

**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:

6515NS

MDC 12538

PRODUCT

Microscopes, Ear

Direct Power Transformers:

a) Transformer Model #75210. This transformer is a plug in power supply that powers the Domestic LumiView (110 volt version). The LumiView is a portable binocular microscope used to view the ear, nose, throat and other small cavities. The plug-in transformer is sold as an accessory for the LumiView. This device is also included in sets identified below:

b) Product No. 20510H Headband LumiView with Direct Plug Power;

c) Product No. 20510HV (Same as 20510H - Labeled For Veterinary Use);

d) Product No. 20510S Spectacle LumiView with Direct Plug-In; and

e) Product No. 20510SV (Same as 20510S - Labeled For Veterinary Use).

Recall #Z-193/197-8.

CODE

Date Code July 96 through December 96.

MANUFACTURER

Sino-American Electronic Company, Ltd., Kaohsiung Hsien, Taiwan, R.O.C.

RECALLED BY

Welch Allyn, Inc., Skaneateles Falls, New York, by memorandum dated October 21, 1997, and by letter dated November 997. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide and international.

QUANTITY

810 units were distributed.

REASON

The transformers secondary fuse was incorrectly wired and therefore not functional, compromising the safety of the transformer that could result in a burn and/or a shock hazard to anyone touching the transformer under certain conditions.

None Present

Action Taken _____

MDC 17728

PRODUCT

Information Systems, Blood Bank

LifeTec Community Blood Center System Computer Software, Revision 2.00.

Recall #B-285-8.

CODE

LifeTec Revision 2.00 and User Manuals for the software; User Manual: Sec II, Laboratory and Component Processing, Page II 3.2.2 dated 3/1/96.

MANUFACTURER

Systec Computer Associates, Inc., Mt. Sinai, New York.

RECALLED BY

Manufacturer, by memorandum on April 2, 1997, by fax on October 27, 1997, and additional memorandum on October 28, 1997. Firm-initiated field correction ongoing.

DISTRIBUTION

Georgia, Iowa, Louisiana, Mississippi, South Carolina, Tennessee.

QUANTITY

7 donor centers received software and manuals.

REASON

Computer software did not perform as stated in the product's labeling.

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 13 FEB 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 (343-7445)

CLASS I RECALLS:

NSN	6505 Nonstandard
PRODUCT	OTC Skin-Cap Spray, Cream, and Shampoo (Pyrrhione Zinc), all sizes, all strengths:
	a) Pyrrhione Zinc Hair Shampoo, contained in a white plastic bottle with a blue label, made in Spain, and is packaged in a cardboard box with blue bubbles printed on it. Boxes are packed 200 units to a case.
	b) Pyrrhione Zinc Topical Spray, contained in a blue can with a white cap, packaged in a blue cardboard box. Boxes are packed 200 units to a case.
	c) Pyrrhione Zinc Topical Cream, contained in a white plastic tube printed in blue and black, made in Spain, the tubes are packed into a cardboard box labeled similarly to the tube, but also with a lot number and expiration date. The boxes are packed 200 units to the case.
	d) Skin Cap DISPLAY units which are promotional

displays given to distributors which contain each of the above listed products to aid in the sales of the product.

Recall CODE MANUFACTURER #D-273/275-7.
All codes and expiration dates.
Aerosols Preval, Complejo Industrial, Madrid, Spain (contract manufacturer).

RECALLED BY Cheminova America, Miami, Florida (importer/initial distributor), by fax on September 4, 1997, and by mail on September 8, 1997. Firm-initiated recall ongoing. See also FDA Statement dated August 8, 1997.

DISTRIBUTION QUANTITY Nationwide and Puerto Rico.
Amount distributed is undetermined; firm estimated that 19,916 units were in commerce at time of recall initiation.

REASON Presence of undeclared clobetasol propionate (corticosteroids).
 None Present
 Action Taken _____

CLASS II RECALLS:

NSN PRODUCT 6505 Nonstandard
Glucophage Metformin HCl Tablets, 500 mg, in bottles of 180 tablets, Rx oral antihyperglycemic. NDC#0339-6022-14.
Recall #D-042-8.

CODE MANUFACTURER Lot #LN041021 EXP 06/30/98.
Bristol Laboratories Corporation, a Bristol-Myers Squibb Company, Mayaguez, Puerto Rico.

RECALLED BY Caremark, Inc., Prescription Services Division, Northbrook, Illinois, on November 13, 1997. Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY Florida, Texas, Illinois, Virginia.
1,066 bottles were distributed; firm estimates that little, if any of the lot remains on the market.

REASON Tablet mix-up - At least one bottle was found to contain Relafen Nabumetone Tablets, 500 mg (nonsteroidal anti-inflammatory-white oval tablets).
 None Present
 Action Taken _____

NSN PRODUCT 6505 Nonstandard
Theocron Tablets (Theophylline Anhydrous, USP), Extended-Release, 200 mg, in 100 count unit dose strips, Rx. NDC #0182-1590-89.

CODE Recall #D-054-8.
MANUFACTURER Lot numbers: 42H7473 and 42H7474.
Ivax Company, Quebec, Canada
(repacker/responsible firm).
RECALLED BY Zenith Goldline Pharmaceuticals, Fort
Lauderdale, Florida, by letter on November 26,
1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 4,723 unit dos boxes of 100 were distributed.
REASON Mislabeling - Labeling fails to bear the
extended-release statement.
 None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT OXY 10 Medicated Face Wash (10% Benzyl
Peroxide), in 8 fluid ounce plastic bottles,
OTC, intended for young adults who regularly
have pimples and oily skin. Recall #D-055-8.
CODE Lot #7F25 EXP 6/99.
MANUFACTURER SmithKline Beecham Consumer Healthcare, L.P.,
St. Louis, Missouri.
RECALLED BY SmithKline Beecham Consumer Healthcare, L.P.,
Parsippany, New Jersey, by telephone on August
19, 1997, and by letters on August 22 and 29,
1997, and September 9, 1997. Firm-initiated
recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 152 cases were distributed.
REASON Product contaminated with Burkholderia
cepacia.
 None Present
 Action Taken _____

NSN 6505 Nonstandard
UPDATE The Victor Medical (St. Louis, MO) recall of
Oxygen USP, in aluminum high pressure
cylinders, M-6, M-7, and M-9 Cylinders, Recall
#D-032-8, which appeared in the November 12,
1997 Enforcement Report has been extended to
include Valve date (Victor) coded as VBD, VCD,
VDD or VED.
 None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) Red Blood Cells; b) Recovered Plasma.
Recall #B-371/372-8.

CODE Unit numbers: 10500-8925, 10496-3333.
MANUFACTURER United Blood Services, Scottsdale, Arizona.
RECALLED BY Blood Systems, Inc., Scottsdale, Arizona, by
letter dated October 28, 1997. Firm-initiated
recall ongoing.
DISTRIBUTION Illinois, New Mexico, Switzerland.
QUANTITY 2 units of each component were distributed.
REASON Blood products were collected from a donor
who had ear piercing within 12 months of
donation.
 None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Source Plasma. Recall #B-376-8.
CODE Unit numbers: FT11006586, FT11006548,
FT11006467, FT11006447, FT11006449,
FT11006366, FT11006315.
MANUFACTURER Serologicals, Inc., Clarkston, Georgia.
RECALLED BY Manufacturer, by fax on June 25, 1996.
Firm-initiated recall ongoing.
DISTRIBUTION Federal Republic of Germany.
QUANTITY 7 units were distributed.
REASON Blood products tested negative for the
antibody to Hepatitis B Surface antigen
(anti-HBsAg), but collected from a donor who
previously tested repeat reactive for
anti-HBsAg, non-neutralizable and anti-HBc
negative.
 None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Human Tissue for Transplant:
a) Human Corneal Tissue; b) Whole Eye Globes.
CODE Recall #B-224/225-8.
All product harvested and distributed between the
date of the interim rule on Human Tissue Intended
for Transplantation (12/04/93) and the date the
firm received the final rule (04/30/97).
MANUFACTURER Utah Lions Eye Bank, Salt Lake City, Utah.
RECALLED BY Manufacturer, by letter dated November 3, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Utah and California.
QUANTITY a) 73 units; b) 2 units were distributed.
REASON Human Tissues for Transplant were collected from
donors who tested repeat reactive for HBsAg,
supplemental testing as negative.
 None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) Red Blood Cells; b) Platelets;
c) Recovered Plasma. Recall #B-348/350-8.
CODE Unit numbers: a) 49F95927 and 49W15371
b) 49W15371; c) 49F95927 and 49W15371.
MANUFACTURER American Red Cross Blood Services, Tulsa,
Oklahoma.
RECALLED BY Manufacturer, by letter dated August 21, 1997,
or September 25, 1997. Firm-initiated recall
ongoing.
DISTRIBUTION California, Oklahoma, Texas.
QUANTITY a) 2 units; b) 1 unit; c) 2 units were
distributed.
REASON Blood products tested negative for the
antibody to the human immunodeficiency virus
type 1 (anti-HIV-1), but were collected from
a donor who previously tested repeatedly
reactive for anti-HIV-1, Western Blot
indeterminate.
 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT NAG Brachyflex Catheter Implant Set:
a) Cook brand NAG Brachyflex Catheter Implant
Set, Reorder No. BFCS-6.0-30-DT-20
b) Cook brand NAG Brachyflex Catheter Implant
Set, Reorder No. BFCS-6.0-30-ST-20
c) Cook brand NAG Brachyflex Catheter Implant
Set, Reorder No. BFCS-6.0-30-STB-20
d) Cook brand NAG Brachyflex Catheter Implant
Set Reorder No. BFCS-6.0-50-STB-20.
Recall #Z-219/222-8.
CODE All Lot Numbers.
MANUFACTURER Cook, Inc, Bloomington, Indiana.
RECALLED BY Manufacturer, by letter dated July 11, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Arizona, Connecticut, Florida, Hawaii,
Indiana, Maine, Maryland, Minnesota, Ohio,
Pennsylvania, Utah, Canada, Denmark, Germany,
Japan, The Netherlands.
QUANTITY 289 sets were distributed.
REASON The catheters may break or separate during use.
 None Present
 Action Taken _____

NSN 6515 Nonstandard

PRODUCT Bard William Harvey H-130 Over Pressure Safety Valve (OPS), used to prevent negative pressure from building inside the ventricle during left ventricular venting and to reduce the possibility of pumping air or solution into the left ventricle should positive pressure build between the pump and the valve.
Recall #Z-212-8.

CODE H130 Standalone device:
Lot numbers: 43BHV119-43BHV140, 43CHV101-43CHV136, 43DHV101- 43DHV128, 43EHV101-43EHV120, 43FHV101-43FHV118, 43GHV101- 43GHV114, 43HHV101-43HHV117, 43IHV101-43IHV120.
Tube Packs (multiple components):
All Bard Vascular Systems tubing packs which contain the OPS valves with lot numbers: 28GHX---, 28HHX---, 28JHX---. The--- represents any number 0 through 9.
** Recall Extended on 11/25/97 to include lot numbers: 43EHX---, 43FHX---

MANUFACTURER Bard, Las Piedras, Puerto Rico;
A.C. Hoffman Engineering, Riverside California (valve vendor).

RECALLED BY Bard Vascular Systems Division, C.R. Bard Inc., Haverhill, Massachusetts, by letter on October 30, 1997. Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY REASON Nationwide, Canada, Australia.
Approximately 67,000 units were distributed.
Valve is occluded preventing blood flow through valve.
 None Present
 Action Taken _____

NSN PRODUCT 6515 Nonstandard
Hamilton Disposable Precision Tips, used to aspirate and dispense fluid:
a) Part #235300, box of 504 tips
b) Part #235400, case of 504 tips.
Recall #Z-227/228-8.

CODE Lot Numbers: a) 23397R, 33397R, 43397R, 53397R, 63397R, 73397R, 13497R, 23497R, 33497R, 43497R, 53497R, 63497R, 73497R, 13597R, 23597R, 33597R, 13697R, 23697R, 33697R, 53697R
b) 23397R, 33397R, 43397R, 53397R, 63397R, 73397R, 13497R, 23497R, 33497R, 43497R, 63497R, 73497R.

MANUFACTURER RECALLED BY Tech Group Tempe, Tempe, Arizona.
Hamilton Company, Reno, Nevada, by letter on December 17, 1997. Firm-initiated recall

DISTRIBUTION ongoing.
QUANTITY Nationwide and international.
REASON 164 cases were distributed.
The barrels of the tips were manufactured using a non-antistatic polypropylene.
 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Autraumax Reusable Surgical Clamps, used during cardiovascular, peripheral vascular, and general surgery: a) Model A3312; b) Model A3313; c) Model A3314; d) G-5020; e) Model G-5028 ; d) Model G-5050; e) Model G-5128; f) Model G-5040, g) Model G-5740. Recall #Z-229/237-8.
CODE Lot numbers: a) E7H077; b) E7H075; c) E7H076; d) E7F121; e) E7E077; f) E7E003, E7E050, E7E049; g) 97D138; h) RE7E04; i) R7D003.
MANUFACTURER Applied Medical Resources, Laguna Hills, California.
RECALLED BY Manufacturer, by fax between October 10 and 13, 1997, followed by telephone between October 13 and 20, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Australia, Israel, Japan, The Netherlands.
QUANTITY 109 clamps were distributed.
REASON A fracture can occur near the jaw/male box lock interface while the clamp is being placed during surgery.
 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT FibriJet Surgical Sealant Applicators, fibrin sealant delivery systems used during surgery: a) Model SA-4100 (1cc); b) SA-4305 (5 cc) c) SA-4310 (10 cc). Recall #Z-239/241-8.
CODE Model SA-4100, all lot numbers below 12905
Model SA-4305, all lot numbers below 12908
Model SA-4310, all lot numbers below 12907.
MANUFACTURER Micromedics, Inc., Eagan, Minnesota.
RECALLED BY Manufacturer, by letter dated November 12, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 1,166 units were distributed.
REASON The sterile packaging of the products was found to be weak and defective.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Ferrotrinsic Capsules (Hematinic Concentrate with Intrinsic Factor), in 100 tablet bottles, a prescription vitamin. Recall #D-040-8.
CODE Lot numbers 071437 and 072007.
MANUFACTURER Rugby Laboratories, Inc., Norcross, Georgia.
RECALLED BY Manufacturer, by letter on September 3, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY Firm estimates 9,399 bottles remain in commerce.
REASON Mislabeling - Product bears the wrong strength for iron (as ferrous fumarate) labeled as 10 mg, but actually contains 110 mg per capsule.
[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
UPDATE Recall #B-1386-7, Red Blood Cells, Deglycerolized, United Blood Services, Chicago, Illinois, which appeared in the September 17, 1997, Enforcement Report has been extended to include 65 additional units. Contact FDA, Center for Biologics Evaluation and Research, Office of Compliance (301)827-6220 for individual unit numbers recalled.
[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Vivelle(tm) Patches (Estradiol Transdermal System), 0.075 mg/day, a patch system therapy for estrogen replacement in postmenopausal women. Recall #D-041-8.
CODE Lot #6B1219A1 EXP 3/98.
MANUFACTURER Noven Pharmaceuticals, Inc., Miami, Florida.
RECALLED BY Novartis Pharmaceutical Corporation (formerly Ciba-Geigy), Suffern, New York, by telephone on October 22, 1997, and by letter on November 6, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 2,214 cartons (8 pouches/packet per carton) were distributed.
REASON Mislabeling - Product distributed bearing physician sample-not for sale labeling.
[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Hydra-Zide Capsules (Hydralazine HCl and Hydrochlorothiazide), 25 mg/25mg, in bottles of 100, Rx used for the treatment of hypertension, under the following labels:
 Par Pharmaceutical Inc. (NDC 49884-143-01)
 Martec Pharmaceutical, Inc. (NDC 52555-143-01)
 Major Pharmaceuticals (NDC 0904-2855-60)
 Qualitest Pharmaceuticals, Inc. (NDC 0603-3834-21)
 United Research Laboratories, Inc. (NDC 0677-0773-01). Recall #D-043-8.
CODE Lot numbers: 006675, 007194, 007272, 007302, 007492, 008022, 008023, 008124. All lots expire on May 1999.
MANUFACTURER Par Pharmaceutical, Inc., Spring Valley, New York.
RECALLED BY Manufacturer, by letter mailed on November 10, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 11,633 bottles were distributed.
REASON Superpotent for Hydrochlorothiazide (three month stability test station).
 None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Demadex Tablets (Torsemide), 5 mg, 10 mg, 20 mg, 100 mg, in bottles of 100, used for the indication of edema. NDC #53169-104-01. Recall #D-044/047-8.
CODE All lots.
MANUFACTURER Boehringer Mannheim GmbH, Mannheim, Germany.
RECALLED BY Boehringer Mannheim Corporation Therapeutics (BMCT), Gaithersburg, Maryland, by letter sent by fax on November 11, 1997, and by mail on November 12, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 5,880 bottles were distributed.
REASON Labeling - Some bottles do not have a complete printing of the lot number and/or expiration date.
 None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT VHA Plus Dobutamine brand Dobutamine Hydrochloride Injection, 250 mg, in 20 mL single dose vials, Rx, a direct acting inotropic agent. NDC #0002-7375-01 and 0002-7375-10. Recall #D-049-8.
CODE Lots: 0ND89S, EXP Feb 1, 1999; 0NC01M, EXP Feb 1, 1999; 0NE84M, EXP Mar 1, 1999; 1MF86N, EXP April 1, 1999; 1MH14N EXP May 1, 1999; 1MK15M, EXP June 1, 1999; 1ML66N, EXP June 1, 1999; 1MR42M, EXP July 1, 1999; 1MS84N EXP Aug 1, 1999; 1MS57M EXP Aug 1, 1999; 1MU20M, EXP Sept 1, 1999.
MANUFACTURER Eli Lilly and Company, Indianapolis, Indiana.
RECALLED BY Manufacturer, by letter November 7, 1997, and by telephone on November 10, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY Approximately 1.8 million vials were distributed.
REASON Mislabeling - Some immediate container labels are missing the "2" from 20 ml in their strength indication statement - Equiv to 250 mg Dobutamine per 20 ml.
 None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Hemorrhoidal Suppositories (phenylephrine HCl 0.25% Zinc oxide 11%), in 12, 24, and/or 30 units per package, OTC product under the following labels: Eckerd Drug, FDC Wholesale, Genovese Drug Stores, Super G, G & W, Federated Group, McCrory Stres, Navarro Discount Pharmacies, Nash Finch, Federated Foods, Revco D.S., Select Brand Distributors, Venture Stores, CVS, Discount Drug Mart, Fedco Professional Pharmacies, Family Pharmacy, Bindley Western/First Choice, Drug Emporium. NDC numbers: 19458-7011-1, 59085-302-12, 0713-0505-12, 43083-505-10, 52735-715-05, 0713-0505-24. Recall #D-051-8.
CODE Lot Numbers and EXP dates:
 5293-1 5/97, 5293-2 5/97; 5293-3 5/97
 5293-4 5/97; 5321-7 6/97; 5321-8 6/97
 5321-9 6/97; 5322-1 6/97; 5322-2 6/97
 5322-3 6/97; 5322-4 6/97; 6111-5 11/97
 6169-1 1/98; 6180-1 1/98; 6199-1 1/98;
 6199-2 1/98; 6216-9 2/98; 6217-1 2/98;
 6230-3 3/98; 6261-9 4/98; 6269-1 4/98;
 6285-1 4/98; 6291-2 5/98; 6325-2 6/98;
 6345-1 6/98; 6353-8 7/98; 6353-9 7/98;

MANUFACTURER 6366-5 7/98.
G & W Laboratories, Inc., South Plainfield,
New Jersey.
RECALLED BY Manufacturer, by letter sent on May 13, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Puerto Rico.
QUANTITY 409,805 packages of product were distributed.
REASON Subpotent; Phenylephrine HCl.
 None Present
 Action Taken _____
