

**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:

6530NS
MDC 12113 Incubators, Infant (Non-transport)
PRODUCT Isolette, Model C2HS (C2000), incubator used for critically ill newborn premature babies.
 Recall #Z-570-8.
CODE All product marketed since November 1996.
MANUFACTURER Hill-Rom Air-Shields, Hatboro, Pennsylvania.
RECALLED BY Manufacturer, by letter dated May 18, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY Approximately 2000 units were distributed.
REASON The controller and humidity module are subject to temperature fluctuations, humidity
 departures from set points and air flow probe failures.

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

REASON

Incorrect volumes - Vials are labeled with graduation marks that do not indicate an accurate volume.

None Present

Action Taken _____

NSN

6505 Nonstandard

PRODUCT

a) Red Blood Cells; b) Platelets.

CODE

Recall #B-1117/1118-8.

MANUFACTURER

Unit #GW39677.

Metropolitan Washington Blood Bank, Bethesda, Maryland.

RECALLED BY

Manufacturer, by letter dated April 27, 1998. Firm-initiated recall ongoing.

DISTRIBUTION

Virginia.

QUANTITY

1 unit of each component was distributed.

REASON

Blood products were collected from a donor who reported travel to an area designated as endemic for malaria.

None Present

Action Taken _____

NSN

6505 Nonstandard

PRODUCT

a) Amoxicillin for Oral Suspension, USP, 125 mg per 5 mL, 80, 100 and 150 mL when mixed, Rx semisynthetic antibiotic, 125 mg/5 mL, NDC #55953-149-38, -40, -47, also packaged under the Major label, Distributed by Major Pharmaceuticals, Livonia, MI, NDC #0904-2619-04, -07 and Qualitest label, Distributed by Qualitest Pharmaceuticals, Inc. Huntsville, AL, NDC #0603-6500-64, -66
b) Amoxicillin for Oral Suspension, USP, 250 mg per 5 mL, 80, 100 and 150 mL when mixed, 250 mg/5 mL, NDC #55953-130-38, -40, -47, also packaged under the Major label, NDC #0904-2620-04, -07, Rx antibiotic. Recall #D-152/153-8.

CODE

All lots within expiration date.

MANUFACTURER

Novopharm Limited, Scarborough, Ontario, Canada.

RECALLED BY

Novopharm USA, Inc., Schaumburg, Illinois, by letter dated May 8, 1998. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide.

QUANTITY

Amount distributed: a) 28,776 - 80-mL, 96,301 - 100-mL, 203,444 - 150-mL bottles;
b) 40,474 - 80- mL, 246,535 - 100-mL, 970,350 - 150-mL bottles.

REASON

Lack of assurance of homogeneity.

None Present

Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Atenolol Tablets; a synthetic beta-selective
 adrenoceptor blocking agent for the management
 of hypertension; packaged in 100 & 1000 tablet
 bottles: a) 50 mg, NDC #55953-039-40, -80, also
 packaged under the Major label, NDC #0904-7634-60,
 -80, Rugby label, Mfd for Rugby Laboratories,
 Inc., Norcross, Georgia, NDC #0536-3330-01, -10,
 Qualitest label, NDC #0603-2371-21, -32, Martec
 label, Mfd for Martec Pharmaceutical, Inc., Kansas
 City, MO, NDC #52555-531-01, -10 and Mova label,
 Pharmaceutical Corp., Caguas, PR
 00725, NDC #55370-122-07
 b) 100 mg, NDC #55953-401-40, also packaged under
 the Rugby label, NDC #0536-3331-01, Qualitest
 label, NDC #0603-2372-21, Martec label, NDC
 #52555-534-01, and Moore label, Distributed by
 Moore Drug Exchange, New Britain, Conn., NDC
 #0839-7724-06. Recall #D-154/155-8.
 CODE All lots within expiration date.
 MANUFACTURER Novopharm Ltd., Scarborough, Ontario, Canada.
 RECALLED BY Novopharm USA, Inc., Schaumburg, Illinois, by
 letter dated May 8, 1998. Firm-initiated recall
 ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY Amount distributed: a) 67,459 100-tablet and
 49,858 1000-tablet bottles
 b) 225,873 100-tablet bottles.
 REASON Lack of blend uniformity assurance.

[] None Present
 [] Action Taken _____

NSN 6505 Nonstandard
 UPDATE Recall #D-100/103-8, Propranolol HCL (Inwood
 Laboratories, Inc., Inwood, New York), which
 appeared in the April 1, 1998 Enforcement Report
 has been extended to include 29 additional lot
 numbers:
 D-100-8: Propranolol HCl 60 mg Extended Release
 (ER) Capsules, 100 count bottles, NDC #
 0258-3609-01, 16 lots -- 7C003 (9/98), 7C004
 (11/98), 7C005 (11/98), 7C017 (11/98), 7C018
 (11/98), 7C019 (11/98), 7C021 (11/98), 7C022
 (11/98), 7D007 (11/98), 7D008 (11/98), 7D009
 (11/98), 7F042 (11/98), 7F043 (11/98), 7F044
 (11/98), 7F045 (11/98) & 7F046 (11/98).
 D-101-8: Propranolol HCl 80 mg ER Capsules, 100
 count bottles, NDC # 0258-3610-01.
 4 lots - 7C024 (3/99), 7C026 (3/99), 7D014 (3/99)
 & 7F048 (5/99).
 D-102-8: Propranolol HCl 120 mg ER Capsules, 100
 count bottles, NDC # 0258-3611-01, 6 lots - 7C028
 (3/99), 7C029 (3/99), 7F053 (5/99), 7F054 (5/99),
 7F056 (8/99) & 7F057 (8/99).

D-103-8: Propranolol HCl 160 mg ER capsules, 100 count bottles, NDC # 0258-3612-01, 3 lots
- 7C033 (3/99), 7F058 (5/99) & 7F060 (5/99).

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Post Type Cylinder Valves, for medical gas cylinders. Recall #D-134-8.
CODE All lot codes.
MANUFACTURER Ceodeux, Inc., Ultrapure Equipment Technology S.A., Lintgen/Luxembourg.
RECALLED BY Rotarex, Inc., North America, Mt. Pleasant, Pennsylvania, by letter dated March 25, 1998. Firm-initiated field correction ongoing.
DISTRIBUTION Massachusetts, Georgia, California, Pennsylvania, Maryland, North Carolina, Kansas, Canada.
QUANTITY Approximately 125,000 units were manufactured and of that approximately 43,750 remained on market at time of recall initiation.
REASON High velocity valve stem ejection.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT CORFLO - CuBBy LPDG Low Profile Gastrostomy Device; an Rx sterile single patient use device consisting of an inner balloon that rests against the patient's stomach wall and an outer portion that rests on the patient's skin, which provides access to the patient's stomach for enteral feedings and medications:
a) Catalog No. 31-1820, 18FR, 2.0 cm length;
b) Catalog No. 31-2020, 20FR, 2.0 cm length.
Recall #Z-578/579-8.
CODE Lot numbers: a) A01LK and A01LK-1;
b) A01IB.
MANUFACTURER Manufacturing & Research, Inc. (MRI), Tucson, Arizona.
RECALLED BY Corpak MedSystems, Wheeling, Illinois, by letter dated May 1, 1998. Firm-initiated recall ongoing.
DISTRIBUTION Pennsylvania, Florida, California, Connecticut, Missouri, Texas, Maryland, South Carolina, New York, Oklahoma, Michigan, District of Columbia, North Carolina, Tennessee and Kentucky.
QUANTITY 104 units of 31-1820 and 25 units of 31-2020 were distributed between November 1997 through April 1998, firm estimated that 20% remained

REASON on the market at time of recall initiation.
There may be separation or partial separation
of the tube from the dome of the device.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT National Medical Care brand Venous Hemodialysis
Bloodlines. Recall #Z-582-8.
CODE Catalog No. 03-7317-5, Lot Nos. R7J001, R7J002 and
R7J004.
MANUFACTURER Fresenius Medical Care North America, Lexington,
Massachusetts.
RECALLED BY Fresenius Medical Care North America, Renal
Product Technologies, Lexington, Massachusetts, by
letter on April 29, 1998. Firm-initiated recall
ongoing.
DISTRIBUTION Nationwide and Puerto Rico.
QUANTITY 1,595 cases (24 units per case) were distributed.
REASON There is a possibility that a portion of the lots
were not processed according to validated
sterilization cycle, therefore, compromising the
sterility of the bloodlines.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Apnea slow breath and heart rate monitors:
a) Assurance 2000 Heart/Respiration Monitor
b) Assurance 2000 Hospital Monitor.
Recall #Z-583/584-8.
CODE Model Number Serial Number
2000WH 7057
A-2000 11935***
*** = 077, 562, 565 through 595, 597
through 621, 624, 627, 629
through 640, 642 through 648,
651, 653, 655, 658 through 691,
696, 701, through 706, 708
through 777, 779 through 819,
821 through 853, 855 through 999
11936***
*** = 000 through 048, 051 through
086 through. 088 through 116, 118, 119,
121 through 133, 135 through
217, 219 through 221, 223
through 247, 249 through
252, 254 through 290, 292, 294
through 311, 313 through 375,
377 through 381, 384 through
386, 388 through 393, 395

through 418, 420 through 433,
435 through 456, 458 through
483, 485 through 579, 582, 584
through 594, 596, 597, 598,604
through 666, 668, 670 through
681, 683 through 703, 705
through 715, 717 through 731,
733, 734, 735, 737, 738, 740,
741, 742
11938***
*** = 830, 832, 865, 870, 871, 874
33495
A2000H 8890 through 8901, 8906, 8907,
8908, 8910 through 8913.
MANUFACTURER Nellcor Puritan Bennett, Inc., Minneapolis,
Minnesota.
RECALLED BY Manufacturer, by letter dated May 13, 1998.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY Approximately 1,143 devices were distributed.
REASON Contaminated circuit boards could cause a product
malfunction. The devices could fail to alarm,
when an alarm is appropriate to warn of apnea or
abnormal heart rate.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Bipolar Rx Pacing Leads, intended for use with
pulse generators for long-term cardiac pacing.
Recall Z-585-8.
CODE All leads manufactured since 1983.
MANUFACTURER Aulzer Oscor, Inc. (Formerly Oscor Medical
Corporation), Palm Harbor, Florida.
RECALLED BY Manufacturer, by letter mailed beginning April 20,
1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 21,000 leads were distributed.
REASON The polyurethane insulation of the device is
cracking resulting in higher than normal failure
rates.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Ranitidine Tablets, USP (Ranitidine
Hydrochloride), 150 mg, in 500 tablet bottles,
Rx for the short-term treatment of active

duodenal ulcer. NDC #55953-544-70.
Recall #D-145-8.
CODE Lot #108969C.
MANUFACTURER Novopharm, Ltd, Scarborough, Ontario, Canada.
RECALLED BY Novopharm USA, Inc., Schaumburg, Illinois, by
telephone on May 5, 1998. Firm-initiated
recall ongoing.
DISTRIBUTION Maine, Florida, Louisiana, Pennsylvania,
Wisconsin, Missouri, Alabama, South Dakota,
Georgia, Ohio, Tennessee, Connecticut,
Minnesota.
QUANTITY 1,638 bottles were distributed; firm estimated
that 80 percent of the product remained on
market at time of recall initiation.
REASON Incorrect bottle desiccant.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Kendall Sher-I-Bronch Left-Sided Endobronchial
Tube a) Product Code: 5-16039 (39Fr); b) Product
Code: 5-16037 (37Fr) , indicated for
use in thoracic surgery, bronchspirometry,
for the administration of endobronchial
anesthesia and other uses commonly associated
with endobronchial tubes.

Recall #Z-573/574-8.
CODE Lot Numbers: a) 063534; b) 063532.
MANUFACTURER Kendall Sheridan, Argyle, New York.
RECALLED BY Kendall Healthcare Products Company,
Mansfield, Massachusetts, by letter between
March 23 and 25, 1998. Firm-initiated recall
ongoing.
DISTRIBUTION Nationwide.
QUANTITY a) 306 units; b) 312 units were distributed.
REASON Unit pouch is mislabeled with incorrect French
size.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT a) OTO-Care (otic), Antipyrine 810 mg/Benzocaine
210 mg, 1/2 fluid ounce bottles, used for the
treatment of superficial infections of the
external auditory canal complicated by
inflammation caused by organisms susceptible to
the action of the antimicrobial, and is also
labeled to control itching; b) OTO Care HC (Otic)
Chloroxylenol USP 1 mg/Benzocaine 14 mg
Hydrocortisone, USP, 10 mg 1/2 fluid ounce
bottles, used to treat acute otitis media of

various etiologies. Recall #D-147/148-8.
CODE Lot numbers: a) F-2465 EXP 6/99;
b) F-2459 EXP 6/99.
MANUFACTURER Propharma, Inc., Miami, Florida.
RECALLED BY Manufacturer, by a) telephone followed by fax on
April 3, 1998; b) by telephone and fax on May 4,
1998. Firm-initiated recall ongoing.
DISTRIBUTION Puerto Rico.
QUANTITY Approximately 6,760 bottles were distributed.
REASON Stability - Accelerated stability testing failures
for benzocaine/hydrocortisone in OTC care HC and
antipyrine/benzocaine in OTC care.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Neomycin and Polymyxin B Sulfate and
Hydrocortisone Otic Solution, USP (Neomycin
sulfate, equivalent To 3.5 mg Neomycin
base/Polymyxin B Sulfate 10,000
units/Hydrocortisone 10 mg), 10 mL bottles of 30,
used for otic use only, under the following
labels: Schein Pharmaceutical, Steris Laboratories
Inc., Akorn, Carlisle, Erva, Fougere, Geneva,
Generics of Puerto Rico, Goldline, IDE, H. L.
Moore, Major, Marlop Pharmaceuticals Inc., Mason,
Parmed, Robar Inc., Rugby, Teral, Teva, and United
Research Laboratories. Recall #D-149-8.

CODE 95C960, 95C961, 95D370, 95D371, 95D420, 95D620,
95D950, 95D951, 95D970, 95E040, 95E260, 95E410,
95E790, 95E990, 95F380, 95F570, 95G200, 95G450,
95G830, 95H020, 95H021, 95H640, 95H880, 95H881,
95J070, 95J120, 95L240, 95L820, 96A360, 96A490.
MANUFACTURER Steris Laboratories, Inc., Phoenix, Arizona.
RECALLED BY Manufacturer, by letter on March 18, 1998.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Puerto Rico.
QUANTITY 2,230,007 bottles were distributed; firm estimated
that 16,000 bottles remained on the market at time
of recall initiation.
REASON Stability - Lack of data at labeled storage
conditions.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Piroxicam Capsules, USP; for acute or long-term
use in the relief of signs and symptoms of
osteoarthritis and rheumatoid arthritis; packaged
in bottles of 100, 500 & 1000 capsules: a) 10 mg,
NDC #55953-617-40

b) 20 mg, NDC #55953-640-40, -70, -80 also packaged under the Moore label, NDC #0839-7774-06, -16; Major label, NDC #0904-5063-60, -40; and Mova label, NDC #55370-841-07. Recall #D-156/157-8. All lots within expiration date.

CODE
 MANUFACTURER
 RECALLED BY
 DISTRIBUTION
 QUANTITY
 REASON

Novopharm, Ltd., Scarborough, Ontario, Canada.
 Novopharm USA, Inc., Schaumburg, Illinois, by letter dated May 8, 1998. Firm-initiated recall ongoing.
 Nationwide.
 Amount distributed: a) 15,390 100-capsule bottles; b) 52,366 100-capsule, 14,892 500-capsule and 5,147 1000-capsule bottles.
 Lack of blend uniformity assurance.

None Present
 Action Taken _____

NSN
 PRODUCT
 CODE
 MANUFACTURER
 RECALLED BY
 DISTRIBUTION
 QUANTITY
 REASON

6515 Nonstandard
 Suture Retrievers: a) BTS Mini-Laparotomy MMK Set, Model No. UM250 (Part No. 120089)
 b) Laparotomy Bladder Neck Suspension Kit, Model No. MW-100
 c) BTS Urethropexy Suture Placement Set, Model No. UM-300, (Part No. 120148).
 Recall #Z-575/577-8.
 Lot numbers: a) 9ML80206-04;
 b) 9ML7015-01, 9ML70814-01, 9ML71021-04, 9SL71023-7, 9ML71023-01;
 c) 9ML80206-01, 9ML71201-03.
 Louisville Laboratories, Inc., Louisville, Kentucky.
 Medworks Corporation, Louisville, Kentucky, by letter dated April 16, 1998. Firm-initiated recall ongoing.
 California, Colorado, Florida, Georgia, Illinois, Kentucky, Massachusetts, Maryland, Missouri, New Jersey, Nevada, New York, Oklahoma, Pennsylvania, Texas, Virginia, Washington state.
 a) 52 devices; b) 43 devices; c) 97 devices were distributed.
 That the plastic handle of the suture retriever may crack at the point where the stainless steel needle attaches to the plastic handle.

None Present
 Action Taken _____

MEDICAL DEVICE SAFETY ALERTS:

NSN
UPDATE

6515 Nonstandard
Recall #Z-561-8, Adult BagEasy Disposable
Manual Resuscitators (All Types and Models),
Lot Nos. A960521 through A971201 and B960521
through B971201 (Respironics, Murrysville,
PA), which appeared in the May 13, 1998
Enforcement Report, has been reclassified as a
voluntary Safety Alert and assigned Safety
Alert #N-005-8.

None Present
 Action Taken _____
