

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:

6515 NS

MDC 10145, 14360, 14361
PRODUCT

Ventilators (General)

Nellcor Puritan Bennett 740 Ventilator and 760 Ventilator System.
Recall #Z-209/210-0.

CODE

All ventilators that operate at the consignee at a main voltage of 110v.

MANUFACTURER
RECALLED BY

Nellcor Puritan Bennett Ireland, Galway, Ireland.
Mallinckrodt, Inc., St. Louis, Missouri, by letter dated September 24, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY

Nationwide and international.
2,359 ventilators were distributed.

REASON

Battery power can deplete when power supply switches voltage due to spikes.

[] None Present

[] Action Taken _____

6515 NS

MDC 17634
PRODUCT

Infusion Pump, Multi Channel

IMED Gemini PC-4 Volumetric Infusion Pump and Controller with Version 1.85 Software:

a) PC-4 Infusion Pump, Model 1340, 110 volts;

b) PC-4 Infusion Pump, Model 1341, 220 volts.

Recall #Z-174/175-0.

CODE

All pumps that carry software version 1.85.

MANUFACTURER
RECALLED BY

Alaris Medical Systems, Inc., San Diego, California.

Manufacturer, by letter on September 22, 1999. Firm-initiated field correction ongoing.

DISTRIBUTION
QUANTITY

Nationwide and International.

4,753 (model 1340, 110 volts) and 132 (model 1341, 220 volts) pumps were distributed.

REASON

Due to a software modification, the devices will stop infusing and alarm if the processors receive conflicting or confusing messages.

[] 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 February 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	<p>a) Ana-KitÆ Anaphylaxis Emergency Treatment Kit- consisting of 1 syringe (1.0 mL) containing two single doses (0.3 mL) of Epinephrine Injection USP, (1:1000), 4 tablets (Chlorpheniramine Maleate) of antihistamine, and 2 sterile isopropyl alcohol (70%) swabs, labeled in part "Pkgd. and Dist. By: Bayer Corporation Pharmaceutical Division Spokane, WA 99207 ** Epinephrine Mfg by: Wyeth-Ayerst Laboratories Philadelphia, PA 19101***", for treatment of severe anaphylactic or anaphylactoid reactions and severe asthma. Sold as individual kits or 6-packs. NDC 0026-9988-01 and 0026-9988-06;</p> <p>b) Ana-GuardÆ Epinephrine Injection USP (1:1000)- consisting of 1 syringe (1.0 mL) containing two single doses (0.3 mL) of Epinephrine Injection USP, (1:1000). labeled in part "ANA-GUARD EPINEPHRINE INJECTION, USP (1:1000) ** Pkgd. and Dist. By: Bayer Corporation Pharmaceutical Division Spokane, WA 99207 USA Epinephrine Mfg. By: Wyeth-Ayerst Laboratories Philadelphia, PA 19101***. NDC 0026-9984-01 and 0026-9984-06;</p> <p>c) Epinephrine Injection, USP (1:1,000) Syringe - a refill item for the above two products sold as 500 syringes/box under NDC# 0026-9982-01 each containing two single doses (0.3 mL) of Epinephrine Injection USP, (1:1000). Recall #D-059/061-0.</p>														
CODE	<p>Ana-Kit:</p> <table border="0"> <tr> <td>AK344 EXP Date 8-99</td> <td>AK345 EXP Date 8-99</td> </tr> <tr> <td>AK346 EXP Date 9-99</td> <td>AK347 EXP Date 11-99</td> </tr> <tr> <td>AK348 EXP Date 1-2000</td> <td>AK349 EXP Date 5-2000</td> </tr> <tr> <td>AK350 EXP Date 9-99</td> <td>AK351 EXP Date 11-99</td> </tr> <tr> <td>AK352 EXP Date 9-99</td> <td>AK353 EXP Date 5-2000</td> </tr> <tr> <td>AK354 EXP Date 6-2000</td> <td>AK355 EXP Date 6-2000</td> </tr> <tr> <td>AK356 EXP Date 7-2000</td> <td>AK357 EXP Date 9-99</td> </tr> </table>	AK344 EXP Date 8-99	AK345 EXP Date 8-99	AK346 EXP Date 9-99	AK347 EXP Date 11-99	AK348 EXP Date 1-2000	AK349 EXP Date 5-2000	AK350 EXP Date 9-99	AK351 EXP Date 11-99	AK352 EXP Date 9-99	AK353 EXP Date 5-2000	AK354 EXP Date 6-2000	AK355 EXP Date 6-2000	AK356 EXP Date 7-2000	AK357 EXP Date 9-99
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AK358 EXP Date 1-2000 AK359 EXP Date 8-2000
AK360 EXP Date 9-99 AK361 EXP Date 9-99
AK362 EXP Date 11-99 AK363 EXP Date 1-2000
AK366 EXP Date 7-2000

Ana-Guard:

G00196 thru G00203 (inclusive) EXP Date September 1999
G00204 & G00205 EXP Date November 1999
G00206, G00207, G00208 EXP Date January 2000
G00209 EXP Date May 2000
G00210 EXP Date June 2000
G00211, G00212, G00213 EXP Date July 2000
G00214 through G00220 (inclusive), G00222, G00223
EXP Date August 2000

Epinephrine Injection Refills:

S315 EXP Date Aug 1999
S316 through S320 (inclusive) EXP Date Sept 1999
S321, S322, S323 EXP Date Nov. 1999
S324 through S327 (inclusive) EXP Date Jan 2000
S328 through S333 (inclusive) EXP Date May 2000
S334, S335, S336 EXP Date July 2000
S337 through S340 (inclusive) EXP Date Aug 2000.

MANUFACTURER

Epinephrine: Wyeth-Ayerst Laboratories, Philadelphia, Pennsylvania (responsible firm);
Ana-Kit and Ana-Guard: Hollister-Stier Laboratories LLC, Spokane, Washington (formerly a Bayer Corporation Pharmaceutical Division Company).

RECALLED BY

Hollister-Stier Laboratories LLC., Spokane, Washington, by letters dated August 24, 25, and 30, 1999, and by fax on August 24, 1999. Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY

Nationwide and international.
Ana-Kit: 456,036 kits were distributed
Ana-Guard: 55,238 kits were distributed
Refills: 62,027 distributed

REASON

Subpotency of the Epinephrine.

[] None Present

[] Action Taken _____

NSN PRODUCT

6505 Nonstandard
DERM/BURO INSECT STING KIT, Rx - consisting of 1 syringe (1.0 mL) containing two single doses (0.3 mL) of Epinephrine Injection USP, (1:1000), 4 chewable tablets (Chlorpheniramine Maleate) of antihistamine, 2 sterile isopropyl alcohol (70%) swabs and one tourniquet. Per label: "Pkgd. and Dist. by: Derm/Buro Inc., Deerfield, IL 60015". Recall #D-062-0.

CODE

Derm/Buro KIT Lot #/EXP Date Epinephrine Lot #/EXP Date
(in Kit)
#0397, 11/99 2971529, 11/99
#0497, 11/99 2971529, 11/99
#0497, 02/00 2971534, 02/00
#0597, 02/00 2971534, 02/00
#8141, 02/00 2971534, 02/00
#8141, 05/00 2971538, 05/00
#8139, 05/00 2971538, 05/00

	#11464, 05/00	2971538, 05/00
	#11464, 05/00	2983265, 07/00
	#13239, 05/00	2983265, 07/00.
MANUFACTURER	Wyeth Ayerst Laboratories, West Chester, Pennsylvania (maker of Epinephrine/responsible firm).	
RECALLED BY	Derm/Buro, Inc., Plainview, New York (distributor of sting kit), by letter dated August 23, 1999. Firm-initiated recall ongoing.	
DISTRIBUTION QUANTITY	U.S. government military installations nationwide. 59,964 kits were distributed.	
REASON	Subpotency of the Epinephrine.	

None Present
 Action Taken _____

NSN	6505 Nonstandard	
PRODUCT	Epinephrine Injection, USP, 1:1000, Rx, in 1 mg/1 mL Tubex Æ syringes, (25 gauge 5/8 inch needle) units of 10, used to treat respiratory distress in bronchial asthma or during severe, acute asthma attacks, reversible bronchospasms, severe acute anaphylactic reactions, cardiac arrest - to restore cardiac rhythm, and hypersensitivity reactions to drugs, sera, insect stings or other allergens. (NDC# 0008-0263-01) and 50 (NDC# 0008-0263-02). Recall #D-063-0.	
CODE	NDC 0008-0263-01 - Lots: 2971529 EXP 11/99, 2971530 EXP 9/99, 2971534 EXP 2/00, 2971535 EXP 3/00, 2971536 EXP 4/00, 2971538 EXP 5/00, EXP 2983265 EXP 7/00. NDC 0008-0263-02 - Lots: 2971525 EXP 8/99, 2971526 EXP 9/99, 2971531 EXP 11/99, 2971533 EXP 1/00, 2971537 EXP 5/00, 2983255 EXP 6/00, 2983256 EXP 7/00, and 2983257 EXP 8/00.	
MANUFACTURER	Wyeth Ayerst Laboratories, West Chester, Pennsylvania.	
RECALLED BY	Wyeth Ayerst Research, inc., Radnor, Pennsylvania, by letter dated August 19, 1999. Firm-initiated recall ongoing.	
DISTRIBUTION QUANTITY	Nationwide and Sweden. 516,610 tubex/syringes of NDC 0008-0263-01 and 651,600 tubex/syringes of NDC 0008-0263-02 were distributed.	
REASON	Subpotency.	

None Present
 Action Taken _____

NSN	6505 Nonstandard	
PRODUCT	Invigorate(tm) Liquid Drink in 32 fluid ounce plastic bottles. Product label declares as an ingredient “2 (3H) “2(3H) Furanone Di-hydro”, which is also known as gammabutyrolactone (GBL). The supplement which stimulates the body’s own production of human growth hormone and as a sleep aid which “will induce deep invigorating sleep that will last 3-4 hours. Recall #D-057-0.	
CODE	All lot codes remaining on the market.	
MANUFACTURER	Invigorate International, New York, New York.	
RECALLED BY	Cabot Industries, LLC, West Babylon, New York, by letter on June 1, 1999, followed by telephone. FDA Requested and subsequently ordered by the Eastern District Court of New York.	

DISTRIBUTION

New York, New Jersey, Massachusetts, Pennsylvania, Maryland, Virginia, Ohio, South Carolina, Florida, Alabama, Mississippi, Michigan, Illinois, Kansas, Colorado.

QUANTITY

Undetermined.

REASON

Product is an unapproved new drug.

None Present

Action Taken _____

CLASS II RECALLS:

NSN

6505 Nonstandard

PRODUCT

Various Rx products:

1. Dobutamine Injection, USP, 250 mg, 20 mL Single Dose Vial
2. Etoposide Injection, USP, 100 mg, 5 mL Multiple Dose Vial
3. Etoposide Injection, USP, 150 mg, 7.5 mL Multiple Dose Vial
4. Etoposide Injection, USP, 500 mg, 25 mL Multiple Dose Vial
5. Etoposide Injection, USP, 1 g, 50 mL Multiple Dose Vial
6. Fentanyl Citrate Injection, USP, 1000 mcg, 20 mL Single Dose Vial
7. Fentanyl Citrate Injection, USP, 2500 mcg, 50 mL Single Dose Vial
8. Heparin Sodium Injection, USP, 1000 USP units/mL, 5 mL Ampul
9. Lorazepam Injection, USP, 1 mg/0.5mL syringe
10. Lorazepam Injection, USP, 4 mg/mL , 1 mL syringe
11. Lorazepam Injection, USP, 2 mg/mL , 1 mL and 10 mL Multiple Dose Vials
12. Lorazepam Injection, USP, 4 mg/mL , 1 mL and 10 mL Multiple Dose Vials
13. Morphine Sulfate Injection, USP, 15 mg/mL, 20 mL Multiple Dose Vial
14. Morphine Sulfate Injection, USP, 100mg/4mL, 4 mL Single Use Vial
15. Morphine Sulfate Injection, USP, 250/10mL, 10 mL Single Use Vial
16. Morphine Sulfate Injection, USP, 500 mg/20mL, 20 mL Single Use Vial
17. Morphine Sulfate Injection, USP, 1g/40mL, 40 mL Single Use Vial
18. Morphine Sulfate Injection, USP, NO BACTERIOSTAT ADDED, 500 mg/10mL, 10 mL Single Use Vial
19. Morphine Sulfate Injection, USP, NO BACTERIOSTAT ADDED, 1g/20mL, 20 mL Single Use Vial
20. Morphine Sulfate Injection, USP, NO BACTERIOSTAT ADDED, 2g/40mL, 40 mL Single Use Vial
21. Morphine Sulfate Injection, USP, PRESERVATIVE FREE, 100mg/4mL, 4 mL Single Use Vial
22. Morphine Sulfate Injection, USP, PRESERVATIVE FREE, 250mg/10mL, 10 mL Single Use Vial
23. Morphine Sulfate Injection, USP, PRESERVATIVE FREE, 500mg/20mL, 10 and 20 mL Single Use Vial
24. Morphine Sulfate Injection, USP, PRESERVATIVE FREE, 1g/40mL, 40 mL Single Use Vial
25. Neostigmine Methylsulfate Injection, USP, 0.5mg/mL, 10 mL

Multiple Dose Vial
 26. Neostigmine Methylsulfate Injection, USP, 1mg/mL, 10 mL
 Multiple Dose Vial
 27. Tobramycin Sulfate Injection, USP, 20 mg, 2 mL vial
 28. Tobramycin Sulfate Injection, USP, 80 mg, 2 mL vial
 29. Tobramycin Sulfate Injection, USP, 40 mg/mL, 30 mL Multiple
 Dose Vial. Recall #D-064/092-0.

CODE All lot codes.
 MANUFACTURER Marsam Pharmaceuticals, Inc., Cherry Hill, New Jersey.
 RECALLED BY Manufacturer, by letter on July 1 and 7, 1999. Firm-initiated
 recall ongoing.
 DISTRIBUTION Nationwide and Canada.
 QUANTITY Undetermined.
 REASON Insufficient equipment cleaning (equipment residues detected talc
 and aliphatic hydrocarbon).

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Dexamethasone Sodium Phosphate Injection, USP, 4 mg/mL, in 30 ml
 vial, an adrenocortical steriodal anti-inflammatory drug,
 intended for administration by intravenous, intramuscular, intra-
 articular, intra-lesional, and soft tissue routes, under the
 following labels: NDC 0402,-0807-30 (Steris Laboratories, Inc.);
 NDC 0364-6681-56 (Schein Pharmaceutical, Inc.); NDC 0182-3007-66
 (Zenith Goldline)
 NDC 12671-807-30 (Ace Surgical Supply).
 Recall #D-096-0.

CODE Lot Numbers: 98B790 EXP 9/99, 98E010 EXP 9/99, and 98E020 EXP
 10/99.
 MANUFACTURER Steris Laboratories, Inc., Phoenix, Arizona.
 RECALLED BY Manufacturer, by letter on August 20, 1999. Firm-initiated
 recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 81,958 units were distributed.
 REASON Insufficient test methods for product release to assure identity,
 strength, purity, and quality.

None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Gentamicin Sulfate, USP, bulk and in 50 kg fiber drums, Rx, for
 manufacturing use only. Recall #D-104-0.
 CODE All lots with prefix SC-GM 96, SC-GM 97, SC-GM 98 and SCGM99.
 MANUFACTURER Long March Pharmaceutical Plant, Leshan, Sichuan, Peoples
 Republic of China.
 RECALLED BY Helm New York, Inc., Piscataway, New Jersey, by telephone between
 September 8 and 16, 1999, followed by letter. Firm-initiated
 recall ongoing.

DISTRIBUTION Missouri, New York, Illinois, California, New Jersey, Iowa, Iowa,
Arizona, Ohio.
QUANTITY 26,953 kg. were distributed; firm estimated that 1,500 kg.
remained on market at time of recall initiation.
REASON Current good manufacturing practice deviations (at manufacturing
site in China).

 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Stealth Surgical Clamps, indicated for surgical clamping during
cardiovascular, peripheral vascular, and general surgery: a)
Model No. A3220; Model No. A3219.
Recall #Z-207/208-0.
CODE a) Lot Nos. E9C012, E9C083, E9C084, 99E040, 99E419;
b) Lot Nos. E9C014, E9C015, E9C087, 99F476, 99E418, 99E417.
MANUFACTURER Applied Medical Resources, Laguna Hills, California.
RECALLED BY Manufacturer, by fax on August 11, 1999, and by voice mail.
Firm-initiated recall ongoing.
DISTRIBUTION Michigan, Mississippi, New York, Ohio, Texas.
QUANTITY a) 71 clamps; b) 418 clamps were distributed.
REASON The clamps have a potential for misalignment under high pressure
which could cause the clamps to release prematurely or to tear
the tissue held by the clamp.

 None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT 3M Sarns Brand Myocardial Protection Sets in clear plastic trays,
indicated for delivery of cardioplegic solutions to the heart
during cardiopulmonary bypass surgery:
1. Conducer Cardioplegia Set with MP-4, 4:1 ratio, no
recirculation. Catalog #: 165720 Product Order #: 98-0702-0012-
0. Lots: W504044, W503670, W502672, W502889, W502825, W502931,
W503155, W503265, W503014, W503573, W503408, W504193.
2. Integrated Cardioplegia Delivery System Blood Mix
Cardioplegia Disposable Tubset. Catalog #: 14915 Product Order
#: 98-0702-0108-6 Lots: W503643, W503311, W502914, W503419,
W503095.
3. MP-4 Clear Cardioplegia Set Recirculation from the Cannula
Connection. Catalog #: 15486 Product Order #: 98-0702-0123-5
Lots: W503231, W503503, W502742, W503099, W502917.
4. MP-4 Clear Cardioplegia Set Recirculation for the Monitor
Module. Catalog #: 15501 Product Order #: 98-0702-0125-0 Lots:
W503642, W503866, W503151, W502740, W503360, W503405, W502951,
W504284.
5. MP-4 Blood Cardioplegia Set 4:1 Ratio, Recirculation from the
Cannula Connection. Catalog #: 15928 Product Order #: 98-0702-
0139-1 Lot: W503042.
6. MP-4 Blood Cardioplegia Set 4:1 Ratio, No Recirculation.

Catalog #: 16010 Product Order #: 98-0702-0142-5 Lots: W503784, W503394, W503682, W503111, W503260, W503479, W503623, W502829, W502993, W504097, W504161.

7. MP-4 Clear Cardioplegia Set Filtered Recirculation from the Monitor Module. Catalog #: 16010 Product Order #: 98-0702-0143-3 Lots: W503020, W503229, W502870, W503454.

8. MP-4 Clear Cardioplegia Set Filtered Recirculation from the Cannula Connection. Catalog #: 16015 Product Order #: 98-0702-0012-0 Lot: W503248.

9. Custom MP-4 Hackensack Medical Center. Catalog #: N/A Product Order #: 98-0702-0153-2 Lots: W503681, W503113, W503471, W503361, W502833, W504045.

10. MP-4 Blood Cardioplegia Set 2:1 Ratio, No Recirculation. Catalog #: 16200 Product Order #: 98-0702-0224-1 Lots: W503621, W502721, W502990.

11. Conducer Cardioplegia Set 4:1 Ratio, No Recirculation. Catalog #: 9457 Product Order #: 98-0702-0344-7 Lots: W503634, W503364, W503439, W503439, W502984, W504080.

12. Conducer Cardioplegia Set with MP-4, 2:1 Ratio, No Recirculation. Catalog #: 9499 Product Order #: 98-0702-0554-1 Lots: W503956, W503358, W502915, W503590, W504150.

13. Custom MP-4 Conducer Rochester General. Catalog #: N/A Product Order #: 98-0702-0594-7 Lots: W504030, W50337, W503722, W503864, W503489, W502846, W503050, W504269.

14. Conducer Cardioplegia Set 1:1 Ratio, No Recirculation. Catalog #: 4414 Product Order #: 98-0702-0630-9 Lots: W502926, W502675, W503451, W502847.

15. Conducer Cardioplegia Set with MP-4 8:1 Ratio, No Recirculation. Catalog #: 4459 Product Order #: 98-0702-0656-4 Lots: W503717, W503200, W503594, W503362, W502731, W504152.

16. Custom MP-4 St Luke's Hospital. Catalog #: N/A Product Order #: 98-0702-0686-1 Lots: W503770, W503309, W502874, W504076.

17. Custom Conducer Houston Life Support. Catalog #: N/A Product Order #: 98-0702-0720-8 Lots: W503392, W502832.

18. Custom MP-4 Conducer Hill. Catalog #: N/A Product Order #: 98-0702-0723-2 Lots: W503352, W503135, W503710.

19. Custom MP-4 Conducer Presbyterian New York. Catalog #: N/A Product Order #: 98-0702-0756-2 Lots: W503583, W503407, W502928, W503258.

20. Custom 4:1 Hackensack Medical Center. Catalog #: N/A Product Order #: 98-0702-0760-4 Lots: W504074, W503660, W502863, W503022, W503421.

21. Custom Conducer 8:1 Sacred Heart Hospital. Catalog #: N/A Product Order #: 98-0702-0845-3 Lots: W503661, W503143, W503452, W502848.

22. Custom MP-4 Conducer CPMC Ozomiser Infusion System. Catalog #: N/A Product Order #: 98-0702-0955-0 Lot: W502788.

23. Conducer Cardioplegia St with Bridge 4:1, No Recirculation. Catalog #: 6376 Product Order #: 98-0702-0966-7 Lots: W503150, W502708, W503403, W503601, W503232, W502950, W504159.

24. Conducer Cardioplegia Set with PM-4 and Bridge 4:1 Ratio, No Recirculation. Catalog #: 6375 Product Order #: 98-0702-0967-5 Lots: W504040, W503882, W503830, W503480, W503591, W503202, W503266, W503404, W503052, W503635, W502730, W504242, W504288, W504148.

25. Custom MP-4 Conducer B Trap, Pump Recirculation 4/cs.

Catalog #: N/A Product Order #: 98-0702-0969-1 Lots: W503910, W502804.

26. Customized: Bld, Conducer B Trap, Pump Recirculation 4/cs. Catalog #: N/A Product Order #: 98-0702-1005-3 Lots: W503356.

27. Conducer Cardioplegia Set Low-Prime 4:1 Ratio. Catalog #: 5852 Product Order #: 98-0702-1022-8 Lots: W503338, W502676, W502918.

28. Custom MP-4 Conducer 8:1 with Bridge Perfusion Products. Catalog #: N/A Product Order #: 98-0702-1118-4 Lots: W503217, W503547.

29. Custom MP-4 Houston Life Support SETA. Catalog #: N/A Product Order #: 98-0702-1154-9 Lots: W503295, W502859.

30. Custom Conducer 4:1 Bridge University of Iowa. Catalog #: N/A Product Order #: 98-0702-1181-2. Lot W503676.

31. Customized: MUF, BLD, 4:1 Conducer, B Trap, Bridge 4/cs. Catalog #: N/A Product Order #: 98-0702-1209-1 Lots: W503871, W503619, W502706, W503336.

32. Custom Conducer with MP-4 University of Virginia Medical Center. Catalog #: N/A Product Order #: 98-0702-1210-9 Lot: W502691.

33. Customized: Clear Conducer Reverse Flow D.C. 4/cs. Catalog #: N/A Product Order #: 98-0702-1243-0 Lot: W502858.

34. Customized: Blood 4:1 MP-4 Coil, Pump Recirculation 4/cs. Catalog #: N/A Product Order #: 98-0702-1250-5 Lots W503680, W503194, W503484, W502912.

35. Custom MP-4 with Recirculation UPMC. Catalog #: N/A Product Order #: 98-0702-1205-7 Lots: W504031, W503416, W503096, W503555, W502771, W504120.

36. Customized: Blood 4:1 MP-4 Coil 4/cs. Catalog #: N/A Product Order #: 98-0702-1307-3 Lots: W503712, W502741, W502986, W503423, W504111.

37. Custom MP-4 4:1 Ratio with Recirculation Bellin Hospital. Catalog #: N/A Product Order #: 98-0702-1420-4 Lots: W504032, W503114, W503600, W503355.

38. Custom MP-4 Clear with Recirculation St Vincent Hospital. Catalog #: N/A Product Order #: 98-0702-1441-0 Lots: W503228, W502831, W503455.

39. Customized: Blood 4:1 Conducer Bubble Trap No Recirculation 4/cs. Catalog #: N/A Product Order #: 98-0702-1458-4 Lot: W503193.

40. Customized: Blood 4:1 Conducer MP-4 120' Table Line 4/cs. Catalog #: N/A Product Order #: 98-0702-1469-1 Lots: W503552, W503256.

41. Customized: Blood 2:1 MP-4 Conducer Bridge. Catalog #: N/A Product Order #: 98-0702-1504-5 Lots: W503440, W502772.

42. Customized: Blood Conducer Bubble Trap 4/cs. Catalog #: N/A Product Order #: 98-0702-1510-2 Lots: W503192, W502769, W503649, W504147.

43. Customized: Blood 4:1 Coil Bridge 4/cs. Catalog #: N/A Product Order #: 98-0702-1553-2 Lots: W502999, W502727.

44. Customized: Blood 4:1 MP-4 B Trap Conducer MUF. Catalog #: N/A Product Order #: 98-0702-1572-2 Lot: W503550.

45. Customized: Clear MP-4 Coil Double Spike, Recirculation. Catalog #: N/A Product Order #: 98-0702-1589-6 Lots: W503620, W503911, W503267, W503453, W502739, W503021, W504100.

46. Customized: Blood 4:1 MP-4 Prelief Conducer Low Prime.

Catalog #: N/A Product Order #: 98-0702-1594-6 Lots: W503666, W502927, W504233.

47. Customized: Blood 8:1 B Trap Conducer. Catalog #: N/A Product Order #: 98-0702-1672-0 Lots: W502948, W503437, W503677, W503067, W504114.

48. Customized: Blood 4:1 B Trap Conducer MUF. Catalog #: N/A Product Order #: 98-0702-1679-5 Lots: W503726, W502983, W503585, W502770.

49. Customized: Blood Conducer RFDC Isolater Single Spike. Catalog #: N/A Product Order #: 98-0702-1786-8 Lot: W503796.

50. Customized: Blood 4:1 Conducer Bubble Trap Filter. Catalog #: Product Order #: 98-0702-1786-8 Lot: W503796.

51. Customized: Blood 4:1 Conducer Bubble Trap Filter. Catalog #: N/A Product Order #: 98-0702-1789-2 Lots: W503917, W502705, W503593, W503006, W503789, W503043.

52. Customized ICDS Blood Set Bridged Table Line. Catalog #: N/A Product Order #: 98-0702-1798-3 Lots: W503255, W503496.

53. Customized: Conducer B Trap Single Spike MUF. Catalog #: N/A Product Order #: 98-0702-1804-9 Lot: W502716.

54. Customized: Blood 4:1 Bridge MP-4 Coil Prelief 4/cs. Catalog #: N/A Product Order #: 98-0702-1819-7 Lots: W502723, W503000, W503195.

55. Customized: Blood 4:1 Conducer MP-4 Prelief 4/cs. Catalog #: N/A Product Order #: 98-0702-1850-2 Lots: W503438, W503297, W503718.

56. Customized: Blood 4:1 Bridge Coil MP-4 Double Spike 4/cs. Catalog #: N/A Product Order #: 98-0702-1859-3 Lots: W503870, W503595.

57. Customized: Conducer Low Prime 4/cs. Catalog #: N/A Product Order #: 98-0702-1862-7 Lot: W503597.

58. Customized: Blood 4:1 B Trap Conducer Bridge. Catalog #: N/A Product Order #: 98-0702-1877-5 Lots: W503932, W504070, W504144. Recall #Z-214-0.

CODE

See above. All sets in clear plastic trays are under recall. Products have a three year expiry period.

MANUFACTURER
RECALLED BY

Terumo Cardiovascular Systems Corporation, Ann Arbor, Michigan. Manufacturer, by letter dated September 22, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
34,756 units were distributed.
Seals between the tyvek lid and the clear plastic tray are inadequate resulting in poor seal integrity, thereby compromising the sterility of the devices.

None Present
 Action Taken _____

NSN
PRODUCT

6550 Nonstandard
Promotional Material for TAB250 Mouse Anti-HER2[c-erbB-2] Antibody. Recall #Z-213-0

CODE

Immunochemica Newsletter Vol. 11, No. 1
Immunochemica Newsletter Vol. 11, No. 2
V-Liner Mailer

HER2 Flyer
 Labels and Specification Sheet:
 Catalog No. 28-0003, Lot No. 9034624
 Zymed Laboratories, Inc., South San Francisco, California.
 Manufacturer, by letters: promotional material on November 12, 1999; label and specification sheet on November 10, 1999 Firm-initiated field correction ongoing.

MANUFACTURER RECALLED BY

DISTRIBUTION QUANTITY
 Nationwide.
 33,659 promotional material and 38 label & specification sheets were distributed.

REASON
 Devices were labeled for an intended use not included in the existing 510(k) or PMA.

None Present
 Action Taken _____

CLASS III RECALLS:

NSN
 PRODUCT 6505 Nonstandard
 Anzemet Tablets (Dolasetron Mesylate), 100 mg, bottles of 5 tablets, Rx anti-nauseant and anti-emetic. NDC #0088-1203-05. Recall #D-093-0.

CODE
 Lot Numbers: 3001616 EXP 2/01, 3003145 EXP 2/01, and 3003148 EXP 4/01.

MANUFACTURER RECALLED BY
 Hoechst Marion Roussel, Inc., Cincinnati, Ohio.
 Manufacturer, by letter on October 5, 1999. Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY
 Ohio and Missouri.
 10,329 bottles were distributed.

REASON
 Stability (6 month) test failure elevated degradation product.

None Present
 Action Taken _____

NSN
 PRODUCT 6505 Nonstandard
 Klonopin (brand of Clonazepam) Tablets, 0.5 mg, 1 mg, and 2 Mg, distributed in bottles of 100 tablets and cartons each: a) Klonopin (Clonazepam) tablets, 0.5 mg, 25 and 100 tablet units:
 b) Klonopin (Clonazepam) tablets, 1 mg, 25 and 100 tablet units;
 c) Klonopin (Clonazepam) Tablets, 2 mg, 25 and 100 tablet units. Recall #D-097/099-0.

CODE
 All lots. NDC 0004-0068-01, 0004-0068-50, 0004-0058-01, 0004-0058-50, 0004-0098-01 AND 0004-0098-50.

MANUFACTURER RECALLED BY
 Roche Pharma, Inc., Humacao, Puerto Rico.
 Roche Laboratories, Inc., Nutley, New Jersey, by letter on August 3, 1999. Firm-initiated recall ongoing.

DISTRIBUTION
 Nationwide.

QUANTITY Approximately 48,706 pieces of all three strengths combined were distributed.
REASON Impurity level exceeds specification.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Duratuss G Tablets, (Guaifensin), 1200 mg, in 500 tablet bottles, Rx 12-hour sustained release expectorant.
Recall #D-100-0.

CODE Lot Numbers: J980726A and J9800727A.
MANUFACTURER Mikart, Inc., Atlanta, Georgia.
RECALLED BY Manufacturer, by telephone on June 22, 1999, and by letter on June 23, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Wisconsin.
REASON Dissolution failure.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Koleprin DM Caplets, in 30 caplet bottles, OTC prompt release, cough and cold medication.
NDC #0927-018-07. Recall #D-101-0.

CODE Lot #98603 EXP 2/01.
MANUFACTURER SSS/Pfeiffer Pharmaceuticals, Inc., Atlanta, Georgia.
RECALLED BY Manufacturer, by letter on June 14, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 2,659 units were distributed; firm estimated that 2,540 units remained on market at time of recall initiation.
REASON Friability failure (at 3 month stability).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Streptomycin Sulfate, USP, bulk, in 5 kg fiber drums, Rx for manufacturing use only. Recall #D-105-0.

CODE Lot Numbers: SC-SM980802, SC-SM 980701, SC-SM980203, SC-SM980204, SC-SM980205.
MANUFACTURER Long March Pharmaceutical Plant, Leshan, Sichuan, Peoples Republic of China.
RECALLED BY Helm New York, Inc., Piscataway, New Jersey, by telephone between September 8 and 16, 1999, followed by letter. Firm-initiated recall ongoing.
DISTRIBUTION New York, New Jersey, Ohio, Missouri, Arkansas, North Carolina, Iowa, California.

QUANTITY 780 kg. were distributed; firm estimated that 25 kg remained on market at time of recall initiation.
REASON Current good manufacturing practice deviations (at manufacturing site in China).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Aldoril D50 Tablets, (Methyldopa (500mg)-Hydrochlorothiazide (50mg)), in 100 Tablet bottles, Rx used to control hypertension. NDC #0006-0935-68
CODE Recall #D-106-0.
Lot Numbers: B5511 EXP 1/00, D5714 EXP 4/00, D5719 EXP 4/00, E6156 EXP 4/00, E6172 EXP 2/00, H3896 EXP 4/00.
MANUFACTURER Merck and Company, Inc., West Point, Pennsylvania.
RECALLED BY Manufacturer, by letter dated September 23, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 15,424 bottles were distributed.
REASON Dissolution failure for Hydrochlorothiazide.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Hibistat Germicidal hand rinse, (Chlorhexidine gluconate), 0.5% w/w, OTC, used by health care professional as a germicidal hand rinse.
CODE NDC #0310-0575-08. Recall #D-107-0.
Lot #3152B EXP 4/01.
MANUFACTURER Accupac, Inc., Mainland, Pennsylvania.
RECALLED BY AstraZeneca, a business unit of Zeneca, Inc., Wilmington, Delaware, by letter on October 14, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Saudi Arabia.
QUANTITY 33,432 bottles were distributed.
REASON Alcohol low potency and specific gravity failure; rework without current good manufacturing practice control.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Spectinomycin Dihydrochloride Pentahydrate, Bulk Drug Substance, Rx non-sterile special grade bulk antibiotic.
CODE Recall #D-110-0.
Lot Numbers: 53-049-CD, 53-059-CD, 53-060-CD, 53-061-CD, 53-085-CD, 53-086-CD, 53-087-CD, 53-088-CD and 54-188-CD.

MANUFACTURER

Abbott Laboratories, Inc., Chemical and Agricultural Products Division, North Chicago, Illinois.

RECALLED BY

Manufacturer, by letter dated October 1, 1999, and by telephone on October 4, 1999. Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY

Italy, Switzerland, France, Hong Kong, Korea, Taiwan. 4,459.04-kg of bulk drug substance were distributed.

REASON

Iron contamination.

None Present

Action Taken _____
