

**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, Mr. Dave Baker, DSN 343-7487)

CLASS I RECALLS:

UPDATE: SureStep Consumer Blood Glucose Meters (LifeScan, Milpitas, California), Recall #Z-631-8, which appeared in the July 1, 1998 FDA Enforcement Report and was published in AFMLL 7-98 should read: CODE: All Models, Serials #'s: L6000 XX XXXXX through L7205 XX XXXXX and L7206 GA 00001 through L7206 GA 01128. The complete recall with corrected serial numbers is as follows:

6630NS	
MDC 15102	<u>Glucose Analyzers</u>
PRODUCT	SureStep Blood Glucose Monitoring System (Meter), Catalog No. 010-341(retail; meter shipped as part of a system) intended for use outside the body (in-vitro diagnostic), to quantitatively measure glucose (sugar) levels in whole blood taken during home-care use. Recall #Z-631-8.
CODE	Serial Nos. L6000 XX XXXXX through L7205 XX XXXXX and L7206 GA 00001 through L7206 GA 01128
MANUFACTURER	LifeScan, Inc., Milpitas, California.
RECALLED BY	Manufacturer, by press release on June 4, 1997, and by letters sent beginning on June 17, 1998. Firm-initiated recall complete.
DISTRIBUTION	Nationwide and international.
QUANTITY	727,004 meters were distributed.
REASON	The meters may give an Er 1 (Error 1) message if a patients blood glucose is 500mg/dL or greater.

None Present
 Action Taken _____

CLASS II RECALLS:

6615NS	
MDC 10144	<u>Anesthesia Unit Vaporizers</u>
PRODUCT	Ohmeda Tec 6 Desflurane Vaporizers (Note: Excludes North American Drager (NAD) and Dragerwerk Tec 6 Variant Vaporizers). Potentially affected vaporizers would include:

Model	Part Number
Tec 6 120v-USA	1107-9001-000
Tec 6 120v-Canada	1107-9012-000
Tec 6 120v-France	1107-9003-000
Tec 6 220/240v-England	1107-9002-000
Tec 6 220/240v-Germany	1107-9004-000
Tec 6 220/240v-Italy	1107-9005-000
Tec 6 220/240v-Dutch	1107-9006-000
Tec 6 220/240v-Sweden	1107-9007-000
Tec 6 220/240v-Spain	1107-9008-000
Tec 6 220/240v-Finland	1107-9009-000
Tec 6 220/240v-Norway	1107-9010-000

Tec 6 220/240v-Danish 1107-9011-000
 Tec 6 220/240v-England-Europe 1107-9014-000
 Vaporizers are desflurane anaesthetic vaporizers used on Ohmeda Anesthesia Systems, including: Ohmeda Excel 110, 210, and 210SE; Ohmeda Modulus II and Modulus II Plus; Ohmeda Modulus SE; Ohmeda Modulus CD. Recall #Z-642-8.
 Vaporizers serviced by Datex-Ohmeda from 7/11/97 to 4/14/98. Subject Tec 6 Vaporizers have individual serial numbers which are not sequential.
 Datex-Ohmeda (formerly Ohmeda Medical Systems Division), Madison, Wisconsin.
 Manufacturer, by letter on June 22, 1998. Firm-initiated recall ongoing.
 Nationwide and international.
 6,207 vaporizers were distributed.
 Gas leaks.

None Present
 Action Taken _____

6515NS
 MDC 14360
 PRODUCT

Ventilators, Respirators
 Newport Infant/Adult "Breeze" Ventilator, designed for respiratory support of infants, pediatrics, or adults: a) Model E200D (domestic sales) Ventilator; b) Model E200E (foreign sales) Ventilators. Recall #Z-646/647-8.

CODE The serial numbers of the 61 ventilators under recall are as follows: 9704WD143; 9704WD147; 9709WD312; 9711WE396 through 9711WE415; 9712WE416; 9712WE418; 9712WE421 through 9712WE430; 9712WE432; 9712WE433; 9712WE435 through 9712WE437; 9712WE439 through 9712WE441; 9712WE443; 9712WE444; 9712WE446 through 9712WE449; 9712WE451; 9712WE452; 9712WE454; 9801WE001 through 9801WE003; 9801WE005 through 9801WE007; 9801WE023; 9801WE026; 9802WE032; 9802WE038.

MANUFACTURER Mer-Mar, Inc., Hesperia, California (PC Board); Harris Central Application, Palm Bay, Florida (chip).

RECALLED BY Newport Medical Instruments, Inc., (NMI) Costa Mesa, California, by letter on March 5, 1998. Firm-initiated field correction ongoing.

DISTRIBUTION Nationwide and international.
 QUANTITY 61 ventilators were distributed.

REASON A bad IC (chip) causes inadvertent System Reset, continually during power-up, or randomly during operation, wherein (1) the ventilators cease operation (gas flow ceases and the exhalation valve opens) for about 4 seconds, then restarts at values that were set before the reset (except as follows), (2) the Sigh Function defaults to off, (3) the Nebulizer defaults to off, (4) the Inspiratory Minute Volume Alarm defaults to the 0-50 L. range (an increase by a factor of 10 if originally set in the 1-5 L. range), (5) Apnea Back-up Ventilation will likely commence for foreign units (at 1.5 times the set rate, but with a minimum of 15 breaths/min and a maximum of 100 breaths/min with previously set tidal volumes and pressures), and (6) the low pressure alarm will likely reset, leading to nuisance alarms.

None Present
 Action Taken _____

6665NS
MDC 12660
PRODUCT

Radiation Monitors

Victoreen VeriDose Diodes, designed for use as radiation detection devices encased within a polystyrene material: a) Model 30-472 positive polarity VeriDose diodes; b) Model 30-472-8000 negative polarity VeriDose Diodes. Recall #Z-649/650-8. All serial numbers manufactured since August 1997.

CODE
MANUFACTURER
RECALLED BY
DISTRIBUTION

Victoreen, Inc., Cleveland, Ohio.
Manufacturer, by telephone on May 7, 1998. Firm-initiated recall ongoing. Arizona, Kentucky, New York, Pennsylvania, Florida, Virginia, Maryland, Michigan, Wisconsin, Ohio, Tennessee, Texas, Alabama, Georgia, Mississippi.

QUANTITY
REASON

23 diodes were distributed.
The devices were manufactured with an inappropriate shielding material (build-up cap). The diodes are intended for use at energies of 5 to 11 MV, while the build-up caps are intended for use in diodes for energies of 1 to 4 MV.

None Present
 Action Taken _____

6530NS
MDC 18203
PRODUCT

Lasers, Carbon Dioxide

Model Tru-Pulse CO2 Laser System, used in general surgery. Recall #Z-669-8. Model True-Pulse CO2.

CODE
MANUFACTURER
RECALLED BY

Tissue Medical Lasers, Inc., Albuquerque, New Mexico.
Manufacturer. FDA approved the firm's corrective action plan on July 1, 1998. Firm-initiated field correction ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide and international.
275 units were distributed.
Noncompliance with performance standards for laser products in that the operators manual lacked calibration procedures.

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 **18 September 98** 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	Compressed Oxygen USP, Transfilled in E and M6 size aluminum cylinders. Recall #D-172-8.
CODE	E-size aluminum cylinders with lot # sticker as follows: 04259803-3 units; 01139801-3 units; 01139802-3 units; 01139803-3 units; 01139804-3 units; 01139805-3 units; 01229803-3 units; 01229806-3 units; 01229807-3 units; 01229808-3 units; 01159801-3 units; 01159802-3 units; 01159803-3 units; 01159804-3 units; 01159805-3 units; 01159806-3 units; 01159808-3 units; 01159809-3 units; 01059801-3 units; 01059802-3 units; 01059803-3 units; 01059804-3 units; 01059805-3 units; 01059806-3 units; 01059807-3 units; 12299701-3 units; 12299702-3 units; 12299703-3 units; 12299704-3 units; 10149702-3 units; 10109702-3 units; 10109703-3 units; 10109705-3 units; 10109706-3 units; 10109707-3 units; 10109708-3 units; 10089701-3 units; 10089702-3 units; 10089704-3 units; 10089708-3 units; 10069701-3 units; 10069702-2 units; 10069703-3 units; 10069705-3 units; 10039701-3 units; 10039704-3 units; 10039705-3 units; 10019704-3 units; 10019705-3 units; 10019706-3 units; 09309701-3 units; 09309702-3 units; 09309707-3 units; 09309708-3 units; 09309709-3 units; 09309711-3 units; 09199701-3 units; 09199702-3 units; 09199704-3 units; 09179701-3 units; 09179707-3 units; 09179708-3 units; 09179709-3 units; 08139701-3 units; 08129701-3 units; 08129702-3 units; 08129703-3 units; 08129704-3 units; 08129705-3 units; 08129706-3 units; 08059702-3 units; 08059703-3 units; 08059705-3 units

M6-size aluminum cylinders with lot # sticker as follows: 02279808-3 units; 01229801-3 units; 01229802-3 units; 01229804-3 units; 01229805-3 units; 01159807-3 units; 01029801-3 units; 01029802-3 units; 12299705-3 units; 12299706-3 units; 10109701-3 units; 10109704-2 units; 10109709-3 units; 10089703-1 unit; 10089705-3 units; 10089706-3 units; 10089707-1 unit; 10089709-3 units; 10069704-3 units; 10069706-3 units; 10039702-3 units; 10039703-3 units; 10039706-3 units; 10039707-3 units; 10039708-1 unit; 10019701-3 units; 10019702-3 units; 10019703-3 units; 09309703-3 units; 09309704-3 units; 09309705-3 units; 09309706-3 units; 09309710-3 units; 09309712-3 units; 09199703-3 units; 09179702-3 units; 09179703-3 units; 09179704-3 units; 09179705-3 units; 09179706-3 units; 08139702-3 units; 08139703-3 units; 08059701-3 units; 08059704-3 units

MANUFACTURER

Shiv Respiratory Equipment, Inc., doing business as American Respiratory Equipment, Inc., Latham, New York.

RECALLED BY

Manufacturer, by memorandum dated May 17, 1998. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

New York.
218 E-size cylinders; 125 M6-size cylinders were distributed.
Subpotency.

None Present
 Action Taken _____

NSN
PRODUCT

6505 Nonstandard
Levothroid Tablets (Levothyroxine Sodium Tablets, USP), 50 mcg, packaged in hospital unit dose blister strips of 10 tablets per strip and 10 strips per box, Rx, for use as replacement or substitution therapy for diminished or absent thyroid function. Recall #D-192-8.

CODE
MANUFACTURER
RECALLED BY

Lot #9962 EXP 9/98.
Forest Pharmaceuticals, Inc., Cincinnati, Ohio.
Forest Pharmaceuticals, Inc., subsidiary of Forest Laboratories, Inc., St. Louis, Missouri, by letter dated June 5, 1998. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide.
2,081 boxes (10 tablets x 10 strips) were distributed.
Subpotent at 18 month assay.

None Present
 Action Taken _____

NSN
PRODUCT

6505 Nonstandard
a) Atrovent Nasal Spray .03% (ipratropium bromide), 30 mL;
b) Atrovent Nasal Spray .06% (ipratropium bromide), 15 mL, indicated for the symptomatic relief of rhinorrhea (runny nose) associated with allergic and non-allergic perennial rhinitis in adults and children age 12 years or older. NDC #0597-0081-30; NDC #0597-0086-76.
Recall #D-194/195-8.

CODE

AtroventR Nasal Spray 0.03% AtroventR Nasal Spray 0.06%
LOT # EXP. DATE LOT # EXP. DATE
816011A Jun-98 866009A Jun-98

816014A	Nov-98	866010B	Jul-98
816015A	Nov-98	866012B	Oct-98
816016A	Nov-98	866013A	Nov-98
816017A	Nov-98	867004A	Oct-99
816020A	Dec-98	867006A	Nov-99
816021A	Dec-98	867007A	Nov-99
817001A	Mar-99	867008A	Nov-99
817007A	Oct-99	867009A	Dec-99
817008A	Oct-99	867010A	Dec-99
817009A	Nov-99		
817010A	Nov-99		
817012A	Nov-99		
817013C	Nov-99		
817014A	Nov-99		

MANUFACTURER RECALLED BY Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, Connecticut. Manufacturer, by fax and by letter on June 23, 1998. Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY Nationwide.

REASON a) Approximately 865,000 units; b) Approximately 456,627 units were distributed. Some units found to contain 2,4,-Dichlorobenzoic acid (DCBA) (impurity from fill tubing).

None Present
 Action Taken _____

NSN PRODUCT 6515 Nonstandard

CODE 3M Modular Shoulder System, 14 mm X 125 mm stems, product number 17464; b) 3M Modular Should System, 16 mm X 125 mm stems, product number 17466, a metal stem designed to fit into a surgically-prepared cavity in a humerus bone during shoulder joint replacement surgery. The stems are designed for "press-fit applications", but may also be cemented. Recall #Z-643/644-8

MANUFACTURER RECALLED BY Lot numbers: a) 96 G 398; b) 96 G 348.
 3M Health Care, Rotherham, England.
 3M Health Care, St. Paul, Minnesota, by letter dated June 16, 1998. Firm-initiated recall ongoing.

DISTRIBUTION QUANTITY Nationwide and international.

REASON a) 42 stems; b) 31 stems were distributed. One stem with a 16 mm diameter was in a box labeled as 14 mm diameter.

None Present
 Action Taken _____

NSN PRODUCT 6515 Nonstandard

CODE Medex Injection Adapter, with Male Leur Lock, intended for use in the administration of small volume fluids, using syringes. Recall #Z6458. Catalog #MX492, Lot #27L011175.

MANUFACTURER RECALLED BY Medex, Inc., Dublin, Ohio (packager).
 Medex, Inc., Hillard, Ohio, by letter on June 26, 1998. Firm-initiated recall ongoing.

DISTRIBUTION	Arkansas, Illinois, New Jersey, Pennsylvania, New York, Montana, Connecticut, California, Maryland, Missouri, North Carolina, Tennessee, Texas, Virginia, Iowa, Oregon, Minnesota.
QUANTITY	390 cases (100 units per case) were distributed.
REASON	The sterility of the device cannot be assured due to defective packaging.
	<input type="checkbox"/> None Present
	<input type="checkbox"/> Action Taken _____

NSN	6515 Nonstandard
PRODUCT	Victoreen VeriDose Diodes, designed for use as radiation detection devices encased within a polystyrene material: a) Model 30-472 positive polarity VeriDose diodes; b) Model 30-472-8000 negative polarity VeriDose Diodes. Recall #Z-649/650-8.
CODE	All serial numbers manufactured since August 1997.
MANUFACTURER	Victoreen, Inc., Cleveland, Ohio.
RECALLED BY	Manufacturer, by telephone on May 7, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Arizona, Kentucky, New York, Pennsylvania, Florida, Virginia, Maryland, Michigan, Wisconsin, Ohio, Tennessee, Texas, Alabama, Georgia, Mississippi.
QUANTITY	23 diodes were distributed.
REASON	The devices were manufactured with an inappropriate shielding material (build-up cap). The diodes are intended for use at energies of 5 to 11 MV, while the build-up caps are intended for use in diodes for energies of 1 to 4 MV.
	<input type="checkbox"/> None Present
	<input type="checkbox"/> Action Taken _____

NSN	6515 Nonstandard
PRODUCT	Disposable Manual Resuscitator, Part #DMR2, used to deliver supplemental oxygen. Recall #Z-672-8.
CODE	None. Units shipped between January 28, 1998 and April 22, 1998.
MANUFACTURER	Nellcor Mexico, Tijuana, Mexico.
RECALLED BY	Nellcor Puritan Bennett, Carlsbad, California, by letter on May 22, 1998. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and Italy.
QUANTITY	67,490 units were distributed.
REASON	The duckbill valve can become unseated, allowing rebreathing and/or insufficient inspiratory air pressure; and (2) the pressure relief valve ball can rust, causing it to become inoperative.
	<input type="checkbox"/> None Present
	<input type="checkbox"/> Action Taken _____

NSN
PRODUCT

6515 Nonstandard
Devon Needle Counters, used to assist the medical practitioner in maintaining an accurate count of the number of suture needles used during a surgical procedure: a) Sterile Needle Counter, Individually Packaged, with Reorder Nos. 1105, 1314, 1315, 1330, 1360, 1614, 1615, 1625, 1630, 1635-I, 1660; b) Bulk, Non-sterile Needle Counters, with Reorder Nos. NS-1105, NS-1314, NS-1315, NS-1330, NS-1360, NS-1614, NS-1615, NS-1625, NS-1630, NS-1660; c) Surgi-Start Kits containing Needle Counter, with Reorder Nos. 7519, 7539, 7766, 7815, 7866, K-1615-S, K-1615-S3, K-1615-Z, K-1615-Z3, K-1630-S, K-1660-S, K-1615-S4, K-1614-6PBP, K-1630-3BMM, K-1330-1DOC, K-1630-S3, K-1615-2FAP, K-1615-4SLH, K-1615-2CAC, 7463-COG2, 7416-KCW, 7463-MDW, 7694-SGB3, 7430-BAB, 7463-BVB, 7615-UMD4, 7715-NRA5, 7653-NAS, 7614, 7614-T4, 7735-WII3, 7663-CCL2, 7815-ALA2, 7466-MCW2, 7436-NON, 7466-MCM2, 7514-POW2, 7466-INI2, 7663, 7514-SMR2, 7815-T8, 7415-KCW, 7616-CAC3, 7663-MIM2, 7463-SCN2, 7514-MAF, 7614-KCW, 7416-KCW, 7612-SAB, 7514-NMT, 7661-CAC2. Recall #Z-673/675-8.

CODE

Lot numbers:
71881 72051 72201 72353 72473 72591
71911 72061 72211 72371 72481 72603
71921 72091 72231 72373 72483 72611
71926 72101 72241 72381 72491 72621
71951 72111 72251 72383 72511 72651
71961 72121 72261 72401 72513 72661
71971 72131 72271 72403 72521 72671
71981 72141 72281 72411 72531 72721
71991 72161 72301 72451 72533 72731
72001 72171 72311 72453 72543 72801
72031 72181 72321 72463 72551 72811
72041 72191 72341 72471 72581 72821
72861 72881 72891 72901 72961 72971
73001.

MANUFACTURER
RECALLED BY

Graphic Controls Corporation, Chatsworth, California.
Graphic Controls Corporation, Buffalo, New York, by letter dated June 12, 1998. Firm-initiated recall ongoing.

DISTRIBUTION
QUANTITY
REASON

Nationwide, Canada, France, Spain.
361,864 needle counters were distributed.
The foam insert (strip) has the potential to detach from the plastic needle box.

None Present
 Action Taken _____

NSN
PRODUCT

6515 Nonstandard
GFX Over-The-Wire Coronary Stent System, indicated for use in patients eligible for balloon angioplasty with symptomatic ischemic disease due to discrete de novo lesions in coronary arteries (length 30 mm) with a reference vessel diameter of 3.0 mm to 4.0 mm. Stenting is intended to improve coronary luminal diameter: a) Catalog No. DGF3512; b) Catalog No. DGF3518. Recall #Z-676/677-8.

CODE
MANUFACTURER
RECALLED BY

Lot numbers: a) 8E21E19; b) 8E14E11.
Arterial Vascular Engineering, Inc., (AVE), Santa Rosa, California.
Manufacturer, by telephone on May 28, 1998, followed by letter. Firm-

DISTRIBUTION initiated recall ongoing.
QUANTITY Nationwide.
REASON 170 units were distributed.
The devices are subject to a slow inflation/deflation time of the balloon segment of the coronary stent delivery system.

None Present
 Action Taken _____

NSN 6515 Nonstandard
PRODUCT APR-T Revision Hip Stems, components of the APR Hip System used to replace a diseased or otherwise dysfunctional hip joint: a) APR-T Revision Hip Stem, Left, Catalog No. 7328-01-011; b) APR-T Revision Hip Stem, Right, Catalog No. 7328-02-011. Recall #Z-679/680-8.

CODE All lot numbers.
MANUFACTURER Sulzer Orthopedics, Inc., Austin, Texas.
RECALLED BY Manufacturer, by telephone on June 1, 1998, followed by letter. Firm-initiated recall ongoing.

DISTRIBUTION Arizona, California, Florida, Louisiana, Michigan, New Mexico, Nevada, South Carolina, South Dakota, Tennessee, Texas, Utah, Australia.

QUANTITY 47 units were distributed.
REASON The hip stem may be subject to fracture after being implanted.

None Present
 Action Taken _____

NSN 7610 Nonstandard
PRODUCT Tracheal Intubation Fiberscope Instruction Manual: a) Catalog No. 8080201, LF-P Instruction Manual; b) Catalog No. 8080202, LF-2 Instruction Manual. Recall #Z-667/668-8.

CODE Incorrect Manual Labeling Identification Numbers: Serial numbers of affected units: a) 1700832 1700833 1700840 1810903 1700844 1700851 1700828 1700855 1700827 1700831 1810900 1700841 1700856 1700857 b) 2715299 2715184 2715296 2715277 2815337 2815313 2715179 2815381 2815406 2715281 2815419 2715173 2715170 2715235 2715242 2715258 2715265 2715304 2815420 2815422 2815423 2715260 2715266 2715269 2715270 2715172 2715214 2825457 2815317 2715252 2715233 2715234 2715245 2815325 2815442 2715202 2715232 2815412 2815438 2815371 2815414 2815348 2815353 2815417 2815360 2815355 2715272 2715291 2715186 2815413 2715271 2715221 2815408 2715308 2715294 2715192 2715209 2715286 2825468 2815362 2815370 2715162 2715178 2715185 2815350 2815364 2715241 2815349 2815384 2715158 2715163 2715204 2815345 2715177 2815380 2715227 2815319 2715276 2715279 2815389 2815398 2815396 2815418 2715297 2815339 2715169 2715231 2715191 2815378 2715180 2715287 2715273 2715290 2715152 2815410 2815309 2815344 2715298 2815436 2825326 2815376 2715292 2815328 2815315 2815405 2715217 2715155 2715164 2715278 2815386 2815363 2815428 2715189 2715244 2715239 2815414 2815359

2815335 2815427 2715267 2715284 2715240 2815349 2715167
2715183 2715230 2715237 2715274 2715157 2825454 2815352
2815377 2825466 2715205 2815415 2715254 2715226 2825452
2715302 2715196 2715181 2715176 2815340 2815356 2815327
2715171 2715215 2815387 2815404 2715289 2715301 2715238
2715187 2815416 2815388 2815367 2715282 2715293 2815409
2715280 2815347 2715307 2715211 2815382 2715168 2815383
2815401 2715199 2715198 2715220 2815421 2715300 2715288.

MANUFACTURER

Olympus Optical Company, Ltd., Hinode Plant, Tokyo, Japan and
Olympus Opto-Electronics Company, Ltd., Fufushima-ken, Japan.

RECALLED BY

Olympus American, Inc., Melville, New York (distributor), by letter on
or about June 3, 1998. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide and international.

QUANTITY

a) 27 units; b) 287 units were distributed were distributed.

REASON

The cover pages for the instruction manuals were for the correct
intubation fibroscope, but the rest of the instructions were for the other
one.

None Present

Action Taken _____

CLASS III RECALLS:

NSN

6505 Nonstandard

PRODUCT

a) Q-Tussin Syrup, (Guaifenesin, USP, 100 mg/Dextromethorphan
Hydrobromide, USP 10 mg), in 16 fluid ounce and 1 gallon (128 fluid
ounce) bottles, under the Qualitest label, OTC. NDC 0603-0857-58,
NDC 0603-0857-60; b) Cheratussin DAC Sugar Free Syrup
(Guaifenesin, USP 100mg/Pseudoephedrine HCl, USP 30 mg/Codeine
Phosphate, USP 10 mg) in 16 fluid ounce plastic bottles, a liquid
expectorant/ decongestant/cough suppressant packaged under the
Qualitest Products and Vintage Pharmaceuticals labels; also packaged
under the Goldline label as Guiatuss DAC Syrup. NDC 0603-1078-58
(Qualitest), NDC 0254-9065-58 (Vintage); c) Guiatuss DAC-Sugar
Free Syrup (Guaifenesin, USP, 100mg/Pseudoephedrine HCl, USP 30
mg/Codeine Phosphate, USP 10 mg), in 16 fluid ounce plastic bottles,
packaged under the Goldline label. NDC 0182-1378-40. Recall #D-
183/185-8.

CODE

Lot numbers: a) 004C7A EXP 2/99 and 004C7B EXP 2/99; b) 006A7B
EXP 12/98, 010J7A EXP 8/99, 029B8A EXP 7/99, 006A7A EXP
12/98, 029B8B EXP 7/99, 030B8C EXP 7/99; c) 030B8A EXP 7/99.

MANUFACTURER

Vintage Pharmaceuticals, Inc., Huntsville, Alabama.

RECALLED BY

Manufacturer, by letter May 20, 1998. Firm-initiated recall ongoing.

DISTRIBUTION

Nationwide and Puerto Rico.

QUANTITY

a) 158 128-ounce bottles and 1,488 16-ounce bottles; b) 6,992
bottles (lot 006A7B) 15,608 bottles (Lot 010J7A), 13,780 (Lot
029B8A), 959 bottles (Lot 006A7A), 1,406 bottles (Lot 029B8B),
3,600 bottles (Lot 030B8C) were distributed.

REASON

Inability to support product shelf life through labeled expiration date.

None Present

Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Epinephrine Mist Inhalation Aerosol, USP, Bronchodilator, 15 mL (1/2 ounce), for the temporary relief of shortness of breath, lightness of chest and wheezing due to bronchial asthma, under the following labels: Barre, Longs, Meijer, CVS. NDC 0472-0970-99, NDC 12333-9284-1, NDC 41250-561-56, NDC 50428-583-20. Recall #D-196-8.
 Lot #RJ7627 EXP 11/99.
 CODE Alpharma, Inc., Baltimore, Maryland.
 MANUFACTURER RECALLED BY Manufacturer, by letter dated June 18, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION Nationwide.
 QUANTITY 53,600 units were distributed; firm estimates none remains on the market.
 REASON Failure to meet USP leakage test criteria.
 [] None Present
 [] Action Taken _____

NSN 6505 Nonstandard
 PRODUCT Piroxicam Capsules, USP, Rx, for acute or long-term use in the relief of signs and symptoms of osteoarthritis and rheumatoid arthritis, packaged by Allscripts: a) 10 mg capsules, packaged in bottles of 21 capsules, NDC #54569-3974-0 b) 20 mg capsules, packaged in bottles of: 14 capsules, NDC #54569-3693-0; 10 capsules, NDC #54569-3693-1 7 capsules, NDC #54569-3693-2; 20 capsules, NDC #54569-3693-3 30 capsules, NDC #54569-3693-4; 15 capsules, NDC #54569-3693-5. Recall #D-198/199-8.
 CODE Lot numbers: a) 6323030, 7027038, 7031020, 7035072, 7035102, 7052045, 7097123, 7142140, 7167030, 7174071, 7174093, 7176113, 7188107, 7260077, 7316095, 7323076, 7336137, 7342058 b) 6326092, 7318074, 6317095, 7062139, 6338149, 7316165, 7324091, 6323095, 6311129, 6331073.
 MANUFACTURER RECALLED BY Novopharm Ltd., Scarborough, Ontario, Canada (responsible firm). Allscripts, Inc., Libertyville, Illinois, by letter dated June 8, 1998. Firm-initiated recall ongoing.
 DISTRIBUTION California, Ohio, Washington, New Hampshire, Kansas, Florida, Louisiana, New Mexico, Mississippi, Georgia, Tennessee, Iowa, Idaho, Missouri, Michigan, Indiana, Illinois and South Dakota.
 QUANTITY 552 bottles of 21 - 10 mg capsules, and 283 bottles of 14, 166 bottles of 10, 306 bottles of 7, 55 bottles of 20, 99 bottles of 30 and 84 bottles of 15 - 20 mg. capsules were distributed. The firm estimates that less than 25% of the product remains on the market.
 REASON Lack of blend uniformity assurance.
 [] None Present
 [] Action Taken _____
