

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 [AU]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/FOCO no later than 22 NOV 96 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: None

NSN 6505-00-559-5807
PRODUCT Albumin (Human) U.S.P. 25% (Albuminar - 25)
MANUFACTURER Centeon L.L.C.
NDC NUMBER 0053-7680-02
LOT NUMBER P61205 EXP DATE 5/12/99
REASON: Centeon L.L.C has received several reports of Enterobacter Cloacae Septicemia which may be associated with the administration of a single lot (P61205) of Albumin (human) U.S.P. 25%.

The above materiel is not depot stocked but could have been procured locally. Please examine your inventories of Albuminar -25 to determine whether or not you have any of lot number P61205. Immediately contact Centeon Customer Support at 1-800-683-1288 for the proper forms to notify the manufacturer.

Positive and/or negative responses are required. If you have any questions concerning product returns, please call customer support at the number above.
This confirms Q. A. message 6276-0024.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Apothe'Cure DMSO (Dimethylsulfoxide) for Injection, in 30 ml vials. Recall #D-270-6.
CODE Lots are coded by date of manufacture; the following dates of manufacture are under recall: April 1,3,10,12,18,26,30 1996; May 1,6,9,10,13-16 1996; June 3,4,7,13,20,26,28 1996; July 1,11,30 1996; August 2, 1996.
MANUFACTURER Apothe'Cure, Inc., Dallas, Texas.
RECALLED BY Manufacturer, by letter dated August 5, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY Undetermined.
REASON FDA analysis found samples contaminated with bacteria; and FDA inspection uncovered deficiencies of good manufacturing practices.

None Present
 Action Taken _____

CLASS II RECALLS:

NSN 6505 Nonstandard
PRODUCT Dilantin Kapseals (Extended Phenytoin Sodium), USP, 100 mg, antiepileptic. Recall #D-266-6.
CODE Lot numbers: 05685F, 02595F (bottles of 100); 02895F, 012N5F, 00626F (bottles of 1000). Recall #D-266-6.
MANUFACTURER Warner Lambert Company, Fajardo, Puerto.
RECALLED BY Warner-Lambert Company, Morris Plains, New Jersey, by letter on August 12, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 40,403 bottles of lot 05685F, 40,320 bottles of lot 02595F, 3,900 bottles of lot 02895F, 4,044 bottles of lot 012N5F, 3,879 bottles of lot 00626F were distributed.

REASON Stability test dissolution failure.

None Present

Action Taken _____

NSN 6505 Nonstandard

PRODUCT Nitrostat (nitroglycerin, USP), 0.4 mg
Sublingual Tablets, in bottles of 25,
indicated for the prophylaxis, treatment and
management of patients with angina pectoris.
Recall #D-267-6.

CODE Lot #02415F.

MANUFACTURER Warner-Lambert Company, Fajardo, Puerto Rico.
RECALLED BY Parke-Davis, Division of Warner-Lambert
Company, Morris Plain, New Jersey, by letter
on August 13, 1996. Firm-initiated recall
ongoing.

DISTRIBUTION Nationwide.

QUANTITY 22,817 bottles were distributed.

REASON Stability test assay failure.

None Present

Action Taken _____

NSN 6505 Nonstandard

PRODUCT Altaire Pharmaceutical brand Clear Cough Cough
Suppressant Expectorant (Guaifenesin/
Dextromethorphan), Oral Liquid, in 4 fluid
ounce plastic bottles. Recall #D-271-6.

CODE Lot #60077 EXP 3/99.

MANUFACTURER Altaire Pharmaceutical, Inc., Holbrook, New
York.

RECALLED BY Manufacturer, by letter on August 22, 1996,
and by telephone on August 30, 1996. Firm-
initiated recall ongoing.

DISTRIBUTION New York, New Jersey, Ohio, North Carolina,
Texas, Indiana, Wisconsin, Michigan, Alabama,
California, District of Columbia.

QUANTITY 12,316 units were distributed; firm estimated
that 200 units remained on market at time of
recall initiation.

REASON Product is misbranded because the dosing cup does not bear measurements that are consistent with the labeled dosing instructions.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Altaire Pharmaceuticals OTC pain relievers, in 4 fluid ounce plastic bottles: (a) APRA Cherry-Flavored Children's Acetaminophen Elixir; (b) Altenol Grape-Flavored Children's Acetaminophen Elixir. Recall #D-273/274-6.

CODE Lot numbers and EXP dates:

(a) 50331 8/98
60001 1/98
60002 1/99
60031 1/99
60089 3/99
60096 3/99
60253 7/99
(b) 50477 12/97
50500 12/97
60041 2/98
60152 5/98
60210 5/98.

MANUFACTURER Altaire Pharmaceutical, Inc., Holbrook, New York.

RECALLED BY Manufacturer, by letter on August 22, 1996. Firm-initiated recall ongoing.

DISTRIBUTION Alaska, Arizona, Arkansas, California, Florida, Illinois, Indiana, Michigan, Minnesota, New York, Texas, Puerto Rico.

QUANTITY (a) 67,945 units; (b) 23,012 units were distributed; firm estimated that 12,000 units combined remained on market at time of recall initiation.

REASON Products are misbranded because the dosing cup does not bear measurements that are consistent with the labeled dosing instructions.

None Present
 Action Taken _____

NSN 6515 Nonstandard
 PRODUCT LifeStyles Condoms Lubricated with Nonoxynol-9. Recall #Z-1202-6.
 CODE Lot #311044100 EXP 11/96.
 MANUFACTURER Ansell, Inc., Dothan, Alabama.
 RECALLED BY Manufacturer, by telephone in April 1996.
 DISTRIBUTION Firm-initiated recall complete.
 QUANTITY California, Florida, Georgia, Massachusetts, New Jersey, New York, Ohio, Oregon, Texas, Vermont, Washington state.
 REASON Approximately 78,000 condoms were distributed; firm estimates none remains on the market.
 The condoms failed the water leak test apparently due to deterioration of the latex because of improper storage conditions.

None Present
 Action Taken _____

NSN 6540 Nonstandard
 PRODUCT NewVues (vifilcon A) Soft Contact Lens, hydrophilic contact lens. Recall #Z-1111-6.
 CODE Lot #5348322.
 MANUFACTURER Ciba Vision Corporation, Atlanta, Georgia.
 RECALLED BY Manufacturer, by letter August 16, 1996.
 DISTRIBUTION Firm-initiated recall ongoing.
 QUANTITY Nationwide and international.
 REASON 1,648 multipacks (9,888 lenses) were distributed.
 Lenses may contain a sphere power other than that reflected in the labeling.

None Present
 Action Taken _____

NSN 6550 Nonstandard
 PRODUCT Incstar CMV-vue Test Kit, Catalog #24300, for the direct qualitative detection of early structural protein of CMV (cytomegalovirus). Recall #Z-1220-6.
 CODE Lots 315676 and 315676A.
 MANUFACTURER Incstar Corporation, Stillwater, Minnesota.
 RECALLED BY Manufacturer, by letter on September 9, 1996.
 Firm-initiated recall complete.

DISTRIBUTION Arkansas, Illinois, Maryland, New Mexico, New York, North Carolina, Tennessee, Australia, Germany, Italy, Korea, Portugal, Spain.
QUANTITY 67 kits were distributed.
REASON There was a decreased staining intensity in the positive control. Because of this, low positive samples have a potential to read negative.

[] None Present
[] Action Taken _____

NSN 6550 Nonstandard
PRODUCT Vasoseal Vascular Hemostasis Device (VHD) Kits, indicated for use in reducing time to hemostasis at the femoral arterial puncture side in patients who have undergone diagnostic angiography or percutaneous transluminal coronary angioplasty procedures using an 8 French or smaller procedural Sheath: Catalog Numbers: 75301, 75302, 75303, 75304, 75305, 75306, 75307.

CODE Recall #Z-1221/1227-6.
7 VasoSeal VHD Catalog Numbers:
75301 (Kit # 1 - Yellow)
75302 (Kit # 2 - Blue)
75303 (Kit # 3 - Red)
75304 (Kit # 4 - Green)
75305 (Kit # 5 - Purple)
75306 (Kit # 6 - Gray)
75307 (Kit # 7 - Orange)

Multiple VasoSeal VHD Lot Numbers: 06085171 through 09045171, inclusive, include products involved included product shipment through 10 January 1996.

MANUFACTURER Bioplex Medical B.V., Vaas, The Netherlands.
RECALLED BY Datascope Corporation, Collagen Products Division, Montvale, New Jersey, by letter sent beginning February 20, 1996. Firm-initiated recall complete.

DISTRIBUTION Nationwide.
QUANTITY 5,970 kits were distributed.
REASON There may be a missing component in the kit.

[] None Present
[] Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
PRODUCT Congess SR. (Guaifenesin, 250 mg;
Pseudoephedrine HCl, 120 mg) Capsules,
packaged in bottles of 100, Rx decongestant.
Recall #D-268-6.
CODE 6011467 EXP 9/96.
MANUFACTURER Fleming & Company, Fenton, Missouri.
RECALLED BY Manufacturer, by telephone on September 6,
1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 129 bottles were distributed.
REASON Stability test release rate failure.

None Present

Action Taken _____

NSN 6505 Nonstandard
PRODUCT Beta-HC 1/4% Topical Lotion (Hydrocortisone
Cream USP), antipruritic (anti-itch) lotion,
in 4 fluid ounce bottles. Recall #D-269-6.
CODE Lot KLA.
MANUFACTURER Beta Dermaceuticals, Inc., San Antonio, Texas.
RECALLED BY Manufacturer, by letter dated August 20, 1996.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 1,189 bottles were distributed; firm estimated
that 642 bottles remained on market at time of
recall initiation.
REASON FDA analysis found product to be subpotent.

None Present

Action Taken _____

NSN 6505 Nonstandard
PRODUCT Tussilan Liquid, Rx, in 1 ounce, 4 ounce and
128 ounce containers, antitussive,
expectorant, nasal decongestant,
antihistamine, used in the treatment of colds.
Recall #D-272-6.
CODE Lot #181-5 EXP 8/97.
MANUFACTURER Sein Mendez Laboratories, Rio Piedras, Puerto
Rico.
RECALLED BY Manufacturer, by letter on August 14, 1996.
Firm-initiated recall ongoing.
DISTRIBUTION Puerto Rico.
QUANTITY 12,731 1-ounce units; 9,405 4-units; 172 units

REASON were distributed.
Product does not meet potency specifications.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Cozy/Headrest Retaining Strap, Part #451220
and Posterior Headrest Pads, Part #450100 and
#450102. Recall #Z-1155/1156-6.

CODE None.
MANUFACTURER Quickie Designs, Inc., Fresno, California.
RECALLED BY Manufacturer, by letter dated July 19, 1996.
Firm-initiated recall ongoing.

DISTRIBUTION Pennsylvania, Illinois, Connecticut, Kansas,
Kentucky, Massachusetts, California, Texas,
Florida.

QUANTITY 184 straps were distributed.
REASON The strap of the headrest may slip down the
head of the user which could cause neck
strain, choking, or asphyxiation.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Sterile procedural trays labeled as containing
x-ray detectable gauze. Recall #Z-1164/1191-6.

1. Dental Tray (50-2548)
2. Abdominal Tray (50-4267)
3. Total Hip Tray (50-5195) 151981
4. Ortho Pack 3 per case (50-6236)
5. C-Section Tray 5 per case (50-7664)
6. Abdominal Hysterectomy 4 per case
(50-7998)
7. Dr. Gallo Eye Tray (50-8191)
8. D & C Pack (50-8443)
9. Hand Pack (50-9473)
10. Carpal Tunnel Tray (50-10505)
11. Lap Chole Tray (50-10533)
12. Carotid Endarterectomy Tray (50-11133)
13. Vascular Tracecart (53-0168)
14. Dr. Bichlmeier Heart Tracecart (53-0474)
15. Laparoscopy Tracecart B (53-0551)
16. General Surgery Tracecart B (53-0552)
17. Hand Tracecart (53-0708)
18. Lap Chole Tracecart (53-0810)

19. Pediatric Tracecart II (53-1111)
20. Minor G.U. Tracecart (53-1116)
21. Major Abdominal Tracecart (53-1235)
22. ENT Tracecart I (53-1282)
23. Plastic/Oral Tracecart (53-1283)
24. Craniotomy Tracecart (53-1304)
25. Laparoscopic Tracecart (53-1344)
26. Arthroscopy Tracecart (53-1377)
27. Extremity Tracecart (53-1379)
28. Lap Cholecystectomy Basecart (53-2068)

CODE

Product No.	Lot No.
50-2548	154078
50-4267	150113
50-5195	151981
50-6236	149557
50-7664	152952, 154690
50-7998	154743
50-8191	151274
50-8443	152892
50-9473	148999
50-10505	151751
50-10533	148835
50-11133	149244
53-0168	157836, 159101
53-0474	152483
53-0551	155650, 157044
53-0552	157397, 158784
53-0708	158787
53-0810	155663
53-1111	157442
53-1116	156863
53-1235	158819
53-1282	156868
53-1283	157450
53-1304	157113, 158742
53-1344	158821
53-1377	158830
53-1379	158620
53-2068	157446.

MANUFACTURER

DeRoyal Industries, Inc., Powell, Tennessee.

RECALLED BY

Manufacturer, by telephone on August 12, 1996, followed by letter August 13, 1996. Firm-initiated recall ongoing.

DISTRIBUTION

Connecticut, Delaware, Georgia, Indiana, Kansas, New Hampshire, Oklahoma, Pennsylvania, Utah, Illinois, Missouri, Ohio, New Jersey.

QUANTITY

446 cases were distributed.

REASON

The devices may not contain X-Ray Detectable gauze as labeled.

[] None Present

[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT Terumo Hypodermic Needles:
(a) Terumo Hypodermic Needles, Product Code 3NN*1938R; (b) Terumo Hypodermic Needles, Product Code 3NN*2038R; (c) Terumo Hypodermic Needles, Product Code 3NN*2338R.
Recall #Z-1199/1201-6.
CODE Lot numbers: (a) UG0726; (b) UG1326; (c) UG1426.
MANUFACTURER Terumo Medical Corporation, Elkton, Maryland.
RECALLED BY Manufacturer, by telephone and by fax, followed by letter dated July 2, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 98,000 pieces were distributed.
REASON A hole was found in the bottom web where the needle protector attaches to the needle hub, therefore, compromising the sterility of the product packaging.

[] None Present

[] Action Taken _____

NSN 6515 Nonstandard
MANUFACTURER Stryker Endoscopy Hybrid Electrocautery Tip and Spare Parts Kit:
Laparoscopic Suction Irrigator & Electrosurgical Probe; (a) Catalog #250-070-422 - StrykeFlow 5 mm Suction/Irrigator Tip, 32 cm, Composite, (Hybrid Tip) Endoscopy Hybrid Tip (Electrocautery accessory to Suction Irrigator, sold non-sterile)
(b) Catalog #250-070-430 - StrykeFlow Hybrid Tip Spare Parts Kit (Hubs, O-rings, (Spare Parts Kit) Sleeves) (sold non-sterile).
Recall #Z-1212/1213-6.
CODE Hybrid Tips (p/n 250-070-422) Lot #96049762 96059782; Hybrid Tip Spare Parts Kit (p/n 250-070-430) Lot # 96059782.
MANUFACTURER Stryker Endoscopy, Arroyo, Puerto Rico.
RECALLED BY Stryker Endoscopy, Santa Clara, California, by voicemail sent May 31, 1996, followed by letter June 10, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Canada.

QUANTITY 261 hybrid tips and 8 boxes spare part kits were distributed.
REASON The metal cannula may be exposed as a result of shrinkage of the insulation sleeve following autoclaving procedure, increasing the opportunity for spurious electrocautery discharge if the device is not properly utilized.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Model 5348 Single Chamber Temporary Pacemakers (AAI/VVI). Recall #Z-1214-6.
CODE All units sold prior to June 1, 1996.
MANUFACTURER Medtronic Milaca, Inc., Milaca, Minnesota.
RECALLED BY Medtronic, Inc., Minneapolis, Minnesota, by telephone beginning on August 19, 1996. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 1,381 units were distributed.
REASON The keypad shorts can result in device failure. The effects of failure can be that the device will not turn on, the device turns itself on or off, or rapid atrial pacing is spontaneously initiated.

None Present
 Action Taken _____

URGENT MANUFACTURER'S RECALLS:

NSN 6505 Nonstandard
PRODUCT Kanamycin Sulfate Injection USP, 250 mg/ml,
2ml, cat. 06402
NDC NUMBER 39769-0064-02
LOT NUMBER 950429
ECONO NUMBER 278-0138
REASON Voluntarily recalling due to inadequate testing
of prefiltered materiel.

The above materiel manufactured by Solopak Laboratories, Inc.,
is being recalled. The above materiel is not a depot stocked
item, but could have been procured thru Prime Vendor, DBPA or
locally purchased. If activities have the above materiel,
contact your source of supply for disposition/credit
instructions. A returned goods authorization and shipping
labels are required. For returned goods authorization
number/form/shipping labels contact Solopak Laboratories, Inc.,
Customer Service Dept.,
1-800-225-7626.

This confirms Q. A. message 6284-0027.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Beta HC .25% Lotion, Hydrocortisone Lotion, USP
NDC NUMBER 53062-0015-04
LOT NUMBER KLA
ECONO NUMBER 118-7087
REASON Recent tests show that the above lot number of
this product is subpotent.

The above materiel is not a depot stocked item, but could have
been procured thru Prime Vendor, DBPA or locally purchased. If
activities have the above materiel, contact your source of
supply
for disposition/credit instructions.
This confirms Q. A. message 6284-0027

None Present
 Action Taken _____

NSN 6505-01-389-6245
PRODUCT Albumin Human USP 5% 50 ml
TRADE NAME Albuminar-5
NDC NUMBER F00053767006

LOT NUMBER P18607 EXP. DATE 06/26/99

NSN 6505-00-559-5807
PRODUCT Albumin Human USP 25% 50 ml vial
TRADE NAME Albuminar-25
NDC NUMBER F00053768002
LOT NUMBER M54512 EXP. DATE 12/02/97
M60902 EXP. DATE 02/09/97

NSN 6505-00-680-2136
PRODUCT Albumin Human USP 55 500 ml vial
TRADE NAME Albuminar
NDC NUMBER F00053767002
LOT NUMBER L8212 EXP. DATE 12/20/96

NSN 6505-00-299-8179
PRODUCT Albumin Human USP 25% 100 ml vial
TRADE NAME Albuminar-25
NDC NUMBER 00053768003
LOT NUMBER L58211 EXP. DATE 11/12/96
M61403 EXP. DATE 02/28/97
P61805 EXP. DATE 05/22/99
M54912 EXP. DATE 12/05/97
M63204 EXP. DATE 04/14/97

REASON Some vials may have been damaged during transport,
possibly resulting in cracked vials. Cracked vials have the potential for microbial contamination product has Armour Pharmaceutical Company, label.

If wholesaler/distributor has contacted you comply with their instructions, otherwise, inspect stock for materiel. If found contact you local source of supply for return/credit instructions. A return goods authorization and shipping labels are required. For returned goods authorization number, forms, and shipping labels contact Centeon L.L.C., Customer Service Dept., phone nos., 1-800-683-1288 or (610) 878-4000. Medical questions may be directed to: Centeon Medical info, phone nos: 1 800 504-5434 or (610)878-4000.

This confirms Q. A. message 6278-0025.

None Present

Action Taken _____