

**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-P, Capt D. Troy Molnar, DSN 343-40837487)

CLASS I RECALLS: None.

CLASS II RECALLS:

6515NS
MDC 14360
PRODUCT Kodak Diconix Printer Model No. 180si (All Serial Numbers) used With the Nellcor Puritan Bennett Adult Star Ventilator, Model Nos. 1500 and 2000. Printer is sold as an accessory and is used to record settings and patient parameters to put in patient charts. Recall #Z-033-9.
CODE All serial numbers.
MANUFACTURER Infrasonics, Inc., San Diego, California.
RECALLED BY Nellcor Puritan Bennett, Carlsbad, California, by letter dated July 7, 1998.
DISTRIBUTION Firm-initiated recall ongoing.
QUANTITY Nationwide and international.
REASON 124 units were distributed.
Printers are not compatible with the alarm driver boards on the ventilators.

[] None Present
[] Action Taken _____

6640NS
MDC 16817
PRODUCT Sunquest Blood Bank and Blood Donor System Computer Software Program. Recall #B-1622-8.
CODE All copies of Sunquest Blood Bank Modules Version 5.1, 5.2 & 5.22.
MANUFACTURER Sunquest Information Systems, Tucson, Arizona.
RECALLED BY Manufacturer, by fax on August 7, 1998. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide, Canada, Saudi Arabia, Great Britain, Ireland.
QUANTITY 343 Sunquest clients have this product.
REASON Computer software contains programing errors which could potentially result in the release of unacceptable test results for blood products.

[] None Present
[] Action Taken _____

CLASS III RECALLS:

NSN 6630
MDC 16488
PRODUCT VIA Medical Glucose Calibration Kit. Recall #Z-958-8.
CODE Catalog #GLU2, Lot numbers 9805048 and 9804125.

MANUFACTURER VIA Medical Corporation, San Diego, California.
 RECALLED BY Manufacturer, by letter on June 25, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Arkansas, California, Florida, Illinois, Indiana, Kansas, Oklahoma, South
 Carolina, Texas.
 QUANTITY 570 kits were distributed.
 REASON Some of the kits contain sodium chloride instead of dextrose solution.

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 **04 December 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). (FOM-P), **Bonnie Phillips DSN (343-4170)**

CLASS I RECALLS: None

CLASS II RECALLS:

NSN 6505 Nonstandard
 PRODUCT Methylphenidate Hydrochloride, Rx, USP, used in the treatment of attention deficit disorder and narcolepsy: a) 5 mg in 1,000 tablet bottles; b) 10 mg, in 1,00 tablet bottles; c) 20 mg, in 100 and 1,000 tablet bottles. Recall #D-243/245-8.
 CODE Lot numbers: a) M531R05 EXP 09/00; b) M530T11 EXP 10/00; c) M532R01 EXP 09/00, P532E01 EXP 05/01.
 MANUFACTURER MD Pharmaceutical Inc., (Medeva Pharmaceuticals), Santa Ana, California.
 RECALLED BY Manufacturer, on or about September 4, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY MD label: Lot M532R01 - 960 bottles; Lot M531R05 1,956 bottles; Apothecon label: Lot P532E01 - 9,648 bottles; Lot M530T11 - 2,940 bottles were distributed.
 REASON Product failed content uniformity testing.

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Levothyroxide Sodium Tablets, 25, 50 and 300 microgram, Rx used as replacement or supplemental therapy in patients with hypothyroidism, under the Qualitest and Vintage labels. Recall #D-246-8 and D-263/264-8.

CODE Lot numbers: 25 mcg - 036077A, EXP 12/98 50 mcg - 027027A, 027027B, 27027C, EXP 1/99 300 mcg - 017047A, EXP 3/99.

MANUFACTURER Vintage Pharmaceuticals, Inc., Charlotte, North Carolina.
 RECALLED BY Manufacturer, by letter dated May 18, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 25 mcg: 895 bottles; 50 mcg: 557 bottles of lot 027027A, 284 bottles of lot 27027B and 952 bottles of lot 027027C; 300 mcg: 1,852 bottles were distributed.

REASON Firm has no assurance Levothyroxide Sodium products will maintain potency through expiry.

None Present
 Action Taken _____

NSN 6505 Nonstandard
 UPDATE Recall #D-219-8, Nifedipine Soft Gelatin Capsules, USP, 20 mg, in 300 capsule bottles, which appeared in the August 12, 1998 Enforcement Report should read:
 CODE Lot #7JY06L EXP 5/99.

NSN 6515 Nonstandard
 PRODUCT L-Cath Procedural Trays, and L-Cath Peripherally Inserted Catheter Kits. Recall #Z-959/960-8.

CODE L-Cath Procedural Trays: Model Numbers PE-PIC-05, All tray lots sold (first shipped 2/20/98); Model Numbers PE-NN-02, All tray lots sold (first shipped 5/30/98);
 L-Cath Peripherally Inserted Catheter Kits (with PE-PIC-05 or PE-NN-02 Procedural Trays:
 Model Numbers: (all model numbers have the prefix PE) 16PIC60K, 16PIC60TK, 16PIC20K, 16OIC20TK, 16PIC60DK, 16PIC60DTK, 18PIC60K, 18OIC60TK, 18PIC20K, 18PIC20TK, 18PIC60DK, 18PIC60DTK, 18PIC60STK, 20PIC60K, 20PIC20K, 20PIC60TK, 20PIC20TK, 20PIC60DK, 20PIC60DTK, 3FPIC60TK, 3FPIC20TK, (all kits lots beginning with LMP 4828, first shipped 2/17/98); 23PIC30SK, 23PIC30STK, 24PC8TK, 24P19K, 24P30K, 24PIC30K, 24PIC30TK, 28PIC25K, 28NN8K, 28NN14K, 28NN20K, 28NN25K, (all kit lots beginning with LMP 3251, first shipped 6/3/96).

MANUFACTURER Luther Medical Products, Inc., Tustin, California.
 RECALLED BY Manufacturer, by letter on June 8, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and Israel.
 QUANTITY 21,292 units were distributed.

REASON The products are mislabeled as "Latex-Free," however, they contain dry natural rubber components that may contain natural latex proteins.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Acoma Overhead Tube Support, Model A902000-9, Catalog #0041,a fully

counter-balanced heavy-duty radiographic x-ray tube suspension system intended to support and position the diagnostic x-ray tube housing assembly for a medical radiographic procedure. Recall #Z-010-9.

CODE Serial numbers 05010391001 through 050100698004, all units shipped between March 1991 and June 1998.

MANUFACTURER Acoma Medical Imaging, Inc., Wheeling, Illinois.

RECALLED BY Manufacturer, by sending Equipment Field Modification Bulletin No. 98-01-OTS-001, Acoma Recall #1451001-1998-00001, on 9/24/98 with a cover letter of the same date. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 628 units were distributed.

REASON Defective welds on the end plate allow the end plate on the lower tube column on the overhead tube support to break free from the column, allowing the x-ray tube/collimator assembly to hang from the high tension/power cables.

None Present
 Action Taken _____

NSN 6515 Nonstandard

PRODUCT Wang/Mill-Rose Transbronchial Aspiration Needles, Model SW-121, Part numbers: (P/N) SW-121-1 and SW-121-4, size: 21 gauge, length: 15mm, packaged in a sterile Tyvek pouch, one (1) needle per pouch [P/N SW-121-1] or four (4) needles per pouch [P/N SW-121-4], disposable, single-use needles are intended for use through a bronchoscope to puncture the tracheobronchial wall and to aspirate sufficient tissue and/or cell specimens to stage bronchogenic carcinoma. Recall #Z-011-9.

CODE LOT NUMBERS: 12529, 12644, 12645, 13293, 13448, 12484, 13598, 13674, 14029, 14243, and 13599.

MANUFACTURER Mill Rose Laboratories, Inc., Mentor, Ohio.

RECALLED BY Manufacturer, by telephone on or about September 8, 1998, followed by fax letter dated September 14, 1998. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY 975 units were distributed.

REASON The needle tip may separate from the sheath during a surgical operation.

None Present
 Action Taken _____

NSN 6515 Nonstandard

PRODUCT Disposable Polypectomy Snares, Sterile, used in polypectomy procedures to remove polyps as follows:

- a) Model 4562 Crescent Loop Snare (5.0x2.5cm);
- b) Model 4563 Std. Oval Loop (5.0x2.5cm);
- c) Model 4567 Micro Oval Loop (2.5x1.5cm);
- d) Model 4577 Micro Oval Loop (2.5x1.5cm);
- e) Model 4562-OLY Crescent Loop (5.0x2.5cm);
- f) Model 4563-OLY Std Oval Loop (5.0x2.5cm);
- g) Model 4564-OLY Maxi Oval Loop (5.0x3.5cm);
- h) Model 4565-OLY Mini Oval Loop (3.5x2.0cm).

Recall #Z-001/008-9.

CODE Lot numbers: a) HO5-98-166; b) HO7-98-445; c) HO5-98-187, HO5-98-231; d) HO5-98-232; e) HO6-98-334, HO6-98-362, HO8-98-480;

f) HO5-98-227, HO7-98-435, HO7-98-395, HO8-98-482;
g) HO5-98-228, HO6-98-333; h) HO5-98-169, HO7-98-390
HO8-98-538.
MANUFACTURER RECALLED BY DISTRIBUTION Hobbs Medical, Inc., Stafford Springs, Connecticut.
Manufacturer, by letter on September 23, 1998. Firm-initiated recall ongoing.
Alabama, Connecticut, Florida, New Hampshire, Michigan, Montana, Iowa,
Massachusetts, Texas.
QUANTITY 1,130 units were distributed.
REASON Snare loop separates from the snare wire.

None Present
 Action Taken _____

NSN 6515 Nonstandard
Veridose Diodes Model No. 30-474, packaged under the Nuclear Associates label,
used to provide dose verification and quality assurance for patients undergoing
radiation therapy. Recall #Z-034-9.
CODE Serial number 110 to 134, manufactured prior to September 26, 1997.
MANUFACTURER Victoreen, Inc., Cleveland, Ohio.
RECALLED BY Manufacturer, by telephone on or about August 31, 1998. Firm-initiated recall
ongoing.
DISTRIBUTION Florida, Virginia, Georgia, California, New York.
QUANTITY 8 diodes were distributed.
REASON Devices were manufactured with a serial tag that did not correspond to the
manufacturer's specifications. The serial tags indicate a prescribed energy use
of 6 to 25 MeV electron radiation; however, the diodes are properly color coded
and intended for use for 18 to 25 MV photon radiation.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Storz Tanne Disposable Trepine Blades, sterile, single use, packaged 1 blade
per package, Rx involving the following catalog numbers:
a) Catalog No. E3050 6.0;
b) Catalog No. E3050 6.25;
c) Catalog No. E3050 6.50;
d) Catalog No. E3050 6.75;
e) Catalog No. E3050 7.0;
f) Catalog No. E3050 7.25
g) Catalog No. E3050 7.50
h) Catalog No. E3050 7.75
i) Catalog No. E3050 8.0
j) Catalog No. E3050 8.25
k) Catalog No. E3050 8.50
l) Catalog No. E3050 8.75
m) Catalog No. E3050 9.0
n) Catalog No. E3050 9.25
o) Catalog No. E3050 9.50. Recall #Z-037/051-9.
CODE Lot numbers: a) E3050 6.0, Lot Nos. S0974, S1046, S1211;
b) S1128, S1343;
c) S1129, S1344;
d) S0967, S1047, S1212;

MANUFACTURER RECALLED BY DISTRIBUTION QUANTITY REASON
 e) S0987, S1112, S1066, S1213;
 f) S0968, S0975, S1051, S1120, S1214;
 g) S1052, S1130, S1152, S1215, S1468;
 h) S0976, S1142, S1216, S1345, S1434;
 i) S0966, S1057, S1143, S1346, S1435;
 j) S0977, S1053, S1121, S1217, S1469;
 k) S0978, S1067, S1218, S1436;
 l) S0969, S1122, S1145, S1219;
 m) S1113, S1161;
 n) S1131, S1347;
 o) S1114, S1398, S1532.
 Bausch & Lomb Surgical, St. Louis, Missouri.
 Manufacturer, by letter on August 10, 1998. Firm-initiated recall ongoing.
 Nationwide and international.
 1,114 blades were distributed.
 The blade may be brittle and break during corneal transplant procedures.

None Present
 Action Taken _____

NSN PRODUCT
 6550 Nonstandard
 OctreoScan, Kit for the preparation of Indium In-111 Pentetreotide, 10 mcg.,
 Pentetreotide, 2.0 mg Gentisic Acid, 4.9 mg, Sodium Citrate, Anhydrous, 0.37 mg,
 Citric Acid, Anhydrous, and 10.0 mg Inositol. NDC #0019-9050-40. Recall
 #D-242-8.
 CODE Lot #050-8117 EXP 8/1/98 and 050-8188 EXP 8/2/98.
 MANUFACTURER RECALLED BY
 Manufacturer, by telephone on July 31, 1998, and by letter dated July 31, 1998.
 Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide Canada, Mexico.
 QUANTITY 85 kits were distributed; firm estimates none remains on the market.
 REASON Poor radiolabeling (70%) while the specification requires 95% minimum.

None Present
 Action Taken _____

NSN PRODUCT
 6550 Nonstandard
 a) ANA-SAL HIV 1+2 Saliva test kits (Version 2) b) ANA-SAL HIV 1+2 & Type
 O Saliva test kits HIV-2 (Version 3). Recall #B-1620/1621-8.
 CODE Kits may have an expiration date of 2/28/97.
 MANUFACTURER RECALLED BY
 Manufacturer, by letter dated June 2, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION California, Florida, Illinois, Nevada, New York and international.
 QUANTITY a) Approximately 94 kits; b) approximately 6 kits were distributed.
 REASON Unapproved HIV saliva test kits, that contain non functional components, were
 distributed for promotional/display use without labeling indicating that they
 should not be used for HIV testing.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Tricosal (Salicylic Acid 750 mg) Tablets, in 100 tablet bottles, Rx used for pain relief, under the Qualitest and Vintage label. Recall #D-247-8.
CODE Lot #078037A.
MANUFACTURER Vintage Pharmaceuticals, Inc., Charlotte, North Carolina.
RECALLED BY Manufacturer, by letter dated April 17, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 2,826 bottles were distributed.
REASON Product failed to meet dissolution specifications.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Clorfed Capsules Extended Release product, each capsule contains 8 mg chlorpheniramine maleate, 125 mg pseudoephedrine hydrochloride, in 100 capsule bottles and in 2 count physician sample foil packs, Rx indicated for relief of upper respiratory tract and bronchial congestion. NDC #45985-542. Recall #D-248-8.
CODE Lot #C66090 EXP 3/99.
MANUFACTURER Schwarz Pharma Manufacturing, Inc., Seymour, Indiana.
RECALLED BY Manufacturer, by letters on July 17, 1998, and on August 5, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Alabama, Arkansas, California, Florida, Indiana, Kentucky, Michigan, Mississippi, Missouri, New Jersey, North Carolina, Ohio, Pennsylvania, Tennessee, Texas.
QUANTITY 3,010 bottles of 100 tablet bottles, and approximately 187,063 capsules in two count foil packs were distributed.
REASON Product failed dissolution testing.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) Aconite and Iodine Solution (41.6%/58.4%), in 2 fluid ounce Containers
b) Parachlorophenol Camphorated, USP, (Camphor 65%/Parachlorophenol 35%), in 1 and 2 fluid ounce, and 1 gallon containers;
c) Desensitizer (Phenol, USP 24.2%, Oil of cloves (22.8%), cassia (5.4%), Eucalyptus (4.0%) Benzocaine, USP 2.0%, in 1 fluid ounce container;
d) Novo Devitalizing Paste (Arsenic Trioxide 38.4% Benzocaine 19.2%, Cresol 4.9%, Creosote 2.5%, Thymal 0.5%), in 6.2 g tube;
e) Formocresol (Cresol 48.5%, Formalin 48.5%, Glycerin 3.0%), in 1 and 2 fluid ounce containers, and in 1 gallon containers;
f) Hemostatic Ferric Swabs, (Ferric subsulfate solution 49.96%, Glycerin USP 49.96%, Phenol USP 0.08%), in 50 and 100 swab bottles;
g) Parachlorophenol, Liquefied (Parachlorophenol 97%), in 7 mL and 1 gallon bottles;
h) Perio-Eze 20 (Benzocaine 20%) in 30 g (paste) tubes;
i) Phenol Compound (Phenol 67.5%, Thymol 16.7% Menthol 8.3) in 1

fluid ounce bottles;
 j) Silver Nitrate Ammoniacal (Silver nitrate/Stronger Ammonia/Water), in 0.5 ounce bottle;
 k) Soc-Eze (Blu Pak/Chlorobutanol 4.0%, Balsam Peru 46.0%, Eugenol 46.0%, Benzocaine 4.0%), in 0.5 fluid ounce bottles;
 l) Iodoform Aromatic Paste (Zinc Oxide 31.31%, Iodoform 15.78%), in 8 g paste;
 m) Gysi's Trio Paste (Barium Sulfate 31.2%, Zinc Oxide 10.2%, Cresol 6.6%), in 11 g paste;
 n) Mummifying Paste (Paraformaldehyde 3.0%, Thymol 3.0%), in 6 g paste. Recall #D-249/262-8.

CODE All lots manufactured at the York, PA facility:
 MANUFACTURER Moyco Technologies, Inc., York, Pennsylvania.
 RECALLED BY Manufacturer, by letter dated May 13, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide and international.
 QUANTITY Undetermined.
 REASON Current good manufacturing practice deviations.

None Present
 Action Taken _____

NSN 6520 Nonstandard
 PRODUCT Light-Cure Flowable (Paint-on) Dental Restorative and Veneer Cement, intended for restoring damaged tooth enamel or for cementing dental veneers, distributed under the following brand names: Sci-Pharm CuRAY-Match, Henry Schein Veneer Cement, Master-Dent Flow Composite, Flow Fill, Natural Flow (distributed in Brazil), and Unidentified Brand (distributed in Korea). Recall #Z-035-8.

CODE Batch Nos. 6349, 6367, 6373, and 6380.
 MANUFACTURER Scientific Pharmaceuticals, Inc., Pomona, California.
 RECALLED BY Manufacturer, by letter dated March 31, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION California, New York, North Carolina, Florida, New Jersey, Pennsylvania, Washington state, Brazil, Korea, Taiwan, Italy.
 QUANTITY 3,835 units were distributed.
 REASON Product does not set completely after curing at room temperature as labeled.

None Present
 Action Taken _____

NSN 6550 Nonstandard
 PRODUCT VIA Medical Glucose Calibration Kit. Recall #Z-958-8.
 CODE Catalog #GLU2, Lot numbers 9805048 and 9804125.
 MANUFACTURER VIA Medical Corporation, San Diego, California.
 RECALLED BY Manufacturer, by letter on June 25, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Arkansas, California, Florida, Illinois, Indiana, Kansas, Oklahoma, South Carolina, Texas.
 QUANTITY 570 kits were distributed.
 REASON Some of the kits contain sodium chloride instead of dextrose solution.

None Present
 Action Taken _____
