

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 17728

PRODUCT

Information Systems, Bloodbank

Defense Blood Standard System (DBSS), Blood Bank Software.

Recall #B-1094-9.

CODE

Software Versions 3.00 and 3.01.

MANUFACTURER

Electronic Data Systems (EDS), Herndon, Virginia.

RECALLED BY

U.S. Department of Defense (DBSS)\Composite Health Care System 2, Falls Church, Virginia, by E-mail on June 9 and 16, 1999. Firm-initiated field correction ongoing.

DISTRIBUTION

Nationwide and international.

QUANTITY

Utilized at 78 sites.

REASON

Blood bank computer software does not identify all potential duplicate donor records.

None Present

Action Taken _____

6525 NS

MDC 11757

PRODUCT

X-Ray/Fluoro Units, Fixed

Uro-View X-Ray Imaging Systems: a) Model 2600; b) Model 2500; c) Model 2000. Recall #Z-1156/1158-9.

CODE

None.

MANUFACTURER

OEC Medical Systems, Inc., Salt Lake City, Utah.

RECALLED BY

Manufacturer, by letter July 19, 1999. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide and international.

QUANTITY

951 units were distributed.

REASON

The leg extension can become disengaged and cause a patient to slide to the floor.

None Present

Action Taken _____

6525 NS

MDC 15944

UPDATE

Cameras, Gamma

Millennium VG Neuclear Medicine Scanner and Varicam Neuclear Medicine Scanner, Recall #Z-745/747-9 which appeared in the April 7, 1999 Enforcement Report should read:

CODE: Millennium VG or Varicam Systems with serial numbers below 10000 (ten thousand) except for the following list:

1001, 1756, 1839, 1840, 1890, 1891, 3010, 5008.

None Present

Action Taken _____

6530 NS
MDC 17148
PRODUCT

Oximeters, Pulse

NPB-190 and NPB-195 Pulse Oximeter, Rx, intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin and pulse rate for use on adult, pediatric, and neonatal patients in hospital and home environments. Recall #Z-1154/1155-9.

CODE
MANUFACTURER
RECALLED BY

All units produced prior to October 9, 1998.
Nellcor Puritan Bennett, Inc., Mervue, Galway, Ireland.
Mallinckrodt, Inc., Hazelwood, Missouri, by letter on May 17, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
9,001 units were distributed.
The devices fail to alarm when a pulse oximetry sensor became disconnected from the patient.
[] 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 **01 Oct 99** for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DSCP 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
PRODUCT
CODE
MANUFACTURER
RECALLED BY
DISTRIBUTION
QUANTITY
REASON

6505 Nonstandard
Erythromycin Ophthalmic Ointment, USP, 0.5%, Rx, in 3.5 g tubes.
Recall #D-299-9.
Lot #065151 EXP 5/00.
Bausch & Lomb Pharmaceuticals, Inc., Tampa, Florida.
Manufacturer, by letter mailed on July 22, 1999, followed by letter and telephone. Firm-initiated recall ongoing.
Nationwide.
49,968 units were distributed.
Product mix-up - Correctly labeled Muro 128/E Ointment tube (sodium chloride 5%) found in carton of erythromycin product.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Lonox Tablets (Diphenoxylate HCL, USP 2.5mg / Atropine Sulfate, USP 0.025mg) in 100 and 1,000 tablet bottles, Rx combination ingredient tablet for the management of diarrhea. NDC# 0781-1262-01 (100's) and 0781-1262-10 (1000's). Recall #D-303-9.
CODE Lot #10057 EXP 09/01.
MANUFACTURER Geneva Pharmaceuticals, Inc., Broomfield, Colorado.
RECALLED BY Manufacturer, by letter on August 2, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 5,880,500 tablets were distributed.
REASON Subpotency.
 None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Generic inhalatin solutions sold as Rx drugs under the DEY label:
a) Albuterol Sulfate Inhalation Solution, 0.083%, in 3 mL vials, Sterile, Unit Dose, indicated for the relief of bronchospasm in patients 2 years and older with reversible obstructive airway disease and acute attacks of bronchospasm. NDC 49502-697-03 = 25 vials/carton
NDC 49502-697-33 = 30 vials/carton
NDC 49502-697-60 = 60 vials/carton;
b) Ipratropium Bromide Inhalation Solution, 0.02%, in 2.5 mL vials, Sterile, Unit Dose, indicated as a bronchodilator for maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema. NDC 49502-685-03 = 25 vials/carton, NDC 49502-685-33 = 30 vials/carton
NDC 49502-685-60 = 60 vials/carton. Recall #D-307/308-9.
CODE a) 227 multile lots with EXP dates ranging from 08/99 to 02/01;
b) 223 multiple lots with EXP dates ranging from 01/00 to 09/00.
MANUFACTURER Dey, LP, Napa, California.
RECALLED BY Manufacturer, by letter dated July 27, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY Aproximately 110 million vials of Albuterol Sulfate Solution and 84 million vials of Ipratropium Bromide Inhalation Solution were distributed.
REASON Contamination - Impurity from packaging material (1-Phenoxy-2 Propranol).
 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Medrad Counterpoise System Product Number 75-4000-033.
Recall #Z-957-9.
CODE All Product Manufactured between May 1995 and February 1999.
MANUFACTURER F. Walter Hanel GMBH DBA MAVIG, Munich, Germany.

RECALLED BY Medrad, Inc., Indianola, Pennsylvania, by letter dated May 14, 1999. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY Approximately 1,004 units were distributed.
REASON Dowel pins used in support assembly have potential to back out of position.
 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Screwdriver Blade - Self-Retaining: a) Part 313.922;
CODE b) Part 313.923. Recall #Z-958/959-9.
Lot numbers: a) A4GD466, A4GE246 THRU 251, A4GI665 THRU 666, A4GI985 THRU 986, A4GK114 THRU 116, A4GL610 THRU 934, A4GL985 THRU 986, A4GM750 THRU 751, A4GO312 THRU 313, A4GO695 THRU 696, A4HC274, A4HD827, A4HG576, A4HG670 THRU 672, A4HM425, A4HM603, A4HM622 THRU 624, A4HS178 THRU 180, A4HT467, AND A4HV276; b) A4GE252 THRU 257, A4GL935 THRU 945, A4GP231, A4GP617, A4GQ563, A4HA221, A4HA703, A4HC275 THRU 276, A4HJ489, AND A4HM604 THRU 610.
MANUFACTURER Synthes (USA), West Chester, Pennsylvania.
RECALLED BY Synthes USA, Paoli, Pennsylvania, by letter sent on December 8, 1998, followed by telephone or visit. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and Canada.
QUANTITY 4,391 units were distributed.
REASON The inspection technique used to inspect the blades had the potential to miss some non-conforming blades. In addition, a tolerance issue was noted between screwdrivers with blades on the lower end of the spec and screw slots on the upper end of the spec.
 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Holding Sleeve Part #314.06. Recall #Z-960-9.
CODE Lot numbers: A4HM912, A4HQ981, A4HR969, A4HT934, A4HU333, A4HX551, A4HY193, A4HZ523, and A4JA239.
MANUFACTURER Synthes (USA), West Chester, Pennsylvania.
RECALLED BY Synthes USA, Paoli, Pennsylvania, by letter sent on February 16, 1999, followed by telephone or visit. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 286 units were distributed.
REASON An operation for crimping the back end of the sleeve was not on
 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Wire Tensioner, Part #393.742. Recall #Z-963-9.
CODE Lot numbers: 1008, 1009, 1011 THRU 1018, 1000027, 1000028, 1001644, 1003894.
MANUFACTURER Synthes (USA), Monument, Colorado.

RECALLED BY Synthes USA, Paoli, Pennsylvania, by letter sent on November 16, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide, Canada, Switzerland.
 QUANTITY 512 units were distributed.
 REASON The wire tensioner may or may not accept a 2.0 mm guide wire.
 None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
 PRODUCT Riopan Plus Suspension, OTC buffer antacid plus anti-gas combination:
 a) Riopan Plus Suspension, Antacid & Anti-Gas, in 12 fluid ounce bottles. NDC #0573-3210-20;
 b) Riopan Plus; Double Strength Suspension Antacid & Anti-Gas, in 12 fluid ounce bottles. NDC #0573-3220-20.
 Recall #D-300/301-9.

CODE The following represent all lots currently on the market:
 (a) 3971121 EXP 7/99 3971879 EXP 8/99
 3971960 EXP 9/99 3972064 EXP 11/99
 3981108 EXP 1/00 3981542 EXP 1/00
 3981330 EXP 3/00 3981358 EXP 4/00
 3981670 EXP 6/00 3981596 EXP 7/00
 3982317 EXP 8/00 3982318 EXP 9/00
 3981746 EXP 9/00 3982341 EXP 10/01
 (b) 3971123 EXP 7/99 3971124 EXP 8/99
 3971961 EXP 10/99 3971880 EXP 10/99
 3971965 EXP 12/99 3981109 EXP 1/00
 3981465 EXP 1/00 3981331 EXP 2/00
 3981673 EXP 2/00 3981574 EXP 3/00
 3981349 EXP 4/00 3982023 EXP 5/00
 3982024 EXP 5/00 3982134 EXP 6/00
 3981376 EXP 6/00 3981598 EXP 7/00
 3982319 EXP 8/00 3982320 EXP 8/00
 3982321 EXP 9/00 3981747 EXP 9/00
 3982322 EXP 10/01.

MANUFACTURER Wyeth-Ayerst Laboratories, Rouses Point, New York.
 RECALLED BY Whitehall-Robins Healthcare, Richmond, Virginia, by letter dated June 30, 1999. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 1,421,000 bottles have been distributed between August 1997 and June 1999.
 REASON Mislabeling - Label declares preservatives not in product- Methylparaben, Propylparaben, Citric Acid, and Benzyl Alcohol.
 None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Losopan Antacid (Magaldrate Oral Suspension Antacid 540 mg/5mL, in 12 fluid ounce bottles, OTC indicated for the relief of heartburn, sour stomach and/or acid indigestion and upset stomach associated with these symptoms.
 NDC #0182-6078-39. Recall #D-302-9.
 CODE Lot #81235 EXP 12/00.

| | |
|------------------------------------|--|
| MANUFACTURER RECALLED BY | RIJ Pharmaceutical Corporation, Middletown, New York. Manufacturer, by letter and fax dated July 21, 1999. Firm- initiated recall ongoing. |
| DISTRIBUTION QUANTITY REASON | Kentucky. 5,208 bottles were distributed. Mislabeling - Some bottles bear an incorrect antacid back label (Goldline Genaton(tm)). <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____ |
| NSN PRODUCT | 6505 Nonstandard Indapamide 2.5 mg Tablets, in 100 and 1,000 tablet bottles, oral diuretic indicated for the treatment of hypertension, alone or in combination with other antihypertensive drugs. It is also indicated for the treatment of salt and fluid retention associated with congestive heart failure. This product is labeled under the firm's generic name Arcola. NDC 0070-3000-00 for the 100 count bottles and NDC 0070-3000-99 for the 1000 count bottles. Recall #D-306-9. |
| CODE | Lot #MN3386 EXP 11/02 (bottles of 100) Lot #MN3396 EXP 11/02 (bottles of 1000). |
| MANUFACTURER RECALLED BY | Rhone Poulenc Rorer Puerto Rico, Inc., Manati, Puerto Rico. Rhone Poulenc Rorer Pharmaceuticals, Collegeville, Pennsylvania, by letter dated July 9, 1999. Firm-initiated recall ongoing. |
| DISTRIBUTION QUANTITY | Nationwide and the Caribbean. 32,106 bottles of Lot MN3386 and 35,986 bottles of Lot MN3396 were distributed nationwide. 3,024 bottles of Lot MN3386 were sent to RPR Caribbean; firm estimates that very little of the two lots are left in commercial channels. |
| REASON | Dissolution failure. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____ |
| NSN PRODUCT | 6505 Nonstandard Albumin (Human) 25%, 50 mL, Plasbumin-25 brand; b) Albumin (Human) 5%, 250 mL, Plasbumin-5 brand. Recall #B-1119/1120-9. |
| CODE | a) Lot 684R066; b) Lot 685R048. |
| MANUFACTURER RECALLED BY | Bayer Corporation, Clayton, North Carolina. Manufacturer, by fax and letter on September 25, 1998. Firm-initiated recall ongoing. |
| DISTRIBUTION | Arizona, California, Florida, Illinois, Indiana, Kentucky, Minnesota, New Jersey, Pennsylvania, South Carolina, Tennessee, Texas, Washington state. |
| QUANTITY | a) 16,467 vials; b) 7,493 vials were distributed. |
| REASON | Testing found that two lots of Albumin had Prekallikrein Activator (PKA) levels which exceeded that allowed by the product's licenses. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____ |
| NSN PRODUCT | 6505 Nonstandard Red Blood Cells. Recall #B-1142-9. |

| | |
|--------------|---|
| CODE | Unit #22397-9341. |
| MANUFACTURER | Blood Services, Inc., Las Vegas, California. |
| RECALLED BY | Blood Systems, Inc., Scottsdale, Arizona, by letter dated July 16, 1998. Firm-initiated recall ongoing. |
| DISTRIBUTION | Nevada. |
| QUANTITY | 1 unit was distributed. |
| REASON | Blood product was collected from a donor who reported having lived in an area designated as endemic for malaria. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____ |
| NSN | 6515 Nonstandard |
| PRODUCT | 1.3 mm Box Plate: a) Part #421.095; b) Part #421.096. Recall #Z-961/962-9. |
| CODE | Lot numbers: a) A3LX014; b) A3LX015. |
| MANUFACTURER | Synthes (USA), Monument, Colorado |
| RECALLED BY | Synthes USA, Paoli, Pennsylvania, by letter sent on September 1, 1998, followed by telephone or visit. Firm-initiated recall ongoing. |
| DISTRIBUTION | California, Florida, Georgia, Kansas, Kentucky, Michigan, Minnesota, Missouri, North Carolina, New Jersey, Ohio, Oregon, Pennsylvania, Texas, Utah, Virginia, and one international account. |
| QUANTITY | 144 units were distributed. |
| REASON | Plates were switched during processing resulting in a 5x10 mm box plated labeled as a 10x10 mm box plate and vice versa. 5x10 mm is part #421.095 and 10x10 mm is part #421.096. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____ |
| NSN | 6515 Nonstandard |
| PRODUCT | 7.0 mm Cannulated Screw, 32 mm Thread, 70 mm Length. Recall #Z-964-9. |
| CODE | Part #209.070, Lot #3008307. |
| MANUFACTURER | Synthes (USA), Monument, Colorado. |
| RECALLED BY | Synthes USA, Paoli, Pennsylvania, by letter sent on November 23, 1998, followed by telephone or visit. Firm-initiated recall ongoing. |
| DISTRIBUTION | Nationwide and Canada. |
| QUANTITY | 94 units were distributed. |
| REASON | Package is labeled as 7.0 mm cannulated screw, 32 mm thread, 70 mm length. Package actually contains a 7.0 mm cannulated screw, 16 mm thread, 70 mm length. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____ |
| NSN | 6515 Nonstandard |
| PRODUCT | Synthes (USA) Midfacial System. Recall #Z-965-9. |
| CODE | Part #450-611, Lot #A31D232. |
| MANUFACTURER | Synthes (USA), Monument, Colorado. |
| RECALLED BY | Synthes USA, Paoli, Pennsylvania, by letter sent on February 4, 1999, followed by telephone or letter. Firm-initiated recall ongoing. |

| | |
|--------------|---|
| DISTRIBUTION | California, Florida, Maryland, Pennsylvania. |
| QUANTITY | 61 units were distributed. |
| REASON | The device was anodized gold instead of greengray. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ |
| | |
| NSN | 6515 Nonstandard |
| PRODUCT | Extraction Bolts for 3.5/4.0 screws. Recall #Z-966-9. |
| CODE | Part Number 309.039 - Lot Numbers: 3919791 and 3915138. |
| MANUFACTURER | Synthes (USA), Monument, Colorado. |
| RECALLED BY | Synthes USA, Paoli, Pennsylvania, by letter sent on March 4, 1999, followed by telephone or visit. Firm-initiated recall ongoing. |
| DISTRIBUTION | Nationwide. |
| QUANTITY | 43 units were distributed. |
| REASON | Extraction bolts were mismatched with 6.5/7.0 instead of 3.5/4.0 |
| NSN | 6515 Nonstandard |
| PRODUCT | Intermediate Hi-Lo Pre-Cut Tracheal Tube with Stylet, for airway management by oral intubation of the trachea. |
| CODE | Recall #Z-1143-9. |
| MANUFACTURER | Catalog #86118, Lot #M032120. |
| RECALLED BY | MMJ SA de CV (Mallinckrodt Medical), Juarez, Mexico. Mallinckrodt, Inc., St. Louis, Missouri, by letter dated June 9, 1999. Firm-initiated recall ongoing. |
| DISTRIBUTION | California, Utah, Minnesota. |
| QUANTITY | 250 units were distributed. |
| REASON | The incorrect stylet was used and is too long, extending beyond the tip of the tube. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ |
| | |
| NSN | 6515 Nonstandard |
| PRODUCT | CPI Endotak DSP Implantable Leads: a) Model 0095; b) Model 0125. Recall #Z-1144/1145-9. |
| CODE | All serial numbers less than 230000. |
| MANUFACTURER | Guidant Corporation, St. Paul, Minnesota. |
| RECALLED BY | Manufacturer, by letter. Firm-initiated action consists of providing instructions for detecting and preventing lead insulation damage which could affect some leads. Action is ongoing. |
| DISTRIBUTION | Nationwide and international. |
| QUANTITY | 45,500 were distributed, |
| REASON | The lead is bent sharply away from the header block, the integrity of the lead and/or lead insulation can be compromised. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ |
| | |
| NSN | 6515 Nonstandard |
| PRODUCT | Alcon Surgical Procedure Packs Custom Pak: |
| CODE | a) Product #4345-12; b) #6899-03. Recall #Z-1161/1162-9. |
| MANUFACTURER | a) Lot Code 95801H; b) Lot Code 97286H. Alcon Laboratories, Houston, Texas. DeRoyal, Rose Hill Virginia (light handle covers). |

RECALLED BY Alcon Laboratories, Inc., Fort Worth, Texas, by letter on July 15, 1999. Firm-initiated recall ongoing.
DISTRIBUTION California and Florida.
QUANTITY a) 8 units; b) 10 units were distributed.
REASON Light handle covers did not fit properly onto the light handle. Further, the poor fit might cause the light handle cover to be too loose which might result in the cover falling off the handle in the sterile field or cause the cover to be too tight which might result in the cover splitting during use.
 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Bio-Interference Screw, 8mm size. Recall #Z-1113-9.
CODE Model 1380B, Lot #13258.
MANUFACTURER Arthrex Arthroscopy Instruments, Inc., Naples, Florida.
RECALLED BY Manufacturer, by letters mailed on April 29, 1999 and early June 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Canada.
QUANTITY 1,786 units were distributed.
REASON Screws may crack during insertion.
 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Pedicle Screw is a component of the VSP Spinal Fixation System. Recall #Z-1114-9.
CODE Product Code: 2226-2835, Lot S4578.
MANUFACTURER Depuy Acromed, Raynham, Massachusetts.
RECALLED BY Manufacturer, by fax July 12, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Colorado, Australia, Austria, Italy, and Hong Kong.
QUANTITY 118 units.
REASON The device was incorrectly labeled 6.25 mm diameter/titanium vs. actual product 7.0 mm stainless.
 None Present
 Action Taken _____

NSN 6545 Nonstandard
PRODUCT Various First Aid Kits containing the suspect Povidone-Iodine Pads labeled in part:
1)SAWYER PRODUCTS REMOTE EMERGENCY FIRST AID KIT-NOTE- There is no item number on this product.
2) SAWYER PRODUCTS EMERGENCY FIRST AID KIT**ADVANCED FIRST AID CAPABILITIES**Techniques Preferred by PARAMEDICS & EMERGENCY ROOMS**-NOTE-There is no item number on this product.
3) Sawyer Products FIRST AID TO GO WITH BELT LOOPS ITEM #SP903
4) SAWYER PRODUCTS FIRST AID IN A POUCH**SP905
5) Sawyer Products FIRST AID in a Pouch**10-15 person days**Item #TG905**
6) Sawyer Products FAMILY PACK**ITEM #SP909**
7) Sawyer Products Family First Aid**15-25 person days**Item #

TG910**

- 8) Sawyer Products FAMILY PACK LEVEL 300 **ITEM # SP910**
- 9) SAWYER INTERMEDIATE FIRSTAID KIT Designed for those who know BASIC FIRST AID ITEM # SP910
- 10) SAWYER PRODUCTS GROUP PACK Item # SP925**
- 11) Sawyer Products First Aid Kit**LEVEL 500**For Multi-person excursions and expeditions and for team sports
Item # SP926
- 12) Sawyer Products WOUND CARE module Item #SP932**
- 13) Sawyer Products LARGE WOUND CARE module Item # SP 933
- 14) Sawyer Products FOOT CARE module for prevention and treatment of blisters Item #SP934
- 15) Sawyer Products HUNTING AND FISHING First Aid Kit ITEM #951
- 16) Sawyer Products LEVEL 600 First Aid Kit Item # SP961
- 17) Sawyer Products LEVEL 700 First Aid Kit Item # SP962
- 18) Sawyer Products First Aid Kit DRYBAG Triple Protection of First Aid Supplies Against Exposure to Water Damage** Item # SP973
- 19) Sawyer First Aid Kit WATERPROOF EXCELLENT FOR WATER TRIPS
Item SP 981
- 20) Sawyer Products FIRST AID watertight case Item #SP985**
- 21) Sawyer Products FIRST AID to go Note: no item number listed on label
- 22) Sawyer Products pocket First Aid Item # SP993.
Recall #Z-1120/1141-9.

CODE

The first aid kits are not coded. Kits were shipped out to direct accounts from 2/1/98 through 4/30/99.

MANUFACTURER
RECALLED BY

SAFFETA, Inc., Safety Harbor, Florida.
SAFFETA, Inc., doing business as Sawyer Products, Inc., Safety Harbor, Florida, by letter sent beginning July 23, 1999. Firm-initiated field correction ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and Hong Kong.
35,672 kits that may have the subject pads were distributed.
The kits may contain non-sterile Povidone Iodine pads.
 None Present
 Action Taken _____