

**FOOD AND DRUG ADMINISTRATION (FDA)
RECALLS/ALERT NOTICES**

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, Capt David Zemkosky, DSN 343-4028)

CLASS I RECALLS: None

CLASS II RECALLS:

6515NS
MDC 17116
PRODUCT **Defibrillators, Automated, External**
HeartStart Rechargeable Lead Acid Battery, used in HeartStart Semi-Automatic External Defibrillators, Model numbers HS 2000, HS 3000 QR, HS 3000ATS, and HS 911. Recall #Z-429-7.
CODE Battery lot numbers 960212 through 960319.
MANUFACTURER Panasonic, Secaucus, New Jersey.
RECALLED BY Laerdal Medical Corporation, Wappingers Falls, New York, by letter dated March 11, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide, Chile, Brazil, Colombia.
QUANTITY 885 batteries were distributed.
REASON The batteries are subject to pre-mature and undetectable depletion of charge, which can result in failure to deliver defibrillation therapy to sudden cardiac arrest patients power-up can lead to failure to defibrillate the patient.

None Present
 Action Taken _____

6515NS
MDC 11234
PRODUCT **Dialyzers, Hemodialysis, Hollow-Fiber**
Baxter Capillary Flow Dialyzer, Model CF 15 5M1709, containing fibers from FNR 981, used with an artificial kidney system for the treatment of patients with renal failure or toxemic conditions. Recall #Z-347-7.
CODE Lot H97A14169.
MANUFACTURER Baxter Healthcare Corporation, Mountain Home, Arizona.
RECALLED BY Manufacturer, by telephone on February 17, 1997. Firm-initiated recall ongoing.
DISTRIBUTION California, New Jersey, Pennsylvania, New Mexico, Illinois, Missouri, Texas, New York.
QUANTITY 1,632 units were distributed.
REASON The blood in the dialyzer clearance values fluctuate from the labeled values for the dialyzer.
 None Present

[] Action Taken _____

6515NS
MDC 17678
PRODUCT

Vital Signs Monitor

Infant Monitor, Model 500EXL, available for hospital and home use to monitor respiration, ECG and heart rate: (a) Catalog number: 0500FAA 120 Volts/ 60 Hz English; (b) Catalog number: 0500FAH 230 Volts/ 50 Hz English; (c) Catalog number: 0500FEH 230 Volts/ 50 Hz German. Recall #Z-419/421-7.

CODE

Serial Numbers:

Cat. No.: 0500FAA:

01008736, 01110442, 01313163, 01615535, 01615537 - 01615544 - 01615546 - 01615553, 03313340 04301233, 0482335, 06414241, 07313642, 08111333, 08212735, 08301216, 0882959, 0882984, 09009743, 09009748, 09009758, 09009779, 0983171, 11313882, 11515405-11515408, 11515410 - 11515429, 11907334, 12213073, 12515449 - 12515458, 12515461, 12515462, 12515464, 12515465, 12515466, 12515468 - 12515472, 12515474 - 12515479, 12515481 - 12515487, 12515491 - 12515498, 13000022, 13000023, 13000025, 13000031, 13000034, 13000036, 13000038 - 13000040, 13000042, 13000044, 13000046-13000048, 13000050, 13000052, 13000076 - 13000115, 13000136-13000225, 13000227 - 13000241, 13000263 - 13000265, 13000321 - 13000341, 13000349 - 13000351, 99000002 - 99000015

Cat. No.: 0500FAH:

12515530, 13000002

Cat. No.: 0500FEH:

13000000, 13000010 - 13000051, 13000061, 13000072 - 13000076, 13000081 - 13000084.

MANUFACTURER
RECALLED BY

Corometrics Medical Systems, Inc., Wallingford, Connecticut.
Manufacturer, by Product Notification letter on March 6, 1997, and by fax.
Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY

Nationwide and international.
327 monitors were distributed.

REASON

The battery operating time has been shown to be less than the 16 hours specified due to an integrated circuit (IC) which was found to draw too much current.

[] None Present

[] Action Taken _____

6515NS
MDC 17678
PRODUCT

Vital Signs Monitor

Passport Monitors with saturated oxygen measurement (SP02) Capability supplied by Nellcor Medical Systems, used to monitor CO2, respiration, temperature, and non-invasive blood pressure. Recall #Z-444/446-7.

CODE

(a) Model No. 0998-00-0095N01 - N04, N41-N44, N61-64, B01-04, B41-B44, B61-B64;

(b) Model No. 0998-00-0126N01 - N04, N41-N44, N61-64, B41-B44, B61-B64;

(c) Model No. 0998-00-0133N42.

Recall #Z-444/446-7.

MANUFACTURER Datascope Corp., Paramus, New Jersey.
RECALLED BY Manufacturer, by letter dated August 2, 1996. Firm-initiated field correction ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 1,046 units were distributed.
REASON Due to a noisy power supply line on the Passport, the Nellcor SP02 module provides low readings of SP02.

None Present

Action Taken _____

6515NS

MDC 17148

PRODUCT

Oximeters, Pulse

Novamatrix Model 520A Oxypleth Pulse Oximeter with software version 2.6, used to provide measurement, display and alert for functional pulsatile oxygen saturation (SP02) and pulse rate. Recall #Z-454-7.

CODE Software Version 2.6.

MANUFACTURER Novamatrix Medical Systems, Inc., Wallingford, Connecticut.

RECALLED BY Manufacturer, by letter on March 3, 1997. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide.

QUANTITY 3,364 units were distributed.

REASON There is a software error associated with the displayed pulse rate alert parameter. Under certain monitoring set-ups, the actual pulse rate alert limits set in the monitor may not be the same as those shown on the display.

None Present

Action Taken _____

CLASS III RECALLS: None

MEDICAL EQUIPMENT SAFETY ALERTS: None

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 20 JUN 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 6505 Nonstandard
PRODUCT Infants' Tylenol Acetaminophen Drops USP, 80 mg/ml, oral solution in 15 ml bottles, product was labeled in French and English.
Recall #D-154-7.
CODE Lot #(L) E362.
MANUFACTURER McNeil La Compagnie De Produits, Aux Consommateurs McNeil, Guelph, Canada.
RECALLED BY Edreiss Trading Co., Inc., Bohemia, New York, by letter on March 25, 1997. Firm-initiated recall ongoing.
DISTRIBUTION New York.
QUANTITY 4,584 bottles were distributed.
REASON Product contains unapproved sweetener, sodium cyclamate.

[] None Present
[] Action Taken _____

NSN 6505 Nonstandard
PRODUCT Gaseous Oxygen USP packed in 415 liter or 628 liter aluminum cylinders. Recall #D-155-7.
CODE All units (lot or serial numbers not used).

MANUFACTURER Air Care, Inc., McRae, Georgia.
RECALLED BY Manufacturer, by telephone on or about January
7, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Georgia.
QUANTITY 32 to 42 cylinders were distributed.
REASON Current good manufacturing practice
deficiencies.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Clindamycin Phosphate Topical Solution 1% in
30 and 60 ml bottles, used in the treatment of
acne vulgaris. Recall #D-160-7.
CODE Lot nos. RP4721, RB5079, RA5014, RA5063,
RF5259, RJ5411, RN5631, RS5827, RB6051,
RD6217, RH6349, RJ6417, RK6521, RL6617,
RN6706.
MANUFACTURER Alpha, U.S. Pharmaceuticals Division,
formerly Barre-National, Inc., Baltimore,
Maryland.
RECALLED BY Manufacturer, by letter dated March 26, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Maryland.
QUANTITY 247,364 units were produced; firm estimates
that 10,541 units remained in commerce 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 Venoglobulin-S 5% Solution Immune Globulin
Intravenous (Human): (a) 50 ml (2.5 grams in
50 ml); (b) 100 ml (5.0 grams in 100 ml); (c)
200 ml (10.0 grams in 200 ml).
Recall #B-560/562-7.
CODE Lot #GL7503A EXP1/16/99.
MANUFACTURER Alpha Therapeutic Corporation, Los Angeles,
California.
RECALLED BY Manufacturer, by letter on March 7, 1997.
firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Thailand.
QUANTITY 2,189 vials were distributed; firm estimated
that on March 17, 1997 1,200 vials remained in
commerce.

REASON Immune Globulin products with a higher than expected rate of adverse reactions (urticaria) from patients were distributed.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Clindamycin Phosphate Topical Solution, USP 1% in 30 ml and 60 ml bottles, under the Copley, Goldline, Major and Qualitest labels.
Recall #D-161-7.

CODE: 30 Ml 60 Ml
Copley 628P30 Exp 5/97 628P31 Exp 5/97
 628D01 Exp 7/97 628P35 Exp 5/97
 628D04 Exp 11/97 628D01 Exp 7/97
 628D05 Exp 1/98 628D04 Exp 11/97
 628D06 Exp 1/98 628D05 Exp 1/98
 628D07 Exp 4/98 628D07 Exp 1/98
Major 628P29 Exp 5/97 628P33 Exp 5/97
 628D06 Exp 1/98 628D01 Exp 7/97
 628D07 Exp 4/98 628D06 Exp 1/98
 628D07 Exp 4/98
Goldline 628P28 Exp 5/97 628P32 Exp 5/97
 628D06 Exp 1/98 628D01 Exp 7/97
 628D06 Exp 1/98
Qualitest 628D06 Exp 1/98 628P34 Exp 5/97
 628D06 Exp 1/98.

MANUFACTURER Copley Pharmaceutical, Inc., Canton, Massachusetts.

RECALLED BY Manufacturer, by letter dated March 26, 1997, followed by fax on April 2, 1997. Firm-initiated recall ongoing.

DISTRIBUTION Florida, California, Alabama.

QUANTITY 22,257 30-ml vials and 87,738 60-ml 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 6505 Nonstandard
PRODUCT Cefaclor Capsules USP, Rx: (a) 250mg Capsules; (b) 500mg Capsules; Cefaclor Oral Suspensions USP, Rx - (c) 125mg/5ml; (d) 187mg/5ml; (e) (250mg/5ml; (f) 375mg/5ml, a semisynthetic cephalosporin antibiotic for oral administration, supplied by Zenith Goldline Pharmaceuticals in 250mg capsules in bottles

of 15's, 100's, 500's, and 1000's, 500mg capsules in bottles of 15's, 100's, and 500's. Oral Suspensions are available in 125mg/5ml and 250mg/5ml bottles, reconstituted to 75ml and 150ml, and also 187mg/5ml and 375mg/5ml bottles, reconstituted to 50ml and 100ml, under the following labels: Zenith Goldline, Major, Mova, Rugby, Schein, h.l. Moore, Warner Chilcott, URL.

Recall #D-162/167-7.

CODE All lots/all sizes.
 MANUFACTURER Zenith Goldline Pharmaceuticals, Inc., Northvale, New Jersey.
 RECALLED BY Manufacturer, by letter February 11, 1997.
 DISTRIBUTION Firm-initiated recall ongoing.
 QUANTITY Nationwide.
 Amount Manufactured/Amount Distributed/Amount Quarantined (bottles)

250MG Capsules:		Amount Distributed.
4760-40	15ps	19,418
4760-60	100ps	562,428
4760-70	500ps	5,031
4760-80	1000ps	3,185
500MG Capsules		
4761-40	15ps	44,086
4761-60	100ps	121,801
4761-70	500ps	3,040
125MG/5ML Suspensions		
4611-22	75ml	160,156
4611-23	150ml	497,442
187MG/5ML Suspensions		
4613-20	50ml	77,165
4613-21	100ml	233,740
250MG/5ml Suspensions		
4610-22	75ml	190,792
4610-23	150ml	798,419
375MG/ml Suspensions		
4612-20	50ml	90,481
4612-21	100ml	436,540.

Dates of Shipments: From 5/95 to 2/97.
 Estimated amount of product remaining on market: Approx. 25%

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 Transfilled Compressed Medical Oxygen USP filled into E size cylinders.

Recall #D-168-7.
CODE All codes, all lots and all fill dates.
MANUFACTURER Respiratory Science Industries, Ltd., Elmont,
New York.
RECALLED BY Manufacturer, by telephone on April 11, 1997,
followed by letter on April 14, 1997. Firm-
initiated recall ongoing.
DISTRIBUTION New York.
QUANTITY 81 cylinders were distributed.
REASON Current good manufacturing practice
deficiencies.

None Present

Action Taken _____

NSN 6505 Nonstandard
PRODUCT Indomethacin Suppositories USP, 50 mg, Rx
nonsteroidal anti-inflammatory agent, under
the Qualitest, Zenith and G&W labels.
Recall #D-169-7.
CODE All lots within expiration date.
MANUFACTURER G & W Laboratories, Inc., South Plainfield,
New Jersey.
RECALLED BY Manufacturer, by letter dated January 30,
1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 20 lots were distributed.
REASON Product lacks stability (potency assay is as
low as 58% of labeled strength).

None Present

Action Taken _____

NSN 6505 Nonstandard
PRODUCT Red Blood Cells. Recall #B-618-7.
CODE Unit numbers: 2226275, 2226277, 2226941,
2226279, 2226942, 2226276, 1812016, 1812489,
1812001, 1812492, 1812003, 1812491, 2227887,
2226955, 1812490, 1812000.
MANUFACTURER Oklahoma Blood Institute, Oklahoma City,
Oklahoma.
RECALLED BY Manufacturer, by fax followed by letter on
January 25, 1996. Firm-initiated recall
ongoing.
DISTRIBUTION Massachusetts, Oklahoma, Texas, California.
QUANTITY 16 units were distributed.
REASON Blood products were prepared from units of
Whole Blood that were stored at room
temperature for more than 12 hours.

None Present

[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT InstaTrak Straight and Frontal Aspirators:
(a) InstaTrak Straight Aspirator, Catalog No.
ENT-100AS-01,
(b) InstaTrak Frontal Aspirator, Catalog No.
ENT-101AF-01. Recall #Z-431/432-7.
CODE Lot Numbers: (a) JAZ6263-1; (b) JAZ626-2.
MANUFACTURER Visualization Technology, Inc., Woburn,
Massachusetts.
RECALLED BY Manufacturer, by telephone on January 13,
1997, and by issuing a Dear Doctor letter on
January 13, 1997. Firm-initiated recall
complete.
DISTRIBUTION Alabama, California, Georgia, Illinois,
Massachusetts, Minnesota, New York, Ohio,
Tennessee.
QUANTITY (a) 36 boxes (10 units per box); (b) 35 boxes
(10 units per box) were distributed.
REASON The aspirating instruments may be stressed
beyond their design limits when used for
prying and dissecting. The excessive side
forces generated by these applications may
degrade the devices' accuracy.

[] None Present
[] Action Taken _____

NSN 6515 Nonstandard
PRODUCT RX5000 Software Operating System 2.01.02 and
lower for Marathon SR and DR Pacemakers.
Recall #Z-433-7.
CODE Serial Numbers 01000 through 06093 (not
inclusive).
MANUFACTURER Sulzer Intermedics, Inc., Angleton, Texas.
RECALLED BY Manufacturer, by letter March 13, 1997. Firm-
initiated field correction ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY Approximately 3,300 units were distributed.
REASON A software condition caused the parameters of
the two pacemakers to become reversed. That
is, the software cannot distinguish Marathon
DR (dual-chamber) from Marathon SR
(single-chamber) USER PRESET values; whichever
values were most recently stored will be
recalled.

[] None Present
[] Action Taken _____

NSN
UPDATE

6515 Nonstandard
Recall Z-064/077-7 reported in the 11/13/96 Enforcement Report contained incorrect identifications of devices listed. The correct identifications are as follows:
Z-064-7 - Angiographic Catheters bearing the catalog product prefix HNBR4.1;
Z-065-7 - Angiographic Catheters bearing the catalog product prefix HNBR5.0;
Z-066-7 - Angiographic Catheters bearing the catalog product prefix HNBR6.0;
Z-067-7 - Angiographic Catheters bearing the catalog product prefix HNBR7.0;
Z-075-7 - D'AGOSTINO ACCESS SET; Reorder # NPAS-100-D'AGOSTINO-A-050393 and NPAS-100-D'AGOSTINO-B-050393.
Recall Z-274/281-7 reported in the 2/26/97 Enforcement Report contained a mistyped catalog number and should read:
Z-279-7 - COOK BRAND ROYAL FLUSH PLUG ANGIOGRAPHIC SET WITH BEACON TIP 4 FR PIGTAIL. SET INCLUDES 1/4.0 FRENCH 70CM PIGTAIL CATHETER WITH 10 SIDEPORTS, 1/.035 IN. 145CM TFE COATED WIRE GUIDE WITH 3MM J, 1/19UT GAUGE NEEDLE. REORDER # HNRS-405-70.PIG-SH-012795; QUICK REORDER # 234728.
In addition, the recall included catheters that were sold individually that were inadvertently omitted from the list. These devices are as followed with their assigned recall numbers:
Z-440-7 - ROYAL FLUSH PLUG ANGIOGRAPHIC CATHETERS WITH BEACON ENHANCED RADIOPAQUE TIPS, CATALOG PREFIX HNR4.0;
Z-441-7 - ROYAL FLUSH PLUG ANGIOGRAPHIC CATHETERS WITH BEACON ENHANCED RADIOPAQUE TIPS, CATALOG PREFIX HNR5.0.

[] None Present
[] Action Taken _____

CLASS III RECALL:

NSN 6505 Nonstandard
PRODUCT Bausch and Lomb Muro 128 5% Ophthalmic
 Ointment (sodium chloride), OTC, in 1/8 ounce
 tubes, for the temporary relief of corneal
 edema. Recall #D-153-7.
CODE Lot #853571.
MANUFACTURER Bausch and Lomb Pharmaceuticals, Inc., Tampa,
 Florida.

RECALLED BY Manufacturer, by letter dated March 24, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 18,240 tubes were distributed.
REASON Labeling mix-up -- some tubes may be
mislabeled as containing erythromycin
ointment; the actual tube contents are Muro
128 and the unit carton label is correct.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Nycomed brand Hypaque (Diatrizoate Sodium)
Oral Powder and Liquid, and Oral Solution,
USP, used as an imaging agent, under the
Nycomed and Sanofi Winthrop labels.
Recall #D-156-7.
CODE All lots within expiration date.
MANUFACTURER Bayer Corporation, Myerstown, Pennsylvania.
RECALLED BY Nycomed, Inc., Princeton, New Jersey, by
letter dated March 4, 1997. Firm-initiated
recall ongoing.
DISTRIBUTION Nationwide and Canada.
QUANTITY 1,231,572 bottles were distributed.
REASON Product lacks stability (free iodide exceeds
upper limit - spec is not more than 0.02% and
the product is as high as 0.05% as early as 24
months.

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Zantac Injection Premixed (Ranitidine HCl), 50
mg/50ml, used in the treatment of ulcers.
Recall #D-157-7.
CODE Lot #20193FJ.
MANUFACTURER Glaxo Wellcome, Inc., Zebulon, North Carolina.
RECALLED BY Manufacturer, by letter sent on January 27,
1997. Firm-initiated recall complete.
DISTRIBUTION Nationwide.
QUANTITY 4,126 cases (24 prefilled flexible bags per
case) were distributed.
REASON Label mix-up (overwrap labeled as "Ciprol I.V.
(Ciprofloxacin)" may have been used on some
otherwise correctly labeled bags containing
Rantidine HCl).

None Present
 Action Taken _____

NSN 6505 Nonstandard
PRODUCT Zaroxolyn Tablets (Metolazone, USP), 2.5 mg,
unit dose, Rx diuretic and anti-hypertensive.
Recall #D-158-7.
CODE Lot #60751 EXP 12/01.
MANUFACTURER Medeva Pharmaceuticals Manufacturing, Inc.,
Rochester, New York.
RECALLED BY Manufacturer, by telephone during the week of
March 31, 1997, and by letter dated April 3,
1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 956 cartons were distributed.
REASON Unit carton label mix-up - 5 mg strength
cartons used in packaging this 2.5 mg lot
(immediate foil packaging and shipping cartons
bear the correct label).

None Present

Action Taken _____

NSN 6505 Nonstandard
PRODUCT Baclofen Tablets, 20 mg, USP, in bottles of
100, Rx muscle relaxant and antispastic.
Recall #D-159-7.
CODE Lot numbers: 24060 EXP 6/1/97 and 26221 EXP
6/1/98.
MANUFACTURER Biocraft Laboratories, Inc., (TEVA
Pharmaceuticals USA), Elmwood Park, New
Jersey.
RECALLED BY TEVA Pharmaceuticals USA, Sellersville,
Pennsylvania, by letter on March 28, 1997.
Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 9,413 bottles of 100 were distributed.
REASON Product lacks stability (fails potency assay
as early as 19 months -- spec is 90-110%LS;
actual is 89%).

None Present

Action Taken _____

NSN 6505 Nonstandard
PRODUCT Elase Ointment (Fibrinolysin &
Desoxyribonuclease Combined (Bovine)
Ointment). Recall #B-636-7.
CODE Lot #52D4 EXP 9/97.
MANUFACTURER Parke-Davis, Sterile Products Division,
Rochester, Michigan.

RECALLED BY Parke-Davis, Division of Warner-Lambert Company, Morris Plains, New Jersey, by letter on May 16, 1996. Firm-initiated recall complete.

DISTRIBUTION Nationwide.

QUANTITY 35,328 tubes were distributed.

REASON Product failed the 15 month 30 degree C stability assay for desoxyribonuclease.

[] None Present
 [] Action Taken _____

NSN 6515 Nonstandard

PRODUCT Micro Jewel Arrhythmia Management Device, Model 7221Cx. Recall #Z-437-7.

CODE MODEL 7221Cx BUILT WITH CONNECTOR MODULE PART NUMBER 149312-004 FROM THE FOLLOWING LOTS:

Lot No.	Serial No.
557723	PFK202624H
571132	PFK200059H
571132	PFK200110H
571513	PFK200260H
571513	PFK200291H
571513	PFK200301H
571513	PFK200304H
571513	PFK200401H
571513	PFK200403H
571513	PFK200444H
Lot No.	Serial No.
571513	PFK200447H
572744	PFK200148R
572744	PFK200195R
572744	PFK200270R
572744	PFK200398R
572744	PFK200399R
572744	PFK200449R
572744	PFK200470R
573320	PFK200556R
573320	PFK201432H
Lot No.	Serial No.
573320	PFK201483H
573320	PFK201690H
573320	PFK201717H
573320	PFK201718H
573320	PFK201720H
573320	PFK201721H
573320	PFK201722H
573320	PFK201724H
573320	PFK201727H
573320	PFK201728H
573320	PFK201735H
573320	PFK201738H
573320	PFK201748H

573320	PFK201749H
573599	PFK200354H
573599	PFK200373R
573599	PFK200426H
573599	PFK200493H
573599	PFK200520H
573599	PFK200626H
573599	PFK201612H
573599	PFK201661H
573599	PFK201701H
574366	PFK200376H
574366	PFK200578H
574366	PFK200602H
574366	PFK200607H
574451	PFK200555H
574451	PFK200601R
574451	PFK200647H
574451	PFK200655H
574451	PFK200701H
574451	PFK200712R
574451	PFK200779H
574564	PFK200650H
574564	PFK200676H
574564	PFK200679R
574564	PFK200680R
574564	PFK200688H
574564	PFK200688R
574564	PFK200715H
574564	PFK200724H
574564	PFK200765H
574650	PFK200086R
Lot No.	Serial No.
574650	PFK200318H
574650	PFK200581R
574650	PFK200706H
574650	PFK200743H
574650	PFK200848H
574650	PFK200874H
574891	PFK200113H
574891	PFK200856H
574891	PFK200922H
574891	PFK200981H
575083	PFK200888H
575143	PFK200979H
575143	PFK200982H
575143	PFK200993H
575143	PFK200996H
575143	PFK201033H
575143	PFK201141H
575143	PFK201151H
575245	PFK200559H
575245	PFK200592H
575245	PFK200617H
575245	PFK201139H
575245	PFK201142H

575245	PFK201142H
575245	PFK201144H
575245	PFK201268H
575245	PFK201268H
575245	PFK201269H
575353	PFK201252H
575353	PFK201253H
575353	PFK201253H
575353	PFK201258H
575482	PFK201230H
575482	PFK201232H
575482	PFK201254H
575537	PFK201181H
575537	PFK201182H
575537	PFK201231H
575537	PFK201289H
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575775	PFK201600H
575776	PFK200499H
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575776	PFK201368H
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575776	PFK201608H
575778	PFK201358H
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575927	PFK201444H
575927	PFK201445H
575927	PFK201452H
575927	PFK201491H
575927	PFK201622H
576266	PFK201832H
576266	PFK201879H
576266	PFK201913H
576266	PFK201934H
576266	PFK201958H
576266	PFK201960H
576266	PFK201981H
576266	PFK202121H
576359	PFK201820H
576359	PFK201837H
576360	PFK201657H
576360	PFK201782H
576360	PFK201806H
576360	PFK201862H
576447	PFK201907H
576447	PFK202016H
576482	PFK201225H
576539	PFK201829H
576539	PFK201895H
576539	PFK202105H
576765	PFK202881H
576765	PRK202823H
576901	PFK202187H

576901	PFK202195H
576901	PFK202222H
576901	PFK202228H
576901	PFK202388H
576901	PFK202469H
576986	PFK202034H
576986	PFK202046H
576986	PFK202055H
576986	PFK202060H
576986	PFK202081H
576986	PFK202083H
Lot No.	Serial No.
576986	PFK202117H
576986	PFK202170H
576986	PFK202214H
576986	PFK202220H
577090	PFK202436H
577413	PFK202181H
577413	PFK202291H
577413	PFK202323H
577413	PFK202335H
577413	PFK202338H
577413	PFK202416H
577413	PFK202420H
577413	PFK202437H
577413	PFK202484H
577413	PFK202506H
577413	PFK202533H
577413	PFK202538H
577413	PFK202562H
577413	PFK202594H
577413	PFK202609H
577413	PFK202634H
577413	PFK202635H
577413	PFK202707H
577413	PFK202721H
577413	PFK202743H
577413	PFK202766H
577413	PFK202822H
577723	PFK202604H
577723	PFK202607H
577723	PFK202611H
577723	PFK202615H
577723	PFK202625H
577723	PFK202628H
577723	PFK202670H
577723	PFK202675H
577723	PFK202681H
577723	PFK202692H
577723	PFK202702H
577723	PFK202724H
577723	PFK202734H
577723	PFK202741H
577723	PFK202744H
577723	PFK202826H

577723 PFK202826H
 Lot No. Serial No.
 577723 PFK202886H
 577846 PFK202495H
 577846 PFK202503H
 577846 PFK202660H
 577846 PFK202683H
 577846 PFK202732H
 577846 PFK202759H
 577846 PFK202884H
 578985 PFK202799H
 578985 PFK202800H
 578985 PFK202801H
 578985 PFK202803H
 578985 PFK202847H
 578985 PFK202848H
 578985 PFK202852H
 578985 PFK202858H
 578985 PFK202863H
 578985 PFK202900H.

MANUFACTURER Medtronic Med Rel, Inc., Humacao, Puerto Rico.
 RECALLED BY Medtronic, Inc., Minneapolis, Minnesota, by
 device retrieval plan dated March 10, 1997.
 Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
 QUANTITY 2,358 units were distributed.
 REASON The device was distributed with
 out-of-specification connector header blocks
 resulting in device failure due to setscrew
 problems.

[] None Present
 [] Action Taken _____

NSN 6515 Nonstandard
 PRODUCT Various size colored "TAMPS" for osteochondral
 Autograft (5mm, 6mm, 7mm, 8mm, 9mm and 10mm),
 Catalog numbers AR-1985-05 through AR-1985-10.
 Recall #Z-442-7.

CODE All codes.
 MANUFACTURER Arthrex, Inc., Naples, Florida.
 RECALLED BY Manufacturer, by letter on February 14, 1997.
 Firm-initiated recall ongoing.

DISTRIBUTION Nationwide.
 QUANTITY 455 units were distributed.
 REASON There is a potential for the pin in the tamps
 to become dislodged and fall out. If the pin
 were to fall out in surgery, it may be hard to
 retrieve because of its small size.

[] None Present
 [] Action Taken _____

NSN 6505 Nonstandard
UPDATE Recall #D-156-7, which appeared in the April 23, 1997 Enforcement Report should have been listed as Nycomed brand Hypaque (Diatrizoate Sodium) Oral Solution. The powder is not included in this recall action.

[] None Present
[] Action Taken _____

NSN 6550 Nonstandard
PRODUCT SickScreen Sickling Hemoglobin Screening Test. Recall #Z-422-7.
CODE Catalog No. 251-050, Lot No. 250A03, Catalog No. 262-375, Lot No. 258A04.
MANUFACTURER Pacific Hemostasis, Huntersville, North Carolina.
RECALLED BY Manufacturer, by telephone beginning November 4, 1996, followed by letter on or about November 6, 1996. Firm-initiated recall complete.
DISTRIBUTION Nationwide and Greece.
QUANTITY 501 kits of lot 250A03 and 208 kits of lot 258A04 were distributed.
REASON Device can produce false negative results with known positive patient samples and positive controls.

[] None Present
[] Action Taken _____

NSN 6550 Nonstandard
PRODUCT Staphylase Test Kit, a slide identification for Staphylococcus aureus. Recall #Z-434-7.
CODE Catalog #DR595A, Lot #102614.
MANUFACTURER Oxoid, Inc. (formerly Unipath), Basingstoke, England.
RECALLED BY Oxoid, Inc., (formerly Unipath), Ogdensburg, New York, by letter issued dated January 1997. Firm-initiated recall complete.
DISTRIBUTION Tennessee.
QUANTITY 1 kit was distributed.
REASON There are stability problems with the sensitized sheep red blood cells used as positive quality controls.

[] None Present
[] Action Taken _____

NSN 6550 Nonstandard
PRODUCT Thrombostat (Thrombin, USP-Bovine Origin).
Recall #B-528-7.
CODE Lot #00556P EXP 2/16/99.
MANUFACTURER Parke-Davis, Sterile Products Division,
Rochester, Michigan.
RECALLED BY Parke-Davis, Division of Warner-Lambert
Company, Morris Plains, New Jersey, by letter
February 27, 1997. Firm-initiated recall
ongoing.
DISTRIBUTION Nationwide.
QUANTITY 5,915 vials were distributed.
REASON Parke-Davis improperly made fill volume
adjustments for potency of the product.

None Present

Action Taken _____

NSN 6550 Nonstandard
PRODUCT Baxter Gammagard & Polygam Solvent/Detergent
Treated Infusion Sets (Immune Globulin
Intravenous(Human):
(a) Baxter's Gammagard S/D 5G
(b) Baxter's Gammagard S/D 10G
(c) Baxter's Polygam S/D 5G
(d) Baxter's Polygam S/D 10G.
Recall #B-579/582-7.
CODE Lot number after 2620E061AA and after
26206056AA.
MANUFACTURER Baxter Healthcare Corporation, Glendale,
California.
RECALLED BY Manufacturer, by letter dated November 15,
1996. Firm-initiated recall complete.
DISTRIBUTION Nationwide and international.
QUANTITY Approximately 232,921 units were distributed.
REASON Baxter's IGIV solvent/detergent infusion sets,
have defective transfer devices which pushes
the stopper into vials of accompanying sterile
water injection producing particulate matter.

None Present

Action Taken _____

NSN 6550 Nonstandard
PRODUCT Coatest APC Resistance Diagnostic Test Kits.
Recall #Z-427-7.
CODE Type -SC Kits, Lot Nos. X3118 and X3235;
Type -C Kits, Lot. No. X3234.
MANUFACTURER Chromogneix AB, Nykoping, Sweden.

RECALLED BY DiaPharma Group, Inc., Franklin, Ohio
 (importer/distributor), by letter on March 19
 and 20, 1997. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide.
QUANTITY 204 kits were distributed.

