FDA DRUG AND DEVICE PRODUCT APPROVALS

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

17-450 02-15-91 (SUPPL)	MONISTAT 7 (CREAM)	RW JOHNSON RARITAN, NJ 08869	MICONAZOLE NITRATE 2% [RX TO OTC SWITCH] (OTC)
18-520 02-15-91 (SUPPL)	MONISTAT 7 (SUPPOSITORY)	RW JOHNSON RARITAN, NJ 08869	MICONAZOLE NITRATE 100MG [RX TO OTC SWITCH] (OTC)
19-964 02-21-91 (5 C)	TERAZOL 3 (CREAM)	RW JOHNSON RARITAN, NJ 08869	TERCONAZOLE 0.8% (ANTIFUNGAL)

NDA NUMBER / APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

NDA NUMBER / APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
19-531 02-08-91	NUTRILIPID 10% (INJECTABLE)	MCGAW IRVINE, CA 92713	SOYBEAN OIL 10% (NUTRIENT REPLENISHER)
19-531 02-08-91	NUTRILIPID 20% (INJECTABLE)	MCGAW IRVINE, CA 92713	SOYBEAN OIL 20% (NUTRIENT REPLENISHER)
20-069 02-19-91	DIANEAL PD-2 ELECTROLYTE CONCENTRATE IN PLASTIC CONTAINER (SOLUTION)	BAXTER ROUND LAKE, IL 60073	CALCIUM CHLORIDE 514MG/100ML MAGNESIUM CHLORIDE 102MG/100ML SODIUM CHLORIDE 10.76GM/100ML SODIUM LACTATE 8.96GM/100ML (PERITONEAL DIALYSATE)
20-089 02-27-91	ZOVIRAX (TABLET)	BURROUGHS WELLC RES TRIANGLE PK, NC 27709	ACYCLOVIR 400MG 800MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE	(DOSAGE FORM)		STRENGTH(S)
	CLASSIFICATION(S)		

APPROVABLE ORIGINAL NDAs

(ANTIVIRAL)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

88-999 DIPYRIDAMOLE LEDERLE DIPYRIDAMOLE
02-05-91 (TABLET) PEARL RIVER, NY 25MG
10965 (PLATELET ADHESION INHIBITOR)

89-000 DIPYRIDAMOLE LEDERLE DIPYRIDAMOLE
02-05-91 (TABLET) PEARL RIVER, NY 50MG
10965 (PLATELET ADHESION INHIBITOR)

89-001 DIPYRIDAMOLE LEDERLE DIPYRIDAMOLE
02-05-91 (TABLET) PEARL RIVER, NY 75MG
10965 (PLATELET ADHESION INHIBITOR)

89-573 A-METHAPRED ABBOTT METHYLPREDNISOLONE
02-22-91 (INJECTABLE) ABBOTT PARK, IL SODIUM SUCCINATE
60064 EQ 40MG BASE/VIAL
(CORTICOSTEROID)

89-574 A-METHAPRED ABBOTT METHYLPREDNISOLONE
02-22-91 (INJECTABLE) ABBOTT PARK, IL SODIUM SUCCINATE
60064 EQ 125MG BASE/VIAL
(CORTICOSTEROID)

89-575 A-METHAPRED ABBOTT METHYLPREDNISOLONE
02-22-91 (INJECTABLE) ABBOTT PARK, IL SODIUM SUCCINATE
60064 EQ 500MG BASE/VIAL
(CORTICOSTEROID)

89-576 A-METHAPRED ABBOTT METHYLPREDNISOLONE
02-22-91 (INJECTABLE) ABBOTT PARK, IL SODIUM SUCCINATE
60064 EQ 1GM BASE/VIAL
(CORTICOSTEROID)

71-405 TRAZODONE HCL MYLAN TRAZODONE HYDROCHLORIDE
02-27-91 (TABLET) MORGANTOWN, WV 50MG
26505 (ANTIDEPRESSANT)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

71-406 TRAZODONE HCL MYLAN TRAZODONE HYDROCHLORIDE
02-27-91 (TABLET) MORGANTOWN, WV 100MG
26505 (ANTIDEPRESSANT)

89-567* ORTHO-EST RW JOHNSON ESTROPIPATE
02-27-91 (TABLET) RARITAN, NJ 0.75MG
08869 (ESTROGEN)

71-618 RITODRINE HCL ABBOTT RITODRINE HYDROCHLORIDE
02-28-91 (INJECTABLE) ABBOTT PARK, IL 10MG/ML
60064 (UTERINE RELAXANT)

71-619 RITODRINE HCL ABBOTT RITODRINE HYDROCHLORIDE
02-28-91 (INJECTABLE) ABBOTT PARK, IL 15MG/ML
60064 (UTERINE RELAXANT)

72-295 MICRODERM JOHNSON AND JOHNSON CHLORHEXIDINE GLUCONATE
02-28-91 (SPONGE) ARLINGTON, TX 4%
76014 (ANTIMICROBIAL)
(OTC)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

* First Time Product Available Generically

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

12-320* RAUZIDE SQUIBB BENDROFLUMETHIAZIDE
02-01-91 (TABLET) NEW BRUNSWICK, NJ 4MG
08903 RAUWOLFIA SERPENTINA
50MG
(REVISED LABELING --
LABELING FORMAT
REVISION PROGRAM)

18-716 TRANDATE GLAXO LABETALOL HYDROCHLORIDE
02-01-91 (TABLET) RES TRIANGLE PK, NC 100MG
27709 200MG
300MG (REVISED LABELING --
CONTRAINDICATIONS; PRECAUTIONS)

19-174 TRANDATE HCT GLAXO HYDROCHLOROTHIAZIDE
02-01-91 (TABLET) RES TRIANGLE PK, NC 25MG
27709 LABETALOL HYDROCHLORIDE
100MG
(REVISED LABELING --
CONTRAINDICATIONS; PRECAUTIONS)

19-174 TRANDATE HCT GLAXO HYDROCHLOROTHIAZIDE
02-01-91 (TABLET) RES TRIANGLE PK, NC 25MG
27709 LABETALOL HYDROCHLORIDE
200MG
(REVISED LABELING --
CONTRAINDICATIONS; PRECAUTIONS)

19-174 TRANDATE HCT GLAXO HYDROCHLOROTHIAZIDE
02-01-91 (TABLET) RES TRIANGLE PK, NC 25MG
27709 LABETALOL HYDROCHLORIDE
300MG
(REVISED LABELING --
CONTRAINDICATIONS; PRECAUTIONS)

19-425 TRANDATE GLAXO LABETALOL HYDROCHLORIDE
02-01-91 (INJECTABLE) RES TRIANGLE PK, NC 5MG/ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		27709	(REVISED LABELING -- CONTRAINDICATIONS; PRECAUTIONS)

* Permitted

18-998	VASOTEC	MS&D	ENALAPRIL MALEATE
02-06-91	(TABLET)	W POINT, PA	2.5MG
		19486	5MG
			10MG
			20MG
			(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-221	VASERETIC	MS&D	ENALAPRIL MALEATE
02-06-91	(TABLET)	W POINT, PA	10MG
		19486	HYDROCHLOROTHIAZIDE
			25MG
			(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)
19-309	VASOTEC	MS&D	ENALAPRILAT
02-06-91	(INJECTABLE)	W POINT, PA	1.25MG/ML
		19486	(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)
19-558	PRINIVIL	MS&D	LISINOPRIL
02-06-91	(TABLET)	W POINT, PA	5MG
		19486	10MG
			20MG
			40MG
			(REVISED LABELING -- WARNINGS; PRECAUTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-778	PRINZIDE 12.5	MS&D	HYDROCHLOROTHIAZIDE
02-06-91	(TABLET)	W POINT, PA	12.5MG
	19486	LISINOPRIL	
		20MG	
		(REVISED LABELING --	
		WARNINGS; PRECAUTIONS;	
		ADVERSE REACTIONS)	

19-778	PRINZIDE 25	MS&D	HYDROCHLOROTHIAZIDE
02-06-91	(TABLET)	W POINT, PA	25MG
	19486	LISINOPRIL	
		20MG	
		(REVISED LABELING --	
		WARNINGS; PRECAUTIONS;	
		ADVERSE REACTIONS)	

18-333	CARAFATE	MARION MERRELL DOW	SUCRALFATE
02-12-91	(TABLET)	KANSAS CITY, MO	1GM
	64114	(REVISED LABELING --	
		ADVERSE REACTIONS)	

17-638	THYPINONE	ABBOTT	PROTIRELIN
02-19-91	(INJECTABLE)	ABBOTT PARK, IL	0.5MG/ML
	60064	(REVISED LABELING --	
		CONTRAINDICATIONS;	
		ADVERSE REACTIONS;	
		DOSAGE AND ADMINISTRATION)	

17-503	COMBIPRES	BOEHRINGER INGELHEIM	CHLORTHALIDONE
02-20-91	(TABLET)	RIDGEFIELD, CT	15MG
	06877	CLONIDINE HYDROCHLORIDE	
		0.1MG	
		(REVISED LABELING --	
		LABELING FORMAT	

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

REVISION PROGRAM)

17-503 COMBIPRES BOEHRINGER INGELHEIM CHLORTHALIDONE
02-20-91 (TABLET) RIDGEFIELD, CT 15MG
06877 CLONIDINE HYDROCHLORIDE
0.2MG
(REVISED LABELING --
LABELING FORMAT
REVISION PROGRAM)

17-503 COMBIPRES BOEHRINGER INGELHEIM CHLORTHALIDONE
02-20-91 (TABLET) RIDGEFIELD, CT 15MG
06877 CLONIDINE HYDROCHLORIDE
0.3MG
(REVISED LABELING --
LABELING FORMAT
REVISION PROGRAM)

18-240 TENORMIN ICI ATENOLOL
02-21-91 (TABLET) WILMINGTON, DE 25MG
19897 50MG
100MG
(REVISED LABELING --
DESCRIPTION; WARNINGS;
PRECAUTIONS;
POTENTIAL ADVERSE EFFECTS;
OVERDOSAGE;
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-643	MEVACOR	MS&D RES LABS	LOVASTATIN
02-21-91	(TABLET)	W POINT, PA	20MG
		19486	40MG
		(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS)	
19-888	ZESTORETIC 20/12.5	IMPERIAL CHEM	HYDROCHLOROTHIAZIDE
02-21-91	(TABLET)	CHESHIRE, ENGLAND	12.5MG
			LISINOPRIL
			20MG
		(REVISED LABELING -- ADVERSE REACTIONS; HOW SUPPLIED)	
19-888	ZESTORETIC 20/25	IMPERIAL CHEM	HYDROCHLOROTHIAZIDE
02-21-91	(TABLET)	CHESHIRE, ENGLAND	25MG
			LISINOPRIL
			20MG
		(REVISED LABELING -- ADVERSE REACTIONS; HOW SUPPLIED)	

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT LABELING CHANGE(S)	ACTIVE INGREDIENTS(S) STRENGTH(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

1130 02-08-91	NONE (INJECTABLE)	READING HOSP MED CTR W READING, PA 19611	PLASMA (TRANSFUSION) (A&B)
1130 02-08-91	NONE (INJECTABLE)	READING HOSP MED CTR W READING, PA 19611	RED BLOOD CELLS (TRANSFUSION) (A&B)

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

1130 02-08-91	NONE (INJECTABLE)	READING HOSP MED CTR W READING, PA 19611	WHOLE BLOOD (TRANSFUSION) (A&B)
1080 02-20-91	NEUPOGEN (INJECTABLE)	AMGEN THOUSAND OAKS, CA 91320	FILGRASTIM FEBRILE NEUTROPENIA ASSOCIATED WITH CHEMOTHERAPY (B)

(A) Establishment License Issued
(B) Product License Issued

DEVICE NUMBER TRADE NAME MANUFACTURER PROPER NAME
APPROVAL DATE (DESCRIPTION)

BIOLOGICAL PRODUCT DEVICE APPROVALS

LICENSE NUMBER TRADE NAME MANUFACTURER PROPER NAME
LICENSE DATE (DOSAGE FORM) (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

THERE ARE NO BIOLOGICAL PRODUCT DEVICE APPROVALS FOR FEBRUARY 1991.

DEVICE NUMBER TRADE NAME MANUFACTURER PROPER NAME
APPROVAL DATE (DESCRIPTION)

BIOLOGICAL PRODUCT DEVICE APPROVALS

LICENSE NUMBER TRADE NAME MANUFACTURER PROPER NAME
LICENSE DATE (DOSAGE FORM) (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

P900037 MODEL U101-1P ISOTECHNICS, INC. APPROVAL FOR MODEL
02-28-91 ULTRAVIOLET- LARGO, FL U101-1P
ABSORBING 34641 ULTRAVIOLET-ABSORBING
POSTERIOR CHAMBER POSTERIOR CHAMBER
INTRAOCULAR LENS INTRAOCULAR LENS (IOL)
AND ALL OTHER IOL MODELS
MANUFACTURED BY DGR, INC

P900053 MODELS A21-A VISION TECHNOLOGIES APPROVAL FOR MODELS A21-A
02-28-91 AND 121-B INTERNATIONAL AND A21-B
ULTRAVIOLET- SAN DIMAS, CA ULTRAVIOLET-ABSORBING
ABSORBING 91773 POSTERIOR CHAMBER
POSTERIOR CHAMBER INTRAOCULAR LENSES
INTRAOCULAR LENSES

APPLICATION NUMBER	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

PMA SUPPLEMENTAL APPROVALS

N17676/S22	BAUSCH & LOMB® (HEFILCON B) OPTIMA™ TORIC SOFT CONTACT LENS	BAUSCH & LOMB OPTICS CENTER ROCHESTER, NY 14692	REVISED LABELING IN THE "INITIAL LENS SELECTION" SECTION OF THE FITTING GUIDE	02-07-91
N18020/S35	LENS PLUS™ SOLUTION (BUFFERED)	ALLERGAN OPTICAL IRVINE, CA 92715-1599	REDUCTION OF THE IRRADIATION STERILIZING DOSE	02-05-91
N5798/S05	OXYCEL OXIDIZED CELLULOSE	DECTON DICKINSON AND COMPANY FRANKLIN LAKES, NJ 07417-1880	MODIFIED STERILIZATION PROCESS	02-08-91
P780013-S05	PDC(POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES	GBF CONTACT LENSES, INC. VIRGINIA BEACH, VA 23452	ALTERNATE DESIGN TO INCLUDE AN ASPHERIC BACK SURFACE AND AN ALTERNATE MANUFACTURING SITE TO GRIND THE ASPHERIC BACK SURFACE	02-26-91
P800022/S16	ZYDERM® COLLAGEN IMPLANT, ZYPLAST® IMPLANT, KERAGEN® IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3334	REVISED PHYSICIAN PACKAGE INSERTS	02-08-91
P800024/S16	BAUSCH & LOMB®	BAUSCH & LOMB	SUBSTITUTING PART OF THE	

APPLICATION NUMBER	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

02-28-91	RENU[R] SALINE SOLUTION	ROCHESTER, NY 14692-0450	SODIUM CHLORIDE CONTAINED IN THE RENU[R] SALINE SOLUTION WITH POTASSIUM CHLORIDE AND REVISING THE LABELING	
P820003/S57 TEMPORARY	MODEL 5342 AND PULSE GENERATORS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MANUFACTURING CHANGES - TEST CONSOLE SOFTWARE	02-06-91 5345
P820040/S29 02-04-91	AOSEPT[R] DISINFECTION-NEUTRALIZATION SOLUTION, LENSEPT[R] DISINFECTION SOLUTION	CIBA VISION CORPORATION ATLANTA, GA 30348	CHANGE OF COLOR OF THE DROPPER TIP OF THE CONTAINERS FROM WHITE TO RED	
P820049/S52 02-21-91	MODEL PC10 POSTERIOR CHAMBER INTRAOCULAR LENS CHANGE IN STERILIZATION CYCLE	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	CHANGE STERILIZATION CYCLE TO 100% ETHYLENE OXIDE CYCLE WITH A NITROGEN PURGE	
P820051/S12 02-15-91	OCU-FLEX (OCUFILCON B) SOFT (HYDROPHILIC) CONTACT LENS	OCU-EASE OPTICAL PRODUCTS, INC. PINOLE, CA 94564	ALTERNATE MANUFACTURING SITE AND PRIVATE LABEL DISTRIBUTOR	
P820063/S48	PARAPERM[R] O_2 (PASIFOCON A) RIGID GAS PERMEABLE	PARAGON OPTICAL MESA, AZ 85204	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	02-05-91

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
	CONTACT LENS (CLEAR AND TINTED)		
P820065/S73 02-04-91	THE BOSTON LENS® II (ITAFOCON A) AND THE BOSTON LENS® IV (ITAFOCON B) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ADDITIONAL CONTACT LENS FINISHING LABORATORY
P830060/S22 02-08-91	VENTAK™ EXTERNAL CARDIOVERTER DEFIBRILLATOR (ECD)	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	REVISED LABELING AND FIRMWARE REVISION
P840006/S06 02-07-91	SYNSOFT® (POLYMACON) BIFOCAL CONTACT LENS	SALVATORI OPHTHALMICS SARASOTA, FL 34234	ALTERNATE DESIGN CONFIGURATION
P850007/S11 02-15-91	PHYSIO/STIM® AND SPINAL/STIM™	AMERICAN MEDICAL ELECTRONICS, INC. DALLAS, TX 75244-2011	CHANGE IN THE LOCATION OF MANUFACTURING FACILITIES
P850020/S03 02-06-91	PROSORBA® COLUMN	IMRE CORPORATION SEATTLE, WA 98109-4933	REVISED LABELING
P850021/S12 02-04-91	HYBRID PERCUTANEOUS TRANSLUMINAL	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA	REVISED LABELING, INCREASE THE WALL THICKNESS OF THE 3.0 MM

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CORONARY ANGIOPLASTY CATHETER/SLINKY™	92711-1150	BALLOON, AND MODIFIY SPECIFICATION FOR WALL THICKNESS OF THE DISTAL OUTER BODY TUBING
P850038/S15 02-05-91	PARAPERM® EW (PASIFOCON C) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P850051/S28 02-06-91	ACTIVITRAX PACING SYSTEM-ROTATED ANTENNA	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	CHANGE TO THE POSITIONING OF THE PACEMAKER ANTENNA
P860003/S18 02-13-91	UVAR® PHOTOPHERESIS SYSTEM	THERAKOS, INC. WEST CHESTER, PA 19380	CHANGE IN MATERIALS FORMULATIONS OF MATERIAL USED TO MANUFACTURE SYSTEM
P860022/S32 02-04-91	THE BOSTON® EQUALENS® (ITAFLUOROFOCON A) CONTACT LENS	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ADDITIONAL CONTACT LENS FINISHING LABORATORY
P860034/S08 02-21-91	MODELS AC-21 AND AC21B ANTERIOR CHAMBER INTRAOCULAR LENSES	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	CHANGE THE STERILIZATION CYCLE TO 100% ETHYLENE OXIDE CYCLE WITH A NITROGEN PURGE
P870015/S09 02-06-91	MEDSTONE 1050 EXTRACORPOREAL SHOCK WAVE LITHOTRIPTER	MEDSTONE INTERNATIONAL, INC. IRVINE, CA 92718	APPROVAL OF "PHYSICIANS REFERENCE GUIDE FOR THE MEDSTONE STS™"

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P870024/S23 02-12-91	FLUOROPERM[R] 92 (PAFLUFOCON A), FLUOROPERM[R] 60 (PAFLUFOCON B), FLUOROPERM[R] 30 (PAFLUFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON OPTICAL INC. MESA, AZ 85204	LABELING CHANGE IN THE JACKET LABEL		
P870024/S24 02-05-91	FLUOROPERM[R] 92 (PAFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE		
P870069/S03 02-22-91	BIOBRANE[R] II	STERLING DRUG, INC. NEW YORK, NY 10016	ALTERNATE TESTING OF DODECYLAMINE BY GAS CHROMATOGRAPHY AND LAL PROCEDURE FOR PYROGEN TESTING		
P870071/S07 02-08-91	LASTAC[R] SYSTEM	GV MEDICAL, INC. MINNEAPOLIS, MN 55447	SIMPLIFICATION OF THE LASTAC[R] BALLOON CATHETER HANDLE		
P880025/S01	AML[R] POROCOAT[R] PROSTHESIS	DEPUY WARSAW, IN 46580	DEVICE DESIGN MODIFICATIONS	02-08-91	ACETABULAR CUP
P880029/S10	BAUSCH & LOMB[R]	BAUSCH & LOMB OPTICS	REVISED LABELING IN THE		

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

02-12-91	FW TORIC (LIDOFILCON A) SOFT CONTACT LENS	CENTER ROCHESTER, NY 14692	"INITIAL LENS SELECTION" SECTION OF THE FITTING GUIDE
P880081/S06 02-21-91	MODELS SI-20NB, SI-20NGB AND SI-22NB ULTRAVIOLET-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	MODELS SI-20NB, SI-20NGB AND SI-22NB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES APPROVAL
P880081/S09 02-21-91	MODELS SI-18B AND SI-18NB ULTRAVIOLET-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	CHANGE THE STERILIZATION CYCLE TO 100% ETHYLENE OXIDE CYCLE WITH A NITROGEN PURGE
P880086/S07 02-13-91	SYNCHRONY^{R} II AND SOLUS^{TM} PACING SYSTEMS-MODELS 2023M/S AND 2003M/S	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	SOLUS^{TM} MODEL 2003M/S AND THE SYNCHRONY^{R} II MODEL 2023M/S APPROVAL
P890043/S08 02-21-91	SIMPSON CORONARY ATHEROCATH^{R}	DEVICES FOR VASCULAR INTERVENTION REDWOOD CITY, CA 94063	REVISED LABELING
P890046/S07 02-12-91	0-> PERM F60^{R} (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	IDEAL OPTICS, INC. ATLANTA, GA 30339	ADDITIONAL CONTACT LENS FINISHING LABORATORIES

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

140-578	SOLU-TET 324	CHICKENS	VETRI TECH	TETRACYCLINE
02-26-91	(POWDER)		MONTVALE, NJ	HYDROCHLORIDE
			07645	324GM/LB

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR FEBRUARY 1991.

FDA DRUG AND DEVICE PRODUCT APPROVALS

Center for Drug Evaluation and Research
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Mary Jo Robinson (301) 427-1186

Center for Biologics Evaluation and Research
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This report is compiled by the Division of Drug Information Resources, OM, CDER. It is available by subscription from the National Technical Information Service, Springfield, VA 22161.

Volume 14 (3)
March 1991

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

19-152 03-06-91 (SUPPL)	ISOPTIN SR (TABLET, EXTENDED RELEASE)	KNOLL WHIPPANY, NJ 07981	VERAPAMIL HYDROCHLORIDE 120MG (NEW STRENGTH)
17-920 03-07-91 (SUPPL)	TAGAMET (TABLET)	SKF PHILADELPHIA, PA 19101	CIMETIDINE 200MG 300MG 400MG 800MG (NEW INDICATION -- EROSIVE GASTROESOPHAGEAL REFLUX DISEASE)
19-946 03-07-91 (1 C)	NUROMAX (INJECTABLE) 27709	BURROUGHS WELLC RES TRIANGLE PK, NC	DOXACURIUM CHLORIDE EQ 1MG BASE/ML (SKELETAL MUSCLE RELAXANT) [ADJUNCT TO GENERAL ANESTHESIA]
19-643 03-28-91 (SUPPL)	MEVACOR (TABLET) 19486	MS&D W POINT, PA	LOVASTATIN 10MG (NEW STRENGTH)
20-037	VOLTAREN	CIBA GEIGY	DICLOFENAC SODIUM

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
(CLASSIFICATION) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

03-28-91 (SOLUTION/DROPS) SUMMIT, NJ 0.1%
(3 B) 07901 (NONSTEROIDAL ANTI-INFLAMMATORY)

17-808 MIACALCIN SANDOZ CALCITONIN, SALMON
03-29-91 (INJECTABLE) E HANOVER, NJ 200IU/ML
(SUPPL) 07936 (NEW STRENGTH

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

19-981 ULTRATAG MALLINCKRODT TECHNETIUM TC-99M LABELED
03-01-91 (INJECTABLE) ST LOUIS, MO RED BLOOD CELL KIT
63134 (RADIOACTIVE DIAGNOSTIC)

20-048 DEXTROSE 50% BAXTER DEXTROSE
03-18-91 IN PLASTIC CONTAINER ROUND LAKE, IL 50GM/100ML
(INJECTABLE) 60073 (PERITONEAL DIALYSATE)

20-018 METHASITE INSITE VISION FLUOROMETHOLONE
03-19-91 (SUSPENSION/DROPS) ALAMEDA, CA 0.1%
94501 (CORTICOSTEROID)

20-101 PROZAC LILLY FLUOXETINE HYDROCHLORIDE
03-21-91 (SOLUTION) INDIANAPOLIS, IN 20MG BASE/5ML
46285 (ANTIDEPRESSANT)

19-433 HYTRETIC ABBOTT METHYCLOTHIAZIDE
03-28-91 (TABLET) ABBOTT PARK, IL 5MG
60064 TERAZOSIN HYDROCHLORIDE
EQ 1MG BASE
(ANTIHYPERTENSIVE)

19-433 HYTRETIC ABBOTT METHYCLOTHIAZIDE
03-28-91 (TABLET) ABBOTT PARK, IL 5MG

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

60064 TERAZOSIN HYDROCHLORIDE
EQ 2MG BASE
(ANTIHYPERTENSIVE)

19-433 HYTRETIC ABBOTT METHYCLOTHIAZIDE
03-28-91 (TABLET) ABBOTT PARK, IL 5MG
60064 TERAZOSIN HYDROCHLORIDE
EQ 5MG BASE
(ANTIHYPERTENSIVE)

20-000 DEXTROSE 5% IN MCGAW CALCIUM CHLORIDE
03-28-91 RINGER'S IRVINE, CA 33MG/100ML
IN PLASTIC CONTAINER 92713 DEXTROSE
(INJECTABLE) 5GM/100ML
POTASSIUM CHLORIDE
30MG/100ML
SODIUM CHLORIDE
860MG/100ML
(FLUID AND ELECTROLYTE
REPLENISHER)

50-657 CYCLOPS FAULDING PHARM MINOCYCLINE HYDROCHLORIDE
03-28-91 (CAPSULE) SALISBURY, S AUSTRALIA EQ 50MG BASE
EQ 100MG BASE (ANTIBIOTIC, TETRACYCLINE)

20-002 RINGER'S MCGAW CALCIUM CHLORIDE
03-29-91 IN PLASTIC CONTAINER IRVINE, CA 33MG/100ML
(INJECTABLE) 92713 POTASSIUM CHLORIDE
30MG/100ML
SODIUM CHLORIDE
860MG/100ML
(FLUID AND ELECTROLYTE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE	(DOSAGE FORM)		STRENGTH(S)
	CLASSIFICATION(S)		

APPROVABLE ORIGINAL NDAs

REPLENISHER)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

72-710 SULINDAC WARNER CHILCOTT SULINDAC
03-25-91 (TABLET) MORRIS PLAINS, NJ 150MG
07950 (NONSTEROIDAL ANTI-INFLAMMATORY)

72-711 SULINDAC WARNER CHILCOTT SULINDAC
03-25-91 (TABLET) MORRIS PLAINS, NJ 200MG
07950 (NONSTEROIDAL ANTI-INFLAMMATORY)

63-002 ANCEF BAXTER CEFAZOLIN SODIUM
03-28-91 IN PLASTIC CONTAINER ROUND LAKE, IL EQ 10MG BASE/ML
(INJECTABLE) 60073 EQ 20MG BASE/ML
(ANTIBIOTIC, CEPHEM)

72-553 LORAZEPAM MUTUAL PHARM LORAZEPAM
03-29-91 (TABLET) PHILADELPHIA, PA 0.5MG
19124 (ANXIOLYTIC)

72-554 LORAZEPAM MUTUAL PHARM LORAZEPAM
03-29-91 (TABLET) PHILADELPHIA, PA 1MG
19124 (ANXIOLYTIC)

72-555 LORAZEPAM MUTUAL PHARM LORAZEPAM
03-29-91 (TABLET) PHILADELPHIA, PA 2MG
19124 (ANXIOLYTIC)

72-985 DOXEPIN HCL ROYCE DOXEPIN HYDROCHLORIDE
03-29-91 (CAPSULE) MIAMI, FL EQ 10MG BASE
33014 (ANTIDEPRESSANT)

72-986 DOXEPIN HCL ROYCE DOXEPIN HYDROCHLORIDE
03-29-91 (CAPSULE) MIAMI, FL EQ 25MG BASE
33014 (ANTIDEPRESSANT)

72-987 DOXEPIN HCL ROYCE DOXEPIN HYDROCHLORIDE
03-29-91 (CAPSULE) MIAMI, FL EQ 50MG BASE
33014 (ANTIDEPRESSANT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	APPROVAL DATE	(DOSAGE FORM)	STRENGTH(S)	LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs							
18-225	BUMEX	ROCHE	BUMETANIDE	03-01-91	(TABLET)	NUTLEY, NJ 07110	0.5MG 1MG 2MG (REVISED LABELING -- WARNINGS)
18-226	BUMEX	ROCHE	BUMETANIDE	03-01-91	(INJECTABLE)	NUTLEY, NJ 07110	0.25MG/ML (REVISED LABELING -- WARNINGS)
19-152	ISOPTIN SR	KNOLL	VERAPAMIL HYDROCHLORIDE	03-06-91	(TABLET, EXTENDED RELEASE)	WHIPPANY, NJ 07981	120MG 180MG 240MG (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
17-920	TAGAMET	SKF	CIMETIDINE	03-07-91	(TABLET)	PHILADELPHIA, PA 19101	200MG 300MG 400MG 800MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
17-924	TAGAMET	SKF	CIMETIDINE HYDROCHLORIDE	03-07-91	(SOLUTION)	PHILADELPHIA, PA 19101	EQ 300MG BASE/5ML (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-939	TAGAMET	SKF	CIMETIDINE HYDROCHLORIDE
03-07-91	(INJECTABLE)	PHILADELPHIA, PA	EQ 300MG BASE/2ML
		19101	(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			DOSAGE AND ADMINISTRATION)
18-662	ACCUTANE	ROCHE	ISOTRETINOIN
03-07-91	(CAPSULE)	NUTLEY, NJ	10MG
		07110	20MG
			40MG
			(REVISED LABELING --
			PATIENT INFORMATION BROCHURE)
19-434	TAGAMET HCL	SKF	CIMETIDINE HYDROCHLORIDE
03-07-91	IN SODIUM	PHILADELPHIA, PA	EQ 6MG BASE/ML
	CHLORIDE 0.9%	19101	(REVISED LABELING --
	(INJECTABLE)		CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			DOSAGE AND ADMINISTRATION)
15-874	ALUPENT	BOEHRINGER INGELHEIM	METAPROTERENOL SULFATE
03-11-91	(TABLET)	RIDGEFIELD, CT	10MG
		06877	20MG
			(REVISED LABELING --
			DESCRIPTION; HOW SUPPLIED)
50-585	ROCEPHIN	ROCHE	CEFTRIAXONE SODIUM
03-11-91	(INJECTABLE)	NUTLEY, NJ	EQ 250MG BASE/VIAL
		07110	EQ 500MG BASE/VIAL
			EQ 1GM BASE/VIAL
			EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(REVISED LABELING --
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

16-909	LIDEX	SYNTEX	FLUOCINONIDE
03-12-91	(OINTMENT)	PALO ALTO, CA	0.05%
	94304	(REVISED LABELING -- PRECAUTIONS)	

17-373	LIDEX	SYNTEX	FLUOCINONIDE
03-12-91	(GEL)	PALO ALTO, CA	0.05%
	94304	(REVISED LABELING -- PRECAUTIONS)	

18-013	PAMELOR	SANDOZ	NORTRIPTYLINE HYDROCHLORIDE
03-13-91	(CAPSULE)	E HANOVER, NJ	EQ 10MG BASE
	07936	EQ 25MG BASE	
		EQ 50MG BASE	
		EQ 75MG BASE	
		(REVISED LABELING -- HOW SUPPLIED)	

50-550	MOXAM	LILLY	MOXALACTAM DISODIUM
03-14-91	(INJECTABLE)	INDIANAPOLIS, IN	EQ 250MG BASE/VIAL
	46285	EQ 500MG BASE/VIAL	
		EQ 1GM BASE/VIAL	EQ 2GM BASE/VIAL
		EQ 10GM BASE/VIAL	
		(REVISED LABELING -- ADVERSE REACTIONS)	

18-533	NIZORAL	JANSSEN	KETOCONAZOLE
03-15-91	(TABLET)	PISCATAWAY, NJ	200MG
	08854	(REVISED LABELING -- PRECAUTIONS)	

18-986	PRALIDOXIME CHLORIDE	SURVIVAL TECH	PRALIDOXIME CHLORIDE
03-18-91	(INJECTABLE)	BETHESDA, MD	300MG/ML

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20814 (REVISED LABELING --
DESCRIPTION; PRECAUTIONS;
HOW SUPPLIED)

17-577 DITROPAN MARION MERRELL DOW OXYBUTYNIN CHLORIDE
03-19-91 (TABLET) KANSAS CITY, MO 5MG
64137 (REVISED LABELING --
CONTRAINDICATIONS)
18-211 DITROPAN MARION MERRELL DOW OXYBUTYNIN CHLORIDE
03-19-91 (SYRUP) KANSAS CITY, MO 5MG/5ML
64137 (REVISED LABELING --
CONTRAINDICATIONS)

06-488 XYLOCAINE ASTRA LIDOCAINE HYDROCHLORIDE
03-21-91 (INJECTABLE) WESTBOROUGH, MA 2%
01581 (REVISED LABELING --
DESCRIPTION;
DOSAGE AND ADMINISTRATION)
06-488 XYLOCAINE ASTRA EPINEPHRINE
03-21-91 W/ EPINEPHRINE WESTBOROUGH, MA 0.01MG/ML
(INJECTABLE) 01581 LIDOCAINE HYDROCHLORIDE
1%
(REVISED LABELING --
DESCRIPTION;
DOSAGE AND ADMINISTRATION)

06-488 XYLOCAINE ASTRA EPINEPHRINE
03-21-91 W/ EPINEPHRINE WESTBOROUGH, MA 0.01MG/ML
(INJECTABLE) 01581 LIDOCAINE HYDROCHLORIDE
2%
(REVISED LABELING --
DESCRIPTION;
DOSAGE AND ADMINISTRATION)

06-488 XYLOCAINE ASTRA LIDOCAINE HYDROCHLORIDE
03-21-91 (INJECTABLE) WESTBOROUGH, MA 0.5%

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

01581 1%
1.5%
(REVISED LABELING --
DESCRIPTION;
DOSAGE AND ADMINISTRATION)

06-488 XYLOCAINE ASTRA EPINEPHRINE
03-21-91 W/ EPINEPHRINE WESTBOROUGH, MA 0.005MG/ML
(INJECTABLE) 01581 LIDOCAINE HYDROCHLORIDE
0.5%
(REVISED LABELING --
DESCRIPTION;
DOSAGE AND ADMINISTRATION)

06-488 XYLOCAINE ASTRA EPINEPHRINE
03-21-91 W/ EPINEPHRINE WESTBOROUGH, MA 0.005MG/ML
(INJECTABLE) 01581 LIDOCAINE HYDROCHLORIDE
1.5%
(REVISED LABELING --
DESCRIPTION;
DOSAGE AND ADMINISTRATION)

06-488 XYLOCAINE ASTRA EPINEPHRINE
03-21-91 W/ EPINEPHRINE WESTBOROUGH, MA 0.005MG/ML
(INJECTABLE) 01581 LIDOCAINE HYDROCHLORIDE
1%
(REVISED LABELING --
DESCRIPTION;
DOSAGE AND ADMINISTRATION)

06-488 XYLOCAINE ASTRA EPINEPHRINE
03-21-91 W/ EPHINEPHRINE WESTBOROUGH, MA 0.005MG/ML
(INJECTABLE) 01581 LIDOCAINE HYDROCHLORIDE
2%

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)	
		LABELING CHANGE(S)		

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(REVISED LABELING -- DESCRIPTION; DOSAGE AND ADMINISTRATION)	
18-343	CAPOTEN	BRISTOL MYERS SQUIBB	CAPTOPRIL	
03-21-91	(TABLET)	PRINCETON, NJ	12.5MG	
		08543	25MG	
			50MG	
			100MG	(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)
18-709	CAPOZIDE 25/15	SQUIBB	CAPTOPRIL	
03-21-91	(TABLET)	NEW BRUNSWICK, NJ	25MG	
		08903	HYDROCHLOROTHIAZIDE	
			15MG	
			(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)	
18-709	CAPOZIDE 25/25	SQUIBB	CAPTOPRIL	
03-21-91	(TABLET)	NEW BRUNSWICK, NJ	25MG	
		08903	HYDROCHLOROTHIAZIDE	
			25MG	
			(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)	
18-709	CAPOZIDE 50/15	SQUIBB	CAPTOPRIL	
03-21-91	(TABLET)	NEW BRUNSWICK, NJ	50MG	
		08903	HYDROCHLOROTHIAZIDE	
			15MG	
			(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)	

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-709 CAPOZIDE 50/25 SQUIBB CAPTOPRIL
03-21-91 (TABLET) NEW BRUNSWICK, NJ 50MG
08903 HYDROCHLOROTHIAZIDE
25MG
(REVISED LABELING --
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS; OVERDOSAGE)

17-628 TOLECTIN RW JOHNSON TOLMETIN SODIUM
03-25-91 (TABLET) SPRING HOUSE, PA EQ 200MG BASE
19477 EQ 600MG BASE
(REVISED LABELING --
ADVERSE REACTIONS)

18-084 TOLECTIN DS RW JOHNSON TOLMETIN SODIUM
03-25-91 (CAPSULE) SPRING HOUSE, PA EQ 400MG BASE
19477 (REVISED LABELING --
ADVERSE REACTIONS)

12-836 PERSANTINE BOEHRINGER INGELHEIM DIPYRIDAMOLE
03-26-91 (TABLET) RIDGEFIELD, CT 25MG
06877 50MG
75MG
(REVISED LABELING --
DESCRIPTION; ADVERSE REACTIONS)

18-405 AYGESTIN WYETH AYERST NORETHINDRONE ACETATE
03-27-91 (TABLET) PHILADELPHIA, PA 5MG
19101 (REVISED LABELING --
WARNINGS; PRECAUTIONS; PATIENT PACKAGE INSERT;
PHYSICIAN REFERENCES;
INFORMATION FOR PATIENT)

19-558 PRINIVIL MS&D LISINOPRIL

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

03-28-91 (TABLET) W POINT, PA 5MG
19486 10MG
20MG
40MG
(REVISED LABELING --
ADVERSE REACTIONS)

19-643 MEVACOR MS&D LOVASTATIN
03-28-91 (TABLET) W POINT, PA 10MG
19486 20MG
40MG
(REVISED LABELING --
DESCRIPTION;
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED)

19-778 PRINZIDE 12.5 MS&D HYDROCHLOROTHIAZIDE
03-28-91 (TABLET) W POINT, PA 12.5MG
19486 LISINOPRIL
20MG
(REVISED LABELING --
ADVERSE REACTIONS)

19-778 PRINZIDE 25 MS&D HYDROCHLOROTHIAZIDE
03-28-91 (TABLET) W POINT, PA 25MG
19486 LISINOPRIL
20MG
(REVISED LABELING --
ADVERSE REACTIONS)

19-886 SYNAREL SYNTEX NAFARELIN ACETATE
03-28-91 (SPRAY, METERED) PALO ALTO, CA EQ 2MG BASE/ML
94304 (REVISED LABELING --
PRECAUTIONS)

17-808 MIACALCIN SANDOZ CALCITONIN, SALMON

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

03-29-91	(INJECTABLE)	E HANOVER, NJ	200 IU/ML
	07936	(REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)	

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER	PROPER NAME (DESCRIPTION)
BIOLOGICAL PRODUCT LICENSES ISSUED			
239 03-01-91	NONE (INJECTABLE)	HOUCHIN COMM BLOOD BANK BAKERSFIELD, CA 93301	RED BLOOD CELLS (TRANSFUSION) (B)
1131 03-04-91	NONE (INJECTABLE)	PERSONAL BLOOD STORAGE OF MEMPHIS MEMPHIS, TN 38118	RED BLOOD CELLS (TRANSFUSION) (A&B)
1131 03-04-91	NONE (INJECTABLE)	PERSONAL BLOOD STORAGE OF MEMPHIS MEMPHIS, TN 38118	WHOLE BLOOD (TRANSFUSION) (A&B)
1132 03-05-91	LEUKINE (INJECTABLE)	IMMUNEX SEATTLE, WA 98101	SARGRAMOSTIM * (ACCELERATION OF MYELOID RECOVERY IN PATIENTS WITH NON- HODGKIN'S LYMPHOMA, HODGKIN'S DISEASE, & ACUTE LYMPHOBLASTIC LEUKEMIA UNDERGOING AUTOLOGOUS BONE MARROW TRANSPLANTATION) (A&B)
0043 03-19-91	CORZYME (IN VITRO)	ABBOTT LABS N CHICAGO, IL 60064	HEPATITIS B VIRUS CORE ANTIGEN (RECOMBINANT)* [DETECTION OF TOTAL (ANTI-HBC) FOR USE IN SCREENING BLOOD PRODUCTS INTENDED FOR TRANSFUSION] (B)

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

(A) Establishment License Issued
(B) Product License Issued
* New Product Manufactured Under License

0989 03-19-91	EIT-AB-COREK AB-COREK AB-COREK J (IN-VITRO)	SORIN BIOMEDICA SPA SALUGGIA, ITALY	HEPATITIS B VIRUS CORE ANTIGEN (RECOMBINANT)* [DETECTION OF TOTAL (ANTI-HBC) FOR USE IN SCREENING BLOOD PRODUCTS INTENDED FOR TRANSFUSION] (B)
1133 03-20-91	EPITOPE HIV-1 WESTERN BLOT (IN-VITRO)	EPITOPE BEAVERTON, OR 97005	HIV-1 (WESTERN BLOT) (DETECTION OF ANTIBODIES TO INDIVIDUAL PORTIONS) (A&B)
0605 03-26-91	NONE (INJECTABLE)	BIO LAB BIRMINGHAM, AL 35255	WHOLE BLOOD (TRANSFUSION) (B)
1103 03-29-91	ANTICORE (IN-VITRO)	ORGANON TEKINKA B V BOXTEL THE NETHERLANDS 5281 RM	HEPATITIS B VIRUS (CORE ANTIGEN (RECOMBINANT)* [DETECTION OF TOTAL (ANTI-HBC) FOR USE IN SCREENING BLOOD PRODUCTS INTENDED FOR TRANSFUSION] (B)
1106 03-29-91	ANTICORE (IN-VITRO)	CHIRON CORP EMERYVILLE, CA	HEPATITIS B VIRUS CORE ANTIGEN (FOR

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT LICENSES ISSUED

	94608	FURTHER MANUFACTURING USE)* (FURTHER MANUFACTURING) (B)

(A) Establishment License Issued
(B) Product License Issued
* New Product Manufactured Under License

LICENSE NUMBER TRADE NAME MANUFACTURER PROPER NAME
LICENSE DATE (DOSAGE FORM) (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

BK900011 GENETIC SYSTEMS GENETIC SYS GENERAL LABORATORY
03-15-91 BLOOD VIRUS SEATTLE, WA SOFTWARE
SOFTWARE 98112 (C)

BP900002 IMX CORE-M ASSAY ABBOTT LABS HEPATITIS B CORE
03-20-91 N CHICAGO, IL (A)
60064

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT DEVICE APPROVALS

(A) Approved
(C) Substantially Equivalent

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

P890057 03-29-91	3100 HIGH FREQUENCY OSCILLATORY VENTILATOR (HFOV)	SENSORMEDICS CORPORATION YORBA LINDA, CA 92687	HIGH FREQUENCY OSCILLATORY VENTILATOR
P890064 03-11-91	VIRATYPE[R] HUMAN PAPILLOMAVIRUS DNA TYPING KIT	DIGENE DIAGNOSTICS, INC. GAITHERSBURG, MD 20877	VIRATYPE[R] HUMAN PAPILLOMAVIRUS DNA TYPING KIT
P900010 03-29-91	ORCOLON[R]	OPTICAL RADIATION CORPORATION AZUSA, CA 91702	ORCOLON[R] AS A SURGICAL AID IN ANTERIOR SEGMENT SURGERY INCLUDING CATARACT EXTRACTION AND INTRAOCULAR LENS IMPLANTATION

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

N17003/S02 03-07-91	SURGICAL SIMPLEX® P BONE CEMENT	HOWMEDICA RUTHERFORD, NJ 07070	CHANGE IN LOCATION OF MANUFACTURING FACILITY FOR THE MONOMER COMPONENT OF THE BONE CEMENT TO LIMERICH, REPUBLIC OF IRELAND
N17004/S02 03-07-91	SURGICAL SIMPLEX® P RADIOPAQUE BONE CEMENT	HOWMEDICA RUTHERFORD, NJ 07070	CHANGE IN LOCATION OF MANUFACTURING FACILITY FOR THE MONOMER COMPONENT OF THE BONE CEMENT TO LIMERICH, REPUBLIC OF IRELAND
N18020/S34 03-06-91	LENS PLUS® REWETTING DROPS	ALLERGAN OPTICAL IRVINE, CA 92715-1599	ALTERNATE MANUFACTURING SITE
N18466/S11 03-07-91	CMW™ RADIOPAQUE BONE CEMENT, HALF PACK	DENTSPLY INTERNATIONAL YORK, PA 17405-0872	APPROVAL TO MARKET CMW™-3 RADIOPAQUE BONE CEMENT FOR USE IN A HALF/SIZE PACKAGE
P790008/S05 03-29-91	ZIMMER® DIRECT CURRENT BONE GROWTH STIMULATOR (DCBGS™)	ZIMMER WARSAW, IN 46580-0708	MANUFACTURING CHANGE TO SUBSTITUTE BATTERY USED WITH DEVICE
P790017/S22 03-14-91	USCI® GRUNTZIG DILACA CATHETER	C.R. BARD, INC. BILLERICA, MA 01821	NEW MANUFACTURING AND PACKAGING FACILITY AT PARKMORE INDUSTRIAL ESTATE, GALWAY, IRELAND

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P790032/S02 03-28-91	CLINICAL ASSAYS™ GAMMADAB[R] [125I] ALPHA-FETAPROTEIN RADIOIMMUNOASSAY KIT	BAXTER HEALTHCARE CORPORATION MIAMI, FL 33152-0672	APPROVAL FOR THE MANUFACTURE OF THE KITS AT INCSTAR CORPORATION'S MANUFACTURING FACILITIES LOCATED IN STILLWATER, MN AND TO INCLUDE THE FACILITY AS A SITE FOR KIT PACKAGING, FINAL QUALITY CONTROL TESTING AND DISTRIBUTION OF THE KIT
P800060/S07 03-05-91	THE SOFTRINSE™ 250 SYSTEM	SOFTRINSE™ CORPORATION WISCONSIN RAPIDS, WI 54494	REVISED LABELING
P810005/S25 03-21-91	CIBASOFT[R] (TEFILCON) SOFT (HYDROPHILIC) CONTACT LENS	CIBA VISION CORPORATION ATLANTA, GA 30360	MODIFY THE CONTACT LENS BY INCORPORATING OPAQUE PIGMENTS IN AN IRIS PATTERN BETWEEN TWO LAYERS OF THE TEFILCON POLYMER
P810046/S95 03-20-91	SIMPSON ROBERT[R] CORONARY BALLOON DILATATION CATHETER-ACS[R] STACK PERFUSION[R] CORONARY (25 MM LENGTH BALLOON)	ADVANCED CARDIOVASCULAR SYSTEMS, INC. SANTA CLARA, CA 95052-8167	APPROVAL FOR THE ACS[R] STACK PERFUSION[R] CORONARY DILATATION CATHETER WITH 25 MM LENGTH BALLOON AND ELIMINATION OF THE VENT TUBE

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P810046/S97 03-20-91	SIMPSON-ROBERT[R] CORONARY BALLOON DILATATION CATHETER-ACS	ADVANCED CARDIOVASCULAR SYSTEMS, INC. SANTA CLARA, CA 95052-8167	ADDITION OF A 1.5MM BALLOON SIZE TO THE ACS PINKERTON .018[TM] CORONARY DILATATION CATHETER PINKERTON .018[TM] CORONARY DILATATION CATHETER WITH 1.5MM BALLOON
P810055/S42 03-20-91	ONE PIECE CM[TM] BLUE UVEX[TM] POSTERIOR CHAMBER INTRAOCULAR LENSES	KABI PHARMACIA OPHTHALMICS, INC. MONROVIA, CA 91017-7136	ONE-PIECE INTRAOCULAR LENSES WITH HAPTICS MANUFACTURED FROM CM[TM] BLUE POLYMETHYLMETHACRYLATE (PHARMACIA UVEX[TM]) AND WITH OPTICS MANUFACTURED FROM UVEN[TM] IN THE SAME DESIGNS
P810055/S42 03-20-91	ONE-PIECE CM[TM] BLUE UVEX[TM] POSTERIOR CHAMBER INTRAOCULAR LENSES	KABI PHARMACIA OPHTHALMICS, INC. MONROVIA, CA 91017-7136	ONE-PIECE INTRAOCULAR LENSES WITH HAPTICS MANUFACTURED FROM CM[TM] BLUE POLYMETHYLMETHACRYLATE (PHARMACIA UVEX[TM]) WITH OPTICS MANUFACTURED FROM UVEX[TM]
P810055/S47 03-20-91	ONE-PIECE CM[TM] CLEAR UVEX[TM] AND MODEL RD11 POSTERIOR CHAMBER INTRAOCULAR LENSES	KABI PHARMACIA OPHTHALMICS, INC. MONROVIA, CA 91017-7136	ONE-PIECE INTRAOCULAR LENSES MANUFACTURED FROM CM[TM] CLEAR POLYMETHYLMETHACRYLATE (PHARMACIA UVEX[TM])

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P810057/S09 03-28-91	MYSTIQUE[R] (POLYMACON) HYDROPHILIC CONTACT LENSES	COOPERVISION, INC. ROCHESTER, NY 14623	ADDITION OF FOUR COLORS, HEATHER GRAY, MISTY GRAY, COCOA BROWN, AND LIGHT BROWN FOR THE OPAQUE COLORED LENSES
P820018/S39 03-26-91	AUTIMA MODEL 2251: AURORA II MODEL 6296	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	AURORA II MODEL 6296 DUAL CHAMBER PULSE GENERATOR AND MODEL 5603 PROGRAMMER VERSION 3.1P AND 4.31P
P820018/S48 03-14-91	AUTIMA[TM] PACING SYSTEM-AURORA MODELS 6291 AND 6292	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	MODIFICATION TO THE SPECIFICATION FOR THE ABSOLUTE REFRACTORY PERIOD OF THE AURORA MODEL 6291 AND 6292 PULSE GENERATORS
P820065/S74 03-21-91	THE BOSTON LENS[R] II (ITAFOCON A) AND THE BOSTON LENS[R] (ITAFOCON B) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ADDITIONAL CONTACT LENS FINISHING LABORATORY
P820088/S08 03-28-91	BSD-1000 HYPERTHERMIA SYSTEM, BSD-500 HYPERTHERMIA SYSTEM, THERMAL MAPPING WITH BSD-500	BSD MEDICAL CORPORATION SALT LAKE CITY, UT 84108	APPROVAL FOR USE OF THE THERMAL MAPPING OPTION FOR THE BSD-500 HYPERTHERMIA SYSTEM
P830061/S15 03-20-91	MEDTRONIC[R] CAPSURE[R] MODELS 4003-4503 PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	CHANGE IN THE CRIMP CORE SIZES FOR CAPSURE[R] LEAD MODELS 4003M, 4503M, 4004M AND 4504M

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P830079/S08 03-22-91	INSTAT™ COLLAGEN ABSORBABLE HEMOSTAT	JOHNSON & JOHNSON MEDICAL, INC. NEW BRUNSWICK, NJ 08903	NEW PROCESSING FACILITY, DEVRO LTD., BELLSHILL, SCOTLAND
P840020/S03 03-14-91	BAUSCH & LOMB® QUICK/SEPT® SYSTEM	BAUSCH & LOMB OPTICS CENTER ROCHESTER, NY 14692	SUBSTITUTE INTO THE BAUSCH & LOMB® QUIK/SEPT® SYSTEM, A MODIFIED NEUTRALIZING AND RINSING SOLUTION FORMULA
P840024/S14 03-29-91	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	NEW PACKAGE INSERTS
P840040/S23 03-08-91	MEDI-TECH HEART TRAK™ CORONARY BALLOON DILATION CATHETER SYSTEM/SLIDER™ CATHETERS (QUARTER SIZE BALLOONS)	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	FOUR ADDITIONAL QUARTER SIZE BALLOON DIAMETERS TO THE TRIFURCATED AND BIFURCATED SLIDER .014 AND .018 PTCA CATHETERS
P840051/S04 03-29-91	MAXON® POLYGLYCONATE MONOFILAMENT SUTURES	AMERICAN CYANAMID COMPANY DANBURY, CT 06810	MODIFICATION OF THE IN VIVO TENSILE STRENGTH CLAIMS IN THE PRODUCT LABELING
P840064/S09 03-19-91	VISCOAT®	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	ALTERNATE MANUFACTURING SITE
P850009/S04 03-28-91	CENTOCOR® CA 125™ RIA	CENTOCOR, INC. MALVERN, PA 19355	MODIFICATION OF THE QC CRITERIA SECTION IN THE PRODUCT PACKAGE INSERT

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P850055/S09 03-18-91	MIRAFLOW® EXTRA STRENGTH CLEANER	CIBA VISION CORPORATION ATLANTA, GA 30348	CHANGING COLOR OF THE DROPPER TIP OF THE CONTAINER FROM WHITE TO RED
P850061/S02 03-08-91	BIAS™ FIBER METAL TOTAL HIP SYSTEM	ZIMMER WARSAW, IN 46580-0708	CHANGE IN THE LOCATION OF IRRADIATION STERILIZATION USE OF A UNIVERSAL BIOLOGICAL INDICATOR RATHER THAN INOCULATED PRODUCT USE OF LASER HOLOGRAPHIC METHODS FOR INSPECTION OF THE FIBER METAL PAD BONDING AND ADDITION OF A FOAM RETAINER TO THE PACKAGING
P850088/S21 03-21-91	LENS PLUS® OXYSEPT® DISINFECTING SOLUTION	ALLERGAN OPTICAL IRVINE, CA 92715-1599	ALTERNATE MANUFACTURING SITE
P860003/S19 03-11-91	UVAR® PHOTOPHERESIS SYSTEM	THERAKOS, INC. WEST CHESTER, PA 19380	CHANGE IN THE MANUFACTURING PROCESS FOR THE ACRYLIC PLATES USED IN THE PHOTOCEPTOR® PHOTOACTIVATION CHAMBER
P860004/S13 03-11-91	SYNCHROMED® INFUSION SYSTEM FOR EPIDURAL INFUSION OF PRESERVATIVE-FREE MORPHINE SULFATE	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	EPIDURAL INFUSION OF PRESERVATIVE-FREE MORPHINE SULFATE STERILE SOLUTION FOR THE TREATMENT OF CHRONIC INTRACTABLE PAIN OF MALIGNANT ORIGIN

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P860008/S09 03-25-91	ARZCO ESOPHAGEAL CARDIAC RECORDING AND PACING CATHETER	ARZCO MEDICAL ELECTRONICS, INC. VERNON HILLS, IL 60061	APPROVAL FOR THE ARZCO TAPCATTM
P860019/S31 03-20-91	SCIMED® PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETERS-DGWTM	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	REVISED LABELING
P860022/S33 03-21-91	THE BOSTON EQUALENS® (ITAFLUOROFOCON A) AND THE BOSTON® RXD® (ITABISFLUOROFOCON A) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ADDITIONAL CONTACT LENS FINISHING LABORATORY
P860061/S05 03-25-91	LENS PLUS® HEAT ENZYME WEEKLY CLEANER	ALLERGAN OPTICAL IRVINE, CA 92715-1599	ALTERNATE FORMULATION OF HYDROZYMETM ENZYMATIC CLEANER FOR THE WEEKLY ENZYMATIC CLEANING OF SOFT (HYDROPHILIC) CONTACT LENSES DURING HEAT DISINFECTION
P870002/S09 03-07-91	APPLIED LABORATORIES STERILE SALINE SOLUTION	APPLIED LABORATORIES, INC. COLUMBUS, IN 47202-0448	ALTERNATE CONTAINER TO PACKAGE SOLUTION

APPLICATION NUMBER	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P870018/S04	SIEMENS LITHOSTAR LITHOTRIPTER	SIEMENS MEDICAL SYSTEMS, INC. ISELIN, NJ 08830	IMPLEMENTATION OF THE MEMOSKOP U-25 IMAGE STORAGE DEVICE OPTION IMAGE REVERSAL CHANGING KV WHILE RELEASING SHOCK WAVES DELIVERY OF UP TO 500 SHOCK WAVES WITHOUT INTERRUPTION NEW CROSS HAIRS THREE WAY FOOTSWITCH FOR FLUORO RELEASE	03-18-91
P870036/S11	VERSAFLEX™ BUCHBINDER® OMNIFLEX™ PTCA CATHETER SYSTEM-18K	MEDTRONIC INTERNATIONAL VASCULAR SAN DIEGO, CA 92121-1405	ALTERNATE DESIGN TO THE 18K WHICH INCLUDES A RADIOPAQUE TIP MARKER	03-20-91
P870045/S23	MODEL SP17UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	INTRAOPTICS, INC. BOCA RATON, FL 33429-1710	MODEL SP17UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	03-20-91
P880001/S28	FLUOREX™ 700 (FLUSILFOCON A), FLUOREX™ 500 (FLUSILFOCON B), AND FLUOREX™ 300 (FLUSILFOCON C) RIGID GAS PERMEABLE CONTACT LENSES	G.T. LABORATORIES CHICAGO, IL 60601	PROTOCOL TO EXTEND THE SHELF-LIFE	03-18-91

APPLICATION NUMBER	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P880027/S13	SCHNEIDER "17CM" MONORAIL PICCOLINO[R], MICROSOFTRAC-XLP[TM], MAGNUM-MEIER[TM] AND MONORAIL PICCOLINO[R] FORTE[TM] PTCA CATHETERS	SCHNEIDER(USA) INC. PLYMOUTH, MN 55442	ADDITION OF A THIRD LABEL TO THE TRAY BOTTOM TO IMPROVE CATHETER RECOGNITION	03-14-91
P880032/S01	BIO-RAD CYCLOSPORINE BY HPLC TEST	BIO-RAD LABORATORIES HERCULES, CA 94547	USE OF CYCLOSPORINE C (CY C) AS AN ALTERNATIVE INTERNAL STANDARD TO CYCLOSPORINE D (CY D)	03-14-91
P880055/S02	MICROSS PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) DILATATION CATHETER-MICROSS/SL[TM]	DATASCOPE CORPORATION OAKLAND, NJ 07436	USE OF POLYETHYLENE TEREPTHLATATE (PET) FOR THE INNER LUMEN AND OUTER CATHETER USE OF PET FOR THE BALLOON MEMBRANE REDUCTION IN CATHETER SIZE CHANGE IN RESIN IN "Y" FITTING TO LEXAN 112 USE OF CYANACRYLATE GLUE FOR BONDING BALLOON TO CATHETER	03-28-91
P890001/S03	LEOCOR PTC CATHETER-PICOCATH[TM] PTCA CATHETER	LEOCOR INCORPORATED HOUSTON, TX 77058	PICOCATH[TM] PTCA CATHETER	03-08-91

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P890019/S01 03-01-91	AB-HAVK	SORIN BIOMEDICA, S.P.A. STILLWATER, MN 55082	MODIFICATION OF THE AB-HAVK ASSAY FROM A RADIOIMMUNOASSAY (RIA) TO A MICROTITER ENZYME IMMUNOASSAY (EIA)
P890031/S01 03-06-91	OTI-05 (POLYMACON) SOFT CONTACT LENS AND LATHE-40 (POLYMACON) SOFT CONTACT LENS	OCULAR TECHNOLOGIES, INC. RALEIGH, NC 27609	ALTERNATE MANUFACTURING SITE
P890043/S06 03-19-91	SIMPSON CORONARY ATHEROCATH™/ SCA-LP™	DEVICES FOR VASCULAR INTERVENTION REDWOOD CITY, CA 94063	NEW MODEL SIMPSON CORONARY ATHEROCATH™ WITH A MODIFIED NOSECONE AND A POLYETHYLENE TEREPHTHALATE BALLOON
P890044/S12 03-18-91	BIS.45 (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND BLUE TINTED)	BENTEC ENGINEERING INC. SACRAMENTO, CA 95834	ELEVEN ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P890058/S08 03-21-91	NOVALENS (ROSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND BLUE TINTED)	OCUTEC CORPORATION RALEIGH, NC 27615	SIXTEEN CONTACT LENS FINISHING LABORATORIES TO BECOME ADDITIONAL MANUFACTURING AND DISTRIBUTION SITES

APPLICATION NUMBER APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890062/S03 03-21-91	CIBA VISION® CLEANER	CIBA VISION CORPORATION ATLANTA, GA 30348	CHANGE COLOR OF DROPPER TIP OF THE CONTAINER FROM WHITE TO RED
P890070/S01 03-20-91	PURE-DENT® B851	GRAIN PROCESSING CORPORATION MUSCATINE, IA 52761	CHANGE THE MAGNESIUM OXIDE FROM MAGCHEM 40 TO A 1:1 MIXTURE OF MAGCHEM 20M AND MAGCHEM 30
P900001/S01 03-18-91	SGP 3™ (UNIFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR, BLUE AND GREEN TINTED)	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NJ 07751	ELEVEN ADDITIONAL CONTACT LENS FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES

NADA NUMBER / APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR MARCH 1991.

SUPPLEMENTAL VETERINARY NADAs

042-841 02-21-91	AMFOROL (TABLET)	DOGS	FT DODGE LABS FT DODGE, IO 50501	ACTIVATED ATTAPULGITE 500MG BISMUTH SUBCARBONATE 200MG KANAMYCIN SULFATE 100MG PECTIN 25MG
130-951 03-01-91	STENOROL (PREMIX)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	HALOFUGINONE HYDROBROMIDE 6GM/KG
131-673 03-08-91	SAFE-GUARD TYPE A MEDICATED ARTICLE (PREMIX)	SWINE	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	FENBENDAZOLE 4% 8% 20%
140-338 03-15-91	NAXCEL (POWDER)	BEEF CATTLE DAIRY CATTLE	UPJOHN KALAMAZOO, MI 49001	CEFTIOFUR SODIUM 1GM/20ML 4GM/80ML

FDA DRUG AND DEVICE PRODUCT APPROVALS

Center for Drug Evaluation and Research
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Center for Devices and Radiological Health
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This report is compiled by the Division of Drug Information Resources, OM, CDER. It is available by subscription from the National Technical Information Service, Springfield, VA 22161.

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April 1991

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-057 CEREDASE GENZYME ALGLUCERASE
04-05-91 (INJECTABLE) BOSTON, MA 80 UNITS/ML
(1 A, V*) 02111 (BETA-GLUCOCEREBROSIDASE
ENZYME REPLENISHER) [GAUCHER'S DISEASE]

20-038 FLUDARA BERLEX FLUDARABINE PHOSPHATE
04-18-91 (INJECTABLE) ALAMEDA, CA 50MG/VIAL
(1 A) 94501 (ANTIMETABOLITE)

19-797 NULYTELY BRAINTREE POLYETHYLENE GLYCOL 3350
04-22-91 (POWDER FOR BRAINTREE, MA 420GM/BOT
(3 C) RECONSTITUTION) 02184 POTASSIUM CHLORIDE
1.48GM/BOT
SODIUM BICARBONATE
5.72GM/BOT
SODIUM CHLORIDE
11.2GM/BOT
(GASTROINTESTINAL LAVAGE)

20-101 PROZAC LILLY FLUOXETINE HYDROCHLORIDE
04-24-91 (SOLUTION) INDIANAPOLIS, IN EQ 20MG BASE/5ML
(3 B) 46285 (ANTIDEPRESSANT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-089	ZOVIRAX	BURROUGHS WELLC	ACYCLOVIR
04-30-91	(TABLET)	RES TRIANGLE PK, NC	400MG
(3 C)		27709	800MG
			(ANTIVIRAL)

V* - Designated Orphan Drug

NDA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-004 03-29-91	SODIUM LACTATE 1/6M IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	SODIUM LACTATE 1.87GM/100ML (METABOLIC ALKALINIZER; ELECTROLYTE REPLENISHER)
20-006 03-29-91	MANNITOL IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	MANNITOL 5GM/100ML 10GM/100ML 15GM/100ML 20GM/100ML (DIURETIC)
19-830 04-12-91	LIDOCAINE HCL 0.1% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	LIDOCAINE HYDROCHLORIDE 100MG/100ML (ANTIARRHYTHMIC)
19-830 04-12-91	LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	LIDOCAINE HYDROCHLORIDE 200MG/100ML (ANTIARRHYTHMIC)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

APPROVABLE ORIGINAL NDAs

19-830	LIDOCAINE HCL 0.4%	MCGAW	LIDOCAINE HYDROCHLORIDE
04-12-91	AND DEXTROSE 5%	IRVINE, CA	400MG/100ML
	IN PLASTIC CONTAINER	92713	(ANTIARRHYTHMIC)
	(INJECTABLE)		
19-830	LIDOCAINE HCL 0.8%	MCGAW	LIDOCAINE HYDROCHLORIDE
04-12-91	AND DEXTROSE 5%	IRVINE, CA	800MG/100ML
	IN PLASTIC CONTAINER	92713	(ANTIARRHYTHMIC)
	(INJECTABLE)		
19-915	MONOPRIL	SQUIBB	FOSINOPRIL SODIUM
04-19-91	(TABLET)	PRINCETON, NJ	5MG
		08543	10MG
			20MG
			(ANTIHYPERTENSIVE)
20-047	DEXTROSE	BAXTER	DEXTROSE
04-29-91	IN PLASTIC CONTAINER	ROUND LAKE, IL	50GM/100ML
	(INJECTABLE)	60073	60GM/100ML
			70GM/100ML
			(FLUID AND NUTRIENT
			REPLENISHER)
19-953	HEPARIN SODIUM	MCGAW	HEPARIN SODIUM
04-30-91	IN SODIUM	IRVINE, CA	100 UNITS/100ML
	CHLORIDE 0.9%	92713	200 UNITS/100ML
	(INJECTABLE)		(ANTICOAGULANT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

72-255	MICRODERM	JOHNSON AND JOHNSON	CHLORHEXIDINE GLUCONATE
04-15-91	(SOLUTION)	ARLINGTON, TX	4%
	76004	(ANTIMICROBIAL)	
		(OTC)	
63-180	LINCOMYCIN HCL	STERIS	LINCOMYCIN HYDROCHLORIDE
04-16-91	(INJECTABLE)	PHOENIX, AZ	EQ 300MG BASE/ML
	85043	(ANTIBIOTIC, LINCOMYCIN)	
72-050	SULINDAC	MUTUAL PHARM	SULINDAC
04-17-91	(TABLET)	PHILADELPHIA, PA	150MG
	19124	(NONSTEROIDAL	
		ANTI-INFLAMMATORY)	
72-051	SULINDAC	MUTUAL PHARM	SULINDAC
04-17-91	(TABLET)	PHILADELPHIA, PA	200MG
	19124	(NONSTEROIDAL	
		ANTI-INFLAMMATORY)	
62-986	CEPHALEXIN	SQUIBB MARK	CEPHALEXIN
04-18-91	(POWDER FOR	PRINCETON, NJ	EQ 125MG BASE/5ML
	RECONSTITUTION)	08543	(ANTIBIOTIC, CEPHEM)
63-113	TOBRAMYCIN SULFATE	LEDERLE	TOBRAMYCIN SULFATE
04-26-91	(INJECTABLE)	CAROLINA, PR	EQ 10MG BASE/ML
	00630	(ANTIBIOTIC, AMINOGLYCOSIDE)	
63-117	TOBRAMYCIN SULFATE	LEDERLE	TOBRAMYCIN SULFATE
04-26-91	(INJECTABLE)	CAROLINA, PR	EQ 40MG BASE/ML
	00630	(ANTIBIOTIC, AMINOGLYCOSIDE)	
63-080	TOBRAMYCIN SULFATE	ABBOTT	TOBRAMYCIN SULFATE
04-30-91	(INJECTABLE)	ABBOTT PARK, IL	EQ 10MG BASE/ML

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

60064 (ANTIBIOTIC, AMINOGLYCOSIDE)

63-111 TOBRAMYCIN SULFATE ABBOTT TOBRAMYCIN SULFATE
04-30-91 (INJECTABLE) ABBOTT PARK, IL EQ 40MG BASE/ML
60064 (ANTIBIOTIC, AMINOGLYCOSIDE)

63-112 TOBRAMYCIN SULFATE ABBOTT TOBRAMYCIN SULFATE
04-30-91 (INJECTABLE) ABBOTT PARK, IL EQ 10MG BASE/ML
60064 (ANTIBIOTIC, AMINOGLYCOSIDE)

72-472 FENOPROFEN CALCIUM WARNER CHILCOTT FENOPROFEN CALCIUM
04-30-91 (CAPSULE) MORRIS PLAINS, NJ EQ 300MG BASE
07950 (NONSTEROIDAL ANTI-INFLAMMATORY)

72-946 FENOPROFEN CALCIUM WARNER CHILCOTT FENOPROFEN CALCIUM
04-30-91 (CAPSULE) MORRIS PLAINS, NJ EQ 200MG BASE
07950 (NONSTEROIDAL
ANTI-INFLAMMATORY)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-624 ROCEPHIN W/ DEXTROSE ROCHE CEFTRIAXONE SODIUM
03-11-91 IN PLASTIC CONTAINER NUTLEY, NJ EQ 20MG BASE/ML
(INJECTABLE) 07110 EQ 40MG BASE/ML
(REVISED LABELING --
DIRECTIONS FOR USE)

18-781 HUMULIN N LILLY INSULIN ISOPHANE
04-03-91 (INJECTABLE) INDIANAPOLIS, IN BIOSYNTHETIC HUMAN
46285 100 UNITS/ML
(REVISED LABELING --
PATIENT PACKAGE INSERT)

19-058 TENORMIN ICI ATENOLOL
04-05-91 (INJECTABLE) WILMINGTON, DE 0.5MG/ML
19897 (REVISED LABELING --
DESCRIPTION; WARNINGS;
PRECAUTIONS;
POTENTIAL ADVERSE EFFECTS;
OVERDOSAGE)

17-769 CALCIMAR RHONE POULENC RORER CALCITONIN SALMON
04-08-91 (INJECTABLE) FT WASHINGTON, PA 200 IU/ML
19034 (REVISED LABELING --
PRECAUTIONS)

18-044 ROCALTROL ROCHE CALCITRIOL
04-08-91 (CAPSULE) NUTLEY, NJ 0.25 MCG
07110 0.5 MCG
(REVISED LABELING --
WARNINGS; OVERDOSAGE)

18-936 PROZAC LILLY FLUOXETINE HYDROCHLORIDE
04-09-91 (CAPSULE) INDIANAPOLIS, IN EQ 20MG BASE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	APPROVAL DATE	(DOSAGE FORM)	STRENGTH(S)	LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		46285	(REVISED LABELING -- CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; OVERDOSAGE)				
19-906	ANAFRANIL	CIBA	CLOMIPRAMINE HYDROCHLORIDE				
04-09-91	(CAPSULE)	SUMMIT, NJ	25MG				
		07901	50MG				
			75MG				
			(REVISED LABELING -- CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS; OVERDOSAGE; HOW SUPPLIED)				
17-926	INSULIN	NOVO NORDISK	INSULIN PORK				
04-10-91	(INJECTABLE)	PRINCETON, NJ	40 UNITS/ML				
		08540	100 UNITS/ML				
			(REVISED LABELING -- PATIENT INSTRUCTIONS)				
18-778	NOVOLIN R	NOVO NORDISK	INSULIN SEMISYNTHETIC	04-10-91	(INJECTABLE)	PRINCETON, NJ	PURIFIED HUMAN
		08540	100 UNITS/ML				
			(REVISED LABELING -- PATIENT INSTRUCTIONS)				
19-643	MEVACOR	MSD	LOVASTATIN				
04-10-91	(TABLET)	W POINT, PA	10MG				
		19486	20MG				
			40MG				

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	APPROVAL DATE	(DOSAGE FORM)	STRENGTH(S)	LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

(REVISED LABELING --
CLINICAL PHARMACOLOGY;
WARNINGS;
DOSAGE AND ADMINISTRATION)

50-092	PATHOCIL	WYETH AYERST	DICLOXACILLIN SODIUM	04-10-91	(POWDER FOR RECONSTITUTION)	PHILADELPHIA, PA 19101	EQ 62.5MG BASE/5ML (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
50-111	UNIPEN	WYETH AYERST	NAFCILLIN SODIUM	04-10-91	(CAPSULE)	PHILADELPHIA, PA 19101	EQ 250MG BASE (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
50-199	UNIPEN	WYETH AYERST	NAFCILLIN SODIUM	04-10-91	(POWDER FOR RECONSTITUTION)	PHILADELPHIA, PA 19101	EQ 250MG BASE/5ML (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
09-218	COUMADIN	DUPONT	WARFARIN SODIUM	04-11-91	(TABLET)	WILMINGTON, DE 19880	1MG 2MG 2.5MG 5MG 7.5MG 10MG (REVISED LABELING -- PRECAUTIONS)
19-508	AXID	LILLY	NIZATIDINE	04-11-91	(CAPSULE)	INDIANAPOLIS, IN 46285	150MG 300MG (REVISED LABELING

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

--
CLINICAL PHARMACOLOGY)

19-777 ZESTRIL ICI LISINOPRIL
04-11-91 (TABLET) WILMINGTON, DE 5MG
19897 10MG 20MG
40MG
(REVISED LABELING --
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS)

19-888 ZESTORETIC 20/12.5 ICI LISINOPRIL 04-11-91 (TABLET)
WILMINGTON, DE 20MG 19897 HYDROCHLOROTHIAZIDE
12.5MG
(REVISED LABELING --
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS)

19-888 ZESTORETIC 20/25 ICI LISINOPRIL
04-11-91 (TABLET) WILMINGTON, DE 20MG
19897 HYDROCHLOROTHIAZIDE
25MG
(REVISED LABELING --
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS)

18-017 BLOCADREN MSD TIMOLOL MALEATE
04-17-91 (TABLET) W POINT, PA 5MG
19486 10MG
20MG
(REVISED LABELING --

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)	
		LABELING CHANGE(S)		

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			PRECAUTIONS)	
19-058	TENORMIN	ICI	ATENOLOL	
04-17-91	(INJECTABLE)	WILMINGTON, DE	0.5MG/ML	
	19897	(REVISED LABELING -- WARNINGS; PRECAUTIONS)		
08-809	M.V.I.-12	USV	ASCORBIC ACID	
04-19-91	(INJECTABLE)	FT WASHINGTON, PA	10MG/ML	
	19034	BIOTIN		0.006MG/ML
		CYANOCOBALAMIN 0.0005MG/ML		
		DEXPANTHENOL		

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

1.5MG/ML
ERGOCALCIFEROL
20 IU/ML
FOLIC ACID
0.04MG/ML
NIACINAMIDE
4MG/ML
PYRIDOXINE HYDROCHLORIDE
0.4MG/ML
RIBOFLAVIN PHOSPHATE SODIUM
0.36MG/ML
THIAMINE HYDROCHLORIDE
0.3MG/ML
VITAMIN A
330 IU/ML
VITAMIN E
1 IU/ML
(REVISED LABELING --
CONTRAINDICATIONS;
PRECAUTIONS;
DOSAGE AND ADMINISTRATION)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

16-723 NORLESTRIN 28 1/50 PARKE DAVIS ETHINYL ESTRADIOL
04-22-91 (TABLET) FAJARDO, PR 0.05MG
00648 NORETHINDRONE ACETATE
1MG
(REVISED LABELING --
CONTRAINDICATIONS; WARNINGS;
PRECAUTIONS; ADVERSE REACTIONS;
PATIENT PACKAGE INSERT)

16-749 NORLESTRIN 21 1/50 PARKE DAVIS ETHINYL ESTRADIOL
04-22-91 (TABLET) FAJARDO, PR 0.05MG
00648 NORETHINDRONE ACETATE
1MG
(REVISED LABELING --
CONTRAINDICATIONS; WARNINGS;
PRECAUTIONS; ADVERSE REACTIONS;
PATIENT PACKAGE INSERT)

16-766 NORLESTRIN FE 1/50 PARKE DAVIS ETHINYL ESTRADIOL
04-22-91 (TABLET) FAJARDO, PR 0.05MG
00648 FERROUS FUMARATE
75MG
NORETHINDRONE ACETATE
1MG
(REVISED LABELING --
CONTRAINDICATIONS; WARNINGS;
PRECAUTIONS; ADVERSE REACTIONS;
PATIENT PACKAGE INSERT)

16-852 NORLESTRIN 21 2.5/50 PARKE DAVIS ETHINYL ESTRADIOL
04-22-91 (TABLET) FAJARDO, PR 0.05MG
00648 NORETHINDRONE ACETATE
2.5MG
(REVISED LABELING --

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

CONTRAINDICATIONS; WARNINGS;
PRECAUTIONS; ADVERSE REACTIONS;
PATIENT PACKAGE INSERT)

16-854 NORLESTRIN FE 2.5/50 PARKE DAVIS ETHINYL ESTRADIOL
04-22-91 (TABLET) FAJARDO, PR 0.05MG
00648 FERROUS FUMARATE
75MG
NORETHINDRONE ACETATE
2.5MG
(REVISED LABELING --
CONTRAINDICATIONS; WARNINGS;
PRECAUTIONS; ADVERSE REACTIONS;
PATIENT PACKAGE INSERT)

17-354 LOESTRIN FE 1/20 PARKE DAVIS ETHINYL ESTRADIOL
04-22-91 (TABLET) MORRIS PLAINS, NJ 0.02MG
07950 FERROUS FUMARATE
75MG
NORETHINDRONE ACETATE
1MG
(REVISED LABELING --
CONTRAINDICATIONS; WARNINGS;
PRECAUTIONS; ADVERSE REACTIONS;
PATIENT PACKAGE INSERT)

17-355 LOESTRIN FE 1.5/30 PARKE DAVIS ETHINYL ESTRADIOL
04-22-91 (TABLET) MORRIS PLAINS, NJ 0.03MG
07950 FERROUS FUMARATE
75MG
NORETHINDRONE ACETATE
1.5MG
(REVISED LABELING --
CONTRAINDICATIONS; WARNINGS;

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

PRECAUTIONS; ADVERSE REACTIONS;
PATIENT PACKAGE INSERT)

17-875 LOESTRIN 21 1.5/30 PARKE DAVIS ETHINYL ESTRADIOL
04-22-91 (TABLET) MORRIS PLAINS, NJ 0.03MG
07950 NORETHINDRONE ACETATE
1.5MG
(REVISED LABELING --
CONTRAINDICATIONS; WARNINGS;
PRECAUTIONS; ADVERSE REACTIONS;
PATIENT PACKAGE INSERT)

17-876 LOESTRIN 21 1/20 PARKE DAVIS ETHINYL ESTRADIOL
04-22-91 (TABLET) MORRIS PLAINS, NJ 0.02MG
07950 NORETHINDRONE ACETATE
1MG
(REVISED LABELING --
CONTRAINDICATIONS; WARNINGS;
PRECAUTIONS; ADVERSE REACTIONS;
PATIENT PACKAGE INSERT)

12-462 LOMOTIL SEARLE ATROPINE SULFATE
04-23-91 (TABLET) SAN JUAN, PR 0.025MG
00936 DIPHENOXYLATE HYDROCHLORIDE
2.5MG
(REVISED LABELING --
OVERDOSAGE)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

12-699 LOMOTIL SEARLE ATROPINE SULFATE
04-23-91 (SOLUTION) SAN JUAN, PR 0.025MG/5ML
00936 DIPHENOXYLATE HYDROCHLORIDE
2.5MG/ML
(REVISED LABELING --
OVERDOSAGE)

17-037 HEPARIN SODIUM ELKINS SINN HEPARIN SODIUM
04-23-91 (INJECTABLE) CHERRY HILL, NJ 1,000 UNITS/ML 08003
5,000 UNITS/ML
10,000 UNITS/ML (REVISED LABELING --
DOSAGE AND ADMINISTRATION)

17-037 HEP-LOCK ELKINS SINN HEPARIN SODIUM
04-23-91 (INJECTABLE) CHERRY HILL, NJ 10 UNITS/ML
08003 100 UNITS/ML
(REVISED LABELING -- DOSAGE AND ADMINISTRATION)

17-037 HEP-LOCK U/P ELKINS SINN HEPARIN SODIUM
04-23-91 (INJECTABLE) CHERRY HILL, NJ 10 UNITS/ML
08003 100 UNITS/ML
(REVISED LABELING --
DOSAGE AND ADMINISTRATION)

17-064 HEPARIN SODIUM STERIS HEPARIN SODIUM
04-23-91 (INJECTABLE) PHOENIX, AZ 1,000 UNITS/ML
85043 5,000 UNITS/ML
10,000 UNITS/ML
20,000 UNITS/ML
40,000 UNITS/ML

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

(REVISED LABELING --
HOW SUPPLIED)

18-087 RELEFACT TRH HOECHST ROUSSEL PROTIRELIN
04-23-91 (INJECTABLE) SOMERVILLE, NJ 0.5MG/ML
08876 (REVISED LABELING --
PRECAUTIONS)

19-268 CYTOTEC SEARLE MISOPROSTOL
04-23-91 (TABLET) SKOKIE, IL 0.1MG
60077 0.2MG
(REVISED LABELING --
ADVERSE REACTIONS)

17-820 DOBUTREX LILLY DOBUTAMINE HYDROCHLORIDE
04-26-91 (INJECTABLE) INDIANAPOLIS, IN EQ 12.5MG BASE/ML
46285 (REVISED LABELING --
DOSAGE AND ADMINISTRATION)

18-760 TENORETIC 50 STUART ATENOLOL
04-26-91 (TABLET) WILMINGTON, DE 50MG
19897 CHLORTHALIDONE
25MG
(REVISED LABELING --
WARNINGS; PRECAUTIONS;
MISCELLANEOUS;
POTENTIAL ADVERSE EFFECTS;
OVERDOSAGE)

18-760 TENORETIC 100 STUART ATENOLOL

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

04-26-91 (TABLET) WILMINGTON, DE 100MG
19897 CHLORTHALIDONE
25MG
(REVISED LABELING --
WARNINGS; PRECAUTIONS;
MISCELLANEOUS;
POTENTIAL ADVERSE EFFECTS;
OVERDOSAGE)

18-828 ZOVIRAX BURROUGHS WELLC ACYCLOVIR
04-30-91 (CAPSULE) RES TRIANGLE PK, NC 200MG
27709 (REVISED LABELING --
DESCRIPTION;
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED)

19-817 IV PERSANTINE BOEHRINGER INGELHEIM DIPYRIDAMOLE
04-30-91 (INJECTABLE) RIDGEFIELD, CT 5MG/ML
06877 (REVISED LABELING -- HOW SUPPLIED)

19-909 ZOVIRAX BURROUGHS WELLC ACYCLOVIR
04-30-91 (SUSPENSION) RES TRIANGLE PK, NC 200MG/5ML
27709 (REVISED LABELING --
DESCRIPTION;
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED)

LICENSE NUMBER TRADE NAME MANUFACTURER PROPER NAME
LICENSE DATE (DOSAGE FORM) (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

1134 NONE AMERICAN PLASMA SERV SOURCE PLASMA
04-09-91(INJECTABLE)HOUSTON, TX(FURTHER MANUFACTURING)
77019(A&B)

606NONEMED LABWHOLE BLOOD
04-10-91(INJECTABLE)BIRMINGHAM, AL(TRANSFUSION)
35255(B)

1122NONESARASOTA COMM PLATELETS
04-10-91(INJECTABLE)BLOOD BANK(TRANSFUSION)
SARASOTA, FL (B)
34236

1135NONEST JOHNS CTY PLASMA
04-16-91(INJECTABLE)BLOOD BANK(TRANSFUSION)
ST AUGUSTINE, FL(B)
32086

1135NONEST JOHNS CTY RED BLOOD CELLS
04-16-91(INJECTABLE)BLOOD BANK(TRANSFUSION)
ST AUGUSTINE, FL(B)
32086

1135NONEST JOHNS CTY WHOLE BLOOD
04-16-91(INJECTABLE)BLOOD BANK(TRANSFUSION)
ST AUGUSTINE, FL(A&B)
32086

1136HEPROFILEADI DIAGNSHEPATITIS B SURFACE
04-16-91HBSAG ONTARIO, CANADAANTIGEN
(IN-VITRO) M9W 4Z7(AN ENZYME LINKED
IMMUNOSORBANT ASSAY USED
TO SCREEN BLOOD AND
PLASMA DONATIONS FOR THE

LICENSE NUMBER TRADE NAME MANUFACTURER PROPER NAME
LICENSE DATE (DOSAGE FORM) (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

PRESENCE OF ANTIBODY TO
HEPATITIS B SURFACE
ANTIGEN)
(A&B)

(A) Establishment License Issued
(B) Product License Issued

1136HEPROFILEADI DIAGNSANTIBODY TO HEPATITIS B
04-16-91ANTI-HBS ANDONTARIO, CANADASURFACE ANTIGEN (AN
HEPROFILE M9W 4Z7ENZYME LINKED
ANTI-HBSIMMUNOSORBANT ASSAY USED
SPECIFICITYTO SCREEN BLOOD AND
(IN-VITRO)PLASMA DONATIONS FOR THE
PRESENCE OF ANTIBODY TO
HEPATITIS B SURFACE ANTIGEN)
(B)

0156ORTHOORTHO DIAGNS SYSHEPATITIS B VIRUS CORE
04-18-91(IN-VITRO)RARITAN, NJ ANTIGEN
08869(RECOMBINANT)
(B)

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT LICENSES ISSUED

(B) Product License Issued

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK900027 04-19-91	790 ESP COLLECTION SET	HAEMONETICS BRAINTREE, MA 02184	EMPTY CONTAINERS FOR THE COLLECTION OF BLOOD AND BLOOD COMPONENTS (C)

DEVICE NUMBER TRADE NAME MANUFACTURER PROPER NAME
APPROVAL DATE (DESCRIPTION)

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

89-0104 PENTASPAN DUPONT MERCK PHARM 10% PENTASTARCH IN
04-04-91 (INJECTABLE) WILMINGTON, DE 0.9% SODIUM CHLORIDE 19880
(D)

89-0105 HESPAN DUPONT MERCK PHARM 6% HETASTARCH IN
04-04-91 (INJECTABLE) WILMINGTON, DE 0.9% SODIUM CHLORIDE
19880 (D)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT NDA APPROVALS

(D) Approved

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

P890048 04-17-91	USCI PROBE III BALLOON-ON-A-WIRE DILATATION SYSTEM WITH 2.5 CM TIP	C.R. BARD, INC. MURRAY HILL, NJ 07974	USCI PROBE III BALLOON-ON-A-WIRE DILATATION SYSTEM WITH 2.5 CM TIP AND 2.0, 2.5 AND 3.0 MM BALLOON DIAMETERS
P900052 04-22-91	PORT-A-CATH EPIDURAL IMPLANTABLE ACCESS	PHARMACIA DELTEC, INC. ST. PAUL, MN 55112	PORT-A-CATH EPIDURAL IMPLANTABLE ACCESS SYSTEM

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

N18146/S11	SOF-FORM (DELTAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES	SALVATORI OPHTHALMICS, INC. ROSWELL, GA 30076-2480	RELOCATION OF MANUFACTURING FACILITY	04-24-91
P810046/S101	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER/ACS RX ALPHA .014 CATHETER WITH QUARTER SIZE BALLOONS	ADVANCED CARDIOVASCULAR SYSTEMS, INC. SANTA CLARA, CA 95052-8167	ACS RX ALPHA .014 CATHETER WITH QUARTER SIZE BALLOONS	04-25-91
P820003/S56	VERSATRAX PULSE GENERATOR MODEL 9751A SEM PRINTER	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODEL 9751A SYSTEM ENHANCEMENT MODULE (SEM) PRINTER	04-02-91
P820005/S8	SOF-FORM II (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES (SPHERICAL AND TORIC)	SALVATORI OPHTHALMICS, INC. ROSWELL, GA 30076-2480	RELOCATION OF OPHTHALMICS FACILITY	04-24-91
P820024/S15	SOLUTION SYSTEM TOTAL HIP PROSTHESIS WITH POROCOAT	DEPUY WARSAW, IN 46580	CHANGE OF DEVICE NAME FROM AML TOTAL HIP SYSTEM WITH POROCOAT TO SYSTEM TOTAL HIP PROSTHESIS WITH POROCOAT	04-02-91
P820062/S2	PARAPERM O_2 (PASIFOCON A)	SALVATORI OPHTHALMICS, INC. ROSWELL, GA	RELOCATION OF OPHTHALMICS FACILITY	04-24-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND BLUE)	30076-2480		
P820065/S75	THE BOSTON LENS II (ITAFOCON A) AND THE BOSTON LENS IV (ITAFOCON B) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	04-05-91
P830055/S16	POSTERIOR CRUCIATE RETAINING LCS TOTAL KNEE SYSTEM WITH POROCOAT POROUS COATING	DEPUY NEW JERSEY WARSAW, IN 46580	REVISED LABELING	04-02-91
P840001/S23	ITREL TOTALLY IMPLANTABLE SPINAL CORD	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MEDTRONIC MODEL 7441 NC CORDIS/ITREL II ADAPTOR	04-03-91
P840006/S5	SYNSOFT (POLYMACON) BIFOCAL SOFT (HYDROPHILIC) CONTACT LENSES	SALVATORI OPHTHALMICS, INC. ROSWELL, GA 30076-2480	RELOCATION OF OPHTHALMICS FACILITY	04-24-91
P840012/S07	LASAG MICRORUPTOR Q-SWITCH ND:YAG	LASAG MEDICAL-LASERS EDEN PRAIRIE, MN	IRIDECTOMY/IRIDOTOMY	04-05-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

55344

P850021/S13	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER/THE INTREPID PTCA CATHETER	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	INTREPID PTCA CATHETER	04-22-91
P850079/S18	HYDRASOFT, HYDRASOFT TORIC, HYDRASOFT XW, AND HYDRASOFT TORIC XW (METHAFILCON B) HYDROPHILIC CONTACT LENSES	COASTVISION, INC. HUNTINGTON BEACH, CA 92648	ADDITION OF A LIGHT BLUE VISIBILITY TINT	04-25-91
P860019/S35	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER/MOCA	SCIMED LIFE SYSTEMS, INC. MINNEAPOLIS, MN 55441-3870	APPROVAL TO ELIMINATE INNER SPRING COIL AND MOLDED TIP, AND CHANGE THE HUB FOR THE MOCA CATHETER MODELS	04-05-91
P860019/S39	SCIMED PERCUTANEOUS TRANSLUMINAL	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	ADDITION OF MARKER BANDS TO THE EXPRESS	04-03-91

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CORONARY ANGIOPLASTY CATHETER/EXPRESS		
P860022/S31 04-16-91	BOSTON RXD (SPHERICAL LENS DESIGN), BOSTON ENVISION (ASPHERICAL LENS DESIGN) (ITABISFLUOROFOCON A) RIGID GAS PERMEABLE CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ALTERNATE MANUFACTURING PROCESS FOR THE ITABISFLUOROFOCON A MATERIAL
P860022/S34 04-05-91	THE BOSTON EQUALENS (ITAFLUOROFOCON A) AND THE BOSTON RXD (ITABISFLUOROFOCON A) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ADDITIONAL CONTACT LENS FINISHING LABORATORY
P860027/S8 04-25-91	MAESTRO SERIES 500 PULSE GENERATORS AND MAESTRO 1006 PACEMAKER PROGRAMMER/MAESTRO MODEL 1006P PACEMAKER PROGRAMMER	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	ADDITION OF THE MAESTRO MODEL 1006P PACEMAKER PROGRAMMER AND DISCONTINUATION OF THE MAESTRO MODEL 509 PULSE GENERATOR
P860035/S03	IVAC TITRATOR	IVAC CORPORATION	CHANGES TO THE SOFTWARE

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	SODIUM NITROPRUSSIDE CLOSED LOOP MODULE - MODEL 1OK	SAN DIEGO, CA 92138-5335	OF THE CONTROL ALGORITHM, THE USER INTERFACE, AND DIRECTIONS FOR USE	04-18-91
P880027/S11	MICROSOFTRAC PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER/"17 CM" MONORAIL PICCOLINO, MICROSOFTRAC-XLP PTCA CATHETERS	SCHNEIDER (USA) INC. MINNEAPOLIS, MN 55442	ADDITION OF NEW BALLOON MODELS IN QUARTER-MM INCREMENTS, AND REVISION OF PACKAGE LABELS AND INSTRUCTIONS FOR USE FOR ALL MODELS	04-03-91
P890003/S03	SYNERGYST PACING SYSTEM/ELITE PACING SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	ELITE MODELS 7074/7075/ 7076/7077 PULSE GENERATORS THE MODEL 9760 PROGRAMMER WITH THE MODEL 9852 SOFTWARE AND THE MODEL 9743 MEMORYMOD FOR USE IN THE MODEL 9710 PROGRAMMER	04-24-91
P890031/S03	OTI-05 (POLYMACON) SOFT CONTACT LENSES AND LATHE-40 (POLYMACON) SOFT CONTACT LENSES (CLEAR)	OCULAR TECHNOLOGIES, INC. RALEIGH, NC 27609	UPDATED VERSION OF PRODUCTION METHODS AT BEIJING, CHINA SITE	04-25-91
P890032/S10	CORDIS ORION STEERABLE PTCA	CORDIS CORPORATION MIAMI, FL	CORDIS STEERING DEVICE	04-26-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	BALLOON CATHETER	33102-5700		
P890039/S02	MAESTRO SAVVI SYSTEM/MAESTRO MODEL 1006P PACEMAKER PROGRAMMER	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	ADDITION OF THE MAESTRO 1006P PACEMAKER PROGRAMMER	04-25-91
P890040/S2	SOF-FORM 55 (METHAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES (SPHERICAL AND TORIC)	SALVATORI OPHTHALMICS, INC. ROSWELL, GA 30076-2480	RELOCATION OF OPHTHALMICS FACILITY	04-24-91
P890043/S09	SIMPSON CORONARY ATHEROCATH/SURLYN BALLOON DEVICE	DEVICES FOR VASCULAR INTERVENTION REDWOOD CITY, CA 94063	ADDITION OF A FORWARD CUTTER LOCK TO THE SIMPSON CORONARY ATHEROCATH WITH THE SURLYN BALLOON	04-03-91
P890044/S11	BIS-45 (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR	BENTEC ENGINEERING INC. SACRAMENTO, CA 95834	MANUFACTURING AND MARKETING THE LENS IN ADDITIONAL COLORS (DARK BLUE, GRAY, GREEN, FOREST, BROWN, YELLOW AND VIOLET)	04-05-91
P890046/S08	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	IDEAL OPTICS, INC. ATLANTA, GA 30339	ADDITIONAL CONTACT LENS FINISHING LABORATORY	04-22-91
P890063/S02	GENESIS HOME UTERINE ACTIVITY	TOKOS MEDICAL CORPORATION SANTA ANA, CA	PATIENT INSTRUCTION VIDEOTAPE TO SUPPLEMENT	04-10-91

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

MONITORING SYSTEM, MODEL 100-A	92705	WRITTEN PATIENT LABELING

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR APRIL 1991.

SUPPLEMENTAL VETERINARY NADAs

134-779 03-25-91	PARATECT FLEX TRILAMINATE (CYLINDER/SHEET)	CATTLE	PFIZER NEW YORK, NY 10017	MORANTEL TARTRATE 19.8GM/UNIT (11.8GM MORANTEL BASE)
39-417 04-17-91	DECCOX (PREMIX)	CALVES (NON-RUMINATING)	RHONE POULENC MONMOUTH JUNCTION, NJ 08852	DECOQUINATE 27.2GM/LB

FDA DRUG AND DEVICE PRODUCT APPROVALS

Center for Drug Evaluation and Research
*George R. Scott (301) 443-3910

Center for Devices and Radiological Health
Mary Jo Robinson (301) 427-1186

Center for Biologics Evaluation and Research
Joseph Wilczek (301) 295-8428

Center for Veterinary Medicine
Melanie R. Berson, D.V.M.
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MAY 1991

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

19-915 05-16-91 (1 C)	MONOPRIL (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	FOSINOPRIL SODIUM 10MG 20MG (ANTIHYPERTENSIVE)
19-856 05-30-91 (3 B)	SINEMET CR (TABLET, EXTENDED RELEASE)	MSD W POINT, PA 19486	CARBIDOPA 50MG LEVODOPA 200MG (ANTIPARKINSON)

NDA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM) CLASSIFICATION(S)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-090 04-19-01	FLUCONAZOLE (SUSPENSION) (ANTIFUNGAL)	PFIZER GROTON, CT 06340	FLUCONAZOLE 10MG/ML 40MG/ML
19-952 05-01-91	HEPARIN SODIUM IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE) (ANTICOAGULANT)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 4,000 UNITS/100ML 5,000 UNITS/100ML 10,000 UNITS/100ML
19-851 05-10-91	LOTENSIN (TABLET) (ANTIHYPERTENSIVE)	CIBA SUMMIT, NJ 07901	BENAZEPRIL HYDROCHLORIDE 5MG 10MG 20MG 40MG
19-802 05-31-91	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 5,000 UNITS/100ML (ANTICOAGULANT)

NDA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

(INJECTABLE)

19-802 05-31-91	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 5,000 UNITS/100ML 10,000 UNITS/100ML (ANTICOAGULANT)
19-802 05-31-91	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 5,000 UNITS/100ML (ANTICOAGULANT)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

72-639 METOCLOPRAMIDE HCL LEDERLE METOCLOPRAMIDE HYDROCHLORIDE
05-09-91 (TABLET) PEARL RIVER, NY EQ 10MG BASE
10965 (UPPER GI TRACT
MOTILITY STIMULATOR)

72-744 METOCLOPRAMIDE HCL PHARMS ASSOC METOCLOPRAMIDE HYDROCHLORIDE
05-28-91 (SYRUP) CONESTEE, SC EQ 5MG BASE/5ML
29636 (UPPER GI TRACT
MOTILITY STIMULATOR)

63-161 TOBRAMYCIN SULFATE ABBOTT TOBRAMYCIN SULFATE
05-29-91 (INJECTABLE) ABBOTT PARK, IL EQ 40MG BASE/ML
60064 (ANTIBIOTIC, AMINOGLYCOSIDE)

73-144 CYCLOBENZAPRINE HCL MYLAN CYCLOBENZAPRINE HYDROCHLORIDE
05-31-91 (TABLET) MORGANTOWN, WV 10MG
26505 (SKELETAL MUSCLE RELAXANT)

89-797 TRIAMCINOLONE G AND W TRIAMCINOLONE ACETONIDE
05-31-91 ACETONIDE S PLAINFIELD, NJ 0.025%
(CREAM) 07080 (CORTICOSTEROID)

89-798 TRIAMCINOLONE G AND W TRIAMCINOLONE ACETONIDE
05-31-91 ACETONIDE S PLAINFIELD, NJ 0.1%
(CREAM) 07080 (CORTICOSTEROID)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-462 UNIPEN WYETH AYERST NAFCILLIN SODIUM
04-10-91 (TABLET) PHILADELPHIA, PA EQ 500MG BASE
19101 (REVISED LABELING --
DESCRIPTION; HOW SUPPLIED)

18-680 COPPER T POP COUNCIL CBR COPPER
05-03-91 MODEL TCU 380A NEW YORK, NY 309MG
(INTRAUTERINE DEVICE) 10021 (REVISED LABELING --
CONTRAINDICATIONS; WARNINGS;
CLINICAL STUDIES;
PATIENT PACKAGE INSERT)

50-182 ERYTHROCIN ABBOTT ERYTHROMYCIN LACTOBIONATE
05-03-91 LACTOBIONATE ABBOTT PARK, IL EQ 500MG BASE/VIAL
(INJECTABLE) 60064 (REVISED LABELING --
WARNINGS)

11-287 KAYEXALATE STERLING SODIUM POLYSTYRENE SULFONATE
05-07-91 (POWDER) NEW YORK, NY 453.6GM/BOT
10016 (REVISED LABELING --
LABELING FORMAT
REVISION PROGRAM)

10-679 CANTIL MERRELL DOW MEPENZOLATE BROMIDE
05-08-91 (TABLET) CINCINNATI, OH 25MG
45215 (REVISED LABELING --
LABELING FORMAT
REVISION PROGRAM)

18-381 REGULAR PURIFIED NOVO NORDISK INSULIN PURIFIED PORK
05-17-91 PORK INSULIN PRINCETON, NJ 100 UNITS/ML
(INJECTABLE) 08540 (REVISED LABELING --
PATIENT PACKAGE INSERT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

10-611	HALOTESTIN	UPJOHN	FLUOXYMESTERONE
05-20-91	(TABLET)	KALAMAZOO, MI	2MG
		49001	5MG
			10MG
			(REVISED LABELING --
			DRUG ABUSE AND DEPENDENCE)
12-209	FLUOROURACIL	ROCHE	FLUOROURACIL
05-20-91	(INJECTABLE)	NUTLEY, NJ	50MG/ML
		07110	(REVISED LABELING --
			ADVERSE REACTIONS; PRECAUTIONS)
06-035	METHERGINE	SANDOZ	METHYLERGONOVINE MALEATE
05-28-91	(INJECTABLE)	E HANOVER, NJ	0.2MG/ML
		07936	(REVISED LABELING --
			CLINICAL PHARMACOLOGY)
06-035	METHERGINE	SANDOZ	METHYLERGONOVINE MALEATE
05-28-91	(TABLET)	E HANOVER, NJ	0.2MG
		07936	(REVISED LABELING --
			CLINICAL PHARMACOLOGY)
17-362	PROGESTERONE	STERIS	PROGESTERONE
05-29-91	(INJECTABLE)	PHOENIX, AZ	50MG/ML
		85043	(REVISED LABELING --
			LABELING FORMAT
			REVISION PROGRAM;
			PATIENT PACKAGE INSERT)

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

1083	NONE	OZARKS MED CTR	PLASMA
05-02-91	(INJECTABLE)	WHITE PLAINS, MO	(TRANSFUSION)
		65775	(B)
1137	NONE	MCDONOUGH	WHOLE BLOOD
05-02-91	(INJECTABLE)	CNTY HOSP DIST	(TRANSFUSION)
		MACOMB, IL	(A&B)
		61455	
1138	NONE	BAXTER DIAGN AG	BLOOD GROUPING REAGENT
05-21-91	(NONE)	MIAMI, FL	(FURTHER MANUFACTURING)
		33172	(A&B)

LICENSE NUMBER TRADE NAME MANUFACTURER PROPER NAME
LICENSE DATE (DOSAGE FORM) (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

(A) Establishment License Issued
(B) Product License Issued

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT DEVICE APPROVALS

THERE ARE NO BIOLOGICAL PRODUCT DEVICE APPROVALS FOR MAY 1991.

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

P890061 05-02-91	VENTAK P MODEL 1600 AICD AND THE MODEL 2830 SOFTWARE MODULE	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	VENTAK P MODEL 1600 AICD AND THE MODEL 2830 SOFTWARE MODULE
P890072 05-03-91	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED) WITH AN ULTRAVIOLET LIGHT ABSORBER	PROGRESSIVE CHEMICAL RESEARCH, LTD. CALGARY, ALBERTA CANADA	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED) WITH AN ULTRAVIOLET LIGHT ABSORBER

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

N18020/S37	LENS PLUS STERILE SALINE SOLUTION PRESERVATIVE-FREE	ALLERGAN, INC. IRVINE, CA 92715	APPROVAL FOR SOLUTION TO BE USED AS A RINSING SOLUTION AFTER CLEANING AND DILUENT FOR ENZYME TABLETS WITH SILICONE ACRYLATE, FLUOROSILICONE ACRYLATE, AND POLYPERFLUOROETHER RIGID GAS PERMEABLE LENSES	05-28-91
N18073/S20	SOFT MATE DAILY CLEANING SOLUTION, SOFT MATE PS DAILY CLEANING SOLUTION AND SOFT MATE HANDS-OFF DAILY CLEANER	SOLA-BARNES-HIND SUNNYVALE, CA 94086-5200	ALTERNATE ETHYLENE OXIDE STERILIZATION CYCLE FOR THE CONTAINER-CLOSURE COMPONENTS	05-28-91
N18078/S45	SOFT MATE SALINE SOLUTION AND SOFT MATE PS SALINE SOLUTION	SOLA-BARNES-HIND SUNNYVALE, CA 94086-5200	ALTERNATE ETHYLENE OXIDE STERILIZATION CYCLE FOR THE CONTAINER-CLOSURE COMPONENTS	05-28-91
P790020/S53	PERMAFLEX NATURALS (SURFILCON A) AND PERMEAFLEX UV NATURALS (VASURFILCON A) HYDROPHILIC CONTACT LENSES FOR DAILY AND EXTENDED WEAR	COOPERVISION, INC. ROCHESTER, NY 14623	APPROVAL FOR A CONSOLIDATED PACKAGE INSERT FOR PERMAFLEX NATURALS (SURFILCON A) AND PERMAFLEX UV NATURALS (VASURFILCON A) HYDROPHILIC CONTACT LENSES	05-30-91
P790029/S20	SOFT MATE	SOLA-BARNES-HIND	ALTERNATE ETHYLENE OXIDE	

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	DISINFECTING SOLUTION	SUNNYVALE, CA 94086-5200	STERILIZATION CYCLE FOR THE CONTAINER-CLOSURE COMPONENTS	05-28-91
P800018/S15	SOFT MATE COMFORT DROPS, SOFT MATE PS COMFORT DROPS AND BARNES-HIND GAS PERMEABLE COMFORT DROPS	SOLA-BARNES-HIND SUNNYVALE, CA 94086-5200	ALTERNATE ETHYLENE OXIDE STERILIZATION CYCLE FOR THE CONTAINER-CLOSURE COMPONENTS	05-28-91
P810002/S10	ST. JUDE MEDICAL CARDIAC VALVE PROSTHESIS	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	ST. JUDE MEDICAL, INC. TO MANUFACTURE THE COMPONENTS FOR THE ST. JUDE MEDICAL PROSTHETIC HEART VALVE	05-02-91
P810017/S18	SOFT MATE WEEKLY CLEANING SOLUTIION, SOFT MATE PS WEEKLY CLEANING SOLUTION, SOFT MATE PROTEIN REMOVER SOLUTION	SOLA-BARNES-HIND SUNNYVALE, CA 94086-5200	ALTERNATE ETHYLENE OXIDE STERILIZATION CYCLE FOR THE CONTAINER-CLOSURE COMPONENTS	05-28-91
P810046/S96	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER-ACS RX ALPHA .018	ADVANCED CARDIOVASCULAR SYSTEMS, INC. SANTA CLARA, CA 95052-8167	ACS RX ALPHA .018 CORONARY DILATATION CATHETER	05-30-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CORONARY DILATATION CATHETER			
P820003/S53	VERSATRAX PACING SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFIED SPECTRAX FEEDTHROUGH: A MODIFIED IS-1 OUTER SEALING RING CONFIGURATION A REDUCTION IN THE HYBRID BASELINE TESTING REQUIREMENTS AND THE USE OF A REDUCED CURE TIME MEDICAL ADHESIVE	05-08-91
P820003/S58	VERSATRAX PACING SYSTEM-MODIFICATION TO THE FEEDTHROUGH AND ADHESION PROMOTE MATERIALS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	INTRODUCTION OF AN ALTERNATIVE FEEDTHROUGH POTTING MATERIAL AND THE USE OF A DIFFERENT ADHESION PROMOTE	05-08-91
P820053/S16	BARNES-HIND GAS PERMEABLE DAILY CLEANER AND BARNES-HIND GAS PERMEABLE WETTING AND SOAKING SOLUTION	SOLA-BARNES-HIND SUNNYVALE, CA 94086-5200	ALTERNATE ETHYLENE OXIDE STERILIZATION CYCLE FOR THE CONTAINER-CLOSURE COMPONENTS	05-28-91
P830026/S45	COSMOS PACING SYSTEM	INTERMEDICS, INC. FREEPORT, TX 77541-0617	CHANGE IN THE HEADER SYSTEM OF THE INTERMEDICS NOVA II MODEL 282-04 IMPLANTABLE PULSE	05-16-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
P830026/S46	COSMOS PACING SYSTEM	INTERMEDICS, INC. FREEPORT, TX 77541-0617	CHANGE IN THE HEADER OF THE INTERMEDICS NOVA II MODEL 282-04 IMPLANTABLE PULSE GENERATOR	05-16-91
P830033/S23	MODELS PCUB-56DO AND PCUB-32DO ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	SURGIDEV CORPORATION GOLETA, CA 93117	MODELS PCUB-56DO AND PCUB-32DO ONE-PIECE ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	05-28-91
P830034/S13	OPTI-SOFT SOLUTION, OPTI-CLEAN DAILY CLEANER AND OPTI-TEARS COMFORT DROPS, OPTI-FREE RINSING, DISINFECTING AND STORAGE SOLUTION	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO EXPAND THE INDICATION FOR THE USE OF OPTI-FREE RINSING, DISINFECTING AND STORAGE SOLUTION TO INCLUDE THERMAL (HEAT) DISINFECTION OF SOFT (HYDROPHILIC) CONTACT LENSES	05-22-91
P830060/S14	VENTAK MODEL 1550 PULSE GENERATOR	CARDIAC PACEMAKER, INC. ST. PAUL, MN	CPI DEL CARIBE, DORADO, PUERTO RICO, FOR THE	05-17-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

		55112-5798	ASSEMBLY AND TESTING OF DEVICES AND STERI-TECH, INC., SALINAS, PUERTO RICO, FOR STERILIZATION OF THE PRODUCTS	
P830060/S24	VENTAK AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	MODEL 6837 AND 6839 INDUCTION-MONITOR ASSEMBLIES AND MODEL 6871 O-RINGS	05-16-91
P840024/S31	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR POSTLINGUALLY DEAFENED ADULTS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	RAUMEDIC ADHESIVE SI 1511 AS AN ALTERNATIVE SILASTIC COATING	05-16-91
P840040/S26	HEART TRAK CORONARY BALLOON DILATATION CATHETER SYSTEM- NITECH CORONARY BALLOON DILATATION CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	NITECH CORONARY BALLOON DILATATION CATHETER	05-30-91
P840055/S22	SGP (TELEFOCON A) AND SGP II (TELEFOCON B) RIGID GAS PERMEABLE	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NU 07751	FIVE ADDITIONAL CONTACT LENS FINISHING LABORATORIES	05-06-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CONTACT LENSES (CLEAR, BLUE AND GREEN TINTED)			
P840066/S24	SOFT MATE CONSEPT-1 CLEANING AND DISINFECTING SOLUTION	SOLA-BARNES-HIND SUNNYVALE, CA 94086-5200	ALTERNATE ETHYLENE OXIDE STERILIZATION CYCLE FOR THE CONTAINER-CLOSURE COMPONENTS	05-28-91
P840068/S12	VISTA T PULSE GENERATOR AND MODEL 2046 SOFTWARE MODULE	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	CPI DEL CARIBE, DORADO, PUERTO RICO, FOR THE ASSEMBLY AND TESTING OF DEVICES AND STERI-TECH, INC., SALINAS, PUERTO RICO, FOR STERILIZATION OF THE PRODUCTS	05-17-91
P850049/S02	GIANTURCO-ROEHM BIRD'S NEST VENA CAVA FILTER	COOK INCORPORATED BLOOMINGTON, IN 47402	NEW DEDICATED LABEL FOR THE GIANTURCO-ROEHM BIRD'S NEST VENA CAVA FILTER AND A NEW SLIP-OVER CARD WHICH REMINDS THE USER THAT THE CRANK MUST BE TURNED COUNTER CLOCKWISE TO DISENGAGE THE FILTER FROM THE DETACHMENT WIRE	05-02-91
P850051/S31	VERSATRAX PACING SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFIED FEEDTHROUGH: A MODIFIED IS-1 OUTER SEALING RING CONFIGURATION A REDUCTION IN THE HYBRID BASELINE TESTING	05-08-91

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

			REQUIREMENTS AND THE USE OF A REDUCED CURE TIME MEDICAL ADHESIVE
P860008/S10 05-09-91	ARZCO OCTAPOLAR ESOPHAGEAL CARDIAC PACING AND RECORDING CATHETER AND SWITCHING PREAMPLIFIER UNIT	ARZCO MEDICAL ELECTRONICS, INC. VERNON HILLS, IL 60061	ARZCO OCTAPOLAR ESOPHAGEAL CARDIAC PACING AND RECORDING CATHETER AND SWITCHING-PREAMPLIFIER UNIT
P860047/S02 05-21-91	OCCUCOAT (2% HYDROXYPROPYL-METHYLCELLULOSE) VISCOELASTIC	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	CHANGE SITE OF STERILIZATION OF OCCUCOAT TO 1365 HAMLET AVENUE, CLEARWATER, FL 34616
P870045/S17 05-28-91	MODEL SAL2UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	INTRAOPTICS, INC. BOCA RATON, FL 33429-1710	MODEL SAL2UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES
P880027/S12 05-16-91	MICROSOFTRAC PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER-MONORAIL PICCOLINO FORTE PTCA CATHETER	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	INCLUSION OF A THICKER STIFFENING WIRE EMBEDDED IN THE PROXIMAL HUB
P880027/S15 05-21-91	MICROSOFTRAC PERCUTANEOUS TRANSLUMINAL CORONARY	SCHNEIDER (USA) INC. MINNEAPOLIS, MN 55442	OPTION FOR INCLUSION OR NON-INCLUSION OF THE FLUSHING STYLET IN THE PACKAGING AND TO REVISE

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	ANGIOPLASTY CATHETER-"17 CM" MONORAIL PICCOLINO AND MONORAIL PICCOLINO-FORTE PTCA CATHETERS		THE NON-INCLUSION FLUSHING STYLET INSTRUCTIONS FOR USE FOR ALL MODELS	
P880027/S16	MICROSOFTRAC PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER-"17 CM" MONORAIL PICCOLINO AND MONORAIL PICCOLINO-FORTE PTCA CATHETERS	SCHNEIDER (USA) INC. MINNEAPOLIS, MN 55442	ALTERNATE VENDOR FOR THE FLUSHING STYLET INCLUDED IN THE PACKAGING FOR ALL MODELS	05-21-91
P880078/S02	VH8500 VOLUMETRIC HYPERTHERMIA TREATMENT SYSTEM	COOK INCORPORATED BLOOMINGTON, IN 47402	CHANGE IN THE TESTING PROCEDURES IMPLEMENTED BY SHORTING THE THERMISTORS DURING THE CURRENT LEAKAGE TEST AND ALSO BY VERIFYING THERMISTOR READINGS ON ALL COMPLETED CATHETERS AGAINST A KNOWN TEMPERATURE READING	05-02-91
P880082/S11	RESTERILIZATION OF ULTRAVIOLET-ABSORBING	EYE TECHNOLOGY, INC. ST. PAUL, MN 55117	SINGLE RESTERILIZATION OF INTRAOCULAR LENSES IN UNOPENED TYVEK POUCHES	05-01-91

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	POSTERIOR CHAMBER INTRAOCULAR LENSES		
P890012/S02 05-28-91	SIGNATURE (NETRAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS	SOLA-BARNES-HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SITE
P890027/S02 05-16-91	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	RAUMEDIC ADHESIVE SI 1511 AS AN ALTERNATE SILASTIC COATING
P890044/S13 05-17-91	TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR	BENTEC ENGINEERING, INC. SACRAMENTO, CA 95834	CHANGES IN SPECIFICATIONS FOR THREE OF THE ADDITIONAL COLORS USED IN COLORING LENSES
P890046/S09 05-17-91	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	IDEAL OPTICS, INC. ATLANTA, GA 30339	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES
P890058/S09 05-28-91	NOVALENS (ROSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS	OCUTEC CORPORATION RALEIGH, NC 27615	10 CONTACT LENS FINISHING LABORATORIES TO BECOME ADDITIONAL MANUFACTURING AND DISTRIBUTION SITES

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	(CLEAR AND BLUE TINTED)		
P900001/S02 05-06-91	SGP 3 (UNIFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR, BLUE AND GREEN TINTED)	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NJ 07751	FOUR ADDITIONAL CONTACT LENS FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR MAY 1991.

SUPPLEMENTAL VETERINARY NADA's

46-592	BMD PREMIX	SWINE	AL LABS	BACITRACIN METHYLENE
04-29-91	(PREMIX)		FT LEE, NJ	DISALICYLATE
			07024	25GM/LB
				30GM/LB
				40GM/LB
				50GM/LB
				60GM/LB
				75GM/LB

FDA DRUG AND DEVICE PRODUCT APPROVALS

Center for Drug Evaluation and Research
*George R. Scott (301) 443-3910

Center for Devices and Radiological Health
Mary Jo Robinson (301) 427-1186

Center for Biologics Evaluation and Research
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June 1991

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

19-981 06-10-91 (3 C)	ULTRATAG (INJECTABLE) 63134	MALLINCKRODT ST LOUIS, MO N/A	TECHNETIUM TC-99M RED BLOOD CELL KIT (RADIOACTIVE DIAGNOSTIC)
07-529 06-12-91 (SUPPL)	QUINIDINE GLUCONATE (INJECTABLE) 46285	LILLY INDIANAPOLIS, IN	QUINIDINE GLUCONATE 80MG/ML (NEW INDICATION -- LIFE THREATENING PLASMODIUM FALCIPARUM MALARIA)
19-810 06-12-91 (SUPPL)	PRILOSEC (CAPSULE, DELAYED RELEASE PELLETS) 19486	MSD W POINT, PA	OMEPRAZOLE 20MG (NEW INDICATION -- SHORT-TERM TREATMENT OF ACTIVE DUODENAL ULCER)
19-757 06-17-91 (3 C)	CHIBROXIN (SOLUTION/DROPS) 19486	MSD W POINT, PA	NORFLOXACIN 0.3% (ANTIBACTERIAL)
19-851	LOTENSIN	CIBA	BENAZEPRIL HYDROCHLORIDE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

06-25-91	(TABLET)	SUMMIT, NJ	EQ 5MG BASE
(1 C)		07901	EQ 10MG BASE
			EQ 20MG BASE
			EQ 40MG BASE
			(ANTIHYPERTENSIVE)
19-938	NOVOLIN R	NOVO NORDISK	INSULIN BIOSYNTHETIC HUMAN
06-25-91	(INJECTABLE)	PRINCETON, NJ	100 UNITS/ML
(5 C)		08540	(BLOOD GLUCOSE REGULATOR)
			(OTC)
19-965	NOVOLIN L	NOVO NORDISK	INSULIN ZINC SUSP
06-25-91	(INJECTABLE)	PRINCETON, NJ	BIOSYNTHETIC HUMAN
(5 C)		08540	100 UNITS/ML
			(BLOOD GLUCOSE REGULATOR)
			(OTC)
19-991	NOVOLIN 70/30	NOVO NORDISK	INSULIN BIOSYNTHETIC HUMAN
06-25-91	(INJECTABLE)	PRINCETON, NJ	30 UNITS/ML
(5 C)		08540	INSULIN SUSP ISOPHANE
			BIOSYNTHETIC HUMAN
			70 UNITS/ML
			(BLOOD GLUCOSE REGULATOR)
			(OTC)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

19-775	MINIPRESS XL	PFIZER INC	PRAZOSIN HYDROCHLORIDE
03-01-91	(TABLET, EXTENDED RELEASE)	NEW YORK, NY 10017	2.5MG 5MG 10MG (ANTIHYPERTENSIVE)
19-664	SELDANE-D	MERRELL DOW	PSEUDOEPHEDRINE HYDROCHLORIDE
06-12-91	(TABLET, EXTENDED RELEASE)	CINCINNATI, OH 45215	120MG TERFENADINE 60MG (ANTIHISTAMINE; DECONGESTANT)
19-977	ROXANOL SR	ROXANE	MORPHINE SULFATE
06-14-91	(TABLET, EXTENDED RELEASE)	COLUMBUS, OH 43216	30MG 60MG 100MG (ANALGESIC)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

89-614	ISOETHARINE HCL	ARMOUR	ISOETHARINE HYDROCHLORIDE
06-13-91	(SOLUTION)	BLUE BELL, PA	0.062%
	19422	(BRONCHODILATOR)	
89-615	ISOETHARINE HCL	ARMOUR	ISOETHARINE HYDROCHLORIDE
06-13-91	(SOLUTION)	BLUE BELL, PA	0.125%
	19422	(BRONCHODILATOR)	
89-616	ISOETHARINE HCL	ARMOUR	ISOETHARINE HYDROCHLORIDE
06-13-91	(SOLUTION)	BLUE BELL, PA	0.167%
	19422	(BRONCHODILATOR)	
89-617	ISOETHARINE HCL	ARMOUR	ISOETHARINE HYDROCHLORIDE
06-13-91	(SOLUTION)	BLUE BELL, PA	0.2%
	19422	(BRONCHODILATOR)	
89-618	ISOETHARINE HCL	ARMOUR	ISOETHARINE HYDROCHLORIDE
06-13-91	(SOLUTION)	BLUE BELL, PA	0.25%
	19422	(BRONCHODILATOR)	
73-421	NIFEDIPINE	CHASE	NIFEDIPINE
06-19-91	(CAPSULE)	NEWARK, NJ	20MG
	07105	(CALCIUM ION INFLUX INHIBITOR)	
72-755*	LORAZEPAM INTENSOL	ROXANE	LORAZEPAM
06-28-91	(CONCENTRATE)	COLUMBUS, OH	2MG/ML
	43216	(ANXIOLYTIC)	
72-878	AMOXAPINE	GENEVA	AMOXAPINE
06-28-91	(TABLET)	BROOMFIELD, CO	100MG
	80038	(ANTIDEPRESSANT)	
72-879	AMOXAPINE	GENEVA	AMOXAPINE

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

06-28-91 (TABLET) BROOMFIELD, CO 150MG
80038 (ANTIDEPRESSANT)

* First Time Product Available Generically

72-943 AMOXAPINE GENEVA AMOXAPINE
06-28-91 (TABLET) BROOMFIELD, CO 25MG
80038 (ANTIDEPRESSANT)

72-944 AMOXAPINE GENEVA AMOXAPINE
06-28-91 (TABLET) BROOMFIELD, CO 50MG
80038 (ANTIDEPRESSANT)

81-127 HYDROXYZINE GENEVA HYDROXYZINE PAMOATE
06-28-91 PAMOATE BROOMFIELD, CO EQ 25MG HCL
(CAPSULE) 80038 (ANXIOLYTIC/ANTIPRURITIC)

81-128 HYDROXYZINE GENEVA HYDROXYZINE PAMOATE
06-28-91 PAMOATE BROOMFIELD, CO EQ 50MG HCL
(CAPSULE) 80038 (ANXIOLYTIC/ANTIPRURITIC)

81-129 HYDROXYZINE GENEVA HYDROXYZINE PAMOATE
06-28-91 PAMOATE BROOMFIELD, CO EQ 100MG HCL
(CAPSULE) 80038 (ANXIOLYTIC/ANTIPRURITIC)

81-222 ADRUCIL ADRIA FLUOROURACIL
06-28-91 (INJECTABLE) COLUMBUS, OH 50MG/ML
43216 (ANTINEOPLASTIC)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	APPROVAL DATE	(DOSAGE FORM)	STRENGTH(S)	LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-439	HYROXYPROGESTERONE CAPROATE	STERIS PHOENIX, AZ 85043	HYDROXYPROGESTERONE CAPROATE	05-14-91	(INJECTABLE)	125MG/ML 250MG/ML	(REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; HOW SUPPLIED; PATIENT PACKAGE INSERT)
02-282	INULIN AND SODIUM CHLORIDE	ISO TEX FRIENDSWOOD, TX 77546	INULIN	06-05-91	(INJECTABLE)	100MG/ML	(REVISED LABELING -- HOW SUPPLIED)
18-716	TRANDATE	GLAXO RES TRIANGLE PK, NC 27709	LABETALOL HYDROCHLORIDE	06-05-91	(TABLET)	100MG 200MG 300MG	(REVISED LABELING -- CONTRAINDICATIONS; ADVERSE REACTIONS)
19-174	TRANDATE HCT	GLAXO RES TRIANGLE PK, NC 27709	HYDROCHLOROTHIAZIDE LABETALOL HYDROCHLORIDE	06-05-91	(TABLET)	25MG 100MG	(REVISED LABELING -- CONTRAINDICATIONS; ADVERSE REACTIONS)
19-174	TRANDATE HCT	GLAXO RES TRIANGLE PK, NC 27709	HYDROCHLOROTHIAZIDE LABETALOL HYDROCHLORIDE	06-05-91	(TABLET)	25MG 200MG	(REVISED LABELING --

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	APPROVAL DATE	(DOSAGE FORM)	STRENGTH(S)	LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs							
							CONTRAINDICATIONS; ADVERSE REACTIONS)
19-174	TRANDATE HCT	GLAXO	HYDROCHLOROTHIAZIDE	06-05-91	(TABLET)	RES TRIANGLE PK, NC 27709	25MG LABETALOL HYDROCHLORIDE 300MG (REVISED LABELING -- CONTRAINDICATIONS; ADVERSE REACTIONS)
19-425	TRANDATE	GLAXO	LABETALOL HYDROCHLORIDE	06-05-91	(INJECTABLE)	RES TRIANGLE PK, NC 27709	5MG/ML (REVISED LABELING -- CONTRAINDICATIONS; ADVERSE REACTIONS)
19-817	IV PERSANTINE	BOEHRINGER INGELHEIM	DIPYRIDAMOLE	06-05-91	(INJECTABLE)	RIDGEFIELD, CT 06877	5MG/ML (REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-614	VERELAN	ELAN	VERAPAMIL HYDROCHLORIDE	06-06-91	(CAPSULE, EXTENDED RELEASE)	GAINSVILLE, GA 30501	120MG 240MG (REVISED LABELING -- ADVERSE REACTIONS)
17-638	THYPINONE	ABBOTT	PROTIRELIN	06-07-91	(INJECTABLE)	ABBOTT PARK, IL	0.5MG/ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		60064	(REVISED LABELING -- ADVERSE REACTIONS; PRECAUTIONS)
19-687	LUTREPULSE	RW JOHNSON	GONADORELIN ACETATE
06-10-91	PUMP KIT (INJECTABLE)	RARITAN, NJ 08869	0.8MG/VIAL 3.2MG/VIAL (REVISED LABELING -- PRECAUTIONS)
50-573	SANDIMMUNE	SANDOZ	CYCLOSPORINE
06-10-91	(INJECTABLE)	E HANOVER, NJ 07936	50MG/ML (REVISED LABELING -- BOXED WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
50-574	SANDIMMUNE	SANDOZ	CYCLOSPORINE
06-10-91	(SOLUTION)	E HANOVER, NJ 07936	100MG/ML (REVISED LABELING -- BOXED WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
50-625	SANDIMMUNE	SANDOZ	CYCLOSPORINE
06-10-91	(CAPSULE)	E HANOVER, NJ 07936	25MG 100MG (REVISED LABELING -- BOXED WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
50-639	CLEOCIN PHOSPHATE	UPJOHN	CLINDAMYCIN PHOSPHATE
06-11-91	IN DEXTROSE 5% IN PLASTIC	KALAMAZOO, MI 49001	EQ 6MG BASE/ML EQ 12MG BASE/ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

	CONTAINER		(REVISED LABELING --
	(INJECTABLE)		DOSAGE AND ADMINISTRATION)
07-529	QUINIDINE	LILLY	QUINIDINE GLUCONATE
06-12-91	GLUCONATE	INDIANAPOLIS, IN	80MG/ML
	(INJECTABLE)	46285	(REVISED LABELING --
			INDICATIONS AND USAGE)
19-667	SANDOSTATIN	SANDOZ	OCTREOTIDE ACETATE
06-12-91	(INJECTABLE)	E HANOVER, NJ	EQ 50UGM BASE/ML
		07936	EQ 100UGM BASE/ML
			EQ 500UGM BASE/ML
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
19-758	CLOZARIL	SANDOZ	CLOZAPINE
06-12-91	(TABLET)	E HANOVER, NJ	25MG
		07936	100MG
			(REVISED LABELING --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			CONTRAINDICATIONS; WARNINGS;
			PRECAUTIONS; ADVERSE REACTIONS;
			DRUG ABUSE AND DEPENDENCE;
			OVERDOSAGE;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
19-810	PRILOSEC	MSD	OMEPRAZOLE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	APPROVAL DATE	(DOSAGE FORM)	STRENGTH(S)	LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs							
06-12-91	(CAPSULE, DELAYED RELEASE PELLETS)	W POINT, PA 19486	20MG				(REVISED LABELING -- INDICATIONS AND USAGE)
18-602	CARDIZEM	MARION MERRELL DOW	DILTIAZEM HYDROCHLORIDE				
06-13-91	(TABLET)	KANSAS CITY, MO 64137	30MG 60MG 90MG 120MG				(REVISED LABELING -- ADVERSE REACTIONS; OVERDOSAGE OR EXAGGERATED RESPONSE)
19-471	CARDIZEM SR	MARION MERRELL DOW	DILTIAZEM HYDROCHLORIDE				
06-13-91	(CAPSULE, EXTENED RELEASE)	KANSAS CITY, MO 64137	60MG 90MG 120MG				(REVISED LABELING -- ADVERSE REACTIONS; OVERDOSAGE OR EXAGGERATED RESPONSE)
17-563	COLESTID	UPJOHN	COLESTIPOL HYDROCHLORIDE				
06-17-91	(GRANULE)	KALAMAZOO, MI 49001	5GM/PACKET 500GM/BOT				(REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

07-517	TAPAZOLE	LILLY	METHIMAZOLE
06-20-91	(TABLET)	INDIANAPOLIS, IN	5MG
	46285		10MG
		(REVISED LABELING -- WARNINGS)	
12-703	ELAVIL	MSD	AMITRIPTYLINE HYDROCHLORIDE
06-24-91	(TABLET)	W POINT, PA	10MG
	19486		25MG
			50MG
			75MG
			100MG
			150MG
		(REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; HOW SUPPLIED)	
12-704	ELAVIL	MSD	AMITRIPTYLINE HYDROCHLORIDE
06-24-91	(INJECTABLE)	W POINT, PA	10MG/ML
	19486	(REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; HOW SUPPLIED)	
18-644	WELLBUTRIN	BURROUGHS WELLC	BUPROPION HYDROCHLORIDE
06-24-91	(TABLET)	RES TRIANGLE PK, NC	75MG
	27709		100MG
		(REVISED LABELING -- DESCRIPTION; WARNINGS; ADVERSE REACTIONS; HOW SUPPLIED)	
10-104	MEPHYTON	MSD	PHYTONADIONE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

06-28-91	(TABLET)	W POINT, PA	5MG
	19486	(REVISED LABELING -- CLINICAL PHARMACOLOGY)	

11-751	PROLIXIN	SQUIBB	FLUPHENAZINE HYDROCHLORIDE
06-28-91	(TABLET)	NEW BRUNSWICK, NJ	1MG
	08903		2.5MG
			5MG
			10MG
		(REVISED LABELING -- DESCRIPTION)	

12-223	AQUAMEPHYTON	MSD	PHYTONADIONE
06-28-91	(INJECTABLE)	W POINT, PA	2MG/ML
	19486		10MG/ML
		(REVISED LABELING -- CLINICAL PHARMACOLOGY)	

LICENSE NUMBER TRADE NAME MANUFACTURER PROPER NAME
LICENSE DATE (DOSAGE FORM) (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

1139 NONE BOGALUSA PLASMA SOURCE PLASMA
06-18-91 (INJECTABLE) PINE BLUFF, AR (FURTHER MANUFACTURING)
71611 (A&B)

454 NONE HCSC BLOOD CTR PLATELETS
06-21-91 (INJECTABLE) BETHLEHEM, PA (TRANSFUSION)
18018 (B)

1140 NONE TEXARKANA PLASMA CTR SOURCE PLASMA
06-21-91 (INJECTABLE) PINE BLUFF, AR (FURTHER MANUFACTURING)
71611 (A&B)

1141 NONE HEMACARE FRESH FROZEN PLASMA
06-21-91 (INJECTABLE) SHERMAN OAKS, CA (TRANSFUSION)
91403 (B)

1141 NONE HEMACARE PLASMA
06-21-91 (INJECTABLE) SHERMAN OAKS, CA (TRANSFUSION)
91403 (B)

1141 NONE HEMACARE PLATELETS
06-21-91 (INJECTABLE) SHERMAN OAKS, CA (TRANSFUSION)
91403 (B)

1141 NONE HEMACARE RED BLOOD CELLS
06-21-91 (INJECTABLE) SHERMAN OAKS, CA (TRANSFUSION)
91403 (B)

1141 NONE HEMACARE THERAPEUTIC EXCHANGE PLASMA
06-21-91 (NONE) SHERMAN OAKS, CA (FURTHER MANUFACTURING)
91403 (B)

1141 NONE HEMACARE WHOLE BLOOD
06-21-91 (INJECTABLE) SHERMAN OAKS, CA (TRANSFUSION)

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT LICENSES ISSUED

91403		(B)	

(A) Establishment License Issued
(B) Product License Issued

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK890015	BLOOD SCREENING	BLACKHAWK BIOSYS	BLOOD SCREENING DIAGNOSTIC
06-04-91	DIAGNOSTIC SERUM CONTROLS	SAN RAMON, CA 94583 (C)	SERUM CONTROLS
BK900016	CLOSED SYSTEM	BAXTER HLTHCARE	EMPTY CONTAINER FOR
06-07-91	APHERESIS KIT CS-3000 BLOOD CELL SEPARATOR	ROUNDLAKE, IL 60073 (C)	COLLECTION AND PROCESSING OF BLOOD AND BLOOD COMPONENTS
BK900025	SEBRA	ENGINEERING RES	BLOOD BANK SUPPLIES
06-26-91	MODEL #2470 MOBILE TUBE SEALER	TUCSON, AZ 85716	(C)
BK900026	SEBRA	ENGINEERING RES	BLOOD MIXING AND
06-26-91	MODEL #1040 DIGITAL BLOOD SHAKER WEIGHT MONITOR	TUCSON, AZ 85716 (C)	WEIGHING DEVICES
BK900029	SEBRA	ENGINEERING RES	BLOOD BANK SUPPLIES
06-26-91	MODEL #2390 MOBILE TUBE SEALER	TUCSON, AZ 85716	(C)

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

P880085	MODEL 405	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MODEL 405 ANTERIOR CHAMBER INTRAOCULAR LENS	06-27-91 ANTERIOR CHAMBER INTRAOCULAR LENS
P900016	MIRA-FLO STARCH	A.E. STALEY MANUFACTURING COMPANY DECATUR, IL 62525	MIRA-FLO STARCH (BIOLOGICALLY ABSORBABLE DUSTING POWDER)	06-17-91
P900050	ACCESS MOBILITY SYSTEM	QUEST TECHNOLOGIES CORPORATION SUNNYVALE, CA 94086-9716	ACCESS MOBILITY SYSTEM	06-27-91 SYSTEM

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
N18120/S27	POLYCON II (SILAFOCON A) TORIC	SOLA-BARNES-HIND, INC. SUNNYVALE, CA 94086-5200	NEW LOCATION, 6416 PARKLAND DRIVE, SARASOTA, FL 34243 AS AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE FOR CONTACT LENSES	06-24-91
N18466/S11	CMW-1 RADIOPAQUE BONE CEMENT, HALF/SIZE PACKAGE	DENTSPLY INTERNATIONAL YORK, PA 17405-0872	CMW-1 RADIOPAQUE BONE CEMENT FOR USE IN A HALF PACK	06-04-91
P800022/S22	ZYDERM I IMPLANT, ZYDERM II IMPLANT, ZYPLAST IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3334	SANTOPRENE RUBBER ELASTOMERIC CLOSURE CAP FOR THE SYRINGES CONTAINING ZYDERM I, ZYDERM II, AND ZYPLAST	06-07-91
P810046/S103	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS, INC. SANTA CLARA, CA 95052-8167	ACS SPECTRUM CORONARY DILATATION CATHETER, PREVIOUSLY CALLED THE ACS HP CORONARY DILATATION SPECTRUM CORONARY DILATATION CATHETER	06-25-91
P810046/S98	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS, INC. SANTA CLARA, CA 95052-8167	ACS RX ALPHA .010 CORONARY DILATATION CATHETER-ACS RX ALPHA .010 CORONARY DILATATION CATHETER	06-27-91
P810046/S99	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETERS- MICRO XT, MICRO 600, MICRO 600S, MICRO II, ULTRA-LOW PROFILE II, TEN (.010) CORONARY DILATATION CATHETERS	ADVANCED CARDIOVASCULAR SYSTEMS, INC. TEMECULA, CA 92390-1856	ADDITION OF A HYDROPHILIC MATERIAL TO THE SELF-VENT OF THE HARTZLER MICRO, MODIFICATION OF THE SELF-VENT ACX, ACX II, SIMPSON PINKERTON-.018, AND ACS	06-17-91
P820040/S27	AOSEPT DISINFECTION- STERILIZATION FOR THE	CIBA VISION CORPORATION ATLANTA, GA 30360	USE OF GAMMA IRRADIATION AS AN ALTERNATE METHOD OF NEUTRALIZATION SOLUTION, LENSEPT PLASTIC COMPONENTS OF	06-03-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	DISINFECTION SOLUTION CONTAINERS AT NEUTRALIZING AND	AOSEPT AND LENSEPT LENSEPT CROWN COURT, WHITBY, ONTARIO LIN 7B1	SOLUTION, AND ISOMEDIX CORPORATION, 184 RINSING/STORAGE SOLUTION	
P820049/S51	MODEL PC-36CNB ULTRAVIOLET- INTRAOCULAR LENS	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	MODEL PC-36CNB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	06-20-91 ABSORBING
P820076/S12	PMS-600 PROGRAMMER	BIOTRONIK, INC. LAKE OSWEGO, OR 97035-5369	REVISION TO THE PMS-600 PROGRAMMER TECHNICAL MANUAL	06-17-91
P830056/S70	MODELS C41OH, C410F, AND U210F5 ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER	OPTICAL RADIATION CORPORATION AZUSA, CA 91702	MODELS C410H, C410F, C410F5, AND U210F5 ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	06-12-91 C410F5
P850002/S06	ALGES (HEFILCON A) (HYDROPHILIC)	UNILENS CORPORATION LARGO, FL 34647-1511	DESIGN MODIFICATION TO INCORPORATE A CONCENTRIC ASPHERIC TRANSITION ZONE	06-12-91 SOFT BIFOCAL CONTACT LENS
P850007/S12	PHYSIO/STIM, PHYSIO/STIM	AMERICAN MEDICAL ELECTRONICS, INC. RICHARDSON, TX 75081	NEW LIGHTWEIGHT MODEL 215 TREATMENT TRANSDUCER DESIGNED TO CONFORM TO THE HIP	06-27-91 MODEL 215 TREATMENT TRANSDUCER
P850055/S06	MIRAFLOW EXTRA STRENGTH CLEANER	CIBA VISION CORPORATION ATLANTA, GA 30360	USE OF GAMMA IRRADIATION AS AN ALTERNATE METHOD OF STERILIZATION FOR THE MIRAFLOW SOLUTION CONTAINER AT ISOMEDIX CORPORATION, 184 CROWN	06-03-91 PLASTIC COMPONENTS OF THE

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

		COURT, WHITBY, ONTARIO	LIN 7B1	
P860004/S17	MEDTRONIC SYNCHROMED INFUSION SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	SYNCHROMED INFUSION SYSTEM WITH SUTURE-LOOPS ATTACHED AS AN ANCHORING METHOD	06-26-91
P870024/S25	FLUOROPERM 92 (PAFLUFOCON A), AND TO EXTEND THE AND FLUOROPERM 30 (PAFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS	PARAGON OPTICAL, INC. MESA, AZ 85204	PROTOCOL FOR THE FUTURE EXTENSION OF SHELF-LIFE (PAFLUFOCON B), FLUOROPERM 92 FLUOROPERM 60 (PAFLUFOCON B) AND FLUOROPERM 30 (PAFLUFOCON C) RIGID GAS PERMEABLE CONTACT LENS	06-28-91 FLUOROPERM 60 SHELF-LIFE OF (PAFLUFOCON C) (CLEAR AND TINTED)
P870071/S06	LASTAC SYSTEM	GV MEDICAL, INC. MINNEAPOLIS, MN 55447	CHANGES TO THE LASER ENHANCEMENT FIBER (LEF) MEMBER OF THE GV MEDICAL LASTAC SYSTEM, SPECIFICALLY REPLACING LEF II MODELS WITH LEF III MODELS	06-25-91
P880027/S18	MICROSOFTRAC PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER, MONORAIL PICCOLINO FORTE CATHETER	SCHNEIDER (USA), INC. PLYMOUTH, MN 55442	CHANGE OF THE DEVICE NAME ON THE CATHETER HUB, AN EDITORIAL CHANGE TO THE LABELING, AND PLACEMENT OF A SMALL PLASTIC PIECE IN THE MOLDED PETG TRAY TO BETTER POSITION THE PTCA CATHETERS IN THE TRAY	06-13-91
P880072/S18	MODEL PL70C-OUV	DGR, INC.	MODEL PL70C-OUV	06-04-91 ULTRAVIOLET-

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	ST. PETERSBURG, FL	ULTRAVIOLET-ABSORBING	ABSORBING	33716
POSTERIOR CHAMBER		POSTERIOR CHAMBER	INTRAOCULAR LENS	
INTRAOCULAR LENS				
P880076/S01	WHITESIDE TOTAL	DOW CORNING WRIGHT	EXTENSION OF THE POROUS	06-17-91
HIP SYSTEM	ARLINGTON, TN	COATING TO THE DISTAL TIP	38002	
OF THE LATERAL FIN ON THE		FEMORAL COMPONENT AND A		
CHANGE OF THE TRADE NAME		OF THE MODIFIED		
FEMORAL		COMPONENT TO EPS FEMORAL		
HIP PROSTHESIS				
P880080/S04	DYNASOL 4	STERIDYNE LABORATORIES, INC.	EXTENDING THE DISCARD	06-20-91
PRESERVATIVE-FREE	HOLLYWOOD, CA	DATE FROM 15 TO 30 DAYS	SALINE SOLUTION	90068
P880086/S09	SYNCHRONY CARDIAC	PACESETTER SYSTEMS, INC.	SOLUS MODEL 2002L AND THE	06-26-91
PACING SYSTEM	SYLMAR, CA	SYNCHRONY II MODEL 2022L	91342	
PULSE GENERATORS				
P890001/S04	LEOCOR	LEOCOR, INC.	LEOCOR CORFLO PTCA	06-12-91
PERCUTANEOUS	HOUSTON, TX	CATHETER, MODEL 7.5PT	TRANSLUMINAL	77058
CORONARY ANGIOPLASTY				
CATHETER, MODEL 5S				
P890043/S04	SIMPSON CORONARY	DEVICES FOR VASCULAR	NEW MANUFACTURING	06-12-91
ATHEROCATH	INTERVENTION	FACILITY, DEVICES FOR	REDWOOD CITY, CA	
VASCULAR INTERVENTION,		94063	INC., 26201A YNEZROAD,	
TEMECULA, CALIFORNIA			92390	
P890046/S10	0-> PERM F60	IDEAL OPTICS, INC.	FOUR ADDITIONAL CONTACT	06-04-91
(OXYFLUFOCON A)	ATLANTA, GA	LENS FINISHING	RIGID GAS PERMEABLE	30339
LABORATORIES		CONTACT LENS		
(CLEAR AND TINTED)				

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890057/S01	MODELS 3100 AND 3100A HIGH FREQUENCY OSCILLATORY VENTILATOR (HFOV)	SENSORMEDICS CORPORATION YORBA LINDA, CA 92687	DESIGN CHANGES TO THE CONTROLS, THE NUMERIC READOUTS, THE PATIENT CIRCUIT, AND THE OSCILLATOR	06-27-91

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR JUNE 1991.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR JUNE 1991.

FDA DRUG AND DEVICE PRODUCT APPROVALS

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This report is compiled by the Division of Drug Information Resources, OM, CDER. It is available by subscription from the National Technical Information Service, Springfield, VA 22161.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

19-959 NOVOLIN N NOVO NORDISK INSULIN SUSP ISOPHANE
07-01-91 (INJECTABLE) PRINCETON, NJ BIOSYNTHETIC HUMAN
(5 C) 08540 100 UNITS/ML
(BLOOD GLUCOSE REGULATOR)
(OTC)

20-032 SURVANTA ROSS BERACTANT
07-01-91 (SUSPENSION) COLUMBUS, OH 25MG/ML
(1 C, V*) 43215 (SYNTHETIC LUNG SURFACTANT)
[PREVENTION AND TREATMENT OF
RESPIRATORY DISTRESS SYNDROME
IN PREMATURE INFANTS]

20-047 DEXTROSE 50% BAXTER DEXTROSE
07-02-91 IN PLASTIC CONTAINER ROUND LAKE, IL 50GM/100ML
(5 C) (INJECTABLE) 60073 (FLUID AND NUTRIENT
REPLENISHER)

20-047 DEXTROSE 60% BAXTER DEXTROSE
07-02-91 IN PLASTIC CONTAINER ROUND LAKE, IL 60GM/100ML
(5 C) (INJECTABLE) 60073 (FLUID AND NUTRIENT
REPLENISHER)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-047	DEXTROSE 70%	BAXTER	DEXTROSE
07-02-91	IN PLASTIC CONTAINER	ROUND LAKE, IL	70GM/100ML
(5 C)	(INJECTABLE)	60073	(FLUID AND NUTRIENT REPLENISHER)

V* - Designated Orphan Drug

19-880	PARAPLATIN	BRISTOL MYERS SQUIBB	CARBOPLATIN
07-05-91	(INJECTABLE)	WALLINGFORD, CT	50MG/VIAL
(SUPPL)		06492	150MG/VIAL
			450MG/VIAL
			(NEW INDICATION -- INITIAL TREATMENT OF ADVANCED OVARIAN CARCINOMA IN COMBINATION WITH OTHER APPROVED CHEMOTHERAPEUTIC AGENTS)

19-798	NASACORT	RHONE POULENC RORER	TRIAMCINOLONE ACETONIDE
07-11-91	(AEROSOL, METERED)	FT WASHINGTON, PA	55UGM/INH
(3 C)		19034	(CORTICOSTEROID)

19-565	INFUMORPH	ELKINS SINN	MORPHINE SULFATE
07-19-91	(INJECTABLE)	CHERRY HILL, NJ	10MG/ML
(SUPPL, V*)		08003	25MG/ML
			(NEW STRENGTHS)

19-565	INFUMORPH	ELKINS SINN	MORPHINE SULFATE
07-19-91	(INJECTABLE)	CHERRY HILL, NJ	10MG/ML
(SUPPL, V*)		08003	25MG/ML
			(NEW INDICATION -- FOR USE IN MICROINFUSION

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

DEVICES FOR INTRASPINAL
ADMINISTRATION IN THE
TREATMENT OF INTRACTABLE
CHRONIC PAIN)

19-508	AXID	LILLY	NIZATIDINE
07-26-91	(CAPSULE)	INDIANAPOLIS, IN	150MG
(SUPPL)		46285	300MG
		(NEW INDICATION --	
		ENDOSCOPICALLY DIAGNOSED	
		ESOPHAGITIS, INCLUDING	
		EROSIVE AND	
		ULCERATIVE ESOPHAGITIS, AND	
		ASSOCIATED HEARTBURN DUE TO	
GASTROESOPHAGEAL REFLUX			
		DISEASE)	

V* - Designated Orphan Drug

19-834	PLENDIL	MSD	FELODIPINE
07-26-91	(TABLET,	W POINT, PA	5MG
(1 C)	EXTENDED RELEASE)	19486	10MG
		(CALCIUM ION INFLUX	
		INHIBITOR)	
		[HYPERTENSION]	

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

19-834 PLENDIL MSD FELODIPINE
07-08-91 (TABLET, W POINT, PA 5MG
EXTENDED RELEASE) 19486 10MG
(CALCIUM ION INFLUX INHIBITOR)
[HYPERTENSION]

20-064 MACROBID NORWICH EATON NITROFURANTOIN
07-30-91 (CAPSULE, NORWICH, NY 100MG
EXTENDED RELEASE) 13815 (ANTI-INFECTIVE)

19-962 METOPROLOL AB HASSLE METOPROLOL SUCCINATE
07-31-91 SUCCINATE MOLNDAL, SWEDEN 50MG
(TABLET, 07033 100MG
EXTENDED RELEASE) 200MG
(BETA ADRENERGIC BLOCKER)

20-010 LOTRISONE SCHERING BETAMETHASONE DIPROPIONATE
07-31-91 (LOTION) KENILWORTH, NJ 0.05%
07033 CLOTRIMAZOLE
1%
(CORTICOSTEROID; ANTIFUNGAL)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

APPROVABLE ORIGINAL NDAs

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

89-582*	ORTHO-EST	JOHNSON RW	ESTROPIPATE
07-17-91	(TABLET)	RARITAN, NJ	1.5MG
		08869	(ESTROGEN)
73-334	AMILORIDE HCL AND	ROYCE	AMILORIDE HYDROCHLORIDE
07-19-91	HYDROCHLOROTHIAZIDE	MIAMI, FL	5MG
	(TABLET)	33014	HYDROCHLOROTHIAZIDE
			50MG
			(DIURETIC)
72-600	CLOFIBRATE	NOVOPHARM	CLOFIBRATE
07-25-91	(CAPSULE)	SCARBOROUGH	500MG
		ONTARIO, CANADA	(ANTIHYPERLIPIDEMIC)
63-118	TOBRAMYCIN SULFATE	LEDERLE	TOBRAMYCIN SULFATE
07-29-91	(INJECTABLE)	CAROLINA, PR	EQ 40MG BASE/ML
		00630	(ANTIBIOTIC, AMINOGLYCOSIDE)
81-019	CHLORZOXAZONE	DANBURY	CHLORZOXAZONE
07-29-91	(TABLET)	DANBURY, CT	500MG
		06813	(SKELETAL MUSCLE RELAXANT)
63-082	CLINDAMYCIN HCL	DANBURY	CLINDAMYCIN HYDROCHLORIDE
07-31-91	(CAPSULE)	DANBURY, CT	EQ 75MG BASE
		06813	(ANTIBIOTIC, LINCOMYCIN)
63-083	CLINDAMYCIN HCL	DANBURY	CLINDAMYCIN HYDROCHLORIDE
07-31-91	(CAPSULE)	DANBURY, CT	EQ 150MG BASE
		06813	(ANTIBIOTIC, LINCOMYCIN)
71-716	FLURAZEPAM HCL	GENEVA	FLURAZEPAM HYDROCHLORIDE
07-31-91	(CAPSULE)	BROOMFIELD, CO	15MG
		80038	(SEDATIVE, HYPNOTIC)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

71-717	FLURAZEPAM HCL	GENEVA	FLURAZEPAM HYDROCHLORIDE
07-31-91	(CAPSULE)	BROOMFIELD, CO 80038	30MG (SEDATIVE, HYPNOTIC)

* First Time Product Available Generically

72-917	TIMOLOL MALEATE	DANBURY	TIMOLOL MALEATE
07-31-91	(TABLET)	DANBURY, CT 06813	5MG (BETA ADRENERGIC BLOCKER)

72-918	TIMOLOL MALEATE	DANBURY	TIMOLOL MALEATE
07-31-91	(TABLET)	DANBURY, CT 06813	10MG (BETA ADRENERGIC BLOCKER)

72-919	TIMOLOL MALEATE	DANBURY	TIMOLOL MALEATE
07-31-91	(TABLET)	DANBURY, CT 06813	20MG (BETA ADRENERGIC BLOCKER)

72-996	INDOMETHACIN	DANBURY	INDOMETHACIN
07-31-91	(CAPSULE)	DANBURY, CT 06813	25MG (NONSTEROIDAL ANTI-INFLAMMATORY)

72-997	INDOMETHACIN	DANBURY	INDOMETHACIN
07-31-91	(CAPSULE)	DANBURY, CT 06813	50MG (NONSTEROIDAL ANTI-INFLAMMATORY)

73-191	TRIAMTERENE AND HYDROCHLOROTHIAZIDE	GENEVA	HYDROCHLOROTHIAZIDE
07-31-91	(CAPSULE)	BROOMFIELD, CO 80038	25MG TRIAMTERENE 50MG (DIURETIC)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

81-165	HYDROXYZINE PAMOATE	DANBURY	HYDROXYZINE PAMOATE
07-31-91	(CAPSULE)	DANBURY, CT	EQ 25MG HCL
		06813	(ANXIOLYTIC/ANTIPRURITIC)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

11-793	ESIDRIX	CIBA	HYDROCHLOROTHIAZIDE
06-05-91	(TABLET)	SUMMIT, NJ	25MG
		07901	50MG
			100MG
			(REVISED LABELING --
			ADVERSE REACTIONS;
			HOW SUPPLIED)
17-447	NORPACE	SEARLE	DISOPYRAMIDE PHOSPHATE
07-03-91	(CAPSULE)	SKOKIE, IL	EQ 100MG BASE
		60077	EQ 150MG BASE
			(REVISED LABELING --
			INDICATIONS AND USAGE; WARNINGS)
18-537	TRIDIL	DUPONT MERCK	NITROGLYCERIN
07-03-91	(INJECTABLE)	WILMINGTON, DE	0.5MG/ML
		19880	5MG/ML
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			CONTRAINDICATIONS; PRECAUTIONS;
			ADVERSE REACTIONS; OVERDOSAGE)
18-655	NORPACE CR	SEARLE	DISOPYRAMIDE PHOSPHATE
07-03-91	(CAPSULE,	SKOKIE, IL	EQ 100MG BASE
	EXTENDED RELEASE)	60077	EQ 150MG BASE
			(REVISED LABELING --
			INDICATIONS AND USAGE; WARNINGS)
19-368	MOCTANIN	ETHITEK	MONOCTANOIN
07-03-91	(LIQUID)	SKOKIE, IL	100%
		60077	(REVISED LABELING --
			CONTRAINDICATIONS; WARNINGS;
			ADVERSE REACTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	APPROVAL DATE	(DOSAGE FORM)	STRENGTH(S)	LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-880	PARAPLATIN	BRISTOL MYERS SQUIBB	CARBOPLATIN	07-05-91	(INJECTABLE)	WALLINGFORD, CT 06492	50MG/VIAL 150MG/VIAL 450MG/VIAL (REVISED LABELING -- INDICATIONS AND USAGE)
09-386	MYLERAN	BURROUGHS WELLC	BUSULFAN	07-15-91	(TABLET)	RES TRIANGLE PK, NC 27709	2MG (REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
12-429	TABLOID	BURROUGHS WELLC	THIOGUANINE	07-15-91	(TABLET)	RES TRIANGLE PK, NC 27709	40MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
11-316	TEMARIL	HERBERT	TRIMEPRAZINE TARTRATE	07-22-91	(TABLET, EXTENDED RELEASE)	IRVINE, CA 92715	EQ 2.5MG BASE (REVISED LABELING -- LABELING FORMAT REVISION PROGRAM)
11-316	TEMARIL	HERBERT	TRIMEPRAZINE TARTRATE	07-22-91	(SYRUP)	IRVINE, CA	EQ 2.5MG BASE/5ML

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

92715 (REVISED LABELING --
LABELING FORMAT REVISION
PROGRAM)

11-316 TEMARIL HERBERT TRIMEPRAZINE TARTRATE
07-22-91 (CAPSULE) IRVINE, CA EQ 5MG BASE
92715 (REVISED LABELING --
LABELING FORMAT REVISION
PROGRAM)

05-264 HEPARIN SODIUM ABBOTT HEPARIN SODIUM
07-24-91 (INJECTABLE) ABBOTT PARK, IL 10 UNITS/ML
60064 100 UNITS/ML
(REVISED LABELING --
PRECAUTIONS)

18-911 HEPARIN SODIUM ABBOTT HEPARIN SODIUM
07-24-91 10,000 UNITS IN ABBOTT PARK, IL 10,000 UNITS/100ML
DEXTROSE 5% 60064 (REVISED LABELING --
(INJECTABLE) PRECAUTIONS)

18-911 HEPARIN SODIUM ABBOTT HEPARIN SODIUM
07-24-91 12,500 UNITS IN ABBOTT PARK, IL 5,000 UNITS/100ML
DEXTROSE 5% 60064 (REVISED LABELING --
(INJECTABLE) PRECAUTIONS)

18-911 HEPARIN SODIUM ABBOTT HEPARIN SODIUM
07-24-91 25,000 UNITS IN ABBOTT PARK, IL 10,000 UNITS/100ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	APPROVAL DATE	(DOSAGE FORM)	STRENGTH(S)	LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

	DEXTROSE 5% (INJECTABLE)	60064	(REVISED LABELING -- PRECAUTIONS)				
18-911 07-24-91	HEPARIN SODIUM 25,000 UNITS IN DEXTROSE 5% (INJECTABLE)	ABBOTT ABBOTT PARK, IL 60064	HEPARIN SODIUM 5,000 UNITS/100ML (REVISED LABELING -- PRECAUTIONS)				
17-015 07-25-91	PAVULON (INJECTABLE)	ORGANON W ORANGE, NJ 07052	PANCURONIUM BROMIDE 1MG/ML 2MG/ML (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)				
19-508 07-26-91	AXID (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	NIZATIDINE 150MG 300MG	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)			
18-735 07-29-91	ISOVUE-M 200 (INJECTABLE)	SQUIBB PRINCETON, NJ 08543	IOPAMIDOL 41% (REVISED LABELING -- ADVERSE REACTIONS)				
18-735 07-29-91	ISOVUE-M 300 (INJECTABLE)	SQUIBB PRINCETON, NJ 08543	IOPAMIDOL 61% (REVISED LABELING -- ADVERSE REACTIONS)				

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-268	CYTOTEC	SEARLE	MISOPROSTOL
07-29-91	(TABLET)	SKOKIE, IL	0.1MG
		60077	0.2MG
		(REVISED LABELING -- ADVERSE REACTIONS)	
18-587	WYTENSIN	WYETH AYERST	GUANABENZ ACETATE
07-31-91	(TABLET)	PHILADELPHIA, PA	EQ 4MG BASE
		19101	EQ 8MG BASE
		(REVISED LABELING -- ADVERSE REACTIONS)	
18-731	BUSPAR	BRISTOL	BUSPIRONE HYDROCHLORIDE
07-31-91	(TABLET)	SYRACUSE, NY	5MG
		13221	10MG
		(REVISED LABELING -- INDICATIONS AND USAGE)	

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT LICENSES ISSUED

THERE ARE NO BIOLOGICAL PRODUCT LICENSE APPROVALS FOR JULY 1991.

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT DEVICE APPROVALS

THERE ARE NO BIOLOGICAL PRODUCT DEVICE APPROVALS FOR JULY 1991.

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

THERE ARE NO PREMARKET APPROVAL APPLICATIONS FOR JULY 1991.

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P810055/S50	MODEL 722D ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	KABI PHARMACIA OPHTHALMICS, INC. MONROVIA, CA 91017-7136	MODEL 722D ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	07-03-91
P820018/S50	AUTIMA PACING SYSTEM	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	CHANGE THE TRAY MATERIAL FROM PVC TO PETG AND MODIFY THE DEVICE SPECIFICATION TO REQUIRE PIND ON AN ASSURANCE QUALITY LEVEL (AQL) BASIS AND DELETE THERMAL SHOCK TESTING	07-31-91
P820076/S10	DIPLOS CARDIAC PACING SYSTEM-GEMNOS CARDIAC PACEMAKER	BIOTRONIK, INC. LAKE OSWEGO, OR 97035-5369	GEMNOS CARDIAC PACEMAKER AND THE MODEL SWM 2.25 SOFTWARE MODULE	07-26-91
P830026/S48	COSMOS PACING SYSTEM	INTERMEDICS, INC. FREEPORT, TX 77541-0617	ALTERNATIVE VIBRATION SCREENING METHOD	07-31-91
P830040/S17	ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES: POST/STERILIZATION PROCEDURAL CHANGE	3M VISION CARE ST PAUL, MN 55133-1000	MODIFY THE POST/STERILIZATION PROCESS USED IN THE MANUFACTURE OF LENSES	07-03-91
P830047/S06	HYDRON X-70 (LIDOFILCON A) HYDROPHILIC	ALLERGAN OPTICAL IRVINE, CA 92713-9534	TINT, FOR VISIBILITY PURPOSES, LIDOFILCON A LENS MATERIAL BLUE WITH A	07-26-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CONTACT LENS, OMNIFLEX SOFBLUE (LIDOFILCON A) HYDROPHILIC CONTACT LENS		COLOR ADDITIVE
P840008/S24	DORNIER LITHOTRIPTER, MODEL HM3, DORNIER MULTIFUNCTIONAL LITHOTRIPTER MFL 5000	DORNIER MEDICAL SYSTEMS MARIETTA, GA 30067	MODIFICATIONS TO THE DORNIER LITHOTRIPTER, MODEL HM3 AND MARKETED, AS MODIFIED, UNDER THE TRADE NAME DORNIER MULTIFUNCTIONAL LITHOTRIPTER MFL 5000
07-03-91			
P840008/S25	DORNIER LITHOTRIPTER, MODEL HM3, DORNIER MULTIFUNCTIONAL LITHOTRIPTER MFL5000 MOBILE	DORNIER MEDICAL SYSTEMS MARIETTA, GA 30067	MOBILE VERSION OF THE MFL5000 LITHOTRIPTER
07-03-91			
P840008/S29	DORNIER LITHOTRIPTER MODELS HM3 AND HM4	DORNIER MEDICAL SYSTEMS MARIETTA, GA 30067	SPECIFIC MODIFICATIONS TO THE NORMAL AND LONG TERM-HIGH CURRENT FLUOROSCOPIC MODES
07-25-91			
P840040/S24	MEDI-TECH CORONARY BALLOON DILATATION CATHETER SYSTEM/SLIDER .014 AND .018 CATHETERS WITH LONG BALLOON	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	SLIDER .014 AND .018 CATHETERS WITH LONG BALLOONS (30 MM)
07-12-91			

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

			(30 MM)	
P840040/S25	MEDI-TECH HEART TRAK CORONARY BALLOON DILATATION CATHETER/SLIDER ST PTCA CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	SLIDER ST PTCA CATHETER	07-12-91
P850051/S30	ACTIVITRAX PACING SYSTEM-ACTIVITRAX, LEGEND, AND MICROMINIX PULSE GENERATOR SYSTEMS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	INTRODUCTION OF AN ALTERNATIVE FEEDTHROUGH POTTING MATERIAL AND THE USE OF A DIFFERENT ADHESION PROMOTE	07-26-91
P860004/S01	SYNCHROMED INFUSION SYSTEM FOR INTRATHECAL MORPHINE SULFATE ADMINISTRATION	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	SYNCHROMED INFUSION SYSTEM (MODEL 8611H PUMP AND MODEL 8703 CATHETER)	07-25-91
P860007/S05	INTERTACH PACING SYSTEM, INTERTACH II MODEL 262-16R IMPLANTABLE PULSE GENERATOR	INTERMEDICS, INC. FREEPORT, TX 77541-0617	CHANGE IN THE HEADER SYSTEM OF INTERTACH II MODEL 262-16 IMPLANTABLE PULSE GENERATOR	07-02-91
P860044/S02	ENZYMUN-TEST AFP, IMMUNOENZYMETRIC ASSAY TO AID IN THE MANAGEMENT OF TESTICULAR CANCER	BOEHRINGER MANNHEIM DIAGNOSTICS DIV INDIANAPOLIS, IN 46250-0100	MOVE THE PACKAGING OPERATION FROM PENZBERG TO MANNHEIM, WEST GERMANY	07-19-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P880049/S01	EPCON/SOFT (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENS	EPCON LABORATORIES EL PASO, TX 79912	APPROVAL FOR BENZ RESEARCH AND DEVELOPMENT, 6447 PARKLAND DRIVE, SARASOTA, FLORIDA 34230 AS AN ALTERNATE SUPPLIER OF THE POLYMACON LENS BLANKS	07-19-91
P880055/S03	MICROSS PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) DILATATION CATHETER-MICROSS/SL	DATASCOPE CORPORATION OAKLAND, NJ 07436	REVISED LABELING AND UPDATED STANDARD OPERATING PROCEDURES AND SPECIFICATIONS FOR THE MANUFACTURE AND CONTROL OF THE CATHETER	07-19-91
P880079/S10	SOFTWEAR STERILE SALINE SOLUTION	CIBA VISION CORPORATION ATLANTA, GA 30360	REVISED LABELING TO INCLUDE A LENS STORAGE TIME OF UP TO 30 DAYS AFTER DISINFECTION	07-15-91
P880082/S09	PRIVATE DISTRIBUTION AGREEMENT WITH 3M VISION CARE	EYE TECHNOLOGY INC. ST. PAUL, MN 55117	3M VISION CARE TO DISTRIBUTE EYE TECHNOLOGY MODELS 24055-125 AND 25055-125 AS 3M MODELS 65X AND 165X POSTERIOR CHAMBER INTRAOCULAR LENSES	07-23-91
P890003/S06	SYNERGYST II PACING SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN	INTRODUCTION OF AN ALTERNATIVE FEEDTHROUGH	07-26-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
APPROVAL DATE			

MEDICAL DEVICE - PMA SUPPLEMENTALS

		55432-3576	POTTING MATERIAL AND THE USE OF A DIFFERENT ADHESION PROMOTE
P890032/S09 07-25-91	CORDIS ORION STEERABLE PTCA BALLOON CATHETER, ORION STEERABLE PTCA BALLOON CATHETER WITH GLISSADE HYDROPHILIC COATING	CORDIS CORPORATION MIAMI, FL 33102-5700	ORION STEERABLE PTCA BALLOON CATHETER WITH GLISSADE HYDROPHILIC COATING
P890040/S03 07-23-91	SOF-FORM 55 SPHERICAL (METHAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES FOR DAILY WEAR AND EXTENDED WEAR AND SOF-FORM 55 TORIC LENSES	SALVATORI OPHTHALMICS, INC. SARASOTA, FL 34234	CAL BIONICS, INC., 1777 INDIAN VALLEY ROAD, NOVATO, CALIFORNIA 94947, AS AN ALTERNATE SUPPLIER OF METHAFILCON A OPTICAL BUTTONS
P890044/S14 07-08-91	TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR	BENTEC ENGINEERING, INC. SACRAMENTO, CA 95834	CHANGING THE SPECIFICATIONS OF THE BROWN TINTED LENS PREVIOUSLY APPROVED, AND MANUFACTURING AND MARKETING A RED TINTED VERSION OF THE LENS
P890044/S15 07-19-91	BIS.45 (AMSILFOCON A)	BENTEC ENGINEERING, INC. SACRAMENTO, CA	TWO ADDITIONAL CONTACT LENS FINISHING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND BLUE TINTED)	95834	LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P890046/S11 07-19-91	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	IDEAL OPTICS, INC. ATLANTA, GA 30339	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P890049/S02 07-19-91	LC-55 (METHAFILCON A) SPHERICAL SOFT (HYDROPHILIC) CONTACT LENS FOR DAILY AND EXTENDED WEAR AND LL-55 (METHAFILCON A) TORIC SOFT LENSES	LOMBART LENSES, LTD. NORFOLK, VA 23507	CAL BIONICS, INC., 1777 INDIAN VALLEY ROAD, NOVATO, CALIFORNIA 94947 AS AN ALTERNATE SUPPLIER OF THE METHAFILCON A OPTICAL BUTTONS
P890058/S07 07-19-91	NOVALENS (ROSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND BLUE TINTED)	OCUTEC CORPORATION RALEIGH, NC 27615	RELOCATION OF MANUFACTURING FACILITY FOR BUTTONS USED IN THE MANUFACTURE OF LENS FROM OCUTEC CORP., 160 WIND CHIME COURT, RALEIGH, NC 27615 TO MATERIALS DEVELOPMENT CORPORATION, 6003-121 CHAPEL HILL ROAD, RALEIGH, NC 27607

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890072/S02 07-02-91	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED) WITH AN ULTRAVIOLET LIGHT ABSORBER	PROGRESSIVE CHEMICAL RESEARCH, LTD CALGARY, ALBERTA CANADA	PROTOCOL TO ADD CONTACT FINISHING LABORATORIES AS ALTERNATE MANUFACTURERS AND DISTRIBUTORS
P890072/S03 07-19-91	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED) WITH ULTRAVIOLET LIGHT ABSORBER	PROGRESSIVE CHEMICAL RESEARCH, LTD. CALGARY, ALBERTA CANADA	20 ADDITIONAL CONTACT LENS FINISHING LABORATORIES
P900010/S01 07-03-91	ORCOLON	OPTICAL RADIATION CORPORATION AZUSA, CA 91702	A PRINTING CORRECTION TO THE PACKAGE INSERT FOR ORCOLON
P900010/S02 07-31-91	ORCOLON	OPTICAL RADIATION CORPORATION AZUSA, CA 91702	CHANGE IN THE BUFFERING SYSTEM IN THE MANUFACTURING PROCESS
N17676/S25	NATURVUE	BAUSCH & LOMB OPTICS	MODIFICATION OF THE

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	(HEFILCON A) SOFT (HYDROPHILIC) CONTACT LENS BAUSCH & LOMB (HEFILCON C) CONTACT LENSES, CLEAR VERSION	CENTER ROCHESTER, NY 14692-0450	CURRENTLY APPROVED HEFILCON B LENS MATERIAL BY CHANGING THE RATIO OF THE MONOMERS AND TO CHANGE THE MANUFACTURING PROCESS TO A POLYMER BUTTON CASTING	07-02-91
N18020/S36	ALLERGAN PRESERVED SALINE SOLUTION	ALLERGAN OPTICAL, INC. IRVINE, CA 92715-1599	USE OF THE ALLERGAN PRESERVED SALINE SOLUTION AS A STORAGE SOLUTION FOLLOWING HYDROGEN PEROXIDE DISINFECTION WITH A RECOMMENDED LENS STORAGE TIME FOR UP TO 30 DAYS AFTER DISINFECTION	07-15-91
N18466/S12	CMW 2 QUICK SETTING BONE CEMENT	DENTSPLY INTERNATIONAL YORK, PA 17405-0872	MOVE THE IRRADIATION WITNESS DISC FROM THE BAG TO THE PEELABLE ENVELOPE OVERWRAP FOR ALL CMW BONE CEMENTS AND MARKETING CMW 2 BONE CEMENT	07-02-91
N18466/S13	INTERLOC BONE CEMENT ACRYLOC BONE CEMENT	DENTSPLY INTERNATIONAL YORK, PA 17405-0872	CHANGE OF THE NAME OF INTERLOC BONE CEMENT TO ACRYLOC BONE CEMENT	07-02-91
P810046/S100	SIMPSON-ROBERT	ADVANCED CARDIOVASCULAR	ADDITIONAL HEAT AND	

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

07-25-91	CORONARY BALLOON DILATATION CATHETER-BALLOON FOLDING AND SHEATHING MODIFICATION	SYSTEMS, INC. SANTA CLARA, CA 95052-8167	PRESSURE PROCESSING STEP USED ON THE BALLOON PORTION OF THE PTCA CATHETERS PRIOR TO ATTACHING IT TO THE CATHETER

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR JULY 1991.

***SUPPLEMENTAL VETERINARY NADAs ***

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR JULY 1991.

FDA DRUG AND DEVICE PRODUCT APPROVALS

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This report is compiled by the Division of Drug Information Resources, OM, CDER. It is available by subscription from the National Technical Information Service, Springfield, VA 22161.

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August 1991

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

18-680 08-13-91 (SUPPL)	PARAGARD T 380A (INTRAUTERINE DEVICE)	POP COUNCIL NEW YORK CITY, NY 10021	COPPER 309MG (NEW DOSAGE REGIMEN -- EXTENSION OF THE USAGE OF THE PREPARATION FROM SIX TO EIGHT YEARS)
19-501 08-13-91 (SUPPL)	ROGAINE (SOLUTION)	UPJOHN KALAMAZOO, MI 49001	MINOXIDIL 2% (NEW INDICATION -- FEMALE ANDROGENETIC ALOPECIA)
19-977 08-15-91 (5 C)	ORAMORPH SR (TABLET, EXTENDED RELEASE)	ROXANE COLUMBUS, OH 43216	MORPHINE SULFATE 30MG 60MG 100MG (NARCOTIC ANALGESIC)
19-664 08-19-91 (4 C)	SELDANE-D (TABLET, EXTENDED RELEASE)	MERRELL DOW CINCINNATI, OH 45215	PSEUDOEPHEDRINE HYDROCHLORIDE 120MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

			TERFENADINE (DECONGESTANT; ANTIHISTAMINE)	60MG
50-512	DURICEF	MEAD JOHNSON	CEFADROXIL	
08-30-91	(CAPSULE)	EVANSVILLE, IN	EQ 500MG BASE	
(SUPPL)		47721	(NEW DOSAGE REGIMEN -- ONCE DAILY DOSING AT 30MG/KG IN THE TREATMENT OF CHILDREN WITH SKIN AND SKIN STRUCTURE INFECTIONS CAUSED BY STAPHYLOCOCCI, STREPTOCOCCI OR BOTH)	
50-527	DURICEF	MEAD JOHNSON	CEFADROXIL	
08-30-91	(POWDER FOR	EVANSVILLE, IN	EQ 125MG BASE/5ML	
(SUPPL)	RECONSTITUTION)	47721	EQ 250MG BASE/5ML EQ 500MG BASE/5ML (NEW DOSAGE REGIMEN -- ONCE DAILY DOSING AT 30MG/KG IN THE TREATMENT OF CHILDREN WITH SKIN AND SKIN STRUCTURE INFECTIONS CAUSED BY STAPHYLOCOCCI, STREPTOCOCCI OR BOTH)	
50-528	DURICEF	MEAD JOHNSON	CEFADROXIL	
08-30-91	(TABLET)	EVANSVILLE, IN	EQ 1GM BASE	
(SUPPL)		47721	(NEW DOSAGE REGIMEN -- ONCE DAILY DOSING AT 30MG/KG	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

IN THE TREATMENT OF CHILDREN
WITH SKIN AND SKIN STRUCTURE
INFECTIONS CAUSED BY
STAPHYLOCOCCI, STREPTOCOCCI
OR BOTH)

ERRATA

18-565**	INFUMORPH	ELKINS SINN	MORPHINE SULFATE
07-19-91	(INJECTABLE)	CHERRY HILL, NJ	10MG/ML
(SUPPL, V*)		08003	25MG/ML
		(NEW STRENGTHS)	

18-565**	INFUMORPH	ELKINS SINN	MORPHINE SULFATE
07-19-91	(INJECTABLE)	CHERRY HILL, NJ	10MG/ML
(SUPPL, V*)		08003	25MG/ML
		(NEW INDICATION -- FOR USE IN MICROINFUSION DEVICES FOR INTRASPINAL ADMINISTRATION IN THE TREATMENT OF INTRACTABLE CHRONIC PAIN)	

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
(CLASSIFICATION) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

V* - Designated Orphan Drug
** - Corrected NDA Number

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

19-885 ACCUPRIL PARKE DAVIS QUINAPRIL HYDROCHLORIDE
08-15-91 (TABLET) ANN ARBOR, MI 5MG
48106 10MG
20MG
(ANGIOTENSIN-CONVERTING
ENZYME INHIBITOR)
[HYPERTENSION]

50-662 BIAXIN ABBOTT CLARITHROMYCIN
08-29-91 (TABLET) ABBOTT PARK, IL 250MG
60064 500MG
(ANTIBIOTIC, MACROLIDE)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

72-080	FUROSEMIDE	STERLING	FUROSEMIDE
08-13-91	(INJECTABLE)	NEW YORK, NY	10MG/ML
		10016	(DIURETIC)
72-981	FENOPROFEN CALCIUM	DANBURY	FENOPROFEN CALCIUM
08-19-91	(CAPSULE)	DANBURY, CT	EQ 200MG BASE
		06810	(NONSTEROIDAL ANTI-INFLAMMATORY)
72-982	FENOPROFEN CALCIUM	DANBURY	FENOPROFEN CALCIUM
08-19-91	(CAPSULE)	DANBURY, CT	EQ 300MG BASE
		06810	(NONSTEROIDAL ANTI-INFLAMMATORY)
63-107*	E/GEL	FULTON	ERYTHROMYCIN
08-23-91	(GEL)	NEWPORT BEACH, CA	2%
		92663	(ANTIBIOTIC, MACROLIDE)
73-115	AMANTADINE HCL	COPLEY	AMANTADINE HYDROCHLORIDE
08-23-91	(SYRUP)	CANTON, MA	50MG/5ML
		02021	(ANTIVIRAL/ANTIPARKINSONIAN)
81-242	FOLEX PFS	ADRIA	METHOTREXATE SODIUM
08-23-91	(INJECTABLE)	COLUMBUS, OH	EQ 25MG BASE/ML
		43216	(ANTINEOPLASTIC)
72-113	HALOPERIDOL	DANBURY	HALOPERIDOL
08-27-91	(TABLET)	DANBURY, CT	10MG
		06810	(ANTIPSYCHOTIC)
72-353	HALOPERIDOL	DANBURY	HALOPERIDOL
08-27-91	(TABLET)	DANBURY, CT	20MG
		06810	(ANTIPSYCHOTIC)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

72-764 ALBUTEROL SULFATE WATSON ALBUTEROL SULFATE
08-28-91 (TABLET) CORONA, CA EQ 2MG BASE
91720 (BRONCHODILATOR)

* First Time Product Available Generically

72-765 ALBUTEROL SULFATE WATSON ALBUTEROL SULFATE
08-28-91 (TABLET) CORONA, CA EQ 4MG BASE
91720 (BRONCHODILATOR)

81-225 ADRUCIL ADRIA FLUOROURACIL
08-28-91 (INJECTABLE) COLUMBUS, OH 50MG/ML
43216 (ANTINEOPLASTIC)

72-712 SULINDAC GENEVA SULINDAC
08-30-91 (TABLET) BROOMFIELD, CO 150MG
80038 (NONSTEROIDAL
ANTI-INFLAMMATORY)

72-713 SULINDAC GENEVA SULINDAC
08-30-91 (TABLET) BROOMFIELD, CO 200MG
80038 (NONSTEROIDAL
ANTI-INFLAMMATORY)

72-768 SULFAMETHOXAZOLE ROXANE SULFAMETHOXAZOLE
08-30-91 AND TRIMETHOPRIM COLUMBUS, OH 400MG
(TABLET) 43216 TRIMETHOPRIM
80MG
(ANTIBACTERIAL)

72-769 SULFAMETHOXAZOLE ROXANE SULFAMETHOXAZOLE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)	STRENGTH(S)	APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

08-30-91	AND TRIMETHOPRIM	COLUMBUS, OH	800MG				
	DOUBLE STRENGTH	43216	TRIMETHOPRIM				
	(TABLET)		160MG				
			(ANTIBACTERIAL)				
73-034	METAPROTERENOL	COPLEY	METAPROTERENOL SULFATE				
08-30-91	SULFATE	CANTON, MA	10MG/5ML				
	(SYRUP)	02021	(BRONCHODILATOR)				
73-058	FLUPHENAZINE HCL	COPLEY	FLUPHENAZINE HYDROCHLORIDE				
08-30-91	(CONCENTRATE)	CANTON, MA	5MG/ML				
		02021	(ANTIPSYCHOTIC)				
73-122*	LOPERAMIDE HCL	NOVOPHARM	LOPERAMIDE HYDROCHLORIDE				
08-30-91	(CAPSULE)	SCARBOROUGH, CANADA	2MG				
			(ANTIDIARRHEAL)				
81-079	HYDROCODONE	WATSON	ACETAMINOPHEN				
08-30-91	BITARTRATE	CORONA, CA	500MG				
	AND ACETAMINOPHEN	91720	HYDROCODONE BITARTRATE				
	(TABLET)		2.5MG				(ANALGESIC)
81-080	HYDROCODONE	WATSON	ACETAMINOPHEN				
08-30-91	BITARTRATE	CORONA, CA	500MG				
	AND ACETAMINOPHEN	91720	HYDROCODONE BITARTRATE				
	(TABLET)		7.5MG				
			(ANALGESIC)				
81-083	HYDROCODONE	WATSON	ACETAMINOPHEN				
08-30-91	BITARTRATE	CORONA, CA	750MG				

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

AND ACETAMINOPHEN	91720		HYDROCODONE BITARTRATE
(TABLET)			7.5MG
		(ANALGESIC)	

* First Time Product Available Generically

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-708	DORAL	WALLACE	QUAZEPAM
08-05-91	(TABLET)	PRINCETON, NJ	7.5MG
		08540	15MG
			(REVISED LABELING -- DRUG ABUSE AND DEPENDENCE; OVERDOSAGE; HOW SUPPLIED)
19-080	PROSOM	ABBOTT	ESTAZOLAM
08-05-91	(TABLET)	ABBOTT PARK, IL	1MG
		60064	2MG
			(REVISED LABELING -- HOW SUPPLIED)
17-563	COLESTID	UPJOHN	COLESTIPOL HYDROCHLORIDE
08-06-91	(GRANULE)	KALAMAZOO, MI	5GM/PACKET
		49001	500GM/BOT
			(REVISED LABELING -- DRUG INTERACTIONS)
19-687	LUTREPULSE	JOHNSON RW	GONADORELIN ACETATE
08-07-91	PUMP KIT	RARITAN, NJ	0.8MG/VIAL
	(INJECTABLE)	08869	3.2MG/VIAL
			(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
18-061	TIMOLIDE 10-25	MSD	HYDROCHLOROTHIAZIDE
08-12-91	(TABLET)	W POINT, PA	25MG
		19486	TIMOLOL MALEATE
			10MG
			(REVISED LABELING -- DESCRIPTION; PRECAUTIONS; ADVERSE REACTIONS;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	APPROVAL DATE	(DOSAGE FORM)	STRENGTH(S)	LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs							
							DOSAGE AND ADMINISTRATION)
18-817	CALAN	SEARLE	VERAPAMIL HYDROCHLORIDE				
08-12-91	(TABLET)	SKOKIE, IL	40MG				
		60077	80MG				
			120MG				
			(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)				
18-869	NIMOTOP	MILES	NIMODIPINE				
08-12-91	(CAPSULE)	W HAVEN, CT	30MG				
		06516	(REVISED LABELING -- CLINICAL PHARMACOLOGY; PRECAUTIONS; DOSAGE AND ADMINISTRATION)				
18-680	PARAGARD T 380A	POP COUNCIL	COPPER				
08-13-91	(INTRAUTERINE DEVICE)	NEW YORK CITY, NY	309MG				
		10021	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; PATIENT PACKAGE INSERT)				
50-579	MONOCID	SKF	CEFONOCID SODIUM				

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

08-13-91	(INJECTABLE)	PHILADELPHIA, PA	500MG BASE/VIAL
		19101	1GM BASE/VIAL
			10GM BASE/VIAL
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY)
16-848	ANADROL-50	SYNTEX	OXYMETHOLONE
08-14-91	(TABLET)	PALO ALTO, CA	50MG
		94304	(REVISED LABELING --
			CONTRAINDICATIONS; WARNINGS;
			PRECAUTIONS; ADVERSE REACTIONS;
			DRUG ABUSE AND DEPENDENCE)
50-605	CEFTIN	GLAXO	CEFUROXIME AXETIL
08-19-91	(TABLET)	RES TRIANGLE PK, NC	EQ 125MG BASE
		27709	EQ 250MG BASE
			EQ 500MG BASE
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			ADVERSE REACTIONS)
11-340	CERUMENEX	PURDUE FREDERICK	TRIETHANOLAMINE POLYPEPTIDE
08-21-91	(SOLUTION/DROPS)	NORWALK, CT	OLEATE CONDENSATE
		06856	10%
			(REVISED LABELING --
			LABELING FORMAT
			REVISION PROGRAM)
50-370	ILOTYCIN	DISTA	ERYTHROMYCIN GLUCEPTATE
08-21-91	GLUCEPTATE	INDIANAPOLIS, IN	EQ 250MG BASE/VIAL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

	(INJECTABLE)	46206	EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL (REVISED LABELING -- WARNINGS)
17-468	ECONOPRED	ALCON	PREDNISOLONE ACETATE
08-22-91	(SUSPENSION)	FORT WORTH, TX 76134	0.125% (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
17-469	ECONOPRED PLUS	ALCON	PREDNISOLONE ACETATE
08-22-91	(SUSPENSION)	FORT WORTH, TX 76134	0.25% (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-655	NALLPEN	BAXTER	NAFCILLIN SODIUM
08-22-91	IN PLASTIC CONTAINER (INJECTABLE)	ROUND LAKE, IL 60073	EQ 20MG BASE/ML EQ 40MG BASE/ML (REVISED LABELING -- DESCRIPTION; WARNINGS)
50-006	VIBRAMYCIN	PFIZER	DOXYCYCLINE
08-23-91	(POWDER FOR RECONSTITUTION)	NEW YORK, NY 10017	EQ 25MG BASE/5ML (REVISED LABELING -- CLINICAL PHARMACOLOGY)
50-007	VIBRAMYCIN	PFIZER	DOXYCYCLINE HYCLATE
08-23-91	(CAPSULE)	NEW YORK, NY 10017	EQ 50MG BASE EQ 100MG BASE (REVISED LABELING -- CLINICAL PHARMACOLOGY)
50-480	VIBRAMYCIN	PFIZER	DOXYCYCLINE CALCIUM
08-23-91	(SUSPENSION)	NEW YORK, NY 10017	EQ 50MG BASE/5ML (REVISED LABELING -- CLINICAL PHARMACOLOGY)
50-533	VIBRA-TABS	PFIZER	DOXYCYCLINE HYCLATE
08-23-91	(TABLET)	NEW YORK, NY 10017	EQ 100MG BASE (REVISED LABELING -- CLINICAL PHARMACOLOGY)
19-643	MEVACOR	MSD	LOVASTATIN
08-28-91	(TABLET)	W POINT, PA 19486	20MG 40MG (REVISED LABELING --

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			CLINICAL PHARMACOLOGY;
			PRECAUTIONS; ADVERSE REACTIONS)
19-886	SYNAREL	SYNTEX	NAFARELIN ACETATE
08-28-91	(SPRAY, METERED)	PALO ALTO, CA	EQ 2MG BASE/ML
	94304		(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			PRECAUTIONS)
50-444	MINOCIN	LEDERLE	MINOCYCLINE HYDROCHLORIDE
08-28-91	(INJECTABLE)	PEARL RIVER, NY	EQ 100MG BASE/VIAL
	10965		(REVISED LABELING --
			ADVERSE REACTIONS)
50-316	LINCOCIN	UPJOHN	LINCOMYCIN HYDROCHLORIDE
08-29-91	(CAPSULE)	KALAMAZOO, MI	EQ 250MG BASE
	49001		EQ 500MG BASE
			(REVISED LABELING --
			WARNINGS)
50-317	LINCOCIN	UPJOHN	LINCOMYCIN HYDROCHLORIDE
08-29-91	(INJECTABLE)	KALAMAZOO, MI	EQ 300MG BASE/ML
	49001		(REVISED LABELING --
			WARNINGS)
50-512	DURICEF	MEAD JOHNSON	CEFADROXIL
08-30-91	(CAPSULE)	EVANSVILLE, IN	EQ 500MG BASE
	47721		(REVISED LABELING --
			OVERDOSAGE;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-527	DURICEF	MEAD JOHNSON	CEFADROXIL
08-30-91	(POWDER FOR RECONSTITUTION)	EVANSVILLE, IN 47721	EQ 125MG BASE/5ML EQ 250MG BASE/5ML EQ 500MG BASE/5ML (REVISED LABELING -- OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
50-528	DURICEF	MEAD JOHNSON	CEFADROXIL
08-30-91	(TABLET)	EVANSVILLE, IN 47721	EQ 1GM BASE (REVISED LABELING -- OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

1142 08-02-91	NONE (INJECTABLE)	CEDARS SINAI MED CTR LOS ANGELES, CA 90048	RED BLOOD CELLS (TRANSFUSION) (A&B)
1142 08-02-91	NONE (INJECTABLE)	CEDARS SINAI MED CTR LOS ANGELES, CA 90048	WHOLE BLOOD (TRANSFUSION) (A&B)
1143 08-07-91	NONE (INJECTABLE)	BOX BUTTE GEN HOSP ALLIANCE, NE 69301	PLASMA (TRANSFUSION) (A&B)
1143 08-07-91	NONE (INJECTABLE)	BOX BUTTE GEN HOSP ALLIANCE, NE 69301	RED BLOOD CELLS (TRANSFUSION) (A&B)
1143 08-07-91	NONE (INJECTABLE)	BOX BUTTE GEN HOSP ALLIANCE, NE 69301	WHOLE BLOOD CELLS (TRANSFUSION) (A&B)

LICENSE NUMBER TRADE NAME MANUFACTURER PROPER NAME
LICENSE DATE (DOSAGE FORM) (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

(A) Establishment License Issued
(B) Product License Issued

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910010	ENDOTOXIN	WHITTAKER BIOPRODUCTS	ENDOTOXIN CHALLENGE VIALS
08-09-91	CHALLENGE VIALS	WALKERSVILLE, MD 21793	(C)

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

P900047	DURACARE REWETTER	ALLERGAN OPTICAL IRVINE, CA 92715-1599	LUBRICATE AND REWET SILICONE ACRYLATE, FLUOROSILICONE ACRYLATE, AND FLUOROPOLYMER RIGID GAS PERMEABLE CONTACT LENSES	08-21-91
P900058	TECHNICON-45 SOFT (HEFILCON A) CONTACT LENS	WESTCON CONTACT LENS COMPANY GRAND JUNCTION, CO 81506	SPHERICAL TECHNICON-45 SOFT (HEFILCON A) CONTACT LENS	08-26-91
P900065	TECHNICON 38 (POLYMACON) HYDROPHILIC CONTACT LENSES (SPHERICAL AND TORIC)	WESTCON CONTACT LENS COMPANY GRAND JUNCTION, CO 81506	SPHERICAL AND TORIC CONFIGURATIONS OF THE TECHNICON 38 (POLYMACON) HYDROPHILIC CONTACT LENSES	08-26-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

N16895/S74	DAILY WEAR LENSES (CLEAR AND TINTED), EXTENDED WEAR LENSES (CLEAR AND TINTED), PRIVATE LABEL PRODUCTS	BAUSCH & LOMB ROCHESTER, NY 14692-0450	MODIFICATION IN THE MANUFACTURING PROCESS OF POLYMACON CONTACT LENS BLANKS TO INCLUDE MOLD MATERIALS AND MODIFICATIONS IN HYDRATION METHODS	08-13-91
N16895/S75	OPTIMA FW, MEDALIST, SEEQUENCE 2, (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	MODIFICATION OF THE LENS DESIGN TO EXPAND THE OPTIC ZONE SIZE OF THE LENSES FOR EXTENDED WEAR FROM 8.0MM TO 9.0MM THROUGH 10.0MM IN THE MINUS POWER RANGE OF -0.25D TO -9.00D	08-08-91
N17679/S24	AQUAFLEX (TETRAFILCON A) HYDROPHILIC CONTACT LENS, VANTAGE UV AND VANTAGE THIN UV (TETRAFILCON A) HYDROPHILIC CONTACT LENSES	COOPERVISION OPHTHALMIC PRODUCTS ROCHESTER, NY 14623	ADDITION OF AN ULTRAVIOLET (UV) LIGHT-ABSORBER, 2-(3'-T-BUTYL-2'-HYDROXY-5'-VINYL PHENYL)-5 CHLORO-BENZOTRIAZOLE (UVAM) TO THE TETRAFILCON A LENS MATERIAL	08-29-91
P780013/S06	V-X (POLYMACON) ASPHERIC SOFT (HYDROPHILIC) CONTACT LENSES	GBF CONTACT LENSES, INC. VIRGINIA BEACH, VA 23452	BENZ RESEARCH & DEVELOPMENT, 6447 PARKLAND DRIVE, SARASOTA, FL 34230 AS AN ALTERNATE SUPPLIER OF THE POLYMACON MATERIAL (BUTTONS) USED IN THE MANUFACTURE OF THE	08-13-91

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

LENSES

P800058/S14 08-29-91	BIOPOLYMERIC VASCULAR GRAFT (FORMERLY N.C.G.T. GRAFT)	ST. JUDE MEDICAL, INC. ST PAUL, MN 55117	MODIFICATION OF THE LABELING TO INCLUDE A CONTRAINDICATION FOR USE OF THE GRAFT AS A CORONARY OR PULMONARY SHUNT GRAFT, AND TO INCLUDE RECOMMENDATIONS ABOUT ANTICOAGULANT OR ANTIPLATELET THERAPY TO BE USED WITH THE GRAFT
P810002/S20 08-29-91	SJM AORTIC EXPANDED CUFF (AEC) MECHANICAL VALVES	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	ADDITIONAL INSPECTION PROCEDURES AND DOCUMENTATION FOR MANUFACTURING THE AORTIC EXPANDED CUFF VALVE
P810005/S26 08-06-91	CIBASOFT, CIBATHINR, BISOFT, TORISOFT AND CIBA OPAQUE (TEFILCON) SOFT (HYDROPHILIC) CONTACT LENSES	CIBA VISION CORPORATION ATLANTA, GA 30360	ADDITION OF A GREEN TINTED VERSION OF THE LENSES
P810046/S105 08-15-91	ACS RX ALPHA .014 CORONARY	ADVANCED CARDIOVASCULAR SYSTEMS, INC.	ACS RX ALPHA .014 CORONARY DILATATION

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	DILATATION CATHETER, ACS RX STREAK .014 CORONARY DILATATION CATHETER	SANTA CLARA, CA 95052-8167	CATHETER IN AN ASPIRATION PREP VERSION TO BE MARKETED UNDER THE TRADE NAME ACS RX STREAK .014 CORONARY DILATATION CATHETER, AND INTENDED FOR PTCA USE
P810046/S108 08-06-91	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER-ACS RX ALPHA .014 AND .018 CORONARY DILATATION CATHETERS	ADVANCED CARDIOVASCULAR SYSTEMS, INC. SANTA CLARA, CA 95052-8167	ADDITION OF NEW CAUTIONARY NOTES TO THE INSTRUCTIONS FOR USE FOR THE RX ALPHA .014 AND .018 CORONARY DILATATION CATHETERS
P810055/S52 08-27-91	INTRAOCULAR LENSES: VALIDATION OF GETINGE ETHYLENE OXIDE STERILIZER	PHARMACIA OPHTHALMICS, INC. MONROVIA, CA 91017-7136	GETINGE ETHYLENE OXIDE STERILIZER
P820018/S49 08-21-91	AUTIMA MODEL 2251 AND MODEL 2600-MODEL 5603 PROGRAMMER VERSION	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	MODEL 5603 PROGRAMMER WITH SOFTWARE VERSION 5.21P (CHAPTER 0 REVISION 0.10 AND CHAPTER 1

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
		MEDICAL DEVICE - PMA SUPPLEMENTALS		
	5.21P		REVISION 4.23)	
P820021/S23	SOFTCON, SPECTRUM, FOCUS AND NEWVUES (VIFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES	CIBA VISION CORPORATION ATLANTA, GA 30360	ADDITION OF A GREEN TINTED VERSION OF THE CONTACT LENSES	08-06-91
P820033/S02	PLASMAFLO AP-05H ASAHI PLASMA SEPARATOR, PLASMAFLO AP-05H(L) ASAHI PLASMA SEPARATOR	ASAHI CHEMICAL INDUSTRY AMERICA, INC. NEW YORK, NY 10118	MODIFICATION TO THE SEPARATOR TO INCLUDE A MODEL WITH LUER-TYPE BLOOD PORT CONNECTORS	08-27-91
P820040/S26	AOSEPT DISINFECTION-NEUTRALIZATION SOLUTION, LENSEPT DISINFECTION SOLUTION, AND LENSEPT NEUTRALIZING AND RINSING/STORAGE SOLUTION	CIBA VISION CORPORATION ATLANTA, GA 30360	ALTERNATE BOTTLE AND ALTERNATE SOLUTION MANUFACTURING SITE BOTH LOCATED AT CIBA VISION, STERILE PHARMACEUTICALS, 6515 KITIMAT ROAD, MISSISSAUGA, ONTARIO, L5N, 2X5 AND AN ALTERNATE BOTTLE STERILIZATION PROCESS	08-08-91
P820051/S09	OCU-FLEX 53	OCU-EASE OPTICAL PRODUCTS,	CHANGE MANUFACTURING	

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

08-22-91	(OCUFILCON B) SOFT (HYDROPHILIC) CONTACT LENS, OCU-FLEX 65 (OCUFILCON E) SOFT (HYDROPHILIC) CONTACT LENS	INC. PINOLE, CA 94564	PROCESS OF THE OCUFILCON B LENS TO INCREASE THE WATER CONTENT FROM 53% TO 65% AND MARKET IT UNDER THE TRADE NAME OCU-FLEX 65 (OCUFILCON E) SOFT (HYDROPHILIC) CONTACT LENS	
P820052/S08 08-06-91	RAINEN (3H) PROGESTIN RECEPTOR ASSAY KIT, RAINEN (125I) PROGESTIN RECEPTOR ASSAY KIT (NEA-116)	NEW ENGLAND NUCLEAR NORTH BILLERICA, MA 01862	MODIFICATION IN WHICH THE TRACER MATERIAL, [3H]-R5020 (17 ALPHA-METHYL-[3H]-PROMEGE STONE) IS REPLACED WITH [125]I/SH-D 510 {Z -17 ALPHA-(2[125I]-IODOVINYL) -19-NORTESTOSTERONE} AND R5020 IS REPLACED WITH SH-D 510 AS THE COLD COMPETITOR	
P820056/S48 08-07-91	OPTACRYL 60 (KOLFOCON A) CLEAR AND TINTED RIGID GAS PERMEABLE CONTACT LENSES	PARAGON OPTICAL MESA, AZ 85204	CONTACT LENS FINISHING LABORATORY, MIAMI CONTACT LENS, 4928 LE JUNE ROAD, CORAL GABLES, FL 33146, TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	
P820056/S49 08-15-91	OPTACRYL 60 (KOLFOCON A) CLEAR AND TINTED RIGID GAS PERMEABLE CONTACT LENSES	PARAGON OPTICAL MESA, AZ 85204	CONTACT LENS FINISHING LABORATORY CRM OPTICAL, EAST 112 FIRST AVENUE TAFC-20, SPOKANE, WA 99220 TO BECOME AN	

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

			ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	
P820063/S49	PARAPERM 0_2 (PASIFOCON A) RIGID GAS PERMEABLE CONTACT LENS	PARAGON OPTICAL MESA, AZ 85204	CONTACT LENS FINISHING LABORATORY, CRM OPTICAL, EAST 112 FIRST AVENUE TAFC-20, SPOKANE, WA 99220, TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	08-15-91
P830034/S20	OPTI-FREE RINSING, DISINFECTING AND STORAGE SOLUTION	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	REVISION OF DIRECTIONS FOR USE TO ALLOW EYECARE PRACTITIONERS TO USE OPTI-FREE RINSING, DISINFECTING AND STORAGE SOLUTION FOR STORAGE OF SOFT (HYDROPHILIC) TRIAL LENSES FOR UP TO 90 DAYS	08-06-91
P830045/S30	AFP CARDIAC PACING SYSTEM, PARAGON II AND PHOENIX PULSE GENERATORS	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	PARAGON II MODEL 2016L AND PHOENIX 2 MODELS 2005L AND 2008L PULSE GENERATOR	08-07-91
P830060/S25	EXTERNAL CARDIOVERTER DEFIBRILLATOR (ECD) SYSTEM, MODEL 2801, VENTAK ECD MODEL 2806	CARDIAC PACEMAKERS INC. ST. PAUL, MN 55112-5798	MODIFICATIONS TO ENHANCE THE MECHANICAL DURABILITY OF THE VENTAK ECD MODEL 2806	08-12-91
P830061/S10	CAPSURE SP MODELS 4023-4523 PACING	MEDTRONIC, INC. MINNEAPOLIS, MN	ADDITION OF THE MODELS 4023-4523 TO THE CAPSURE	08-07-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	LEADS	55432-3576	SP PRODUCT LINE	
P830061/S12	CAPSURE MODELS 4003-4503 PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	ADDITION OF THE MODELS 4024-4524 TO THE CAPSURE SP PRODUCT LINE	08-19-91
P840001/S24	ITREL TOTALLY IMPLANTABLE SPINAL CORD STIMULATION SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	THREE MODIFICATIONS TO THE MANUFACTURING PROCESS FOR THE MODEL 7420-21 ITREL AND 7424 ITREL II IMPLANTABLE PULSE GENERATORS (IPGS)	08-29-91
P840008/S26	DORNIER LITHOTRIPTER, MODEL HM3, DORNIER MULTIPURPOSE LITHOTRIPTER MPL 9000	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	MODIFICATIONS TO THE DORNIER LITHOTRIPTER, MODEL HM4, RESULTING IN A NEW LITHOTRIPTER MODEL TO BE MARKETED UNDER THE TRADE NAME DORNIER MULTIPURPOSE LITHOTRIPTER MPL 9000	08-12-91
P840008/S28	DORNIER LITHOTRIPTER, MODEL HM3, DORNIER MULTIPURPOSE LITHOTRIPTER MPL 9000 MOBILE	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	A MOBILE VERSION OF THE MPL 9000 LITHOTRIPTER TO BE MARKETED UNDER THE TRADE NAME DORNIER MULTIPURPOSE LITHOTRIPTER MPL 9000 MOBILE	08-13-91
P840008/S30	DORNIER LITHOTRIPTER, MODEL HM3	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	ADDITION OF TWO MOTION/STOP BUTTONS TO THE MODEL HM3 LITHOTRIPTER	08-06-91

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P840024/S32 08-15-91	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR POSTLINGUALLY DEAFENED ADULTS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	CHANGES TO THE KMOS INTEGRATED CIRCUIT AND PRINTED CIRCUIT BOARD ASSEMBLY OF THE NUCLEUS 22 CHANNEL COCHLEAR IMPLANT MINI SPEECH PROCESSOR
P840024/S33 08-15-91	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR POSTLINGUALLY DEAFENED ADULTS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	A SHORTENED CABLE BETWEEN THE HEADSET MICROPHONE AND THE TRANSMITTING COIL
P840055/S23 08-07-91	SGP (TELEFOCON A) AND SGP II (TELEFOCON B) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR, BLUE AND GREEN TINTED)	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NJ 07751	THREE ADDITIONAL CONTACT LENS FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P850002/S07 08-28-91	ALGES (HEFILCON A) SOFT (HYDROPHILIC) CONTACT LENS, UNISOFT (HEFILCON A) SOFT (HYDROPHILIC) ASPHERIC CONTACT LENS	UNILENS CORPORATION USA LARGO, FL 34647-1511	NEW DESIGN MODIFICATION OF THE ALGES (HEFILCON A) SOFT (HYDROPHILIC) CONTACT LENS TO BE MARKETED UNDER THE TRADE NAME UNISOFT (HEFILCON A) SOFT (HYDROPHILIC) ASPHERIC CONTACT LENS
P850035/S12 08-12-91	SPF-4T IMPLANTABLE SPINAL FUSION	ELECTRO-BIOLOGY, INC. PARSIPPANY, NJ	INCREASE THE STANDARD LEAD LENGTH FOR ALL

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	STIMULATOR	07054-1079	APPROVED CONFIGURATIONS FROM THE PRESENT 15-20 CM STANDARD LENGTH UP TO A MAXIMUM LEAD LENGTH OF 30 CM	
P850038/S16	PARAPERM EW (PASIFOCON C) RIGID GAS PERMEABLE CONTACT LENS	PARAGON OPTICAL MESA, AZ 85204	CONTACT LENS FINISHING LABORATORY, CRM OPTICAL, EAST 112 FIRST AVENUE TAFC-20, SPOKANE, WA 99220, TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	08-15-91
P850053/S04	FIBREL GELATIN MATRIX IMPLANT	MENTOR CORPORATION GOLETA, CA 93117	MODIFICATIONS TO THE DEVICE LABELING TO INCLUDE AN ADDITIONAL WARNING STATEMENT	08-14-91
P850077/S15	SUNSOFT SOFT CONTACT LENS, SUNFOCAL SOFT ASPHERIC MULTIFOCAL AND REVOLUTION (METHAFILCON A) SOFT (HYDROPHILIC) APHAKIC CONTACT LENS	SUNSOFT CORPORATION ALBUQUERQUE, NM 87109	DESIGN MODIFICATION (ASPHERIC MULTIFOCAL) OF THE REVOLUTION (METHAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS	08-27-91
P850088/S19	LENS PLUS OXYSEPT DISINFECTION	ALLERGAN OPTICAL IRVINE, CA	ALTERNATE MANUFACTURING SITE, UNIX PLASTICS,	08-06-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	SYSTEM	92715-1599	INC., NO. 86-4, SHANG TA TSUEN, KUANG YIN HSIANG, TAO YUAN HSIEN, TAIWAN 32811, FOR THE OXYTAB CUP, THE LENS CASE PORTION OF THE DISINFECTION SYSTEM	
P860019/S41	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	LABELING CHANGES	08-27-91
P860019/S43	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER ACE AND LONG ACE	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	ADDING AN ADHESIVE PRIMER TO BE USED WITH THE CYANOACRYLATE BOND ADHESIVE ON THE ACE AND LONG ACE CATHETER MODELS	08-29-91
P860040/S10	BIOCURVE SOFT, BIOCURVE SOFT TORIC AND BIOCURVE SOFT EW, (METHAFILCON A) HYDROPHILIC CONTACT LENS	CAL BIONICS, INC. NOVATO, CA 94947	RELOCATION OF WESTCON CONTACT LENS COMPANY FROM 2775 CROSSROADS BLVD., SUITE 110, GRAND JUNCTION, CO 81506 TO 715 HORIZON DR., SUITE 170, GRAND JUNCTION, CO 81506	08-29-91
P870024/S26	FLUOROPERM (PAFLUFOCON A) RIGID GAS PERMEABLE	PARAGON OPTICAL MESA, AZ 85204	CONTACT LENS FINISHING LABORATORY, CRM OPTICAL, EAST 112 FIRST AVENUE	08-15-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CONTACT LENSES (CLEAR AND TINTED)	TAFC-20, SPOKANE, WA 99220	TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	
P870043/S13	TRIMEDYNE'S SPECTRAPROBE-PLR CATHETER AND MODEL 900 OPTILASE CONTACT LASER SOURCE SYSTEM, MULTI-FIBER SPECTRAPROBE AND SPECTRACATH CATHETERS	TRIMEDYNE, INC. IRVINE, CA 92714	ADDITION OF THE 1.6, 2.0, 2.5, AND 3.0MM MULTI-FIBER SPECTRAPROBE CATHETERS AND THE 3.0MM HALOCATH CATHETER TO THE PRODUCT LINE AND CHANGING THE NAME OF THE MODEL 5000 PULSED HOLMIUM:YAG LASER SYSTEM TO THE MODEL 1210 OMNIPULSE HOLMIUM LASER SYSTEM	08-20-91
P870045/S26	MODEL SP24UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	INTRAOPTICS, INC. BOCA RATON, FL 33429-1710	MODEL SP24UB ULTRAVIOLET ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	08-22-91
P870045/S27	MODEL CM11UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	INTRAOPTICS, INC. BOCA RATON, FL 33429-1710	MODEL CM11UB ULTRAVIOLET ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	08-22-91
P870062/S02	PRENTIF CAVITY-RIM CERVICAL CAP	LAMBERTS DALSTON LIMITED LONDON, ENGLAND	PROTOCOL TO CONDUCT A RETROSPECTIVE POSTAPPROVAL STUDY TO DETERMINE THE RISK	08-20-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

			FACTORS AT 3 MONTHS POST FITTING THAT MAY PREDISPOSE CERVICAL CAP USERS TO CERVICAL CYTOLOGICAL CHANGES	
P870071/S08	LASTAC SYSTEM	GV MEDICAL, INC. MINNEAPOLIS, MN 55447	ADDITIONAL INFORMATION ON THE ADDITION OF POLYIMIDE TUBING TO THE DEVICE	08-06-91
P880001/S30	FLUOREX 700 (FLUSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	G.T. LABORATORIES CHICAGO, IL 60602	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	08-21-91
P880003/S05	CORDIS HELIX PTCA DILATATION CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	CORDIS HELIX PTCA DILATATION CATHETER	08-06-91
P880009/S04	VIRAPAP HUMAN PAPILLOMAVIRUS DNA DETECTION KIT	DIGENE DIAGNOSTICS, INC. SILVER SPRING, MD 20904	SPECIFIC LABELING REVISIONS AND ADDITIONS TO THE PACKAGE INSERT	08-19-91
P880027/S14	SCHNEIDER MICROSOFTRAC-XLP PTCA CATHETER	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	CHANGE NAME FROM SCHNEIDER MICROSOFTRAC-XLP PTCA CATHETER TO SCHNEIDER XLP PTCA CATHETER	08-06-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P880038/S13	META MV PACING SYSTEM-META II PACING SYSTEM INCLUDING MODEL 1204 PULSE GENERATOR, MODEL 5600S VERSION V1.30A1 AND MODEL 5603 VERSION V5.11P	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	META II PACING SYSTEM WHICH INCLUDES THE MODEL 1204 PULSE GENERATOR AND THE MODEL 5600S PROGRAMMER	08-06-91
P880041/S02	INTRAOCULAR LENSES: VALIDATION OF GETINGE ETHYLENE OXIDE STERILIZER	PHARMACIA OPHTHALMICS, INC. MONROVIA, CA 91017-7136	GETINGE ETHYLENE OXIDE STERILIZER	08-27-91
P880070/S03	INTRAOCULAR LENSES: VALIDATION OF GETINGE ETHYLENE OXIDE STERILIZER	PHARMACIA OPHTHALMICS, INC. MONROVIA, CA 91017-7136	GETINGE ETHYLENE OXIDE STERILIZER	08-27-91
P880082/S13	ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	EYE TECHNOLOGY, INCORPORATED SAINT PAUL, MN 55117	PROPOSAL TO EXTEND SHELF-LIFE AND STERILITY EXPIRATION TO 59 MONTHS	08-06-91
P880086/S13	SYNCHRONY CARDIAC PACING SYSTEM, SOLUS MODELS 2002	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	ADDITIONAL TESTS TO THE SOLUS MODELS 2002 AND 2003 AND THE SYNCHRONY II	08-19-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	AND 2003 AND THE SYNCHRONY II MODELS 2022 AND 2023 PULSE GENERATORS		MODELS 2022 AND 2023 PULSE GENERATORS	
P890003/S08	SYNERGYST II MODELS 7070 AND 7071, MODEL 9760 PROGRAMMER SYSTEM WITH MODEL 9852 SOFTWARE	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	LABELING CHANGES TO THE MODEL 9760 PROGRAMMER SYSTEM MANUAL WHEN USING THE MODEL 9852 SOFTWARE	08-19-91
P890027/S03	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	CHANGES TO THE KMOS INTEGRATED CIRCUIT AND PRINTED CIRCUIT BOARD ASSEMBLY OF THE NUCLEUS 22 CHANNEL COCHLEAR IMPLANT MINI SPEECH PROCESSOR	08-15-91
P890027/S04	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	SHORTENED CABLE BETWEEN THE HEADSET MICROPHONE AND THE TRANSMITTING COIL	08-15-91
P890043/S11	SIMPSON CORONARY ATHEROCATH SCA-LP DEVICE	DEVICES FOR VASCULAR INTERVENTION REDWOOD CITY, CA	MATERIAL CHANGE FOR THE BALLOON INFLATION TUBE OF THE SCA-LP DEVICE	08-27-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

94063

P900001/S03	SGP 3 (UNIFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR, BLUE AND GREEN TINTED)	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NJ 07751	FOUR ADDITIONAL CONTACT LENS FINISHING LABORATORIES	08-06-91
P900058/S01	TECHNICON-45 SOFT (HEFILCON A) CONTACT LENS	WESTCON CONTACT LENS COMPANY GRAND JUNCTION, CO 81506	RELOCATION OF MANUFACTURING FACILITY USED IN THE MANUFACTURE OF THE LENSES FROM 2775 CROSSROADS BLVD., SUITE 110, GRAND JUNCTION, CO 81506 TO 715 HORIZON DRIVE, SUITE 170, GRAND JUNCTION, CO 81506	08-29-91
P900065/S01	TECHNICON 38 (POLYMACON) HYDROPHILIC CONTACT LENSES (SPHERICAL AND TORIC)	WESTCON CONTACT LENS COMPANY GRAND JUNCTION, CO 81506	RELOCATION OF MANUFACTURING FACILITY USED IN THE MANUFACTURE OF THE LENSES FROM 2775 CROSSROADS BLVD., SUITE 110, GRAND JUNCTION, CO 81506 TO 715 HORIZON	08-29-91

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

DRIVE, SUITE 170, GRAND
JUNCTION, CO 81506

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR AUGUST 1991.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR AUGUST 1991.

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER TRADE NAME SPECIES APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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Center for Biologics Evaluation and Research
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September 1991

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
(CLASSIFICATION) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

19-568 DERMATOP HOECHST ROUSSEL PREDNICARBATE
09-23-91 (OINTMENT) SOMERVILLE, NJ 0.1%
(2 C) 08876 (CORTICOSTEROID)

19-593 ZANTAC GLAXO RANITIDINE HYDROCHLORIDE
09-27-91 IN PLASTIC RES TRIANGLE PK, NC EQ 1MG BASE/ML
(SUPPL) CONTAINER 27709 (NEW STRENGTH)
(INJECTABLE)

20-068 FOSCAVIR ASTRA PHARM PRDTS FOSCARNET SODIUM
09-27-91 (INJECTABLE) WESTBOROUGH, MA 24MG/ML
(1B,AA*,E**) 01581 (ANTIVIRAL)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

AA* - Refers to the Priority Classification for AIDS Drugs
E** - Drug for Severely Debilitating/Life Threatening Illness

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
(CLASSIFICATION) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

50-670 ZITHROMAX PFIZER AZITHROMYCIN
09-03-91 (CAPSULE) GROTON, CT EQ 250MG BASE
06340 (ANTIBIOTIC, MACROLIDE)

19-773 VENTOLIN GLAXO ALBUTEROL SULFATE
09-09-91 (SOLUTION) RES TRIANGLE PK, NC EQ 0.083% BASE
27709 (BRONCHODILATOR)

19-979 TICLID SYNTEX TICLOPIDINE HYDROCHLORIDE
09-16-91 (TABLET) PALO ALTO, CA 125MG
94304 250MG
(PLATELET INHIBITOR)

19-839 ZOLOFT PFIZER SERTRALINE HYDROCHLORIDE
09-30-91 (TABLET) GROTON, CT EQ 50MG BASE
06340 EQ 100MG BASE
EQ 150MG BASE
EQ 200MG BASE
(ANTIDEPRESSANT)

20-068 FOSCAVIR ASTRA PHARM PRDTS FOSCARNET SODIUM
09-24-91 (INJECTABLE) WESTBOROUGH, MA 24MG/ML
01581 (ANTIVIRAL)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

73-261 SULINDAC LEDERLE SULINDAC
09-06-91 (TABLET) PEARL RIVER, NY 150MG
10965 (NONSTEROIDAL ANTI-INFLAMMATORY)

73-262 SULINDAC LEDERLE SULINDAC
09-06-91 (TABLET) PEARL RIVER, NY 200MG
10965 (NONSTEROIDAL ANTI-INFLAMMATORY)

81-169 GLYCOPYRROLATE GENSIA GLYCOPYRROLATE
09-10-91 (INJECTABLE) IRVINE, CA 0.2MG/ML
92718 (ANTICHOLINERGIC)

73-025 ATENOLOL GENEVA ATENOLOL
09-17-91 (TABLET) BROOMFIELD, CO 50MG
80038 (BETA ADRENERGIC BLOCKER)

73-026 ATENOLOL GENEVA ATENOLOL
09-17-91 (TABLET) BROOMFIELD, CO 100MG
80038 (BETA ADRENERGIC BLOCKER)

72-741 LOPERAMIDE HCL MYLAN LOPERAMIDE HYDROCHLORIDE
09-18-91 (CAPSULE) MORGANTOWN, WV 2MG
26505 (ANTIDIARRHEAL)

72-824 BACLOFEN DANBURY BACLOFEN
09-18-91 (TABLET) DANBURY, CT 10MG
06810 (SKELETAL MUSCLE RELAXANT)

72-825 BACLOFEN DANBURY BACLOFEN
09-18-91 (TABLET) DANBURY, CT 20MG
06810 (SKELETAL MUSCLE RELAXANT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

71-041	NORETHINDRONE AND	WATSON	ETHINYL ESTRADIOL
09-24-91	ETHINYL ESTRADIOL	CORONA, CA	0.035MG
	(7/14)-21	91720	NORETHINDRONE
	(TABLET)		0.5MG AND 1 MG
			(HORMONAL CONTRACEPTIVE)

71-042	NORETHINDRONE AND	WATSON	ETHINYL ESTRADIOL
09-24-91	ETHINYL ESTRADIOL	CORONA, CA	0.035MG
	(7/14)-28	91720	NORETHINDRONE
	(TABLET)		0.5MG AND 1MG
			(HORMONAL CONTRACEPTIVE)

72-786	FENTANYL CITRATE	STERLING	FENTANYL CITRATE
09-24-91	(INJECTABLE)	NEW YORK, NY	EQ 0.05MG BASE/ML
		10016	(ANALGESIC)

81-142	AMINOPHYLLINE	GENSIA	AMINOPHYLLINE
09-25-91	(INJECTABLE)	IRVINE, CA	25MG/ML
		92718	(BRONCHODILATOR)

89-363	ACETAMINOPHEN AND	MIKART	ACETAMINOPHEN
09-25-91	CODEINE PHOSPHATE	ATLANTA, GA	650MG
	(TABLET)	30318	CODEINE PHOSPHATE
			60MG
			(ANALGESIC)

70-770	DISOBROM	GENEVA	DEXBROMPHENIRAMINE MALEATE
09-30-91	(TABLET,	BROOMFIELD, CO	6MG
	EXTENDED RELEASE)	80038	PSEUDOEPHEDRINE SULFATE
			120MG
			(ANTIHISTAMINE/DECONGESTANT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

(OTC)

73-373	MORPHINE SULFATE	STERIS	MORPHINE SULFATE
09-30-91	(INJECTABLE)	PHOENIX, AZ	0.5MG/ML
	85043	(ANALGESIC)	
73-374	MORPHINE SULFATE	STERIS	MORPHINE SULFATE
09-30-91	(INJECTABLE)	PHOENIX, AZ	1MG/ML
	85043	(ANALGESIC)	
73-375	MORPHINE SULFATE	STERIS	MORPHINE SULFATE
09-30-91	(INJECTABLE)	PHOENIX, AZ	0.5MG/ML
	85043	(ANALGESIC)	
73-376	MORPHINE SULFATE	STERIS	MORPHINE SULFATE
09-30-91	(INJECTABLE)	PHOENIX, AZ	1MG/ML
	85043	(ANALGESIC)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

11-856	SOLU-MEDROL	UPJOHN	METHYLPREDNISOLONE
09-04-91	(INJECTABLE)	KALAMAZOO, MI	SODIUM SUCCINATE
		49001	EQ 40MG BASE/VIAL
			EQ 125MG BASE/VIAL
			EQ 500MG BASE/VIAL
			EQ 1GM BASE/VIAL
			EQ 2GM BASE/VIAL
			(REVISED LABELING --
			DESCRIPTION)
19-771	COADVIL	WHITEHALL LABS	IBUPROFEN
09-04-91	(TABLET)	NEW YORK, NY	200MG
		10017	PSEUDOEPHEDRINE HYDROCHLORIDE
			30MG
			(REVISED LABELING --
			NEW TRADE NAME)
16-099	ATROMID-S	WYETH AYERST	CLOFIBRATE
09-05-91	(CAPSULE)	PHILADELPHIA, PA	500MG
		19101	(REVISED LABELING --
			ADVERSE REACTIONS)
19-090	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
09-05-91	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 25MG BASE/ML
		27709	(REVISED LABELING --
			ADVERSE REACTIONS)
19-593	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
09-05-91	IN PLASTIC	RESEARCH TRIANGLE, NC	EQ 50MG BASE/100ML
	CONTAINER	27709	(REVISED LABELING --
	(INJECTABLE)		ADVERSE REACTIONS)
50-614	KEFTAB	LILLY	CEPHALEXIN HYDROCHLORIDE

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

09-06-91 (TABLET) INDIANAPOLIS, IN EQ 250MG BASE
46285 EQ 500MG BASE
(REVISED LABELING --
WARNINGS; ADVERSE REACTIONS)

16-640 QUESTRAN BRISTOL MYERS CHOLESTYRAMINE
09-10-91 (POWDER) EVANSVILLE, IN EQ 4GM RESIN/PACKET
47721 EQ 4GM RESIN/SCOOPFUL
(REVISED LABELING --
DOSAGE AND ADMINISTRATION)

19-669 QUESTRAN LIGHT BRISTOL MYERS CHOLESTYRAMINE
09-10-91 (POWDER) EVANSVILLE, IN EQ 4GM RESIN/PACKET
47721 EQ 4GM RESIN/SCOOPFUL
(REVISED LABELING --
DOSAGE AND ADMINISTRATION)

50-477 NEBCIN LILLY TOBRAMYCIN SULFATE
09-12-91 (INJECTABLE) INDIANAPOLIS, IN EQ 10MG BASE/ML
46285 (REVISED LABELING --
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED)

07-513 LEVOPHED STERLING NOREPINEPHRINE BITARTRATE
09-13-91 (INJECTABLE) NEW YORK, NY EQ 1MG BASE/ML
10016 (REVISED LABELING --
ADVERSE REACTIONS;
HOW SUPPLIED)

11-971 ORETIC ABBOTT HYDROCHLOROTHIAZIDE
09-13-91 (TABLET) ABBOTT PARK, IL 25MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)	
			LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		60064	50MG	(REVISED LABELING -- LABELING FORMAT REVISION PROGRAM)
19-478	ADALAT	MILES	NIFEDIPINE	
09-13-91	(CAPSULE)	W HAVEN, CT	10MG	
		06516	20MG	(REVISED LABELING -- CLINICAL PHARMACOLOGY; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)
19-532	MYKROX	FISONS	METOLAZONE	
09-13-91	(TABLET)	BEDFORD, MA	0.5MG	
		01730		(REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)
19-614	VERELAN	ELAN	VERAPAMIL HYDROCHLORIDE	
09-13-91	(CAPSULE, EXTENDED RELEASE)	GAINESVILLE, GA	120MG	
		30501	240MG	(REVISED LABELING -- CLINICAL PHARMACOLOGY)
12-728	ORTHO-NOVUM	JOHNSON RW	MESTRANOL	
09-16-91	1/50-21	RARITAN, NJ	0.05MG	
	(TABLET)	08869	NORETHINDRONE 1MG	(REVISED LABELING -- WARNINGS; PATIENT PACKAGE INSERT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

16-709	ORTHO-NOVUM	JOHNSON RW	MESTRANOL
09-16-91	1/50-28	RARITAN, NJ	0.05MG
	(TABLET)	08869	NORETHINDRONE
			1MG
			(REVISED LABELING --
			WARNINGS;
			PATIENT PACKAGE INSERT)
16-954	MICRONOR	JOHNSON RW	NORETHINDRONE
09-16-91	(TABLET)	RARITAN, NJ	0.35MG
	08869		(REVISED LABELING --
			WARNINGS;
			PATIENT PACKAGE INSERT)
17-488	MODICON 21	JOHNSON RW	ETHINYL ESTRADIOL
09-16-91	(TABLET)	RARITAN, NJ	0.035MG
	08869		NORETHINDRONE
			0.5MG
			(REVISED LABELING --
			WARNINGS;
			PATIENT PACKAGE INSERT)
17-489	ORTHO-NOVUM	JOHNSON RW	ETHINYL ESTRADIOL
09-16-91	1/35-21	RARITAN, NJ	0.035MG
	(TABLET)	08869	NORETHINDRONE
			1MG
			(REVISED LABELING --
			WARNINGS;
			PATIENT PACKAGE INSERT)
17-735	MODICON 28	JOHNSON RW	ETHINYL ESTRADIOL
09-16-91	(TABLET)	RARITAN, NJ	0.035MG
	08869		NORETHINDRONE

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

0.5MG
(REVISED LABELING --
WARNINGS;
PATIENT PACKAGE INSERT)

17-919 ORTHO-NOVUM JOHNSON RW ETHINYL ESTRADIOL
09-16-91 1/35-28 RARITAN, NJ 0.035MG
(TABLET) 08869 NORETHINDRONE
1MG
(REVISED LABELING --
WARNINGS;
PATIENT PACKAGE INSERT)

18-354 ORTHO-NOVUM JOHNSON RW ETHINYL ESTRADIOL
09-16-91 10/11-21 RARITAN, NJ 0.035MG
(TABLET) 08869 NORETHINDRONE
0.5MG
1MG
(REVISED LABELING -- WARNINGS;
PATIENT PACKAGE INSERT)

18-354 ORTHO-NOVUM JOHNSON RW ETHINYL ESTRADIOL
09-16-91 10/11-28 RARITAN, NJ 0.035MG
(TABLET) 08869 NORETHINDRONE
0.5MG
1MG (REVISED LABELING --

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			WARNINGS;
			PATIENT PACKAGE INSERT)
18-985	ORTHO-NOVUM	JOHNSON RW	ETHINYL ESTRADIOL
09-16-91	7/7/7-21	RARITAN, NJ	0.035MG
	(TABLET)	08869	NORETHINDRONE
			0.5MG
			0.75MG
			1MG
			(REVISED LABELING --
			WARNINGS;
			PATIENT PACKAGE INSERT)
18-985	ORTHO-NOVUM	JOHNSON RW	ETHINYL ESTRADIOL
09-16-91	7/7/7/-28	RARITAN, NJ	0.035MG
	(TABLET)	08869	NORETHINDRONE
			0.5MG
			0.75MG
			1MG
			(REVISED LABELING --
			WARNINGS;
			PATIENT PACKAGE INSERT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-316	MAGNESIUM SULFATE	LYPHOMED	MAGNESIUM SULFATE
09-16-91	(INJECTABLE)	MELROSE PARK, IL	500MG/ML
	60160	(REVISED LABELING --	
		DESCRIPTION;	
		CLINICAL PHARMACOLOGY;	
		INDICATIONS AND USAGE;	
		CONTRAINDICATIONS; WARNINGS;	
		PRECAUTIONS;	
		ADVERSE REACTIONS;	
		OVERDOSAGE;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	
19-653	ORTHO CYCLEN-21	JOHNSON RW	ETHINYL ESTRADIOL
09-17-91	(TABLET)	RARITAN, NJ	0.035MG
	08869	NORGESTIMATE	
		0.25MG	
		(REVISED LABELING --	
		WARNINGS;	
		PATIENT PACKAGE INSERT)	
19-653	ORTHO CYCLEN-28	JOHNSON RW	ETHINYL ESTRADIOL
09-17-91	(TABLET)	RARITAN, NJ	0.035MG
	08869	NORGESTIMATE	
		0.25MG	
		(REVISED LABELING --	
		WARNINGS;	
		PATIENT PACKAGE INSERT)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)	
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)	
		LABELING CHANGE(S)		

LABELING SUPPLEMENTS TO ORIGINAL NDAs

11-958	HYDROPRES 25	MSD	HYDROCHLOROTHIAZIDE	
09-18-91	(TABLET)	W POINT, PA	25MG	
		19486	RESERPINE	
			0.125MG	
			(REVISED LABELING --	
			INDICATIONS AND USAGE;	
			CONTRAINDICATIONS;	
			WARNINGS; PRECAUTIONS;	ADVERSE REACTIONS;
			OVERDOSAGE;	
			DOSAGE AND ADMINISTRATION;	
			HOW SUPPLIED)	
11-958	HYDROPRES 50	MSD	HYDROCHLOROTHIAZIDE	
09-18-91	(TABLET)	W POINT, PA	50MG	
		19486	RESERPINE	
			0.125MG	
			(REVISED LABELING --	
			INDICATIONS AND USAGE;	
			CONTRAINDICATIONS;	
			WARNINGS; PRECAUTIONS;	ADVERSE REACTIONS;
			OVERDOSAGE;	
			DOSAGE AND ADMINISTRATION;	
			HOW SUPPLIED)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-240	TENORMIN	ICI	ATENOLOL
09-18-91	(TABLET)	WILMINGTON, DE 19897	25MG 50MG 100MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; POTENTIAL ADVERSE EFFECTS)

18-303	LOPRESSOR	CIBA	HYDROCHLOROTHIAZIDE
09-18-91	HCT 50/25	SUMMIT, NJ	25MG
	(TABLET)	07901	METOPROLOL TARTRATE 50MG (REVISED LABELING -- PRECAUTIONS)

18-303	LOPRESSOR	CIBA	HYDROCHLOROTHIAZIDE
09-18-91	HCT 100/25	SUMMIT, NJ	25MG
	(TABLET)	07901	METOPROLOL TARTRATE 100MG (REVISED LABELING -- PRECAUTIONS)

18-303	LOPRESSOR	CIBA	HYDROCHLOROTHIAZIDE
09-18-91	HCT 100/50	SUMMIT, NJ	50MG
	(TABLET)	07901	METOPROLOL TARTRATE 100MG

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
			(REVISED LABELING -- PRECAUTIONS)
18-760 09-18-91	TENORETIC 50 (TABLET)	STUART WILMINGTON, DE 19897	ATENOLOL 50MG CHLORTHALIDONE 25MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; POTENTIAL ADVERSE EFFECTS)
18-760 09-18-91	TENORETIC 100 (TABLET)	STUART WILMINGTON, DE 19897	ATENOLOL 100MG CHLORTHALIDONE 25MG (REVISED LABELING -- ADVERSE REACTIONS; POTENTIAL ADVERSE EFFECTS) PRECAUTIONS;
19-058 09-18-91	TENORMIN (INJECTABLE)	ICI WILMINGTON, DE 19897	ATENOLOL 0.5MG/ML (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; POTENTIAL ADVERSE EFFECTS)
18-012* 09-19-91	PAMELOR (SOLUTION)	SANDOZ E HANOVER, NJ 07936	NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE/5ML (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; HOW SUPPLIED)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-013*	PAMELOR	SANDOZ	NORTRIPTYLINE HYDROCHLORIDE
09-19-91	(CAPSULE)	E HANOVER, NJ	EQ 10MG BASE
		07936	EQ 25MG BASE
			EQ 50MG BASE
			EQ 75MG BASE
			(REVISED LABELING --
			DESCRIPTION; HOW SUPPLIED)
18-554	EULEXIN	SCHERING	FLUTAMIDE
09-19-91	(CAPSULE)	KENILWORTH, NJ	125MG
		07033	(REVISED LABELING --
			WARNINGS)
18-654	VERSED	ROCHE	MIDAZOLAM HYDROCHLORIDE
09-19-91	(INJECTABLE)	NUTLEY, NJ	EQ 1MG BASE/ML
		07110	EQ 5MG BASE/ML
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			CONTRAINDICATIONS;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)

* Permitted

19-753	ETHMOZINE	DUPONT	MORICIZINE HYDROCHLORIDE
09-20-91	(TABLET)	WILMINGTON, DE	200MG
		19880	250MG
			300MG
			(REVISED LABELING --

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			INDICATIONS AND USAGE;
			WARNINGS)
17-016	CHORIONIC	STERIS LABS	GONADOTROPIN, CHORIONIC
09-23-91	GONADOTROPIN	PHOENIX, AZ	2,000 UNITS/VIAL
	(INJECTABLE)	85063	5,000 UNITS/VIAL
			10,000 UNITS/VIAL
			15,000 UNITS/VIAL
			20,000 UNITS/VIAL
			(REVISED LABELING --
			DESCRIPTION; PRECAUTIONS;
			HOW SUPPLIED; HOW TO USE)
10-796	HARMONYL	ABBOTT	DESERPIDINE
09-25-91	(TABLET)	ABBOTT PARK, IL	0.25MG
		60064	(REVISED LABELING --
			LABELING FORMAT
			REVISION PROGRAM)
12-775	ENDURONYL	ABBOTT	DESERPIDINE
09-25-91	(TABLET)	ABBOTT PARK, IL	0.25MG
		60064	METHYCLOTHIAZIDE
			5MG
			(REVISED LABELING --
			LABELING FORMAT
			REVISION PROGRAM)
12-775	ENDURONYL FORTE	ABBOTT	DESERPIDINE
09-25-91	(TABLET)	ABBOTT PARK, IL	0.5MG
		60064	METHYCLOTHIAZIDE
			5MG
			(REVISED LABELING --
			LABELING FORMAT

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

REVISION PROGRAM)

18-538	LOZOL	RHONE POULENC RORER	INDAPAMIDE
09-25-91	(TABLET)	FORT WASHINGTON, PA	2.5MG
		19034	(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
17-922	DDAVP	RHONE POULENC RORER	DESMOPRESSIN ACETATE
09-27-91	(SOLUTION)	FORT WASHINGTON, PA	0.01%
		19034	(REVISED LABELING -- WARNINGS; PRECAUTIONS)
18-817	CALAN	SEARLE	VERAPAMIL HYDROCHLORIDE
09-27-91	(TABLET)	SKOKIE, IL	40MG
		60077	80MG
			120MG
			(REVISED LABELING -- CLINICAL PHARMACOLOGY)
50-580	AZACTAM	SQUIBB	AZTREONAM
09-30-91	(INJECTABLE)	NEW BRUNSWICK, NJ	500MG/VIAL
		08903	1GM/VIAL
			2GM/VIAL
			(REVISED LABELING -- ADVERSE REACTIONS)
50-632	AZACTAM	SQUIBB	AZTREONAM
09-30-91	IN PLASTIC	NEW BRUNSWICK, NJ	10MG/ML
	CONTAINER	08903	20MG/ML
	(INJECTABLE)		40MG/ML
			(REVISED LABELING -- ADVERSE REACTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT LICENSES ISSUED

978 09-25-91	GENETIC SYSTEMS HIV-1/HIV-2 EIA (IN-VITRO)	GENETIC SYS CORP REDMOND, WA 98073	HUMAN IMMUNODEFICIENCY VIRUS TYPES 1 AND 2 (DETECTION OF ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS TYPES 1 AND 2 IN HUMAN SERUM OR PLASMA) (B)

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

(B) Product License Issued

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910015 09-11-91	SEBRA MODEL #1290, BLOOD/PLATELET	ENGINEERING AND RES ASSOC TUCSON, AZ 85716	BLOOD STORAGE REFRIGERATOR/ BLOOD PLATELET COOLANT
BK910009 09-18-91	ALPHA PLASMA POOLING BOTTLE II (SIGNIFICANT REVISIONS)	ALPHA THERPTC LOS ANGELES, CA 90032	EMPTY CONTAINERS FOR THE THE COLLECTION AND PROCESSING OF BLOOD AND BLOOD COMPONENTS (C)
BK910014 09-18-91	SEPACELL R-200 PRE-STAGE LEUKOCYTE DEPLETION SET FOR RED BLOOD CELLS	BAXTER HLTHCARE CORP ROUND LAKE, IL 60073	TRANSFER SET (FILTER) (C)

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

P860057	CARPENTIER-EDWARDS PERICARDIAL BIOPROSTHESIS	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	SIZES 19, 21, 23, 25, 27, AND 29 CARPENTIER-EDWARDS PERICARDIAL BIOPROSTHESIS MODEL 2700	09-26-91
P870038	STARR-EDWARDS SILASTIC BALL HEART VALVE PROSTHESIS	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	SIZES AORTIC MODEL 1260, SIZES 21, 23, 24, 26, 27, 29, AND 31 MM AND MITRAL MODELS 1260 AND 6120 MODEL 6120, SIZES 26, 28, 30, 32, AND 34 MM	09-27-91
P870056	CARPENTIER-EDWARDS BIOPROSTHESIS	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	SIZES AORTIC MODEL 2625, SIZES 19, 21, 23, 25, 27, 29, AND 31 MM, AND THE MODELS 2625 AND 6625 MITRAL MODEL 6625 SIZES 25, 27, 29, 31, 33, AND 35 MM	09-25-91
P870077	CARPENTIER-EDWARDS DURAFLEX BIOPROSTHESIS	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	SIZES 27, 29, 31, 33, AND 35 MM IN MODELS 6625 LP AND 6625-ESR-LP MODELS 6625 LP AND 6625-ESR-LP	09-25-91
P880091	STAAR MODEL AA-4203 ELASTIC LENS AND CHAMBER INTRAOCULAR LENS	SOFTLENSCO, INC. LOS ANGELES, CA	ELASTIC MODEL AA-4203 SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS MODEL 32-C10XX CHIROFLEX SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	09-16-91
P890013	RICHARD WOLF PIEZOLITH E.P.L. LITHOTRIPTER, MODEL 2300	RICHARD WOLF MEDICAL INSTRUMENTS CHIRON ROSEMONT, IL 60018	RICHARD WOLF PIEZOLITH E.P.L. LITHOTRIPTER, MODEL 2300	09-09-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

P890017	PALMAZ BALLOON-EXPANDABLE	JOHNSON & JOHNSON INTERVENTIONAL STENT	PALMAZ BALLOON-EXPANDABLE STENT	09-27-91 WARREN, NJ 07059
P890047	PROVISC	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	PROVISC (VISCOELASTIC MATERIAL INDICATED FOR USE AS A SURGICAL AID IN ANTERIOR SEGMENT PROCEDURES)	09-26-91
P900022	CHORUS DDD MODELS 6001, 6003, AND 6033, CPR1 MICROCOMPUTER PROGRAMMER AND P2A MICROCOMPUTER HANDHELD PROGRAMMER	ELA MEDICAL, INC. MINNETONKA, MN 55345	CHORUS DDD PACEMAKER MODELS 6001, 6003, AND 6033, CPR1 MICROCOMPUTER PROGRAMMER AND P2A HANDHELD PROGRAMMER	09-06-91
P900048	ELASTIMIDE SILICONE AQ-1002, AQ-1005, AND SILICONE 32-C21 SX-XX, 32-C22 32-C24 SX-XX SILICONE	SOFTLENSCO, INC. LOS ANGELES, CA 90071	ELASTIMIDE MODELS AQ-1000, AQ-1001, AND CHIROFLEX II MODELS 32-C20 SX-XX, INTRAOCULAR LENSES	09-17-91 POSTERIOR CHAMBER INTRAOCULAR LENSES AQ-1016, AND CHIROFLEX II POSTERIOR CHAMBER SX-XX, 32-C23 SX-XX AND POSTERIOR CHAMBER INTRAOCULAR LENSES
P910007	ABBOTT IMX PSA	ABBOTT LABORATORIES ABBOTT PARK, IL 60064-3500	ABBOTT IMX PSA	09-25-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

N17679/S25	AQUAFLEX STD. AND VANTAGE-VANTAGE ACCENTS CONTACT LENS, VANTAGE THIN HYDROPHILIC CONTACT LENSES (TETRAFILCON A)	COOPERVISION, INC. ROCHESTER, NY 14623	CONSOLIDATED PACKAGE INSERT FOR HYDROPHILIC THIN ACCENTS (TETRAFILCON A) EXTENDED WEAR	09-13-91 SUPERTHIN, PERMATHIN AND VANTAGE THIN-VANTAGE ACCENTS HYDROPHILIC CONTACT LENSES
N18120/S24	POLYCON (SILAFOCON A)	SOLA-BARNES-HIND SUNNYVALE, CA 94086-5200	ALTERNATE DESIGN FOR THE POLYCON (SILAFOCON A) LENS TO BE MANUFACTURED AT PILKINGTON DIFFRAX BARNES-HIND, LTD., 1 BOTLEY RD., HEDGE END, SO3 3HB, UNITED KINGDOM BIFOCAL CONTACT LENS WHICH IS TO BE MARKETED UNDER THE TRADE NAME DIFFRAX BIFOCAL CONTACT LENS	09-06-91 GAS PERMEABLE CONTACT LENS, (SILAFOCON A) SOUTHAMPTON, HAMPSHIRE
P780007/S36	HYDRON (POLYMACON) HYDROPHILIC CONTACT LENSES	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ALTERNATE MANUFACTURING SITE LOCATED AT ALLERGAN OPTICAL, INC., 8301 MARS DRIVE, WACO, TX 76712	09-10-91
P800022/S25	ZYPLAST IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	ADDITION OF LABELING STATEMENT WHICH ADDS INFORMATION ABOUT AN ADVERSE REACTION	09-30-91
P800058/S11	ST. JUDE MEDICAL BIOPOLYMERIC GRAFT	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	DISCONTINUATION OF REPORTING FOR THE POST-APPROVAL STUDY FOR VASCULAR GRAFT (FORMERLY N.C.G.T.) THE UNANASTOMOSED LARGE DIAMETER VERSION OF THE GRAFT	09-19-91
P810002/S18	ST. JUDE MEDICAL AORTIC VALVED GRAFT PROSTHESIS	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	CHANGES TO THE POSTAPPROVAL STUDY PROTOCOL WHICH WAS APPROVED JANUARY 8, 1985 FOR THE GRAFTS PROSTHESIS AND PULMONIC VALVED	09-30-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
P810006/S13	COLLASTAT ABSORBABLE COLLAGEN	VITAPHORE CORPORATION MENLO PARK, CA 94025	PROPOSED DATA SHEET FOR COLLASTAT MICROFIBRILLAR COLLAGEN AND A REVISED HEMOSTATIC SPONGE INDICATION STATEMENT FOR COLLASTAT ABSORBABLE COLLAGEN	09-17-91
P810046/S109	SIMPSON-ROBERT CORONARY BALLOON CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS, INC. SANTA CLARA, CA 95052-8167	CHANGE OF THE DEVICE NAME FROM THE ASC RX ALPHA .010 CORONARY DILATATION CATHETER TO THE ACS RX CORONARY DILATATION CATHETER	09-04-91
P820003/S59	VERSATRAX CARDIAC PACING SYSTEM 9751B	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODEL 9751B SYSTEM ENHANCEMENT MODULE PRINTER	09-27-91
P830040/S18	STYLE 38XE ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	3M VISION CARE ST. PAUL, MN 55144-1000	STYLE 38XE ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	09-23-91
P830045/S31	AFP MODEL 283 PULSE GENERATOR MODEL 3070 AND PULSE GENERATORS	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	PACESETTER MODEL 3070 (VERSION 4.4) AND PACE MEDICAL MODEL 4553 PROGRAMMER EXTERNAL DUAL CHAMBER TEMPORARY CARDIAC PACEMAKERS	09-11-91
P830045/S33	AFP MODEL 283 PULSE GENERATOR PROGRAMMER APS-II MODEL 3003 PROGRAMMER	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	ADDITION OF LABELING TO THE APS-II MODEL 3003 PROGRAMMER	09-16-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P840024/S30	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	DISTRIBUTION OF THE NUCLEUS 22 CHANNEL MINI SPEECH PROCESSOR (MSP)	09-10-91 FOR POSTLINGUALLY DEAFENED ADULTS WITH THE ADDED POTENTIOMETER FOR MINIMIZING OFFSET VOLTAGE
P840049/S01	PCA TOTAL KNEE SYSTEM	HOWMEDICA RUTHERFORD, NJ 07070	MODIFICATIONS IN THE PCA TOTAL KNEE SYSTEM (CEMENTLESS USE)	09-10-91
P850021/S14	HYBRID PERCUTANEOUS CORONARY ANGIOPLASTY CATHETER EDGE PTCA CATHETER	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	MODIFIED VERSION OF THE SLINKY PTCA CATHETER TRANSLUMINAL	09-16-91
P860004/S19	MEDTRONIC MODEL 8810 SYNCHROMED PROGRAMMER	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	ALTERNATIVE LAP-TOP COMPUTER, A COMPONENT OF THE MODEL 8810 SYNCHROMED PROGRAMMER	09-24-91
P860044/S03	ENZYMUN TEST AFP	BOEHRINGER MANNHEIM INDIANAPOLIS, IN 46250-0100	CHANGE MEASURING RANGE FROM 1.5-150 NG-ML TO 1.8-185 NG-ML IN THE MEASURING RANGE AND SENSITIVITY SECTIONS OF THE PACKAGE INSERT AND THE APPLICATION SHEET	09-03-91
P870045/S25	MODEL SP39UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	INTRAOPTICS, INC. BOCA RATON, FL 33429-1710	MODEL SP39UB ULTRAVIOLET-ABSORBING POSTERIOR-CHAMBER INTRAOCULAR LENS	09-05-91
P870075/S03	MODEL MP-2410	NEWLENSCO	MODEL MP-2410 POSTERIOR	09-13-91 POSTERIOR

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	CHAMBER	MONROVIA, CA	CHAMBER INTRAOCULAR LENS	INTRAOCULAR LENS 91016
P880006/S08	SENSOLOG 703 PULSE GENERATOR FEEDTHROUGH AND EPOXY DIALOG II 2037 AND IN DIALOG II	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	MODIFICATIONS TO THE PACEMAKER CHIP, AND 2034, AND SENSOLOG III MODELS 2033 AND 2034 AND MODELS 2037 AND 2038	09-03-91 SENSOLOG III 2033 AND 2038 CONNECTOR HEADER IN
P880006/S10	SENSOLOG MODEL 703 PULSE GENERATOR PROGRAMMER	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	ADDITION OF LABELING TO THE APS-II MODEL 3003 PROGRAMMER	09-16-91 AND P700 PROGRAMMER APS-II MODEL 3003 PROGRAMMER
P880082/S12	MODELS 24050-125, 24150-125, 25350-125 ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	EYE TECHNOLOGY, INC. ST. PAUL, MN 55117	MODELS 24050-125, 24150-125, 25050-125, 25150-125 AND 25350-125	09-04-91
P880086/S11	SYNCHRONY MODEL 2020T PULSE GENERATOR PROGRAMMER	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	ADDITION OF LABELING TO THE APS-II MODEL 3003 PROGRAMMER	09-16-91 APS-II MODEL 3003 PROGRAMMER
P880086/S14	SYNCHRONY MODEL 2020T, SYNCHRONY II MODEL 2022T AND SOLUS MODEL 2002T	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	LABELING CHANGES	09-16-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890014/S01	HA-IGMK,	SORIN BIOMEDICA S.P.A. SALUGGIA(VC), ITALY	CHANGE FROM A RADIOIMMUNOASSAY FOR THE DETECTION OF IGM ANTIBODIES TO HEPATITIS A VIRUS (IGM ANTI-HAV) TO A MICROTITER ENZYME IMMUNOASSAY	09-16-91
P890023/S01	HYDRON (OCUFILCON D) H55	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ALTERNATE MANUFACTURING SITE LOCATED AT ALLERGAN OPTICAL, INC., 8301 MARS DRIVE, WACO, TX 76712	09-10-91
P890027/S01	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT SPEECH PROCESSOR (MSP)	COCHLEAR CORPORATION ENGLEWOOD, CO	DISTRIBUTION OF THE NUCLEUS 22 CHANNEL MINI CHILDREN AGES 2 THROUGH 17 YEARS FOR USE IN WITH THE ADDED POTENTIOMETER FOR MINIMIZING OFFSET VOLTAGE	09-10-91 80112
P890044/S16	BIS.45 (AMSIFOCON A)	BENTEC INCORPORATED SACRAMENTO, CA	FOUR ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES FOR RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND BLUE TINTED)	09-19-91 95834
P890046/S12	0-> PERM F60 (OXYFLUFOCON A)	IDEAL OPTICS, INC. ATLANTA, GA 30339	ADDITIONAL CONTACT LENS FINISHING LABORATORY LOCATED AT ART OPTICAL CONTACT LENS (CLEAR AND TINTED)	09-13-91 RIGID GAS PERMEABLE CONTACT LENS CONTACT LENS, INC., 3175 THREE MILL ROAD, NW, WALKER, MI 49504

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADA's FOR SEPTEMBER 1991.

SUPPLEMENTAL VETERINARY NADA's

044-759	FLAVOMYCIN	CHICKEN	HOECHST ROUSSEL	BAMBERMYCINS
09-30-91	ANTIBIOTIC	SWINE	AGRI VET	4GM/LB
	(PREMIX)	TURKEY	SOMERVILLE, NJ 08876	

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER TRADE NAME SPECIES APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

Center for Drug Evaluation and Research
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Center for Devices and Radiological Health
Mary Jo Robinson (301) 427-1186

Center for Biologics Evaluation and Research
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
(CLASSIFICATION) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-154 VIDEX BRISTOL MYERS SQUIBB DIDANOSINE
10-09-91 (TABLET, CHEWABLE) WALLINGFORD, CT 25MG
(1 A,AA**,E***) 06492 50MG
100MG
150MG
(ANTIVIRAL)

20-155 VIDEX BRISTOL MYERS SQUIBB DIDANOSINE
10-09-91 (POWDER WALLINGFORD, CT 100MG/PACKET
(3 A,AA**,E***) FOR RECONSTITUTION) 06492 167MG/PACKET
250MG/PACKET
375MG/PACKET
(ANTIVIRAL)

20-156 VIDEX BRISTOL MYERS SQUIBB DIDANOSINE
10-09-91 (POWDER WALLINGFORD, CT 10MG/ML

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
(CLASSIFICATION) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

(3 A,AA**,E***) FOR RECONSTITUTION) 06492 (ANTIVIRAL)

20-122 NIPENT PARKE DAVIS PENTOSTATIN
10-11-91 (INJECTABLE) ANN ARBOR, MI 10MG/VIAL
(1 A,V*,E***) 48106 (ADENOSINE DEAMINASE
INHIBITOR)
[ADULT TREATMENT OF
ALPHA-INTERFERON-REFRACTORY
HAIRY CELL LEUKEMIA]

AA** - Refers to the Priority Classification for AIDS Drugs
E*** - Drug for Severely Debilitating/Life Threatening Illness
V* - Designated Orphan Drug

18-830 TAMBOCOR 3M FLECAINIDE ACETATE
10-23-91 (TABLET) ST PAUL, MN 50MG
(SUPPL) 55144 100MG
150MG
(NEW INDICATION --
PREVENTION OF
SUPRAVENTRICULAR
TACHYCARDIAS)

18-709 CAPOZIDE 25/15 SQUIBB CAPTOPRIL
10-24-91 (TABLET) NEW BRUNSWICK, NJ 25MG
(SUPPL) 08903 HYDROCHLOROTHIAZIDE
15MG
(NEW INDICATION --
ONCE DAILY INITIAL
TREATMENT OF HYPERTENSION)

18-709 CAPOZIDE 25/25 SQUIBB CAPTOPRIL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

10-24-91	(TABLET)	NEW BRUNSWICK, NJ	25MG
(SUPPL)		08903	HYDROCHLOROTHIAZIDE
			25MG
			(NEW INDICATION --
			ONCE DAILY INITIAL
			TREATMENT OF HYPERTENSION)
18-709	CAPOZIDE 50/15	SQUIBB	CAPTOPRIL
10-24-91	(TABLET)	NEW BRUNSWICK, NJ	50MG
(SUPPL)		08903	HYDROCHLOROTHIAZIDE
			15MG
			(NEW INDICATION --
			ONCE DAILY INITIAL
			TREATMENT OF HYPERTENSION)
18-709	CAPOZIDE 50/25	SQUIBB	CAPTOPRIL
10-24-91	(TABLET)	NEW BRUNSWICK, NJ	50MG
(SUPPL)		08903	HYDROCHLOROTHIAZIDE
			25MG
			(NEW INDICATION --
			ONCE DAILY INITIAL TREATMENT OF HYPERTENSION)

19-081	ESTRADERM	CIBA	ESTRADIOL
10-24-91	(FILM,	SUMMIT, NJ	0.05MG/24HR
(SUPPL)	EXTENDED RELEASE)	07901	0.1MG/24HR
			(NEW INDICATION --
			PREVENTION AND TREATMENT
			OF POSTMENOPAUSAL
			OSTEOPOROSIS)

20-027	CARDIZEM	MARION MERRELL DOW	DILTIAZEM HYDROCHLORIDE
10-24-91	(INJECTABLE)	KANSAS CITY, MO	25MG/VIAL
(3 C)		64134	50MG/VIAL
			(CALCIUM ION
			INFLUX INHIBITOR)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

[ATRIAL FIBRILLATION/FLUTTER;
PAROXYSMAL SUPRAVENTRICULAR
TACHYCARDIA]

18-163	RESTORIL	SANDOZ	TEMAZEPAM
10-25-91	(CAPSULE)	E HANOVER, NJ	7.5MG
(SUPPL)		07936	(NEW STRENGTH)

18-163	RESTORIL	SANDOZ	TEMAZEPAM
10-25-91	(CAPSULE)	E HANOVER, NJ	7.5MG
(SUPPL)		07936	15MG
			30MG
			(NEW INDICATION --
			TRANSIENT INSOMNIA)
			(NEW INDICATION --
			SLEEP LATENCY)

19-898	PRAVACHOL	BRISTOL MYERS SQUIBB	PRAVASTATIN SODIUM
10-31-91	(TABLET)	PRINCETON, NJ	10MG
(1 C)		08543	20MG
			(ANTIHYPERLIPOPROTEINEMIC,
			ANTI-ATHEROSCLEROTIC)

19-979	TICLID	SYNTEX	TICLOPIDINE HYDROCHLORIDE
10-31-91	(TABLET)	PALO ALTO, CA	250MG
(1 B)		94304	(PLATELET AGGREGATION
			INHIBITOR)

20-036	AREDIA	CIBA GEIGY	PAMIDRONATE DISODIUM
10-31-91	(INJECTABLE)	SUMMIT, NJ	30MG/VIAL
(1 B)		07901	(BONE-RESORPTION INHIBITOR)
			[HYPERCALCEMIA OF MALIGNANCY]

50-662	BIAXIN	ABBOTT	CLARITHROMYCIN
10-31-91	(TABLET)	ABBOTT PARK, IL	250MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

(1 B)		60064	500MG
			(ANTIBIOTIC, MACROLIDE)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-027 CARDIZEM MARION MERRELL DOW DILTIAZEM HYDROCHLORIDE
10-04-91 (INJECTABLE) KANSAS CITY, MO 25MG/VIAL
64134 50MG/VIAL
(CALCIUM ION
INFLUX INHIBITOR)
[ATRIAL FIBRILLATION/FLUTTER;
PAROXYSMAL SUPRAVENTRICULAR
TACHYCARDIA]

19-651 ASACOL NORWICH EATON MESALAMINE
10-10-91 (TABLET, NORWICH, NY 400MG
EXTENDED RELEASE) 13815 (NONSTEROIDAL
ANTI-INFLAMMATORY)
[ULCERATIVE COLITIS]

20-062 CARDIZEM CD MARION MERRELL DOW DILTIAZEM HYDROCHLORIDE
10-10-91 (CAPSULE, KANSAS CITY, MO 180MG
EXTENDED RELEASE) 64134 240MG
300MG
(CALCIUM ION
INFLUX INHIBITOR)
[HYPERTENSION]

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE	(DOSAGE FORM)		STRENGTH(S)
			CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

19-604	VOLMAX	GLAXO	ALBUTEROL SULFATE
10-31-91	(TABLET,	RES TRIANGLE PK, NC	EQ 4MG BASE
	EXTENDED RELEASE)	27709	EQ 8MG BASE
			(BRONCHODILATOR)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

73-250	NIFEDIPINE	RP SCHERER	NIFEDIPINE
10-08-91	(CAPSULE)	ST PETERSBURG, FL 33716	10MG (CALCIUM ION INFLUX INHIBITOR)

73-007	PERPHENAZINE AND	ROYCE	AMITRIPTYLINE HYDROCHLORIDE
10-17-91	AMITRIPTYLINE HCL	MIAMI, FL 33014	10MG PERPHENAZINE 2MG
	(TABLET)		(ANTIDEPRESSANT/ANXIOLYTIC)

73-008	PERPHENAZINE AND	ROYCE	AMITRIPTYLINE HYDROCHLORIDE
10-17-91	AMITRIPTYLINE HCL	MIAMI, FL 33014	25MG PERPHENAZINE 2MG
	(TABLET)		(ANTIDEPRESSANT/ANXIOLYTIC)

73-009	PERPHENAZINE AND	ROYCE	AMITRIPTYLINE HYDROCHLORIDE
10-17-91	AMITRIPTYLINE HCL	MIAMI, FL 33014	10MG PERPHENAZINE 4MG
	(TABLET)		(ANTIDEPRESSANT/ANXIOLYTIC)

73-010	PERPHENAZINE AND	ROYCE	AMITRIPTYLINE HYDROCHLORIDE
10-17-91	AMITRIPTYLINE HCL	MIAMI, FL 33014	25MG PERPHENAZINE 4MG
	(TABLET)		(ANTIDEPRESSANT/ANXIOLYTIC)

89-346	CARISOPRODOL	MUTUAL PHARM	CARISOPRODOL
10-17-91	(TABLET)	PHILADELPHIA, PA 19124	350MG (SKELETAL MUSCLE RELAXANT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

40-023	ADRUCIL	ADRIA LABS	FLUOROURACIL
10-18-91	(INJECTABLE)	COLUMBUS, OH	50MG/ML
		43216	(ANTIMETABOLITE)
72-999	DOPAMINE HCL	GENSIA	DOPAMINE HYDROCHLORIDE
10-23-91	(INJECTABLE)	IRVINE, CA	40MG/ML
		92718	(INOTROPIC/VASOPRESSOR)
73-000	DOPAMINE HCL	GENSIA	DOPAMINE HYDROCHLORIDE
10-23-91	(INJECTABLE)	IRVINE, CA	80MG/ML
		92718	(INOTROPIC VASOPRESSOR)
81-043	PREDNISOLONE SODIUM	STERIS	PREDNISOLONE SODIUM PHOSPHATE
10-24-91	PHOSPHATE	PHOENIX, AZ	EQ 0.11% PHOSPHATE
	(SOLUTION/DROPS)	85043	(CORTICOSTEROID)
81-044	PREDNISOLONE SODIUM	STERIS	PREDNISOLONE SODIUM PHOSPHATE
10-24-91	PHOSPHATE	PHOENIX, AZ	EQ 0.9% PHOSPHATE
	(SOLUTION/DROPS)	85043	(CORTICOSTEROID)
73-229	VALPROIC ACID	RP SCHERER	VALPROIC ACID
10-29-91	(CAPSULE)	ST PETERSBURG, FL	250MG
		33716	(ANTICONVULSANT)
89-452	PHENDIMETRAZINE	MIKART	PHENDIMETRAZINE TARTRATE
10-30-91	TARTRATE	ATLANTA, GA	35MG
	(TABLET)	30318	(ANOREXIANT)
72-926	LORAZEPAM	ROYCE	LORAZEPAM
10-31-91	(TABLET)	MIAMI, FL	0.5MG
		33014	(ANXIOLYTIC)
72-927	LORAZEPAM	ROYCE	LORAZEPAM

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

10-31-91	(TABLET)	MIAMI, FL	1MG
		33014	(ANXIOLYTIC)
72-928	LORAZEPAM	ROYCE	LORAZEPAM
10-31-91	(TABLET)	MIAMI, FL	2MG
		33014	(ANXIOLYTIC)
73-209	AMILORIDE	MYLAN PHARM	AMILORIDE HYDROCHLORIDE
10-31-91	HYDROCHLORIDE AND	MORGANTOWN, WV	5MG
	HYDROCHLOROTHIAZIDE	26505	HYDROCHLOROTHIAZIDE
	(TABLET)		50MG
			(DIURETIC)
73-303	SULFAMETHOXAZOLE AND	GENSIA	SULFAMETHOXAZOLE
10-31-91	TRIMETHOPRIM	IRVINE, CA	80MG/ML
	(INJECTABLE)	92718	TRIMETHOPRIM
			16MG/ML
			(ANTIBACTERIAL)
73-585	SUDAFED 12 HOUR	BURROUGHS WELLC	PSEUDOEPHEDRINE HYDROCHLORIDE
10-31-91	(TABLET,	RES TRIANGLE PK, NC	120MG
	EXTENDED RELEASE)	27709	(DECONGESTANT)
			(OTC)
81-113	ERGOLOID MESYLATES	MUTUAL PHARM	ERGOLOID MESYLATES
10-31-91	(TABLET)	PHILADELPHIA, PA	1MG
		19124	(COGNITION ADJUVANT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

12-026	APRESOLINE-ESIDRIX	CIBA	HYDRALAZINE HYDROCHLORIDE
10-02-91	(TABLET)	SUMMIT, NJ	25MG
		07901	HYDROCHLOROTHIAZIDE
			15MG
			(REVISED LABELING --
			PRECAUTIONS)
18-916	HEPARIN SODIUM	ABBOTT	HEPARIN SODIUM
10-02-91	1000 UNITS IN	ABBOTT PARK, IL	200 UNITS/100ML
	SODIUM CHLORIDE 0.9%	60064	(REVISED LABELING --
	IN PLASTIC CONTAINER		PRECAUTIONS)
	(INJECTABLE)		
18-916	HEPARIN SODIUM	ABBOTT	HEPARIN SODIUM
10-02-91	2000 UNITS IN	ABBOTT PARK, IL	200 UNITS/100ML
	SODIUM CHLORIDE 0.9%	60064	(REVISED LABELING --
	IN PLASTIC CONTAINER		PRECAUTIONS)
	(INJECTABLE)		
07-335	PRONESTYL	SQUIBB	PROCAINAMIDE HYDROCHLORIDE
10-03-91	(CAPSULE)	NEW BRUNSWICK, NJ	250MG
		08903	375MG
			500MG
			(REVISED LABELING --
			DESCRIPTION;
			INDICATIONS AND USAGE;
			WARNINGS)
07-335	PRONESTYL	SQUIBB	PROCAINAMIDE HYDROCHLORIDE
10-03-91	(INJECTABLE)	NEW BRUNSWICK, NJ	100MG/ML
		08903	500MG/ML
			(REVISED LABELING --
			DESCRIPTION;
			INDICATIONS AND USAGE;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

WARNINGS)

09-561	HYPAQUE	STERLING	DIATRIZOATE SODIUM
10-03-91	(INJECTABLE)	NEW YORK, NY	25%
		10016	50%
		(REVISED LABELING -- PRECAUTIONS;	ADVERSE REACTIONS)

09-561	HYPAQUE	STERLING	DIATRIZOATE SODIUM
10-03-91	(SOLUTION)	NEW YORK, NY	20%
		10016	(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)

10-220	HYPAQUE-M,90%	STERLING	DIATRIZOATE MEGLUMINE
10-03-91	(INJECTABLE)	NEW YORK, NY	60%
		10016	DIATRIZOATE SODIUM 30% (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)

16-403	HYPAQUE	STERLING	DIATRIZOATE MEGLUMINE
10-03-91	(INJECTABLE)	NEW YORK, NY	30%
		10016	60% (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

16-403	HYPAQUE-CYSTO	STERLING	DIATRIZOATE MEGLUMINE
10-03-91	(SOLUTION)	NEW YORK, NY	30%
		10016	(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
17-371	PRONESTYL	SQUIBB	PROCAINAMIDE HYDROCHLORIDE
10-03-91	(TABLET)	NEW BRUNSWICK, NJ	250MG
		08903	375MG
			500MG
			(REVISED LABELING -- DESCRIPTION; INDICATIONS AND USAGE; WARNINGS)
17-808	MIACALCIN	SANDOZ	CALCITONIN SALMON
10-03-91	(INJECTABLE)	E HANOVER, NJ	100 IU/ML
		07936	200 IU/ML
			(REVISED LABELING -- PRECAUTIONS)
18-922	LODINE	WYETH AYERST	ETODOLAC
10-04-91	(CAPSULE)	PHILADELPHIA, PA	200MG
		19101	300MG
			(REVISED LABELING --

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			CLINICAL PHARMACOLOGY;
			PRECAUTIONS)
19-667	SANDOSTATIN	SANDOZ	OCTREOTIDE ACETATE
10-04-91	(INJECTABLE)	E HANOVER, NJ	EQ 50UGM BASE/ML
		07936	EQ 100UGM BASE/ML
			EQ 500UGM BASE/ML
			(REVISED LABELING --
			ADVERSE REACTIONS)
19-643	MEVACOR	MSD	LOVASTATIN
10-09-91	(TABLET)	WEST POINT, PA	10MG
		19486	20MG
			40MG
			(REVISED LABELING --
			DESCRIPTION;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
11-287	KAYEXALATE	STERLING	SODIUM POLYSTYRENE SULFONATE
10-21-91	(POWDER)	NEW YORK, NY	453.6GM/BOT
		10016	(REVISED LABELING --
			DESCRIPTION; HOW SUPPLIED)
18-873	MEXITIL	BOEHRINGER INGELHEIM	MEXILETINE HYDROCHLORIDE
10-21-91	(CAPSULE)	RIDGEFIELD, CT	150MG
		06877	200MG
			250MG
			(REVISED LABELING --
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			ADVERSE REACTIONS)
19-386	BREVIBLOC	DUPONT	ESMOLOL HYDROCHLORIDE
10-21-91	(INJECTABLE)	WILMINGTON, DE	10MG/ML
		19880	250MG/ML
			(REVISED LABELING --
			DESCRIPTION; WARNINGS;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
13-718	OXANDRIN	GYNEX	OXANDROLONE
10-23-91	(TABLET)	DEERFIELD, IL	2.5MG
		60015	(REVISED LABELING --
			NEW TRADE NAME; DESCRIPTION;
			DRUG ABUSE AND DEPENDENCE)
16-273	LASIX	HOECHST ROUSSEL	FUROSEMIDE
10-23-91	(TABLET)	SOMERVILLE, NJ	20MG
		08876	40MG
			80MG
			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS)
17-688	LASIX	HOECHST ROUSSEL	FUROSEMIDE
10-23-91	(SOLUTION)	SOMERVILLE, NJ	10MG/ML
		08876	(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

16-640	QUESTRAN	BRISTOL MYERS	CHOLESTYRAMINE
10-24-91	(POWDER)	EVANSVILLE, IN	EQ 4GM RESIN/PACKET
		47721	EQ 4GM RESIN/SCOOPFUL
			(REVISED LABELING --
			ADVERSE REACTIONS)
19-643	MEVACOR	MSD	LOVASTATIN
10-24-91	(TABLET)	W POINT, PA	10MG
		19486	20MG
			40MG
			(REVISED LABELING --
			ADVERSE REACTIONS)
18-163	RESTORIL	SANDOZ	TEMAZEPAM
10-25-91	(CAPSULE)	E HANOVER, NJ	7.5MG
		07936	15MG
			30MG
			(REVISED LABELING --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			CONTRAINDICATIONS;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
19-270	BETOPTIC	ALCON	BETAXOLOL HYDROCHLORIDE
10-28-91	(SOLUTION/DROPS)	FORT WORTH, TX	EQ 0.5% BASE
		76115	(REVISED LABELING --
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

ADVERSE REACTIONS)

50-477	NEBCIN	LILLY	TOBRAMYCIN SULFATE
10-28-91	(INJECTABLE)	INDIANAPOLIS, IN	EQ 10MG BASE/ML
	46285	(REVISED LABELING -- DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	
50-519	NEBCIN	LILLY	TOBRAMYCIN SULFATE
10-28-91	(INJECTABLE)	INDIANAPOLIS, IN	EQ 1.2GM BASE/VIAL
	46285	(REVISED LABELING -- DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

1144 10-01-91	ATNATIV (INJECTABLE)	KABI PHARMACIA AB UPPSALA, SW (A&B)	ANTITHROMBIN III (HUMAN)
1144 10-01-91	RHESONATIVE (INJECTABLE)	KABI PHARMACIA AB UPPSALA, SW (A&B)	Rh_0 (D) IMMUNE GLOBULIN (HUMAN)
1144 10-01-91	KABIKINASE (INJECTABLE)	KABI PHARMACIA AB UPPSALA, SW	STREPTOKINASE (A&B)
464 10-29-91	NONE (INJECTABLE)	FAIRBANKS COMM BLOOD BANK FAIRBANKS, AK 99701	PLASMA (TRANSFUSION) (B)
464 10-29-91	NONE (INJECTABLE)	FAIRBANKS COMM BLOOD BANK FAIRBANKS, AK 99701	RED BLOOD CELLS (TRANSFUSION) (B)
1131 10-29-91	NONE (INJECTABLE)	PERSONAL BLOOD STORAGE OF MEMPHIS MEMPHIS, TN 38118	PLASMA (TRANSFUSION) (B)

LICENSE NUMBER TRADE NAME MANUFACTURER PROPER NAME
LICENSE DATE (DOSAGE FORM) (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

(A) Establishment License Issued
(B) Product License Issued

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910017 10-21-91	CONTROL STANDARD ENDOTOXIN/ PEPYROGENERATION VALIDATION	ASSOC OF CAPE COD WOOD HOLE, MA 02543 (C)	CONTROL STANDARD ENDOTOXIN (CCSE)

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

THERE ARE NO PREMARKET APPROVALS FOR OCTOBER, 1991.

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

N16895/S77	DAILY WEAR LENSES, EXTENDED WEAR LENSES (CLEAR AND TINTED), PRIVATE LABEL LENSES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	INCORPORATING BLUE DYE LEAK TEST PROCEDURE FOR PACKAGE INTEGRITY TESTING IN THEIR STABILITY PROTOCOL	10-30-91
N17676/S27	NATURVUE (HEFILCON A) SOFT (HYDROPHILIC) LENS, B&L (HEFILCON B) TORIC CONTACT LENS, B&L (HEFILCON B) TORIC CONTACT LENS OPTIMA SERIES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	INCORPORATING BLUE DYE LEAK TEST PROCEDURE FOR PACKAGE INTEGRITY TESTING IN THEIR STABILITY PROTOCOL	10-30-91
N17852/S33	DURASOFT 2 (PHEMFILCON A) SOFT (HYDROPHILIC) CONTACT LENS	WESLEY-JESSEN CORPORATION CHICAGO, IL 60610	ALTERNATE MANUFACTURING SITE LOCATED AT WESLEY-JESSEN, CIDRA OPERATIONS S-P PRODUCTS, INC., CIDRA, PUERTO RICO 00639	10-04-91
P780012/S05	HAVAB, IMX HAVAB	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	MODIFICATION TO HAVAB EIA FROM AN ENZYME IMMUNOASSAY (EIA) TO AN AUTOMATED MICROPARTICLE ENZYME IMMUNOASSAY (MEIA)	10-25-91
P820018/S51	AUTIMA MODEL 2251 PULSE GENERATOR AND MODEL 2600 PROGRAMMER, REFLEX DDD MODEL 8223E AND MODEL 8224	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	REFLEX DDD MODEL 8223E AND MODEL 8224 DUAL CHAMBER PULSE GENERATORS, NEW TORQUE-LIMITING HEXDRIVER AND ALTERNATE TERMINAL ASSEMBLIES	10-25-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

PULSE GENERATORS

P820018/S52	AUTIMA MODEL 2251 PULSE GENERATOR AND MODEL 2600 PROGRAMMER, REFLEX MODEL 8218 AND SIMPLEX MODEL 8232 PULSE GENERATORS	TELECTRONICS PACING SYSTEMS ENGLEWOOD, CO 80112	REFLEX MODEL 8218 AND SIMPLEX MODEL 8232 SINGLE CHAMBER PULSE GENERATORS AND ALTERNATE TERMINAL ASSEMBLIES	10-25-91
P820075/S05	LAMICEL OSMOTIC CERVICAL DILATOR	CABOT MEDICAL CORPORATION LANGHORNE, PA 19047	CHANGE THE SHELF LIFE INTERVAL PRINTED IN THE PACKAGE INSERT FROM 48 MONTHS TO 15 MONTHS	10-09-91
P820082/S03	SOFT LENS THERMAL DISINFECTING UNIT MODEL 6726, LENS PLUS COMPACT HEAT UNIT	ALLERGAN OPTICAL IRVINE, CA 92713-9534	COMPACT, CORDLESS, AND LOW-TEMPERATURE HEAT DISINFECTOR UNIT TO BE MANUFACTURED AT BECKMAN INSTRUMENTS, INC., 167 WEST POPLAR AVE., PORTERVILLE, CA 93257-5395	10-28-91
P830033/S24	MODEL 56BUV20-24DO ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	SURGIDEV CORPORATION GOLETA, CA 93117	MODEL 56BUV20-24DO ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	10-07-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P830037/S32	DURASOFT 3 (PHEMFILCON A) SOFT (HYDROPHILIC) CONTACT LENS	WESLEY-JESSEN CORPORATION CHICAGO, IL 60610	ALTERNATE MANUFACTURING SITE LOCATED AT WESLEY-JESSEN, CIDRA OPERATIONS S-P PRODUCTS, INC., CIDRA, PUERTO RICO 00639	10-04-91
P830040/S23	INTRAOCULAR LENSES: REQUEST TO MODIFY QUALITY ASSURANCE PROCEDURES	3M VISION CARE ST. PAUL, MN 55144-1000	REDUCE THE AMOUNT OF TESTING PERFORMED ON EACH LOT OF PERSPEX CQ-UV PMMA	10-17-91
P830045/S35	AFP MODEL 283 PULSE GENERATOR WITH MODEL 370 PROGRAMMER, PARAGON MODEL 2010T, PARAGON II MODEL 2016T, AND PHOENIX MODELS 2005T AND 2008T	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	LABELING CHANGES TO THE PARAGON MODEL 2010T, PARAGON II MODEL 2016T, AND PHOENIX MODELS 2005T AND 2008T PULSE GENERATORS	10-28-91
P840008/S33	DORNIER LITHOTRIPTER, MODEL HM3, DORNIER MULTIPURPOSE LITHOTRIPTER MPL 9000	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	ADDENDUM TO THE LABELING FOR THE DORNIER MPL 9000 LITHOTRIPTER	10-04-91
P850023/S11	OLD NAME: NOVACOL TEXTURED COLLAGEN HEMOSTATIC AGENT	BIOPLEX CORP. OAKLAND, NJ 07436	CHANGE TO THE LABELING WHICH ADDS A NEW PROPRIETARY NAME, CATALOG	10-04-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	NEW NAME: HEMAFLEX HEMOSTATIC AGENT		NUMBER, AND DISTRIBUTOR NAME AND ADDRESS	
P850039/S06	BAUSCH & LOMB (ETAFILCON A) CONTACT LENSES (DAILY WEAR AND EXTENDED WEAR)	B&L 58	BAUSCH & LOMB ROCHESTER, NY 14692-0450	INCORPORATING THE BLUE DYE LEAK TEST PROCEDURE FOR PACKAGE INTEGRITY IN THEIR STABILITY PROTOCOL
10-30-91				
P850051/S33	ACTIVITRAX PACING SYSTEM, MEDTRONIC LEGEND PACEMAKERS MODEL 8416 AND 8418		MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	ADDITION OF A WARNING TO THE TECHNICAL MANUAL FOR THE BIPOLAR MODELS 8416 AND 8418 LEGEND PACEMAKERS
10-25-91				
P850068/S07	BAUSCH & LOMB SILSOFT (ELASTOFILCON A) CONTACT LENSES FOR DAILY AND EXTENDED WEAR		BAUSCH & LOMB ROCHESTER, NY 14692-0450	INCORPORATING THE BLUE DYE LEAK TEST PROCEDURE FOR PACKAGE INTEGRITY TESTING IN THEIR STABILITY PROTOCOL
10-30-91				
P860004/S20	SYNCHROMED INFUSION SYSTEM FOR INTRATHECAL MORPHINE SULFATE ADMINISTRATION		MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	INTRASPINAL ADMINISTRATION OF PRESERVATIVE-FREE MORPHINE SULFATE STERILE SOLUTION
10-28-91				
P860007/S07	INTERTACH PACING SYSTEM, INTERTACH AND INTERTACH II PULSE GENERATORS		INTERMEDICS, INC. FREEPORT, TX 77541-0617	ALTERNATE PRODUCTION VIBRATION SCREENING METHOD TO THE CURRENT MANUFACTURING PROCESS FOR THE INTERTACH FACILITY OF PULSE GENERATORS
10-16-91				

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P860040/S08 10-29-91	BIOCURVE SOFT, BIOCURVE SOFT TORIC, BIOCURVE SOFT EW, HYDROPHILIC CONTACT LENS, SOFTECH -55, SOFTECH -55 TORIC AND SOFTECH -55EW LENSES	CAL BIONICS, INC. NOVATO, CA 94947	MANUFACTURE OF SOFT CONTACT LENSES FROM METHAFILCON A BLANKS SUPPLIED BY CAL BIONICS, INC. AT CALIFORNIA OPTICS, 19042 SAN JOSE ST., UNIT J, CITY OF INDUSTRY, CA 91748
P860059/S51 10-09-91	MODEL UP675 ULTRAVIOLET- ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MODEL UP675 ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS
P860059/S53 10-09-91	MODEL UP350 ULTRAVIOLET- ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MODEL UP350 ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS
P860059/S59 10-09-91	MODEL UPB350S ULTRAVIOLET- ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MODEL UPB350S ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS
P860059/S64 10-30-91	MODEL UPB240 ULTRAVIOLET- ABSORBING NARROW PROFILE SURFACE	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MODEL UPB240 POSTERIOR CHAMBER INTRAOCULAR LENS

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	MODIFIED POSTERIOR CHAMBER INTRAOCULAR LENS			
P870024/S27	FLUOROPERM 92 (PAFLUFOCON A), FLUOROPERM 60 (PAFLUFOCON B), FLUOROPERM 30 (PAFLUFOCON C) RIGID GAS PERMEABLE CONTACT LENSES	PARAGON OPTICAL MESA, AZ 85204	MANUFACTURE AND MARKET TWO ADDITIONAL COLORS, VIOLET AND SKY BLUE	10-23-91
P870036/S12	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC 18K	MEDTRONIC INTERVENTIONAL VASCULAR SAN DIEGO, CA 92121-1405	CHANGE THE MODEL NUMBERS AND THE PACKAGING CONFIGURATIONS FOR MEDTRONIC 18K	10-04-91
P870059/S01	PERIOCHECK ENZYME ACTIVITY TEST KIT PERIODONTAL CARE MONITORING SYSTEM	ADVANCED CLINICAL TECHNOLOGIES, INC. WESTWOOD, MA 02090	CHANGE IN THE DEVICE TRADE NAME AND THE COMPANY NAME	10-16-91
P880003/S06	CORDIS PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY DILATATION CATHETER, CORDIS HELIX PTCA DILATATION CATHETERS WITH Y-CONNECTOR	CORDIS CORPORATION MIAMI, FL 33102-5700	CORDIS HELIX PTCA DILATATION CATHETER WITH Y-CONNECTOR AND THE IMPLEMENTATION OF A NEW 100 PERCENT LEAK (INFLATION-DEFLATION) TEST	10-04-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P880029/S13	BAUSCH & LOMB B&L 70 (LIDOFILCON A) SOFT (HYDROPHILIC) CONTACT LENS, BAUSCH & LOMB CW 79 (LIDOFILCON B) CONTACT LENSES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	INCORPORATING BLUE DYE LEAK TEST PROCEDURE FOR PACKAGE INTEGRITY IN THEIR STABILITY PROTOCOL	10-30-91
P880038/S13	META MV PACING SYSTEM-META II PACING SYSTEM INCLUDING THE MODEL 1204 PULSE GENERATOR AND THE MODEL 5600S PROGRAMMER	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	META II PACING SYSTEM, WHICH INCLUDES THE MODEL 1204 PULSE GENERATOR AND THE MODEL 5600S PROGRAMMER	10-11-91
P880078/S05	VOLUMETRIC HYPERTHERMIA TREATMENT SYSTEM MODEL VH 8500, VH8500 VOLUMETRIC HYPERTHERMIA TREATMENT SYSTEM	COOK, INC. BLOOMINGTON, IN 47402	UPGRADE FROM A MAXIMUM DELIVERY VOLTAGE OF 10 VOLTS TO AN ADJUSTABLE MAXIMUM VOLTAGE WITH A 30 VOLT CEILING	10-28-91
P890001/S06	LEOCOR PTCA CATHETER, CORFLO MODELS 5S, 7.5S, 7.5PT AND MODEL PICO/ST	LEOCOR, INC. HOUSTON, TX 77058	MODIFICATION IN THE PACKAGING OF THE LEOCOR CATHETER, CORFLO MODELS 5S, 7.5S, 7.5PT AND MODEL PICO/ST	10-25-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890019/S02	AB-HAVK, MICROTRAK TOTAL ANTI-HAV EIA	SORIN BIOMEDICA, S.P.A. SALUGGIA(VC), ITALY	LABELING CHANGES TO ETI-AB-HAVK	10-11-91
P890032/S11	CORDIS ORION STEERABLE PTCA BALLOON CATHETER AND 3.5MM ORION STEERABLE PTCA BALLOON CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	CHANGES TO THE INSTRUCTIONS FOR USE AND PACKAGE LABELS	10-04-91
P890039/S04	MAESTRO SAVVI MODEL 305 PACING SYSTEM, POLYSAFE A-TRACK MODELS AT-333 AND AT-334 ENDOCARDIAL PACING LEADS	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	2000 VOLT "HIPOT" QUALITY CONTROL TEST FOR EXISTING POLYSAFE A-TRACK MODELS AT-333 AND AT-334 ENDOCARDIAL PACING LEADS WHICH REMAIN UNIMPLANTED	10-04-91
P890039/S05	MAESTRO SAVVI MODEL 305 PACING SYSTEM, POLYSAFE A-TRACK MODELS AT-333 AND AT-334 ENDOCARDIAL PACING LEADS	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	MODIFICATIONS TO THE MANUFACTURING PROCESS FOR THE POLYSAFE A-TRACK MODELS AT-333 AND AT-334 ENDOCARDIAL PACING LEADS	10-04-91
P890044/S17	BIS.45 (AMSILFOCON A), TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENSES FOR	BENTEC ENGINEERING, INC. SACRAMENTO, CA 95834	SEVEN ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	10-23-91

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	DAILY WEAR (CLEAR AND TINTED)		
P890046/S13 10-30-91	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	IDEAL OPTICS, INC. ATLANTA, GA 30339	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)

ORIGINAL VETERINARY NADAs

140-912 07-19-91	RINTAL (TABLET)	CATS DOGS	MOBAY SHAWNEE MISSION, KS 66201	FEBANTEL 27.2MG 163.3MG
140-883 09-12-91	LEGEND (INJECTABLE)	HORSES	MOBAY SHAWNEE MISSION, KS 66201	HYALURONATE SODIUM 20MG/2ML

SUPPLEMENTAL VETERINARY NADA

133-953 09-12-91	VERCOM ANTHELMINTIC (PASTE)	CATS DOGS	MOBAY SHAWNEE MISSION, KS 66201	FEBANTEL 3.4% PRAZIQUANTEL 0.34%

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER TRADE NAME SPECIES APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
(CLASSIFICATION) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

50-670 ZITHROMAX PFIZER AZITHROMYCIN
11-01-91 (CAPSULE) GROTON, CT 250MG
(1 B) 06340 (ANTIBIOTIC, MACROLIDE)

19-677 ENLON-PLUS ANAQUEST ATROPINE SULFATE
11-06-91 (INJECTABLE) MURRAY HILL, NJ 0.14MG/ML
(4 C) [VIAL] 07974 EDROPHONIUM CHLORIDE
10MG/ML
(NONDEPOLARIZING
NEUROMUSCULAR RELAXANT
ANTAGONIST)

19-678 ENLON-PLUS ANAQUEST ATROPINE SULFATE
11-06-91 (INJECTABLE) MURRAY HILL, NJ 0.14MG/ML
(4 C) [AMPULE] 07974 EDROPHONIUM CHLORIDE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

			10MG/ML
			(NONDEPOLARIZING
			NEUROMUSCULAR RELAXANT
			ANTAGONIST)
20-165	NICODERM	MERRELL DOW	NICOTINE
11-07-91	(FILM,	KANSAS CITY, MO	7MG/24HR
(3 C)	EXTENDED RELEASE)	64137	14MG/24HR
			21MG/24HR
			(SMOKING DETERRENT)
17-939	TAGAMET	SKF	CIMETIDINE HYDROCHLORIDE
11-13-91	(INJECTABLE)	PHILADELPHIA, PA	EQ 300MG BASE/2ML
(SUPPL)		19101	(NEW INDICATION --
			PREVENTION OF UPPER GI
			BLEEDING IN CRITICALLY ILL
			PATIENTS)
18-983	COLYTE-FLAVORED	REED AND CARNRICK	POLYETHYLENE GLYCOL 3350
11-14-91	(POWDER FOR	JERSEY CITY, NJ	227.1GM/BOT
(SUPPL)	RECONSTITUTION)	07302	POTASSIUM CHLORIDE
			2.82GM/BOT
			SODIUM BICARBONATE
			6.36GM/BOT
			SODIUM CHLORIDE
			5.53GM/BOT
			SODIUM SULFATE, ANHYDROUS
			21.5GM/BOT
			(GASTROINTESTINAL LAVAGE)
			[NEW PRODUCT]
18-983	COLYTE-FLAVORED	REED AND CARNRICK	POLYETHYLENE GLYCOL 3350
11-14-91	(POWDER FOR	JERSEY CITY, NJ	240GM/BOT
(SUPPL)	RECONSTITUTION)	07302	POTASSIUM CHLORIDE
			2.98GM/BOT
			SODIUM BICARBONATE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

			6.72GM/BOT
			SODIUM CHLORIDE
			5.84GM/BOT
			SODIUM SULFATE, ANHYDROUS
			22.72GM/BOT
			(GASTROINTESTINAL LAVAGE)
			[NEW PRODUCT]
19-885	ACCUPRIL	PARKE DAVIS	QUINAPRIL HYDROCHLORIDE
11-19-91	(TABLET)	ANN ARBOR, MI	EQ 5MG BASE
(1 C)		48105	EQ 10MG BASE
			EQ 20MG BASE
			EQ 40MG BASE
			(ANGIOTENSIN-CONVERTING
			ENZYME INHIBITOR)
			[HYPERTENSION]
50-585	ROCEPHIN	ROCHE	CEFTRIAXONE SODIUM
11-22-91	(INJECTABLE)	NUTLEY, NJ	EQ 250MG BASE/VIAL
(SUPPL)		07110	EQ 500MG BASE/VIAL
			EQ 1GM BASE/VIAL
			EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(NEW DOSAGE REGIMEN --
			TREATMENT OF SKIN AND SKIN
			STRUCTURE INFECTIONS IN
			PEDIATRIC PATIENTS USING ONCE
			DAILY THERAPY OR IN EQUALLY

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

DIVIDED DOSES TWICE A DAY)

20-076	HABITROL	CIBA GEIGY	NICOTINE
11-27-91	(FILM,	SUMMIT, NJ	7MG/24HR
(3 C)	EXTENDED RELEASE)	07901	14MG/24HR
			21MG/24HR
			(SMOKING DETERRENT)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM) STRENGTH(S)
CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-066 NICORETTE DS MARION MERRRELL DOW NICOTINE POLACRILEX
11-07-91 (GUM, CHEWING) CINCINNATI, OH 4MG
45215 (SMOKING DETERRENT)

20-076 HABITROL CIBA GEIGY NICOTINE
11-07-91 (FILM, SUMMIT, NJ 7MG/24HR
EXTENDED RELEASE) 07901 14MG/24HR
21MG/24HR
(SMOKING DETERRENT)

50-664 CEFZIL BRISTOL MYERS SQUIBB CEFPROZIL
11-29-91 (TABLET) WALLINGFORD, CT 250MG
06492 500MG
(ANTIBIOTIC, CEPHEM)

50-665 CEFZIL BRISTOL MYERS SQUIBB CEFPROZIL
11-29-91 (SUSPENSION) WALLINGFORD, CT 125MG/5ML
06492 250MG/5ML
(ANTIBIOTIC, CEPHEM)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

72-854	CYCLOBENZAPRINE HCL	GENEVA	CYCLOBENZAPRINE HYDROCHLORIDE
11-19-91	(TABLET)	BROOMFIELD, CO	10MG
		80038	(SKELETAL MUSCLE RELAXANT)
63-106	GENTAMICIN SULFATE	GENSIA	GENTAMICIN SULFATE
11-21-91	(INJECTABLE)	IRVINE, CA	EQ 40MG BASE/ML
		92718	(ANTIBIOTIC, AMINOGLYCOSIDE)
63-149	GENTAMICIN SULFATE	GENSIA	GENTAMICIN SULFATE
11-21-91	(INJECTABLE)	IRVINE, CA	EQ 10MG BASE/ML
		92718	(ANTIBIOTIC, AMINOGLYCOSIDE)
72-966	ALBUTEROL SULFATE	COPLEY	ALBUTEROL SULFATE
11-22-91	(TABLET)	CANTON, MA	EQ 2MG BASE
		02021	(BRONCHODILATOR)
72-967	ALBUTEROL SULFATE	COPLEY	ALBUTEROL SULFATE
11-22-91	(TABLET)	CANTON, MA	EQ 4MG BASE
		02021	(BRONCHODILATOR)
72-974	METHYLDOPATE HCL	GENSIA	METHYLDOPATE HYDROCHLORIDE
11-22-91	(INJECTABLE)	IRVINE, CA	50MG/ML
		92718	(ANTIHYPERTENSIVE)
72-758*	TRIPROLIDINE HCL AND	KV	PSEUDOEPHEDRINE HYDROCHLORIDE
11-25-91	PSEUDOEPHEDRINE HCL	ST LOUIS, MO	120MG
	(TABLET, EXTENDED RELEASE)	63144	TRIPROLIDINE HYDROCHLORIDE 5MG
			(DECONGESTANT/ANTIHISTAMINE)
			(OTC)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

* First Time Product Available Generically

20-079*	ENDOSOL-PLUS	ENTRAVISION	CALCIUM CHLORIDE
11-27-91	(SOLUTION)	LENOIR, NC	0.154MG/ML
		28645	DEXTROSE
			0.92MG/ML
			GLUTATHIONE DISULFIDE
			0.184MG/ML
			MAGNESIUM CHLORIDE
			0.2MG/ML
			POTASSIUM CHLORIDE
			0.38MG/ML
			SODIUM BICARBONATE
			2.1MG/ML
			SODIUM CHLORIDE
			7.14MG/ML
			SODIUM PHOSPHATE
			0.42MG/ML
			(IRRIGANT)
63-127	TOBRAMYCIN SULFATE	ELKINS SINN	TOBRAMYCIN SULFATE
11-27-91	(INJECTABLE)	CHERRY HILL, NJ	EQ 40MG BASE/ML
		08003	(ANTIBIOTIC, AMINOGLYCOSIDE)
63-128	TOBRAMYCIN SULFATE	ELKINS SINN	TOBRAMYCIN SULFATE
11-27-91	(INJECTABLE)	CHERRY HILL, NJ	EQ 10MG BASE/ML
		08003	(ANTIBIOTIC, AMINOGLYCOSIDE)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

ORIGINAL ABBREVIATED NDAs

73-080 11-27-91	LOPERAMIDE HCL (CAPSULE)	ROXANE COLUMBUS, OH 43216	LOPERAMIDE HYDROCHLORIDE 2MG (ANTIDIARRHEAL)
73-135 11-27-91	METOCLOPRAMIDE HCL (INJECTABLE)	GENSIA IRVINE, CA 92718	METOCLOPRAMIDE HYDROCHLORIDE EQ 10MG BASE/2ML (UPPER GI TRACT MOTILITY STIMULATOR)
73-143 11-27-91	CYCLOBENZAPRINE HCL (TABLET)	WATSON CORONA, CA 91720	CYCLOBENZAPRINE HYDROCHLORIDE 10MG (SKELETAL MUSCLE RELAXANT)

* First Time Product Available Generically

73-290* 11-27-91	TOLMETIN SODIUM (CAPSULE)	NOVOPHARM SCARBOROUGH ONTARIO, CANADA	TOLMETIN SODIUM EQ 400MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
73-307* 11-27-91	ALBUTEROL SULFATE (SOLUTION)	COPLEY CANTON, MA 02021	ALBUTEROL SULFATE EQ 0.5% BASE (BRONCHODILATOR)
73-310* 11-27-91	TOLMETIN SODIUM (TABLET)	MUTUAL PHARM PHILADELPHIA, PA 19124	TOLMETIN SODIUM EQ 200MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
73-311* 11-27-91	TOLMETIN SODIUM (CAPSULE)	MUTUAL PHARM PHILADELPHIA, PA 19124	TOLMETIN SODIUM EQ 400MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

73-357	AMILORIDE HCL AND	GENEVA	AMILORIDE HYDROCHLORIDE
11-27-91	HYDROCHLOROTHIAZIDE	BROOMFIELD, CO	5MG
	(TABLET)	80038	HYDROCHLOROTHIAZIDE
			50MG
			(DIURETIC)
73-520	DROPERIDOL	STERIS	DROPERIDOL
11-27-91	(INJECTABLE)	PHOENIX, AZ	2.5MG/ML
	[VIAL]	85043	(TRANQUILIZER)
73-521	DROPERIDOL	STERIS	DROPERIDOL
11-27-91	(INJECTABLE)	PHOENIX, AZ	2.5MG/ML
	[VIAL]	85043	(TRANQUILIZER)
73-523	DROPERIDOL	STERIS	DROPERIDOL
11-27-91	(INJECTABLE)	PHOENIX, AZ	2.5MG/ML
	[AMPULE]	85043	(TRANQUILIZER)

* First Time Product Available Generically

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-768	VEPESID	BRISTOL	ETOPOSIDE
11-01-91	(INJECTABLE)	SYRACUSE, NY	20MG/ML
	13221	(REVISED LABELING -- CLINICAL PHARMACOLOGY; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)	
19-557	VEPESID	BRISTOL	ETOPOSIDE
11-01-91	(CAPSULE)	SYRACUSE, NY	50MG
	13221	(REVISED LABELING -- CLINICAL PHARMACOLOGY; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)	
18-460	DIALYTE LM/	MCGAW	CALCIUM CHLORIDE
11-05-91	DEXTROSE 1.5%	IRVINE, CA	26MG/100ML
	IN PLASTIC CONTAINER	92713	DEXTROSE
	(SOLUTION)		1.5GM/100ML
			MAGNESIUM CHLORIDE 5MG/100ML
			SODIUM CHLORIDE 530MG/100ML
			SODIUM LACTATE 450MG/100ML
			(REVISED LABELING -- DESCRIPTION)
18-460	DIALYTE LM/	MCGAW	CALCIUM CHLORIDE
11-05-91	DEXTROSE 2.5%	IRVINE, CA	26MG/100ML
	IN PLASTIC CONTAINER	92713	DEXTROSE
	(SOLUTION)		2.5GM/100ML
			MAGNESIUM CHLORIDE 5MG/100ML
			SODIUM CHLORIDE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			530MG/100ML SODIUM LACTATE 450MG/100ML (REVISED LABELING -- DESCRIPTION)
18-460 11-05-91	DIALYTE LM/ DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION)	MCGAW IRVINE, CA 92713	CALCIUM CHLORIDE 26MG/100ML DEXTROSE 4.25GM/100ML MAGNESIUM CHLORIDE 5MG/100ML SODIUM CHLORIDE 530MG/100ML SODIUM LACTATE 450MG/100ML (REVISED LABELING -- DESCRIPTION)
11-745 11-06-91	KONAKION (INJECTABLE)	ROCHE NUTLEY, NJ 07110	PHYTONADIONE 1MG/0.5ML 10MG/ML (REVISED LABELING -- CLINICAL PHARMACOLOGY; DOSAGE AND ADMINISTRATION)
19-998 11-06-91	CHEMET (CAPSULE)	MCNEIL FORT WASHINGTON, PA 19034	SUCCIMER 100MG (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
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			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-631	TRENTAL	HOECHST ROUSSEL	PENTOXIFYLLINE
11-07-91	(TABLET, EXTENDED RELEASE)	SOMERVILLE, NJ 08876	400MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; ADVERSE REACTIONS)
17-892	HALCION	UPJOHN	TRIAZOLAM
11-13-91	(TABLET)	KALAMAZOO, MI 49001	0.125MG 0.25MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; DRUG ABUSE AND DEPENDENCE; DOSAGE AND ADMINISTRATION)
17-920	TAGAMET	SKF	CIMETIDINE
11-13-91	(TABLET)	PHILADELPHIA, PA 19101	200MG 300MG 400MG 800MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-924	TAGAMET	SKF	CIMETIDINE HYDROCHLORIDE
11-13-91	(SOLUTION)	PHILADELPHIA, PA	EQ 300MG BASE/5ML
	19101	(REVISED LABELING --	CLINICAL PHARMACOLOGY;
		INDICATIONS AND USAGE;	
		DOSAGE AND ADMINISTRATION)	

17-939	TAGAMET	SKF	CIMETIDINE HYDROCHLORIDE
11-13-91	(INJECTABLE)	PHILADELPHIA, PA	EQ 300MG BASE/2ML
	19101	(REVISED LABELING --	
		CLINICAL PHARMACOLOGY;	
		INDICATIONS AND USAGE;	
		DOSAGE AND ADMINISTRATION)	

19-434	TAGAMET HCL IN	SKF	CIMETIDINE HYDROCHLORIDE
11-13-91	SODIUM CHLORIDE 0.9%	PHILADELPHIA, PA	EQ 6MG BASE/ML
	IN PLASTIC CONTAINER	19101	(REVISED LABELING -- (INJECTABLE)
	CLINICAL PHARMACOLOGY;		
		INDICATIONS AND USAGE;	
		DOSAGE AND ADMINISTRATION)	

16-927	DEMULEN 1/50-21	SEARLE	ETHINYL ESTRADIOL
11-14-91	(TABLET)	SAN JUAN, PR	0.05MG
	00936	ETHYNODIOL DIACETATE	
		1MG	
		(REVISED LABELING --	
		DESCRIPTION;	
		CLINICAL PHARMACOLOGY;	
		CONTRAINDICATIONS; WARNINGS;	
		PRECAUTIONS;	
		ADVERSE REACTIONS;	
		OTHER HEALTH BENEFITS;	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			PATIENT PACKAGE INSERT)
16-936	DEMULEN 1/50-28	SEARLE	ETHINYL ESTRADIOL
11-14-91	(TABLET)	SAN JUAN, PR	0.05MG
	00936		ETHYNODIOL DIACETATE
			1MG
			(REVISED LABELING --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			CONTRAINDICATIONS; WARNINGS;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			OTHER HEALTH BENEFITS;
			PATIENT PACKAGE INSERT)
18-168	DEMULEN 1/35-21	SEARLE	ETHINYL ESTRADIOL
11-14-91	(TABLET)	SAN JUAN, PR	0.035MG
	00936		ETHYNODIOL DIACETATE
			1MG
			(REVISED LABELING --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			CONTRAINDICATIONS; WARNINGS;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			OTHER HEALTH BENEFITS;
			PATIENT PACKAGE INSERT)
18-680	DEMULEN 1/35-28	SEARLE	ETHINYL ESTRADIOL
11-14-91	(TABLET)	SAN JUAN, PR	0.035MG
	00936		ETHYNODIOL DIACETATE
			1MG

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
			(REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OTHER HEALTH BENEFITS; PATIENT PACKAGE INSERT)
50-579 11-14-91	MONOCID (INJECTABLE)	SKF PHILADELPHIA, PA 19101	CEFONICID SODIUM EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (REVISED LABELING -- PRECAUTIONS)
50-263 11-15-91	ACHROMYCIN V (SYRUP)	LEDERLE PEARL RIVER, NY 10965	TETRACYCLINE EQ 125MG HCL/5ML (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
50-273 11-15-91	ACHROMYCIN (INJECTABLE)	LEDERLE PEARL RIVER, NY 10965	TETRACYCLINE HYDROCHLORIDE 250MG/VIAL 500MG/VIAL (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
50-278 11-15-91	ACHROMYCIN V (CAPSULE)	LEDERLE PEARL RIVER, NY 10965	TETRACYCLINE HYDROCHLORIDE 250MG 500MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS)
19-698	TORADOL	SYNTEX	KETOROLAC TROMETHAMINE
11-18-91	(INJECTABLE)	PALO ALTO, CA	15MG/ML
		94304	30MG/ML
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			ADVERSE REACTIONS)
18-680	COPPER T	POP COUNCIL CBR	COPPER
11-20-91	MODEL TCU 380A	NEW YORK, NY	309MG COPPER
	(INTRAUTERINE DEVICE)	10021	(REVISED LABELING --
			WARNINGS;
			PATIENT PACKAGE INSERT)
50-261	DECLOMYCIN	LEDERLE	DEMECLOCYCLINE HYDROCHLORIDE
11-20-91	(TABLET)	PEARL RIVER, NY	150MG
		10965	300MG
			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS)
50-262	DECLOMYCIN	LEDERLE	DEMECLOCYCLINE HYDROCHLORIDE
11-20-91	(CAPSULE)	PEARL RIVER, NY	150MG
		10965	(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS)
50-276	ACHROMYCIN	LEDERLE	TETRACYCLINE HYDROCHLORIDE

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

11-20-91 (INJECTABLE) PEARL RIVER, NY 100MG/VIAL
10965 (REVISED LABELING --
PRECAUTIONS;
ADVERSE REACTIONS)

17-638 THYPINONE ABBOTT PROTIRELIN
11-21-91 (INJECTABLE) ABBOTT PARK, IL 0.5MG/ML
60064 (REVISED LABELING --
PRECAUTIONS; ADVERSE REACTIONS)

18-473 VENTOLIN GLAXO ALBUTEROL
11-22-91 (AEROSOL, METERED) RES TRIANGLE PK, NC 0.09MG/INH
27709 (REVISED LABELING --
PRECAUTIONS)

11-721 NEPTAZANE LEDERLE METHAZOLAMIDE
11-25-91 (TABLET) PEARL RIVER, NY 25MG
10965 50MG
(REVISED LABELING --
LABELING FORMAT
REVISION PROGRAM)

18-680 COPPER T POP COUNCIL CBR COPPER
11-25-91 MODEL TCU 380A NEW YORK, NY 309MG COPPER
(INTRAUTERINE DEVICE) 10021 (REVISED LABELING --
INDICATIONS AND USAGE;
PRECAUTIONS;
CLINICAL STUDIES;
INSTRUCTIONS FOR USE;
PATIENT PACKAGE INSERT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-703	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
11-25-91	(TABLET)	RES TRIANGLE PK, NC	EQ 150MG BASE
	27709	(REVISED LABELING -- ADVERSE REACTIONS; OVERDOSAGE)	
18-703	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
11-25-91	(TABLET)	RES TRIANGLE PK, NC	EQ 300MG BASE
	27709	(REVISED LABELING -- ADVERSE REACTIONS; OVERDOSAGE)	
19-090	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
11-25-91	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 25MG BASE/ML
	27709	(REVISED LABELING -- ADVERSE REACTIONS; OVERDOSAGE)	
19-508	AXID	LILLY	NIZATIDINE
11-25-91	(CAPSULE)	INDIANAPOLIS, IN	150MG
	46285		300MG
		(REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; OVERDOSAGE; HOW SUPPLIED)	
19-593	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
11-25-91	IN PLASTIC CONTAINER	RES TRIANGLE PK, NC	EQ 1MG BASE/ML
	(INJECTABLE)	27709	EQ 50MG BASE/100ML
		(REVISED LABELING -- ADVERSE REACTIONS;	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			OVERDOSAGE)
19-675	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
11-25-91	(SYRUP)	RES TRIANGLE PK, NC	EQ 15MG BASE/ML
	27709	(REVISED LABELING --	ADVERSE REACTIONS;
			OVERDOSAGE)
50-588	CEFOTAN	STUART	CEFOTETAN DISODIUM
11-25-91	(INJECTABLE)	WILMINGTON, DE	EQ 1GM BASE/VIAL
	19897		EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(REVISED LABELING --
			INDICATIONS AND USAGE;
			PRECAUTIONS)
19-384	NOROXIN	MSD	NORFLOXACIN
11-26-91	(TABLET)	W POINT, PA	400MG
	19486		(REVISED LABELING --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT LICENSES ISSUED

185 11-25-91	NONE (INJECTABLE)	MEMORIAL BLOOD CTR OF MINNEAPOLIS MINNEAPOLIS, MN 55404	CRYOPRECIPITATED AHF POOLED (TRANSFUSION) (B)

LICENSE NUMBER TRADE NAME MANUFACTURER PROPER NAME
LICENSE DATE (DOSAGE FORM) (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

(B) Product License Issued

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE			(DESCRIPTION)

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK900023	QC-HIV	NORTH AM BIOL	QUALITY CONTROL KITS
11-13-91		MIAMI, FL	FOR BLOOD BANKING
		33169	REAGENTS
			(C)

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

P910059 11-29-91	STARR MODEL AA-4203 ELASTIC LENS SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	STARR SURGICAL COMPANY MONROVIA, CA 91016	ELASTIC MODEL AA-4203 SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS
P910060 11-29-91	ELASTIMIDE MODELS AQ-1000, AQ-1001, AQ-1002, AQ-1005, AND AQ-1016 SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES	STARR SURGICAL COMPANY MONROVIA, CA 91016	ELASTIMIDE MODELS AQ-1000, AQ-1001, AQ-1002, AQ-1005, AND AQ-1016

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

N16895/S70	SOFLENS, OPTIMA, SOFSPIN, BI-TECH, OPTIMA FW, NATURALTINT AND MEADLIST (POLYMACON) CONTACT LENSES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	LABELING REVISIONS TO THE PACKAGE INSERTS	11-12-91
N16895/S71	SOFLENS, OPTIMA, SOFSPIN, BI-TECH, OPTIMA FW, NATURALTINT (POLYMACON) CONTACT LENSES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	LABELING REVISIONS TO THE PACKAGE INSERTS	11-12-91
N17676/S20	NATURVUE (HEFILCON A) SOFT (HYDROPHILIC), BAUSCH & LOMB (HEFILCON B) TORIC AND, OPTIMA SERIES CONTACT LENSES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	LABELING REVISIONS TO THE PACKAGE INSERTS	11-12-91
N17676/S21	NATURVUE (HEFILCON A) SOFT (HYDROPHILIC), BAUSCH & LOMB (HEFILCON B) TORIC AND, OPTIMA SERIES CONTACT LENSES	BAUSCH AND LOMB ROCHESTER, NY 14692-0450	LABELING REVISIONS TO THE PACKAGE INSERTS	11-12-91
P810002/S21	ST. JUDE MEDICAL AORTIC VALVED GRAFT	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	ADDITION OF AN INSERTION TOOL TO THE PACKAGE AND THE AVAILABILITY OF THE	11-06-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

DEVICE IN STERILE CONDITION

P810032/S41	MODEL MC40CM ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	MODEL MC40CM ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	11-26-91
P810046/S107	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, REDUCTION OF ETO EXPOSURE TIME DURING STERILIZATION	ADVANCED CARDIOVASCULAR TEMECULA, CA 92591-4628	REDUCTION OF ETO EXPOSURE TIME FROM 10 HOURS TO 6 HOURS DURING STERILIZATION	11-20-91
P820018/S47	AUTIMA MODEL 2251 PULSE GENERATOR AND MODEL 2600 PROGRAMMER, MODEL 9600 NETWORK PROGRAMMER	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	MODEL 9600 PROGRAMMER V3.64/3.66 FOR PROGRAMMING TELECTRONICS X92 PULSE GENERATORS	11-13-91
P820018/S55	AUTIMA PACING SYSTEMS, INC. MODEL 5603 PROGRAMMER SOFTWARE VERSION V5.21UE	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	MODEL 5603 PROGRAMMER SOFTWARE VERSION V5.21UE	11-20-91
P820088/S14	BSD-1000	BSD MEDICAL	THERMAL MAPPING WITH	

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

11-26-91	HYPERTHERMIA SYSTEM, THERMAL MAPPING FOR THE BSD-1000 AND BSD-300 HYPERTHERMIA SYSTEMS	CORPORATION SALT LAKE CITY, UT 84119	THE BSD-1000 AND BSD-300 HYPERTHERMIA SYSTEMS	
P830026/S47 11-26-91	COSMOS PACING SYSTEM	INTERMEDICS, INC. FREEPORT, TX 77541-0617	RELEASE STERILIZATION BATCHES ON A PARAMETRIC BASIS AND NO LONGER USE BIOLOGICAL INDICATORS IN EACH BATCH	
P830026/S49 11-20-91	COSMOS PACING SYSTEM, COSMOS II	INTERMEDICS, INC. FREEPORT, TX 77541-0617	SOFTWARE AND HYBRID MODULE CHANGES TO THE COSMOS II MODELS 284-05 AND 283-03 AND SOFTWARE CHANGES TO THE MODEL 531-32 GRAPHICS PROGRAM MODULE	
P830056/S72 11-27-91	MODEL C420F ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	OPTICAL RADIATION CORPORATION AZUSA, CA 91702	MODEL C420F ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER LENS	
P830060/S26 11-20-91	AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM, MODEL 6577 STERILIZABLE	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	MODIFICATIONS TO THE MODEL 6577 STERILIZABLE TELEMETRY WAND	

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	TELEMETRY WAND			
P840008/S32	DORNIER HM4 MOBILE LITHOTRIPTER	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	TWO ALTERNATE TRAILER MANUFACTURERS FOR THE HM4 MOBILE LITHOTRIPTER	11-06-91
P840068/S15	DELTA PULSE GENERATOR AND PROGRAMMING SYSTEM, MODEL 6577 TELEMETRY WAND STERILIZABLE TELEMETRY WAND	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	MODIFICATIONS TO THE MODEL 6577 STERILIZATION	11-20-91
P850051/S32	ACTIVITRAX PACING SYSTEM, LEGEND II MODELS 8424, 8426, 8427, AND 8430 PULSE GENERATORS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	LEGEND II MODELS 8424, 8426, 8427, AND 8430 PULSE GENERATORS	11-25-91
P850068/S05	BAUSCH & LOMB SILSOFT (ELASTOFILCON A) CONTACT LENS FOR DAILY AND EXTENDED WEAR	BAUSCH & LOMB ROCHESTER, NY 14692-0450	LABELING REVISIONS TO THE PACKAGE INSERTS	11-15-91
P850068/S06	BAUSCH & LOMB SILSOFT (ELASTOFILCON A) CONTACT LENSES FOR DAILY AND EXTENDED WEAR	BAUSCH & LOMB ROCHESTER, NY 14692-0450	LABELING REVISIONS TO THE PACKAGE INSERTS	11-15-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P860007/S06	INTERTACH PACING SYSTEM MODEL 262-12 AND INTERTACH II PACING SYSTEM, MODEL 262-16	INTERMEDICS, INC. FREEPORT, TX 77541	ALTERNATE METHOD TO VERIFY STERILIZATION BASED ON CONTROL AND MONITORING OF STERILIZATION PARAMETERS KNOWN AS PARAMETRIC RELEASE	11-19-91
P860019/S40	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, TRAPPER EXCHANGE DEVICE	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	ACCESSORY EXCHANGE DEVICE TO BE USED WITH PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETERS	11-19-91
P860019/S44	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETERS, ACE AND EXPRESS CATHETERS	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	LABELING CHANGES TO THE ACE AND EXPRESS CATHETERS AND MODIFICATIONS OF THE ACCESSORY DEVICES PACKAGED WITH THE EXPRESS CATHETER	11-19-91
P860019/S46	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, MIRAGE P-18 AND THE P-14	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	MODIFYING THE P-14 CATHETER BY CHANGING THE MANIFOLD DESIGN AND ADDING PROXIMAL SHAFT MARKERS, AND NEW	11-27-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
			MEDICAL DEVICE - PMA SUPPLEMENTALS	
			MODEL CATHETER IN BALLOON SIZES 1.5 - 4.0 MM	
P860026/S03	DIAPHRAGM PACER, S232G/I110A DIAPHRAGMATIC/ PHRENIC NERVE STIMULATOR	AVERY LABORATORIES, INC. GLEN COVE, NY 11542-1243	S232G-I110A DIAPHRAGMATIC/PHRENIC NERVE STIMULATOR	11-06-91
P860059/S66	ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	ADDITION OF GLAXFLEX CORPORATION AS AN ALTERNATE VENDOR FOR UV-PMMA	11-27-91
P870015/S12	MEDSTONE 1050 STS EXTRACORPOREAL SHOCK WAVE LITHOTRIPTER	MEDSTONE INTERNATIONAL INCORPORATED IRVINE, CA 92718	REVISED LABELING	11-07-91
P870049/S11	MICROSCAN RAPID PANELS	BAXTER HEALTHCARE CORPORATION WEST SACRAMENTO, CA 95691	READING OF ANTIMICROBIAL SUSCEPTIBILITY TEST RESULTS FROM MICROSCAN RAPID PANELS ON THE MICROSCAN WALKAWAY-40	11-06-91
P870049/S12	MICROSCAN RAPID PANELS	BAXTER HEALTHCARE CORPORATION WEST SACRAMENTO, CA 95691	REVISION OF QUALITY CONTROL FOR THE RAPID NEG BREAKPOINT TYPE 2 PANEL	11-06-91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P870049/S13	MICROSCAN RAPID PANELS	BAXTER HEALTHCARE CORPORATION WEST SACRAMENTO, CA 95691	REVISION OF QUALITY CONTROL FOR MICROSCAN RAPID PANELS	11-06-91
P890003/S09	SYNERGYST II MODELS 7070 AND 7071, MODEL 9760 PROGRAMMER SYSTEM WITH MODEL 9855E AND 9853E SOFTWARE DISKETTES	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODEL 9855E AND 9853E SOFTWARE DISKETTES FOR USE WITH MODEL 9760 PROGRAMMER SYSTEM	11-25-91
P890061/S02	VENTAK P MODEL 1600 AICD, MODEL 6577 STERILIZABLE TELEMETRY WAND	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	MODIFICATIONS TO MODEL 6577 STERILIZABLE TELEMETRY WAND	11-26-91

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR NOVEMBER 1991.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR NOVEMBER 1991.

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER TRADE NAME SPECIES APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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December 1991

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
(CLASSIFICATION) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

17-659 ALUPENT BOEHRINGER INGELHEIM METAPROTERENOL SULFATE
11-14-91 (SOLUTION, RIDGEFIELD, CT 5%
(SUPPL) INHALATION) 06877 (NEW INDICATION --
TREATMENT OF ACUTE ASTHMATIC
ATTACKS IN CHILDREN AGE
6 YEARS AND OLDER)

50-588 CEFOTAN ICI CEFOTETAN DISODIUM
11-25-91 (INJECTABLE) WILMINGTON, DE EQ 1GM BASE/VIAL
(SUPPL) 19897 EQ 2GM BASE/VIAL
EQ 10GM BASE/VIAL
(NEW DOSAGE REGIMEN --
ONCE DAILY DOSAGE IN SKIN
AND SKIN STRUCTURE
INFECTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

19-384	NOROXIN	MSD	NORFLOXACIN
11-26-91	(TABLET)	WEST POINT, PA	400MG
(SUPPL)		19486	(NEW INDICATION -- UNCOMPLICATED GONORRHEA)

19-384	NOROXIN	MSD	NORFLOXACIN
11-26-91	(TABLET)	WEST POINT, PA	400MG
(SUPPL)		19486	(NEW DOSAGE REGIMEN -- UNCOMPLICATED URINARY TRACT INFECTIONS, 400MG EVERY 12 HOURS FOR 3 DAYS)

50-585	ROCEPHIN	ROCHE	CEFTRIAXONE SODIUM
12-09-91	(INJECTABLE)	NUTLEY, NJ	EQ 250MG BASE/ML
(SUPPL)		07110	EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (NEW INDICATION -- PHARYNGEAL GONORRHEA)

19-462	PEPCID	MSD	FAMOTIDINE
12-10-91	(TABLET)	W POINT, PA	20MG
(SUPPL)		19486	40MG (NEW INDICATION -- SHORT TERM TREATMENT OF PATIENTS WITH SYMPTOMS OF GASTROESOPHAGEAL REFLUX DISEASE (GERD), AND FOR THE SHORT TERM TREATMENT OF ESOPHAGITIS DUE TO GERD INCLUDING EROSIVE OR ULCERATIVE DISEASE DIAGNOSED BY ENDOSCOPY)

08-107	LEUCOVORIN CALCIUM	LEDERLE	LEUCOVORIN CALCIUM

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
(CLASSIFICATION) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

12-12-91 (INJECTABLE) PEARL RIVER, NY EQ 3MG BASE/ML
(SUPPL, V*) 10965 EQ 50MG BASE/VIAL
EQ 100MG BASE/VIAL
EQ 350MG BASE/VIAL
(NEW INDICATION --
USE IN COMBINATION WITH
5-FLUOROURACIL TO PROLONG
SURVIVAL IN THE PALLIATIVE
TREATMENT OF PATIENTS WITH
ADVANCED COLORECTAL CANCER)

19-890 STADOL BRISTOL MYERS SQUIBB BUTORPHANOL TARTRATE
12-12-91 (SPRAY, METERED) WALLINGFORD, CT 1MG/INH
(3 C) 06492 (ANALGESIC)

V* - Designated Orphan Drug

50-590 TIMENTIN BEECHAM CLAVULANATE POTASSIUM
12-17-91 (INJECTABLE) BRISTOL, TN EQ 100MG ACID/VIAL
(SUPPL) 37620 TICARCILLIN DISODIUM
EQ 3GM BASE/VIAL
(NEW INDICATION --
INTRA-ABDOMINAL INFECTIONS,
INCLUDING PERITONITIS)

50-590 TIMENTIN BEECHAM CLAVULANATE POTASSIUM
12-17-91 (INJECTABLE) BRISTOL, TN EQ 200MG ACID/VIAL
(SUPPL) 37620 TICARCILLIN DISODIUM
EQ 3GM BASE/VIAL
(NEW INDICATION --
INTRA-ABDOMINAL INFECTIONS,
INCLUDING PERITONITIS)

50-590 TIMENTIN BEECHAM CLAVULANATE POTASSIUM
12-17-91 (INJECTABLE) BRISTOL, TN EQ 1GM ACID/VIAL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

(SUPPL)	37620		TICARCILLIN DISODIUM EQ 30GM BASE/VIAL (NEW INDICATION -- INTRA-ABDOMINAL INFECTIONS, INCLUDING PERITONITIS)
08-719	LEVO DROMORAN	ROCHE	LEVORPHANOL TARTRATE
12-19-91	(INJECTABLE)	NUTLEY, NJ	2MG/ML
(SUPPL)	07110		(ANALGESIC) (APPROVED IN ACCORDANCE WITH 40FR224 PUBLISHED NOVEMBER 19, 1975)
08-720	LEVO DROMORAN	ROCHE	LEVORPHANOL TARTRATE
12-19-91	(TABLET)	NUTLEY, NJ	2MG
(SUPPL)	07110		(ANALGESIC) (APPROVED IN ACCORDANCE WITH 40FR224 PUBLISHED NOVEMBER 19, 1975)
20-015	AMINOSYN II 10%	ABBOTT	AMINO ACIDS
12-19-91	IN PLASTIC CONTAINER	ABBOTT PARK, IL	10%
(5 C)	(INJECTABLE)	60064	(NUTRIENT REPLENISHER)
20-041	AMINOSYN II 15%	ABBOTT	AMINO ACIDS
12-19-91	IN PLASTIC CONTAINER	ABBOTT PARK, IL	15%
(3 C)	(INJECTABLE)	60064	(NUTRIENT REPLENISHER)
19-645	TORADOL	SYNTEX	KETOROLAC TROMETHAMINE
12-20-91	(TABLET)	PALO ALTO, CA	10MG
(3 C)	94304		(NONSTEROIDAL ANTI-INFLAMMATORY)
20-073	MAZICON	ROCHE	FLUMAZENIL
12-20-91	(INJECTABLE)	NUTLEY, NJ	0.1MG/ML
(1 B)	07110		(BENZODIAZEPINE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

			RECEPTOR ANTAGONIST)
			[REVERSAL OF THE
			SEDATIVE EFFECTS
			OF BENZODIAZEPINES]
19-766	ZOCOR	MSD	SIMVASTATIN
12-23-91	(TABLET)	W POINT, PA	5MG
(1 C)		19486	10MG
			20MG
			40MG
			(ANTIHYPERLIPIDEMIC)
50-664	CEFZIL	BRISTOL MYERS SQUIBB	CEFPROZIL
12-23-91	(TABLET)	WALLINGFORD, CT	250MG
(1 C)		06492	500MG
			(ANTIBIOTIC, CEPHEM)
50-665	CEFZIL	BRISTOL MYERS SQUIBB	CEFPROZIL
12-23-91	(POWDER	WALLINGFORD, CT	125MG/5ML
(3 C)	FOR RECONSTITUTION)	06492	250MG/5ML
			(ANTIBIOTIC, CEPHEM)
19-583	RELAFEN	SMITHKLINE BEECHAM	NABUMETONE
12-24-91	(TABLET)	PHILADELPHIA, PA	500MG
(1 C)		19101	750MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
			[OSTEOARTHRITIS AND
			RHEUMATOID ARTHRITIS]
19-836	SUPPRELIN	JOHNSON RW	HISTRELIN ACETATE
12-24-91	(INJECTABLE)	RARITAN, NJ	EQ 0.2MG BASE/ML
(1A, V*)		08869	EQ 0.5MG BASE/ML
			EQ 1MG BASE/ML
			(GONADOTROPIN RELEASING

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

			HORMONE AGONIST) [CONTROL OF CENTRAL PRECOCIOUS PUBERTY]
20-064	MACROBID	NORWICH EATON	NITROFURANTOIN MACROCRYSTALLINE
12-24-91	(CAPSULE,	NORWICH, NY	
(3 C)	EXTENDED RELEASE)	13815	25MG NITROFURANTOIN 75MG (ANTI-INFECTIVE)
18-182	MYCELEX-7	MILES	CLOTRIMAZOLE
12-26-91	(TABLET,	W HAVEN, CT	100MG
(SUPPL)	VAGINAL)	06516	(NEW OTC PRODUCT) (OTC)
18-230	MYCELEX-7	MILES	CLOTRIMAZOLE
12-26-91	(CREAM)	W HAVEN, CT	1%
(SUPPL)		06516	(NEW OTC PRODUCT) (OTC)
20-062	CARDIZEM CD	MARION MERRELL DOW	DILTIAZEM HYDROCHLORIDE
12-27-91	(CAPSULE,	KANSAS CITY, MO	180MG
(5 C)	EXTENDED RELEASE)	64134	240MG 300MG (CALCIUM ION INFLUX INHIBITOR) [HYPERTENSION]
19-091	ISMO	WYETH AYERST	ISOSORBIDE MONONITRATE
12-30-91	(TABLET)	RADNOR, PA	20MG
(1 C)		19087	(VASODILATOR)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
(CLASSIFICATION) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

V* - Designated Orphan Drug

19-839 ZOLOFT PFIZER SERTRALINE HYDROCHLORIDE
12-30-91 (TABLET) GROTON, CT EQ 50MG BASE
(1 C) 06340 EQ 100MG BASE
EQ 150MG BASE*
EQ 200MG BASE*
(ANTIDEPRESSANT)

18-450 NITROPRESS ABBOTT SODIUM NITROPRUSSIDE
12-31-91 (INJECTABLE) ABBOTT PARK, IL 50MG/VIAL
(SUPPL) 60064 (NEW INDICATION --
TREATMENT OF ACUTE
CONGESTIVE HEART FAILURE)

19-616 PENETREX PARKE DAVIS ENOXACIN
12-31-91 (TABLET) ANN ARBOR, MI 200MG
(1 C) 48106 400MG
(ANTIBACTERIAL)

19-627 DIPRIVAN ICI PROPOFOL
12-31-91 (INJECTABLE) WILMINGTON, DE 10MG/ML
(SUPPL) 19897 (NEW INDICATION --
INITIATE AND MAINTAIN
MONITORED ANESTHESIA CARE
(MAC) SEDATION DURING
DIAGNOSTIC PROCEDURES)

19-967 ULTRAVATE WESTWOOD SQUIBB HALOBETASOL PROPIONATE
12-31-91 (CREAM) BUFFALO, NY 0.05%
(SUPPL) 14213 (NEW DOSAGE REGIMEN --
ONCE DAILY APPLICATION)

19-968 ULTRAVATE WESTWOOD SQUIBB HALOBETASOL PROPIONATE
12-31-91 (OINTMENT) BUFFALO, NY 0.05%
(SUPPL) 14213 (NEW DOSAGE REGIMEN --
ONCE DAILY APPLICATION)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
(CLASSIFICATION) CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-105 TRIOSTAT SMITHKLINE BEECHAM LIOTHYRONINE SODIUM
12-31-91 (INJECTABLE) KING OF PRUSSIA, PA EQ 0.01MG BASE/ML
(3 A) 19406 (SYNTHETIC THYROID HORMONE)

* Not Marketed at This Time
50-667 LORABID ELI LILLY LORACARBEF
12-31-91 (POWDER INDIANAPOLIS, IN 100MG/5ML
(1 C) FOR RECONSTITUTION) 42685 200MG/5ML
(ANTIBIOTIC, CARBACEPHEM)

50-668 LORABID ELI LILLY LORACARBEF
12-31-91 (CAPSULE) INDIANAPOLIS, IN 200MG
(3 C) 42685 (ANTIBIOTIC, CARBACEPHEM)

NDA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-075 12-26-91	LIORESAL (INJECTABLE)	MEDTRONIC MINNEAPOLIS, MN 55432	BACLOFEN 0.5MG/ML 2MG/ML (SKELETAL MUSCLE RELAXANT)
19-734 12-31-91	CARDENE (INJECTABLE)	DUPONT MERCK WILMINGTON, DE 19880	NICARDIPINE HYDROCHLORIDE 2.5MG/ML (CALCIUM ION INFLUX INHIBITOR) [SHORT TERM TREATMENT OF HYPERTENSION]

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

71-498	PROPRANOLOL HCL AND	DANBURY	HYDROCHLOROTHIAZIDE
12-18-91	HYDROCHLOROTHIAZIDE	DANBURY, CT	25MG
	(TABLET)	06810	PROPRANOLOL HYDROCHLORIDE
			40MG
			(DIURETIC/
			BETA ADRENERGIC BLOCKER)
71-501	PROPRANOLOL HCL AND	DANBURY	HYDROCHLOROTHIAZIDE
12-18-91	HYDROCHLOROTHIAZIDE	DANBURY, CT	25MG
	(TABLET)	06810	PROPRANOLOL HYDROCHLORIDE
			80MG
			(DIURETIC/
			BETA ADRENERGIC BLOCKER)
72-901	IBUPROFEN	LUCHEM	IBUPROFEN
12-19-91	(TABLET)	SHREVEPORT, LA	200MG
	71106		(NONSTEROIDAL
			ANTI-INFLAMMATORY)
			(OTC)
72-903	IBUPROFEN	LUCHEM	IBUPROFEN
12-19-91	(TABLET)	SHREVEPORT, LA	200MG
	71106		(NONSTEROIDAL
			ANTI-INFLAMMATORY)
			(OTC)
73-542	ATENOLOL	LEDERLE	ATENOLOL
12-19-91	(TABLET)	PEARL RIVER, NY	50MG
	10965		(BETA ADRENERGIC BLOCKER)
73-543	ATENOLOL	LEDERLE	ATENOLOL
12-19-91	(TABLET)	PEARL RIVER, NY	100MG
	10965		(BETA ADRENERGIC BLOCKER)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

62-832	NYSTATIN	ROXANE	NYSTATIN
12-27-91	(SUSPENSION)	COLUMBUS, OH 43216	100,000 UNITS/ML (ANTIBIOTIC, POLYENE)
63-207	CEFAZOLIN SODIUM	HANFORD	CEFAZOLIN SODIUM
12-27-91	(INJECTABLE)	SYRACUSE, NY 13201	EQ 1GM BASE/VIAL (ANTIBIOTIC, CEPHEM)
63-208	CEFAZOLIN SODIUM	HANFORD	CEFAZOLIN SODIUM
12-27-91	(INJECTABLE) [PIGGYBACK]	SYRACUSE, NY 13201	EQ 1GM BASE/VIAL (ANTIBIOTIC, CEPHEM)
63-209	CEFAZOLIN SODIUM	HANFORD	CEFAZOLIN SODIUM
12-27-91	(INJECTABLE)	SYRACUSE, NY 13201	EQ 10GM BASE/VIAL (ANTIBIOTIC, CEPHEM)
63-214	CEFAZOLIN SODIUM	HANFORD	CEFAZOLIN SODIUM
12-27-91	(INJECTABLE)	SYRACUSE, NY 13201	EQ 500MG BASE/VIAL (ANTIBIOTIC, CEPHEM)
63-216	CEFAZOLIN SODIUM	HANFORD	CEFAZOLIN SODIUM
12-27-91	(INJECTABLE) [PIGGYBACK]	SYRACUSE, NY 13201	EQ 500MG BASE/VIAL (ANTIBIOTIC, CEPHEM)
73-352	ATENOLOL	DANBURY	ATENOLOL
12-27-91	(TABLET)	DANBURY, CT 06810	50MG (BETA ADRENERGIC BLOCKER)
73-353	ATENOLOL	DANBURY	ATENOLOL
12-27-91	(TABLET)	DANBURY, CT	100MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

06810 (BETA ADRENERGIC BLOCKER)

73-481*	FLUOCINONIDE	LEMMON	FLUOCINONIDE
12-27-91	(OINTMENT)	SELLERSVILLE, PA	0.05%
	18960	(CORTICOSTEROID)	

89-849	METHOCARBAMOL	MARSAM	METHOCARBAMOL
12-27-91	(INJECTABLE)	CHERRY HILL, NJ	100MG/ML
	08034	(SKELETAL MUSCLE RELAXANT)	

*First Time Product Available Generically

63-065	MINOCYCLINE HCL	DANBURY	MINOCYCLINE HYDROCHLORIDE
12-30-91	(CAPSULE)	DANBURY, CT	EQ 100MG BASE
	06810	(ANTIBIOTIC, TETRACYCLINE)	

63-181	MINOCYCLINE HCL	DANBURY	MINOCYCLINE HYDROCHLORIDE
12-30-91	(CAPSULE)	DANBURY, CT	EQ 50MG BASE
	06810	(ANTIBIOTIC, TETRACYCLINE)	

72-720*	ETHYNODIOL DIACETATE	WATSON	ETHINYL ESTRADIOL
12-30-91	AND ETHINYL ESTRADIOL	CORONA, CA	0.035MG
1/35-21	91720	ETHYNODIOL DIACETATE	
(TABLET)		1MG	
		(HORMONAL CONTRACEPTIVE)	

72-721*	ETHYNODIOL DIACETATE	WATSON	ETHINYL ESTRADIOL
12-30-91	AND ETHINYL ESTRADIOL	CORONA, CA	0.035MG
1/35-28	91720	ETHYNODIOL DIACETATE	
(TABLET)		1MG	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

(HORMONAL CONTRACEPTIVE)

72-722*	ETHYNODIOL DIACETATE	WATSON	ETHINYL ESTRADIOL
12-30-91	AND ETHINYL ESTRADIOL	CORONA, CA	0.05MG
	1/50-21	91720	ETHYNODIOL DIACETATE
	(TABLET)		1MG
		(HORMONAL CONTRACEPTIVE)	

72-723*	ETHYNODIOL DIACETATE	WATSON	ETHINYL ESTRADIOL
12-30-91	AND ETHINYL ESTRADIOL	CORONA, CA	0.05MG
	1/50-28	91720	ETHYNODIOL DIACETATE
	(TABLET)		1MG
		(HORMONAL CONTRACEPTIVE)	

* First Time Product Available Generically

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-659	ALUPENT	BOEHRINGER INGELHEIM	METAPROTERENOL SULFATE
11-14-91	(SOLUTION)	RIDGEFIELD, CT 06877	5% (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
17-431	OCUSERT PILO-20	ALZA	PILOCARPINE
12-02-91	(INSERT, EXTENDED RELEASE)	PALO ALTO, CA 94303	5MG (REVISED LABELING -- ADVERSE REACTIONS)
17-464	SODIUM CHLORIDE 0.9%	MCGAW	SODIUM CHLORIDE
12-02-91	IN PLASTIC CONTAINER (INJECTABLE)	IRVINE, CA 92713	900MG/100ML (REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION)
17-548	OCUSERT PILO-40	ALZA	PILOCARPINE
12-02-91	(INSERT, EXTENDED RELEASE)	PALO ALTO, CA 94303	11MG (REVISED LABELING -- ADVERSE REACTIONS)
18-184	SODIUM CHLORIDE 0.45%	MCGAW	SODIUM CHLORIDE
12-02-91	IN PLASTIC CONTAINER (INJECTABLE)	IRVINE, CA 92713	450MG/100ML (REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION)
17-362	PROGESTERONE	STERIS	PROGESTERONE
12-03-91	(INJECTABLE)	PHOENIX, AZ 85063	50MG/ML (REVISED LABELING -- PRECAUTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-744	MOTOFEN	CARNRICK	ATROPINE SULFATE
12-03-91	(TABLET)	CEDAR KNOLLS, NJ 07927	0.025MG DIFENOXIN HYDROCHLORIDE 1MG (REVISED LABELING -- DESCRIPTION; PRECAUTIONS)
50-564	AUGMENTIN '250'	BEECHAM	AMOXICILLIN
12-05-91	(TABLET)	BRISTOL, TN 37620	250MG CLAVULANATE POTASSIUM EQ 125MG ACID (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION; ADVERSE REACTIONS)
50-564	AUGMENTIN '500'	BEECHAM	AMOXICILLIN
12-05-91	(TABLET)	BRISTOL, TN 37620	500MG CLAVULANATE POTASSIUM EQ 125MG ACID (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION; ADVERSE REACTIONS)
50-575	AUGMENTIN '125'	BEECHAM	AMOXICILLIN
12-05-91	(POWDER FOR RECONSTITUTION)	BRISTOL, TN 37620	125MG/5ML CLAVULANATE POTASSIUM EQ 31.25MG ACID/5ML (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			ADVERSE REACTIONS)
50-575	AUGMENTIN '250'	BEECHAM	AMOXICILLIN
12-05-91	(POWDER FOR RECONSTITUTION)	BRISTOL, TN 37620	250MG/5ML CLAVULANATE POTASSIUM EQ 62.5MG ACID/5ML (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION; ADVERSE REACTIONS)
50-597	AUGMENTIN '125'	BEECHAM	AMOXICILLIN
12-05-91	(TABLET, CHEWABLE)	BRISTOL, TN 37620	125MG CLAVULANATE POTASSIUM EQ 31.25MG ACID (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION; ADVERSE REACTIONS)
50-597	AUGMENTIN '250'	BEECHAM	AMOXICILLIN
12-05-91	(TABLET, CHEWABLE)	BRISTOL, TN 37620	250MG CLAVULANATE POTASSIUM EQ 62.5MG ACID (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION; ADVERSE REACTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-585	ROCEPHIN	ROCHE	CEFTRIAXONE SODIUM
12-09-91	(INJECTABLE)	NUTLEY, NJ	EQ 250MG BASE/VIAL
	07110		EQ 500MG BASE/VIAL
			EQ 1GM BASE/VIAL
			EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(REVISED LABELING --
			INDICATIONS AND USAGE)
19-462	PEPCID	MSD	FAMOTIDINE
12-10-91	(TABLET)	W POINT, PA	20MG
	19486		40MG
			(REVISED LABELING --
			INDICATIONS AND USAGE;
			DOSAGE AND ADMINISTRATION)
19-510	PEPCID	MSD	FAMOTIDINE
12-10-91	(INJECTABLE)	W POINT, PA	10MG/ML
	19486		(REVISED LABELING --
			INDICATIONS AND USAGE;
			DOSAGE AND ADMINISTRATION)
19-527	PEPCID	MSD	FAMOTIDINE
12-10-91	(POWDER	W POINT, PA	40MG/5ML
	FOR RECONSTITUTION)	19486	(REVISED LABELING --
			INDICATIONS AND USAGE;
			DOSAGE AND ADMINISTRATION)
14-399	NORPRAMIN	MERRELL DOW	DESIPRAMINE HYDROCHLORIDE
12-11-91	(TABLET)	CINCINNATI, OH	10MG
	45215		25MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			50MG 75MG 100MG 150MG (REVISED LABELING -- DESCRIPTION; ADVERSE REACTIONS; OVERDOSAGE)
17-962	PARLODEL	SANDOZ	BROMOCRIPTINE MESYLATE
12-11-91	(TABLET)	E HANOVER, NJ 07936	EQ 2.5MG BASE (REVISED LABELING -- HOW SUPPLIED)
17-962	PARLODEL	SANDOZ	BROMOCRIPTINE MESYLATE
12-11-91	(CAPSULE)	E HANOVER, NJ 07936	EQ 5MG BASE (REVISED LABELING -- HOW SUPPLIED)
08-107	LEUCOVORIN CALCIUM	LEDERLE	LEUCOVORIN CALCIUM
12-12-91	(INJECTABLE)	PEARL RIVER, NY 10965	EQ 3MG BASE/ML EQ 50MG BASE/ML EQ 100MG BASE/VIAL EQ 350MG BASE/VIAL (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
12-885	WINSTROL	STERLING	STANOZOLOL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

12-13-91	(TABLET)	NEW YORK, NY	2MG
		10016	(REVISED LABELING --
			DRUG ABUSE AND DEPENDENCE)
11-839	PROVERA	UPJOHN	MEDROXYPROGESTERONE ACETATE
12-18-91	(TABLET)	KALAMAZOO, MI	2.5MG
		49001	5MG
			10MG
			(REVISED LABELING --
			BOXED WARNING; PRECAUTIONS)
17-563	COLESTID	UPJOHN	COLESTIPOL HYDROCHLORIDE
12-18-91	(GRANULE)	KALAMAZOO, MI	5GM/PACKET
		49001	500GM/BOT
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY)
19-643	MEVACOR	MSD	LOVASTATIN
12-19-91	(TABLET)	W POINT, PA	10MG
		19486	20MG
			40MG
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
50-640	BACTOCILL	BAXTER	OXACILLIN SODIUM
12-19-91	IN PLASTIC CONTAINER	ROUND LAKE, IL	EQ 20MG BASE/ML
	(INJECTABLE)	60073	EQ 40MG BASE/ML
			(REVISED LABELING --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

WARNINGS; PRECAUTIONS;
OVERDOSAGE;
DOSAGE AND ADMINISTRATION)

08-370	BENTYL	MERRELL DOW	DICYCLOMINE HYDROCHLORIDE
12-23-91	(INJECTABLE)	CINCINNATI, OH	10MG/ML
	45215	(REVISED LABELING --	
		DESCRIPTION)	
19-638	ARDUAN	ORGANON	PIPECURONIUM BROMIDE
12-24-91	(INJECTABLE)	W ORANGE, NJ	10MG/VIAL
	07052	(REVISED LABELING --	
		CLINICAL PHARMACOLOGY;	
		INDICATIONS AND USAGE;	
		PRECAUTIONS)	
16-749	NORLESTRIN 21 1/50	PARKE DAVIS	ETHINYL ESTRADIOL
12-26-91	(TABLET)	FAJARDO, PR	0.05MG
	00648	NORETHINDRONE ACETATE	
		1MG	
		(REVISED LABELING --	
		DESCRIPTION;	
		INDICATIONS AND USAGE;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED;	
		PATIENT PACKAGE INSERT)	
16-766	NORLESTRIN FE 1/50	PARKE DAVIS	ETHINYL ESTRADIOL
12-26-91	(TABLET)	FAJARDO, PR	0.05MG
	00648	FERROUS FUMARATE	
		75MG	

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
APPROVAL DATE (DOSAGE FORM) STRENGTH(S)
LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

NORETHINDRONE
1MG
(REVISED LABELING --
DESCRIPTION;
INDICATIONS AND USAGE;
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED;
PATIENT PACKAGE INSERT)

16-852 NORLESTRIN 21 2.5/50 PARKE DAVIS ETHINYL ESTRADIOL
12-26-91 (TABLET) FAJARDO, PR 0.05MG
00648 NORETHINDRONE ACETATE
2.5MG
(REVISED LABELING --
DESCRIPTION;
INDICATIONS AND USAGE;
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED;
PATIENT PACKAGE INSERT)

16-854 NORLESTRIN FE 2.5/50 PARKE DAVIS ETHINYL ESTRADIOL
12-26-91 (TABLET) FAJARDO, PR 0.05MG
00648 FERROUS FUMARATE
75MG
NORETHINDRONE
2.5MG
(REVISED LABELING --
DESCRIPTION;
INDICATIONS AND USAGE;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

DOSAGE AND ADMINISTRATION;
HOW SUPPLIED;
PATIENT PACKAGE INSERT)

18-299	VIROPTIC	BURROUGHS WELLC	TRIFLURIDINE
12-30-91	(SOLUTION/DROPS)	RES TRIANGLE PK, NC	1%
	27709	(REVISED LABELING -- PRECAUTIONS)	
18-634	BETADINE	PURDUE FREDERICK	POVIDONE-IODINE
12-30-91	(SOLUTION)	NORWALK, CT	5%
	06856	(REVISED LABELING -- DESCRIPTION; PRECAUTIONS; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	
18-713	MYCELEX	MILES	CLOTRIMAZOLE
12-30-91	(TROCHE/LOZENGE)	W HAVEN, CT	10MG
	06516	(REVISED LABELING -- HOW SUPPLIED)	
17-962	PARLODEL	SANDOZ	BROMOCRIPTINE MESYLATE
12-31-91	(TABLET)	EAST HANOVER, NY	EQ 2.5MG BASE
	07936	(REVISED LABELING -- INDICATIONS AND USAGE)	
17-962	PARLODEL	SANDOZ	BROMOCRIPTINE MESYLATE
12-31-91	(CAPSULE)	EAST HANOVER, NY	EQ 5MG BASE
	07936	(REVISED LABELING -- INDICATIONS AND USAGE)	
19-627	DIPRIVAN	ICI	PROPOFOL
12-31-91	(INJECTABLE)	WILMINGTON, DE	10MG/ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		19897	(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			CONTRAINDICATIONS;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-967	ULTRAVATE	WESTWOOD SQUIBB	HALOBETASOL PROPIONATE
12-31-91	(CREAM)	BUFFALO, NY	0.05%
		14213	(REVISED LABELING --
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-968	ULTRAVATE	WESTWOOD SQUIBB	HALOBETASOL PROPIONATE
12-31-91	(OINTMENT)	BUFFALO, NY	0.05%
		14213	(REVISED LABELING --
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
50-344	STATROL	ALCON	NEOMYCIN SULFATE
12-31-91	(OINTMENT)	FORT WORTH, TX	EQ 3.5MG BASE/GM
		76134	POLYMYXIN B SULFATE
			10,000 UNITS/GM
			(REVISED LABELING --

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
			LABELING CHANGE(S)

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
50-456	STATROL	ALCON	NEOMYCIN SULFATE
12-31-91	(SOLUTION)	FORT WORTH, TX 76134	EQ 3.5MG BASE/ML POLYMYXIN B SULFATE 16,250 UNITS/ML (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
50-592	TOBRADEX	ALCON	DEXAMETHASONE
12-31-91	(SUSPENSION/DROPS)	FORT WORTH, TX 76134	0.1% TOBRAMYCIN 0.3% (REVISED LABELING -- CLINICAL PHARMACOLOGY)

LICENSE NUMBER LICENSE DATE	TRADE NAME (DOSAGE FORM)	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

1145 12-09-91	OCULINUM (INJECTABLE)	ALLERGAN IRVINE, CA 92713 (A&B)	BOTULINUM TOXIN TYPE A (BLEPHAROSPASM & STRABISMUS)
17 12-17-91	ACEL-IMUNE (INJECTABLE)	LEDERLE LABS PEARL RIVER, NY 10965 (FOR FURTHER MANUFACTURING USE) (B)	DIPHTHERIA AND TETANUS TOXOIDS AND ACELLULAR PERTUSSIS VACCINE ABSORBED
1146 12-17-91	NONE (INJECTABLE)	TAKEDA CHEM OSAKA, JAPAN (FOR FURTHER MANUFACTURING USE) (A&B)	ACELLULAR PERTUSSIS VACCINE CONCENTRATE
73 12-27-91	NONE (INJECTABLE)	CONNAUGHT LABS ONTARIO, CANADA M2R 3T4 (B)	RABIES VACCINE (IMMUNIZATION)
8 12-30-91	THROMBATE III (INJECTABLE)	MILES BERKELEY, CA 94701 (B)	ANTITHROMBIN III (HUMAN)

LICENSE NUMBER TRADE NAME MANUFACTURER PROPER NAME
LICENSE DATE (DOSAGE FORM) (DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

(A) Establishment License Issued
(B) Product License Issued

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER (DESCRIPTION)	PROPER NAME

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910011 12-19-91	MT-200 FROZEN PLASMA THAWER 95742	INSTACOOL OF N AM RANCHO CORDOVA, CA (C)	MT-200 FROZEN PLASMA THAWER

DEVICE NUMBER APPROVAL DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT NDA APPROVALS

90-0223 12-27-91	ADSOL IN PLASTIC CONTAINER	BAXTER HLTHCARE ROUND LAKE, IL 60073	RED CELL PRESERVATION SOLUTION SYSTEM IN PL 2209 PLASTIC CONTAINER (TO PROVIDE FOR AN ALTERNATE CONTAINER, PL 2209 PLASTIC CONTAINER) (A)
90-0224 12-27-91	CPD BLOOD BAG UNIT	BAXTER HLTHCARE ROUND LAKE, IL 60073	CPD BLOOD BAG UNIT (PL 2209 PLASTIC) (TO PROVIDE FOR AN ALTERNATE CONTAINER, PL 2209 PLASTIC CONTAINER) (A)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT NDA APPROVALS

(A) Approved

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

P880042 12/12/91	EDAP LT.01 LITHEDAP SHOCK WAVE LITHOTRIPTER	EDAP INTERNATIONAL CORP. AMHERST, MA 01002	EDAP LT.01 LITHEDAP SHOCK WAVE LITHOTRIPTER
P890034 12/13/91	APT 1010 ULTRAHIGH FREQUENCY VENTILATOR	ADVANCED PULMONARY TECHNOLOGIES, INC. GLASTONBURY, CT 06033-1280	APT 1010 ULTRAHIGH FREQUENCY VENTILATOR
P890066 12/20/91	THERASONIC LITHOTRIPSY TREATMENT SYSTEM	DIASONICS, INC. MILPITAS, CA 95035	THERASONIC LITHOTRIPSY TREATMENT SYSTEM

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P790017/S39	USCI GRUNTZIG DILACA CORONARY ARTERY BALLOON DILATATION CATHETER, USCI FORCE 20, 30, 40, BALLOON DILATATION CATHETER WITH PRO/PEL COATING	C.R. BARD INC. BILLERICA, MA 01821	NEW MODEL CATHETER IN BALLOON SIZES RANGING FROM 2.0MM TO 4.0MM IN 0.25MM INCREMENTS	12/06/91
P790017/S40	USCI GRUNTZIG DILACA CORONARY ARTERY BALLOON DILATATION CATHETER, USCI SPRINT BALLOON DILATATION CATHETER WITH PRO/PEL COATING	C.R. BARD, INC. BILLERICA, MA 01821	NEW MODEL CATHETER IN BALLOON SIZES RANGING FROM 2.0MM TO 4.0MM IN 0.25MM INCREMENTS	12/06/91
P800049/S04	REQUEST TO MANUFACTURE SINGLE-PIECE AND MULTIPIECE INTRAOCULAR LENSES (IOLS)	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	MANUFACTURE SINGLE-PIECE AND MULTIPIECE IOLS AT EITHER HUNTINGTON, WEST VIRGINIA OR POMONA, CALIFORNIA FACILITIES	12/20/91
P810001/S09	REQUEST TO MANUFACTURE SINGLE-PIECE AND MULTIPIECE INTRAOCULAR LENSES (IOLS)	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	MANUFACTURE SINGLE-PIECE AND MULTIPIECE IOLS AT EITHER HUNTINGTON, WEST VIRGINIA OR POMONA, CALIFORNIA FACILITIES	12/20/91
P810018/S30	REQUEST TO	ALCON LABORATORIES, INC.	MANUFACTURE	

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

				12/20/91
MANUFACTURE SINGLE-PIECE AND MULTIPIECE INTRAOCULAR LENSES (IOLS)	FORT WORTH, TX 76134-2099		SINGLE-PIECE AND MULTIPIECE IOLS AT EITHER HUNTINGTON, WEST VIRGINIA OR POMONA, CALIFORNIA FACILITIES	
P810032/S42 REQUEST TO MANUFACTURE SINGLE-PIECE AND MULTIPIECE INTRAOCULAR LENSES (IOLS)	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099		MANUFACTURE SINGLE-PIECE AND MULTIPIECE IOLS AT EITHER HUNTINGTON, WEST VIRGINIA OR POMONA, CALIFORNIA FACILITIES	12/20/91
P820016/S01 REQUEST TO MANUFACTURE SINGLE PIECE AND MULTIPIECE INTRAOCULAR LENSES (IOLS)	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099		MANUFACTURE SINGLE-PIECE AND MULTIPIECE IOLS AT EITHER HUNTINGTON, WEST VIRGINIA OR POMONA, CALIFORNIA FACILITIES	12/20/91
P820035/S11 REQUEST TO MANUFACTURE SINGLE-PIECE AND MULTIPIECE INTRAOCULAR LENSES (IOLS)	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099		MANUFACTURE SINGLE-PIECE AND MULTIPIECE INTRAOCULAR LENSES AT EITHER HUNTINGTON, WEST VIRGINIA OR POMONA, CALIFORNIA FACILITIES	12/20/91
P820047/S01 REQUEST TO	ALCON LABORATORIES, INC.		MANUFACTURE	

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	MANUFACTURE SINGLE-PIECE AND MULTIPIECE INTRAOCULAR LENSES (IOLS)	FORT WORTH, TX 76134-2099	SINGLE-PIECE AND MULTIPIECE IOLS AT EITHER HUNTINGTON, WEST VIRGINIA OR POMONA, CALIFORNIA FACILITIES	12/20/91
P840033/S02	REQUEST TO MANUFACTURE SINGLE-PIECE AND MULTIPIECE INTRAOCULAR LENSES (IOLS)	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	MANUFACTURE SINGLE-PIECE AND MULTIPIECE IOLS AT EITHER HUNTINGTON, WEST VIRGINIA OR POMONA, CALIFORNIA FACILITIES	12/20/91
P840060/S18	REQUEST TO MANUFACTURE SINGLE-PIECE AND MULTIPIECE INTRAOCULAR LENSES (IOLS)	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	MANUFACTURE SINGLE-PIECE AND MULTIPIECE IOLS AT EITHER HUNTINGTON, WEST VIRGINIA OR POMONA, CALIFORNIA FACILITIES	12/20/91
P880010/S14	REQUEST TO MANUFACTURE SINGLE-PIECE AND MULTIPIECE INTRAOCULAR LENSES (IOLS)	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	MANUFACTURE SINGLE-PIECE AND MULTIPIECE IOLS AT EITHER HUNTINGTON, WEST VIRGINIA OR POMONA, CALIFORNIA FACILITIES	12/20/91
P880087/S03	REQUEST TO MANUFACTURE	ALCON LABORATORIES, INC. FORT WORTH, TX	MANUFACTURE SINGLE-PIECE AND	12/20/91

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

SINGLE-PIECE AND MULTIPIECE INTRAOCULAR LENSES (IOLS)	76134-2099	MULTIPIECE IOLS AT EITHER HUNTINGTON, WEST VIRGINIA OR POMONA, CALIFORNIA FACILITIES
P800049/S05 12/20/91 USE OF ZIRCONIA SILICATE BEADS AS ALTERNATE TUMBLE POLISHING MATERIAL	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	USE OF ZIRCONIA SILICATE BEADS AS AN ALTERNATE TUMBLE POLISHING MATERIAL
P810001/S10 12/20/91 USE OF ZIRCONIA SILICATE BEADS AS ALTERNATE TUMBLE POLISHING MATERIAL	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	USE OF ZIRCONIA SILICATE BEADS AS AN ALTERNATE TUMBLE POLISHING MATERIAL
P810018/S31 12/20/91 USE OF ZIRCONIA SILICATE BEADS AS ALTERNATE TUMBLE POLISHING MATERIAL	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	USE OF ZIRCONIA SILICATE BEADS AS AN ALTERNATE TUMBLE POLISHING MATERIAL
P810032/S43 12/20/91 USE OF ZIRCONIA SILICATE BEADS AS ALTERNATE TUMBLE POLISHING MATERIAL	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	USE OF ZIRCONIA SILICATE BEADS AS AN ALTERNATE TUMBLE POLISHING MATERIAL
P820035/S12 12/20/91 USE OF ZIRCONIA SILICATE BEADS AS ALTERNATE TUMBLE POLISHING MATERIAL	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	USE OF ZIRCONIA SILICATE BEADS AS AN ALTERNATE TUMBLE POLISHING MATERIAL
P820047/S02 USE OF ZIRCONIA	ALCON LABORATORIES, INC.	USE OF ZIRCONIA

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTALS	
12/21/91	SILICATE BEADS AS ALTERNATE TUMBLE POLISHING MATERIAL	FORT WORTH, TX 76134-2099	SILICATE BEADS AS AN ALTERNATE TUMBLE POLISHING MATERIAL
P840033/S03 12/20/91	USE OF ZIRCONIA SILICATE BEADS AS ALTERNATE TUMBLE POLISHING MATERIAL	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	USE OF ZIRCONIA SILICATE BEADS AS AN ALTERNATE TUMBLE POLISHING MATERIAL
P840060/S19 12/20/91	USE OF ZIRCONIA SILICATE BEADS AS ALTERNATE TUMBLE POLISHING MATERIAL	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	USE OF ZIRCONIA SILICATE BEADS AS AN ALTERNATE TUMBLE POLISHING MATERIAL
P880010/S15 12/20/91	USE OF ZIRCONIA SILICATE BEADS AS ALTERNATE TUMBLE POLISHING MATERIAL	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	USE OF ZIRCONIA SILICATE BEADS AS AN ALTERNATE TUMBLE POLISHING MATERIAL
P880087/S04 12/20/91	USE OF ZIRCONIA SILICATE BEADS AS ALTERNATE TUMBLE POLISHING MATERIAL	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	USE OF ZIRCONIA SILICATE BEADS AS AN ALTERNATE TUMBLE POLISHING MATERIAL
P800022/S27 12/16/91	ZYDERM I COLLAGEN IMPLANT, ZYDERM II COLLAGEN IMPLANT, ZYPLAST COLLAGEN	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	ADDITION OF REMOVABLE PRODUCT IDENTIFICATION LABELS

APPLICATION NO. / APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	IMPLANT, AND COLLAGEN TEST IMPLANT		
P800022/S29 12/16/91	ZYPLAST COLLAGEN IMPLANT/ NEW FILL VOLUME FOR SYRINGES	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	ADDITIONAL FILL VOLUME OF 1.5 ML IN A 3 ML SYRINGE FOR ZYPLAST COLLAGEN IMPLANT
P800022/S30 12/06/91	ZYDERM AND ZYPLAST COLLAGEN IMPLANTS/ WARNING STATEMENT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	REVISED WARNING STATEMENT TO BE INCLUDED IN PRODUCT LABELING FOR ZYDERM AND ZYPLAST COLLAGEN IMPLANTS
P810005/S27 12/10/91	WEICON (TEFILCON) SOFT (HYDROPHILIC) CONTACT LENS, CIBA OPAQUE (TEFILCON) SOFT (HYDROPHILIC) TINTED CONTACT LENS	CIBA VISION CORPORATION ATLANTA, GA 30360	REVISED LABELING
P810031/S13 12/06/91	HEALON G.V.	PHARMACIA OPHTHALMICS, INC. MONROVIA, CA 91017-7136	HIGHER MOLECULAR WEIGHT, HIGHER VISCOSITY VISCOELASTIC (SODIUM HYALURONATE) FORM OF HEALON

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P820003/S60	MEDTRONIC MODELS 7000 VERSATRAX PACING SYSTEM, 9710A PROGRAMMER, 9712 PRINTER, 9751B PRINTER AND 9742 MEMORYMOD SOFTWARE CARTRIDGE	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	RELABELING OF MODELS TO ALLOW CARDIAC PACEMAKERS, INC. TO COMMERCIALLY DISTRIBUTE THESE PRODUCTS UNDER ITS OWN BRAND NAME AND MODEL NUMBERS	12/18/91
P820018/S53	AUTIMA MODEL 2251 PULSE GENERATOR AND MODEL 2600 PROGRAMMER, MODEL 030-221 UNIPOLAR UPSIZING ADAPTOR	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	USE OF THE MODEL 030-221 UNIPOLAR UPSIZING ADAPTOR WITH THE REFLEX MODEL 8220E AND REFLEX DDD MODEL 8223E PULSE GENERATORS	12/20/91
P820018/S54	AURORA PACING SYSTEM	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	META DDD MODEL 1230H AND NEW TORQUE LIMITING WRENCH	12/06/91
P820024/S16	POROCOAT MODIFIED AUSTIN MOORE HEMI/TOTAL HIP SYSTEM	DEPUY WARSAW, IN 46580	ADDITION OF A PRODUCT STERILIZATION VENDOR, RADIATION STERILIZERS, INC., LOCATED IN WESTERVILLE, OHIO AND SCHAUMBURG, ILLINOIS	12/04/91
P830055/S19	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY WARSAW, IN	ADDITION OF A PRODUCT STERILIZATION VENDOR,	12/04/91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

		46580	RADIATION STERILIZERS INC., LOCATED IN WESTERVILLE, OHIO AND SCHAUMBURG, ILLINOIS	
P880025/S03	AML ACETABULAR CUP WITH POROCOAT	DEPUY WARSAW, IN	ADDITION OF A PRODUCT STERILIZATION VENDOR,	12/04/91
		46580	RADIATION STERILIZERS, INC., LOCATED IN WESTERVILLE, OHIO AND SCHAUMBURG, ILLINOIS	
P820040/S31	SEPTICON DISINFECTION SYSTEM, LENSEPT DISINFECTION SOLUTION AND LENSEPT NEUTRALIZER	CIBA VISION CORPORATION ATLANTA, GA 30360	ADDITIONAL STATEMENTS TO CURRENT LABELING TO INFORM USERS OF AN INCOMPATIBILITY OF THIS LENS CARE SYSTEM WITH THE ILLUSIONS (TEFILCON) SOFT (HYDROPHILIC) LENS	12/10/91
P820076/S11	DIPLOS-03 PULSE GENERATOR AND MODEL EPR-400 PROGRAMMER, EPR-500 PROGRAMMER WITH SOFTWARE VERSION 2.4/4.34	BIOTRONIK, INC. LAKE OSWEGO, OR 97035-5369	EPR-500 PROGRAMMER WITH SOFTWARE VERSION 2.4/4.34	12/20/91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P830045/S34	AFP MODEL 283 PULSE GENERATOR WITH MODEL 370 PROGRAMMER, APS-II MODEL 3003 PROGRAMMER WITH MODEL 3037A FUNCTION PACK	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	PACESETTER APS-II MODEL 3003 PROGRAMMER WITH THE MODEL 3037A FUNCTION PACK	12/24/91
P830060/S27	AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM, AICD SPLICE TOOL KIT AND RELATED ACCESSORIES	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	MARKET RELEASE OF MODEL 6866 AICD SPLICE TOOL KIT AND RELATED ACCESSORIES	12/18/91
P830060/S29	AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	MODELS 6843 AND 6856 BIPOLAR CABLE, MODELS 6872 AND 6873 HIGH VOLTAGE CABLE, MODEL 6874 HIGH VOLTAGE MONITORING CABLE, AND MODELS 6858 AND 6958 THUMB SCREWS	12/26/91
P840008/S31	DORNIER LITHOTRIPTERS, MODELS HM3 AND HM4, DORNIER MULTIFUNCTIONAL MFL5000 LITHOTRIPTER	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	ADDITIONS OF A TRACKBALL LOCALIZATION SYSTEM, AND A COLLAR FOR THE WATER CUSHION, AND MODIFICATION TO BRACES FOR THE MOBILE	12/20/91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

MFL5000 LITHOTRIPTER

P840068/S16	MODEL 925 DELTA PULSE GENERATOR	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	LABELING MODIFICATIONS	12/09/91
P850051/S34	ACTIVITRAX PACING SYSTEM, MEDTRONIC LEGEND PACEMAKER PULSE GENERATOR SYSTEM INCLUDING MODELS 8416, 8417, 8418, AND 8419	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFY AND RELABEL THE LEGEND PACEMAKER MODELS 8416, 8417, 8418 AND 8419	12/18/91
P850086/S01	SANDIMMUN RADIOIMMUNOASSAY KIT	SANDOZ PHARMACEUTICAL CORP. EAST HANOVER, NJ 07936	CHANGE IN THE POLYCLONAL ANTIBODY ASSAY TO A MONOCLONAL SPECIFIC AND MONOCLONAL NON-SPECIFIC ANTIBODY ASSAY	12/06/91
P850088/S24	LENS PLUS OXYSEPT 1 DISINFECTION SYSTEM	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ADDITIONAL STATEMENTS TO THE CURRENT LABELING FOR THE LENS PLUS OXYSEPT 1 DISINFECTION SYSTEM	12/10/91
P850089/S16	STERX TIP PACING LEADS MODEL 5025/5525,	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	IS-1 CONNECTOR VERSION (MODEL 5524M) OF THE MEDTRONIC	12/20/91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CAPSURE SP MODEL 5524M BIPOLAR PACING LEAD		CAPSURE SP MODEL 5524 LEAD	
P850089/S17	STERX TIP PACING LEADS MODELS 5025/5525, CPI DEXATIP MODELS 4162/4262 PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	REVISED LABELING	12/20/91
P860019/S47	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, SCIMED COBRA 14 CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	NEW MODEL CATHETER	12/20/91
P860022/S35	THE BOSTON EQUALENS (ITALFLUOROFOCON A) AND THE BOSTON RXD (ITABIS- FLUOROFOCON A) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	12/02/91
P860064/S06	DU PEN LONG-TERM EPIDURAL CATHETER	DAVOL, INC. SALT LAKE CITY, UT 84104	NEW MANUFACTURING/ PACKAGING FACILITY	12/26/91
P840066/S32	SOFT MATE PEROXIDE SYSTEM,	SOLA/BARNES-HIND SUNNYVALE, CA	CHANGE COLOR OF PLUG CURRENTLY USED AS	12/26/91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CONSEPT-1 CLEANING AND DISINFECTION SOLUTION	94086-5200	PART OF THE CONTAINER CLOSURE FOR THE CONSEPT-1 CLEANING AND DISINFECTION SOLUTION FROM WHITE TO RED
P870045/S31 12/06/91	MODEL CM19UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	INTRA OPTICS, INC. BOCA RATON, FL 33429-1710	MODEL CM19UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS
P870045/S32 12/06/91	MODEL JM19UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	INTRA OPTICS, INC. BOCA RATON, FL 33429-1710	MODEL JM19UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS
P870049/S15 12/18/91	MICROSCAN RAPID PANELS	BAXTER DIAGNOSTICS, INC. WEST SACRAMENTO, CA 95691	ADDITION OF MICROSCAN AS AN ALTERNATE VENDOR
P870075/S04 12/06/91	POSTERIOR CHAMBER INTRAOCULAR LENSES: LABELING CHANGES	NEWLENSCO MONROVIA, CA 91016	LABELING CHANGES
P880006/S11 12/24/91	SENSOLOG MODEL 703 PULSE GENERATOR AND P700 PROGRAMMER, APS-11 MODEL 3003 PROGRAMMER WITH MODEL 3037A	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	PACESETTER APS-II MODEL 3003 PROGRAMMER WITH THE MODEL 3037A FUNCTION PACK

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

FUNCTION PACK

P880029/S08 12/04/91	BAUSCH & LOMB B&L 70 (LIDOFILCON A), BAUSCH & LOMB FW TORIC (LIDOFILCON A) AND BAUSCH & LOMB CW 79 (LIDOFILCON B) CONTACT LENSES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	LABELING REVISIONS TO PACKAGE INSERTS
P880029/S09 12/04/91	BAUSCH & LOMB B&L 70 (LIDOFILCON A), BAUSCH & LOMB FW TORIC (LIDOFILCON A) AND BAUSCH & LOMB CW 79 (LIDOFILCON B) CONTACT LENSES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	LABELING REVISIONS TO THE PACKAGE INSERTS
P880038/S18 12/09/91	META MV PACING SYSTEM	TELECTRONICS PACING SYSTEMS ENGLEWOOD, CO 80112	META MV MODEL 1202H AND META II MODEL 1204H, AND A NEW TORQUE LIMITING WRENCH
P880079/S11 12/03/91	CIBA VISION STERILE BUFFERED SALINE AND CIBA	CIBA VISION CORPORATION ATLANTA, GA 30360	INCREASE MAXIMUM ALLOWABLE TIME INTERVAL BETWEEN

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

	VISION STERILE UNBUFFERED SALINE		FORMULATION AND GAMMA STERILIZATION FROM 48 TO 120 HOURS	
P880086/S12	SYNCHRONY MODELS 2020T PULSE GENERATOR, APS-II 3000 PROGRAMMER, APS-II 3003 PROGRAMMER WITH 3037A FUNCTION PACK	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	PACESETTER APS II MODEL 3003 PROGRAMMER WITH THE MODEL 3037A FUNCTION PACK	12/24/91
P880101/S05	AQUAFLEX (TETRAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS	WESLEY-JESSEN CORPORATION CHICAGO, IL 60610	ALTERNATE MANUFACTURING SITE FOR THE PRODUCTION OF THE POLYMER (TETRAFILCON A) USED IN MANUFACTURING THE LENS	12/03/91
P890003/S10	SYNERGYST II PULSE GENERATORS, 9710 PROGRAMMER WITH 9739A MEMORYMOD, MEDTRONIC AND SYNERGYST II PACEMAKER PULSE GENERATOR	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFY AND RELABEL MEDTRONIC MODELS 7070, 7071, AND 7071M SYNERGYST II PACEMAKER PULSE GENERATORS	12/18/91
P890032/S12	CORDIS ORION STEERABLE PTCA BALLOON CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	REVISION OF INSTRUCTIONS FOR USE AND PACKAGE LABELS	12/03/91

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890044/S18	BIS.45 (AMSILFOCON A) AND TRANS-AIRE (AMSILFOCON A), RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED)	BENTEC ENGINEERING, INC. SACRAMENTO, CA 95834	SEVEN ADDITIONAL CONTACT LENS FINISHING LABORATORIES	12/18/91
P890046/S14	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	IDEAL OPTICS, INC. ATLANTA, GA 30339	ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	12/18/91

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
ORIGINAL VETERINARY NADAs				
140-927 11-22-91	CHORULON (INJECTABLE)	CATTLE	INTERVET AM MILLSBORO, DE 19966	CHORIONIC GONADOTROPIN (10,000 IU/VIAL)
140-897 11-27-91	REVALOR-S (IMPLANT)	STEERS	HOECHST ROUSSEL AGRIVET SOMERVILLE, NJ 08876	TRENBOLONE ACETATE 120MG ESTRADIOL 24MG
SUPPLEMENTAL VETERINARY NADAs				
THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR DECEMBER 1991.				