

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:**

**6540 NS**

**MDC 16944**

**PRODUCT**

**CODE**

**MANUFACTURER**

**RECALLED BY**

**DISTRIBUTION**

**QUANTITY**

**REASON**

**Lasers**

Model Elite/Corium Laser Systems, for use in dermatology, dentistry, ophthalmology, ENT, etc. Recall #Z-683-0.

None.

FISMA, Inc., Salt Lake City, Utah.

Manufacturer. FDA approved the firm's corrective action plan on May 10, 2000.

Firm-initiated field correction ongoing.

Nationwide and international.

147 units were distributed.

If a single component on the light feedback circuit were to fail, the laser would emit full power at any power setting.

None Present

Action Taken \_\_\_\_\_

**6515 NS**

**MDC 14360, 14361**

**PRODUCT**

**CODE**

**MANUFACTURER**

**RECALLED BY**

**DISTRIBUTION**

**QUANTITY**

**REASON**

**Ventilators, Intensive Care, Neonatal/Pediatric**

Infant and Pediatric Ventilators, intended for neonatal, infant, and pediatric ventilation:

a) Model IV-100B/Model IV-200 infant and Pediatric Ventilator;

b) Model IV-100B/Model IV-200 SAVI System (Ventilator with Synchronized Assisted Ventilation of infants Module).

Recall #Z-685/686-0.

Model IV-100B Series w/serial numbers 13460-14490;

Model IV-200 Series w/serial numbers 22209-23030 are subject to this recall.)

Affected factory overhauls wherein the firm would have attached a battery bracket include any IV-100B or IV-200 Ventilator that received an overhaul between June 10, 1998 and November 19, 1999.

Seachrist Industries, Inc., Anaheim, California.

Manufacturer, by Product Advisory letters dated November 23, 1999 and

December 21, 1999. Firm-initiated field correction ongoing.

Nationwide and international.

1,831 units were distributed.

The metallic battery brackets can become dislodged from the inside back cover of the ventilator and contact the main circuit board assembly of the ventilator's operating system.

None Present

Action Taken \_\_\_\_\_

**CLASS III RECALLS:**

**6630 NS**

**MDC 16298**

**PRODUCT**

**Clinical Chemistry Analyzer, Automated**

Roche Reflotron Plus Analyzer, Catalog #747461, a bench top photometric chemistry analyzer for clinical use, which utilizes reagent strips for testing of multiple analytes. Recall #Z-668-0.

**CODE**

All serial numbers from 4027788 through 4031233 plus all units serviced since November 1997 and had the lower heating plate replaced.

**MANUFACTURER**

Roche Diagnostics GmbH, Mannheim, Germany.

**RECALLED BY**

Roche Diagnostics Corporation, Indianapolis, Indianapolis, by a product removal letter (Customer Bulletin #00-077) dated April 24, 2000. Firm-initiated recall ongoing.

**DISTRIBUTION**

Nationwide.

**QUANTITY**

Approximately 5,000 units were distributed.

**REASON**

There is a potential for erroneous results due to a loose screw in the lower heating plate, which affects the lower heating unit of the analyzer.

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 **28 JUL 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:**

NSN	6505 Nonstandard
PRODUCT	Herbal dietary supplements in oral dose capsules: a) Diabetes Hypoglucose Capsules,OTC, 70 capsules per bottle; b) Pearl Hypoglycemic Capsules, 60 capsules per bottle. Recall #D-338/339-0.
CODE	All lot codes.
MANUFACTURER	a) Pingchuan Group*Pingchuan International Economic Trade Harbin, China; b) Tongyi Tang Pharmaceutical, Harbin, China.
RECALLED BY	Chinese Angel Health Products, Inc., Blaine, Washington (responsible firm), by letter dated February 7, 2000. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	a) Approximately 2,139 bottles; b) Approximately 535 bottles were distributed.
REASON	Misbranding - Product contains the undeclared antidiabetic prescription drug glyburide.

None Present  
 Action Taken \_\_\_\_\_

NSN	6505 Nonstandard
PRODUCT	TriCitrasol (46.7% trisodium citrate), Citra and Medcomp part/catalog #PN6030. Recall #Z-679-0.
CODE	All lot numbers.
MANUFACTURER	Cytosol Laboratories, Inc., Braintree, Massachusetts.
RECALLED BY	Medical Components, Inc., Harleysville, Pennsylvania, by letter s on April 14 and 18, 2000. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	16,950 vials were distributed.

REASON TriCitrasol may be inadvertently administered into patients at full strength (46.7 percent) rather than being diluted as intended. In addition, the devices were distributed without appropriate clearances from FDA.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6505 Nonstandard  
PRODUCT TriCitrasol Anticogulant Sodium Citrate Concentrate 46.7%  
Trisodium Citrate, 30 mL glass vial, used to keep bloodlines open.  
Recall #Z-692-0.

CODE PN6030 (50/pack) and PN6032 (12/pack). All Lots.  
MANUFACTURER Cytosol Laboratories, Inc., Braintree, Massachusetts.  
RECALLED BY Manufacturer, by fax on April 14, 2000. Firm-initiated recall ongoing. See also  
FDA talk paper T00-16, April 14, 2000.

DISTRIBUTION Nationwide and Canada.  
QUANTITY 420,968 30mL-vials were distributed.  
REASON TriCitrasol may be inadvertently administered into patients at full strength (46.7%)  
rather than being diluted as intended. In addition, the device was distributed  
without appropriate clearances from FDA.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT Medcomp Bio-Flex Catheter (CS100) containing triCitrasol,  
Model No. BFR-6T. Recall #Z-678-0.

CODE All lot numbers.  
MANUFACTURER Medical Components, Inc., Harleysville, Pennsylvania.  
RECALLED BY Manufacturer, by telephone on April 6, 2000, and by letters on April 9 and 12,  
2000. Firm-initiated recall ongoing.

DISTRIBUTION Undetermined.  
QUANTITY 5 units were distributed.  
REASON TriCitrasol may be inadvertently administered into patients at full strength (46.7  
percent) rather than being diluted as intended. In addition, the devices were  
distributed without appropriate clearances from FDA.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT Sterile Custom Surgical & Procedure Kits/Trays packaged by Allegiance  
Healthcare Corp., McGaw Park, IL, under three divisions,  
Custom Sterile Division, Medsurg/Isolyser Division and Custom Products/PBDS  
Division. These kits, containing antiseptic products recalled by Clinipad  
Corporation, are packed according to the special order requirements of the  
customer. Recall #Z-604-0.

CODE (Note: If necessary a complete list of model information, codes/lot numbers can be  
obtained from the Chicago District Recall Coordinator).

MANUFACTURER RECALLED BY Allegiance Healthcare Corporation, Custom Sterile Divis, McGaw Park, Illinois. Manufacturer, by letter dated April 5, 2000, informing the accounts that the Allegiance trays contained Clilipad products subject to recall for lack of assurance of sterility. The letter also included a list of the affected products shipped to the account, as well as a supply of red stickers that stated, "URGENT! Product Correction STOP Remove and Discard any CLINIPAD Antiseptics in This Item", which the accounts were instructed to affix to any of the affected inventory in their possession. Firm-initiated recall ongoing.

COMPONENT MANUFACTURER Clinipad Corporation, Rocky Hill, Connecticut.

DISTRIBUTION Nationwide.

QUANTITY 341,746 kits/trays were distributed.

REASON Class I - Kits/trays contain Clinipad antiseptic products that may be contaminated with bacteria. Class II - Kits/trays contain Clinipad products for which the sterility could not be assured. Recall has been classified as Class I and Class II Devices packaged and distributed by Allegiance Healthcare Medsurg and PBDS Division - Class I. Kits/Trays packaged and distributed by the firm's Custom Sterile Division, which was able to identify the Clinipad products and lots used, for which the sterility could not be assured - Class II.

[ ] None Present

[ ] Action Taken \_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT Ash Split Cath II Hemodialysis Catheter containing triCitrasol:  
a) Model No. ASPC24-2T; b) Model No. ASPC28-2T;  
c) Model No. ASPC32-2T; d) Model No. ASPC36-2T;  
e) Model No. ASPC55-2T; f) Model No. TRAY552-2T;  
g) Model No. TRAY553-2T; h) Model No. TRAY593-2T;  
i) Model No. TRAY594-2T. Recall #Z-669/677-0.

CODE

All lots numbers.

MANUFACTURER RECALLED BY Medical Components, Inc., Harleysville, Pennsylvania. Manufacturer, by telephone on April 6, 2000, and by letters on April 9 and 12, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Puerto Rico, Canada.

QUANTITY 7,175 units were distributed.

REASON TriCitrasol may be inadvertently administered into patients at full strength (46.7 percent) rather than being diluted as intended. In addition, the devices were distributed without appropriate clearances from FDA.

[ ] None Present

[ ] Action Taken \_\_\_\_\_

NSN 6515 Nonstandard  
Medline SPT Surgical and Procedure Kits and Trays containing recalled Clinipad products.  
Recall #Z-524-0

CODE The affected kits/trays contain the following Clinipad components alone or in combination:

Medline/SPT Part #	Clinipad Reorder #	Description
05766	1245S-B	Alcohol Swabstick 3/PK
06235	1247S-B	Acetone Alcohol Swabstick

05413	1248S-B	Acetone Alcohol Swabstick
07762	3943S-B	Clinidine Povidone Iodine
CLI1243	1243	Iodine Tincture Swabstick
CLI372211	372211	E-Z Prep PVP Wing Sponge
CLI4444CD	4444CD	Clinidine PVP Sol. 4 oz.
CLI4474CD	4474CD	Cliniscrub PVP Scrub 4 oz.
00546	1291B	Iodorphor PVP Swabstick 3pk
01200	9153B	Iodophor PVP Prep Pad
02176	1230B	Swabstick BZK 3:1 PK
05160	0250B	Alcohol Prep Pad
05165	1241B	PVP Swabstick 1/PK
05481	1233B	Skin Protectant Swabstick
95488	1251B	Alcohol Swabstick
05768	4339B	Ointment Iodophor PVP 1
GR		
05789	1242B	PVP Scrub Swabstick 1/PK
05836	0310B	Acetone Alcohol Pad
06070	3925B	Isopropyl Alcohol 1 oz.
06233	1231B	Compound Benzoin Tincture Swabstick
08990	1244B	PVP Scrub Swabstick 3/PK
10096	8133	Skin Protectant Prep Pad

(NOTE: If necessary a complete list of kits and part numbers can be obtained from the Chicago District Recall Coordinator).

MANUFACTURER  
RECALLED BY

Medline Industries, Inc., SPT Division, Waukegan, Illinois.  
Medline Industries, Inc., Mundelein, Illinois, by letter dated March 16, 2000, instructing users not to use Clinipad products within kits and Medline sales representatives will visit and apply stickers that state "RECALL Do Not Use The Clinipad Products Within This Kit Destroy The Clinipad Product". Firm-initiated recall ongoing.

MANUFACTURER  
DISTRIBUTION  
QUANTITY  
REASON

Clinipad Corporation, Rocky Hill, Connecticut.  
Nationwide and international.  
175,500 kits in commerce by FDA estimate.  
Kits contain Clinipad antiseptic products that may be contaminated with bacteria.

[ ] None Present  
[ ] Action Taken \_\_\_\_\_

NSN  
PRODUCT

6515 Nonstandard  
Sterile Surgical and Procedure Kits/Trays distributed under labels identifying: Medikmark Inc., 900 Asbury Drive, Buffalo Grove, IL 60089; Medikmark, Inc., 3600 Bur Wood Drive, Waukegan, IL 60085; Distributed by Maxxim Medical, Case Management Division, Clearwater, FL 34622; Manufactured for R&J Medical Supply, Milwaukee, WI 53223; Distributed by Triad Medical, Laguna Hills, CA 92653. Recall #Z-525-0.

CODE

One or more of the following Clinipad products were packaged in each of the Medikmark manufactured kits/trays, but the lot numbers of the Clinipad products are unknown:

- a) 0250B, Clinipad Alcohol Prep
- b) 0310S-B, Clinipad Acetone Alcohol Prep Pad
- c) 1251S-B, Cliniswab Isopropyl Alcohol Swabstick
- d) 1248S-B, Cliniswab Acetone Alcohol Swabstick, 3 swabs
- e) 0110BS, CliniPad Alcohol Prep

- f) 1245S-B, Cliniswab Isopropyl Alcohol Swabstick, 3 swabs
- g) 1230BS
- h) 1231S-B, Cliniswab Compound Benzoin Tincture Swabstick
- i) 1233S-B, Cliniguard Protective Dressing Swabstick
- j) 3943S-B, Clinidine Povidone Iodine 1% USP Solution, 1oz.
- k) 9153S-B, Clinipad Iodophor PVP Povidone Iodine USP Prep Pad
- l) 1244S-B, Cliniswab Iodophor PVP Scrub Povidone Iodine USP, 3 Swabsticks
- m) 1241S-B, Cliniswab Iodophor PVP Povidone Iodine USP, 1 Swabstick
- n) 1291S-B, Cliniswab Iodophor PVP Povidone Iodine USP, 3 Swabsticks
- o) 2395B3, Clinipad Antiseptic Towelette
- p) 3925B, Clinipad Isopropyl Alcohol 70%, 1 oz.
- q) 4444-D, Clinidine Solution, Povidone Iodine, 4 oz.
- r) 4446, Clinidine Solution, Povidone Iodine, 2 oz.
- s) 4474-SC, Cliniscrub Surgical Scrub, Povidone Iodine, 4 oz.
- t) 4476, Cliniscrub Surgical Scrub, Povidone Iodine, 2 oz.
- u) 4484
- v) HK4444, Clinidine Solution, Povidone Iodine, 4 oz.
- x) 4338SB

All lots of kits/trays manufactured in the last three years are being recalled.  
 (NOTE: If necessary, a complete list of lot numbers can be obtained from the Chicago District Office Recall Coordinator.)

MANUFACTURER  
 RECALLED BY

Medikmark, Inc., Waukegan, Illinois.  
 Manufacturer, by letter dated March 16, 2000, providing stickers advising users not to use the Clinipad components and to them. Firm-initiated recall ongoing.

COMPONENT MANUFACTURER  
 DISTRIBUTION

Clinipad Corporation, Rocky Hill, Connecticut.  
 Nationwide.

QUANTITY  
 REASON

1,350,000 kits in commerce FDA estimate.  
 The kits/trays contain Clinipad antiseptic products that may be contaminated with bacteria.

- None Present
- Action Taken \_\_\_\_\_

NSN  
 PRODUCT

- 6515 Nonstandard  
 Various sterile skin preparations:
- a) Clinipad Alcohol Prep, Antiseptic. NDC #19154-1245-3.
  - b) Clinipad Alcohol Prep. NDC #19154-1245-8
  - c) Cliniswab Iodophar PVP Povidone Iodine USP, Antiseptic, 1 Saturated Swabstick. NDC #19154-1241-2
  - d) Cliniswab Iodophar PVP Scrub Povidone Iodine USP 3 Saturated Swabsticks. NDC #19154-1242-7
  - e) Cliniswab Isoprophyl Alcohol Antiseptic, 1 Saturated Swabstick. NDC #19154-1245-9
  - f) Cliniswab Iodophar PVP Scrub, Povidone Iodine USP, Antiseptic, 1 Saturated Swabstick. NDC #19154-1242-9
  - g) Cliniswab Iodophar PVP Povidone Iodine USP, Antiseptic, 3 Saturated Swabsticks. NDC #19154-1241-3
  - h) Cliniswab Iodophor PVP Antiseptic Cleanser, Povidone 10% USP, 3 Saturated Swabsticks.

NDC #19154-1241-0

i) Clinipad Iodophor-PVP, Povidone-Iodine USP, Titratable Iodine 1% Solution, Antiseptic

1 fluid ounce  
(30 ml). NDC #19154-1241-4

j) Clinidine Povidone Iodine 1% USP Solution Topical Anti-Infective, 1 fluid ounce (30ml). NDC #19154-1241-5

k) Clinidine Povidone Iodine 10% USP Solution Antiseptic Cleanser, 3/4 fluid ounce (30ml).  
NDC #19154-1241-7.

l) Clinidine Ointment Povidone USP Titratable Iodine 1% Antiseptic Germicide net weight .033 ounce  
(1.0g). NDC #19154-4341-4

m) Clinipad Iodophor PVP Povidone Iodine USP 1 Prep Pad. NDC #19154-1241-1. Recall #D-325/337-0.

CODE

Clinipad Reorder Code	Lot No.	Product Code
a) 0110	806610	0110
0110BS	802270	0110BS
b) 0250R	716313	0250R
c) 1241S-B	812304, 811612	1261S
1261S	812467	HK1241S
HK1241S	919882	1241S-B
d) HK1244S	919862	HK1244S
e) 1251S-B	805817	1251S-B
f) 1262S	920324, 918333	
	810014, 812302	1262S
g) 1291S-B	715786, 812873	129S-B
HK1291S	911485, 919827	HK1291S
h) 1291SK	919249	1291SK
i) 3941S-BC	812422	3941S-BC
HK3941S	812891, 911939	HK3941S
j) 3943S-B	917141	3943S-B
k) 3944S-B	919888	3944S-B
l) 4339SC	811937, 920315	4339SC
HK4339S	919864, 812893	HK4339S
m) 9153SBD	812556, 919526	HK9153S
HK9153S	919915	9153SBD.

MANUFACTURER  
RECALLED BY

Clinipad Corporation, Charlotte, North Carolina.  
The Clinipad Corporation, Rocky Hill, Connecticut, by letters beginning March 10, 2000. Firm-initiated recall ongoing. See also FDA press release P00-7, March 10, 2000.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and international.  
Undetermined.  
Microbial contamination.

[ ] None Present  
[ ] Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN  
PRODUCT

6515 Nonstandard  
Various sterile procedure kits containing antiseptic products recalled by Clinipad Corporation under the Kendall brand (Curity, Kenguard and Sage); and private label: Allegiance, Source and Respiratory Support Products, Inc. (RSP).

Recall #Z-605-0

CODE All lots containing the recalled Clinipad antiseptic Item #3944S-B, Lot #91988 and other Clinipad products. (NOTE: If necessary, a complete detailed list and product codes can be obtained from the New England District Office Recall Coordinator.)

MANUFACTURER KenMex, Tijuana, Mexico, Kendall Healthcare, Chatswork, California.

RECALLED BY The Kendall Company, LP, Mansfield, Massachusetts, by letter March 24, 2000, providing stickers and advising end users to discard Clinipad antiseptics in kits. Firm-initiated recall ongoing.

COMPONENT MANUFACTURER Clinipad Corporation, Rocky Hill, Connecticut.

DISTRIBUTION Nationwide and international.

QUANTITY 100,000 cases were distributed.

REASON Class I - Kits contain antiseptic products that may be contaminated with bacteria. Class II - Kits contain Clinipad antiseptic products labeled as sterile for which Clinipad is unable to assure the sterility.

Recall has been classified as Class I and II:  
 Kits manufactured with the recalled antiseptic product (assigned Kendall Lot Numbers 9348004 and 9355014) - Class I Kits not containing those specific lots, but which contain Clinipad products for which the sterility could not be assured – Class II

None Present  
 Action Taken \_\_\_\_\_

**CLASS II RECALLS:**

NSN 6505 Nonstandard

PRODUCT Feosol(r) Elixir Iron Supplement Therapy 44mg, in 16-ounce (473ml) bottles. Recall #D-347-0.

CODE Lot Numbers: 9H23A and 9J11A.

MANUFACTURER SmithKline Beecham Consumer Healthcare, Aiken, South Carolina.

RECALLED BY SmithKline Beecham Consumer Healthcare, Parsippany, New York, by letter and public warning on February 18, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 884 cases (12 bottles per case) were distributed.

REASON Subpotent iron content (stability testing) and crystalline precipitate.

None Present  
 Action Taken \_\_\_\_\_

NSN 6505 Nonstandard

PRODUCT Jordan Epinephrine Injection, USP, 1:1000, 1 mg/mL, 1mL ampuls, Rx sterile solution intended for subcutaneous or intramuscular administration for the treatment of respiratory distress in bronchial asthma or during severe, acute asthma attacks, severe anaphylactic reactions and shock, and cardiac arrest to restore cardiac rhythm. NDC #58196-065-31. Recall #D-349-0.

CODE Lot Numbers: 980308, 980401, 980402, 980501, 980601, 990205, 990307, 990308.

MANUFACTURER Bioniche Teo, Republic of Ireland.

RECALLED BY Jordan Pharmaceuticals Inc., Elk Grove Village, Illinois, by letter dated March 15, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Pennsylvania, Mississippi, California.

<p>QUANTITY REASON</p>	<p>2,167 100-ampule boxes were distributed. Subpotency - During stability testing.</p> <p><input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____</p> <hr/>
<p>NSN PRODUCT</p>	<p>6505 Nonstandard Mintezol(r) Chewable (Thiabendazole) Tablets, USP, 500 mg, in unit dose packages of 36 tablets, Rx for the treatment of parasitic infections. Recall #D-352-0.</p>
<p>CODE</p>	<p>Lot Numbers and EXP Dates: J800 EXP Jan 04, J8001 EXP Jan 04, J8002 EXP Jan 04, J8003 EXP Jan 04, J8004 EXP Jan 04, J8005 EXP Jan 04, J8011 EXP Feb 04, J8012 EXP Feb 04, J8013 EXP Mar 04, J8014 EXP Feb 04, J8016 EXP Feb 04, J8017 EXP Feb 04.</p>
<p>MANUFACTURER RECALLED BY DISTRIBUTION QUANTITY REASON</p>	<p>Merck and Company, West Point, Pennsylvania. Manufacturer, by letter dated March 20, 2000. Firm-initiated recall ongoing. Nationwide and international. 24,163 units were distributed. Use of an unapproved binding agent was used in formulation.</p> <p><input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____</p> <hr/>
<p>NSN PRODUCT</p>	<p>6505 Nonstandard Meperidine HCL Injection, USP, Rx for relief of moderate to severe pain, for pre-operative medication, for support on anesthesia, and for obstetrical analgesia: a) 50 mg/mL in 30mL vial, NDC #0008-0258-01; b) 100 mg/mL in 20 mL vial, b) NDC #0008-0259-01. Recall #D-356/357-0.</p>
<p>CODE</p>	<p>Lot numbers: a) 4970174 EXP 11/00, 4980176 EXP 6/01, 4980216 EXP 7/01, 4990104 EXP 2/02; b) 4970175 EXP 11/00, 4980213 EXP 6/01, 4980214 EXP 9/01, 4990084 EXP 3/02.</p>
<p>MANUFACTURER RECALLED BY DISTRIBUTION QUANTITY</p>	<p>Wyeth Laboratories, Marietta, Pennsylvania. Wyeth Ayerst Laboratories, St. Davids, Pennsylvania, by letter dated March 13, 2000. Firm-initiated recall ongoing. Nationwide. 95,786 vials were distributed.</p> <p><input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____</p> <hr/>
<p>NSN PRODUCT</p>	<p>6505 Nonstandard Spartan(r) Antiseptic Hand Cleaner, Hair &amp; Shampoo, OTC, in 800 mL bags, 1 and 5-gallon pails, and 15, 30 and 55-gallon drums. Recall #D-363-0.</p>
<p>CODE</p>	<p>Lot Numbers: 0987 through 0993, and all codes prior to "04/03/00" expiration date.</p>
<p>MANUFACTURER RECALLED BY DISTRIBUTION</p>	<p>Steiner Company, Inc., Holland, Ohio (packager). Spartan Chemical Company, Maumee, Ohio (responsible firm), by letter on April 14, 2000. Firm-initiated recall ongoing. Nationwide.</p>

QUANTITY 100,800 gallons were distributed.  
 REASON Product contains unapproved dyes.  
  
 None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

NSN 6505 Nonstandard  
 PRODUCT Copaxone(r) (glatiramer acetate for injection, formerly known as Copolymer-1) Self Injection Administration package containing 100 units of Alcohol Prep (Swab) recalled by Clinipad Corporation. Recall #D-366-0.  
 CODE The Clinipad lot numbers that had been packaged into the kits were:  
 803902 812094 812879 814063 910806 814314 915860  
 805963 812158 813314 814747 910089 915435 916061  
 805829 811229 813550 815368 910599 915110 916415  
 805206 812091 813313 815970 910594 915461 915937  
 809016 811658 803206 910559 910093 915860 915504  
 809018 812878 800521 910089 911739 915728 917479  
 809019 814065 910092 911313 917040.  
 COMPONENT MANUFACTURER The Clinipad Corporation, Charlotte, North Carolina (responsible firm).  
 RECALLED BY Aventis Pharmaceuticals, Inc., Kansas City, (distributor), by fax and letter dated March 20, 2000. Firm-initiated recall ongoing.  
 DISTRIBUTION Nationwide.  
 QUANTITY 376,689 administration kits were distributed between 3/19/97 through 3/13/2000.  
 REASON Administration kits contain alcohol preps for which Clinipad Company is unable to assure the sterility.  
  
 None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

NSN 6505 Nonstandard  
 PRODUCT Goldline Brand: a) Doxycycline Hyclate Capsules, 100 mg, in blister packs in boxes of 100;  
 c) Indomethacin Capsules, 50 mg, in blister packs in boxes of 100.  
 d) Recall #D-367/368-0.  
 CODE Lot Numbers: a) T-1474 EXP 10/01; b) T-1475 EXP 10/01.  
 MANUFACTURER Zenith Goldline Pharmaceuticals, Northvale, New Jersey.  
 International Labs, St. Petersburg, Florida (responsible repacker/packager (contract)).  
 RECALLED BY Zenith Goldline Pharmaceuticals, Miami, Florida, by letter beginning on April 10, 2000. Firm-initiated recall ongoing.  
 DISTRIBUTION Nationwide.  
 QUANTITY a) 604 boxes; b) 366 boxes were distributed; firm estimated that 50 percent of the product remained on market at time of recall  
 REASON initiation.  
 Mislabeling - Indomethacin Capsules were incorrectly labeled as Doxycycline Hyclate Capsules.  
  
 None Present  
 Action Taken \_\_\_\_\_  
 \_\_\_\_\_

NSN 6505 Nonstandard  
 PRODUCT Licensed, sterile, stable, lyophilized blood factors derived from pooled human plasma; Centeon L.L.C., Kankakee, Illinois 60901; these products were packaged with vials of Sterile Water for Injection for reconstitution, as well as administration sets:  
 a) Mononine Coagulation Factor IX (Human), Monoclonal Antibody Purified; for the prevention and control of bleeding in Factor IX deficiency, also known as Hemophilia B or Christmas disease; 1000 Units, NDC #0053-7668-04  
 b) Monoclote-P Antihemophilic Factor (Human), Factor VII:C Pasteurized Monoclonal Antibody Purified; for treatment of classical hemophilia, also known as Hemophilia A  
 i) 250 Units, NDC #0053-7656-01  
 ii) 500 Units, NDC #0053-7656-02  
 iii) 1000 Units, NDC #0053-7656-04  
 The Mononine and Monoclote-P products were packaged with administration set packets labeled in part: Sterile Administration Components for I.V. Infusion, Manufacturer: B. Braun Medical Inc., Bethlehem, PA 18018. The alcohol swabs packaged within this packet were labeled as Sterile Steri Wipe 1 Alcohol Swab, Anajay, Inc., Charlotte, NC 28213.  
 Recall #B-637/638-0.  
 CODE All in-date lots of both products which expire prior to April 2002.  
 MANUFACTURER Aventis Behring L.L.C., Bradley, Illinois.  
 RECALLED BY Aventis Behring L.L.C., King of Prussia, Pennsylvania, by telephone on March 20 and 21, 2000, by fax on March 20-22, 2000, followed by letters. Firm-initiated recall ongoing.  
 SWAB COMPONENT MANUFACTURER Clinipad Corporation, Rocky Hill, Connecticut.  
 DISTRIBUTION Nationwide and international.  
 QUANTITY a) 65,700 vials; b) 13,000 250-unit vials, 19,000 500-unit vials, 28,500 1000-unit vials were distributed.  
 REASON The Steri Wipe Alcohol Swabs, packaged with Mononide and Monoclote-P were recalled by Clinipad Corporation due to lack of assurance of sterility.  
 [ ] None Present  
 [ ] Action Taken \_\_\_\_\_  
 \_\_\_\_\_

NSN 6505 Nonstandard  
 UPDATE Rugby Hemorrhoid Preparation Suppositories in cardboard box containing 12 suppositories, Recall #D-113-0, which appeared in the December 15, 1999 Enforcement Report has been extended to include Lot #908222.  
 [ ] None Present  
 [ ] Action Taken \_\_\_\_\_  
 \_\_\_\_\_

NSN 6515 Nonstandard  
 PRODUCT B-D 1 ml Safety-Lok Insulin Syringe, 29G 1/2 Ultrafine Needle, Reorder No. 329464. Recall #Z-684-0.  
 CODE Lot numbers 0005853 and 0106646.  
 MANUFACTURER Becton Dickinson, BD Medical Systems, Franklin Lakes, New Jersey.  
 RECALLED BY Manufacturer, by telephone on March 2, 2000, followed by letter dated March 9 or 23, 2000. Firm-initiated recall complete.  
 DISTRIBUTION Mississippi, Louisiana, Tennessee, Texas, Pennsylvania, Indiana, Minnesota, Ohio,

QUANTITY  
REASON

Michigan.  
10,500 units were distributed.  
Product was marked in ml scale instead of insulin units.

None Present  
 Action Taken \_\_\_\_\_

NSN  
PRODUCT

6515 Nonstandard  
Various Nonsterile Skin Preparations:  
1) CLINIPAD Acetone Alcohol Prep, 1 Prep Pad, 100 units/folding box, 10 boxes/case and 8,000/case. NDC #NDC 19154-1247-2  
2) CLINISWAB Iodophor-PVP Scrub, Povidone-Iodine USP, 3 Saturated Swabsticks/unit, 25 units/folding box; 10 boxes/case 2490SW. NDC 19154-1242-2  
3) CLINIPAD Iodophor, Poloxamer-Iodine Complex, 3 Towelettes, Antiseptic, 1000/case. NDC 19154-9152-6  
4) CLINIPAD Isopropyl Alcohol 70%, 1 fl. oz. (30 ml), 50 units/folding box; 4 boxes/case and 200 units/case. NDC 19154-1245-5  
5) Clinipad Alcohol Prep, 200 units/folding box, 10 boxes/case. NDC #19154-0110-2  
6) Clinipad Alcohol Swab, 200 units/folding box, 10 boxes/case. NDC #19154-0110-2  
7) Cliniswab Lemon Glycerin, 3 Saturated Swabsticks/unit, 25 units/folding box, 10 boxes/case/.  
8) Cliniswab Benzalkonium Chloride, 3 Saturated Swabsticks/unit, 25 units/folding box, 10 boxes/case. NDC #19154-3912-2  
9) Cliniswab Benzalkonium Chloride, 3 Saturated swabsticks/unit, 500 units/case. NDC #19154-3911-1  
10) Cliniswab Tincture of Green Soap, 1 Saturated Swabstick, 50 units/folding box, 10 boxes/case. NDC #19154-1235-1  
11) Cliniswab Isopropyl Alcohol, 1 and 3 Saturated Swabsticks/unit, 25 units/folding box, 10 boxes/case and 50 units/folding box, 10 boxes/case. NDC #19154-1245-1 and 19154-1245-6.  
12) Cliniswab Povidone-Iodine USP, 1 Saturated Swabstick/unit, 50 units/folding box, 10 boxes/case. NDC #19154-9153-2  
13) Cliniswab Iodophor-PVP Scrub, Povidone-Iodine USP, 1 Saturated Swabstick/unit, 50 units/folding box, 10 boxes/case. NDC #19154-1242-1  
14) Cliniswab Iodophor, Poloxamer-Iodine Complex, 3 Saturated Swabsticks/unit, 25 units/folding box, 10 boxes/case. NDC #19154-9152-3  
15) Cliniswab Iodophor-PVP Povidone-Iodine, 3 Saturated Swabsticks/ unit, 25 units/folding box, 10 boxes/case. NDC #19154-9153-3.  
16) Clinipad Antiseptic, 1 Towelette, 100 units/folding box, 10 boxes/case and 2,500 units/case. NDC #19154-3912-3  
17) Clinipad Iodophor, Poloxamer-Iodine Complex, 3 Towelettes, Antiseptic, 100/case. NDC #19154-9152-6  
18) Clinidine Povidone Iodine USP Solution, 1 fluid ounce (30ml), 50 units/folding box, 4 boxes/case. NDC #19154-9153-4  
19) Clinidine Ointment, 0.33 ounce (1.0g), 250 units/folding box, 4 boxes/case. NDC #19154-4341-2  
20) Clinidine Solution, Povidone Iodine, 1 Gal. (3.78L), 16 fl. oz. (473 ml), 8 fl. oz.

(237 ml), 4 fl. oz. (118 ml), 2 fl. oz. (59 ml), 1 fl. oz. (30 ml). NDC 19154-9153-6, NDC 19154-9153-7, NDC 19154-9153-5  
 NDC 19154-4444-0, NDC 19154-4444-1, NDC 19154-4444-9  
 NDC 19154-4445-1  
 21) Cliniscrub Surgical Scrub, Povidone Iodine, 1 gallon (3.78L), 4 fluid ounces (118ml), 2 fluid ounces (50ml), 50 units/case.  
 NDC #19154-4471-4, NDC #19154-4471-6, NDC #19154-4474-1  
 22) Clinipad Iodophor PVD, Povidone Iodine USP, 1 Prep Pad, 200 units/folding box, 10 boxes/case. NDC #19154-9153-1  
 23) Moore Medical, Povidone Iodine USP Antiseptic Swabstick, Reorder #08485, 50 units/folding box, 10 boxes/case.  
 NDC #00839-8074-04  
 24) Randex Hemorrhoidal Wipes, 900 units/case and 100 units/case folding box, 10 boxes/case. NDC #19154-3912-9  
 25) Bidette Cloth Towelettes, 100 units/folding box, 10 boxes/case.  
 NDC (n/a)  
 26) Vionex Antimicrobial Skin Wipe Towelette (Metrex MX-1510), 50 units/folding box, 10 boxes case. NDC #55443-0102-1  
 27) E-Z-Prep, 1 Winged Sponge, Iodophor Scrub Solution, 50 units/case. NDC #19154-0310-1  
 28) E-Z Prep, 2.8" Sponge Sticks Povidone-Iodine Topical Solution, 70 units/case. NDC #19154-1480-1  
 29) E-Z-Prep, 4 Winged Sponges, Iodophor Scrub Solution, 50 units/case. NDC #19154-0311-5  
 30) E-Z Prep Solo-Prep Topical Gel, 115 units/case. NDC #19154-1459-1  
 31) Clinidine Solution, Povidone Iodine, 4-fluid ounces (118ml), and 2-fluid ounces (59ml), 50 units/case. NDC #19154-4444-1 and NDC #19154-4444-9  
 32) E-Z-Prep Scrub Solution, 4-fluid ounces (118ml), 115 units/case. NDC #19154-0311-4.  
 33) E-Z-Prep Paint Solution, 2.7-fluid ounces (80ml), 115 units/case. NDC #19154-1460-2.  
 Recall #D-264-296-0.

CODE

Clinipad Reorder Cod	Lot No.
1) 0310, 0310SB	All lots
2) 1244	All lots
3) 2490SW	All lots
4) 3925, 3925D, 3925B	All lots
5) 0610	920842
6) 0610E	913380
7) 1225	905197, 917536, 913121, 914355
8) 1230, 1230CRB	806552, 813702, 814648
9) 1230BK	807004, 810660, 904181
10) 1235	914805
11) 1245, 1251	715480, 912553, 913661, 914449
12) 1261	913244, 914953, 921951
13) 1262	806550, 913512
14) 1290	914080
15) 1291	912164, 914485, 914962, 921451, 921714

- 16) 2395, 2395B3 811478, 910288, 911943, 911955,  
913496, 921469, 911206
- 17) 2490SW All lots
- 18) 3941 912129, 912448, 914594
- 19) 4339 916825
- 20) 4441, 4442, 4443 813184, 913558, 914231, 915916,  
4448, 4444, 4444-D 914730, 914478, 807340, 809320,  
4446, 4447 913256, 914477, 904783, 808772
- 21) 4474, 4474-SC 915508, 810288, 916829, 913556  
4476, 4471 915421, 915940, 912322, 809454  
HK4474 914965
- 22) 9153 903940, 911636, 911803, 911804,  
914127, 920843, 921206, 921456,  
913648
- 23) 93469 913663, 914568
- 24) 94526, 99619 911275, 911631, 901844, 911272,  
912201, 912441, 912985, 913688
- 25) 99270 913597
- 26) 99528, 99533 911283, 912850, 913598, 903193
- 27) 372211 913565
- 28) HK0593 911734
- 29) HK0595 919941
- 30) HK1570 913554
- 31) HK4444, HK4446 813557, 809427, 807342
- 32) HK1629 914451
- 33) HK1630 912323.

MANUFACTURER  
RECALLED BY

Clinipad Corporation, Charlotte, North Carolina.  
The Clinipad Corporation, Rocky Hill, Connecticut, by letters beginning March 10, 2000. Firm-initiated recall ongoing. See also FDA press release P00-07, March 2001. 10, 2000.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and international.  
Undetermined.  
Lack of assurance product meets microbial release specifications.

[ ] None Present  
[ ] Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN  
PRODUCT

- 6515 Nonstandard
- 1. CLINIPAD Alcohol Prep, Antiseptic. NDC #19154-1245-3.  
Except lot #806610-Product code 0110 tc "Except lot #806610-Product code 0110 " \l 2 #802270 0110BS tc " #802270 0110BS " \l 2
- 2) CLINIPAD Alcohol Prep, Antiseptic. NDC #19154-1245-8  
Except Lot # 716313-Product code 0250R tc "Except Lot # 716313-Product code 0250R " \l
- 3) Moore Medical Corp. Alcohol Prep Pad 70% Isopropyl Alcohol Medium 2 Ply. NDC #00839-8072-06, Reorder No. 30839 Box/200  
Reorder No. 08481 Box/100
- 4) CLINIPAD Acetone Alcohol Prep, 1 Prep Pad. NDC #19154-1245-7
- 5) Steri Wipe 1 Alcohol Swab. NDC #19154-1245-7
- 5) Rauscher Alcotupf Alkoholtupfer Tampons alcoolises Alcohol wabs REF
- 6) ALKT. NDC (n/a)
- 7) CLINISWAB Compound Benzoin Tincture Topical Protectant, 1 Saturated
- 8) Swabstick. NDC #19154-1231-2

- 8) CLINIGUARD Protective Dressing, 1 Saturated Swabstick. NDC (n/a)
- 9) CLINISWAB Iodophor PVP Povidone Iodine USP, Antiseptic, 1 Saturated Swabstick. NDC #19154-1241-2 Except Lot # 812304, 811612-Product code 1261S tc "Except Lot # 812304, 811612-Product code 1261S " \ 2 # 812467  
HK1241S # 919882 1241S-B
- 10) CLINISWAB Iodine Tincture, 2% U.S.P. Topical Anti-Infective, 1 Saturated Swabstick. NDC #19154-1243-3
- 11) CLINISWAB Iodophor PVP Scrub Povidone Iodine USP 3 Saturated Swabsticks. NDC #19154-1242-7 Except Lot # 919862-Product code HK1244S tc "Except Lot # 919862-Product code HK1244S  
D-307-0 " \ 2
- 12) CLINISWAB Isopropyl Alcohol Antiseptic, 3 Saturated Swabsticks.  
NDC #19154-1245-0
- 13) CLINISWAB Acetone Alcohol Topical Anti-Infective, 1 Saturated Swabstick.  
NDC #19154-1247-3
- 14) CLINISWAB Acetone Alcohol Topical Anti-Infective, 3 Saturated Swabsticks.  
NDC #19154-1247-5
- 15) CLINISWAB Isopropyl Alcohol Antiseptic, 1 Saturated Swabstick.  
NDC #19154-1245-9 Except Lot # 805817-Product code 1251S-B tc "Except Lot # 805817-Product code 1251S-B " \ 2
- 16) CLINISWAB Iodophor PVP Scrub, Povidone Iodine USP, Antiseptic, 1 Saturated Swabstick. NDC #19154-1242-9 Except Lot # 920324, 918333, 810014, 812302-Product code 1262S tc "Except Lot # 920324, 918333, 810014, 812302-Product code 1262S " \ 2
- 17) CLINISWAB Iodophor PVP Povidone Iodine USP, Antiseptic, 3 Saturated Swabsticks. NDC #19154-1241-3 Except Lot # 715786, 812873-Product code 1291S-B tc "Except Lot # 715786, 812873-Product code 1291S-B " \ 2 # 911485,  
919827-Product code HK1291S tc " # 911485, 919827-Product code HK1291S " \ 2
- 18) CLINISWAB Iodophor PVP Antiseptic Cleanser, Povidone Iodine 10% USP, 3 Saturated Swabsticks. NDC #19154-1241-0  
Except Lot # 919249-Product code 1291SK tc "Except Lot # 919249-Product code 1291SK "  
\ 2
- 19) EZ PREP 220 Povidone Iodine (Minimum Available Iodine 0.5%) 2-8" SpongeSticks. NDC  
#19154-1462-1
- 20) CLINIPAD IODOPHOR-PVP, Povidone-Iodine USP, Titratable Iodine 1%, Solution,  
Antiseptic 1 fl.oz (30ml.). NDC #19154-1241-4  
Except Lot # 812422 Product code 3941S-BC  
# 812891, 911939, Product code HK3941S tc " #  
812891,911939, -----Product code HK3941S " \ 2
- 21) CLINIDINE Povidone Iodine 1% USP Solution Topical Anti-Infective, 1 fl. oz (30 ml).  
NDC #19154-1241-5  
Except Lot # 917141-Product code 3943S-B.
- 22) CLINIDINE Povidone Iodine 10% USP Solution Antiseptic Cleanser, 3/4 fl. oz (21ml).  
NDC #19154-1241-7.  
Except Lot # 919888-Product code 3944S-B
- 23) CLINIDINE OINTMENT Povidone Iodine USP Titratable Iodine 1% Antiseptic Germicide Net  
WT.033 oz. (1.0g). NDC #19154-4341-4

Except Lot # 811937, 920315-Product code 4339SC.  
 919864, 812893-Product code HK4339S tc " 919864,  
 812893-Product code HK4339S " \l 2  
 24) CLINIGUARD Protective Dressing Prep, 1 Prep Pad. NDC # (n/a)  
 25) CLINIPAD Iodophor PVP Povidone Iodine USP 1 Prep Pad.  
 NDC #19154-1241-1  
 Except Lot tc "Except Lot " \l 2  
 # 812556, 919526 Product code HK9153S  
 # 919915 Product code 9153SBD tc " # 919915  
 -----Product code 9153SBD " \l 2  
 26) CLINIPAD Iodophor, Poloxamer-Iodine Complex, 3 Towelettes, Antiseptic.  
 NDC #19154-  
 9152-9  
 27) CLINIPAD Snapsule PVP Iodine Solution 10% USP Swab Applicator Net 0.67  
 ml Product  
 No.9151S. NDC #19154-1241-9  
 28) Cooper Instrument Corporation Antibacterial Probe Wipes Single Use Packet.  
 NDC (n/a)  
 Recall #D-324-0.

CODE

All codes except where noted above.

Clinipad Reorder Numbers:

- 1) 0110 0110B3 0110BS 0110CRB 0110M 0110R 0110T  
 0110TA 99510 99512 HK0110 90110
- 2) 0250B 0250R
- 3) 0110H HK0110H
- 4) 0310S-B HK0310S
- 5) 0510 0510B 0510-BT 93461
- 6) 0610ER-RAU
- 7) 1231S-B HK1231S
- 8) 1233S-B HK1233S
- 9) 1241S-B 1261S HK1241S
- 10) 1243S-B HK1243S
- 11) 1244S-B HK1244S
- 12) 1245S-B HK1245S
- 13) 1247S-B HK1247S
- 14) 1248S-B HK1248S
- 15) 1251S-B HK1251S
- 16) 1262S
- 17) 1291S-B HK1291S
- 18) 1291SK 1291SKB
- 19) 372201 3941S-B
- 20) 3941S-BC HK3941S
- 21) 3943S-B
- 22) 3944S-B
- 23) 4339S-B 4339SC HK4339S
- 24) 8133S-B HK8133S
- 25) 9153S-B 9153-SBD HK9153S
- 26) HK2490S
- 27) HK9151S
- 28) 99529.

MANUFACTURER  
 RECALLED BY

Clinipad Corporation, Charlotte, North Carolina.  
 Clinipad Corporation, Rocky Hill, Connecticut, by letters beginning March 10,  
 2000. Firm-initiated recall ongoing. See also FDA press Release P00-7, March 10,  
 2000.

DISTRIBUTION

Nationwide and international.

QUANTITY Undetermined.  
REASON Lack of assurance for sterility.  
  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6550 Nonstandard  
PRODUCT Boehringer Mannheim Creatinine Jaffe Reagent, for the quantitative determination of creatinine in serum, plasma, and urine. Recall #Z-680-0.  
CODE Catalog #1875647. Lot numbers: 69938801 EXP 07/31/01, 69692201 EXP 01/01, and 69518201 EXP 01/01.  
MANUFACTURER Roche Diagnostics GmbH, Mannheim, Germany.  
RECALLED BY Roche Diagnostics Corporation, Indianapolis, Indiana, by letter (Customer Bulletin #00-066) dated April 5, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION California, Colorado, Florida, Hawaii, Illinois, Indiana, Michigan, Mississippi, New Jersey, New York, North Carolina, Wisconsin.  
QUANTITY 127 kits were distributed.  
REASON Product does not meet the specifications for bilirubin interference.  
  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_  
\_\_\_\_\_

**CLASS III RECALLS:**

PRODUCT 6505 Nonstandard  
Promethazine with Codeine Cough Syrup (6.25 mg/5 mL and 10 mg/5 mL), in 4 and 16-fluid ounce (pint) bottles, Rx schedule V narcotic oral liquid for the temporary relief of coughs and upper respiratory symptoms associated with allergy or the common cold, under the following labels:  
a) MGP, 4-ounce - NDC #60432-606-04 and 16-ounce - NDC #60432-606-16  
b) Zenith Goldline, 16-ounce - NDC #0182-1712-40  
c) Major Pharmaceuticals, 4-ounce - NDC #0904-1510-00 and 16-ounce - NDC #0904-1510-16  
d) Qualitest, 4-ounce - NDC #0603-1578-54 and 16-ounce - NDC #0603-1578-58  
e) URL, 16-ounce - NDC #0677-0963-33. Recall #D-340-0.  
CODE Lot Numbers: 22128, 22161, 22238, 22295, 22369, 22500, 22555.  
MANUFACTURER Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois.  
RECALLED BY Manufacturer, by letter dated March 28, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 54,587 4-ounce bottles and 172,512 16-ounce bottles were distributed; firm estimated that less than 20% of the product remained on market at time of recall initiation.

REASON	Subpotency of the Promethazine Hydrochloride ingredient.  <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____
NSN PRODUCT	6505 Nonstandard Clindamycin Phosphate Topical Solution USP, 1%, Rx, packaged in 1-fluid ounce bottles - NDC #60432-693-30 and 2-fluid ounce bottles - NDC #60432-693-60. Recall #D-341-0.
CODE MANUFACTURER RECALLED BY DISTRIBUTION QUANTITY	Lot Numbers: 21796 and 22334. Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois. Manufacturer, by letter dated April 7, 2000. Firm-initiated recall ongoing. Nationwide. 5,273 1-ounce bottles and 2,966 2-ounce bottles were distributed; firm estimated that less than 20 percent of the product remained on market at time of recall initiation.
REASON	One degradant exceeded specification during stability testing.  <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____
NSN PRODUCT	6505 Nonstandard Promethazine VC Plain Syrup, (6.25mg/5mL and 5 mg/5mL), in 4-ounce and 16-ounce (pint) bottles, an Rx oral liquid intended for the temporary relief of upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold, distributed under the following labels:a) MGP, 4-ounce NDC #60432-605-04, 16-ounce - NDC #60432-605-16 b) Major Pharmaceuticals, 16-ounce - NDC #0904-1512-16 c) Qualitest, 4-ounce - NDC #0603-1582-54, 16-ounce - NDC #0603-1582-58. Recall #D-342-0.
CODE MANUFACTURER RECALLED BY DISTRIBUTION QUANTITY	Lot 22110 (sublots A,C,E) EXP 04/00 and lot 22227(sublots A,C,E,F,H,K) EXP 06/00. Morton Grove Pharmaceuticals, Inc., Morton Grove, Illinois. Manufacturer, by letter dated May 2, 2000. Firm-initiated recall ongoing. Nationwide. 10,618 4-ounce bottles and 29,038 16-ounce bottles were distributed; firm estimated that less than 10 percent of the product remained on market at time of recall initiation.
REASON	Subpotency of the Promethazine Hydrochloride ingredient.  <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____
NSN PRODUCT	6505 Nonstandard Triamcinolone Acetonide Cream USP, 0.1%, in 15-gram tubes, Rx. NDC #49159-140-20. Recall #D-343-0.
CODE MANUFACTURER RECALLED BY DISTRIBUTION	Lot #M793 EXP 3/03. Thames Pharmacal Company, Inc., Ronkonkoma, New York. Manufacturer, by letter dated March 15, 2000. Firm-initiated recall ongoing. Florida, California, Michigan, New York, Georgia, Colorado, Connecticut,

QUANTITY  
REASON

North Carolina, Arkansas, Hawaii.  
30,000 units were distributed.  
Mispackaging - Some of the tubes are incorrectly labeled to contain Gentamicin Sulfate.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN  
PRODUCT

6505 Nonstandard  
Dimethyl Sulfoxide, USP Grade DMSO (active ingredient bulk), 500 mL and 1 liter amber glass bottles, Rx. Recall #D-344-0.

CODE  
MANUFACTURER

Lot Numbers: USP990614, USP990727, and USP990817.  
Gaylord Chemical Corporation, Bogalusa, Louisiana.

RECALLED BY  
DISTRIBUTION

Manufacturer, by letter dated February 18, 2000. Firm-initiated recall ongoing.  
Nationwide and international.

QUANTITY

96 liters (232 pounds) of material in 500 mL and 1-liter amber glass bottles were distributed.

REASON

Package integrity/product leakage.

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN  
PRODUCT

6505 Nonstandard  
Lorazepam Injection, USP, 4 mg/ml, in 10 mL multiple dose vial (NDC #0074-1539-10) and 1 mL Carpujec(r)/needle prefilled syringe (NDC #0074-1539-11), Rx for preanesthetic medication of adult patients to produce sedation, relief of anxiety and a decreased ability to recall events related to the day of surgery. Recall #D-345-0.

CODE  
MANUFACTURER

Lot Numbers: 44-635-3B, 49-650-3B, 46-315-3A  
Abbott Laboratories, Inc., McPherson, Kansas.

RECALLED BY  
DISTRIBUTION

Abbott Laboratories, Hospital Products Division, Abbott Park, Illinois, by letter dated March 16, 2000. Firm-initiated recall ongoing.  
Nationwide.

QUANTITY

55,750 1-mL syringes and 2,392 10-mL vials were distributed. Firm estimated that less than 5,000 1-mL syringes and 1,500 10-mL vials remained on the market at time of recall initiation.

REASON

Mislabeling - Incorrect drug concentration declared (2 mg lorazepam). (Drug title correctly cites 4 mg/ml).

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN  
PRODUCT

6505 Nonstandard  
Urecholine(r) Injection (Bethanechol Chloride), 5.15 mg/mL, 1 mL injection, Rx for the treatment of acute post-operative/post-partum non-obstructive urinary retention, and for neurogenic atony of urinary bladder with retention. NDC #07786-29-00. Recall #D-358-0.

CODE

Lot Numbers: 0019E EXP 3/01, 0947E EXP 3/01, 0327J EXP 8/01, 0346J EXP 8/01, 1323J EXP 8/01, 1324J EXP 8/01, 1374H EXP 8/01, 1606H EXP 8/01, 1898H EXP 8/01.

MANUFACTURER Merck and Company, Inc., West Point, Pennsylvania.  
RECALLED BY Manufacturer, by letter dated March 23, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide, France, Australia, Italy, Sweden, Lebanon, South Africa.  
QUANTITY 20,858 units were distributed; firm estimated that 600 units remained on market at  
time of recall initiation.  
REASON pH failure (at stability testing).

None Present  
 Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6505 Nonstandard  
PRODUCT Lanoxin(r) Tablets (digoxin), 0.125mg, in bottles of 1,000, Rx indicated for the  
treatment of mild to moderate heart failure and for  
the control of ventricular response rate in patients with chronic atrial fibrillation.  
NDC #0173-0242-075. Recall #D-359-0.

CODE Lot #9ZP1665 EXP 6/02.  
MANUFACTURER Glaxo Wellcome, Inc., Zebulon, North Carolina.  
RECALLED BY Manufacturer, by letter on March 27, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION Alabama, Connecticut, Florida, Georgia, Massachusetts, Maryland, Maine,  
Mississippi, New Jersey, New York, North Carolina,  
Pennsylvania, South Carolina, Tennessee, Virginia, West Virginia, Puerto Rico.  
QUANTITY Firm estimated that 22,639 bottles remained on market at time of recall initiation.  
REASON Tablet thickness failure.

None Present  
 Action Taken \_\_\_\_\_  
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NSN 6505 Nonstandard  
PRODUCT Digoxin Tablets, 0.125 mg, repacked in unit dose blister packs (10x31) with and  
without a grid card, Rx indicated for the treatment of mild to moderate heart failure,  
and for the control of ventricular response rate in patients with chronic atrial  
fibrillation. NDC #00615-0547-63 (uncarded) and NDC #00615-0547-53 (carded).  
Recall #D-360-0.

CODE Lot #0547-0003 EXP 1/31/01.  
MANUFACTURER Glaxo Wellcome, Inc., Research Triangel Park, North Carolina (responsible firm).  
RECALLED BY NCS Health Care of KY, doing business as Vanguard Labs, Inc., Glasgow,  
Kentucky (repacker/distributor), by letter on April 6, 2000.  
DISTRIBUTION Firm-initiated recall ongoing.  
Pennsylvania, Massachusetts, Illinois, New York, Tennessee, North Carolina,  
California, Vermont, Maryland, Ohio, Maine.  
QUANTITY 90 blister pack units were distributed.  
REASON Tablet thickness failure.

None Present  
 Action Taken \_\_\_\_\_  
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NSN 6505 Nonstandard  
PRODUCT Vancomycin Hydrochloride, USP, Sterile, 10 g, in pharmacy bulk package,  
Rx for IV Infusion after dilution. NDC #0469-3140-61. Recall #D-362-0.  
CODE Lot Numbers: 180266, 180432, 180449, 180465, 180490, 180635, 180647, 180693.

MANUFACTURER American Pharmaceutical Partners, Inc., formerly known as Fujisawa USA, Melrose Park, Illinois.  
RECALLED BY American Pharmaceutical Partners, Inc., Melrose Park, Illinois, by letter dated April 6, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 44,006 100-mL vials were distributed. Firm estimated that 20 percent of the product remained on market at time of recall initiation.  
REASON Moisture failure during stability testing.

None Present  
 Action Taken \_\_\_\_\_  
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NSN 6505 Nonstandard  
PRODUCT Estrostep(r) Fe Tablets, (norethindrone acetate, ethinyl estradiol and ferrous fumarate), in 28 tablet dispensers, Rx oral contraceptive. NDC #0071-0928-47. Recall #D-364-0.  
CODE Lot Numbers: 44808F EXP 3/00, 44908F EXP 3/00, and 44708F (Expired 2/00).  
MANUFACTURER Warner Lambert, Fajardo, Puerto Rico.  
RECALLED BY Parke-Davis, Division of Warner Lambert Company, Morris Plains, New Jersey, by UPS ground tracking service on February 22, 2000. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 29,703 units were distributed; firm estimated a minimal amount remained on market at time of recall initiation.  
REASON Subpotency (at 12 month stability).

None Present  
 Action Taken \_\_\_\_\_  
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NSN 6550 Nonstandard  
PRODUCT Recall #Z-484-0 which appeared in the April 19, 2000 Enforcement Report should read: PRODUCT: Total B-hCG Controls, for in-vitro diagnostic use.

None Present  
 Action Taken \_\_\_\_\_  
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