

1. 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 30 MAY 97 for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DPSC purchase order number, contract number, and stock record account number (SRAN). (FOM-P), Bonnie Phillips, DSN (343-4170)

CLASS I RECALLS: None

CLASS II RECALLS:

NSN	4110 Nonstandard		
PRODUCT	Blood Storage Freezers, 20 cubic feet chest units and 13 cubic feet upright unit. Recall #B-592-7.		
Code	Brand	Model Number	Serial Number
	Baxter	RC2090A12	315182
	Baxter	RCU1386A14	318792
	Jewett	LTUR-13V14	314749
	Revco	UFRC1386-5-A12	316149
	Revco	UFRC1386-7-A14	320399.
MANUFACTURER	Revco Lindberg, Ashville, North Carolina.		

RECALLED BY Manufacturer, by telephone followed by fax the week of March 3, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Arizona, California, Iowa, Chile, Honduras.

QUANTITY 5 units were distributed.

REASON Blood storage freezers have failing/defective compressors.

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT (a) Transfilled Medical Oxygen in D, E, J, MPs and K cylinders; (b) Liquid Medical Oxygen. Recall #D-132/133-7.

CODE All codes, all lots, and all fill dates.

MANUFACTURER Lewin Agency, Inc., doing business as Lewin Medical Supply, Riverhead, New York.

RECALLED BY Manufacturer, by telephone on March 18, 1997, followed by letter. Firm-initiated recall ongoing.

DISTRIBUTION New York.

QUANTITY 132 cylinders and 2 31-liter cryogenic vessels were distributed.

REASON Current good manufacturing practice deficiencies (FDA inspection found that product was not tested for strength and the oxygen analyzer was not properly maintained).

None Present
 Action Taken _____

NSN 6505 Nonstandard

PRODUCT Clindamycin Phosphate Injection, USP, 150 mg/ml, Rx small volume parenteral semisynthetic antibiotic for IV or IM administration for the treatment of serious infections caused by susceptible anaerobic bacteria; packaged in 2 ml, 4 ml and 6 ml single dose vials, 25 vials per box. Recall #D-137-7.

CODE Catalog 22602, 2 ml fill in 2 ml vial, Catalog 22604, 4 ml fill in 5 ml vial, Catalog 22606, 6 ml fill in 10 ml vial. Lot numbers 951067, 951069, 951222, 951235, 960639, 951040, 951084, 951146, 960126, 960618

MANUFACTURER SoloPak Pharmaceuticals Inc., Elk Grove

Village, Illinois.
RECALLED BY Manufacturer, by letter dated March 13, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 320,000 vials were distributed; firm estimated
that 1 percent of product remained on market
at time of recall initiation.
REASON Bulk Clindamycin was recalled by Roussel
Corporation (parent firm of Biochimica Opos)
due to AADA discrepancies regarding the
manufacturing process; AADA was withdrawn.

None Present

Action Taken _____

NSN 6505 Nonstandard
PRODUCT Clindamycin Phosphate Injection, USP sterile
solution (150mg/ml) in 2ml, 4ml, 6ml, and 60ml
single dose containers (SDC) which are
packaged 25 SDCs per intermediate carton, a
prescription drug given intramuscularly or
intravenously for the treatment of serious
infections caused by susceptible anaerobic
bacteria. Recall #D-138-7.
CODE (2ml) Lot Nos. 1450605038, 1450608035.
(4ml) Lot Nos. 1451509066, 1451601040,
1451603105, 1451605035, 1451606048,
1451609805, and 1451609806.
(6ml) Lot Nos. 1452509065, 1452603109,
1452605033, 1452606051, and 1452609804.
Lot Nos. 1453510021, 1453601100 and
1453610040.
MANUFACTURER Astra USA Inc. Westboro, Massachusetts.
RECALLED BY Manufacturer, by letter dated March 20, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 47,757 saleable units were distributed; firm
estimated that 3,100 units of product shipped
prior to January 31, 1997, were still in
distribution at time of recall initiation.

REASON Bulk Clindamycin was recalled by Roussel Corporation (parent firm of Biochemicia Opos) due to AADA discrepancies regarding the manufacturing process; AADA was withdrawn.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Phenytoin Oral Suspension, USP packaged in unit dose cups and oral syringes, Rx oral antiepileptic drug, unit dose cups are packaged 10 cups per tray, with 5 or 10 trays per case, 100 mg 4-ml unit dose cup, 50 cups/case; 100 mg 4-ml unit dose cup, 100 cups/case; 100 mg 4-ml oral syringe, 50 syringes/case; 300 mg 12-ml unit dose cup, 100 cups/case. Recall #D-140-7.

CODE All lots within expiration date -- 605609, 604610, 603614, 603613, 603601, 602802, 602606, 602605, 601612, 601614, 512609, 512604, 512606, 512607, 512603, 511606, 511605, 510604, 510606, 510607, 509612, 509607, 509606, 509612.

MANUFACTURER Parke-Davis, Division of Warner-Lambert Company, Morris Plains, New Jersey.

RECALLED BY Xactdose, Inc., South Beloit, Illinois (repacker), by letter dated March 4, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 6,116 cases of 50/4 ml cups, 15,372 cases of 100/4 ml cups, 174 cases of 100/12 ml cups, and 116 cases of 50/4 ml oral syringes were distributed; firm estimates that little, if any, product remains on the market.

REASON Product failed content uniformity test.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Minocycline HCl Capsules, USP, 50 mg and 100 mg, used as an antimicrobial, under the Schein, Duramed and Medicis labels. Recall #D-134/135-7.

CODE Lot numbers: Schein label:
50 mg: All lots with exp. dates through 8/98,

PLUS P6K0148 and P6K0149
 100 mg: All lots with exp. dates through
 8/98, PLUS P6K0142 and P6K0143
 Duramed label:
 50 mg: C6A0011, C6A0111, C6C0517, C6C0518
 100 mg: C5M2834, C5M2844, C6C0687
 Medicis label:
 50 mg: All lots with exp. dates through 11/98
 100 mg (bottles of 50) - All lots w/exp dates
 through 7/98 100 mg (bottles of 500) - All lots
 w/exp dates through 6/98.

MANUFACTURER Danbury Pharmacal, Inc., Carmel, New York; and
 Danbury Pharmacal P.R., Inc., Humacao, Puerto
 Rico.
 RECALLED BY Danbury Pharmacal, Inc., Brewster, New York, by
 letter on February 26, 1997. Firm-initiated
 recall ongoing.
 DISTRIBUTION Nationwide and Chile.
 QUANTITY Total distributed
 50 mg 100 mg
 Schein 226,095x100s 538,822x50s
 Duramed 7,470x100s 11,178x50s
 Medicis 46,345x100s 57,107x50s
 Medicis 4,084x500s 4,508x500s.
 REASON Bulk Minocycline was recalled by Roussel
 Corporation (parent firm of Biochimica Opos)
 due to AADA discrepancies regarding the
 manufacturing process; AADA was withdrawn.

[] None Present
 [] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Doxycycline Hyclate 100 mg tablets, 50 mg
 capsules and 100 mg capsules labeled
 "Manufactured by Halsey Drug Co., Inc.,
 Brooklyn, N.Y.", "Manufactured by: Rachelle
 Laboratories, Inc., Culver, Indiana", "Mfd. by:
 Rachelle-Houba Laboratories, Inc., Culver,
 Indiana, a subsidiary of Halsey Drug Co., Inc.,
 Brooklyn, N.Y.", or "Manufactured by Rachelle
 Laboratories, Inc., Culver, Indiana, A
 Subsidiary of Halsey Drug Co., Inc., Brooklyn,
 NY" as follows:
 1. ALIGEN Doxycycline Hyclate Tablets, USP 100
 mg in bottles of 50 tablets distributed by
 Aligen Independent Laboratories, Inc.,
 2. ALIGEN Doxycycline Hyclate Tablets, USP 100
 mg in bottles of 500 tablets distributed by

- Aligen Independent Laboratories, Inc.,
3. APOTHECON Doxycycline Hyclate Tablets, USP 100 mg in bottles of 50 tablets, Manufactured for APOTHECON, A Bristol-Myers Squibb Co.,
 4. APOTHECON Doxycycline Hyclate Tablets, USP 100 mg in bottles of 500 tablets, Manufactured for APOTHECON, A Bristol-Myers Squibb Co.,
 5. APOTHECON Doxycycline Hyclate 100 mg capsules, USP in bottles of 50 capsules, APOTHECON, A Bristol-Myers Squibb Co.,
 6. APOTHECON Doxycycline Hyclate 100 mg capsules, USP in bottles of 500 capsules, APOTHECON, A Bristol-Myers Squibb Co.,
 7. Doxychel Doxycycline Hyclate Tablets USP 100 mg in bottles of 50 tablets, Rachelle Laboratories, Inc.,
 8. Doxychel Doxycycline Hyclate Tablets USP 100 mg in bottles of 500 tablets, Rachelle Laboratories, Inc.,
 9. Doxychel Doxycycline Hyclate Capsules USP 100 mg in bottles of 50 capsules, Rachelle Laboratories, Inc.,
 10. Geneva Doxycycline Hyclate Tablets, USP 100 mg in bottles of 50 tablets, distributed By Geneva Pharmaceuticals, Inc.,
 11. Geneva Doxycycline Hyclate Tablets, USP 100 mg in bottles of 500 tablets, distributed by Geneva Pharmaceuticals, Inc.,
 12. Geneva Doxycycline Hyclate 50 mg capsules, USP in bottles of 50 capsules distributed by Geneva Pharmaceuticals, Inc.,
 13. Geneva Doxycycline Hyclate 100 mg capsules, USP in bottles of 50 capsules distributed by Geneva Pharmaceuticals, Inc.,
 14. Geneva Doxycycline Hyclate 100 mg capsules, USP in bottles of 500 capsules distributed by Geneva Pharmaceuticals, Inc.,
 15. HALSEY Doxycycline Hyclate Tablets, USP 100 mg in bottles of 50 tablets, Manufactured by: Rachelle [or Rachelle-Houba] Laboratories, Inc.,
 16. HALSEY Doxycycline Hyclate Tablets, USP 100 mg in bottles of 500 tablets, Manufactured by: Rachelle [or Rachelle-Houba] Laboratories, Inc.,
 17. HALSEY Doxycycline Hyclate 50 mg capsules, USP in bottles of 50 capsules, Halsey Drug Co., Inc.,
 18. HALSEY Doxycycline Hyclate 100 mg capsules, USP in bottles of 50 capsules, Halsey Drug Co., Inc.,

19. HALSEY Doxycycline Hyclate 100 mg capsules, USP in bottles of 500 capsules, Halsey Drug Co., Inc.,
20. Major Doxycycline Hyclate Tablets, USP 100 mg in bottles of 50 tablets, Manufactured for Major Pharmaceutical Corp.,
21. Major Doxycycline Hyclate Tablets, USP 100 mg in bottles of 500 tablets, Manufactured for Major Pharmaceutical Corp.,
22. Major Doxycycline Hyclate 50 mg capsules, USP in bottles of 50 capsules Major Pharmaceutical Corp.,
23. Major Doxycycline Hyclate 100 mg capsules, USP in bottles of 50 capsules Major Pharmaceutical Corp.,
24. Major Doxycycline Hyclate 100 mg capsules, USP in bottles of 500 capsules distributed by Major Pharmaceutical Corp.,
25. Mason Doxycycline Hyclate 100 mg capsules, USP in bottles of 500 capsules distributed by Mason Distributors, Inc.,
26. Moore Doxycycline Hyclate Tablets, USP 100 mg in bottles of 50 tablets distributed by h.l. Moore Drug Exchange, and labeled
27. Moore Doxycycline Hyclate Tablets, USP 100 mg in bottles of 500 tablets, distributed by h.l. Moore Drug Exchange,
28. Moore Doxycycline Hyclate 50 mg capsules, USP in bottles of 50 capsules distributed by h.l. Moore Drug Exchange,
29. Moore Doxycycline Hyclate 100 mg capsules, USP in bottles of 50 capsules distributed by h.l. Moore Drug Exchange,
30. Moore Doxycycline Hyclate 100 mg capsules, USP in bottles of 500 capsules distributed by h.l. Moore Drug Exchange,
31. PARMED Doxycycline Hyclate 50 mg capsules, USP in bottles of 50 capsules distributed by Parmed Pharmaceuticals, Inc.,
32. PARMED Doxycycline Hyclate 100 mg capsules, USP in bottles of 50 capsules distributed by Parmed Pharmaceuticals, Inc.,
33. Qualitest Doxycycline Hyclate Tablets, USP 100 mg in bottles of 50 tablets, and labeled "Mfg. for: QUALITEST PRODUCTS, INC.,
34. Qualitest Doxycycline Hyclate Tablets, USP 100 mg in bottles of 500 tablets, Mfg. for: QUALITEST PRODUCTS, INC.,
35. Qualitest Doxycycline Hyclate 50 mg capsules, USP in bottles of 50 capsules and labeled "Mfg. for: QUALITEST PRODUCTS, INC.,

36. Qualitest Doxycycline Hyclate 100 mg capsules, USP in bottles of 50 capsules
QUALITEST PRODUCTS, INC.,
37. Qualitest Doxycycline Hyclate 100 mg capsules, USP in bottles of 500 capsules
QUALITEST PRODUCTS, INC.,
38. Warner Chilcott Doxycycline Hyclate Tablets, USP 100 mg in bottles of 50 tablets, Manufactured for WARNER CHILCOTT LABS Div of Warner-Lambert Co.,
39. Warner Chilcott Doxycycline Hyclate Tablets, USP 100 mg in bottles of 500 tablets, Manufactured for WARNER CHILCOTT LABS Div of Warner-Lambert Co.,
40. WARNER CHILCOTT Doxycycline Hyclate 50 mg capsules, USP in bottles of 50 capsules WARNER CHILCOTT LABS, Div of Warner-Lambert Co.,
41. WARNER CHILCOTT Doxycycline Hyclate 100 mg capsules, USP in bottles of 500 capsules
Manufactured for: WARNER CHILCOTT LABS, Div of Warner-Lambert Co. Recall #D-141/143-7.
APOTHECON Lots: 4J98931, 4J98942, 4J98953, 4K98332, 5F06053, 5F07390, 5F07401, 5G06064, 5K09524, 5L09535, 5M08132, 6A18143, 6A18154, 6A19452, 6F16377, 6F16388, 6J16668, 6F16701, 6J16723, 6L16690.

CODE

The following lot numbers of the brands other than APOTHECON are under recall:

50 mg. capsules: These products bear seven digit lot numbers and the first three digits are 552.

For lots ending in the number 5: Lots containing the numbers 02 or a larger number as the fourth and fifth digits and the letter R as the sixth digit. All codes ending in a 5 and containing the letter W.

For lots ending in the number 6: All lots containing the letter A, B, C, D, E, F, G, H, K, or M.

100 mg. capsules: These products bear seven digit lot numbers and the first three digits are 553.

For lots ending in the number 5: All codes containing the letter K, M, R, or W PLUS all codes with the numbers 05 or a larger number in the fourth and fifth positions and containing an H in the code.

For lots ending in the number 6: All lots containing the letter A, B, C, D, E, F, G, H, or K PLUS all codes with the number/letter combination 01M or 02M.

100 mg. tablets: These products bear seven digit lot numbers and the first three digits are 581.

For lots ending in the number 4: All codes containing the letter H, K, M, R, or W.

For lots ending in the number 5: All codes.

For lots ending in the number 6: All codes containing the letter A, B, C, D, E, F, G, H, K, or M.

MANUFACTURER Houba, Inc., A Subsidiary of Halsey Drug Co., Inc., Culver, Indiana.

RECALLED BY letter dated January 3, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY Approximately 150 million capsules were distributed.

REASON ANDA discrepancies and lack of assurance of stability.

None Present

Action Taken _____

NSN 6505 Nonstandard

PRODUCT Lederle brand Cefaclor Capsules, USP, 250 mg and 500 mg, Rx antibiotic.
Recall #D-146/147-7.

CODE All lots within expiration date.

MANUFACTURER Lederle Laboratories, Pearl River, New York.

RECALLED BY Wyeth-Ayerst Laboratories, St. Davids, Pennsylvania, by letter dated February 19, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.

QUANTITY 692,229 bottles were distributed.

REASON Bulk Cefaclor was recalled b Roussel Corp. (parent firm of Biochimica Opos) due to AADA discrepancies regarding the manufacturing process; AADA was withdrawn.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Lederle brand Cefaclor for Oral Suspension, USP, 125 mg/5 ml, 187 mg/5 ml, 250 mg/5 ml, and 375 mg/5 ml, Rx antibiotic. Recall #D-148/151-7.

CODE All lots within expiration date.
 MANUFACTURER Lederle Laboratories, Pearl River, New York.
 RECALLED BY Wyeth-Ayerst Laboratories, St. Davids, Pennsylvania, by letter dated February 19, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
 QUANTITY 1,433,816 bottles were distributed.
 REASON Bulk Cefaclor was recalled by Roussel Corporation (parent firm of Biochimica Opos) due to AADA discrepancies regarding the manufacturing process; AADA was withdrawn.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Lederle brand Clindamycin Phosphate Injection, a prescription drug given intramuscularly or intravenously for the treatment of serious infections caused by susceptible anaerobic bacteria: (a) 2 ml; (b) 4 ml; (c) 6 ml; (d) 60 ml vials. Recall #D-152/155-7.

CODE Lot numbers: (a) 409 835 (EXP 2/97), 409 836 (EXP 2/97), 411 803 (EXP 5/97), 417 827 (EXP 6/97); (b) 409 837 (EXP 2/97), 409 838 (EXP 2/97), 411 804 (EXP 2/97), 413 817 (EXP 6/97), 413 818 (EXP 6/97), 417 828 (EXP 6/97), 417 829 (EXP 6/97), 417 830 (EXP 7/97)
 (c) 409 834 (EXP 2/97), 411 801 (EXP 2/97) 411 802 (EXP 6/97), 413 816 (EXP 6/97) 417 825 (EXP 6/97), 417 826 (EXP 7/97) 418 267 (EXP 7/97),
 (d) 387 801 (EXP 2/97), 411 800 (EXP 7/97) 413 815 (EXP 7/97).

MANUFACTURER Lederle Parenterals, Inc., Carolina, Puerto Rico.
RECALLED BY Wyeth Ayerst Laboratories, St. Davids, Pennsylvania, by letter dated February 19, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 300,389 vials were distributed.
REASON Bulk Clindamycin was recalled by Roussel Corporation (parent firm of Biochimica Opos) due to AADA discrepancies regarding the manufacturing process; AADA was withdrawn.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Baxter InterLink System T-Connector Extension Sets with Luer Slip Adapters,
(a) Catalog No. 2N3326, InterLinkR System T-Connector Extension Set
(b) Catalog No. 2N3329, InterLinkR System T-Connector Extension Set
(c) Catalog No. 2N3330, InterLinkR System Dual Line T-Connector Extension Set
(d) Catalog No. 2N3332, InterLinkR System T-Connector Extension Set, 0.22 Micron Filter
(e) Catalog No. 3C0007, InterLinkR System Continu-Flo Solution Set, 3-Way Stopcock, T-Connector Extension Set
(f) Catalog No. 3C0026, InterLinkR System BuretrolR Solution Set, Extension Set, 3-Way Stopcock, T-Connector Extension Set
(g) Catalog No. 3C0028, InterLinkR System Continu-FloR Solution Set, 3-Way Stopcock, T-Connector Extension Set
(h) Catalog No. 3C0047, InterLinkR System 4-Way Large Bore Stopcock Extension Set, T-Connector Extension Set
(i) Catalog No. 3C0050, InterLinkR System Continu-FloR Set, Three 4-Way Stopcocks Extension Set, T-Connector Extension Set
(j) Catalog No. 1C8567, InterLinkR System Extension Set, T-Connector Set
(k) Catalog No. 1C8571, InterLinkR System Extension Set, T-Connector.
Recall #Z-408/418-7.
CODE All lots.
MANUFACTURER Baxter Healthcare Corporation, Aibonito, Puerto Rico and Cleveland, Mississippi.

RECALLED BY Baxter Healthcare Corporation, Round Lake,
Illinois, by letter dated March 14, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 4,990,004 sets were distributed; firm estimated
that 5 percent remained on market at time of
recall initiation.
REASON The luer slip adapter of the InterLinkR
T-Connector Extension Set may inadvertently
disconnect from mated connections.

None Present
 Action Taken _____

NSN 6550 Nonstandard
RODUCT Chocolate II Agar Plates, for in-vitro
diagnostic use, Catalog Nos. 4321169 & 4321267.
Recall #Z-423-7.
CODE Lot Nos. A3RTWG, A3RTWZ, A3RTXJ, A3RTXNK,
A3RTYB, A4RTZZ, A4RUAA, A4RUAN, A4RUAR, A4RUBN,
A4RUGF, BIRUGU, BIRUGU, BIRUHJ, B2RUJZ, B2RUKR,
B2RULM, B2RULL, B2RUMF, B3RUMI, B3RUNB, B3RUNX,
B3RUOL, B3RUPA, B3RUPO, B3RUPB, B3RUPX, B3RUPP,
B3RUPZ, B4RUST, B4RUTM, B4RUUA, B4RUWA, C2RUYW,
C2RUZS, C3RWBI, C3RWCH, C3RWCZ, C3RWGN,
C4RWHB, C4RWHX, C4RWIR, C4MWJF, C4RWJG, C4RWIZ,
C4RWJU, C5RWKK, C5RWLC, C5MWNH, C5RWLX, C5RWMI,
C5RWMJ.
MANUFACTURER Becton Dickinson Microbiology Systems,
Cockeysville, Maryland.
RECALLED BY Manufacturer, by letter dated January 21, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 4,026,980 units were distributed.
REASON There was decreased growth of QC organism
Haemophilus Influenzae.

None Present
 Action Taken _____

NSN 6550 Nonstandard
 PRODUCT Abbott IMx & AxSYM PSA (Prostate Specific Antigen) Reagent Packs, for in-vitro diagnostic use:
 (a) IMx Kit, Catalog No. 2245-20,
 (b) AxSYM Kit, Catalog No. 7A49-20.
 Recall #Z-424/425-7.

CODE Lot Numbers: (a) 25102Q100, 25104Q100, 25107Q100, 26646Q100, 23569Q100, 25103Q100 (b) 23523Q100, 23523Q101, 23535Q100, 23535Q101, 23547Q100, 24236Q100, 24236Q101, 24239Q100, 25245Q100, 25246Q100, 25293Q100, 25414Q100, 25415Q100, 25440Q100, 25441Q100, 25441Q101, 25442Q100, 25442Q101, 25443Q100, 25443Q101.

MANUFACTURER Abbott Health Products, Inc., Barceloneta, Puerto Rico.

RECALLED BY Abbott Laboratories, Diagnostic Division, Abbott Park, Illinois, by telephone on March 20, 1997, followed by letter. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide and international.

QUANTITY (a) 14,244 packs; (b) 28,138 packs were distributed; firm estimated that 50 percent of product remained on market at time of recall initiation.

REASON The kits give falsely elevated PSA values with samples from patients who have undergone radical prostatectomies.

[] None Present
 [] Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
 PRODUCT Trisoralen Tablets, 5 mg. (Trioxsalen, USP), packaged in bottles of 28 tablets and 100 tablets, (bottles of 10 and 1000 were exported), a prescription drug for oral administration and is indicated for the repigmentation of idiopathic vitiligo; for increasing tolerance to sunlight and for enhancing pigmentation. Recall #D-139-7.

CODE All lot numbers (18 total) within expiration date are under recall. The lot numbers and expiration dates which identify domestic, and possibly, foreign distribution are: E0216

(2/97), E0503 (5/97), E1107 (11/97), E1124 (12/97), F0102 (2/98), F0219 (3/98), F0408A (5/98), F0408B (5/98), F1217B (1/99), F1217B (1/99), G0816A (9/99), G0816B (9/99), G1001A (11/99), G1001B (11/99), H0321A (5/00), H312B (5/00), H0831A (9/98), H1122B (12/98).

The lot numbers which exclusively identify international distribution are: E1228, F0403A, F0403B, F0219E, F0408AE, F0408BE, F0801A, F0801B, H0831B, & H1122A.

MANUFACTURER ICN Pharmaceuticals, Inc., Inc., Costa Mesa, California (responsible firm).
RECALLED BY ICN Pharmaceuticals, Inc., Bryan, Ohio, by letter dated February 25, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 58,514 bottles were shipped to domestic accounts.
REASON Product fails dissolution test requirements (SPEC is NLT 75%; actual is as low as 45%).

None Present

Action Taken _____

NSN 6505 Nonstandard
PRODUCT Gastrografin (Diatrizoate Meglumine 660 mg/ml and Diatrizoate Sodium, 100 mg/ml Solution, USP), Oral/Rectal Solution in 120 ml bottles a prescription iodinated radiopaque contrast medium. Recall #D-144-7.
CODE Lot #ML015 EXP 11/00.
MANUFACTURER Bristol-Myers Squibb Company, Bristol-Myers Squibb U.S. Pharmaceutical and Mead Johnson Nutritional Group, Evansville, Indiana.
RECALLED BY Bracco Diagnostics, Inc., Princeton, New Jersey, by letter on February 18, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 36,012 4-ounce bottles in 3,001 cases of 12 bottles each.

REASON Presence of foreign substance (small rubber particles from filling machine seal found in several units).

[] None Present
[] Action Taken _____

NSN 6505
PRODUCT Transderm-Nitro (Transdermal Nitroglycerin) 100 mg (0.8 mg/hour), Rx, institutional use only, indicated for the prevention of angina pectoris. Recall #D-145-7.

CODE Lot #C9080 EXP 8/97.
MANUFACTURER Reservoir: Ciba Pharmaceuticals Division (Old Name at time of Manufacturing) Ciba-Geigy Corporation, Summit, New Jersey; System Fabrication: Ivers-Lee (now Sharp/Ivers-Lee) West Caldwell, New Jersey.

RECALLED BY Novartis (formerly Ciba) Pharmaceuticals Corporation, Summit, New Jersey, by letter February 20, 1997, followed by telephone. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
QUANTITY 774 cartons (30 systems per carton) were

distributed.

REASON Product lacks stability (failed content assay after two years-- Spec is 85-110mg/system, found as low as 80%)

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Dexamethasone Sodium Phosphate for Injection, USP, 10 mg/ml, in 10 ml multi-dose vials, sterile, injectable glucocorticoid, under the following labels: Steris, Schein, Clint, and Robar. Recall #D-136-7.

CODE LOT EXPIRATION
95E710 7/97
95F530 9/97
95K460 11/97
95L190 11/97
95L770 12/97
96C420 3/98
96H430 7/98.

MANUFACTURER Steris Laboratories, Inc., Phoenix, Arizona.
RECALLED BY Manufacturer, by letter dated January 27,
+ 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Puerto Rico, Peru.
QUANTITY Approximately 94,500 vials were distributed.
REASON Product failed pH specification (SPEC is 7.0-
8.5pH); actual is 8.6.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Simon Nitinol Filter Set, indicated for use in
the prevention of recurrent pulmonary embolism
via placement in the vena cava via a
jugular/femoral approach. Recall #Z-426-7.
CODE Catalog #2220J, Lot #509126D.
MANUFACTURER Nitinol Medical Technologies, Inc., Boston,
Massachusetts.
RECALLED BY Manufacturer, by letter of March 5, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Alabama, New Jersey, Ohio, Pennsylvania.
QUANTITY 7 units were distributed.
REASON The outer box label indicated catalog no. 2120F
(Femoral), which is incorrect while the inner
pouch was labeled 2220J (Jugular) which is
correct.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Abbott HTLV-1 2.0 EIA Diagnostic Kit Human T-
Lymphotropic Virus Type I. Recall #B-549-7.
CODE Lot #2137M301, 21307M302 EXP 3-31-97.
MANUFACTURER Abbott Laboratories, Diagnostic Division,
Abbott Park, Illinois.
RECALLED BY Manufacturer, by telephone on March 10, 1997,
followed by letter. Firm-initiated recall
complete.
DISTRIBUTION Nationwide and international.
QUANTITY 202 kits were distributed

REASON Reconstituted HTLV-I 2.0 EIA Conjugate does not consistently meet the Positive Control validity requirement.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Abbott HIVAG-1 Monoclonal EIA Kit, Antibody to Human Immunodeficiency Virus Type 1 (HIV-1). Recall #B-563-7.
CODE Masterlots to be destroyed: 20387M401, 20388M401, 21204M201, 21205M201, 21259M101, 21260M101, 21375M401, 21376M401, 21453M301, 21454M301, 21456M301, 21673M201, 21674M201, 22043M201, 22182M401, 22371M101, 22383M301, 22384M301, 23087M401, 23088M401, 23286M401, 23287M401, 23812M101, 24035M201, 24560M401, 25006M401, 25491M101
Masterlots to be relabeled with new expiration dates:
22181M401 25345M301 23705M201 25347M301
23821M101 25770M201 24077M401 25778M201
24476M301 25780M201 24495M201 26268M101
24529M201 26425M101 24681M301 26706M201.

MANUFACTURER Abbott Laboratories, Diagnostic Division, Abbott Park, Illinois.
RECALLED BY Manufacturer, by letter on March 31, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 5,632 - 100 test kits and 7,813 - 1000 test kits were distributed.
REASON HIVAG-1 Monoclonal masterlots does not consistently meet the Positive Control validity requirement through the currently labeled expiration dating.

None Present
 Action Taken _____
