Inc., Austin, Texas.
RECALLED BY Manufacturer, by telephone on November 22, 1996, followed by letter on December 2, 1996. Firm-initiated recall ongoing.
DISTRIBUTION California, Florida, Georgia, Illinois, Maryland, Massachusetts, Michigan, New York, North Carolina.
QUANTITY 23 valves were distributed.
REASON The valve may have been placed on the holder upside down.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Cardiac Pacemaker Maestro II, single chamber implantable, multi-modal, multiprogrammable pulse generator with bi-directional telemetry: (a) Model 235; (b) Model 325; (c) Model 333; (d) 533. Recall #Z-212/215-7.
CODE The following serial numbers (prefixed with the model number) are involved in this recall: 235-01001 through 235-01009; 325-01177 through 325-01186; 333-02297 through 333-02308; 333-02371 through 333-02379 and 533-01062 through 533-01071.
MANUFACTURER Cardiac Control Systems, Inc. (CCS), Palm Coast, Florida.
RECALLED BY Manufacturer, by telephone and by letter on November 20, 1996. Firm-initiated recall complete.
DISTRIBUTION Connecticut, Massachusetts, Florida, Pennsylvania, New York, New Jersey, Louisiana, Tennessee, Arkansas.
QUANTITY 30 pacers were distributed.

REASON Loss of connection between the battery and the internal circuitry can result in an inoperable pacemaker.

 [] None Present
 [] Action Taken _____

NSN 6550 Nonstandard
PRODUCT Q.E.D. Saliva Alcohol Test: (a) Product #A150 (31150); (b) Product A350 (31350).
Recall #Z-216/217-6.

CODE	A150	EXP DATE	A350	EXP DATE
	025531	JUN 97	045504	JUL 96
	025537	JUN 97	075521	SEP 96
	025614	JUN 97	046551	SEP 97
	035500	JUL 97	046554	SEP 97
	035503	JUL 97	056509	OCT 97
	035532	JUL 97	056511	OCT 97
	035545	JUL 97		
	035546	JUL 97		
	035582	JUL 97		
	035589	JUL 97		
	035595	JUL 97		
	045548	AUG 97		
	045566	AUG 97		
	045588	AUG 97		
	055541	SEP 97		
	055551	SEP 97		
	055566	SEP 97		
	055588	SEP 97		
	065513	SEP 97		
	065558	SEP 97		
	065612	OCT 97		
	115511	FEB 98		
	115512	FEB 98		
	115551	MAR 98		
	046513	JUL 98		
	046518	JUL 98		
	046527	JUL 98.		

MANUFACTURER STC Technologies, Inc., Bethlehem, Pennsylvania.
RECALLED BY Manufacturer, by letters on December 6 and 12, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 69 units were distributed.
REASON The test reaction does not develop within five minutes for negative samples as specified in the package insert.

 [] None Present
 [] Action Taken _____



CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Klor-Con 10 meq (Potassium Chloride, 750 mg, USP) Extended Release Tablets, Rx.
Recall #D-075-7.
CODE All lots.
MANUFACTURER Uspher-Smith Laboratories, Inc., Minneapolis, Minnesota.
RECALLED BY Physicians Total Care, Tulsa, Oklahoma, by letter on September 23, 1996. Firm-initiated recall complete.
DISTRIBUTION Illinois and Missouri.
QUANTITY 6 bottles were distributed; firm estimates none remains on the market.
REASON Some units may contain Klor-Con 8 Tablets.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Nystatin-Triamcinolone Acetonide Cream, USP, packaged in 15 g tubes, 30 tubes, 60 g tubes, and 120 (4 ounce) jars, Rx topical corticosteroid with anti-inflammatory, anti-pruritic and vasoconstrictive actions (triamcinolone) and an anti-fungal (Nystatin). The product was distributed under the manufacturer's label and the following three private labels:
- Tri-Staton II Cream (Nystatin and Triamcinolone Acetonide Cream, USP) Rugby Laboratories, Inc. Norcross, GA
- Mycobiotic II (Nystatin-Triamcinolone Acetonide Cream) h. l. Moore Drug Exchange New Britain, CT
- MYOCIDIN (nystatin-triamcinolone acetonide cream) Major Pharmaceutical Corp. Chicago, IL
Recall #D-076-7.

CODE	LOT #	EXP DATE	LABEL(S)	SIZE(S)
	5A523	1/97	NMC	15g 60g
	5B540	2/97	NMC Rugby Major h.l. Moore NMC h.l. Moore	15g 15g 15g 15g 30g 30g

		Rugby	30g
		NMC	120g
5B624	2/97	Rugby	15g
		NMC	15g
		Rugby	30g
		NMC	30g
		h. l. Moore	60g
		NMC	60g
		Major	60g
		Rugby	60g
5F800	6/97	NMC	15g
		Major	15g
		NMC	30g
		h. l. Moore	30g
		Major	60g
		NMC	120g.

MANUFACTURER NMC Laboratories, Inc., Glendale, New York.
RECALLED BY Manufacturer, by letter mailed on December 19, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 266,627 units were distributed; firm estimates none remains on the market.
REASON Potency of Triamcinolone is not assured through expiration (stability lot 5B540 failed potency assay at the 18-month timepoint -- 88.3%; SPEC is 90-110%).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Armour Thyroid (2 gr Tablets, 76mcg Levothyroxine and 18 mcg Liothyronine), Rx, in bottles of 100, indicated for use as a replacement or supplemental therapy in patients with thyroid disorders.
Recall #D-078-7.
CODE FP0622 EXP 12/98.
MANUFACTURER Rhone-Poulenc Rorer, Puerto Rico, Inc., Manati, Puerto Rico.
RECALLED BY Forest Pharmaceuticals, Inc., St. Louis, Missouri, by letter dated October 2, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Belgium.
QUANTITY 17,616 bottles were distributed.
REASON Product failed content assay for one active ingredient, Levothyroxine.

None Present

[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT FML Forte (Fluorometholone), 0.25%, Liquifilm Sterile Ophthalmic, in 5, 10, and 15 ml bottles, for use as a topical anti-inflammatory sterile ophthalmic suspension. Recall #D-079-7.

CODE	PRODUCT#	LOT #	EXP Date
	136	5288A	9/96
	136	5289A	3/97
	227	5282X	3/96
	227	5280X	9/96
	227	5281A	10/96
	227CP	5281A	10/96
	227	5282A	2/97
	228	5296X	4/96
	228	5294A	8/96
	228	5295A	5/97
	228	5296A	5/97
	4550	5303X	4/96
	4550	5302A	8/96
	4550	5303A	1/97
	4550	5304A	5/97.

MANUFACTURER Allergan America, Hormingueros, Puerto Rico.
RECALLED BY Allergan, Inc., Irvine, California, by letter dated February 2, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Puerto Rico, Great Britain.

QUANTITY	Lot #	Quantity Shipped
	5288A	9,738
	5289A	3,672
	5282X	38,979
	5280X	10,692
	5281A	39,462
	5282A	24,932
	5296X	18,162
	5294A	18,905
	5295A	17,089
	5296A	2,116
	5303X	3,560
	5302A	4,686
	5303A	4,833
	5304A	381.

REASON Product fails preservative effectiveness test near the end of its 18-month expiration date.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Leucovorin Calcium Tablets, USP: (a) 5 mg, packaged in bottles of 30, 100, and 1000; (b) 25 mg, packaged in bottles of 25 and 500, Rx indicated to diminish the toxicity of Methotrexate, under the following labels: Barr, Rugby, Geneva Pharmaceuticals, Zenith Goldline.
 Recall #D-080/081-7.
 CODE (a) 5K484AY EXP 12/97, 6A484AJ EXP 3/98, 6B484DI EXP 3/98; (b) 6A485AK EXP 1/98.
 MANUFACTURER Barr Laboratories, Inc., Northvale, New Jersey.
 RECALLED BY Barr laboratories, Inc., Pomona, New York, by letter sent on December 20, 1996. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and Puerto Rico.
 QUANTITY 1,776/30's, 802/100s and 60/1000s (lot 5K484AY); 2,892/30s, 72/1000 (lot 6A484AJ); 1,117/30s, 2,109/100s (lot 6B484DI); 1,418/25s, 48/500s (lot 6A485AK) bottles were distributed.
 REASON One lot failed content assay at the 6-month stability timepoint due to higher than normal particle size range. The other lots contain the same active ingredient lot as the failing lot.

[] None Present
 [] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Prenatal multivitamin/mineral products, packaged in bottles of 100:
 (a) Natalcare; (b) Advanced Formula Prenatal Z; (c) Prenatal MTR. Recall #D-084/086-7.
 CODE (a) Lot # Exp Date Lot # Exp Date
 L8332 1/98 L8362 2/98
 L8335 1/98 L8363 2/98
 L8336 1/98 L8364 2/98
 L8337 1/98 L8429 4/98
 L8338 1/98 L8430 4/98
 L8359 1/98 L8431 4/98
 L8360 1/98 L8432 4/98
 L8361 1/98
 (b) L8263 1/98 L8265 2/98

	L8264	1/98	L8354	2/98
	(c) L7580	2/98	L7864	3/98.
MANUFACTURER	KV Pharmaceutical Company, St. Louis, Missouri.			
RECALLED BY	Manufacturer, by telephone on December 17-18, 1996, and by letter dated December 13, 1996. Firm-initiated recall ongoing.			
DISTRIBUTION	Nationwide.			
QUANTITY	96,600 bottles were distributed.			
REASON	Potency of Vitamin D is not assured through the expiration date.			

None Present

Action Taken _____
