

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:

**6525 NS
MDC 12425
PRODUCT**

X-Ray Rad Units, Mannographic

a) Bennett X-Ray Contour Mammography Systems, Model numbers: M-CTR-2000, M-CTR-2000-3P, M-CTR-P, M-CTR-3P;
b) Profile Mammography Systems, Model numbers: M-PRO-2000, M-PRO2000-3P, M-PRO, diagnostic X-ray devices used in mammography.
Recall #Z-739/740-0.

**CODE
MANUFACTURER
RECALLED BY**

None
Bennett X-ray Corporation, Danbury, Connecticut.
Trex Medical Corporation, Danbury, Connecticut. FDA approved the firm's corrective action plan on May 26, 2000. Firm-initiated field correction complete.

**DISTRIBUTION
QUANTITY
REASON**

Nationwide.
607 units were distributed.
The units are noncompliant with 21 CFR 1020.31(m) in that the transmission limit 5-cm beyond the plane of the image receptor support device exceeds 0.1 mR per exposure. This can result in the patient receiving unnecessary exposure.

None Present
 Action Taken _____

**6540 NS
MDC 10673
PRODUCT**

Cataract Extraction Unit

Accurus 200PS Phacoemulsification System, Catalog #8065740742, a phacoemulsification system used for ophthalmic surgery featuring phacoemulsification, irrigation and aspiration capability, anterior vitrectomy, and diathermy functions. Recall #Z-780-0.

CODE

SERIAL NUMBERS:
9901725601X 9902087501X 9901446301X 9901725501X
9901890101X 9901718101X 0001038201X 0001038101X
0001065601X 9901462801X 9901725401X 9901463001X
9901463101X 9901463201X 9901467201X 9901707301X
9901707401X 9901462901X 9901717901X 0001005201X
9901442401X 9901467001X 9901718001X 9902003301X
0001005101X 0001135901X 9901446401X 9901446501X
9901446601X 9901466901X 9901467101X 0001005401X
0001005301X 9901462701X 0001136001X 9801357001X.

**MANUFACTURER
RECALLED BY**

Alcon Laboratories, Inc., Irvine, California.
Alcon Laboratories Inc., also known as Alcon Research LTD, Fort Worth Texas, (responsible firm), by telephone and letter beginning April 25, 2000. Firm-initiated field correction complete.

DISTRIBUTION Florida, Maine, New Mexico, Virginia, Vermont, Australia, Germany, Italy, France.

QUANTITY 33 units were distributed.

REASON The low pressure air output (AVGFI) module used with the Alcon Accurus 200PS may unexpectedly drop to a low setting, resulting in low irrigation or infusion pressure during surgery, while vacuum remains active.

None Present
 Action Taken _____

**6630 NS
MDC 16488
PRODUCT**

Blood Glucose Monitors, Portable

Dexter-ZII Blood Glucose Meter, intended for use in self-monitoring of blood glucose by persons with diabetes:

a) Model 3958K2; b) Model 3958N2; c) Model 3969N2.

Recall #Z-781/783-0.

CODE

Serial Numbers:

4000114 4000162 4000197 4000330 4001008 4001047 4001072
4001118 4001157 4001178 4001185 4001191 4001199 4001200
4001201 4001215 4001409 4001514 4001833 4002475 4002487
4002569 4002578 4003218 4003303 4003329 4003367 4003443
4003523 4004102 4004110 4004112 4004116 4004129 4004139
4004158 4004264 4004273 4004274 4004278 4004280 4004283
4004284 4004298 4004301 4004303 4004308 4004500 4004502
4004505 4004506 4004511 4004517 4004518 4004521 4004526
4004530 4005010 4005011 4005050 4005068 4005322 4005329
4005359.

MANUFACTURER
RECALLED BY

Bayer Corporation, Business Group Diagnostics, Mishawaka, Indiana.
Bayer Corporation, Elkhart, Indiana, by fax on or about April 11, 2000.

Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Japan.
64 units were distributed.
The systems begin to count down prior to the inoculation of the reagent sensor.

None Present
 Action Taken _____

CLASS III RECALLS:

6515 NS
MDC 12712
PRODUCT

Nebulizers

DeVilbiss Portable Ultrasonic Nebulizer DC Power Cord.

Recall #Z-809-0.

CODE

Catalog #5500D-616.

MANUFACTURER
RECALLED BY

Sunrise Medical HHG, Inc., Somerset, Pennsylvania.
Manufacturer, by telephone followed by letter faxed on April 7, 2000.

Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY

Nationwide and Canada.
370 units.

REASON

The wrong DC power cord was supplied with the nebulizer.

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 **1 SEP 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: None

CLASS II RECALLS:

NSN	6505 Nonstandard
PRODUCT	Source Plasma. Recall #B-768-0.
CODE	Unit Numbers: N-06825-178, N-06840-178, G-23972-178, G-24173-178, G-24496-178.
MANUFACTURER	Seramed Bio Center/Melrose Park, Melrose Park, Illinois.
RECALLED BY	Manufacturer, by fax on December 16, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	California.
QUANTITY	5 units were distributed.
REASON	Blood products were collected from a donor who was previously deferred for a positive drug screen.

None Present
 Action Taken _____

NSN	6505 Nonstandard
PRODUCT	Goldline brand Acetaminophen Suppositories, USP, OTC indicated for the temporary relief of fever, ache, pains, and headaches, for rectal administration:
	a) 120 mg, Pediatric, units of 12, NDC #0182-1662-11;
	b) 650 mg, units of 12, NDC #0182-1095-11.
	Recall #D-404/405-0.
CODE	Lot #AL 606 EXP 9/20/02.
MANUFACTURER	Clay-Park Labs, Inc. (CPL), Bronx, New York.
RECALLED BY	Manufacturer, by letter dated November 30, 1999. Firm-initiated recall

DISTRIBUTION ongoing.
QUANTITY Kentucky.
REASON 49,392 suppositories were distributed.
Misbranding - Some 650 mg (correctly labeled) suppositories were packaged into cartons labeled as 120 mg.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT a) Acetone Alcohol in preps (CS-1000-VWR Catalog #15649-000), Swabs (CS-500-VWR-15649-012);
b) Iodophor in swabs (PVP-50-VWR Catalog #15649-002 and 500 C/S Catalog #15649-018), pads (PVP Prep 200 pack VWR Catalog #15649-016);
c) Iodine Tinc. in Swabs (VWR Catalog #15649-006 and 010) and sol ptsn 12x16 oz. Pack (VWR Catalog #15649-034);
d) Alcohol in swabs 25 pack (VWR Catalog #15649-008 and LX15649-008) and prep pads Med NS 20 pack (VWR Catalog #15649-024) and Towelette Clinipad (VWR Catalog #15649-014);
e) Povodone Iodine in Scrub/Gal 4 CS (VWR Catalog #15649-030) and Gal (VWR #BA15649-030AB);
f) Benzalkonium Chloride 1/2-oz. (VWR Catalog #15649-028);
g) Green Soap Tinc. in swabs, 500/CS (VWR #15649-020).
Recall #D-397/403-0.

CODE All lots.
MANUFACTURER Clinipad Corporation, Charlotte, North Carolina.
RECALLED BY VWR Scientific Products Corporation, West Chester, Pennsylvania, by letter on April 4, 2000. Firm-initiated recall ongoing.
DISTRIBUTION Alabama, California, Connecticut, Georgia, Illinois, Indiana, Maryland, Michigan, North Carolina, New Jersey, Ohio, Pennsylvania, Texas.
QUANTITY 133 units were distributed.
REASON Manufacturer (Clinipad Corporation) unable to assure product meets release microbiological specifications.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT Vacutainer Brand Evacuated Blood Container, partial draw sodium citrate tubes. Recall #Z-778-0.

CODE Catalog Numbers: 369711, 369700, 367712, 367703, 367715, 366416, 369705, 367707, 366419.

MANUFACTURER Becton Dickinson & Co., Broken Bow, Nebraska.
RECALLED BY Becton Dickinson & Company, Franklin Lakes, New Jersey, by providing technical information to users beginning April 17, 2000. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide.
QUANTITY Not applicable.
REASON Increased platelet activation in partial draw tubes.

NSN 6515 Nonstandard
PRODUCT Procedure Tray, Fixture Installation, Catalog #25369, dental handpiece and accessories. Recall #Z-779-0.

CODE Lot numbers: 802899, 803109, 803183, 803237, and 803711.
 MANUFACTURER Nobel BioCare AB, Gothenburg, Sweden.
 RECALLED BY Nobel BioCare USA Inc., Yorba Linda, California, by letter and fax on
 March 29, 2000, and by fax on April 11, 2000. Firm-initiated recall
 ongoing.
 DISTRIBUTION Alaska, Alabama, Arizona, California, Iowa, Massachusetts, Michigan,
 Minnesota, Oregon, Nebraska, New Hampshire, New Jersey, New York,
 Pennsylvania, Texas, Virginia, Washington state, Wisconsin, Canada,
 Chile, Colombia.
 QUANTITY 77 units were distributed.
 REASON The spring on the connector to the contra-angle handpiece may fracture
 and come loose.

 None Present
 Action Taken _____

CLASS III RECALLS:

NSN 6505 Nonstandard
 PRODUCT Imitrex(r) (sumatriptan succinate) Rx tablets, 25 mg, in
 9-tablet units. NDC #0173-0460-02. Recall #D-393-0.
 CODE Lot Numbers: OZP0151 and OZP0152.
 MANUFACTURER Glaxo Wellcome, Zebulon, North Carolina.
 RECALLED BY Manufacturer, by letter on April 28, 2000. Firm-initiated recall
 ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY Approximately 12,157 units from lot OZP0151, and 25,553 units from lot
 OZP0152 are in distribution channels.
 REASON Misbranding - Blister text incorrectly declares product strength at 50 mg
 (outer carton is correctly labeled
 (25 mg).

 None Present
 Action Taken _____

NSN 6505 Nonstandard
 UPDATE Quinidine Gluconate Extended Release Tablets, USP, 324 mg, in 100 and 500
 tablet bottles, recalled by Schein Pharmaceuticals, Inc., Brewster, New,
 which appeared in the January 19, 2000 Enforcement Report has been
 extended to include Lot Numbers C8E1069 and C8F1172.

 None Present
 Action Taken _____

NSN 6505 Nonstandard
 PRODUCT a) Doxycycline Hyclate Capsules, USP, 50 MG
 in bottles of 50, NDC 0364-2032-50, and bottles of 100 (10 X 10), NDC
 0364-2033-90;
 in bottles of 50, NDC 0364-2033-50, and bottles of 500, NDC 0364-2033-05.

QUANTITY 11,870,820 units were distributed; firm estimated that 350,000 units remained on market at time of recall initiation.

REASON Stability: (Super-potency) potential for patients to receive a higher dose than labeled of triamcinolone acetone.

[] None Present
 [] Action Taken _____

NSN 6515 Nonstandard

PRODUCT Peripherally Inserted Central Venous Catheter Trays containing Clinipad Cliniguard Protective Dressing Prep.
 Recall #Z-811-0.

CODE Catalog number C-PICS-301. Lot F804662
 Catalog number C-PICS-301-CHOP-103097. Lot F790253.
 Catalog number C-PICS-301J. Lots F833591, 952989, 955791, 950762, 952988, 959369, 950763, F824639, F794489, F796661, F801539, F806269, F811737, F817595, F809235, F822207, F826239, F834114, F839371, F838672, F840052 and F838672X.
 Catalog number C-PICS-301J-SACRED-HEART-062591-PKG. Lots F771187 and F791507.
 Catalog number C-PICS-301J-UTAH-070992. Lots 947003, 947002, 951258, 951257, 956120, 956121 and 956892.
 Catalog number C-PICS-401. Lots 956894 and 960721.
 Catalog number C-PICS-401-CHOP-103097. Lots F794621, F793680, F801365, F02215 and F806310.
 Catalog number C-PICS-401J. Lots 949398, 955792, 949401, 956606, 956607, 956608, 949400, 960481, 948053, 955793, 955795, 932069X, 955794, 949399, 960482, F789187, F796784, F797974, F801540, F806623, F806270, F810223, F816240, F819630, F822721, F824841, F826240, F833302, F791829, F810408 and F828140.
 Catalog number C-PICS-401J-JGH-121698. Lots F794145, F809021 and F811276.
 Catalog number C-PICS-401J-SACRED-HEART-062591-PKG. Lots F784415, F801146, F800823, F818856 and F833973.
 Catalog number C-PICS-401J-UTAH-070992. Lots 951914, 945532, 949403, 951915, 932792X, 956896, 957631, 956895, 956123, 956122 and 945530
 Catalog number C-PICS-401J-X. Lot F811185.
 Catalog number C-PICS-501. Lots F794146, F810409, and F828141.
 Catalog number C-PICS-501-ANDREWS-021191. Lots F804082 and F830783.
 Catalog number C-PICS-501E-MCCREADY-041994. Lot F797212.
 Catalog number C-PICS-501J. Lots F791623, F827945, 959620, 957447, 945802, 959618, 950481, 959621, 950482, F789188, F790483, F794490, F796662, F796785, F799725, F801541, F802192, F806271, F810986, F817596, F819631, F820587, F821289, F826998, F822208, F834115, F839372, F840053, 957446, F810410, F828142, and 945801.
 Catalog number C-PICS-501J-ST-MARK-060391. Lot F792267.
 Catalog number C-PICS-501J-UTAH-070992. Lots F833885, F833992, F832109, F800450, F803795, F81222, F801538, F834317, and F805245.
 Catalog number C-PICSY-301J-RP-011195. Lots 947305 and 954515
 Catalog number C-PICSY-401J. Lots 952430, 952431, 955796, 956899, 954222, 954223, 955797, 963886, 958901, and 956901.
 Catalog number PICS-301-MPIS. Lots 956622, 954243, 954241, 958626, 958628, 958627, 943780, 951932, 951933, 956621, 954242, 957849, 956623,

954244X, 957850, 951930X, 943781, 957851, 960528, 957848, 960529, 958625, 954244 and 932824

Catalog number PICS-301-MPIS-A. Lots 952696, 95049,7 950498, 958629, 940831X, 942163, 942164, 958630, 960216, 960215, 958631 and 936028.

Catalog number PICS-301-MPIS-CMC-072899. Lot F794588.

Catalog number PICS-301-MPIS-NT. Lots F811680, F807565, F823367, F834675, F823631, F788865, and F815245.

Catalog number PICS-301-MPIS-WOC. Lots 953050, 953051, 954930, 959895, 954931, 947316, 944002, 947314, 945820 and 959897

Catalog number PICS-301-MPIS-WOC-NT. Lots F796253, F808401, F793351, F797779, F803200, F808243, F814403, F804945 and F831196

Catalog number PICS-401-MPIS. Lots 951935, 949429, 953673, 953682, 957860, 959652, 951938, 953674, 953676, 956955, 957857, 959654, 959658, 961686, 951944, 956962, 957853, 959655, 959659, 942533X, 953679, 956961, 953680, 951936, 951937, 951947, 953678, 953677, 956960, 956959, 957854, 956958, 959656, 951939, 951940, 953676X, 956956, 959657, 956954, 956957, 951943, 957855, 957856, 951944X, 957852, 951942, 951941, 951945, 953681, 957859, 957858, 953671, 961692, 961689, 953672, 951946, 953675, F796338, 959653, 961690, F790506, F793794, F797481, F794509, F798001, F799742, F801563, F806294, F816278, F809247, F819660, F820610, F822748, F824879, F831102, F840130, F809671 and F828982.

Catalog number PICS-401-MPIS-A. Lots F818826, F832821 and F786275

Catalog number PICS-401-MPIS-A-NT. Lot F784799.

Catalog number PICS-401-MPIS-NT. Lots 953369, 955847, 965127, 960219, 958632, 960217, 958633, 960218, 963916, 962112, 966520, 962111, 953368, 963917, 956427, 953367, 948897, 965128, 955846, 955845, 956428, 966521, F819556 and 948896.

Catalog number PICS-401-MPIS-WOC. Lots F803427, F821904, F841997, 958105, 952170, 953684, 961442, 948125X, 959388, 952169, 948125, 953683, 963918, 961441, 958106, 952169X, 959387, F790507, F822529, F824880 and F828983.

Catalog number PICS-401-MPIS-WOC-NT. Lots 953052, 962113, 958108, 957467, 958107, 957468, 956151, 950097, 950096, 962114, 956152, 953053, 959898, 959899 and 957469.

Catalog number PICS-501-ANDREWS-021191. Lot F817156.

Catalog number PICS-501-MNP-ABMH-071895. Lots F786365, F822816, and F822816X.

Catalog number PICS-501-MPIS. Lots F799511, F799557, F804730, 953083, 953063X, 956432, 956435, 956430, 950830, 955197, 955201, 950826, 950819, 959394, 959395, 959401, 953067, 953062, 953059, 955186, 955177, 956446, 959406, 950832, 953071, 953077, 955172, 956441, 957879, 959391, 957886, 959402, 956447X, 955194, 956437, 961449, 959412, 956436, 956440, 956438, 956442, 956448, 957864, 959396, 959408, 953058, 961460, 953075, 953055, 953068, 953073, 959399, 956445, 963065, 963068, 950818, 956429, 961453, 948931X, 948926X, 950806, 953081, 959409, 950822, 950825, 950831, 953082, 957869, 957870, 959407, 959398, 950833, 959393, 959400, 961462, 961465, 953061, 955202, 955195, 961464, 961459, 953079, 956433, 955184, 955176, 961446, 961444, 961445, 959404, 956447, 955178, 955188, 950824, 955171, 953078, 953063, 956452, 956449, 963083, 963072, 957876, 955196, 957874, 957886, 953084, 953072, 956451, 950817, 953056, 953060, 961452, 961451, 957862, 959397, 961455, 961461, 961463, 953085, 963086, 956450, 955179, 956431, 956444, 957863, 957884, 957880, 957882, 953066, 963084, 950821, 953073X, 963070, 955175, 963078, 955182, 950804, 957875, 955172X, F790508, F794510, F799743, F807506, F809248, F819687, F831103, F836367, F840131, 961454, 961456, 953080, F794069, F809672, F808803, F828984, 950811, 950808, 959410, 957861X, 961448, 957877, 956431X, 955190, 957867,

963067, 950816X, 956453, 953080X and 953081X.
 Catalog number PICS-501-MPIS-A. Lots 957198, 938781, 950836, 957199, 955849, 955848, 959167, 950835 and 950814.
 Catalog number PICS-501-MPIS-MSH-091098. Lot F0802114.
 Catalog number PICS-501-MPIS-NT. Lots 950851, 953089, 953093, 953097, 958645, 953094, 953099, 956966, 956963, 956974, 96972, 959672, 959662, 961103, 962121, 961110, 95494B, 958637, 961106, 953098, 954933, 954934, 954935, 959663, 961111, 954946, 956968, 959670, 961105, 961108X, 961102, 958641, 958644, 959668, 959666, 958634, 956970, 958638, 958640, 962115, 959671, 954942, 961108, 959669, 954947, 956973, 953086, 953088, 950838, 950839, 950846, 950848, 950849, 956969, 956975, 956976, 954939, 956965, 956967, 962123, 962118, 962122, 962125, 954938, 961104, 950852, 959661, 961100, 954944, 958635, 961107, 963642, 954940, 961101, 958639, 953087, 959665, 9533096, 954945, 962117, 962120, 963638, 953091, 961109, 958642, 953095, 953100, 954937, F789125, 953090, 950845, 956977, 953092, 954936, 958643, 956964, 959667, 956971, F796337, 950847, 954943, 948603, F819555, 954950, 961112, 954941, 954932, 958636, 953099X, 954949, 959670X, 959664, 959661X, 962116 and 950844.
 Catalog number PICS-501-NT-MCLELLAN. Lot F793031.
 Catalog number PICS-501-MPIS-NT-PGHC-122396. Lots F832007 and F827711.
 Catalog number PICS-501-MPIS-ON. Lot F801842.
 Catalog number PICS-501-MPIS-WOC. Lots 959674, 951641, 951642, 951644, 954248, 954245, 954246, 958111, 959673, 958112, 948623, 951645, 959676, 954247, 951639, 951643, 958110, 959675, 948617, 954249, 951640, 948622, 929837X, 933160X, 958109, F790509, F788527, F815515, F822749, F834890, F796429, F809673 and F828985.
 Catalog number PICS-501-MPIS-WOC-NT. Lots 957887, 956625, 952439, 952441, 954951, 957889, 952442, 952440, 948625, 960221, 955852, 955851, 960220, 955853, 956626, 957888, 956624, 960220X, F796693, F820611, F840132 and 960222. Catalog number PICS-ST-VINCENT-040593. Lots F828118 and F829634.
 Catalog number PICS-401-MPIS. Lots 946700, 950499, 957890, 957891, 959900, 963332 and 959901.
 Catalog number PICSY-501-MPIS. Lots 950502, 951948, 954955, 951949, 954250, 956978, 956979, 954251, 954956, 950501 and 958646.
 These products are packaged with Clinipad CLINIGUARD, Protective, Dressing, Prep, 1, Prep, Pad-Clinipad, Reorder Code 8133S-B, HK8133S. Lot number 914358 [Contains: Isopropyl, Alcohol, 79%, Butyl, Mono, Ester, Dimethyl, Phthalate].

MANUFACTURER

Cook Inc., Bloomington, Indiana (tray);
 Venetec International, Inc., San Diego, California (stalock anchoring device)

RECALLED BY

Cook, Inc., Bloomington, Indiana, by letter mailed and faxed on March 23, 2000. Firm-initiated recall ongoing.

COMPONENT MANUFACTURER

Clinipad Corporation, Rocky Hill, Connecticut.

DISTRIBUTION

Nationwide and international.

QUANTITY

21,520 Cook kits were distributed.

REASON

Kits/trays contain Clinipad products labeled as sterile for which Clinipad is unable to assure the sterility.

[] None Present
 [] Action Taken _____

NSN 6515 Nonstandard
PRODUCT Osteonics Scorpio Posteriorly Stabilized Total Knee:
a) Catalog Number: 71-5105L; b) Catalog Number: 71-5105R
c) Catalog Number: 71-5107L; d) Catalog Number: 71-5107R
e) Catalog Number: 71-5109L; f) Catalog Number: 71-5109R
g) Catalog Number: 71-5111L; h) Catalog Number: 71-5111R
i) Catalog Number: 71-5113L. Recall #Z-744/752-0.

CODE a) Case Codes: K00A257, K00A87, K00A88, K99W347, K99W348,
K99W349, K99W459, K99W460
b) Case Codes: K00A258, K00A89, K00A90, K99W461
c) Case Codes: K00A91, K00A92, K00A93, K99W462, K99W463,
K99W464, K99W89
d) Case Codes: K00A262, K00A94, K00A95, K00A96, K00A97,
K99S246, K99W465, K99W467, K99W468, K99W469, K99W607
e) Case Codes: K00A100, K00A500, K00A98, K00A99, K99W472,
K99W471, K99W783
f) Case Codes: K00A101, K00A102, K00A103, K00A265, K99W188,
K99W474, K99W475, K99W477, K99W610
g) Case Codes: K00A429, K99W193, K99W749, K99W750, K99W751
h) Case Codes: K99W196, K99W197, K99W753, K99W754
i) Case Code: K99W198.

MANUFACTURE Howmedica Osteonics Corporation, Allendale, New Jersey.
RECALLED BY Manufacturer, by letter dated March 3, 2000. Firm-initiated recall
ongoing.

DISTRIBUTION> Nationwide and international.
QUANTITY 10 units were distributed.

REASON Product labeling has additional line stating "All Polyethylene" below the
product name.

None Present
 Action Taken _____

NSN 6550 Nonstandard
PRODUCT Amplified Mycobacterium Tuberculosis, in-vitro diagnostic test kit:
a) Part No. 301001, Lot Nos. 909399, 911170, 911172, Exp. Date 08/02/00;
Recall Number Z-805/808-0.

INTERNATIONAL KITS: b) Part No. 301001E, Lot Nos. 909400, 909410, 912246, Exp. Date 08/02/00;
c) Part No. 301001F, Lot Nos. 909352, 912294, Exp. Date 08/02/00;
d) Part No. 301002J, Lot Nos. 909135 Exp. Date 02/23/00, 909254 Exp. Date
03/18/00, 910352 Exp. Date 04/11/00;
Part No. 301011J, Lot Nos. 909136 Exp. Date 02/23/00, 909255 Exp. Date
03/18/00, 910353 Exp. Date 04/11/00;

CODE Domestic: a) Lot Nos. 909399, 911170, 911172, Exp. Date 08/02/00;
INTERNATIONAL KITS: b) Lot Nos. 909400, 909410, 912246, Exp. Date
08/02/00; c) Lot Nos. 909352, 912294, Exp. Date 08/02/00; d) Lot Nos.
909135 Exp. Date 02/23/00, 909254 Exp. Date 03/18/00, 910352 Exp. Date
04/11/00 (Part #301002J); Lot Nos. 909136 Exp. Date 02/23/00, 909255 Exp.
Date 03/18/00, 910353 Exp. Date 04/11/00 (Part No. 301011J).

MANUFACTURER Gen-Probe, Inc., San Diego, California.
RECALLED BY Manufacturer, by telephone on February 2, 2000, and by letter on February
7, 2000. Firm-initiated recall ongoing.

DISTRIBUTION Nationwide, Puerto Rico, Switzerland, Canada.
QUANTITY 1,414 kits were distributed.

REASON

The above reagent experienced a reduced shelf life after being reconstituted. The reduced shelf life may result in inadequate amplification of some specimens during a test run. Inadequate amplification may produce false negative results.

None Present

Action Taken _____
