

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:

6525NS

MDC 17669

PRODUCT

X-Ray Rad Units, Podiatric

MinXray Mobile/Portable General Purpose Podiatry Systems, used in general purpose radiographic studies: (a) Model No. PM200 Mobile/Portable Podiatry Systems manufactured before August 9, 1993, but introduced into commerce outside the date of limitations specified by Variance No. 94V-0003; (b) Model No. PW200 Mobile/Portable Podiatry Systems manufactured before August 9, 1993, but introduced into commerce outside the date of limitations specified by Variance No. 94V-0003. Recall #Z-015/016-7.

CODE

Units manufactured prior to August 9, 1993, but shipped subsequent to that date in violation of Variance No. 94V-0003  
Model PM200: tubehead s/n 16645, 16646, 16648, 16649, 16651  
Model PW200: tubehead s/n 16650.

MANUFACTURER

Mikasa X-ray Co. Ltd., Tokyo, Japan.

RECALLED BY

MinXray, Inc., Northbrook, Illinois. FDA approved the firm's corrective action plan October 22, 1996, and by end user notification letters sent on January 15, 1997. Firm-initiated field correction ongoing.

DISTRIBUTION

New Jersey, New York, Pennsylvania, Indiana, Ohio.

QUANTITY

6 units.

REASON

The diagnostic x-ray devices failed to comply with the Federal Performance Standard for Diagnostic X-Ray Systems and their major components for light illuminance and failed the edge contrast ratio required.

None Present

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

6515NS

MDC 96024

PRODUCT

Endoscopes

Olympus Remote Switch Model No. MH-965, designed to be connected to the Olympus Camera Control Unit OTV-S5C, and used in combination with any OTV-S5 System Camera Heads or an OES Laparo-Thoraco Videoscope. This provides the endoscopist fingertip control of the VTR operation or shutter release for still photography using the EVIS Monitor Photo unit SCV-3 or the Olympus Color Video Printer OEP. Recall #Z-234-7.

CODE All lots.  
 MANUFACTURER Olympus Japan, Inc., Shirakawa, Japan.  
 RECALLED BY Olympus America, Inc., Melville, New York, by letter dated  
 October 30, 1996. Firm-initiated recall ongoing.  
 DISTRIBUTION Arizona, Texas, Maryland, Florida, Georgia, California,  
 Illinois, Michigan, Oregon, Pennsylvania.  
 QUANTITY 94 switches were distributed.  
 REASON The Color Bars are inadvertently displayed on the monitor  
 screen, when the MH-965 remote switch for the OTV-S5 is used in  
 conjunction with an active cord from an unipolar accessory.

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

6530NS  
 MDC 14141  
 PRODUCT

**Treadmills**

Quinton Instrument Stress Test Monitors:  
 (a) Model No. Q3000 Monitor;  
 (b) Model No. Q4000 Monitor;  
 (c) Model No. Q4000K Monitor.  
 Recall #Z-235/237-7.

CODE All serial numbers.  
 MANUFACTURER Quinton Instrument Company, Bothell, Washington.  
 RECALLED BY Manufacturer, by letter beginning on January 10, 1997. Firm-  
 initiated recall ongoing.  
 DISTRIBUTION Nationwide and international.  
 QUANTITY (a) 3,196 units; (b) 2,079 units; (c) 1,682 units were  
 distributed.  
 REASON A software anomaly could cause their treadmills to erroneously  
 increase or decrease in speed, and/or grade when the "Stop  
 EXER" key is pressed at the end of a stage

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

6515NS  
 MDC 11179  
 PRODUCT

**Dermatomes**

Padgett Electro Dermatome Power Pak for use with the Model B  
 Padgett Electro Dermatome, for use in cutting skin grafts.  
 Recall #Z-249-7.

CODE Serial numbers (which can be found on both the power pack and  
 the Dermatome):

1-1919	1-6268	1-9054	1-9101	1-9130	1-9168	1-1941
1-7324L	1-9055	1-9102	1-9131	1-9169	1-3609L	1-7419
1-9056	1-9103	1-9132	1-9170	1-36561	1-7587	1-9057
1-9104	1-9133	1-9171	1-3799L	1-7942	1-9058	1-9105
1-9134	1-9172	1-3909	1-8008	1-9059	1-9106	1-9135
1-9173	1-3960	1-8450	1-9060	1-9110	1-9136	1-9174
1-4058	1-8972	1-9061	1-9111	1-9137	1-9175	1-4060
1-9008	1-9072	1-9112	1-9138	1-9176	1-4074	1-9010
1-9073	1-9113	1-9139	1-9177	1-4270	1-9024	1-9074
1-9114	1-9140	1-9178	1-4276	1-9028	1-9075	1-9115
1-9141	1-9179	1-4317	1-9029	1-9076	1-9116	1-9142
1-9202	1-4449A	1-9030	1-9077	1-9117	1-9143	1-9203
1-4644	1-9031	1-9078	1-9118	1-9144	1-9206	1-4863
1-9032	1-9079	1-9119	1-9145	1-9207	1-5045	1-9033

1-9080	1-9120	1-9146	1-9208	1-5152	1-9034	1-9081
1-9121	1-9147	1-5225	1-9035	1-9092	1-9122	1-9148
1-5391A	1-9036	1-9094	1-9123	1-9149	1-5594	1-9037
1-9095	1-9124	1-9150	1-5922	1-9038	1-9096	1-9125
1-9151	1-6023	1-9040	1-9097	1-9126	1-9152	1-6132
1-9051	1-9098	1-9127	1-9165	1-6224	1-9052	1-9099
1-9128	1-9166	1-6225	1-9053	1-9100	1-9129	1-9167.

MANUFACTURER Dadson Manufacturing Company, Grain Valley, Missouri. (contract manufacturer)

RECALLED BY Padgett Instruments, Inc., Kansas City, Missouri, by letter dated December 13, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and Canada.

QUANTITY 129 Dermatome power packs containing the 1/2 amp circuit breaker were distributed; 18 power paks have been corrected.

REASON The power paks may have a circuit breaker that will trip inadvertently and turn off the dermatome.

None Present

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

CLASS III RECALLS: None

MEDICAL EQUIPMENT SAFETY ALERTS: None

2. DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

CLASS I: A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

CLASS II: A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CLASS III: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences. Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of [AU1]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 11 APR 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:

THE FOLLOWING MATERIEL MANUFACTURED BY VENTRITEX IS BEING RECALLED AS A CLASS I RECALL:

NSN: 6515 NONSTANDARD  
PRODUCT: DEFIBRILLATOR/VENTRITEX TIERED THERAPY  
CARDIOVERTER  
MANUFACTURER: VENTRITEX  
MODELS: V-110 AND V-112  
LOT/SERIEL NUMBER: ALL  
REASON: THREE ADVERSE EVENTS HAVE BEEN ASSOCIATED WITH THE  
DEVICE FAILURE THAT RESULTED IN PATIENT DEATH DUE  
TO RAPID BRADYCARDIA PACING (THIS IS A SOFTWARE  
PROBLEM).

DOCTORS WILL CONTACT INDIVIDUALS WHO HAVE THIS DEVICE AND PERFORM AN EFFECTIVENESS CHECK USING MANUFACTURE'S CHECKLIST. A SAFETY FEATURE CAN BE ADDED TO THE DEFIBRILLATOR TO ALERT PATIENT IF PACING IS ABOVE 117 PPM. THIS REPROGRAMMING TAKES ONLY A FEW MINUTES, DOES NOT REQUIRE SURGERY AND PREVENTS THE DELIVERY OF INAPPROPRIATELY RAPID PACING PULSES, EVEN IN THE EVENT OF A COMPONENT FAILURE.

REPORT ALL QUANTITIES (EITHER IMPLANTED IN PATIENT OR IN STOCK) BY PHONING VENTRITEX'S CUSTOMER SERVICE AT 1-800-733-3455 OR 408-738-4883.

THIS CONFIRMS Q. A. MESSAGE 7056-0004.

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

CLASS II RECALLS:

NSN	6505 Nonstandard
PRODUCT	Aredia (Pamidronate Disodium) For Injection, 60 mg vials, Rx indicated for the treatment of patients with moderate hypercalcemia associated with malignancy in conjunction with adequate hydration. Recall #D-087-7.
CODE	Lot #1000500 EXP 3/97.
MANUFACTURER	Ciba Pharmaceuticals, Summit, New Jersey.
RECALLED BY	Manufacturer, by fax on May 10, 1996, followed by letter sent on May 15, 1996. Firm-initiated recall complete.
DISTRIBUTION	Nationwide.
QUANTITY	Approximately 750 vials were distributed.
REASON	Product label mix-up. Some unit carton labels may show two different strengths, 90 mg and 60 mg (correct).

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

NSN  
PRODUCT

6505 Nonstandard  
Sus-Phrine, Epinephrine Injectable Suspension,  
5 mg/ml, in 0.3 ml ampules, Rx indicated for  
use for the symptomatic treatment of bronchial  
asthma, and reversible bronchospasm associated  
with bronchitis and emphysema.  
Recall #D-091-7.

CODE Lot numbers: 95A751 EXP 1/98 (10 per box),  
95E030 EXP 5/98 (10 per box), 95E550 EXP 6/98  
(25 per box).  
MANUFACTURER Steris Laboratories, Inc., Phoenix, Arizona.  
RECALLED BY Forest Pharmaceuticals, Inc., St. Louis,  
Missouri, by letter dated December 30, 1996.  
Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 12,772 boxes were distributed.  
REASON Some packages may be moldy.

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

NSN 6505 Nonstandard  
PRODUCT Bristol Myers Squibb's OVCON35 - 28 Day  
(Norethindrone and Ethinyl Estradiol Tablets,  
USP), Rx oral contraceptive packaged as 28-day  
regimen with 21 active ingredient tablets and  
7 inactive (placebo) tablets in a blister  
strip compact. Recall #D-096-7.

CODE Lot #H6J272A EXP 8/98.  
MANUFACTURER Bristol Laboratories, Corporation, Mayaguez,  
Puerto Rico.  
RECALLED BY Bristol Myers Squibb Company, New Brunswick,  
New Jersey, by letter dated January 15, 1997,  
followed by a revised letter dated January 18,  
1997, and by press release on January 17,  
1997. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 25,056 cartons (6 compacts/carton) were  
distributed.  
REASON Contraceptive tablets are out of sequence (the  
seven inactive tablets were mistakenly  
packaged to be taken the first seven days of  
the 28-day cycle instead of the last seven  
days).

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

NSN 6505 Nonstandard  
PRODUCT (a) Red Blood Cells; (b) Platelets; (c) Fresh  
Frozen Plasma; (d) Cryoprecipitated AHF; (e)  
Single Donor Plasma; (f) Fresh Frozen Plasma,  
for further manufacture; (g) Source  
Leukocytes; (h) Recovered Plasma.

Recall #B-298/305-7.

CODE Unit numbers: (a) 9537728, 9633605, 8965252, 8980568, 9012160, 9027003, 9076560, 9137112, 9137513, 9185851, 9207443, 9342867, 9630976; (b) 9633605, 8980568, 9012160, 9027003, 9692638, 9630976; (c) 8965252, 9038149, 9342867; (d) 9692638, 9630976; (e) 9692638; (f) 8880628, 8934808, 8980568, 9012160, 9027003, 9076560, 9137112, 9137513, 9207443; (g) 9185851; (h) 9407336, 9537919, 9630976.

MANUFACTURER Hoxworth Blood Center, University of Cincinnati Medical Center, Cincinnati, Ohio.

RECALLED BY Manufacturer, by letter dated May 2, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Ohio, Massachusetts, Kentucky, Indiana, Texas, Illinois, Florida.

QUANTITY (a) 13 units; (b) 6 units; (c) 3 units; (d) 2 units; (e) 1 unit; (f) 9 units; (g) 1 unit; (h) 3 units were distributed.

REASON Blood products tested negative for the hepatitis B surface antigen (HBsAg), but were collected from donors who previously were confirmed positive for HBsAg.

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

NSN 6515 Nonstandard

PRODUCT VSI Sigmoidoscope Endosheaths, (sterile, single use): (a) SS-V32 EndoSheath for use with the S-V100 Video Sigmoidoscope, Catalog No. 06-7101; (b) SS-F32 EndoSheath for use with the S-F100 Fiber Optic Sigmoidoscope, Catalog No. 06-2101. Recall #Z-199/200-7.

CODE Product shipped prior to 11/12/96.

MANUFACTURER Vision Sciences, Inc., Natick, Massachusetts.

RECALLED BY Manufacturer, by letter dated November 14, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 23,568 units were distributed.

REASON Hairline cracks were found at the corners of the tray under the sealing flange, therefore compromising the sterility of the devices.

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

NSN 6515 Nonstandard  
PRODUCT Undercover 1,000 cc Urine Collection Bag (The Original Belly Bag). Recall #Z-203-7.  
CODE Catalog #B-1000, Lot #A-8640.  
MANUFACTURER North American Medical, Inc., Lubbock, Texas.  
RECALLED BY Manufacturer, by letter dated November 21, 1996. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 2,860 units were distributed.  
REASON An inadequate seal was found on the device packaging, therefore compromising the sterility of the device.

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

NSN 6515 Nonstandard  
PRODUCT Medtronic Indura Model 8703W Intraspinial Catheter, intended for use with Medtronic SynchroMed Programmable Pumps, for the intraspinal infusion of parenteral drugs. Recall #Z-223-7.  
CODE Lot Numbers: 40841, 40843, 40844, 40845, 40846, 40847, 40848, 41007, 41008, 41009, 41010, 41011, 41012, 41427, 41428, 41429, 41430, 41431, 41432, 41433, 41434, 41435, 41436, 41523, 41526, 41527, 41528, 41529, 41531, 41562.  
MANUFACTURER Medtronic, Inc., Neurological Division, Minneapolis, Minnesota.  
RECALLED BY Medtronic, Inc., Neurological Division, Columbia Heights, Minnesota, by letter dated January 6, 1997. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide, Canada, Australia.  
QUANTITY 1,108 catheters were distributed.

REASON

The radiopaque component (barium sulfate, BaSO4) of the distal catheter segment is insufficient to visualize the catheter using the diagnostic methods of fluoroscopy or x-ray.

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

NSN

6515 Nonstandard

PRODUCT

Elbow with gas sampling port included in various anesthesia breathing circuits:  
 (a) Kendall's Anesthesia Breathing Circuits;  
 (b) Bain Breathing Circuits;  
 (c) Pediatric Anesthesia Breathing Circuits;  
 (d) SafeTrak Anesthesia Breathing Circuits;  
 (e) Customer Special Anesthesia Breathing Circuits. Recall #Z-244/248-7.

CODE

All inventory of the following product codes:

02346	6791	6926	10109	10154
02436	6794	6927	10111	10155
02490	6797	6928	10112	10156
02492	6798	6929	10113	10160
04412	6803	6931	10114	10162
04413	6814	6933	10115	10163
2435	6866	6935	10116	10165
2444	6872	6936	10117	10166
2447	6875	7145	10118	10168
2449	6876	8624	10119	10172
2450	6877	8627	10120	10173
2451	6878	8632	10121	10174
2453	6879	8634	10123	10175
2491	6881	8664	10124	10176
2494	6883	8667	10125	10178
2498	6886	8683	10126	10179
4936	6887	8684	10127	10181
4937	6888	8686	10128	10185
4938	6889	8687	10132	10189
4941	6893	8688	10133	10190
4942	6894	8824	10134	10191
4944	6895	8826	10135	10192
4945	6896	8827	10137	10197
4948	6908	8828	10138	10199
6909	9424	10139	10200	
6679	6911	9425	10141	10206
6777	6912	9521	10142	10207
6778	6913	10101	10143	10212
6780	6915	10103	10145	10214
6785	6916	10105	10146	10215

6787	6917	10106	10151	10217
6788	6919	10107	10152	24499
6790	6925	10108	10153.	

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MANUFACTURER Especialidades Medicals, Kenmex, Tijuana, Mexico.

RECALLED BY Kendall Healthcare Products Company, Mansfield, Massachusetts, by letter November 16, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY Approximately 55,000 - 60,000 circuits were distributed.

REASON Each device contains an Elbow (with gas sampling port only) which may be partially or totally occluded, thus interfering with the ability to adequately ventilate or administer anesthesia to patients.

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

NSN 6515 Nonstandard

PRODUCT Padgett Electro Dermatome Power Pak for use with the Model B Padgett Electro Dermatome, for use in cutting skin grafts.  
 Recall #Z-249-7.

CODE Serial numbers (which can be found on both the power pack and the Dermatome):

1-1919	1-6268	1-9054	1-9101	1-9130
1-9168	1-1941	1-7324L	1-9055	1-9102
1-9131	1-9169	1-3609L	1-7419	1-9056
1-9103	1-9132	1-9170	1-36561	1-7587
1-9057	1-9104	1-9133	1-9171	1-3799L
1-7942	1-9058	1-9105	1-9134	1-9172
1-3909	1-8008	1-9059	1-9106	1-9135
1-9173	1-3960	1-8450	1-9060	1-9110
1-9136	1-9174	1-4058	1-8972	1-9061
1-9111	1-9137	1-9175	1-4060	1-9008
1-9072	1-9112	1-9138	1-9176	1-4074
1-9010	1-9073	1-9113	1-9139	1-9177
1-4270	1-9024	1-9074	1-9114	1-9140
1-9178	1-4276	1-9028	1-9075	1-9115
1-9141	1-9179	1-4317	1-9029	1-9076
1-9116	1-9142	1-9202	1-4449A	1-9030
1-9077	1-9117	1-9143	1-9203	1-4644
1-9031	1-9078	1-9118	1-9144	1-9206
1-4863	1-9032	1-9079	1-9119	1-9145
1-9207	1-5045	1-9033	1-9080	1-9120
1-9146	1-9208	1-5152	1-9034	1-9081

1-9121 1-9147 1-5225 1-9035 1-9092  
 1-9122 1-9148 1-5391A 1-9036 1-9094  
 1-9123 1-9149 1-5594 1-9037 1-9095  
 1-9124 1-9150 1-5922 1-9038 1-9096  
 1-9125 1-9151 1-6023 1-9040 1-9097  
 1-9126 1-9152 1-6132 1-9051 1-9098  
 1-9127 1-9165 1-6224 1-9052 1-9099  
 1-9128 1-9166 1-6225 1-9053 1-9100  
 1-9129 1-9167.

MANUFACTURER Dadson Manufacturing Company, Grain Valley, Missouri. (contract manufacturer)  
 RECALLED BY Padgett Instruments, Inc., Kansas City, Missouri, by letter dated December 13, 1996. Firm-initiated recall ongoing.  
 DISTRIBUTION Nationwide and Canada.  
 QUANTITY 129 Dermatome power packs containing the 1/2 amp circuit breaker were distributed; 18 power paks have been corrected.  
 REASON The power paks may have a circuit breaker that will trip inadvertently and turn off the dermatome.

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

NSN 6515 Nonstandard  
 PRODUCT St. Jude Medical Aortic Valve Graft with Meadox Hemashield Woven Double Velour Graft, Model GAVG-404, a replacement aortic valve and graft used with the aortic valve and the ascending aorta must be replaced.  
 CODE Serial numbers: 10026548, 10026549, 10026552, 10026553, 10026554, 10026558, 10026559, 10026560, 10026563, 10026564, 10026568, and 10026573.  
 MANUFACTURER St. Jude Medical, Inc., St. Paul, Minnesota (aortic replacement valve with graft); Meadox Medical, Inc., Subsidiary of Boston Scientific Corporation, Oakland, New Jersey (Hemashield Graft).  
 RECALLED BY St. Jude Medical, Inc., St. Paul, Minnesota, by telephone on January 7, 1997, followed by letter dated January 9, 1997. Firm-initiated recall complete.  
 DISTRIBUTION California, Colorado, Illinois, Kansas, Kentucky, Missouri, New York, Pennsylvania, Texas, Australia.  
 QUANTITY 12 valves with grafts were distributed.

REASON A change in manufacturing process by the vascular graft supplier permitted a residue of collagen to be deposited on the valve prosthesis.

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

NSN 6550 Nonstandard  
PRODUCT Neisseria Meningitides Polyvalent (Group A-D) Agglutinating Serum, in-vitro diagnostic test kit which consists of one 2 ml vial of product. Recall #Z-239-7.  
CODE Product Code ZM33, Lots K442010\*, K262110, K846210, K255210\* (\*only distributed in United States.)  
MANUFACTURER Murex Biotech, Ltd., Temple Hill, Dartford, England.  
RECALLED BY Murex Diagnostic, Inc., Norcross, Georgia, by telephone, followed by letter dated April 3, 1996. Firm-initiated recall complete.  
DISTRIBUTION Nationwide and international.  
QUANTITY 28 kits were distributed  
REASON The subject lots will not detect N. meningitides Group B, due to activity deterioration.

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

NSN 6550 Nonstandard  
PRODUCT One Touch Test Strips, used in conjunction with Lifescan meters for blood glucose monitoring. Recall #Z-241-7.  
CODE Lot #609816A.  
MANUFACTURER Lifescan, Inc., Milpitas, California.  
RECALLED BY Manufacturer, by telephone on October 11, 1996, and by fax on October 17, 1996. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 3,623 units were distributed.  
REASON The lot of glucose test strips was labeled with an incorrect calibration code which causes glucose results to be inaccurately high.

None Present

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

CLASS III RECALLS:

NSN 6505 Nonstandard  
PRODUCT Extra Strength Tylenol (Acetaminophen)  
Gelcaps, 500 mg, in bottles of 50, 100, or  
300, OTC pain reliever/fever reducer.  
Recall #D-083-7.  
CODE Lot numbers: SPA 664 (50s), SPA 745 (100s),  
SPA 751 (300s).  
MANUFACTURER McNeil Consumer Products Company, Las Piedras,  
Puerto Rico.  
RECALLED BY McNeil Consumer Products Company, Fort  
Washington, Pennsylvania, by letter dated  
December 27, 1996. Firm-initiated recall  
ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 339,912 bottles of lot SPA 664; 96,240 bottles  
of lot SPA 745; 7,272 bottles of lot SPA 751  
were distributed.  
REASON Microbial contamination of non-sterile product  
(gelatin coating exceeded internal  
specification for aerobic microorganisms).

[ ] None Present

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

NSN 6505 Nonstandard  
PRODUCT Leucovorin Calcium Tablets, Rx oral derivative  
of folic acid: (a) 5 mg; (b) 25 mg.  
Recall #D-088/089-7.  
CODE Lot numbers: 6B107, 6H428, 6S162.  
MANUFACTURER Barr Laboratories, Inc., Northvale, New  
Jersey.  
RECALLED BY UDL Laboratories, Inc., Rockford, Illinois, by  
letter dated January 2, 1997. Firm-initiated  
recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY (a) 2,614 unit cartons: (b) 180 unit cartons  
were distributed; firm estimated that 40% of  
the 5 mg and 75% of the 25 mg product remained  
on market at time of recall initiation.  
REASON The particle size range of the bulk active  
ingredient is outside the normal range and  
could cause the product to fail the content

uniformity test.

None Present

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

NSN 6505 Nonstandard  
PRODUCT Cefaclor, USP; Clindamycin Phosphate; and, Minocycline HCl, Rx active pharmaceutical ingredients. Recall #D-113/115-7.  
CODE All lots distributed since 1993.  
MANUFACTURER Biochimica Opos, Italy, a wholly-owned subsidiary of Roussel Uclaf.  
RECALLED BY Roussel Corporation, Montvale, New Jersey, by letter dated November 19, 1996. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide and Puerto Rico.  
QUANTITY Cefaclor - 80,645.3kg; Clindamycin - 17,758.6kg; Minocycline - 21,269.1kg.  
REASON Discrepancies between the filed and actual manufacturing process (Roussel has voluntarily withdrawn their application).

None Present

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

NSN 6505 Nonstandard  
PRODUCT E-Z-EM brand Liquid Polibar, Barium Sulfate Suspension, in 64 fluid ounce bottles, Rx product for use as radiological contrast media for upper and lower gastrointestinal procedures by conventional x-ray or computed tomography. Recall #D-090-7.  
CODE Catalog Number L164, Lot numbers: 1B8687, 1B8688 and 1B8689 EXP 1/97.  
MANUFACTURER Therapex, Division of E-Z-EM Canada, Inc., Quebec, Canada.  
RECALLED BY E-Z-EM, Inc., Westbury, New York, by letter mailed on December 30, 1996. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 367 cases of lot 1B8687; 402 cases of lot 1B8688, 318 cases of lot 1B8689 (4 bottles per case) were distributed.  
REASON Product is not stable (failed total solids and barium content assays on stability).

None Present

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

NSN 6505 Nonstandard  
PRODUCT Dihistine and Phenhist Cough Suppressant,  
decongestant, and expectorant (Codeine  
Phosphate, 10 mg, Pseudoephedrine  
Hydrochloride, 30 mg, and Guaifenesin, 100 mg,  
in 1 pint and 4 fluid ounce jars, under the  
Barre and Rugby labels. Recall #D-092-7.  
CODE Lot numbers: RL6623 EXP 6/98; RJ6420 EXP  
9/98; RJ6468 EXP 7/98; RH6352, EXP 6/98;  
RF6267, EXP 5/98; RD6220 EXP 4/98; RB6055 EXP  
4/98; RS5835 EXP 3/98; RS5836 EXP 3/98; RP5735  
EXP 12/97; RN5638 EXP 11/97; VJ5417 EXP 7/97;  
VC5185 EXP 6/97; VD5227 EXP 6/97; VB5081 EXP  
6/97.  
MANUFACTURER Alpharma (Barre-National), Baltimore,  
Maryland.  
RECALLED BY Manufacturer, by letter dated January 7, 1997.  
Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 236,376 units were distributed; firm estimated  
that 9,922 units of the 4-ounce and 5,530  
units of the 16-ounce units remained on market  
at time of recall initiation.  
REASON Product is not stable; failing potency assay  
for codeine phosphate at the 12-month  
stability timepoint (88%; SPEC is 90-110%).

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

NSN 6505 Nonstandard  
 PRODUCT Guiatuss DAC, a sugar-free cough suppressant, decongestant, and expectorant (codeine-phosphate, 10 mg; Pseudoephedrine Hydrochloride, 30 mg, and Guaifenesin, 100 mg), in one pint jars, under the following labels Barre-National, Rugby, Schein, URL. Recall #D-093-7.

CODE Lots numbers and EXP dates: RA5029 01/97, RB5090 03/97, RC6180 03/98, RD5320 05/97, RL5606 09/97, RJ5430 07/97, VP5744/ 12/97.

MANUFACTURER Alpharma (Barre-National, Baltimore, Maryland.  
 RECALLED BY Manufacturer, by letter on January 14, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.  
 QUANTITY 257,604 units were distributed; firm estimated that 19,470 units remained on the market at time of recall initiation.

REASON Product is not stable; failing potency assay for codeine phosphate at the 18-month stability timepoint (89%; SPEC is 90-110%).

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

NSN 6505 Nonstandard  
 PRODUCT Lidocaine Hydrochloride Oral Topical Solution USP 2% (Viscous) in 100 ml bottles, indicated for the production of topical anesthesia of irritated or inflamed mucous membranes of the mouth and pharynx, and is also useful for reducing gagging during the taking of x-ray pictures and dental impression, under the following labels: Moore, Barre, Rugby, Schein. Recall #D-095-7.

CODE All lots within expiration date to include:  
 RA4023, EXP 4/97, RA4024, EXP 4/97  
 RF4314, EXP 6/97, RH4393, EXP 7/97  
 RK4524, EXP 10/97, RN4662, EXP 11/97  
 RS4788, EXP 12/97, VS4825, EXP 4/98  
 VH5350, EXP 8/98, VJ5437, EXP8/98  
 RL5571, EXP 9/98, RN5664, EXP 11/98  
 RP5752, EXP 12/98, RA6019, EXP 1/99  
 RB6062, EXP 3/99, RC6136, EXP 4/99  
 RC6181, EXP 4/99, RF6316, EXP 7/99.

MANUFACTURER Alpharma (Barre-National), Baltimore, Maryland.  
 RECALLED BY Manufacturer, by letter on January 7, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.  
QUANTITY 1,806,492 units were distributed; firm  
estimated that 26,027 units remained on market  
at time of recall initiation.  
REASON Product fails specification for viscosity on  
stability at the 18-month timepoint (523CPS;  
SPEC is 650CPS - 6000CPS).

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

NSN 6505 Nonstandard  
PRODUCT Esimil, Guanethidine Monosulfate, USP, 10 mg,  
Hydrochlorothiazide, USP, 25 mg 100  
tablets/bottle, a prescription  
antihypertensive-diuretic combination drug  
product for oral administration in the  
treatment of hypertension. CIBA also markets  
the active ingredients in Esimil tablets as  
monotherapy under the brand names Ismelin 10  
mg (Guanethidine Monosulfate, USP) tablets and  
Esidrix 25 mg (Hydrochlorothiazide USP)  
tablets. Recall #D-097-7.

CODE LOT # 1T175538 EXP MAY 00.  
MANUFACTURER CIBA Pharmaceuticals, Suffern, New Jersey.  
RECALLED BY CIBA Pharmaceuticals, Summit, New Jersey, by  
letter mailed on September 13, 1996. Firm-  
initiated recall ongoing.

DISTRIBUTION Nationwide.  
QUANTITY 12,767 bottles were distributed.  
REASON Product fails dissolution for  
Hydrochlorothiazide at the 12-month stability  
timepoint (55%; SPEC is not less than 60%  
after 30 minutes).

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

NSN 6505 Nonstandard  
PRODUCT Thorazine (Chlorpromazine) Syrup, 10 mg/5 ml  
Oral Liquid, in 4 ounce amber glass bottles,  
indicated for the management of manifestations  
of psychotic disorders. Recall #D-098-7.  
CODE Lot #X1-5T72J EXP 3/31/97.  
MANUFACTURER SmithKline Beecham Pharma, Inc., Cidra, Puerto  
Rico.  
RECALLED BY Manufacturer, by letter dated January 10,

1997. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 4,439 bottles were distributed.  
REASON Dissolution failure of potency specification at the 18-month stability timepoint (94.8%; SPEC is 95-105%).

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

NSN 6505 Nonstandard  
PRODUCT Butisol Sodium (butabarbital sodium) Tablets, 100 mg, Rx indicated for use as a sedative/hypnotic. Recall #D-099-7.  
CODE Lot numbers: 3E02T and 3E02U (common bulk lot 3E02).  
MANUFACTURER Wallace Laboratories, Decatur, Illinois.  
RECALLED BY Carter-Wallace, Inc., Cranbury, New Jersey, by telephone starting August 6, 1996, followed by fax. Firm-initiated recall complete.  
DISTRIBUTION Nationwide.  
QUANTITY 2,560 bottles were distributed; firm estimates none remains on the market.  
REASON Failure at the 6-month stability timepoint (67%; SPEC is not less than 75%).

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

NSN 6505 Nonstandard  
PRODUCT Augmentin (Amoxicillin Trihydrate 200 mg and Clavulanate Potassium 28.5 mg) Chewable Tablets, 20 tablets per pack, Rx antibacterial. Recall #D-100-7.  
CODE Lot #DC2981 EXP 9/31/97.  
MANUFACTURER SmithKline Beecham Pharmaceuticals, Bristol, Tennessee.  
RECALLED BY SmithKline Beecham Pharmaceuticals, Philadelphia, Pennsylvania, by letter dated December 31, 1996. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide and Puerto Rico.  
QUANTITY 19,440 packages were distributed.  
REASON Product is not stable due to a poor seal on the blister pack (amoxicillin may be as low as 84% at the 6-month stability timepoint; Clavulanate may be as low as 0% at the 6-month

stability timepoint).

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

NSN 6510 Nonstandard  
PRODUCT Ferris PolyMem Membrane Dressing, 3" x 3"  
Sterile Pad, a non-adhesive sterile wound  
dressing. Recall #Z-238-7.  
CODE Product #5033, Lot #27696E1.  
MANUFACTURER Ferris Manufacturing Corporation, Burr Ridge,  
Illinois.  
RECALLED BY Manufacturer, by letter dated November 12,  
1996. Firm-initiated recall complete.  
DISTRIBUTION Nationwide and The Netherlands.  
QUANTITY 62 cases were distributed.  
REASON Some of the pouches were mislabeled as,  
"Ferris PolyMem 2" x 3" dressings with  
transparent adhesive film borders, Product No.  
405".

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

URGENT VOLUNTARY WITHDRAWAL

BAXTER HEALTHCARE/HYLAND CORP HAS ISSUED A VOLUNTARY WITHDRAWAL  
FOR THE FOLLOWING MATERIEL:

NSN: 6505 NONSTANDARD  
PRODUCT: IMMUNE GLOBULIN INTRAVENOUS, HUMAN 10 GM,  
GAMMAGARD S/D 10 GM

NDC: F00944262004  
MANUFACTURER: BAXTER HEALTHCARE/HYLAND  
LOT/SERIAL NUMBER:

2620D079AA	2620D082AA
2620D084AA	2620D087AA
2620D087AB	2620D089AA
2620D111AA	2620E043AA

NSN: 6505-00-559-5807  
PRODUCT: ALBUMIN HUMAN 25% 50 ML, HEAT TREATED  
TRADE NAME: BUMUNATE

NDC: F00944049002  
MANUFACTURER: BAXTER HEALTHCARE/HYLAND  
LOT/SERIAL NUMBER:

2824D003AA	2837D242AA
2837D262AA	2837D266AA

NSN: 6505 NONSTANDARD  
PRODUCT: ALBUMIN HUMAN 25% 100 ML  
TRADE NAME: BUMINATE  
NDC: F00944049003  
MANUFACTURER: BAXTER HEALTHCARE/HYLAND  
LOT/SERIAL NUMBER:  
2837D243AA

NSN: 6505-00-680-2137  
PRODUCT: ALBUMIN HUMAN 5% 250 ML  
TRADE NAME: BUMINATE  
NDC: F00944049101  
MANUFACTURER: BAXTER HEALTHCARE/HYLAND  
LOT/SERIAL NUMBER:  
2924283AA 2924D150AA  
2924D156AA 2924D182AA  
2924D184AA 2924D218AA  
2924D219AA 2924D220AA

NSN: 6505 NONSTANDARD  
PRODUCT: ALBUMIN HUMAN 5% 500 ML  
TRADE NAME: BUMINATE  
NDC: F00944049102  
MANUFACTURER: BAXTER HEALTHCARE/HYLAND  
LOT/SERIAL NUMBER:  
2924D154AA 2924D155AA

REASON: TWO HEALTHY VOLUNTEER DONORS, WHO CONTRIBUTED TO  
THE POOL OF PLASMA, FROM WHICH THE FOLLOWING  
MATERIEL WAS PROCESSED ARE CONSIDERED TO BE AT  
INCREASED RISK FOR CREUTZFELDT-JAKOB DISEASE (CJD)  
AS A RESULT OF POST DONATION INFORMATION.

ALL BAXTER HEALTHCARE MATERIEL SHOULD BE RETURNED TO PLACE OF  
PURCHASE FOR CREDIT/REPLACEMENT. YOU MUST HAVE A RETURN  
AUTHORIZATION FORM. FOR FURTHER ASISTANCE, CONTCT BAXTER/HYLAND  
CUSTOMER SERVICE/RECALL COORDINATOR AT: 1-800-423-2090/1-800-833-  
7405 OR (908) 905-7689.

THIS CONFIRMS Q. A. MESSAGE 7051-0003.

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