

**FOOD AND DRUG ADMINISTRATION (FDA)
RECALLS/ALERT NOTICES**

1. **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 material 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 **13 November 98** 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	Extra Strength Acetaminophen Tablets, 500 mg, OTC, in 60 and 100 tablet bottles, under the Family Pharmacy and Fred's label. Recall #D-236-8.
CODE	Lot numbers: 8032215 and 8064485.
MANUFACTURER	Granutec, Inc., Wilson, North Carolina.
RECALLED BY	Manufacturer, by telephone on August 7, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	1,441 units of Fred's 60-count and 1,875 units of Family Pharmacy 100-count bottles were distributed.
REASON	Tablet mix-up - Aspirin and caffeine tablets were commingled with these lots during packaging.

None Present
 Action Taken _____

NSN	6505 Nonstandard
PRODUCT	Alenic Alka Antacid, (Aluminum Hydroxide 95 mg/Magnesium Carbonate, Anhydrous 358 mg) Tablespoon, in 12 fluid ounce plastic bottles, OTC product used for the relief of heartburn, acid indigestion, sour stomach, and upset stomach. Recall #D-237-8.
CODE	Lot #70642.
MANUFACTURER	RIJ Pharmaceutical Company, Middeltown, New York.
RECALLED BY	Rugby Laboratories, Inc., Norcross, Georgia (distributor), by letter on April 20, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.

QUANTITY 4,800 bottles were distributed.
REASON Microbial contamination.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Maxalt Tablets (Rizatriptan Benzoate), 10 mg, in complimentary (physician)
sample cartons, Rx. Recall #D-238-8.
CODE Lot #H0602 EXP 3/00.
MANUFACTURER Merck Manufacturing Division, Division of Merck & Company, West Point,
Pennsylvania.
RECALLED BY Manufacturer, by letter on August 3, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 7,256 units were distributed.
REASON Mislabeling - Some cartons contain individual foil packages which are printed
with the incorrect product strength 5 mg while the tablets are actually 10 mg.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Reactive Human Serum. Recall #B-1483-8.
CODE Lot #97-0014L.
MANUFACTURER Centers for Disease Control and Prevention (CDC), Atlanta, Georgia.
RECALLED BY Manufacturer, by letter dated April 17, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 2 vials were distributed.
REASON Blood products were used as a reactive control serum tested positive for
Hepatitis C.

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT a)Starter Kit. Recall #Z-836-8
b)Replacement Cartridge Recall #837-8.
CODE a)Nos. 985000 and 985015
b)Nos. 985001 and 985080.
MANUFACTURER Laerdal Medical Corp., Wappingers, NY.
RECALLED BY Manufacturer, on August 4, 1998, by certified letter. 0 . Firm-initiated
on-going.
DISTRIBUTION Nationwide. Canada, Austrailia, Norway, Costa Rica and military.
QUANTITY 13,300 cases.
REASON The intake valve may be particaly or totally occluded possibly causing
the suction unit to malfunction.

[] None Present
[] Action Taken _____

NSN 6530 Nonstandard
PRODUCT Mobile Shower Commode Chair and Wheeled Leg Extensions.
Recall # Z-822/823-8.
CODE Serial Nos. 71027 through 80511.
MANUFACTURER Invacare Corporation, Elyria, Ohio.
RECALLED BY Manufacturer, by Certified Mail on July 8, 1998. Firm-initiated recall on-going.
DISTRIBUTION Nationwide.
QUANTITY 2,568 distributed.
REASON Devices adulterated in that a newly supplied castor wheel is too soft such that the wheel may buckle under load and while turning.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Reagent Pack. Recall #Z-835-8.
CODE 2A02-60/69. Lot #40354Q100.
MANUFACTURER Abbott Laboratories, Barceloneta, PR.
RECALLED BY Manufacturer, by letter on July 30, 1998. Firm-initiated recall on-going.
DISTRIBUTION Nationwide.
QUANTITY 1,151 kits. Germany, Taiwan, Italy, Bahamas, Japan, Jamaica, Singapore, Chili, Hong Kong, Korea, El Salvador, Canada.
REASON Calibrations curve error.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6515 Nonstandard
PRODUCT Colleague Volumetric Infusion Pumps. Recall #Z-798-8.
CODE 2M8151.
MANUFACTURER Baxter Healthcare Corp., Round Lake, IL.
RECALLED BY Manufacturer, on July 13, 1998 by letter. Firm-initiated recall on-going.
DISTRIBUTION Nationwide.
QUANTITY 4,221 units.
REASON The battery charge level indicator may understate the true battery capacity.

None Present
 Action Taken _____

NSN 6515 Nonstandard
UPDATE Baxter Healthcare Corporation's recall of Colleague Volumetric Infusion Pumps, which appeared in the September 9, 1998, Enforcement Report should be replaced with the following:

PRODUCT Baxter Colleague Single Channel Volumetric Infusion Pump, Model 2M8151, used for continuous or intermittent fluid delivery through clinically acceptable routes

of administration. Recall #Z-798-8.

CODE All pumps manufactured and shipped from the manufacturing facility prior to 11/26/97 with Slave software below version 1.04.

MANUFACTURER Baxter Healthcare Corporation, PTE, Ltd., Singapore.

RECALLED BY Baxter Healthcare Corporation, I.V. Systems Division, Round Lake, Illinois, by letter dated January 13, 1998. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 4,221 units were distributed.

REASON The battery charge level indicator may understate the true battery capacity. Also, the pumps may experience a 6-20% under-delivery due to slippage of the lower shuttle jaw of the pump head mechanism.

[] None Present
 [] Action Taken _____

NSN 6515 Nonstandard

UPDATES Recall #Z-836/837-8, which appeared in the September 9, 1998 Enforcement Report should be replaced with the following:

PRODUCT Replacement Cartridges for V-Vac Hand-powered Suction Unit, a single use Oropharyngeal suction unit for patients in pre-hospital environment: a) Starter Kit, Catalog Nos. 985000 and 985015; b) Replacement Cartridge, Catalog Nos. 985001 and 985080. Recall #Z-836/837-8.

CODE All lots with manufacturing date codes from 050198 (5/1/98) through 072298 (7/22/98).

MANUFACTURER Laerdal Medical Corporation, Wappingers, New York.

RECALLED BY Manufacturer, by letter on August 4, 1998. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Canada, Australia, Norway, Costa Rica.

QUANTITY 13,300 cartridges.

REASON The intake valve may be partially or totally occluded possibly causing the suction unit to malfunction.

Devon Needle Counters, used to assist the medical practitioner in maintaining an accurate count of the number of suture needles used during a surgical procedure, Recall #Z-673/675-8, which appeared in the July 22, 1998 Enforcement Report should read:
 The following PRODUCTS/REORDER #s/LOT #s/PART #s are listed below:

STERILE NEEDLE COUNTERS, INDIVIDUALLY PACKAGED

Reorder #	Lot #	Part #
1105	72451	31142212
1314	72301	31142170
	72261	
	72591	
	71971	
1315	72241	31142188
	72401	
	72591	
	72551	
	72651	
	71951	
1330	72251	31142303
	72191	
	72451	
	72511	
	72591	

	72121	
1360	72271	31142204
	72521	
	72591	
	72651	
	71951	
	71911	
1614	72251	31142295
	72191	
	72181	
	72401	
	72471	
	72521	
1615	72041	31142329
	72241	
	72481	
	71951	
1625	71961	31142444
	72401	
	72621	
1630	72271	31142451
	72191	
	72511	
	72451	
	72131	
	72031	
	71981	

STERILE NEEDLE COUNTERS, INDIVIDUALLY PACKAGED

Reorder #	Lot #	Part #
1635-1	72061	31313425
1660	72091	31142477
	72141	
	72471	
	72611	

SURGI-START KIT CONTAINING AFFECTED NEEDLE COUNTERS

Reorder #	Lot #	Part #
7519	72321	31144507
	72121	
	72463	
	71926	
7539	72661	31144457
7614	72721	31145520
	72543	
7663	72241	31145538
7766	72403	31144978
7815	72403	31144879
	72603	
	72311	
	72811	
7866	72201	31145173
	72403	
7415-KCW	72383	31290854
7416-KCW	72161	31323747
	72811	
7430-BAB	72211	31330643
7436-NON	72531	31149373

7463-BVB	72251	31149902
7463-COG2	72161	31150363
	72451	
7463-MDW	72321	31150355
	72971	
	72161	
7463-SCN2	72513	31149910
7466-INI2	72201	31150173
	72731	
7466-MCM2	72121	31149845
7466-MCW2	72543	31149993
	72821	
7514-MAF	72811	31151437
SURGI-START KITS CONTAINING AFFECTED NEEDLE COUNTERS		
REORDER #	LOT #	PART #
7514-NMT	72821	31151379
7514-POW2	72161	31151742
7514-SMR2	72301	31306981
7612-SAB	72961	31325023
7614-KCW	72811	31152617
7614-T4	72661	31144895
	72881	
7615-UMD4	72311	31152914
	72341	
	72111	
	72861	
7616-CAC3	72801	31317376
7653-NAS	72341	31154480
	72353	
	72661	
7661-CAC2	72881	31175097
7663-CCL2	72591	31154142
	72201	
	72881	
	72121	
	72511	
	72961	
7663-MIM2	72821	31154696
	72451	
7694-SGB3	72211	31329603
	72901	
7715-NRA5	72451	31152575
	72311	
	72671	
	72731	
7735-WII3	72603	31153466
	72383	
	73001	
	72861	
SURGI-START KITS CONTAINING AFFECTED NEEDLE COUNTERS		
REORDER #	LOT #	PART #
7815-ALA2	72533	31152252
	72201	
	72971	
	72121	
7815-T8	72821	31145272

72881

K-1330-1DOC	72261	31151213
K-1614-6PBP	72241	31150918
K-1615-2CAC	72511	31150595
	72891	
K-1615-2FAP	71961	31151155
	72611	
K-1615-4SLH	72383	31151114
	72473	
K-1615-S	71971	31141610
	72091	
	72453	
	72533	
K-1615-S3	72373	31141859
K-1615-S4	72901	31141503
K-1615-Z	72241	31141776
	72581	
K-1615-Z3	72051	31141735
	72121	
	72381	
	72471	
	72551	
K-1630-3BMM	72191	31151171
K-1630-S	72191	31141602
	72061	
K-1630-S3	72403	31141867
	72483	
	71881	
K-1660-S	72061	31141586
	72403	
	72533	
	72473	

BULK, NON-STERILE NEEDLE COUNTERS

REORDER #	LOT #	PART #
NS-1105	72171	31155362
NS-1314	72281	31155644
	72231	
	71961	
	72491	
NS-1315	72281	31155255
	71991	
	72531	
NS-1330	72171	31155354
	72191	
NS-1360	72101	31155248
	71961	
NS-1614	72371	31155743
	72311	
	71911	
	72181	
	72061	
	71961	
NS-1615	71951	31155735
	72411	
NS-1625	72371	31155768
	72411	

NS-1630	72371 72251 71911 72001	31155776
NS-1660	71921 72001 72581.	31155792

None Present
 Action Taken _____

NSN	7610 Nonstandard
PRODUCT	The recalled item to be corrected in the field is the Instruction Manual for the EPIX VT Dual Channel Transcutaneous Electrical Nerve Stimulator (TENS device). Recall # Z-826-8.
CODE	The field correction applies to the TENS devices which were shipped between April 24, 1998 and August 14, 1998. The defective manuals were put with the devices at the time of shipment.
MANUFACTURER	Empi, Inc., St. Paul, MN.
RECALLED BY	Manufacturer, on August 19, 1998 by letter. Firm-initiated recall on-going.
DISTRIBUTION	Nationwide.
QUANTITY	582 shipped.
REASON	The instruction manuals to be corrected in the field lack page 3, which normally has some of the precaution statements and some of the product warnings. Most of the important product warnings are on page 2, which is not missing.

None Present
 Action Taken _____

NSN	6540 Nonstandard
PRODUCT	Series Ten Thousand Endodiode Laser System, used in ophthalmic surgery. Recall #Z-838-8.
CODE	Model numbers L-120-0001-501 and L-130-0001-501.
MANUFACTURER	Alcon Laboratories, Inc., Irvine, California.
RECALLED BY	Manufacturer. FDA approved the firm's corrective action September 8, 1998.
DISTRIBUTION	Firm-initiated field correction ongoing. California, Florida, Georgia, Kentucky, Maryland, Michigan, New York, Ohio, Oregon, Tennessee, international.
QUANTITY	129 units were distributed.
REASON	The system might inadvertently emit a full power beam while in the "Ready" mode regardless of footswitch position, 21 CFR 1003.2(b)(2).

None Present
 Action Taken _____
