

**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 12364

PRODUCT

CODE

MANUFACTURER

RECALLED BY

DISTRIBUTION

QUANTITY

REASON

Linear Accelerators

Mitsubishi Product No. EXL-150 OP Linear Accelerator Patient Couch, uses electronically produced radiation to treat various types of cancers. Recall #Z-557-8.

Serial #4511.

Mitsubishi Electric Corporation, Amagaski City, Hyogo, Japan.

Mitsubishi Electronics America, Somerset, New Jersey, by telephone on October 23, 1997. Firm-initiated recall ongoing.

New York.

1 unit was distributed.

The motor stop functions cannot be controlled via the couch button release, and the "stop" circuit is disabled when the drive unit cover microswitch is actuated, possibly causing patient injury.

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 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 6 July 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). (AFMLO/FOM-P, Mrs. Bonnie Phillips, DSN 343-4170)

CLASS I RECALLS:

NSN 6505 Nonstandard
PRODUCT Kendall Healthcare Products brand Modudose, 0.9% Sodium Chloride (saline Solution), single use vial for respiratory therapy, in 1.5, 3, and 5 mL vials. Reorder 5251 - NDC 50738-010-18; Reorder 5257 - NDC 50738-010-19; Reorder PR5251 - NDC 50738-010-18.
Recall #D-120-8.
CODE All lot numbers.
MANUFACTURER Kendall Healthcare Products Company, Ocala, Florida.
RECALLED BY Kendall Healthcare Products, Mansfield, Massachusetts, by press release on April 9, 1998, followed by letter April 10-13, 1998.
DISTRIBUTION Firm-initiated recall ongoing.
QUANTITY Nationwide and international.
REASON Product code numbers #5251 and #5257 - 41,946 cases and 6,851 cases respectively (1000 vials per case); Product code #PR5251 - 216 cases; Product code #0454 - 200 cases distributed.
Microbial contamination-Ralstonia Pickettii (formerly Bulkholderia Pickettii formerly Pickettii).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Premarin Tablets, (Conjugated Estrogens tablets, USP), Rx, 1.25 mg, repacked into 100 count bottles. NDC #0046-0866-81.
Recall #D-136-8.
CODE Lot #9971786 EXP 5/02.
MANUFACTURER Wyeth-Ayerst Laboratories, Philadelphia, Pennsylvania.
RECALLED BY National PharmPak Services, Inc., Zanesville, Ohio (repacker/responsible firm), by letter faxed on April 20, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 14,750 bottles were distributed.
REASON Mispackaging - Some units may contain Ceftin (Cephalosporin) 250 mg tablets (light blue colored).

None Present
 Action Taken _____

NSN 6505 Nonstandard _____
PRODUCT Levothroid (levothyroxine sodium tablets, USP), 100 mcg tablets, repackaged in 100 count bottles, indicated as replacement therapy for

diminished thyroid function resulting in hypothyroidism, distributed under the AHP American Health Packaging label.
NDC #0456-0323-01. Recall #D-137-8.
Lot #6667 EXP 11/99.
CODE
MANUFACTURER Forest Pharmaceuticals, Inc., St. Louis, Missouri.
RECALLED BY AmeriSource Health Services, doing business as American Health Packaging, Columbus, Ohio, by letter on April 21, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Virginia, Ohio, Kentucky, New Jersey, Tennessee, Massachusetts, Texas, New York, Florida.
QUANTITY 324 bottles were distributed.
REASON Dissolution failure.

None Present
 Action Taken _____

NSN
PRODUCT 6505 Nonstandard
Levothroid Tablets (Levothyroxine sodium tablets, USP), 100 mcg, in 5,000 tablet bottles, Rx, indicated as replacement therapy for diminished thyroid function resulting in hypothyroidism. NDC #0456-0323-51. Recall #D-138-8.
CODE
MANUFACTURER Lot #109732 EXP 11/99.
Forest Pharmaceuticals, Inc., Cincinnati, Ohio.
RECALLED BY Forest Pharmaceuticals, Inc., subsidiary of Forest Laboratories, Inc., St. Louis, Missouri, by letter on April 17, 1998. Firm-initiated recall ongoing.
DISTRIBUTION California, Illinois, New York, Ohio, Oregon.
QUANTITY 282 5,000-tablet bottles were distributed.
REASON Dissolution failure.

None Present
 Action Taken _____

NSN
PRODUCT 6505 Nonstandard
Levothroid (Levothyroxine Sodium Tablets USP), 100 mcg, repackaged in 100 count bottles, under the National PharmPak label, indicated as replacement therapy for diminished thyroid function resulting in hypothyroidism, NDC #0456-0323-01. Recall #D-139-8.
CODE
MANUFACTURER Lot #109732 EXP 11/99.
Forest Pharmaceuticals, Inc., St. Louis, Missouri (responsible firm).
RECALLED BY National PharmPak Services, Inc., Zanesville, Ohio (repacker), by fax on April 27, 1998, followed by telephone on April 28, 1998.

DISTRIBUTION Firm-initiated recall ongoing.
QUANTITY Nationwide.
REASON 2,485 bottles were distributed.
Dissolution failure.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Levothroid Tablets (Levothyroxine sodium, USP), 50 mcg, hospital unit dose blister strips, 10 tablets per strip, 10 strips per carton, Rx, for use as replacement or substitution therapy for diminished or absent thyroid function. Recall #D-142-8.
CODE Lot #69635 EXP 7/98.
MANUFACTURER Forest Pharmaceuticals, Inc., Cincinnati, Ohio.
RECALLED BY Forest Pharmaceuticals, Inc., subsidiary of Forest Laboratories, Inc., St. Louis, Missouri, by letters dated April 22 and 29, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 6,826 boxes were distributed.
REASON Subpotent (stability 18 month interval).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Armour Thyroid Tablets (Thyroid tablets, USP), 1 grain (60 mg), in 50,000 tablet drums, Rx for use as a replacement or supplemental therapy in patients with hypothyroidism. NDC #0456-0459-69. Recall #D-143-8.
CODE Lot #19813 EXP 10/98.
MANUFACTURER Forest Pharmaceuticals, Inc., Cincinnati, Ohio.
RECALLED BY Forest Pharmaceuticals, Inc., subsidiary of Forest Laboratories, Inc., St. Louis, Missouri, by letter on April 16, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Rhode Island, Arkansas, Wisconsin.
QUANTITY 8-50,000 drums were distributed.
REASON Tablets were found out of specification for weight and thickness.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Tesio Extender Adaptor used with the Tesio

Catheter. The catheter extender is connected after the catheter is inserted to allow for easier access during dialysis treatments, and is part of a hemodialysis access kit:

a) Part #MBR-6 Trays; b) Part #MBL-6 Trays.
Recall #Z-544/545-8.

CODE	MBL-6'S	EXP	MBR-6'S	EXP
	M726310	11/02	M722710	09/02
	M726320	11/02	M723740	10/02
	M726920	11/02	M724260	10/02
	M726930	11/02	M724350	10/02
	M727450	11/02	M724640	10/02
	M729700	12/02	M724680	10/02
	M800910	01/03	M724960	10/02
	M801550	01/03	M724980	10/02
	M801850	2003/01	M725160	10/02
	M801940	2003/01	M725170	10/02
	M726330	11/02	M726340	12/02
	M726350	12/02	M727900	11/02
	M727980	12/02	M729000	12/02
	M729430	12/02	M729540	12/02
	M729710	12/02	M729720	12/02
	M730050	01/03	M730730	01/03
	M800180	01/03	M800190	01/03
	M800900	01/03	M801870	2003/01.

MANUFACTURER Martech Medical Products, Inc., Harleysville, Pennsylvania (component).

RECALLED BY Medical Components, Inc. (MEDCOMP), Harleysville, Pennsylvania, by fax letter on March 24, 1998. Firm-initiated recall ongoing. See also FDA press release 98-11, dated March 27, 1998.

DISTRIBUTION California, Florida, Michigan, Minnesota, Missouri, New Jersey, Tennessee, Texas, Utah, Virginia, Washington, and international.

QUANTITY Approximately 7,000 kits were distributed.

REASON The extender may separate from the adaptor.

[] None Present

[] Action Taken _____

CLASS II RECALLS:

NSN 6505 Nonstandard
PRODUCT Various OTC products, distributed under generic and various brand names including Health Care, Pharmacy Classics, Personal Care, and Equality Health Care:
a) Liquid Antacid (Magnesium Hydroxide 200 mg/Aluminum Hydroxide 200 mg) in 12 fluid ounce bottles
b) Liquid Antacid with Simethicone (Magnesium Hydroxide 200 mg/Aluminum Hydroxide 200 mg/Simethicone 20 mg), in 12 fluid ounce bottles
c) Children's Acetaminophen Elixir (Acetaminophen 160 mg) cherry flavored in 4 fluid ounce bottles
d) Sore Throat Spray (Phenol 1.4%) alcohol/sugar free, in 6 fluid ounce bottles

- e) Children's Night Time (Dextromethorphan Hydrobromide 15 mg/Chlorpheniramine Maleate 2 mg/Pseudoephedrine Hydrochloride 30 mg), in 6 fluid ounce bottles
 - f) Nighttime(Nite Time) for Adults (Acetaminophen 1000 mg/Dextromethorphan Hydrobromide 30 mg/Doxylamine Succinate;
 - g) Pink Bismuth (Bismuth subsalicylate 262 mg/tablespoon) in 6 fluid ounce bottles
 - h) Pediatric Tussin (Dextromethorphan Hydrobromide 7.5 mg) in 4 fluid ounce bottles
 - I) Tussin Syrup/Tussin DM (Guaifenesin USP 100 mg/Dextromethorphan Hydrobromide USP 10 mg) in 4 fluid ounce bottles
 - j) Milk of Magnesia (Magnesium Hydroxide 400 mg) in 12 fluid ounce bottles.
- Recall #D-121/130-8.

CODE All lots on the market within expiration date.
 MANUFACTURER South Atlantic Industries, Inc., Greenville, South Carolina.
 RECALLED BY Manufacturer, by letter on or about April 1, 1998.
 DISTRIBUTION Firm-initiated recall ongoing.
 QUANTITY Michigan, Mississippi, North Carolina, Georgia,
 REASON California, Ohio, Illinois, New York.
 Undetermined.
 Lack of good manufacturing practice controls.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Child and Infant Bageasy Disposable Manual Resuscitators:
 a) Child Bageasy Manual Resuscitator
 Part/Catalog Part Number Description
 562042 Child BagEasy with Peep and Mask, Sample (Single)
 562043 Child BagEasy with Peep, Sample (Single)
 562044 Child BagEasy with Mask, Sample (Single)
 562045 Child BagEasy, Sample (Single)
 562052 Large Child BagEasy w/Peep and Mask Sample (Single)
 562053 Large Child BagEasy with Peep, Mask and 10 ft.
 562068 Large Child BagEasy with Mask & 10 ft. Tubing, Box of 12
 562069 Child BagEasy with Peep, Mask & 10 ft. Tubing, Box of 12
 562070 Child BagEasy with Peep and 10 ft. Tubing, Box of 12
 562071 Child BagEasy with Mask & 10 ft, tubing, Box of 12
 562072 Child BagEasy with 10 ft. Tubing, Box of 12

562080 Child BagEasy with Peep & Mask,
 Box of 12
 562081 Child BagEasy with Peep without
 Mask, Box of 12
 562082 Child BagEasy without Peep with
 Mask, Box of 12
 562083 Child BagEasy without Peep
 without Mask, Box of 12
 562132 Child/Large Child BagEasy with
 Mask, Box of 12
 562133 Child/Large Child BagEasy with
 Peep and Mask, Box of 12
 b) Infant Bageasy Manual Resuscitators
 Part/Catalog Part Number Description
 562046 Infant BagEasy with Peep and
 Mask, Sample (Single)
 562047 Infant BagEasy with Peep, Sample
 (Single)
 562048 Infant BagEasy with Mask, Sample
 (Single)
 562049 Infant BagEasy Sample (Single)
 562050 Neonatal/Infant BagEasy with Mask
 Sample (Single)
 562051 Neonatal/Infant BagEasy with Peep
 & Mask Sample (Single)
 562073 Infant BagEasy with Peep, Mask
 and 10 ft. Tubing, Box of 12
 562074 Infant BagEasy with Peep and 10
 ft. Tubing, Box of 12
 562075 Infant BagEasy with Mask and 10
 ft. Tubing, Box of 12
 562076 Infant BagEasy with 10 ft.
 Tubing, Box of 12
 562077 Neonatal/Infant BagEasy with Mask
 and 10 ft.
 562079 Neonatal/Infant BagEasy with
 Peep, Mask and 10 ft
 562084 Infant BagEasy with Peep and
 Mask, Box of 12
 562085 Infant BagEasy with Peep without
 Mask, Box of 12
 562086 Infant BagEasy without Peep with
 Mask, Box of 12
 562087 Infant BagEasy without Peep
 without Mask, Box of 12
 562110 Neonatal/Infant BagEasy with
 Mask, Box of 12
 562111 Neonatal/Infant BagEasy with Peep
 and Mask, Box of 12.
 Recall #Z-559/560-8.
 Lot Nos. A960521 through A971201.
 Respironics, Murrysville, Pennsylvania.
 Manufacturer, by telephone on December 5, 1997,
 followed by letter on December 8, 1997.
 Firm-initiated recall ongoing.
 Nationwide and United Arab Emirate.
 43,000 units were distributed.
 The duckbill valve sticks and will not allow the

CODE
 MANUFACTURER
 RECALLED BY

DISTRIBUTION
 QUANTITY
 REASON

caregiver to ventilate the patient.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Adult Bageasy Disposable Manual Resuscitators, all
types and models. Recall #Z-561-8
CODE A960521 through A971201 and B960521 through
B971201.
MANUFACTURER Respironics, Inc., Murrysville, Pennsylvania.
RECALLED BY Manufacturer, by letter on December 8, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 430,000 units were distributed.
REASON The duckbill valve sticks and will not allow the
caregiver to ventilate the patient.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT IVAC MedSystem III Administration Sets, Model
28080E. Recall #Z-549-8.
CODE Lot #801548.
MANUFACTURER Sistemas Medico Alaris, SA DE C.V., Tijuana,
Mexico.
RECALLED BY Alaris Medical Systems, Inc., San Diego,
California, by telephone and by letter on
April 7, 1998. Firm-initiated recall ongoing.
DISTRIBUTION California, Florida, Illinois, Indiana, North
Carolina, Wisconsin.
QUANTITY 500 sets were distributed; firm estimated that
384 sets remained on market at time of recall
initiation.
REASON Devices were mis-assembled. The tubing
sections were reversed which could result in
medication not being delivered and/or blood
being drawn from the patients IV site.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Dermagraft brand of Human Dermal Replacement,
indicated for use as a temporary wound
covering for surgically excised thermal burn
wounds: a) Dermagraft-TC; b) Dermagraft.
Recall #Z-571/572-8.
CODE Lot numbers: a) 101182 to 102722, non-sequential;
b) 101720 to 12783, non-sequential.
MANUFACTURER Advanced Tissue Sciences, Inc. (ATS), La

RECALLED BY Jolla, California.
 Manufacturer, by letter on March 25, 1998, and
 by press release on March 30, 1998.
 Firm-initiated recall ongoing.

DISTRIBUTIO a) Nationwide and international; b) international.
 QUANTITY a) 478 units; b) 281 units were distributed.

REASON Devices were manufactured and distributed from
 fetal bovine serum that did not meet firms
 specification for endotoxin.

None Present
 Action Taken _____

NSN 7030 Nonstandard
 Hemocare Blood Bank Data Management System
 Computer Software, Revision 5.1 & Version 3.1.
 Recall #B-556-8.

CODE Revision 5.1 and Version 3.1.
 MANUFACTURER Mediware Information Systems, Inc. (MISI),
 Melville, New York.

RECALLED BY Manufacturer, by letter on September 30, 1997, and
 by newsletter on December 15, 1997. Firm-initiated
 recall ongoing.

DISTRIBUTION Nationwide, Canada, Singapore.
 QUANTITY Out of 226 sites, 225 have 5.1 version released
 May 1995 and 1 have 3.1 version released July
 1992.

REASON Computer software that: 1) Was not functioning as
 intended in that discrepant displays of ABO test
 results could be accepted after a system warning
 and supervisory override, which could potentially
 result in the release of mistyped or mislabeled
 blood products; and 2) Possesses limitations for
 use that are not adequately described in labeling.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
 PRODUCT Q-Tuss Sustained Release (SR) Tablets
 (Phenylephrine HCL 25mg/phenylpropanolamine
 HCL 50 mg/Chlorpheniramine Maleate 8
 mg/Hyoscyamine Sulfate 0.19 mg/Atropine
 Sulfate 0.04 mg/Scopolamine Hydrobromine 0.01
 mg), in bottles of 100 and 500,
 antihistaminic, nasal decongestant and
 anti-secretory preparation. Recall #D-131-8.

CODE 043096B 002047B 043096C
 015067A 043096D 015067B
 043096E 016067A 044096A
 016067B 044096B 030106A
 001047D 031106A 001047E

031106B 001047F 031106C
002047A 031106D.
MANUFACTURER Vintage Pharmaceuticals, Inc., Charlotte,
North Carolina.
RECALLED BY Manufacturer, by letter dated January 22,
1998. Firm-initiated recall ongoing.
DISTRIBUTION Alabama.
QUANTITY 78,255 bottles were distributed.
REASON Incomplete validation data.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Atrohist Plus Sustained Release (SR) Tablets,
(Phenylephrine HCL 25 mg/phenylpropanolamine
HCL 50 mg/Chlorpheniramine Maleate 8
mg/Hyoscyamine Sulfate 0.19 mg/Atropine
Sulfate 0.04 mg/Scopolamine Hydrobromide 0.01
mg), in bottles of 100 and 500 tablets, and 4
tablet samples, Rx, antihistaminic, nasal
decongestant and anti-secretory preparation.
Recall #D-132-8.

CODE Lot numbers:
045056A 046056C 047056A
001086A 002086A 003086A
004086A 022106A 023106C
003017A 004017A 064047B
005087C 006087A.

MANUFACTURER Vintage Pharmaceuticals, Inc., Charlotte,
North Carolina.
RECALLED BY Manufacturer, by letter dated January 22,
1998. Firm-initiated recall ongoing.
DISTRIBUTION New York.
QUANTITY 537,692 bottles were distributed.
REASON Incomplete validation data.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Cyanocobalamin Injection, USP, 1,000 mcg/mL,
in 1 mL multiple dose vials, 25 vials per
carton, Rx indicated for Vitamin B12
deficiencies. NDC #0469-1044-25.
Recall #D-133-8.

CODE Lot numbers: 370007, 370080, 370139, 370187,
370305, 370338, 370396, 370489, 370570,
382027.

MANUFACTURER FUJISAWA USA, Inc., Grand Island, New York.
RECALLED BY Manufacturer, by letter dated April 10, 1998.
Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Egypt, Saudi Arabia, Canada.
QUANTITY 1,651,450 units (66,058 cartons) were distributed.

REASON Unapproved change in raw material.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Luvox (Fluvoxamine Maleate) 100 mg, in unit dose blisters (hospital use) of 10 tablets with 10 tablets per blister card, Rx, indicated for the treatment of obsessions and compulsions in patients with Obsessive Compulsive Disorder(OCD), as defined in the DMS-III-R. Recall #D-135-8.

CODE Lot #88007.
MANUFACTURER Solvay Pharmaceuticals, Inc., Marietta, Georgia.

RECALLED BY Manufacturer, by letter sent on April 7, 1998. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 4,944 units were distributed.
REASON Some units are missing the strength declaration.

None Present
 Action Taken _____

NSN 6505 Nonstandard
UPDATE Gliadel Wafer, Polifeprosan 20 with Carmustine Implant, (Rhone Poulenc Rorer Pharmaceuticals, Inc., Collegeville, Pennsylvania), Recall #D-065-8, which appeared in the February 18, 1998 has been extended to include lot #K97B4.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Triflex Sterile Latex Surgical Gloves.
Recall #Z-558-8.
CODE Lot PGJ7N009, size 6-1/2
MANUFACTURER Allegiance Healthcare Corporation, West Malaysia.
RECALLED BY Allegiance Healthcare Corporation, McGaw Park, Illinois, by letter dated April 16, 1998. Firm-initiated ongoing.

DISTRIBUTION Nationwide.
QUANTITY 262,800 pairs of gloves were distributed; firm estimated that 33 percent of product remained on market at time of recall initiation.

REASON Mislabeling - The sterile pouch, labeled as size 6-1/2 gloves, may actually contain size 7-1/2 gloves which are marked properly as size 7-1/2 on the glove and inner wallet. The sterile pouches, boxes and cases are all labeled as size 6-1/2.
 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Ventricular Catheter, Small, Barium Impregnated, 23 cm. Recall #Z-562-8.
CODE Catalog #41207, Lot #L0391 EXP 10/02.
MANUFACTURER Medtronics PS Medical, Goleta, California.
RECALLED BY Manufacturer, by telephone on March 13, 1998.
DISTRIBUTION Firm-initiated recall ongoing.
California, Virginia, Texas, North Carolina, Pennsylvania, Ohio, Wisconsin, Washington state, Indiana, Louisiana, Connecticut, Austria, Belgium.
QUANTITY 100 units were distributed.
REASON The label on the outer carton may not be consistent with the correct label on the inner product package. The outer carton label may state that the catalog number is 41101 and that its catheter size is standard. However, the outer carton should have been labeled with catalog.
 None Present
 Action Taken _____

NSN 6520 Nonstandard
PRODUCT Ormco C-Type Release Module, for orthodontic headgear or neck pads:
a) Part No. 715-2020, medium (white) force;
b) Part No. 715-2021, heavy (gray) force.
Recall #Z-563/564-8.
CODE Lot numbers beginning with 7K, 7L, 7M, 8A, 8B, and 8C, covering lots manufactured in October, November and December 1997, and January, February, and March 1998.
MANUFACTURER Sybron Dental Specialties, Inc., Orange, California (responsible firm).
RECALLED BY Ormco Corporation, subsidiary of Sybron Dental Specialties, Inc., Glendora, California, by letter on March 19, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 1,152 units were distributed.
REASON The release module does not release the neck pad or headgear from the face bow if it is accidentally pulled away from the patient.
 None Present
 Action Taken _____

NSN 6520 Nonstandard
 PRODUCT Motloid Cold Pac Tooth Acrylic, Formula 302M, in 4 fluid ounce and 8 fluid ounce bottles, a liquid self cure temporary crown and bridge resin monomer (cross-linked, colorfast), used to prepare temporary dental work.
 Recall #Z-568-8.
 CODE Lot numbers: 363701 (4 oz), 363702 (8 oz).
 MANUFACTURER The Motloid Company, Chicago, Illinois.
 RECALLED BY Manufacturer, by telephone on February 4, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 200 4-fluid ounce and 144 8-fluid ounce bottles were distributed; firm estimated that 50 percent of the product remained on market at time of recall initiation.
 REASON The resin does not harden.

None Present
 Action Taken _____

NSN 6550 Nonstandard
 PRODUCT QED Salvia Alcohol Tests, in-vitro diagnostic used as a test to determine the alcohol content in a person's saliva:
 a) QED Saliva Alcohol Test A150;
 b) QED Saliva Alcohol Test A350.
 Recall #Z-555/556-8.
 CODE All lot numbers with an expiration date of July 1998 and later.
 MANUFACTURER STC Technologies, Inc., Bethlehem, Pennsylvania.
 RECALLED BY Manufacturer, by telephone on February 3, 1998, and by fax on February 16, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY Firm estimated that less than 10 percent of product remained on market at time of recall initiation.
 REASON The QA stop does not develop within 5 minutes using negative samples, as specified in the product labeling.

None Present
 Action Taken _____

NSN 7610 Nonstandard
 PRODUCT Promotion brochures for (OTC):
 a) DHEA Therapy Tablets, Wild Yam, Ginkgo Biloba, Gotu Kola, Siberian Ginseng, Kelp, L-Tyrosine, L-Glutamine, L-Arginine, L-Ornithine) 90 tablets per bottle;
 b) Pycnogenol Capsules, (Grape seed extract, Pine bark extract...) in 60 capsule bottles.
 Recall #D-140/141-8.

CODE
MANUFACTURER
RECALLED BY

DISTRIBUTION
QUANTITY
REASON

None.
Energy Factors, Inc., Largo, Florida.
Jack Davis and Associates, Inc., Albany,
Georgia (own label distributor/responsible
firm), by instructing sales people to pickup
product on February 26, 1998. Firm-initiated
recall ongoing.
Nationwide.
Undetermined.
Misbranding - Promotional literature makes
unapproved drug claims.

None Present
 Action Taken _____
