

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: None

CLASS III RECALLS: 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 **03 NOV 00** 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	6505 Nonstandard
PRODUCT	AntiCoagulant Citrate Phosphate Double Dextrose Solution (CP2D) 200 mL for Collection of blood components with Haemonetics automated apheresis devices only. Recall #B-868-0.
CODE	Lot Number: CA9M40 (Sub lot D only).
MANUFACTURER	Pall Medical, Covina, California.
RECALLED BY	Haemonetics Corporation, Braintree, Massachusetts, by letter dated May 25, 2000. Firm-initiated recall ongoing.
DISTRIBUTION	California, Florida, Indiana, Kentucky, Kansas, Louisiana, Massachusetts, New Mexico, Nevada, New York, Oklahoma, Pennsylvania, Tennessee, Vermont, Wisconsin, Nevada, Texas.

QUANTITY
REASON

436 foil pouches were distributed.
Foil pouch may have been imprinted with an extended expiration date that varies from the date on the individual solution bags.

None Present
 Action Taken _____

NSN
PRODUCT

6505 Nonstandard
Fenwal Blood-Pack Units with platelet storage containers used in the collection of blood and blood components:
a) Product code C4R1464: Baxter Fenwal Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) Blood-Pack Unit; Transfer Pack Container with Adsol Red Cells Preservation Solution; Quadruple for Collection and Processing of 450 ml Blood; with Integral Donor Tube; contains natural rubber latex; for export only. Lots M99I22163, M99I23161
b) Product code 4R1411P: Baxter Fenwal Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) Blood-Pack Unit; Transfer Pack Container with Adsol Red Cells Preservation Solution; Quadruple for Collection and Processing of 450 ml Blood; with Integral Donor Tube. Lots M99I27188, M99I22189
c) Product code 4R3433: Baxter Fenwal Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) Blood-Pack Unit; Transfer Pack Container with Adsol Red Cells Preservation Solution; Triple for Collection and Processing of 450 ml Blood; with Lab-Site Sampling Site. Lot M99J14045
d) Product code 4R3448: Baxter Fenwal Anticoagulant Citrate Phosphate Dextrose Solution, USP (CPD) Blood-Pack Unit; Transfer Pack Container with Adsol Red Cells Preservation Solution; Quadruple for Collection and Processing of 500 ml Blood; with Lab-Site Sampling Site. Lots M99J01059, M99J01059A. Recall #B-928-0.

CODE
MANUFACTURER
RECALLED BY

See Above.
Baxter Healthcare of Puerto Rico, Maricao, Puerto Rico.
Baxter Healthcare Corporation, Deerfield, Illinois, by fax on June 6, 2000. Firm-initiated recall ongoing.

DISTRIBUTION

Massachusetts, Wisconsin, South Carolina, Florida, Ohio, Texas, South Dakota, Oklahoma.

QUANTITY
REASON

74,916 units distributed.
Platelet containers, labeled with a platelet storage time of five days, was produced in part with a plastic that can not support this expiration period.

None Present
 Action Taken _____

NSN
PRODUCT

6505 Nonstandard
a) Saphenous Vein , Model No. V010
b) Medial Meniscus with Bone - Right, Model No. M010
c) Lateral Meniscus with Bone - Left, Model No. M040
d) Achilles Tendon, Model No. T010
e) Patellar Tendon - Hemi, Model No. T030
Recall #B-954-0.

CODE

a) Serial numbers: 6182275, 6182267, 3873358, 3868354
b) Serial number 4123077

c) Serial number 4124251
d) Serial numbers 4134079, 4124197
e) Serial numbers 4124243, 4124235, 4124227, 4124219
MANUFACTURER RECALLED BY CryoLife, Inc., Kennesaw, Georgia.
Manufacturer, by letter on January 28, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Arkansas, California, Colorado, Florida, Kentucky, Massachusetts, Tennessee.
QUANTITY 12 allografts were distributed.
REASON Various tissues for transplant which were collected from donors who had not been properly evaluated.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Pulmonary Artery, Model M030. Recall #B-956-0.
CODE Serial #3968944.
MANUFACTURER RECALLED BY CryoLife, Inc., Kennesaw, Georgia.
Manufacturer, by letter dated November 9, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Washington state.
QUANTITY 1 unit was distributed.
REASON Tissue for transplant was collected from a donor who had not been properly evaluated.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT New Life Colostrum(tm) Cream (unscented moisturizing/repair skin cream), in 2-ounce jars. Recall #D-442-0.
CODE Lot #A2106990 EXP 1/01.
MANUFACTURER RECALLED BY Vege-Kurl, Glendale, California.
Symbiotics, Inc., Sedona, Arizona, by telephone on or about May 27, 2000 through June 8, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Puerto Rico, Canada.
QUANTITY Undetermined.
REASON Microbial contamination - Pseudomonas putida and Tsukamurella paurometabolum.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Cortef(r) Oral Suspension (hydrocortisone cypionate) 10 mg/5mL, in 4 fluid ounce units. NDC #0009-0142-01.
CODE Recall #D-447-0.
Lot numbers: 62CAT, 63CAT, 64CAT, 23CRW, 24CRW, 04CJX, 05CJX, 19DAJ, 98DXA and 91DTM.
MANUFACTURER RECALLED BY Pharmacia Corporation, Kalamazoo, Michigan.
Manufacturer, by letter dated July 18, 2000. Firm-initiated recall

DISTRIBUTION ongoing.
QUANTITY Nationwide, Belgium, Canada, Chile, Ireland, United Kingdom, Uruguay.
REASON 144,357 bottles were distributed.
Product may not always be effective for the treatment of congenital adrenal hyperplasia.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Elecsys HGC STAT Immunoassay, a pregnancy test kit for use on Roche Elecsys analyzers. Recall #Z-835-0.
CODE Catalog #1731289, All Lots (Lot No. 198859, EXP 02/28/01; 151150, EXP 11/30/01).
MANUFACTURER Roche Diagnostics GmbH, Penzburg, Germany.
RECALLED BY Roche Diagnostics Corporation, Indianapolis, Indiana, by letter (Customer Bulletin #00-096) dated May 11, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY Undetermined.
REASON There is an incidence of false elevation in pregnancy test results for the above method that is not related to HAMA (human anti-mouse antibody) interference. This effect manifests as a repeatable positive result that cannot be confirmed by alternative methodologies.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Pannaz(tm) Tablets, antihistamine-decongestant (Phenylpropanolamine HCl, 75 mg, Chlorpheniramine Maleate 8 mg, Methscopolamine Nitrate 2.5 mg), in 100-tablet bottles, Rx. NDC #0525-0780-01. Recall #D-443-0.
CODE Lot #V6337A01 EXP 5/02.
MANUFACTURER Anabolic Laboratories, Inc., Irvine, California.
RECALLED BY Manufacturer, by letter dated June 14, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Undetermined.
QUANTITY 9,493 bottles were distributed.
REASON Lack of complete manufacturing process validation.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Estratab(r) (Esterified Estrogens Tablets, USP), 2.5 mg, in bottles of 100, Rx intended for hormone replacement.
CODE Recall #D-444-0.
Lot #90654 exp 6/01.

MANUFACTURER Solvay Pharmaceuticals, Inc., Baudette, Minnesota.
RECALLED BY Solvay Pharmaceuticals, Inc., Marietta, Georgia, by letter on June 26,
2000. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 2,282 bottles were distributed.
REASON Tablets did not meet friability specification.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Orasone(tm) 5 Tablets (Prednisone Tablets, USP), 5 mg, in bottles of
1,000, Rx anti-inflammatory agent.
Recall #D-445-0.
CODE Lot #89335.
MANUFACTURER Solvay Pharmaceuticals, Inc., Baudette, Minnesota.
RECALLED BY Solvay Pharmaceuticals, Inc., Marietta, Georgia, by letter on June 26,
2000. Firm-initiated recall ongoing.
DISTRIBUTION California, Colorado, Connecticut, Minnesota, Missouri, New York, North
Dakota, Ohio, South Dakota, Tennessee.
QUANTITY 3,765 bottles were distributed.
REASON Dissolution failure (18 month stability).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) Red Blood Cells; b) Platelets; c) Fresh Frozen Plasma;
d) Plasma; e) Recovered Plasma. Recall #B-986/990-0.
CODE Contact FDA, Center for Biologics Evaluation and Research, Office of
Compliance (301) 827-6220 for individual unit numbers recalled.
MANUFACTURER Department of the Navy, National Naval Medical Center, Bethesda,
Maryland.
RECALLED BY Manufacturer, by telephone starting in May 1994, by fax in June 1994, and
by letters on November 12, 1999 and June 12, 2000. Firm-initiated recall
ongoing.
DISTRIBUTION California, District of Columbia, Georgia, Maryland, New Jersey, New
Mexico.
QUANTITY a) 424 units; b) 21 units; c) 32 units; d) 4 units; e) 389 units were
distributed.
REASON Blood products were collected from donors who had not been questioned
about mucus membrane exposure to blood or body fluids.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Abbott Multiconstituent Calibrator, List #IE65-01, for
in-vitro diagnostic use. Recall #Z-878-0.
CODE Lot #55765M100 EXP 01/10/01.

MANUFACTURER MAS, Inc., Camarillo, California.
RECALLED BY Abbott Laboratories, Inc., South Pasadena, California, by letter June 14,
2000. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Puerto Rico.
QUANTITY 1,621 kits were distributed.
REASON A shift in control values on Creatinine assay.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Abbott A-GENT Uric Acid Standard Kit, for in-vitro diagnostic use.
Recall #Z-879-0.
CODE Catalog #06008-02, Lot #61015HWO0 EXP 11/30/00 and Lot #61070H00 EXP
11/30/00.
MANUFACTURER CASCO/NERL Company, East Providence, Rhode Island.
RECALLED BY Abbott Laboratories, South Pasadena, California, by letter on June 20,
2000. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Germany, St. Martin, Mexico, Venezuela, Taiwan, Dominican
Republic, Colombia, Jamaica, San Salvador, Argentina, Hong Kong, Italy,
Korea, Singapore, Japan, Canada, Bahamas, Brazil, West Indies, Honduras,
Cayman Islands, Paraguay, Uruguay.
QUANTITY 404 kits were distributed.
REASON The standard labeled 6mg/dL is recovering at approximately 5mg/dL. Use
of these Standards on the spectrum instrument will result in a
calibration failure.

None Present
 Action Taken _____
