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) 295-9012

Center for Veterinary Medicine
Melanie R. Berson, D.V.M.
(301) 295-8623

*To whom general inquiries should be directed.

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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

20-123 01-08-93 (1 S)	OMNISCAN (INJECTABLE)	STERLING WINTHROP COLLEGEVILLE, PA 19246	GADODIAMIDE 287MG/ML (DIAGNOSTIC RADIOPAQUE)
19-084 01-27-93 (SUPPL)	NIZORAL (CREAM)	JANSSEN PISCATAWAY, NJ 08854	KETOCONAZOLE 2% (NEW INDICATION -- TREATMENT OF TINEA PEDIS)

ERRATA

19-899* 12-31-92 (5 S)	SINE-AID IB (TABLET)	MCNEIL FORT WASHINGTON, PA 19034	IBUPROFEN 200MG PSEUDOEPHEDRINE HYDROCHLORIDE 30MG (NONSTEROIDAL ANTI-INFLAMMATORY/ DECONGESTANT) (OTC)

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

* - Corrected Classification code

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.

20-198 01-29-93	NIFEDIPINE (TABLET, EXTENDED RELEASE)	MILES WEST HAVEN, CT 06516	NIFEDIPINE 30MG 60MG 90MG (CALCIUM ION INFLUX INHIBITOR)
20-288 01-29-93	MONISTAT 7 COMBINATION PACK (SUPPOSITORY/CREAM)	ADVANCED CARE RARITAN, NJ 08869	MICONAZOLE NITRATE 100MG-SUPPOSITORY 2%-CREAM (ANTIFUNGAL)
20-289 01-29-93	GYNE-LOTRIMIN COMBINATION PACK (INSERT/CREAM)	SCHERING LIBERTY CORNER, NJ 07938	CLOTRIMAZOLE 100MG-INSERT 1%-CREAM (ANTIFUNGAL)

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

ORIGINAL ABBREVIATED NDAs

63-182	MEFOXIN	MERCK	CEFOXITIN SODIUM
01-25-93	IN PLASTIC CONTAINER	WEST POINT, PA	EQ 20MG BASE/ML
	(INJECTABLE)	19486	EQ 40MG BASE/ML
			(ANTIBIOTIC, CEPHEM)
70-998	K+8	ALRA	POTASSIUM CHLORIDE
01-25-93	(TABLET,	GURNEE, IL	8MEQ
	EXTENDED RELEASE)	60031	(ELECTROLYTE REPLACEMENT)
73-466*	GEMFIBROZIL	MYLAN	GEMFIBROZIL
01-25-93	(CAPSULE)	MORGANTOWN, WV	300MG
		26504	(ANTIHYPERLIPIDEMIC)
74-097*	ISOFLURANE	ABBOTT	ISOFLURANE
01-25-93	(LIQUID)	ABBOTT PARK, IL	99.9%
		60064	(GENERAL ANESTHETIC)
73-652	NITROFURANTOIN	ZENITH	NITROFURANTOIN,
01-28-93	(CAPSULE)	NORTHVALE, NJ	MACROCRYSTALLINE
		07647	100MG
			(ANTIBACTERIAL)
73-671	NITROFURANTOIN	ZENITH	NITROFURANTOIN,
01-28-93	(CAPSULE)	NORTHVALE, NJ	MACROCRYSTALLINE
		07647	50MG
			(ANTIBACTERIAL)
63-211	ERYTHROMYCIN	STIEFEL	ERYTHROMYCIN
01-29-93	(GEL)	CORAL GABLES, FL	2%
		33134	(ANTIBIOTIC, MACROLIDE)
64-022	NYSTATIN	TARO	NYSTATIN
01-29-93	(CREAM)	DOWNSVIEW, ONTARIO	100,000 UNITS/GM

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

ORIGINAL ABBREVIATED NDAs

(ANTIFUNGAL)

* - First Time Product Available Generically

72-370	DIAZEPAM	MARSAM	DIAZEPAM
01-29-93	(INJECTABLE)	CHERRY HILL, NJ	5MG/ML
	[VIAL]	08034	(ANXIOLYTIC)
72-371	DIAZEPAM	MARSAM	DIAZEPAM
01-29-93	(INJECTABLE)	CHERRY HILL, NJ	5MG/ML
	[AMPUL]	08034	(ANXIOLYTIC)
72-397	DIAZEPAM	MARSAM	DIAZEPAM
01-29-93	(INJECTABLE)	CHERRY HILL, NJ	5MG/ML
	[SYRINGE]	08034	(ANXIOLYTIC)
72-929	GEMFIBROZIL	PUREPAC	GEMFIBROZIL
01-29-93	(CAPSULE)	ELIZABETH, NJ	300MG
		07207	(ANTIHYPERLIPIDEMIC)
74-014	KETOPROFEN	LEDERLE	KETOPROFEN
01-29-93	(CAPSULE)	PEARL RIVER, NY	25MG
		10965	50MG
			75MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
81-297*	BENZONATATE	PHARMACAPS	BENZONATATE
01-29-93	(CAPSULE)	ELIZABETH, NJ	100MG
		07207	(ANTITUSSIVE)

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 INGREDIENT(S)
TENTATIVE (DOSAGE FORM) STRENGTH(S)
APPROVAL DATE CLASSIFICATION(S)

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDA TENTATIVE APPROVALS FOR JANUARY 1993.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

03-158	ORETON METHYL	SCHERING	METHYLTESTOSTERONE
01-07-93	(TABLET)	KENILWORTH, NJ	10MG
		07033	(REVISED LABELING -- PRECAUTIONS)

50-590	TIMENTIN	SMITHKLINE BEECHAM	CLAVULANATE POTASSIUM
01-07-93	(INJECTABLE)	PHILADELPHIA, PA	EQ 100MG ACID/VIAL
		19101	TICARCILLIN DISODIUM
			EQ 3GM BASE/VIAL
			(REVISED LABELING -- PRECAUTIONS)

50-590	TIMENTIN	SMITHKLINE BEECHAM	CLAVULANATE POTASSIUM
01-07-93	(INJECTABLE)	PHILADELPHIA, PA	EQ 200MG ACID/VIAL
		19101	TICARCILLIN DISODIUM
			EQ 3GM BASE/VIAL
			(REVISED LABELING -- PRECAUTIONS)

50-590	TIMENTIN	SMITHKLINE BEECHAM	CLAVULANATE POTASSIUM
01-07-93	(INJECTABLE)	PHILADELPHIA, PA	EQ 1GM ACID/VIAL
		19101	TICARCILLIN DISODIUM
			EQ 30GM BASE/VIAL
			(REVISED LABELING -- PRECAUTIONS)

18-719	MODRASTANE	STERLING	TRILOSTANE
01-08-93	(CAPSULE)	NEW YORK, NY	30MG
		10016	60MG
			(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

19-901	ALTACE	HOECHST ROUSSEL	RAMIPRIL
01-08-93	(CAPSULE)	SOMERVILLE, NJ	1.25MG
		08876	2.5MG
			5MG
			10MG
			(REVISED LABELING -- CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)
18-922	LODINE	WYETH AYERST	ETODOLAC
01-12-93	(CAPSULE)	PHILADELPHIA, PA	200MG
		19101	300MG
			(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
19-667	SANDOSTATIN	SANDOZ	OCTREOTIDE ACETATE
01-12-93	(INJECTABLE)	EAST HANOVER, NJ	EQ 50UGM BASE/ML
		07936	EQ 100UGM BASE/ML
			EQ 500UGM BASE/ML
			(REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
17-386	ZAROXOLYN	FISONS	METOLAZONE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

01-13-93	(TABLET)	ROCHESTER, NY	2.5MG
	14603		5MG
			10MG
			(REVISED LABELING --
			PRECAUTIONS; ADVERSE REACTIONS)

19-532	MYKROX	FISONS	METOLAZONE
01-13-93	(TABLET)	ROCHESTER, NY	0.5MG
	14603		(REVISED LABELING --
			PRECAUTIONS; ADVERSE REACTIONS)

50-482	KEFLIN	LILLY	CEPHALOTHIN SODIUM
01-19-93	(INJECTABLE)	INDIANAPOLIS, IN	EQ 1GM BASE/VIAL
	46285		EQ 2GM BASE/VIAL
			EQ 20GM BASE/VIAL
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			OVERDOSAGE; HOW SUPPLIED)

50-621	SUPRAX	LEDERLE	CEFIXIME
01-19-93	(TABLET)	PEARL RIVER, NY	200MG
	10965		400MG
			(REVISED LABELING --
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)

50-622	SUPRAX	LEDERLE	CEFIXIME
01-19-93	(POWDER FOR RECONSTITUTION)	PEARL RIVER, NY	100MG/5ML
	10965		(REVISED LABELING --

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
			ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
17-498 01-21-93	MICRONASE (TABLET)	UPJOHN KALAMAZOO, MI 49001	GLYBURIDE 1.25MG 2.5MG 5MG (REVISED LABELING -- PRECAUTIONS)
17-532 01-21-93	DIABETA (TABLET)	HOECHST ROUSSEL SOMERVILLE, NJ 08876	GLYBURIDE 1.25MG 2.5MG 5MG (REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION)
18-245 01-21-93	SYNTOCINON (INJECTABLE)	SANDOZ EAST HANOVER, NJ 07936	OXYTOCIN 10 USP UNITS/ML (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
20-051 01-21-93	GLYNASE (TABLET)	UPJOHN KALAMAZOO, MI 49001	GLYBURIDE 1.5MG 3MG (REVISED LABELING -- PRECAUTIONS)
17-934	SEMILENTE ILETIN	LILLY	INSULIN ZINC SUSP

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

01-22-93	PROMPT INSULIN ZINC	INDIANAPOLIS, IN	PROMPT BEEF
	(SUSPENSION)	46285	100 UNITS/ML
			(REVISED LABELING -- PATIENT INFORMATION; PRODUCT TO BE DISCONTINUED 9/1/93)
			(OTC)
17-935	ULTRALENTE ILETIN	LILLY	INSULIN ZINC
01-22-93	(BEEF-PORK) EXTENDED	INDIANAPOLIS, IN	SUSP EXTENDED
	INSULIN ZINC	46285	100 UNITS/ML
	(SUSPENSION)		(REVISED LABELING -- PATIENT INFORMATION; PRODUCT TO BE DISCONTINUED 9/1/93)
			(OTC)
18-061	TIMOLIDE 10-25	MSD	HYDROCHLOROTHIAZIDE
01-22-93	(TABLET)	WEST POINT, PA	25MG
		19486	TIMOLOL MALEATE
			10MG
			(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
18-477	LENTE ILETIN II	LILLY	INSULIN ZINC SUSP
01-22-93	(INJECTABLE)	INDIANAPOLIS, IN	PURIFIED BEEF
		46285	100 UNITS/ML
			(REVISED LABELING -- PATIENT INFORMATION; PRODUCT

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			TO BE DISCONTINUED 9/1/93)
			(OTC)
18-478	REGULAR ILETIN II	LILLY	INSULIN PURIFIED BEEF
01-22-93	(INJECTABLE)	INDIANAPOLIS, IN	100 UNITS/ML
	46285		(REVISED LABELING --
			PATIENT INFORMATION; PRODUCT
			TO BE DISCONTINUED 9/1/93)
			(OTC)
18-479	NPH ILETIN II	LILLY	INSULIN SUSP
01-22-93	(INJECTABLE)	INDIANAPOLIS, IN	ISOPHANE PURIFIED BEEF
	46285		100 UNITS/ML
			(REVISED LABELING --
			PATIENT INFORMATION; PRODUCT
			TO BE DISCONTINUED 9/1/93)
			(OTC)
19-537	CIPRO	MILES	CIPROFLOXACIN HYDROCHLORIDE
01-22-93	(TABLET)	WEST HAVEN, CT	EQ 100MG BASE
	06516		EQ 250MG BASE
			EQ 500MG BASE
			EQ 750MG BASE
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			ANIMAL PHARMACOLOGY)
19-084	NIZORAL	JANSSEN	KETOCONAZOLE
01-27-93	(CREAM)	PISCATAWAY, NJ	2%

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		08854	(REVISED LABELING -- INDICATIONS AND USAGE)
50-605	CEFTIN	GLAXO	CEFUROXIME AXETIL
01-27-93	(TABLET)	RES TRIANGLE PK, NC	EQ 125MG BASE
		27709	EQ 250MG BASE
			EQ 500MG BASE
			(REVISED LABELING -- ADVERSE REACTIONS)
19-002	VASCOR	JOHNSON RW	BEPRIDIL HYDROCHLORIDE
01-28-93	(TABLET)	SPRING HOUSE, PA	200MG
		19477	300MG
			400MG
			(REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS)
19-357	ETHAMOLIN	REED AND CARNRICK	ETHANOLAMINE OLEATE
01-29-93	(INJECTABLE)	KENILWORTH, NJ	50MG/ML
		07033	(REVISED LABELING -- ADVERSE REACTIONS)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

THERE ARE NO BIOLOGICAL PRODUCT LICENSES ISSUED FOR JANUARY 1993.

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

THERE ARE NO BIOLOGICAL PRODUCT DEVICE APPROVALS FOR JANUARY 1993.

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

BIOLOGICAL PRODUCT NDA APPROVALS

19-862 12-29-92	INDICLOR (INJECTABLE)	AMERSHAM ARLINGTON HEIGHTS, IL 60005	INDIUM IN^{111} CHLORIDE N/A (DIAGNOSTIC)

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

P890045 01/11/93	GELSEAL	CARBOMEDICS AUSTIN, TX 78752-1793	APPROVAL FOR THE GELSEAL VASCULAR GRAFT

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

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

P790018/S21	22 MM AORTIC PROSTHETIC HEART VALVE	MEDTRONIC HEART VALVES MEDTRONIC HALL MINNEAPOLIS, MN 55440	APPROVAL FOR PROTOCOL WHICH WILL BE USED IN THE POSTAPPROVAL STUDY ON THE 22 MM AORTIC MEDTRONIC HALL PROSTHETIC HEART VALVE	01/29/93
P830026/S55	COSMOS PACING SYSTEM, COSMOS II, NOVA 11, AND QUANTUM II PULSE GENERATORS	INTERMEDICS, INC. ANGLETON, TX 77515	DISCONTINUATION OF ONGOING REAL-TIME LIFE TESTING	01/11/93
P860007/S10	INTERTACH PACING SYSTEM, INTERTACH II PULSE GENERATORS MODELS 262-16 AND 262-16R	INTERMEDICS, INC. ANGLETON, TX 77515	DISCONTINUATION OF ONGOING REAL-TIME LIFE TESTING	01/11/93
P910020/S02	RELAY/DASH PACING SYSTEM, RELAY/DASH FAMILY OF PULSE GENERATORS	INTERMEDICS, INC. ANGLETON, TX 77515	DISCONTINUATION OF ONGOING REAL-LIFE TESTING	01/11/93
P830045/S41	AFP MODEL 203 PULSE GENERATOR WITH MODEL 370 PROGRAMMER, MODEL 3038	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	SOFTWARE MODIFICATIONS TO THE MODEL 3038 FUNCTION PACK FOR USE WITH THE APS II MODEL 3003	01/22/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	FUNCTION PACK	PROGRAMMER	
P830055/S24	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY WARSAW, IN 46580	CHANGE IN MATERIAL FOR THE ANCHORING PLATE PIN ON THE PATELLAR COMPONENT	01/08/93
P840040/S29	HEART TRAK CORONARY BALLOON DILATATION CATHETER SYSTEM, SYNERGY CONVERTIBLE RAPID EXCHANGE PTCA CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	APPROVAL FOR SYNERGY CONVERTIBLE RAPID EXCHANGE PTCA CATHETER	01/12/93
P840066/S30	SOFTMATE CONSEPT-1 CLEANING AND DISINFECTION SOLUTION	SOLA/BARNES-HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SITE	01/07/93
P850021/S18	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, QUICK .14 PTCA CATHETER	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	APPROVAL FOR THE QUICK .14 PTCA CATHETER	01/22/93
P850021/S20	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, BAXTER LONG REACH 30 MM	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	APPROVAL FOR THE BAXTER LONG REACH 30 MM PTCA CATHETER	01/29/93

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	PTCA CATHETER			
P860004/S26	MEDTRONIC SYNCHROMED INFUSION SYSTEM, MEDTRONIC SYNCHROMED PUMPS (MODELS 8610H, 8611H, AND 8615)	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN 55440-9087	MODIFICATIONS TO THE ELECTRONIC HYBRID MODULE OF THE SYNCHROMED IMPLANTABLE INFUSION PUMPS	01/26/93
P860019/S53	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, SCIMED ACE AND SCIMED LONG ACE PTCA CATHETERS	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	ONE-PIECE MANIFOLD TO BE USED ON ALL MODELS OF SCIMED ACE AND SCIMED LONG ACE PTCA CATHETERS	01/28/93
P860047/S03	OCCUCOAT, VISCOLON	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	MDR MEDICAL CORPORATION AS A DISTRIBUTOR FOR OCCUCOAT AS AN ALTERNATE TO STORZ OPHTHALMICS, INC., LABELING CHANGE, NEW TOLL-FREE NUMBER	01/11/93
P860047/S04	OCCUCOAT, CELLUCOAT	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	WORLD OPTICS, INC. AS DISTRIBUTOR FOR OCCUCOAT AS AN ALTERNATE TO STORZ	01/11/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

			OPHTHALMICS, INC., LABELING CHANGE, NEW TOLL-FREE NUMBER	
P860047/S05	OCCUCOAT, ZYCON	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	DGR, INC. AS A DISTRIBUTOR FOR OCCUCOAT AS AN ALTERNATE TO STORZ OPHTHALMICS, INC., LABELING CHANGE, NEW TOLL-FREE NUMBER	01/11/93
P870024/S35	FLUOROPERM 92 (PAFLUFOCON A), FLUOROPERM 60 (PAFLUFOCON B) AND FLUOROPERM 30 (PAFLUFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	ADDITIONAL CONTACT LENS FINISHING LABORATORY	01/26/93
P870078/S02	HANCOCK STABILIZED GLUTARALDEHYDE PROCESS BIOPROSTHESIS (MODELS 242, 342, 342C AND 342R)	MEDTRONIC HEART VALVES MINNEAPOLIS, MN 55440	ALTERNATE MILLING PROCESS	01/29/93
P880006/S16	SENSOLOG MODEL 703 PULSE GENERATOR AND P700 PROGRAMMER,	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	SOFTWARE MODIFICATIONS TO THE MODEL 3038 FUNCTION PACK FOR USE WITH THE	01/22/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	MODEL 3038 FUNCTION PACK	APS II MODEL 3003 PROGRAMMER		
P880016/S04	ONCOR B/T GENE REARRANGEMENT TEST, ONCOR B/T BLUE	ONCOR, INCORPORATED GAITHERSBURG, MD 20884	APPROVAL FOR BONE MARROW AS A SAMPLE TYPE WHICH MAY BE TESTED WITH THE ONCOR B/T BLUE KIT	01/13/93
P880038/S20	META MV PACING SYSTEM, META III PACING SYSTEM	TELECTRONICS, INC. ENGLEWOOD, CO 80112	INTRODUCTION OF THE META III MODEL 1206	01/07/93
P890043/S16	SIMPSON CORONARY ATHEROCATH, MOTOR DRIVE UNIT WITH TORQUE CONTROLLER CIRCUIT	DEVICES FOR VASCULAR INTERVENTION, INC. REDWOOD CITY, CA 94063	MODIFICATION TO THE MOTOR DRIVE UNIT COMPONENT TO INCLUDE A TORQUE CONTROLLER CIRCUIT	01/12/93
P890046/S19	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 AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	01/14/93
P900032/S13	AIS EXCIMER LASER ANGIOPLASTY SYSTEM	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA 92718	NEW LASER SOURCE	01/08/93
P900070/S02	META DDDR PACING SYSTEM, V4.1OUE SOFTWARE FOR THE MODEL 9600 NETWORK	TELECTRONICS, INC. ENGLEWOOD, CO 80112	INTRODUCTION OF THE VERSION V4.1OUE SOFTWARE FOR THE MODEL 9600 NETWORK	01/07/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

PROGRAMMER	PROGRAMMER

NADA NUMBER / APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
ORIGINAL VETERINARY NADAs				
140-848 12-17-92	VETEEZE (INJECTABLE)	DOGS	ROCHE NUTLEY, NJ 07110	DIAZEPAM 5MG/ML
ORIGINAL ABBREVIATED VETERINARY NADAs				
200-030 12-31-92	SULFADIMETHOXINE 12.5% (SOLUTION)	CATTLE, CHICKENS, TURKEYS	AGRI LABS ST JOSEPH, MO 64503	SULFADIMETHOXINE 3.75GM/0Z
SUPPLEMENTAL VETERINARY NADAs				
140-915 12-29-92	INTERCEPTOR (TABLET)	DOGS	CIBA GEIGY AN HLTH GREENSBORO, NC 27419	MILBEMYCIN OXIME 2.3MG 5.75MG 11.5MG 23MG

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
*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) 295-9012

Center for Veterinary Medicine
Melanie R. Berson, D.V.M.
(301) 295-8623

*To whom general inquiries should be directed.

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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

19-726 ZOLADEX IMPERIAL CHEM GOSERELIN ACETATE
02-02-93 (IMPLANT) CHESHIRE, ENGLAND EQ 3.6MG BASE
(SUPPL) (NEW INDICATION --
MANAGEMENT OF ENDOMETRIOSIS)

20-007 ZOFRAN GLAXO ONDANSETRON HYDROCHLORIDE
02-02-93 (INJECTABLE) RES TRIANGLE PK, NC EQ 2MG BASE/ML
(SUPPL) 27709 (NEW DOSAGE REGIMEN --
ALTERNATE DOSAGE -
SINGLE 32MG DOSE)

18-859 VIRAZOLE VIRATEK RIBAVIRIN
02-05-93 (POWDER COSTA MESA, CA 6GM/VIAL
(SUPPL) FOR RECONSTITUTION) 92626 (EXPANDED PATIENT
POPULATION --
MECHANICALLY VENTILATED

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

INFANTS)

20-107	NOVAMINE 15%	BAXTER	AMINO ACIDS
02-05-93	SULFITE FREE	ROUND LAKE, IL	15%
(5 S)	IN PLASTIC CONTAINER	60073	(NUTRIENT REPLENISHER)
	(INJECTABLE)		

50-621	SUPRAX	LEDERLE	CEFIXIME
02-05-93	(TABLET)	PEARL RIVER, NY	200MG
(SUPPL)		10965	400MG
			(NEW INDICATIONS -- UNCOMPLICATED URETHRAL AND CERVICAL GONORRHEA)

20-229	LEUSTATIN	JOHNSON RW	CLADRIBINE
02-26-93	(INJECTABLE)	RARITAN, NJ	1MG/ML
(1 P, V*)		08869	(ANTINEOPLASTIC) [HAIRY CELL LEUKEMIA]

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

NDA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT CLASSIFICATION(S)	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.

20-279	DERMATOP	HOECHST ROUSSEL	PREDNICARBATE
02-24-93	(CREAM)	SOMERVILLE, NJ	0.1%
		08876	(CORTICOSTEROID)

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

ORIGINAL ABBREVIATED NDAs

72-733	LEUCOVORIN CALCIUM	ROXANE	LEUCOVORIN CALCIUM
02-22-93	(TABLET)	COLUMBUS, OH	EQ 5MG BASE
		43216	(FOLIC ACID
			ANTAGONIST ANTIDOTE)
72-734	LEUCOVORIN CALCIUM	ROXANE	LEUCOVORIN CALCIUM
02-22-93	(TABLET)	COLUMBUS, OH	EQ 10MG BASE
		43216	(FOLIC ACID
			ANTAGONIST ANTIDOTE)
72-735	LEUCOVORIN CALCIUM	ROXANE	LEUCOVORIN CALCIUM
02-22-93	(TABLET)	COLUMBUS, OH	EQ 15MG BASE
		43216	(FOLIC ACID
			ANTAGONIST ANTIDOTE)
72-736	LEUCOVORIN CALCIUM	ROXANE	LEUCOVORIN CALCIUM
02-22-93	(TABLET)	COLUMBUS, OH	EQ 25MG BASE
		43216	(FOLIC ACID
			ANTAGONIST ANTIDOTE)
72-516	HALOPERIDOL	MARSAM	HALOPERIDOL LACTATE
02-25-93	(INJECTABLE)	CHERRY HILL, NJ	EQ 5MG BASE/ML
	[AMP]	08034	(ANTIPSYCHOTIC)
72-517	HALOPERIDOL	MARSAM	HALOPERIDOL LACTATE
02-25-93	(INJECTABLE)	CHERRY HILL, NJ	EQ 5MG BASE/ML
	[VIAL]	08034	(ANTIPSYCHOTIC)
40-057	LIDOCAINE HCL	STERLING WINTHROP	EPINEPHRINE
02-26-93	AND EPINEPHRINE	NEW YORK, NY	0.02MG/ML
	(INJECTABLE)	10016	LIDOCAINE
			2%
			(VASOCONSTRICTOR/

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

ORIGINAL ABBREVIATED NDAs

40-057	LIDOCAINE HCL	STERLING WINTHROP	EPINEPHRINE
02-26-93	AND EPINEPHRINE	NEW YORK, NY	0.01MG/ML
	(INJECTABLE)	10016	LIDOCAINE
			2%
			(VASOCONSTRICTOR/
			LOCAL ANESTHETIC)
64-035	CEFUROXIME	MARSAM	CEFUROXIME SODIUM
02-26-93	(INJECTABLE)	CHERRY HILL, NJ	EQ 750MG BASE/VIAL
		08034	EQ 1.5GM BASE/VIAL
			(ANTIBIOTIC, CEPHEM)
64-036*	CEFUROXIME	MARSAM	CEFUROXIME SODIUM
02-26-93	(INJECTABLE)	CHERRY HILL, NJ	EQ 7.5GM BASE/VIAL
		08034	(ANTIBIOTIC, CEPHEM)
72-233	VERAPAMIL HCL	MARSAM	VERAPAMIL HYDROCHLORIDE
02-26-93	(INJECTABLE)	CHERRY HILL, NJ	2.5MG/ML
		08034	(CALCIUM ION
			INFLUX INHIBITOR)
73-037	HALOPERIDOL	PHARM ASSOC	HALOPERIDOL LACTATE
02-26-93	(CONCENTRATE)	CONESTEE, SC	EQ 2MG BASE/ML
		29636	(ANTIPSYCHOTIC)

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

ORIGINAL ABBREVIATED NDAs

73-651 02-26-93	PIROXICAM (CAPSULE)	ROXANE COLUMBUS, OH 43216 (NONSTEROIDAL ANTI-INFLAMMATORY)	PIROXICAM 10MG 20MG
73-683 02-26-93	CYCLOBENZAPRINE HCL (TABLET)	INVAMED FAIRFIELD, NJ 07004 (SKELETAL MUSCLE RELAXANT)	CYCLOBENZAPRINE 10MG

* - First Time Product Available Generically

73-687 02-26-93	PINDOLOL (TABLET)	ZENITH NORTHVALE, NJ 07647 (BETA ADRENERGIC BLOCKER)	PINDOLOL 5MG 10MG

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

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

74-207	NAPROXEN	COPLEY	NAPROXEN
02-26-93	(TABLET)	CANTON, MA	250MG
		02021	375MG
			500MG
			(NONSTEROIDAL ANTI-INFLAMMATORY)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-715	DIPENTUM	KABI	OLSALAZINE SODIUM
01-05-93	(CAPSULE)	PISCATAWAY, NJ 08855	250MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; PRECAUTIONS; ADVERSE REACTIONS)
09-218	COUMADIN	DUPONT	WARFARIN SODIUM
02-01-93	(TABLET)	WILMINGTON, DE 19880	1MG 2MG 2.5MG 5MG 7.5MG 10MG (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; OVERDOSAGE)
19-726	ZOLADEX	IMPERIAL CHEM	GOSERELIN ACETATE
02-02-93	(IMPLANT)	CHESHIRE, ENGLAND	EQ 3.6MG BASE (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
20-007	ZOFRAN	GLAXO	ONDANSETRON HYDROCHLORIDE
02-02-93	(INJECTABLE)	RES TRIANGLE PK, NC 27709	EQ 2MG BASE/ML (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

			DOSAGE AND ADMINISTRATION)
18-859	VIRAZOLE	VIRATEK	RIBAVIRIN
02-05-93	(POWDER FOR RECONSTITUTION)	COSTA MESA, CA 92626	6GM/VIAL (REVISED LABELING -- BOXED WARNINGS; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
50-621	SUPRAX	LEDERLE	CEFIXIME
02-05-93	(TABLET)	PEARL RIVER, NY 10965	200MG 400MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
19-264	PENTAM 300	FUJISAWA	PENTAMIDINE ISETHIONATE
02-09-93	(INJECTABLE)	DEERFIELD, IL 60015	300MG/VIAL (REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)
19-926	HEXALEN	US BIOSCIENCE	ALTRETAMINE
02-10-93	(CAPSULE)	WEST CONSHOHOCKEN, PA 19428	50MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
17-016 02-11-93	CHORIONIC GONADOTROPIN (INJECTABLE)	STERIS PHOENIX, AZ 85063	GONADOTROPIN, CHORIONIC 2,000 UNITS/VIAL 5,000 UNITS/VIAL 10,000 UNITS/VIAL 15,000 UNITS/VIAL 20,000 UNITS/VIAL (REVISED LABELING -- ADVERSE REACTIONS)
17-067 02-11-93	CHORIONIC GONADOTROPIN (INJECTABLE)	LYPHOMED MELROSE PARK, IL 60160	GONADOTROPIN, CHORIONIC 5,000 UNITS/VIAL 10,000 UNITS/VIAL 20,000 UNITS/VIAL (REVISED LABELING -- DESCRIPTION; PRECAUTIONS)
19-465 02-16-93	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT ABBOTT PARK, IL 60064	SODIUM CHLORIDE 900MG/100ML (REVISED LABELING -- DESCRIPTION; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-466 02-16-93	DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT ABBOTT PARK, IL 60064	DEXTROSE 5GM/100ML (REVISED LABELING -- DESCRIPTION; PRECAUTIONS; DOSAGE AND ADMINISTRATION;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			HOW SUPPLIED)
19-759 02-16-93	SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT ABBOTT PARK, IL 60064	SODIUM CHLORIDE 450MG/100ML (REVISED LABELING -- DESCRIPTION; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
08-248 02-17-93	WYAMINE SULFATE (INJECTABLE)	WYETH AYERST PHILADELPHIA, PA 19101	MEPHENTERMINE SULFATE EQ 15MG BASE/ML EQ 30MG BASE/ML (REVISED LABELING -- LABELING FORMAT REVISION PROGRAM)
18-154 02-17-93	LONITEN (TABLET)	UPJOHN KALAMAZOO, MI 49001	MINOXIDIL 2.5MG 10MG (REVISED LABELING -- PRECAUTIONS)
06-002 02-18-93	ARALEN (TABLET)	STERLING NEW YORK, NY 10016	CHLOROQUINE PHOSPHATE EQ 300MG BASE (REVISED LABELING -- ADVERSE REACTIONS)
20-103 02-22-93	ZOFRAN (TABLET)	GLAXO RES TRIANGLE PK, NC 27709	ONDANSETRON HYDROCHLORIDE EQ 4MG BASE EQ 8MG BASE (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
50-579	MONOCID	SMITHKLINE BEECHAM	CEFONICID SODIUM

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

02-22-93	(INJECTABLE)	PHILADELPHIA, PA	EQ 500MG BASE/VIAL
		19101	EQ 1GM BASE/VIAL
			EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(REVISED LABELING --
			DESCRIPTION;
			DOSAGE AND ADMINISTRATION;
			COMPATIBILITY AND STABILITY;
			HOW SUPPLIED)
50-624	ROCEPHIN W/ DEXTROSE	ROCHE	CEFTRIAXONE SODIUM
02-22-93	IN PLASTIC CONTAINER	NUTLEY, NJ	EQ 10MG BASE/ML
	(INJECTABLE)	07110	EQ 20MG BASE/ML
			EQ 40MG BASE/ML
			(REVISED LABELING --
			INDICATIONS AND USAGE)
11-683	THIO-TEPA	LEDERLE	THIOTEPA
02-23-93	(INJECTABLE)	PEARL RIVER, NY	15MG/VIAL
		10965	(REVISED LABELING --
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-880	PARAPLATIN	BRISTOL MYERS SQUIBB	CARBOPLATIN
02-23-93	(INJECTABLE)	BUFFALO, NY	50MG/VIAL
		14213	150MG/VIAL
			450MG/VIAL
			(REVISED LABELING --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			WARNINGS)
50-443 02-23-93	BLENOXANE (INJECTABLE)	BRISTOL SYRACUSE, NY 13221	BLEOMYCIN SULFATE EQ 15 UNITS BASE/VIAL (REVISED LABELING -- ADMINISTRATION; STABILITY)
10-402 02-24-93	PREMARIN (INJECTABLE)	WYETH AYERST PHILADELPHIA, PA 19101	ESTROGENS, CONJUGATED 25MG/VIAL (REVISED LABELING -- DESCRIPTION; PATIENT PACKAGE INSERT)
18-998 02-24-93	VASOTEC (TABLET)	MERCK WEST POINT, PA 19486	ENALAPRIL MALEATE 2.5MG 5MG 10MG 20MG (REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)
19-221 02-24-93	VASERETIC (TABLET)	MERCK WEST POINT, PA 19486	ENALAPRIL MALEATE 10MG HYDROCHLOROTHIAZIDE 25MG (REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-309 02-24-93	VASOTEC (INJECTABLE)	MERCK WEST POINT, PA 19486	ENALAPRILAT 1.25MG/ML (REVISED LABELING --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

WARNINGS; ADVERSE REACTIONS)

19-882 02-26-93	TECHNESCAN MAG3 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	TECHNETIUM TC-99M MERTIATIDE KIT N/A (REVISED LABELING -- INSTRUCTIONS FOR PREPARATION)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

0008 02-25-93	KOGENATE (INJECTABLE)	MILES BERKELEY, CA 94701	ANTIHEMOPHILIC FACTOR (RECOMBINANT) *(B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

* - New Product Manufactured Under License
(B) Product License Issued

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BP860031 02-22-93	ETI-CORE	INCSTAR STILLWATER, MN 55082	ETI-CORE (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

P910001	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORPORATION COLORADO SPRINGS, CO 80907	APPROVAL FOR THE SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM	02/19/93
P910053	AIA-PACK CEA	TOSOH MEDICS S. SAN FRANCISCO, CA 94080	APPROVAL FOR THE AIA-PACK CEA	02/19/93
P900067	ISPAN SULFUR HEXAFLUORIDE GAS	SCOTT MEDICAL PRODUCTS PLUMSTEADVILLE, PA 18949	APPROVAL FOR ISPAN SULFUR HEXAFLUORIDE GAS FOR USE AS A SURGICAL AID IN THE TREATMENT OF UNCOMPLICATED RETINAL DETACHMENT BY PNEUMATIC RETINOPEXY	02/25/93
P900066	ISPAN PERFLUOROPROPANE GAS	SCOTT MEDICAL PRODUCTS PLUMSTEADVILLE, PA 18949	APPROVAL FOR ISPAN PERFLUOROPROPANE GAS	02/25/93
P900061	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	02/11/93

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

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

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

N16895/S81 02/26/93	BAUSCH & LOMB MEDALIST (POLYMACON) VISIBILITY TINTED CONTACT LENS	BAUSCH & LOMB ROCHESTER, NY 14692-0450	REVISED LABELING TO CHANGE "FOR USE WITH PLANNED REPLACEMENT" TO "FOR PLANNED REPLACEMENT"
N18466/S14 02/19/93	CMW4 LONG SET BONE CEMENT	DENTSPLY INTERNATIONAL YORK, PA 17405-0872	APPROVAL FOR CMW4 BONE CEMENT
P790007/S10 02/02/93	HANCOCK MODIFIED ORIFICE (MO) BIOPROSTHESIS (MODEL 250)	MEDTRONIC HEART VALVES MINNEAPOLIS, MN 55440	ALTERNATE MILLING PROCESS
P810046/S129 02/11/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS RX STREAK .014 RX STREAK .010 AND ACS FLOWTRACK 40 CORONARY DILATATION CATHETERS	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	ADDITION OF A FLUSHING SHEATH, A COIL CLIP, AND A CUP CLIP TO THE ACS RX STREAK .014, ACS RX STREAK .010 AND ACS FLOWTRACK 40 CORONARY DILATATION CATHETERS
P810046/S135 02/11/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS RX STREAK .010	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE ACS RX STREAK .010 CORONARY DILATATION CATHETER

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	CORONARY DILATATION CATHETER			
P820018/S56	MODEL 5603, 9600 PROGRAMMER NEW SOFTWARE, V4.1OUE	TELECTRONICS PACING SYSTEMS ENGLEWOOD, CO 80112	APPROVAL FOR THE INTRODUCTION OF THE V.4.1OUE SOFTWARE FOR MODEL 9600 NETWORK PROGRAMMER AND CHAPTER 0/V0.12 FOR MODEL 5603 PROGRAMMER	02/05/93
P820051/S15	UNILENS 53 (OCUFILCON B) SOFT (HYDROPHILIC) ASPHERIC CONTACT LENS, MULTI-VUE 53 (OCUFILCON B) SOFT (HYDROPHILIC) ASPHERIC LENS	OCU-EASE OPTICAL PRODUCTS, INC. PINOLE, CA 94564	TRADE NAME CHANGE FROM UNILENS 53 TO MULTI-VUE 53 (OCUFILCON B) SOFT (HYDROPHILIC) ASPHERIC CONTACT LENS FOR DAILY WEAR	02/26/93
P820076/S14	DIPLOS-03 PULSE GENERATOR AND MODEL EPR-400 PROGRAMMER, GEMNOS 04 PULSE GENERATOR	BIOTRONIK, INC. LAKE OSWEGO, OR 97035-5369	APPROVAL FOR THE GEMNOS 04 AND PMS 600 PROGRAMMER WITH MODULE SWM 600 VERSION C00U02	02/09/93
P830045/S38	AFP MODEL 283	SIEMENS PACESETTER, INC.	APPROVAL FOR THE	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

02/05/93	PULSE GENERATOR WITH MODEL 370 PROGRAMMER, SOLUS II PULSE GENERATOR MODELS 2006K, 2006L, 2007K, AND 2007M/S	SYLMAR, CA 91392-9221	SOLUS II PULSE GENERATOR MODELS 2006K, 2006L, 2007K, AND 2007M/S
P840024/S44 02/26/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	APPROVAL TO DISTRIBUTE NEW 6.60 VERSION OF THE DIAGNOSTIC AND PROGRAMMING SYSTEM SOFTWARE
P840068/S18 02/05/93	DELTA PULSE GENERATOR, VISTA PULSE GENERATOR MODELS 443/444, VISTA T PULSE GENERATOR MODELS 445/446/447, VISTA DDD PULSE GENERATOR MODELS 940/941	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	MANUFACTURING MODIFICATIONS
P850020/S04 02/20/93	PROSORBA COLUMN	IMRE CORPORATION SEATTLE, WA 98109-4517	CHANGE IN MANUFACTURING FACILITY LOCATION
P850077/S17 02/10/93	SUNSOFT (METHAFILCON A)	SUNSOFT CORPORATION ALBUQUERQUE, NM	MANUFACTURING MODIFICATIONS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	SOFT (HYDROPHILIC) LENS, SEDUCTIONS AND REVOLUTION (METHAFILCON A) SOFT (HYDROPHILIC) LENSES	87109	
P860019/S54 02/05/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, LONG COBRA 30 AND LONG COBRA 40	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	TWO NEW MODEL CATHETERS
P860019/S55 02/05/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	NEW MODEL CATHETER
P860019/S58 02/05/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	NEW MODEL CATHETER
P860019/S65 02/05/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	MINOR LABELING CHANGES TO THE INSTRUCTIONS FOR USE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
	(PTCA) CATHETER		
P870036/S13 02/12/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	ALTERNATE MANUFACTURING FACILITY
P880013/S01 02/05/93	HFV INFANT STAR VENTILATOR	INFRASONICS, INC. SAN DIEGO, CA 92121	REPLACEMENT OF TWO TYPES OF VALVES, RESTRICTORS, ACCUMULATORS AND AN ORIFICE
P880027/S25 02/12/93	SCHNEIDER MICROSOFTRAC PTCA CATHETER	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	REDUCTION OF THE INCUBATION PERIOD FOR THE AMSCO BIOLOGICAL INDICATORS FROM 7 TO 5 DAYS FOR SOME OF THEIR PTCA CATHETERS
P880053/S06 02/09/93	BARNES-HIND ENZYME + SURFACTANT CLEANER	SOLA BARNES HIND SUNNYVALE, CA 94086-5200	ADDITION OF THE BARNES HIND ENZYME + SURFACTANT CLEANER FOR COMBINED ONE STEP ENZYME CLEANING AND DISINFECTION WITH SOFT MATE CONSEPT-1 SOLUTION
P880086/S16 02/05/93	SYNCHRONY MODEL 2020T	SIEMENS PACESETTER, INC. SYLMAR, CA	APPROVAL FOR THE SOLUS II PULSE

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	PULSE GENERATOR AND APS II MODEL 3000 PROGRAMMER, SOLUS II PULSE GENERATOR MODELS 2006K, 2006L, 2007K, AND 2007M/S	91392-9221	GENERATOR MODELS 2006K, 2006L, 2007K, AND 2007M/S	
P880086/S17	SYNCHRONY MODEL 2020T PULSE GENERATOR AND APS II MODEL 3000 PROGRAMMER, SYNCHRONY III PULSE GENERATOR MODELS 2028T, 2028L, 2029K AND 2029M/S	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	APPROVAL FOR THE SYNCHRONY III PULSE GENERATOR MODELS 2028T, 2028L, 2029K, AND 2029M/S	02/05/93
P890003/S19	SYNERGYST II MODELS 7070 AND 7071, MODEL 9858E SOFTWARE DISKETTES FOR USE WITH THE MODEL 9760 PROGRAMMER SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MODEL 9858E SOFTWARE DISKETTES FOR USE WITH THE MODEL 9760 PROGRAMMER SYSTEM	02/19/93
P890027/S15	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	DISTRIBUTION OF THE NEW 6.60 VERSION OF THE DIAGNOSTIC AND PROGRAMMING SYSTEM SOFTWARE	02/26/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890039/S10	MAESTRO SAVVI MODEL 305 PACING SYSTEM/A-TRACK LEADS	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	EXTENSION OF THE "USE BEFORE:" DATE ON A-TRACK LEADS, INTRODUCTION OF A NEW FEEDTHROUGH, AND MODIFICATION OF THE INCOMING INSPECTION FOR FEEDTHROUGHS	02/12/93
P890043/S13	SIMPSON CORONARY ATHEROCATH	DEVICES FOR VASCULAR INTERVENTION, INC. REDWOOD CITY, CA 94063	ALTERNATE STERILIZATION FACILITY AND A CHANGE IN THE STERILIZATION GAS MIXTURE	02/11/93
P890044/S24	TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR	BENTEC ENGINEERING, INC. SACRAMENTO, CA 95834	ADDITIONAL CONTACT LENS FINISHING LABORATORY	02/05/93
P890044/S25	TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND BLUE TINT)	BENTEC ENGINEERING, INC. SACRAMENTO, CA 95834	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTING SITES	02/09/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890072/S06 02/09/93	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED WITH AN ULTRAVIOLET LIGHT ABSORBER)	PROGRESSIVE OPTICAL RESEARCH, LTD. ALBERTA, CANADA	FOUR ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTING SITES
P900065/S03 02/11/93	TECHNICON 38 (POLYMACON) HYDROPHILIC CONTACT LENS	WESTCON CONTACT LENS COMPANY GRAND JUNCTION, CO 81506	APPROVAL FOR BENZ RESEARCH AND DEVELOPMENT, SARASOTA, FL AS AN ALTERNATE SUPPLIER FOR THE POLYMACON MATERIAL

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

NADA NUMBER / APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
ORIGINAL VETERINARY NADAs				
140-971 01-15-93	HEARTGARD-30 PLUS (TABLET)	DOGS	MERCK RAHWAY, NJ 07065	IVERMECTIN 68MCG PYRANTEL 57MG
140-971 01-15-93	HEARTGARD-30 PLUS (TABLET)	DOGS	MERCK RAHWAY, NJ 07065	IVERMECTIN 136MCG PYRANTEL 114MG
140-971 01-15-93	HEARTGARD-30 PLUS (TABLET)	DOGS	MERCK RAHWAY, NJ 07065	IVERMECTIN 272MCG PYRANTEL 227MG
140-874 02-03-93	ANTAGONIL (SOLUTION)	FREE RANGING OR CONFINED MEMBERS OF THE FAMILY CERVIDAE (ELK, DEER)	WILDLIFE FT COLLINS, CO 80524	YOHIMBINE HYDROCHLORIDE 5MG/ML
ORIGINAL ABBREVIATED VETERINARY NADAs				
THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR FEBRUARY 1993.				

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

ORIGINAL VETERINARY NADAs

SUPPLEMENTAL VETERINARY NADAs

111-798 01-11-93	DRONCIT (TABLET)	CATS	MILES AGRI DIV AN HLTH PRODS SHAWNEE MISSION, KS 66201	PRAZIQUANTEL 11.5MG

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
*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) 295-9012

Center for Veterinary Medicine
Melanie R. Berson, D.V.M.
(301) 295-8623

*To whom general inquiries should be directed.

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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

18-936 PROZAC LILLY FLUOXETINE HYDROCHLORIDE
12-23-92 (CAPSULE) INDIANAPOLIS, IN EQ 10MG BASE
(SUPPL) 46285 (NEW STRENGTH)

19-627 DIPRIVAN ZENECA PHARMS PROPOFOL
03-08-93 (INJECTABLE) WILMINGTON, DE 10MG/ML
(SUPPL) 19897 (NEW INDICATION--
INTENSIVE CARE UNIT
SEDATION)

19-710 OPTIRAY 300 MALLINCKRODT IOVERSOL
03-09-93 (INJECTABLE) SAINT LOUIS, MO 64%
(SUPPL) 63134 (NEW INDICATION --
CONTRAST ENHANCED COMPUTED
TOMOGRAPHIC IMAGING OF THE
BODY AND INTRAVENOUS
EXCRETORY UROGRAPHY)

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

20-200	NALBUPHINE	ABBOTT	NALBUPHINE HYDROCHLORIDE
03-12-93	HYDROCHLORIDE	ABBOTT PARK, IL	1.5MG/ML
(3 S)	(INJECTABLE)	60064	(OPIOID RECEPTOR AGONIST/ANTAGONIST) [ANALGESIC]
19-050	SUFENTA	JANSSEN	SUFENTANIL CITRATE
03-19-93	(INJECTABLE)	PISCATAWAY, NJ	EQ 0.05MG BASE/ML
(SUPPL)		08854	(NEW ROUTE/INDICATION -- EPIDURAL USE IN LABOR AND DELIVERY AS AN ANALGESIC ADJUNCT TO BUPIVACAINE)
50-560	CEFIZOX	FUJISAWA	CEFTIZOXIME SODIUM
03-19-93	(INJECTABLE)	BALA CYNWYD, PA	EQ 10GM BASE/VIAL
(SUPPL)		19004	(NEW STRENGTH)
19-898	PRAVACHOL	BRISTOL MYERS SQUIBB	PRAVASTATIN SODIUM
03-22-93	(TABLET)	PRINCETON, NJ	40MG
(SUPPL)		08543	(NEW STRENGTH)
19-979	TICLID	SYNTEX	TICLOPIDINE HYDROCHLORIDE
03-24-93	(TABLET)	PALO ALTO, CA	125MG*
(SUPPL)		94303	(NEW STRENGTH)
20-186	ZIAC	LEDERLE	BISOPROLOL FUMARATE
03-26-93	(TABLET)	PEARL RIVER, NY	2.5MG
(4 S)		10965	HYDROCHLOROTHIAZIDE 6.25MG (ANTIHYPERTENSIVE)
20-186	ZIAC	LEDERLE	BISOPROLOL FUMARATE
03-26-93	(TABLET)	PEARL RIVER, NY	5MG
(4 S)		10965	HYDROCHLOROTHIAZIDE 6.25MG

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

(ANTIHYPERTENSIVE)

20-186	ZIAC	LEDERLE	BISOPROLOL FUMARATE
03-26-93	(TABLET)	PEARL RIVER, NY	10MG
(4 S)	10965		HYDROCHLOROTHIAZIDE
			6.25MG
			(ANTIHYPERTENSIVE)

20-164	LOVENOX	RHONE POULENC RORER	ENOXAPARIN SODIUM
03-29-93	(INJECTABLE)	COLLEGEVILLE, PA	30MG/0.3ML
(1 P)	19426		(ANTICOAGULANT)
			[PREVENTION OF DEEP VEIN
			THROMBOSIS, WHICH MAY LEAD TO
			PULMONARY EMBOLISM, FOLLOWING
			HIP REPLACEMENT SURGERY]

* - Not Marketed at This Time

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.

20-142 03-30-93	CATAFLAM (TABLET)	GEIGY SUMMIT, NJ 07901	DICLOFENAC POTASSIUM 25MG 50MG (NONSTEROIDAL ANTI-INFLAMMATORY)

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

ORIGINAL ABBREVIATED NDAs

73-535	PIROXICAM	MUTUAL PHARM	PIROXICAM
03-12-93	(CAPSULE)	PHILADELPHIA, PA	10MG
	19124	(NONSTEROIDAL ANTI-INFLAMMATORY)	
73-536	PIROXICAM	MUTUAL PHARM	PIROXICAM
03-12-93	(CAPSULE)	PHILADELPHIA, PA	20MG
	19124	(NONSTEROIDAL ANTI-INFLAMMATORY)	
73-136	TRAZODONE HCL	MUTUAL PHARM	TRAZODONE HYDROCHLORIDE
03-24-93	(TABLET)	PHILADELPHIA, PA	50MG
	19124	(ANTIDEPRESSANT)	
73-137	TRAZODONE HCL	MUTUAL PHARM	TRAZODONE HYDROCHLORIDE
03-24-93	(TABLET)	PHILADELPHIA, PA	100MG
	19124	(ANTIDEPRESSANT)	
63-305	NYSTATIN AND	TARO	NYSTATIN
03-29-93	TRIAMCINOLONE ACETONIDE (OINTMENT)	DOWNSVIEW, ONTARIO	100,OOO UNITS/GM TRIAMCINOLONE ACETONIDE 0.1% (ANTIFUNGAL/CORTICOSTEROID)
73-608	PINDOLOL	GENEVA	PINDOLOL
03-29-93	(TABLET)	BROOMFIELD, CO	5MG
	80038	(BETA ADRENERGIC BLOCKER)	
73-609	PINDOLOL	GENEVA	PINDOLOL
03-29-93	(TABLET)	BROOMFIELD, CO	10MG
	80038	(BETA ADRENERGIC BLOCKER)	
73-475	ATENOLOL	MUTUAL PHARM	ATENOLOL

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAs			
03-30-93	(TABLET) 19124	PHILADELPHIA, PA	50MG (BETA ADRENERGIC BLOCKER)
73-476 03-30-93	ATENOLOL (TABLET) 19124	MUTUAL PHARM PHILADELPHIA, PA	ATENOLOL 100MG (BETA ADRENERGIC BLOCKER)
74-051 03-31-93	DILTIAZEM HCL (TABLET) 08543	APOTHECON PRINCETON, NJ	DILTIAZEM HYDROCHLORIDE 30MG 60MG 90MG 120MG (CALCIUM ION INFLUX INHIBITOR)

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

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

73-138 TRAZODONE HCL MUTUAL PHARM TRAZODONE HYDROCHLORIDE
03-23-93 (TABLET) PHILADELPHIA, PA 150MG
19124 (ANTIDEPRESSANT)

73-653 METOPROLOL TARTRATE MUTUAL PHARM METOPROLOL TARTRATE
03-30-93 (TABLET) PHILADELPHIA, PA 50MG
19124 (BETA ADRENERGIC BLOCKER)

73-654 METOPROLOL TARTRATE MUTUAL PHARM METOPROLOL TARTRATE
03-30-93 (TABLET) PHILADELPHIA, PA 100MG
19124 (BETA ADRENERGIC BLOCKER)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-936	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
12-23-92	(CAPSULE)	INDIANAPOLIS, IN	EQ 10MG BASE
	46285		EQ 20MG BASE
			(REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
17-557	DANOCRINE	STERLING	DANAZOL
03-01-93	(CAPSULE)	NEW YORK, NY	50MG
	10016		100MG
			200MG
			(REVISED LABELING -- CLINICAL PHARMACOLOGY)
11-145	DIURIL	MSD	CHLOROTHIAZIDE
03-02-93	(TABLET)	WEST POINT, PA	250MG
	19486		500MG
			(REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
11-145	DIURIL	MSD	CHLOROTHIAZIDE SODIUM
03-02-93	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
	19486		(REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
11-870	DIURIL	MSD	CHLOROTHIAZIDE
03-02-93	(SUSPENSION)	WEST POINT, PA	250MG/5ML
	19486		(REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION;

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
			HOW SUPPLIED)
12-193* 03-03-93	SER-AP-ES (TABLET)	CIBA SUMMIT, NJ 07901	HYDRALAZINE HYDROCHLORIDE 25MG HYDROCHLOROTHIAZIDE 15MG RESERPINE 0.1MG (REVISED LABELING -- PRECAUTIONS; HOW SUPPLIED)
11-793 03-10-93	ESIDRIX (TABLET)	CIBA SUMMIT, NJ 07901	HYDROCHLOROTHIAZIDE 25MG 50MG 100MG (REVISED LABELING -- PRECAUTIONS)
19-558 03-10-93	PRINIVIL (TABLET)	MERCK WEST POINT, PA 19486	LISINOPRIL 5MG 10MG 20MG 40MG (REVISED LABELING -- ADVERSE REACTIONS)
19-778 03-10-93	PRINZIDE 12.5 (TABLET)	MERCK WEST POINT, PA	HYDROCHLOROTHIAZIDE 12.5MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		19486	LISINOPRIL
			20MG
			(REVISED LABELING --
			WARNINGS; ADVERSE REACTIONS)
19-778	PRINZIDE 25	MERCK	HYDROCHLOROTHIAZIDE
03-10-93	(TABLET)	WEST POINT, PA	25MG
		19486	LISINOPRIL
			20MG
			(REVISED LABELING --
			WARNINGS; ADVERSE REACTIONS)

* - Permitted

17-576	OVCON-50	BRISTOL MYERS SQUIBB	ETHINYL ESTRADIOL
03-12-93	28-DAY	EVANSVILLE, IN	0.05MG
	(TABLET)	47721	NORETHINDRONE
			1MG
			(REVISED LABELING --
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			PATIENT PACKAGE INSERT)
17-716	OVCON-35	BRISTOL MYERS	ETHINYL ESTRADIOL
03-12-93	28-DAY	EVANSVILLE, IN	0.035MG
	(TABLET)	47721	NORETHINDRONE
			0.4MG
			(REVISED LABELING --
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			PATIENT PACKAGE INSERT)
18-127	OVCON-35	BRISTOL MEYERS SQUIBB	ETHINYL ESTRADIOL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

03-12-93	21-DAY	EVANSVILLE, IN	0.035MG
	(TABLET)	47721	NORETHINDRONE
			0.4MG
			(REVISED LABELING --
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			PATIENT PACKAGE INSERT)
18-128	OVCON-50	BRISTOL MYERS SQUIBB	ETHINYL ESTRADIOL
03-12-93	21-DAY	EVANSVILLE, IN	0.05MG
	(TABLET)	47721	NORETHINDRONE
			1MG
			(REVISED LABELING --
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			PATIENT PACKAGE INSERT)
50-182	ERYTHROCIN	ABBOTT	ERYTHROMYCIN LACTOBIONATE
03-12-93	(INJECTABLE)	ABBOTT PARK, IL	EQ 500MG BASE/VIAL
		60064	EQ 1GM BASE/VIAL
			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS)
50-609	ERYTHROCIN	ABBOTT	ERYTHROMYCIN LACTOBIONATE
03-12-93	(INJECTABLE)	ABBOTT PARK, IL	EQ 500MG BASE/VIAL
		60064	EQ 1GM BASE/VIAL
			(REVISED LABELING --
			PRECAUTIONS;

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
			ADVERSE REACTIONS)
19-715 03-15-93	DIPENTUM (CAPSULE)	KABI PISCATAWAY, NJ 08855	OLSALAZINE SODIUM 250MG (REVISED LABELING -- ADVERSE REACTIONS)
09-599* 03-18-93	SUSTAC (TABLET, EXTENDED RELEASE)	KEY PHARMS MIAMI, FL 33137	NITROGLYCERIN 2.6MG** 6.5MG** 10MG** (REVISED LABELING -- DESCRIPTION; PRECAUTIONS; ADVERSE REACTIONS)
11-642* 03-18-93	CARDIOQUIN (TABLET)	PURDUE FREDERICK NORWALK, CT 06856	QUINIDINE POLYGALACTURONATE 275MG (REVISED LABELING -- DESCRIPTION; WARNINGS; DOSAGE AND ADMINISTRATION)
50-617 03-18-93	ERYGEL (GEL)	ALLERGAN HERBERT IRVINE, CA 92713	ERYTHROMYCIN 2% (REVISED LABELING -- PATIENT INSTRUCTIONS)

* - Permitted
** - Not Marketed in U.S.A.

19-050 03-19-93	SUFENTA (INJECTABLE)	JANSSEN PISCATAWAY, NJ 08854	SUFENTANIL CITRATE EQ 0.05MG BASE/ML (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			CLINICAL STUDIES; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)
19-898 03-22-93	PRAVACHOL (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	PRAVASTATIN SODIUM 10MG 20MG 40MG (REVISED LABELING -- DESCRIPTION; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-842 03-23-93	CHILDREN'S MOTRIN (SUSPENSION)	MCNEIL FORT WASHINGTON, PA 19034	IBUPROFEN 100MG/5ML (REVISED LABELING -- ADDITIONAL TRADE NAME)
13-401 03-24-93	ALDOMET (INJECTABLE)	MSD WEST POINT, PA 19486	METHYLDOPATE HYDROCHLORIDE 50MG/ML (REVISED LABELING -- PRECAUTIONS)
13-402 03-24-93	ALDORIL 15 (TABLET)	MSD WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 15MG METHYLDOPA 250MG

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
13-402 03-24-93	ALDORIL 25 (TABLET)	MSD WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 25MG METHYLDOPA 250MG (REVISED LABELING -- PRECAUTIONS)
13-402 03-24-93	ALDORIL D30 (TABLET)	MSD WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 30MG METHYLDOPA 500MG (REVISED LABELING -- PRECAUTIONS)
13-402 03-24-93	ALDORIL D50 (TABLET)	MSD WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 50MG METHYLDOPA 500MG (REVISED LABELING -- PRECAUTIONS)
18-107 03-24-93	MDP-SQUIBB (INJECTABLE)	SQUIBB PRINCETON, NJ 08543	TECHNETIUM TC-99M MEDRONATE KIT N/A (REVISED LABELING -- LABELING FORMAT REVISION PROGRAM)
18-963 03-24-93	CHOLETEC (INJECTABLE)	SQUIBB PRINCETON, NJ	TECHNETIUM TC-99M MEBROFENIN KIT

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

08543	N/A		
			(REVISED LABELING --
			ADVERSE REACTIONS)

19-011	GOLYTELY	BRAINTREE	POLYETHYLENE GLYCOL 3350
03-24-93	(POWDER	BRAINTREE, MA	236GM/BOT
	FOR RECONSTITUTION)	02184	POTASSIUM CHLORIDE
			2.97GM/BOT
			SODIUM BICARBONATE
			6.74GM/BOT
			SODIUM CHLORIDE
			5.86GM/BOT
			SODIUM SULFATE, ANHYDROUS
			22.74GM/BOT
			(REVISED LABELING --
			HOW SUPPLIED)

19-011	GOLYTELY	BRAINTREE	POLYETHYLENE GLYCOL 3350
03-24-93	(POWDER	BRAINTREE, MA	227.1GM/PACKET
	FOR RECONSTITUTION)	02184	POTASSIUM CHLORIDE
			2.82GM/PACKET
			SODIUM BICARBONATE
			6.36GM/PACKET
			SODIUM CHLORIDE
			5.53GM/PACKET
			SODIUM SULFATE, ANHYDROUS
			21.5GM/PACKET

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(REVISED LABELING -- HOW SUPPLIED)
18-057 03-25-93	PLATINOL (INJECTABLE)	BRISTOL MYERS EVANSVILLE, IN 47721	CISPLATIN 10MG/VIAL 50MG/VIAL (REVISED LABELING -- WARNINGS; ADVERSE REACTIONS; OVERDOSAGE)
18-057 03-25-93	PLATINOL-AQ (INJECTABLE)	BRISTOL MYERS EVANSVILLE, IN 47721	CISPLATIN 1MG/ML (REVISED LABELING -- WARNINGS; ADVERSE REACTIONS; OVERDOSAGE)
18-936 03-25-93	PROZAC (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	FLUOXETINE HYDROCHLORIDE EQ 10MG BASE EQ 20MG BASE (REVISED LABELING -- CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; PRECAUTIONS; OVERDOSAGE)
20-101 03-25-93	PROZAC (SOLUTION)	LILLY INDIANAPOLIS, IN 46285	FLUOXETINE HYDROCHLORIDE EQ 20MG BASE/5ML (REVISED LABELING -- CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; PRECAUTIONS; OVERDOSAGE)
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

03-26-93	(INJECTABLE)	EAST HANOVER, NJ	100 IU/ML
		07936	200 IU/ML
			(REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
19-529	HUMULIN BR	LILLY	INSULIN BIOSYNTHETIC HUMAN
03-26-93	(INJECTABLE)	INDIANAPOLIS, IN	100 UNITS/ML
		46285	(REVISED LABELING -- PATIENT INFORMATION; PRODUCT TO BE DISCONTINUED SEPTEMBER 1, 1993)
			(OTC)
19-938	NOVOLIN R	NOVO NORDISK	INSULIN BIOSYNTHETIC HUMAN
03-26-93	(INJECTABLE)	PRINCETON, NJ	100 UNITS/ML
		08540	(REVISED LABELING -- PATIENT PACKAGE INSERT)
			(OTC)
19-959	NOVOLIN N	NOVO NORDISK	INSULIN SUSP ISOPHANE
03-26-93	(INJECTABLE)	PRINCETON, NJ	BIOSYNTHETIC HUMAN
		08540	100 UNITS/ML
			(REVISED LABELING -- PATIENT PACKAGE INSERT)
			(OTC)
19-991	NOVOLIN 70/30	NOVO NORDISK	INSULIN BIOSYNTHETIC HUMAN
03-26-93	(INJECTABLE)	PRINCETON, NJ	30 UNITS/ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		08540	INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN 70 UNITS/ML (REVISED LABELING -- PATIENT PACKAGE INSERT) (OTC)
20-088 03-26-93	NORPLANT SYSTEM (IMPLANT)	WYETH AYERST PHILADELPHIA, PA 19101	LEVONORGESTREL 36MG/IMPLANT (REVISED LABELING -- INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; INSERTION PROCEDURE; PATIENT PACKAGE INSERT)
10-060 03-31-93	FLORINEF (TABLET)	SQUIBB NEW BRUNSWICK, NJ 08903	FLUDROCORTISONE ACETATE 0.1MG (REVISED LABELING -- WARNINGS; PRECAUTIONS)
12-283* 03-31-93	HYGROTON (TABLET)	RHONE POULENC RORER FORT WASHINGTON, PA 19034	CHLORTHALIDONE 25MG 50MG (REVISED LABELING -- PRECAUTIONS)
18-538 03-31-93	LOZOL (TABLET)	RHONE POULENC RORER FORT WASHINGTON, PA 19034	INDAPAMIDE 2.5MG (REVISED LABELING -- PRECAUTIONS)

* - Permitted

19-777 03-31-93	ZESTRIL (TABLET)	IMPERIAL CHEM CHESHIRE, ENGLAND	LISINOPRIL 5MG

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
			10MG 20MG 40MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
19-888 03-31-93	ZESTORETIC 20/12.5 (TABLET)	IMPERIAL CHEM CHESHIRE, ENGLAND	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 20MG (REVISED LABELING -- PRECAUTIONS; WARNINGS; ADVERSE REACTIONS)
19-888 03-31-93	ZESTORETIC 20/25 (TABLET)	IMPERIAL CHEM CHESHIRE, ENGLAND	HYDROCHLOROTHIAZIDE 25MG LISINOPRIL 20MG (REVISED LABELING -- PRECAUTIONS; WARNINGS; ADVERSE REACTIONS)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

0017 03-30-93	TETRAMUNE (INJECTABLE)	LEDERLE LABS DIV AM CYANAMID PEARL RIVER, NY 10965	DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE ADSORBED AND HAEMOPHILUS B CONJUGATE VACCINE (DIPHTHERIA CRM197 PROTEIN CONJUGATE) *(B)
0384 03-30-93	ACTHIB (INJECTABLE)	PASTEUR MERIEUX SERUMS ET VACCINS SA LYON, FRANCE	HAEMOPHILUS B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE) *(B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

* - New Product Manufactured Under License
(B) Product License Issued

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BP910003 03-11-93	CRYOGENIC	CHARTERMED LAKEWOOD, NJ 08701	CRYOGENIC STORAGE CONTAINER USING HEMOFLEX FILM (C)
BP920009 03-25-93	NONE	ONE LAMBDA CANOGA PARK, CA 91303	ANTI-B27 FITC CONJUGATED MONOCLONAL ANTIBODY (C)
BP920019 03-26-93	INVERNESS AUTOMATED ANTIBODY SCREENING	IBG SYS LAYTONSVILLE, MD 20882	AUTOMATED BLOOD GROUPING AND ANTIBODY TEST SYSTEM (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

P920040	CIBA VISION DISINFECTING SOLUTION	CIBA VISION CORPORATION DULUTH, GA 30136-1518	APPROVAL FOR CIBA VISION DISINFECTING SOLUTION	03/24/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

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

P800018/S19	SOFT MATE COMFORT DROPS FOR SENSITIVE EYES AND BARNES-HIND GAS PERMEABLE COMFORT DROPS	SOLA BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SITE	03/25/93
P810046/S134	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS STACK 40-S CORONARY DILATATION CATHETER WITH QUARTER SIZE BALLOONS	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	MODIFIED ACS STACK 40-S CORONARY DILATATION CATHETER WITH QUARTER SIZE BALLOONS	03/18/93
P810046/S136	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS PRISM AND PINKERTON .018 CORONARY DILATATION CATHETERS	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE CONTENT OF CARBON BLACK IN THE ACS PRISM AND PINKERTON .018 CORONARY DILATATION CATHETERS	03/19/93
P830026/S57	COSMOS PACING SYSTEM	INTERMEDICS, INC. ANGLETON, TX 77515	INTRODUCTION OF THE RX222 MODEL 522-10 POCKET PROGRAMMER	03/03/93
P840001/S28	ITREL TOTALLY IMPLANTED SPINAL	MEDTRONIC, INC. MINNEAPOLIS, MN	MODIFICATION OF THE REED SWITCH	03/31/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CORD STIMULATION SYSTEM, ITREL AND ITREL II IMPLANTABLE PULSE GENERATOR, MODEL 7424	55432-3576	SPECIFICATION FOR THE ITREL IMPLANTABLE PULSE GENERATOR, MODEL 7424
P840008/S40 03/08/93	DORNIER LITHOTRIPTER, MODEL HM3, DORNIER MFL5000 LITHOTRIPTER	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	APPROVAL FOR THE DORNIER MFL5000 LITHOTRIPTER
P840024/S47 03/19/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	CHANGE IN THE SPECIFICATIONS FOR THE HEADSET CABLE OF THE NUCLEUS 22 CHANNEL COCHLEAR IMPLANT
P840039/S34 03/31/93	MODELS P323UV, P328UV, P329UV, P351UV, P356UV, AND P359UV ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	APPROVAL FOR THE REFERENCED INTRAOCULAR LENSES
P850074/S08 03/03/93	GORE-TEX CRUCIATE LIGAMENT PROSTHESIS	W.L. GORE & ASSOCIATES, INC. FLAGSTAFF, AZ 86003-2200	NEW MANUFACTURING FACILITY
P850079/S17	HYDRASOFT	COASTVISION, INC.	EXPANSION OF THE

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	(METHAFILCON A) HYDROPHILIC CONTACT LENS, HYDRASOFT XW AND HYDRASOFT TORIC XW (METHAFILCON B) HYDROPHILIC CONTACT LENSES FOR EXTENDED WEAR	HUNTINGTON BEACH, CA 92648	INDICATIONS TO INCLUDE THE CORRECTION OF VISUAL ACUITY IN APHAKIC PERSONS	03/11/93
P850079/S21	HYDRASOFT, HYDRASOFT XW, HYDRASOFT TORIC XW, HYDRASOFT XW EZC AND HYDRASOFT TORIC XW EZC (METHAFILCON A OR METHAFILCON B) HYDROPHILIC CONTACT LENSES	COASTVISION, INC. HUNTINGTON BEACH, CA 92648	ADDITIONAL PARAMETERS IN LENS INDICATIONS ALREADY APPROVED FOR EXTENDED WEAR	03/11/93
P850088/S28	LENS PLUS OXYSEPT DISINFECTION SYSTEM, OXYSEPT 1 DISINFECTION SOLUTION AND ULTRACARE DISINFECTING	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ALTERNATE SUPPLIER OF THE HYDROGEN PEROXIDE RAW MATERIAL USED TO MANUFACTURE OXYSEPT 1 DISINFECTION SOLUTION AND ULTRACARE DISINFECTING SOLUTION	03/09/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	SOLUTION		
P860035/S05 03/10/93	IVAC TITRATOR KIT- MODEL T1000	IVAC CORP. SAN DIEGO, CA 92186-5335	CHANGE IN THE MANUFACTURING, PROCESSING, AND PACKAGING SITE OF THE TITRATOR KIT - MODEL T1000
P870049/S14 03/12/93	MICROSCAN RAPID PANELS	BAXTER DIAGNOSTICS, INC. WEST SACRAMENTO, CA 95691	EXTEND THE READ TIME FROM 3 1/2 - 7 HOURS TO 3 1/2 - 15 HOURS
P880001/S37 03/31/93	FLOUREX 700 (FLUSILFOCON A), FLOUREX 500 (FLUSILFOCON B) AND FLOUREX 300 (FLUSILFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	G.T. LABORATORIES, INC. CHICAGO, IL 60602	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTING SITES
P880027/S24 03/23/93	SCHNEIDER MICROSOFTRAC PTCA CATHETER, SCHNEIDER MYSTIC PTCA CATHETERS MODELS: MYS-015, MYS-020, MYS-225, MYS-025, MYS-275, MYS-030, MYS-325, MYS-035, MYS-040	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	APPROVAL FOR AN ALTERNATIVE DESIGN TO THE CURRENTLY MARKETED XLP PTCA CATHETER

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P880098/S06 03/23/93	MENICON SF-P (MELAFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	MENICON CO., LTD. NAKA-KU, JAPAN	RELOCATION OF THE FINISHING LABORATORY
P890027/S17 03/19/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	CHANGE IN THE SPECIFICATIONS FOR THE HEADSET CABLE OF THE NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS
P890072/S07 03/23/93	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED) WITH AN ULTRAVIOLET LIGHT ABSORBER	PROGRESSIVE OPTICAL RESEARCH, LTD. ALBERTA, CANADA	FIVE ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P900032/S16 03/18/93	AIS EXCIMER LASER ANGIOPLASTY SYSTEM	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA 92718	REVISED LABELING

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

ORIGINAL VETERINARY NADAs

065-505 01-29-93	MICROCILLIN-AG (LIQUID, SUSPENSION)	CATTLE HORSES SHEEP SWINE	ANTHONY PRODS ARCADIA, CA 91006	PENICILLIN G PROCAINE 300,000 UNITS/ML
140-916 01-29-93	DENAGARD CONCENTRATE (LIQUID)	SWINE	FERMENTA AN HLTH KANSAS CITY, MO 64153	TIAMULIN HYDROGEN FUMARATE 12.3% W/V

ORIGINAL ABBREVIATED VETERINARY NADAs

200-037 02-08-93	GENTAMICIN SULFATE (LIQUID)	HORSES	AGRI LABS ST JOSEPH, MO 64503	GENTAMICIN SULFATE 100 MG/ML

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR MARCH 1993.

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 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
*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) 295-9012

Center for Veterinary Medicine
Melanie R. Berson, D.V.M.
(301) 295-8623

*To whom general inquiries should be directed.

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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

17-970 NOLVADEX STUART TAMOXIFEN CITRATE
04-01-93 (TABLET) WILMINGTON, DE EQ 10MG BASE
(SUPPL) 19897 (EXPANDED USE --
TREATMENT OF METASTATIC
BREAST CANCER IN MALES)

19-658 CLARITIN SCHERING LORATADINE
04-12-93 (TABLET) KENILWORTH, NJ 10MG
(1 S) 07033 (ANTIHISTAMINE)

20-263 LUPRON TAP LEUPROLIDE ACETATE
04-16-93 (INJECTABLE) DEERFIELD, IL 5MG/ML
(5 S, V) 60015 (GONADOTROPIN RELEASING
HORMONE ANALOG)
[TREATMENT OF CHILDREN WITH
CENTRAL PRECOCIOUS PUBERTY]

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

20-263	LUPRON DEPOT-PED	TAP	LEUPROLIDE ACETATE
04-16-93	(INJECTABLE)	DEERFIELD, IL	7.5MG/VIAL
(5 S, V)		60015	3.75MG/VIAL & 7.5MG/VIAL
			7.5MG/VIAL & 7.5MG/VIAL
			(GONADOTROPIN RELEASING HORMONE ANALOG)
			[TREATMENT OF CHILDREN WITH CENTRAL PRECOCIOUS PUBERTY]
16-020	SYMMETREL	DUPONT	AMANTADINE HYDROCHLORIDE
04-19-93	(CAPSULE)	WILMINGTON, DE	100MG
(SUPPL)		19880	(NEW DOSAGE REGIMEN -- DOSING OF 100MG DAILY FOR PROPHYLAXIS OF INFLUENZA A VIRUS INFECTION IN ADULTS WHO ARE UNABLE TO TOLERATE 200MG DAILY)
16-023	SYMMETREL	DUPONT	AMANTADINE HYDROCHLORIDE
04-19-93	(SYRUP)	WILMINGTON, DE	50MG/5ML
(SUPPL)		19880	(NEW DOSAGE REGIMEN -- DOSING OF 100MG DAILY FOR PROPHYLAXIS OF INFLUENZA A VIRUS INFECTION IN ADULTS WHO ARE UNABLE TO TOLERATE 200MG DAILY)
18-101	SYMMETREL	DUPONT	AMANTADINE HYDROCHLORIDE
04-19-93	(TABLET)	WILMINGTON, DE	100MG*
(SUPPL)		19880	(NEW DOSAGE REGIMEN -- DOSING OF 100MG DAILY FOR PROPHYLAXIS OF INFLUENZA A VIRUS INFECTION IN ADULTS WHO ARE UNABLE TO TOLERATE 200MG DAILY)

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

20-198	ADALAT CC	MILES	NIFEDIPINE
04-21-93	(TABLET,	WEST HAVEN, CT	30MG
(5 S)	EXTENDED RELEASE)	06516	60MG
			90MG
			(CALCIUM ION
			INFLUX INHIBITOR)
17-450	MONISTAT 7	ADVANCED CARE	MICONAZOLE NITRATE
04-26-93	(CREAM)	RARITAN, NJ	2%
(SUPPL)		08869	(NEW INDICATION --
			RELIEF OF EXTERNAL VULVAR
			ITCHING AND IRRITATION
			ASSOCIATED WITH A YEAST
			INFECTION)
			(OTC)

* - Not Marketed at Present Time

18-052	GYNE-LOTRIMIN	SCHERING	CLOTRIMAZOLE
04-26-93	(CREAM)	KENILWORTH, NJ	1%
(SUPPL)		07033	(NEW INDICATION --
			RELIEF OF EXTERNAL VULVAR
			ITCHING AND IRRITATION
			ASSOCIATED WITH A YEAST
			INFECTION)
			(OTC)
20-288	MONISTAT 7	ADVANCED CARE	MICONAZOLE NITRATE
04-26-93	COMBINATION PACK	RARITAN, NJ	100MG-SUPPOSITORY

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 S) (SUPPOSITORY AND CREAM) 08869 2%-CREAM
(ANTIFUNGAL)
(OTC)

20-289 GYNE-LOTRIMIN SCHERING PLOUGH CLOTRIMAZOLE
04-26-93 COMBINATION PACK LIBERTY CORNER, NJ 100MG-SUPPOSITORY
(3 S) (SUPPOSITORY AND CREAM) 07938 1%-CREAM
(ANTIFUNGAL)
(OTC)

19-757 CHIBROXIN MERCK NORFLOXACIN
04-27-93 (SOLUTION/DROPS) WEST POINT, PA 0.3%
(SUPPL) 19486 (EXPANDED USE --
ADDITIONAL ORGANISM,
PSEUDOMONAS AERUGINOSA)

18-538 LOZOL RHONE POULENC RORER INDAPAMIDE
04-29-93 (TABLET) FORT WASHINGTON, PA 1.25MG
(SUPPL) 19034 (NEW STRENGTH)

18-538 LOZOL RHONE POULENC RORER INDAPAMIDE
04-29-93 (TABLET) FORT WASHINGTON, PA 1.25MG
(SUPPL) 19034 2.5MG
(NEW DOSAGE REGIMEN --
LOWER INITIAL AND
MAINTENANCE DOSING)

19-777 ZESTRIL ZENECA LISINOPRIL
04-29-93 (TABLET) WILMINGTON, DE 2.5MG
(SUPPL) 19897 (NEW STRENGTH)

50-671 VANCOCIN HCL LILLY VANCOMYCIN HYDROCHLORIDE
04-29-93 IN PLASTIC CONTAINER INDIANAPOLIS, IN EQ 500MG BASE/100ML
(3 S) (INJECTABLE) 46285 (ANTIBIOTIC, GLYCOPEPTIDE)

NDA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT CLASSIFICATION(S)	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.

19-843 03-16-93	ISOLYTE S W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE) (ELECTROLYTE/NUTRIENT REPLENISHER)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 30MG/100ML POTASSIUM CHLORIDE 37MG/100ML SODIUM ACETATE 370MG/100ML SODIUM CHLORIDE 530MG/100ML SODIUM GLUCONATE 500MG/100ML
19-844 03-16-93	ISOLYTE H W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 30MG/100ML POTASSIUM CHLORIDE 97MG/100ML SODIUM ACETATE

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

APPROVABLE ORIGINAL NDAs

			220MG/100ML SODIUM CHLORIDE 140MG/100ML (ELECTROLYTE/NUTRIENT REPLENISHER)
19-864 03-16-93	ISOLYTE R W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	CALCIUM CHLORIDE 37MG/100ML DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 31MG/100ML POTASSIUM CHLORIDE 120MG/100ML SODIUM ACETATE 330MG/100ML SODIUM CHLORIDE 88MG/100ML (ELECTROLYTE/NUTRIENT REPLENISHER)
19-870 03-16-93	ISOLYTE M W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML POTASSIUM CHLORIDE 150MG/100ML POTASSIUM PHOSPHATE, DIBASIC 130MG/100ML SODIUM ACETATE 280MG/100ML SODIUM CHLORIDE 91MG/100ML

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

APPROVABLE ORIGINAL NDAs

			(ELECTROLYTE/NUTRIENT REPLENISHER)
19-873	ISOLYTE P	MCGAW	DEXTROSE
03-16-93	W/ DEXTROSE 5%	IRVINE, CA	5GM/100ML
	IN PLASTIC CONTAINER	92713	MAGNESIUM CHLORIDE
	(INJECTABLE)		31MG/100ML
			POTASSIUM CHLORIDE
			130MG/100ML
			POTASSIUM PHOSPHATE, DIBASIC
			26MG/100ML
			SODIUM ACETATE
			320MG/100ML
			(ELECTROLYTE/NUTRIENT REPLENISHER)
20-210	PROPULSID	JANSSEN	CISAPRIDE MONOHYDRATE
04-09-93	(TABLET)	PISCATAWAY, NJ	EQ 10MG/BASE
		08855	EQ 20MG/BASE
			(UPPER GI TRACT MOTILITY STIMULATOR)

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

APPROVABLE ORIGINAL NDAs

20-095	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
04-30-93	(CAPSULE)	RES TRIANGLE PK, NC	EQ 150MG BASE
	27709	(HISTAMINE H-2 RECEPTOR ANTAGONIST)	
20-095	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
04-30-93	(CAPSULE)	RES TRIANGLE PK, NC	EQ 300MG BASE
	27709	(HISTAMINE H-2 RECEPTOR ANTAGONIST)	
50-693	ZITHROMAX	PFIZER	AZITHROMYCIN DIHYDRATE
04-30-93	(SUSPENSION)	GROTON, CT	EQ 1GM BASE/PACKET
	06340	(ANTIBIOTIC, MACROLIDE)	

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

ORIGINAL ABBREVIATED NDAs

40-050 04-15-93	METHADOSE (TABLET)	MALLINCKRODT CHESTERFIELD, MO 63017	METHADONE HYDROCHLORIDE 5MG 10MG (NARCOTIC ANALGESIC)
62-772 04-15-93	AMPICILLIN SODIUM (INJECTABLE)	HANFORD SYRACUSE, NY 13201	AMPICILLIN SODIUM EQ 1GM BASE/VIAL (ANTIBIOTIC, PENICILLIN)
63-139 04-15-93	AMPICILLIN SODIUM (INJECTABLE)	HANFORD SYRACUSE, NY 13201	AMPICILLIN SODIUM EQ 1GM BASE/VIAL (ANTIBIOTIC, PENICILLIN)
63-140 04-15-93	AMPICILLIN SODIUM (INJECTABLE)	HANFORD SYRACUSE, NY 13201	AMPICILLIN SODIUM EQ 2GM BASE/VIAL (ANTIBIOTIC, PENICILLIN)
63-141 04-15-93	AMPICILLIN SODIUM (INJECTABLE)	HANFORD SYRACUSE, NY 13201	AMPICILLIN SODIUM EQ 2GM BASE/VIAL (ANTIBIOTIC, PENICILLIN)
63-142 04-15-93	AMPICILLIN SODIUM (INJECTABLE)	HANFORD SYRACUSE, NY 13201	AMPICILLIN SODIUM EQ 10GM BASE/VIAL (ANTIBIOTIC, PENICILLIN)
63-143 04-15-93	AMPICILLIN SODIUM (INJECTABLE)	HANFORD SYRACUSE, NY 13201	AMPICILLIN SODIUM EQ 125MG BASE/VIAL (ANTIBIOTIC, PENICILLIN)
63-145 04-15-93	AMPICILLIN SODIUM (INJECTABLE)	HANFORD SYRACUSE, NY 13201	AMPICILLIN SODIUM EQ 250MG BASE/VIAL (ANTIBIOTIC, PENICILLIN)

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

ORIGINAL ABBREVIATED NDAs

63-146	AMPICILLIN SODIUM	HANFORD	AMPICILLIN SODIUM
04-15-93	(INJECTABLE)	SYRACUSE, NY	EQ 500MG BASE/VIAL
		13201	(ANTIBIOTIC, PENICILLIN)
63-147	AMPICILLIN SODIUM	HANFORD	AMPICILLIN SODIUM
04-15-93	(INJECTABLE)	SYRACUSE, NY	EQ 500MG BASE/VIAL
		13201	(ANTIBIOTIC, PENICILLIN)
71-536	METOCLOPRAMIDE HCL	MUTUAL PHARM	METOCLOPRAMIDE HYDROCHLORIDE
04-28-93	(TABLET)	PHILADELPHIA, PA	EQ 10MG BASE
		19124	(UPPER GI TRACT
			MOTILITY STIMULATOR)
74-125	PINDOLOL	PUREPAC	PINDOLOL
04-28-93	(TABLET)	ELIZABETH, NJ	5MG
		07207	10MG
			(BETA ADRENERGIC BLOCKER)
40-015	NEOSAR	ADRIA	CYCLOPHOSPHAMIDE
04-29-93	(INJECTABLE)	COLUMBUS, OH	100MG/VIAL
		43216	200MG/VIAL
			500MG/VIAL
			1GM/VIAL
			2GM/VIAL
			(ANTINEOPLASTIC)
63-221	CEFTAZIDIME SODIUM	BAXTER	CEFTAZIDIME SODIUM
04-29-93	IN PLASTIC CONTAINER	ROUND LAKE, IL	EQ 10MG BASE/ML
	(INJECTABLE)	60073	EQ 20MG BASE/ML
			EQ 40MG BASE/ML
			(ANTIBIOTIC, CEPHEM)
63-293	CEFOTAN	ZENECA	CEFOTETAN DISODIUM

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

ORIGINAL ABBREVIATED NDAs

04-29-93	(INJECTABLE)	WILMINGTON, DE	EQ 1GM BASE/VIAL
	19897		EQ 2GM BASE/VIAL
			(ANTIBIOTIC, CEPHAM)
73-165	ALBUTEROL SULFATE	WATSON	ALBUTEROL SULFATE
04-29-93	(SYRUP)	CORONA, CA	EQ 2MG BASE/5ML
	91720		(BRONCHODILATOR)
73-581	ATENOLOL	MUTUAL PHARM	ATENOLOL
04-29-93	AND CHLORTHALIDONE	PHILADELPHIA, PA	50MG
	(TABLET)	19124	CHLORTHALIDONE
			25MG
			(ANTIHYPERTENSIVE)
73-582	ATENOLOL	MUTUAL PHARM	ATENOLOL
04-29-93	AND CHLORTHALIDONE	PHILADELPHIA, PA	100MG
	(TABLET)	19124	CHLORTHALIDONE
			25MG
			(ANTIHYPERTENSIVE)
74-184	METHADOSE	MALLINCKRODT	METHADONE HYDROCHLORIDE
04-29-93	(TABLET,	CHESTERFIELD, MO	40MG
	DISPERSIBLE)	63017	(NARCOTIC ANALGESIC)
81-310	FLUPHENAZINE	COPLEY	FLUPHENAZINE HYDROCHLORIDE
04-29-93	HYDROCHLORIDE	CANTON, MA	2.5MG/5ML
	(ELIXIR)	02021	(ANTIPSYCHOTIC)
81-318	LIDOCAINE HCL	COPLEY	LIDOCAINE HYDROCHLORIDE
04-29-93	(JELLY)	CANTON, MA	2%
	02021		(LOCAL ANESTHETIC)

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

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS FOR APRIL 1993.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-710	OPTIRAY 160	MALLINCKRODT	IOVERSOL
03-09-93	(INJECTABLE)	SAINT LOUIS, MO	34%
		63134	(REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
19-710	OPTIRAY 240	MALLINCKRODT	IOVERSOL
03-09-93	(INJECTABLE)	SAINT LOUIS, MO	51%
		63134	(REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
19-710	OPTIRAY 300	MALLINCKRODT	IOVERSOL
03-09-93	(INJECTABLE)	SAINT LOUIS, MO	64%
		63134	(REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
19-710	OPTIRAY 320	MALLINCKRODT	IOVERSOL
03-09-93	(INJECTABLE)	SAINT LOUIS, MO	68%
		63134	(REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
19-710	OPTIRAY 350	MALLINCKRODT	IOVERSOL
03-09-93	(INJECTABLE)	SAINT LOUIS, MO	74%
		63134	(REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
18-186	SODIUM LACTATE	MCGAW	SODIUM LACTATE
03-24-93	0.167 MOLAR	IRVINE, CA	1.87GM/100ML
	IN PLASTIC CONTAINER	92713	(REVISED LABELING --

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
	(INJECTABLE)		DESCRIPTION; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
18-931 03-24-93	TRAVASOL 10% IN PLASTIC CONTAINER (INJECTABLE)	BAXTER ROUND LAKE, IL 60073	AMINO ACIDS 10% (REVISED LABELING -- DESCRIPTION; PRECAUTIONS; HOW SUPPLIED)
17-970 04-01-93	NOLVADEX (TABLET)	STUART WILMINGTON, DE 19897	TAMOXIFEN CITRATE EQ 10MG BASE (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)
19-471 04-01-93	CARDIZEM SR (CAPSULE, EXTENDED RELEASE)	MARION MERRELL DOW KANSAS CITY, MO 64137	DILTIAZEM HYDROCHLORIDE 60MG 90MG 120MG (REVISED LABELING -- PRECAUTIONS)
50-477 04-01-93	NEBCIN (INJECTABLE)	LILLY INDIANAPOLIS, IN	TOBRAMYCIN SULFATE EQ 10MG BASE/ML

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 -- PRECAUTIONS)
50-519	NEBCIN	LILLY	TOBRAMYCIN SULFATE
04-01-93	(INJECTABLE)	INDIANAPOLIS, IN	EQ 1.2GM BASE/VIAL
		46285	(REVISED LABELING -- PRECAUTIONS)
18-841	DAYPRO	SEARLE	OXAPROZIN
04-02-93	(TABLET)	SKOKIE, IL	600MG
		60077	(REVISED LABELING -- CLINICAL PHARMACOLOGY; PRECAUTIONS)
07-073	AZULFIDINE	KABI	SULFASALAZINE
04-05-93	(TABLET)	PISCATAWAY, NJ	500MG
		08855	(REVISED LABELING -- CLINICAL PHARMACOLOGY; ADVERSE REACTIONS)
07-073	AZULFIDINE EN-TABS	KABI	SULFASALAZINE
04-05-93	(TABLET, EXTENDED RELEASE)	PISCATAWAY, NJ	500MG
		08855	(REVISED LABELING -- CLINICAL PHARMACOLOGY; ADVERSE REACTIONS)
18-703	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
04-05-93	(TABLET)	RES TRIANGLE PK, NC	EQ 150MG BASE
		27709	(REVISED LABELING -- CONTRAINDICATIONS; 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)
18-703	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
04-05-93	(TABLET)	RES TRIANGLE PK, NC	EQ 300MG BASE
		27709	(REVISED LABELING --
			CONTRAINDICATIONS;
			PRECAUTIONS;
			ADVERSE REACTIONS)
19-081	ESTRADERM	CIBA	ESTRADIOL
04-05-93	(FILM,	SUMMIT, NJ	0.05MG/24HR
	EXTENDED RELEASE)	07901	0.1MG/24HR
			(REVISED LABELING --
			CONTRAINDICATIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			PATIENT PACKAGE INSERT)
19-090	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
04-05-93	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 25MG BASE/ML
		27709	(REVISED LABELING --
			DESCRIPTION;
			DOSAGE AND ADMINISTRATION;
			PRECAUTIONS;
			ADVERSE REACTIONS)
19-593	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
04-05-93	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 1MG BASE/100ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		27709	(REVISED LABELING -- DESCRIPTION; DOSAGE AND ADMINISTRATION; PRECAUTIONS; ADVERSE REACTIONS)
19-675 04-05-93	ZANTAC (SYRUP)	GLAXO RES TRIANGLE PK, NC	RANITIDINE HYDROCHLORIDE EQ 15MG BASE/ML
		27709	(REVISED LABELING -- CONTRAINDICATIONS; PRECAUTIONS; ADVERSE REACTIONS)
17-362 04-06-93	PROGESTERONE (INJECTABLE)	STERIS PHOENIX, AZ	PROGESTERONE 50MG/ML
		85063	(REVISED LABELING -- WARNINGS; PATIENT PACKAGE INSERT)
50-674 04-08-93	VANTIN (TABLET)	UPJOHN KALAMAZOO, MI	CEFPODOXIME PROXETIL EQ 100MG BASE
		49001	EQ 200MG BASE (REVISED LABELING -- ADVERSE REACTIONS)
50-675 04-08-93	VANTIN (GRANULE, FOR RECONSTITUTION)	UPJOHN KALAMAZOO, MI 49001	CEFPODOXIME PROXETIL EQ 50MG BASE/5ML EQ 100MG BASE/5ML
			(REVISED LABELING -- ADVERSE REACTIONS)
50-687 04-08-93	BANAN (TABLET)	SANKYO NEW YORK, NY	CEFPODOXIME PROXETIL EQ 100MG BASE**

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		10017	EQ 200MG BASE**
			(REVISED LABELING --
			ADVERSE REACTIONS)
50-688	BANAN	SANKYO	CEFPODOXIME PROXETIL
04-08-93	(GRANULE,	NEW YORK, NY	EQ 50MG BASE/5ML**
	FOR RECONSTITUTION)	10017	EQ 100MG BASE/5ML**
			(REVISED LABELING --
			ADVERSE REACTIONS)
50-579	MONOCID	SMITHKLINE BEECHAM	CEFONICID SODIUM
04-12-93	(INJECTABLE)	PHILADELPHIA, PA	EQ 500MG BASE/VIAL
		19101	EQ 1GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(REVISED LABELING --
			WARNINGS; ADVERSE REACTIONS)
18-342	WELLCOVORIN	BURROUGHS WELLCOME	LEUCOVORIN CALCIUM
04-14-93	(TABLET)	RES TRIANGLE PK, NC	EQ 5MG BASE
		27709	EQ 25MG BASE
			(REVISED LABELING --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			CONTRAINDICATIONS;
			WARNINGS; PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)
17-857	STADOL	BRISTOL MYERS SQUIBB	BUTORPHANOL TARTRATE
04-16-93	(INJECTABLE)	PRINCETON, NJ	1MG/ML
		08543	2MG/ML
			(REVISED LABELING --
			PRECAUTIONS;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

ADVERSE REACTIONS)

** - Not Marketed in USA At This Time

18-869 04-16-93	NIMOTOP (CAPSULE)	MILES WEST HAVEN, CT 06516	NIMODIPINE 30MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; DOSAGE AND ADMINISTRATION)
19-890 04-16-93	STADOL (SPRAY, METERED)	BRISTOL MYERS SQUIBB WALLINGFORD, CT 06492	BUTORPHANOL TARTRATE 1MG/INH (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
16-020 04-19-93	SYMMETREL (CAPSULE)	DUPONT WILMINGTON, DE 19880	AMANTADINE HYDROCHLORIDE 100MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
16-023 04-19-93	SYMMETREL (SYRUP)	DUPONT WILMINGTON, DE 19880	AMANTADINE HYDROCHLORIDE 50MG/5ML (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			WARNINGS; PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)
18-101	SYMMETREL	DUPONT	AMANTADINE HYDROCHLORIDE
04-19-93	(TABLET)	WILMINGTON, DE	100MG*
	19880		(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			CONTRAINDICATIONS;
			WARNINGS; PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)

* - Not Marketed at Present Time

18-701	HALDOL DECANOATE 50	JOHNSON RW	HALOPERIDOL DECANOATE
04-21-93	(INJECTABLE)	RARITAN, NJ	EQ 50MG BASE/ML
	08869		(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS;
			OVERDOSAGE)
18-057	PLATINOL	BRISTOL MYERS	CISPLATIN
04-22-93	(INJECTABLE)	EVANSVILLE, IN	10MG/VIAL
	47721		50MG/VIAL
			(REVISED LABELING --
			INDICATIONS;
			DOSAGE AND ADMINISTRATION)
18-057	PLATINOL-AQ	BRISTOL MYERS	CISPLATIN
04-22-93	(INJECTABLE)	EVANSVILLE, IN	1MG/ML
	47721		(REVISED LABELING --
			INDICATIONS;
			DOSAGE AND ADMINISTRATION)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-603 04-22-93	ZOVIRAX (INJECTABLE)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709 (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	ACYCLOVIR SODIUM EQ 500MG BASE/VIAL
18-828 04-22-93	ZOVIRAX (CAPSULE)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709 (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	ACYCLOVIR 200MG
19-909 04-22-93	ZOVIRAX (SUSPENSION)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709 (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	ACYCLOVIR 200MG/5ML
20-089 04-22-93	ZOVIRAX (TABLET)	BURROUGHS WELLCOME RES TRIANGLE PK, NC	ACYCLOVIR 400MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		27709	800MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
50-484	CERUBIDINE	WYETH AYERST	DAUNORUBICIN HYDROCHLORIDE
04-22-93	(INJECTABLE)	RADNOR, PA	EQ 20MG BASE/VIAL
		19087	(REVISED LABELING -- WARNINGS)
17-450	MONISTAT 7	ADVANCED CARE	MICONAZOLE NITRATE
04-26-93	(CREAM)	RARITAN, NJ	2%
		08869	(REVISED LABELING -- PATIENT LABELING) (OTC)
18-052	GYNE-LOTRIMIN	SCHERING	CLOTRIMAZOLE
04-26-93	(CREAM)	KENILWORTH, NJ	1%
		07033	(REVISED LABELING -- PATIENT LABELING) (OTC)
18-701	HALDOL DECANOATE 50	JOHNSON RW	HALOPERIDOL DECANOATE
04-27-93	(INJECTABLE)	RARITAN, NJ	EQ 50MG BASE/ML
		08869	(REVISED LABELING -- 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

19-757	CHIBROXIN	MERCK	NORFLOXACIN
04-27-93	(SOLUTION/DROPS)	WEST POINT, PA	0.3%
	19486	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE)	
12-122	GLUCAGON	LILLY	GLUCAGON HYDROCHLORIDE
04-28-93	(INJECTABLE)	INDIANAPOLIS, IN	EQ 1MG BASE/VIAL
	46285	EQ 10MG BASE/VIAL (REVISED LABELING -- DOSAGE AND ADMINISTRATION; PATIENT PACKAGE INSERT)	
16-927	DEMULEN 1/50-21	SEARLE	ETHINYL ESTRADIOL
04-28-93	(TABLET)	SAN JUAN, PR	0.05MG
	00936	ETHYNODIOL DIACETATE 1MG (REVISED LABELING -- PATIENT PACKAGE INSERT)	
16-936	DEMULEN 1/50-28	SEARLE	ETHINYL ESTRADIOL
04-28-93	(TABLET)	SAN JUAN, PR	0.05MG
	00936	ETHYNODIOL DIACETATE 1MG (REVISED LABELING -- PATIENT PACKAGE INSERT)	
18-160	DEMULEN 1/35-28	SEARLE	ETHINYL ESTRADIOL
04-28-93	(TABLET)	SAN JUAN, PR	0.035MG
	00936	ETHYNODIOL DIACETATE 1MG (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

18-168	DEMULEN 1/35-21	SEARLE	ETHINYL ESTRADIOL
04-28-93	(TABLET)	SAN JUAN, PR	0.035MG
		00936	ETHYNODIOL DIACETATE
			1MG
			(REVISED LABELING --
			PATIENT PACKAGE INSERT)
20-007	ZOFRAN	GLAXO	ONDANSETRON HYDROCHLORIDE
04-28-93	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 2MG BASE/ML
		27709	(REVISED LABELING --
			ADVERSE REACTIONS)
20-027	CARDIZEM	MARION MERRELL DOW	DILTIAZEM HYDROCHLORIDE
04-28-93	(INJECTABLE)	KANSAS CITY, MO	5MG/ML
		64134	(REVISED LABELING --
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)
20-062	CARDIZEM CD	MARION MERRELL DOW	DILTIAZEM HYDROCHLORIDE
04-28-93	(CAPSULE,	KANSAS CITY, MO	120MG
	EXTENDED RELEASE)	64134	180MG
			240MG
			300MG
			(REVISED LABELING --
			PRECAUTIONS)
13-553	ESIMIL	CIBA	GUANETHIDINE MONOSULFATE
04-29-93	(TABLET)	SUMMIT, NJ	10MG
		07901	HYDROCHLOROTHIAZIDE
			25MG
			(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)
18-240	TENORMIN	ICI	ATENOLOL
04-29-93	(TABLET)	WILMINGTON, DE	25MG
		19897	50MG
			100MG
			(REVISED LABELING --
			WARNINGS; PRECAUTIONS)
18-538	LOZOL	RHONE POULENC RORER	INDAPAMIDE
04-29-93	(TABLET)	FORT WASHINGTON, PA	1.25MG
		19034	2.5MG
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			WARNINGS; PRECAUTIONS;
			DRUG INTERACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
18-760	TENORETIC 50	ICI	ATENOLOL
04-29-93	(TABLET)	WILMINGTON, DE	50MG
		19897	CHLORTHALIDONE
			25MG
			(REVISED LABELING --
			WARNINGS; PRECAUTIONS)
18-760	TENORETIC 100	ICI	ATENOLOL
04-29-93	(TABLET)	WILMINGTON, DE	100MG
		19897	CHLORTHALIDONE
			25MG
			(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

19-058	TENORMIN	ICI	ATENOLOL
04-29-93	(INJECTABLE)	WILMINGTON, DE	0.5MG/ML
	19897	(REVISED LABELING -- WARNINGS; PRECAUTIONS)	
19-190	TRIPHASIL-28	WYETH AYERST	ETHINYL ESTRADIOL
04-29-93	(TABLET)	PHILADELPHIA, PA	0.03MG,0.04MG,0.03MG
	19101	LEVONORGESTREL 0.05MG,0.075MG,0.125MG (REVISED LABELING -- INDICATIONS AND USAGE; PATIENT PACKAGE INSERT)	
19-192	TRIPHASIL-21	WYETH AYERST	ETHINYL ESTRADIOL
04-29-93	(TABLET)	PHILADELPHIA, PA	0.03MG,0.04MG,0.03MG
	19101	LEVONORGESTREL 0.05MG,0.075MG,0.125MG (REVISED LABELING -- INDICATIONS AND USAGE; PATIENT PACKAGE INSERT)	
19-668	CARDURA	PFIZER	DOXAZOSIN MESYLATE
04-29-93	(TABLET)	NEW YORK, NY	EQ 1MG BASE
	10017	EQ 2MG BASE EQ 4MG BASE EQ 8MG BASE (REVISED LABELING -- CLINICAL PHARMACOLOGY; PRECAUTIONS)	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-777	ZESTRIL	ZENECA	LISINOPRIL
04-29-93	(TABLET)	WILMINGTON, DE 19897	2.5MG 5MG 10MG 20MG 40MG (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
50-578	FORTAZ	GLAXO	CEFTAZIDIME
04-29-93	(INJECTABLE)	RES TRIANGLE PK, NC 27709	500MG/VIAL 1GM/VIAL 2GM/VIAL 6GM/VIAL (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
17-533	KLONOPIN	ROCHE	CLONAZEPAM
04-30-93	(TABLET)	NUTLEY, NJ 07100	0.5MG 1MG 2MG (REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DRUG ABUSE AND DEPENDENCE; HOW SUPPLIED)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1165 04-01-93	NONE (INJECTABLE)	SOUTHERN BLOOD SRVCS BIRMINGHAM, AL 35205	PLASMA (TRANSFUSION) (B)
1165 04-01-93	NONE (INJECTABLE)	SOUTHERN BLOOD SRVCS BIRMINGHAM, AL 35205	PLATELETS (TRANSFUSION) (B)
1165 04-01-93	NONE (INJECTABLE)	SOUTHERN BLOOD SRVCS BIRMINGHAM, AL 35205	RED BLOOD CELLS (TRANSFUSION) (B)
1165 04-01-93	NONE (INJECTABLE)	SOUTHERN BLOOD SRVCS BIRMINGHAM, AL 35205	WHOLE BLOOD (TRANSFUSION) (A&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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK920035	RAD-SURE	INTL SPECIALTY PRODS	BLOOD IRRADIATION LABEL
04-01-93		WAYNE, NJ 07470	(C)
BP850001/25	AUTOPHERESIS-C	BAXTER HLTHCARE	AUTOMATED BLOOD SEPARATORS
04-06-93	PLASMAPHERESIS SYSTEM	ROUND LAKE, IL 60073	(C)
BK920036	COBE SPECTRA	COBE BCT	BLOOD COMPONENT
04-06-93	SINGLE NEEDLE EXTENDED LIFE PLATELET (ELP) SET	LAKEWOOD, CO 80215	SEPARATOR (C)
BK920027	PLASMA	MILES	EMPTY CONTAINERS FOR
04-13-93	POOLING BAG	BERKELEY, CA 94701	COLLECTION AND PROCESSING (C)

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

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

P910023 04/30/93	CADENCE TIERED THERAPY DEFIBRILLATOR SYSTEM	VENTRITEX, INC. SUNNYVALE, CA 94086	CADENCE TIERED THERAPY DEFIBRILLATOR SYSTEM FOR USE IN PATIENTS WITH HEMODYNAMICALLY COMPROMISING VENTRICULAR TACHYARRHYTHMIAS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

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

P780007/S38 04/12/93	HYDRON (POLYMACON) HYDROPHILIC CONTACT LENSES, OCULAR SCIENCES/AMERICAN HYDRON CAST MOLDED POLYMACON SOFT HYDROPHILIC LENSES	OSI CORPORATION SO. SAN FRANCISCO, CA 07746	ALTERNATE MANUFACTURING SITE
P790002/S13 04/12/93	EBI BI-OSTEOGEN BONE HEALING SYSTEM	ELECTRO-BIOLOGY, INC. PARSIPPANY, NJ 07054-1079	MODIFIED VERSION OF THE EBI BONE HEALING SYSTEM, MODEL 1020 TO BE DESIGNATED THE EBI BONE HEALING SYSTEM, MODEL 1026
P800002/S09 04/09/93	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT (MCH) NON-WOVEN WEB (NWW)	MEDCHEM PRODUCTS, INC. WOBURN, MA 01801	ALTERNATE BULK MANUFACTURING FACILITY
P800022/S38 04/12/93	ZYDERM AND ZYPLAST COLLAGEN IMPLANTS	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	REVISED LABELING
P810046/S137 04/28/93	SIMPSON-ROBERT CORONARY BALLOON	ADVANCED CARDIOVASCULAR SYSTEMS	ACS TEN (.010) CORONARY DILATATION

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	DILATATION CATHETER, ACS TEN (.010) CORONARY DILATATION CATHETER WITH 2.25 MM, 2.75 MM, 3.25 MM, AND 3.75 MM BALLOONS	SANTA CLARA, CA 95052-8167	CATHETER WITH 2.25 MM, 2.75 MM, 3.25 MM AND 3.75 MM BALLOONS	
P820018/S57	AUTIMA PACING SYSTEM, AUXILIARY INSTRUMENTS INTERFACE CABLE MODEL 042-034	TELECTRONICS, INC. ENGLEWOOD, CO 80112	APPROVAL FOR AUXILIARY INSTRUMENTS INTERFACE CABLE, MODEL 042-034	04/19/93
P820018/S59	AUTIMA PACING SYSTEM, PATIENT BOOKLET	TELECTRONICS, INC. ENGLEWOOD, CO 80112	NEW PATIENT BOOKLET	04/21/93
P820034/S03	REPRO-MED THD (TESTICULAR HYPOTHERMIA DEVICE)	REPRO-MED SYSTEMS, INC. MIDDLETOWN, NY 10940	RELOCATION OF THE SITE OF ALL MANUFACTURING OPERATIONS OF THE REPRO-MED THD	04/28/93
P820034/S04	REPRO-MED THD (TESTICULAR HYPOTHERMIA DEVICE)	REPRO-MED SYSTEMS, INC. MIDDLETOWN, NY 10940	SPECIFIC CHANGES IN MANUFACTURING, ASSEMBLY, DESIGN, MATERIALS AND OTHER CHANGES	04/29/93
P820056/S54	OPTACRYL 60 (KOLFOCON A) RIGID GAS PERMEABLE CONTACT LENSES	PARAGON OPTICAL MESA, AZ 85204	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	04/14/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P820063/S53	PARAPERM 02 (PASIFOCON A) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	04/14/93
P840001/S26	ITREL TOTALLY IMPLANTABLE SPINAL CORD STIMULATION SYSTEM, MEDTRONIC MODEL 7497 NEUROMED ADAPTER	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN 55440-9087	MEDTRONIC MODEL 7497 NEUROMED ADAPTER	04/05/93
P840024/S38	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MODIFICATION OF THE IMPLANTED RECEIVER ANTENNA COIL AND THE ADDITION OF A WARNING STATEMENT TO THE PACKAGE INSERT AND THE PATIENT IDENTIFICATION CARD	04/05/93
P840039/S35	MODEL P399UV POSTERIOR CHAMBER ULTRAVIOLET ABSORBING INTRAOCULAR LENS	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	MODEL P399UV POSTERIOR CHAMBER ULTRAVIOLET-ABSORBING INTRAOCULAR LENS	04/28/93
P840039/S38	POSTERIOR CHAMBER ULTRAVIOLET-ABSORBING	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	APPROVAL FOR MDR MEDICAL CORPORATION TO DISTRIBUTE THE	04/28/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	INTRAOCULAR LENSES: PRIVATE DISTRIBUTION REQUEST	STORZ MODEL 72NUV	ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS
P840040/S32 04/28/93	SLIDER ST/SUPER THIN CORONARY BALLOON DILATATION CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	SLIDER ST/SUPER THIN CORONARY BALLOON DILATATION CATHETER
P840050/S48 04/14/93	OCUSIL (NEFOCON A) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	OSI CORPORATION SO. SAN FRANCISCO, CA 94080	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P850038/S21 04/14/93	PARAPERM EW (PASIFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P850051/S37 04/21/93	MEDTRONIC MICRO MINIX MODEL 8360 AND LEGEND MODELS 8416, 8417, 8418, AND 8419 AND THE CPI TRIUMPH VR PULSE GENERATORS MODELS 1123, 1124, 1125, AND 1126	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFICATIONS TO THE TECHNICAL MANUALS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P850064/S09	LIFE PULSE HIGH FREQUENCY JET VENTILATOR	BUNNELL INCORPORATED SALT LAKE CITY, UT 84115	MANUFACTURING MODIFICATIONS	04/02/93
P850079/S24	HYDRASOFT (METHAFILCON A OR METHAFILCON B) HYDROPHILIC CONTACT LENSES	COASTVISION HUNTINGTON BEACH, CA 92648	REVISED LABELING	04/06/93
P860019/S59	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER, BIOSLIDE HYDROPHILIC COATING	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	MANUFACTURING MODIFICATIONS	04/28/93
P860019/S63	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER, ACE, LONG ACE AND GRAFT ACE	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	MANUFACTURING MODIFICATIONS	04/28/93
P860019/S64	SCIMED PERCUTANEOUS TRANSLUMINAL	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	USE OF THE HYPO-SEAL ACCESSORY ON ALL SCIMED'S PTCA	04/28/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CORONARY ANGIOPLASTY CATHETER, HYPO-SEAL ACCESSORY		CATHETERS WHICH HAVE 1.8F HYPOTUBE PROXIMAL SHAFTS
P870007/S06 04/14/93	STERILE PRESERVED SALINE SOLUTION	OPTOPICS LABORATORIES CORPORATION FAIRTON, NJ 08320-0210	APPROVAL FOR A 24-MONTH SHELF-LIFE FOR THE SOLUTION
P870024/S37 04/02/93	FLUOROPERM 92, 60, AND 30 (PAFLUFOCON A, B, AND C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	MANUFACTURING MODIFICATIONS
P870024/S38 04/14/93	FLUOROPERM 92, 60 AND 30 (PAFLUFOCON A, B, AND C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P870036/S19 04/28/93	MEDTRONIC 14K CORONARY DILATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	ADDITION OF ANOTHER BALLOON DIAMETER TO THE CURRENT BALLOON DIAMETERS
P870073/S07 04/28/93	POSTERIOR CHAMBER INTRAOCULAR LENSES: PRIVATE DISTRIBUTION REQUEST	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	APPROVAL FOR MDR MEDICAL CORPORATION TO DISTRIBUTE THE STORZ

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES

P880038/S22	META MV PACING SYSTEM, AUXILIARY INSTRUMENTS INTERFACE CABLE MODEL 042-034	TELECTRONICS, INC. ENGLEWOOD, CO 80112	APPROVAL FOR AUXILIARY INSTRUMENTS INTERFACE CABLE, MODEL 042-034	04/19/93
P880038/S24	META MV PACING SYSTEM PATIENT BOOKLET	TELECTRONICS, INC. ENGLEWOOD, CO 80112	NEW PATIENT BOOKLET	04/19/93
P890027/S09	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MODIFICATION OF THE IMPLANTED RECEIVER ANTENNA COIL AND ADDITION OF A WARNING STATEMENT TO THE PACKAGE INSERT AND PATIENT IDENTIFICATION CARD	04/05/93
P890039/S07	MAESTRO SAVVI MODEL 305 VDD PACING SYSTEM, MOLDED CABLE ASSEMBLY AND MODIFICATION OF THE MODEL 1401 DAA	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	MANUFACTURING MODIFICATIONS AND DISTRIBUTION OF SYSTEM COMPONENTS AS SEPARATELY PACKAGED ACCESSORIES	04/05/93
P840039/S39	POSTERIOR CHAMBER ULTRAVIOLET-ABSORBING	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	APPROVAL FOR WORLD OPTICS, INC. TO DISTRIBUTE THE STORZ	04/28/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	INTRAOCULAR LENSES: PRIVATE DISTRIBUTION REQUEST		MODEL 72NUV ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS
P890058/S11 04/06/93	NOVALENS (ROSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND BLUE TINTED)	OCUTEC CORPORATION MORRISVILLE, NC 27560	ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P900023/S02 04/08/93	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	INCLUSION OF A REMINDER SHEET IN THE BVS BLOOD PUMP PACKAGE
P900070/S03 04/19/93	META DDDR PACING SYSTEM, AUXILIARY INSTRUMENTS INTERFACE CABLE MODEL 042-034	TELECTRONICS, INC ENGLEWOOD, CO 80112	APPROVAL FOR AUXILIARY INSTRUMENTS INTERFACE CABLE, MODEL 024-034
P900070/S04 04/21/93	META DDDR PACING SYSTEM PATIENT BOOKLET	TELECTRONICS, INC. ENGLEWOOD, CO 80112	NEW PATIENT BOOKLET

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

ORIGINAL VETERINARY NADAs

200-070 04-02-93	ISOFLO (GAS/INHALATION)	DOGS HORSES	ABBOTT LABS N CHICAGO, IL 60064	ISOFLURANE 99.9%

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR APRIL 1993.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR APRIL 1993.

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
*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) 295-9012

Center for Veterinary Medicine
Melanie R. Berson, D.V.M.
(301) 295-8623

*To whom general inquiries should be directed.

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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

18-057 22-APR-93 (SUPPL)	PLATINOL (INJECTABLE)	BRISTOL MYERS EVANSVILLE, IN 47721	CISPLATIN 10MG/VIAL 50MG/VIAL (NEW DOSAGE REGIMEN -- USE IN COMBINATION WITH CYCLOPHOSPHAMIDE FOR METASTATIC OVARIAN TUMORS) [DELETE COMBINATION USE WITH DOXORUBICIN HYDROCHLORIDE FOR METASTATIC OVARIAN TUMORS]

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ORIGINAL AND SUPPLEMENTAL NDAs FOR NEW DRUG PRODUCTS			
18-057 22-APR-93 (SUPPL)	PLATINOL-AQ (INJECTABLE)	BRISTOL MYERS EVANSVILLE, IN 47721	CISPLATIN 1MG/ML (NEW DOSAGE REGIMEN -- USE IN COMBINATION WITH CYCLOPHOSPHAMIDE FOR METASTATIC OVARIAN TUMORS) [DELETE COMBINATION USE WITH DOXORUBICIN HYDROCHLORIDE FOR METASTATIC OVARIAN TUMORS]
19-855 05-MAY-93 (SUPPL)	ELIMITE (CREAM)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709	PERMETHRIN 5% (NEW DOSAGE REGIMEN -- ADDITION OF A RETREATMENT REGIMEN)
20-036 06-MAY-93 (SUPPL)	AREDIA (INJECTABLE)	CIBA GEIGY SUMMMIT, NJ 07901	PAMIDRONATE DISODIUM 60MG/VIAL 90MG/VIAL (NEW STRENGTH)
20-049 10-MAY-93 (3 P)	PENTASA (CAPSULE, EXTENDED RELEASE)	MARION MERRELL DOW KANSAS CITY, MO 64134	MESALAMINE 250MG (NONSTEROIDAL ANTI-INFLAMMATORY) [ULCERATIVE COLITIS]
17-783 11-MAY-93 (SUPPL)	GLUCOTROL (TABLET)	PFIZER NEW YORK, NY 10017	GLIPIZIDE 2.5MG (NEW STRENGTH)

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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

19-032 11-MAY-93 (SUPPL)	TENEX (TABLET)	ROBINS PHILADELPHIA, PA 19101	GUANFACINE HYDROCHLORIDE 1MG 2MG (NEW INDICATION -- USE AS MONOTHERAPY IN HYPERTENSION)
19-660 18-MAY-93 (SUPPL)	TILADE (AEROSOL, METERED)	FISONS ROCHESTER, NY 14603	NEDOCROMIL SODIUM 1.75MG/INH (COMPARATIVE EFFICACY CLAIM -- PRESENTLY AVAILABLE DATA ON THE RELATIVE EFFICACY OF TILADE AND CROMOLYN SODIUM ARE INCONCLUSIVE)
19-531 28-MAY-93 (5 S)	NUTRILIPID 10% (INJECTABLE)	MCGAW IRVINE, CA 92713	SOYBEAN OIL 10% (CALORIC SUPPLEMENT)
19-531 28-MAY-93 (5 S)	NUTRILIPID 20% (INJECTABLE)	MCGAW IRVINE, CA 92713	SOYBEAN OIL 20% (CALORIC SUPPLEMENT)
50-585 28-MAY-93 (SUPPL)	ROCEPHIN (INJECTABLE)	ROCHE NUTLEY, NJ 07110	CEFTRIAXONE SODIUM EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (NEW DOSAGE REGIMEN -- ONCE DAILY USE IN THE TREATMENT OF MENINGITIS IN PEDIATRIC PATIENTS AT A DOSE OF 100MG/KG/DAY)

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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

50-674 28-MAY-93 (SUPPL)	VANTIN (TABLET)	UPJOHN KALAMAZOO, MI 49001	CEFPODOXIME PROXETIL EQ 100MG BASE EQ 200MG BASE (NEW INDICATION -- ACUTE BACTERIAL EXACERBATION OF CHRONIC BRONCHITIS)

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.

20-215 05-MAY-93	MONOKET (TABLET)	SCHWARZ PHARMA MILWAUKEE, WI 53201	ISOSORBIDE MONONITRATE 10MG 20MG (VASODILATOR)
20-070 10-MAY-93	COGNEX (CAPSULE)	PARKE DAVIS ANN ARBOR, MI 48105	TACRINE HYDROCHLORIDE EQ 10MG BASE EQ 20MG BASE EQ 30MG BASE EQ 40MG BASE (ENZYME INHIBITOR) [TREATMENT OF MILD TO MODERATE DEMENTIA OF THE ALZHEIMER'S TYPE]

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ORIGINAL ABBREVIATED NDAs			
71-446 21-MAY-93	TEMAZEPAM (CAPSULE)	DANBURY DANBURY, CT 06810	TEMAZEPAM 15MG (SEDATIVES AND HYPNOTICS)
71-447 21-MAY-93	TEMAZEPAM (CAPSULE)	DANBURY DANBURY, CT 06810	TEMAZEPAM 30MG (SEDATIVES AND HYPNOTICS)
73-393 27-MAY-93	TOLMETIN SODIUM (CAPSULE)	MYLAN MORGANTOWN, WV 26505	TOLMETIN SODIUM EQ 400MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
73-630* 27-MAY-93	SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE (SOLUTION/DROPS)	STERIS PHOENIX, AZ 85043	PREDNISOLONE SODIUM PHOSPHATE EQ O.23% PHOSPHATE SULFACETAMIDE SODIUM 10% (CORTICOSTEROID/ ANTI-INFECTIVE)
73-062 28-MAY-93	LOPERAMIDE HCL (SOLUTION)	WATSON LABS CORONA, CA 91720	LOPERAMIDE HYDROCHLORIDE 1MG/5ML (ANTIDIARRHEAL) (OTC)
73-315 28-MAY-93	ATENOLOL (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	ATENOLOL 50MG (BETA BLOCKERS)

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ORIGINAL ABBREVIATED NDAs

73-316 28-MAY-93	ATENOLOL (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	ATENOLOL 100MG (BETA BLOCKERS)

* - First Time Product Available Generically

73-495 28-MAY-93	ALBUTEROL SULFATE (SOLUTION/ INHALATION)	COPLEY PHARM CANTON, MA 02021	ALBUTEROL SULFATE EQ 0.083% BASE (BRONCHODILATOR)
73-497 28-MAY-93	EVALOSE (SOLUTION)	COPLEY PHARM CANTON, MA 02021	LACTULOSE 10GM/15ML (LAXATIVE/AMMONIA DETOXICANT)
73-504 28-MAY-93	HEPTALAC (SOLUTION)	COPLEY PHARM CANTON, MA 02021	LACTULOSE 10GM/15ML (LAXATIVE/AMMONIA DETOXICANT)
73-685 28-MAY-93	ACILAC (SOLUTION)	TECHNILAB SAINT LAURENT, QUEBEC CANADA	LACTULOSE 10GM/15ML (LAXATIVE/AMMONIA DETOXICANT)

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ORIGINAL ABBREVIATED NDAs			
73-686 28-MAY-93	LAXILOSE (SOLUTION)	TECHNILAB SAINT LAURENT, QUEBEC CANADA	LACTULOSE 10GM/15ML (LAXATIVE/AMMONIA DETOXICANT)
81-203 28-MAY-93	HYDROCORTISONE (OINTMENT)	FOUGERA MELVILLE, NY 11747	HYDROCORTISONE 2.5% (STEROIDAL SKIN PRODUCTS)

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

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

74-199 27-MAY-93	ALPRAZOLAM (TABLET)	ROXANE COLUMBUS, OH 43216	ALPRAZOLAM 0.25MG 0.5MG 1MG (ANXIOLYTIC)
74-201 27-MAY-93	NAPROXEN (TABLET)	LEMMON SELLERSVILLE, PA 18960	NAPROXEN 250MG 375MG 500MG (NONSTEROIDAL ANTI-INFLAMMATORY)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
18-859 01-APR-93	VIRAZOLE (INHALATION)	ICN COSA MESA, CA 92626	RIBAVIRIN 6GM/VIAL (REVISED LABELING -- DESCRIPTION; OVERDOSAGE)
19-855 05-MAY-93	ELIMITE (CREAM)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709	PERMETHRIN 5% (REVISED LABELING -- DESCRIPTION; INDICATION AND USAGE; DOSAGE AND ADMINISTRATION)
19-402 06-MAY-93	HISMANAL (TABLET)	JANSSEN PISCATAWAY, NJ 08854	ASTEMIZOLE 10MG (REVISED LABELING -- CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)

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LABELING SUPPLEMENTS TO ORIGINAL NDAs			
11-909* 07-MAY-93	NARDIL (TABLET)	PARKE DAVIS MORRIS PLAINS, NJ 07950	PHENELZINE SULFATE EQ 15MG BASE (REVISED LABELING -- DESCRIPTION; CONTRAINDICATIONS; WARNINGS; ADVERSE REACTIONS; OVERDOSAGE; HOW SUPPLIED)
14-684 10-MAY-93	AVENTYL HCL (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE EQ 25MG BASE (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
* - Permitted			
14-685 10-MAY-93	AVENTYL HCL (SOLUTION)	LILLY INDIANAPOLIS, IN 46285	NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE/5ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
17-968 10-MAY-93	DEPO-TESTADIOL (INJECTABLE)	UPJOHN KALAMAZOO, MI 49001	ESTRADIOL CYPIONATE 2MG/ML TESTOSTERONE CYPIONATE 50MG/ML (REVISED LABELING -- CONTRAINDICATIONS; PRECAUTIONS)

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LABELING SUPPLEMENTS TO ORIGINAL NDAs			
17-783 11-MAY-93	GLUCOTROL (TABLET)	PFIZER NEW YORK, NY 10017	GLIPIZIDE 2.5MG 5MG 10MG (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
19-032 11-MAY-93	TENEX (TABLET)	WYETH AYERST PHILADELPHIA, PA 19101	GUANFACINE HYDROCHLORIDE 1MG 2MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
18-938 12-MAY-93	DDAVP (INJECTABLE)	RHONE POULENC RORER FORT WASHINGTON, PA 19034	DESMOPRESSIN ACETATE 0.004MG/ML (REVISED LABELING -- WARNINGS; PRECAUTIONS)
19-508 13-MAY-93	AXID (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	NIZATIDINE 150MG 300MG (REVISED LABELING -- ADVERSE REACTIONS)

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LABELING SUPPLEMENTS TO ORIGINAL NDAs			
18-057 17-MAY-93	PLATINOL (INJECTABLE)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	CISPLATIN 10MG/VIAL 50MG/VIAL (REVISED LABELING -- PRECAUTIONS)
18-057 17-MAY-93	PLATINOL AQ (INJECTABLE)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	CISPLATIN 1MG/ML (REVISED LABELING -- PRECAUTIONS)
08-693 18-MAY-93	FURADANTIN (TABLET)	P AND G NORWICH, NY 13815	NITROFURANTOIN 50MG 100MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
09-175 18-MAY-93	FURADANTIN (SUSPENSION)	P AND G NORWICH, NY 13815	NITROFURANTOIN 25MG/5ML (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-660 18-MAY-93	TILADE (AEROSOL, METERED)	FISONS ROCHESTER, NY 14603	NEDOCROMIL SODIUM 1.75MG/INH (REVISED LABELING -- CLINICAL STUDIES; DOSAGE AND ADMINISTRATION;

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LABELING SUPPLEMENTS TO ORIGINAL NDAs

HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
50-611 18-MAY-93	PCE (TABLET, COATED PARTICLES)	ABBOTT LABS ABBOTT PARK, IL 60064	ERYTHROMYCIN 333MG 500MG (REVISED LABELING -- DESCRIPTION; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS)
16-620 18-MAY-93	MACRODANTIN (CAPSULE)	P AND G NORWICH, NY 13815	NITROFURANTOIN, MACROCRYSTALLINE 25MG 50MG 100MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
17-783 19-MAY-93	GLUCOTROL (TABLET)	PFIZER NEW YORK, NY 10017	GLIPIZIDE 2.5MG 5MG 10MG (REVISED LABELING -- PRECAUTIONS)
18-182 24-MAY-93	MYCELEX G (TABLET)	MILES WEST HAVEN, CT 06516	CLOTRIMAZOLE 100MG (REVISED LABELING -- USAGE IN PREGNANCY)
50-589 24-MAY-93	CEFIZOX IN DEXTROSE 5% IN	FUJISAWA PHARM BALA CYNWYD, PA	CEFTIZOXIME SODIUM EQ 20MG BASE/ML

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	LABELING SUPPLEMENTS TO ORIGINAL NDAs		
	PLASTIC CONTAINER (INJECTABLE)	19004	EQ 40MG BASE/ML (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; DOSAGE AND ADMINISTRATION)
18-716 27-MAY-93	TRANDATE (TABLET)	GLAXO RES TRIANGLE PK, NC 27709	LABETALOL HYDROCHLORIDE 100MG 200MG 300MG (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
19-425 27-MAY-93	TRANDATE (INJECTABLE)	GLAXO RES TRIANGLE PK, NC 27709	LABETALOL HYDROCHLORIDE 5MG/ML (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS)
19-651 27-MAY-93	ASACOL (TABLET, DELAYED RELEASE)	P AND G NORWICH, NY 13815	MESALAMINE 400MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)

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LABELING SUPPLEMENTS TO ORIGINAL NDAs			
17-016 28-MAY-93	CHORIONIC GONADOTROPIN (INJECTABLE)	STERIS PHOENIX, AZ 85063	GONADOTROPIN, CHORIONIC 2,000 UNITS/VIAL 5,000 UNITS/VIAL 10,000 UNITS/VIAL 15,000 UNITS/VIAL 20,000 UNITS/VIAL (REVISED LABELING -- PRECAUTIONS)
50-521 28-MAY-93	CECLOR (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	CEFACLOR EQ 250MG BASE EQ 500MG BASE (REVISED LABELING -- ADVERSE REACTIONS)

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LABELING SUPPLEMENTS TO ORIGINAL NDAs			
50-522 28-MAY-93	CECLOR (POWDER FOR RECONSTITUTION)	LILLY INDIANAPOLIS, IN 46285	CEFACLOR EQ 125MG BASE/5ML EQ 250MG BASE/5ML (REVISED LABELING -- ADVERSE REACTIONS)
50-585 28-MAY-93	ROCEPHIN (INJECTABLE)	ROCHE NUTLEY, NJ 07110	CEFTRIAXONE SODIUM EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
50-674 28-MAY-93	VANTIN (TABLET)	UPJOHN KALAMAZOO, MI 49001	CEFPODOXIME PROXETIL EQ 100MG BASE EQ 200MG BASE (REVISED LABELING -- INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

THERE ARE NO BIOLOGICAL PRODUCT LICENSES ISSUED FOR MAY 1993.

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK920015 05-20-93	VIROCHEQC 1	N AM BIOL MIAMI, FL 33169 (C)	QUALITY CONTROL KITS FOR BLOOD BANKING REAGENTS
BK920040 05-20-93	VENOJECT II	TERUMO MED ELKTON, MD 21921 (C)	BLOOD BANK SUPPLY (HOLDER)

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

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

P900039/ 05/28/93	COLLAGRAFT BONE GRAFT MATRIX	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	COLLAGRAFT BONE GRAFT MATRIX FOR USE IN ACUTE LONG BONE FRACTURES AND TRAUMATIC OSSEOUS DEFECTS TO PROVIDE A MATRIX FOR THE REPAIR PROCESS OF BONE
P900056/ 05/28/93	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM	HEART TECHNOLOGY, INC. BELLEVUE, WA 98005	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM FOR USE IN PATIENTS WITH CORONARY ARTERY DISEASE
P910019/ 05/18/93	IVT CORONARY ATHERECTOMY SYSTEM (TEC)	INTERVENTIONAL TECHNOLOGIES, INC. SAN DIEGO, CA 92123	APPROVAL FOR THE IVT CORONARY ATHERECTOMY SYSTEM (TEC)
P910030/ 05/28/93	GIANTURCO-ROUBIN FLEX-STENT CORONARY STENT	COOK, INC. BLOOMINGTON, IN 47402	TO BE USED FOR CHRONIC PLACEMENT IN A CORONARY ARTERY OR GRAFT TO OBTAIN VESSEL PATENCY IN THE TREATMENT OF ACUTE OR THREATENED CLOSURE
P910064/ 05/07/93	REALITY FEMALE CONDOM	WISCONSIN PHARMACAL COMPANY, INC. CHICAGO, IL 60611	REALITY FEMALE CONDOM FOR USE IN PREVENTION OF PREGNANCY AND SEXUALLY TRANSMITTED DISEASES

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

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

N18073/S23 05/18/93	SOFT MATE DAILY CLEANER FOR SENSITIVE EYES AND SOFT MATE HANDS OFF DAILY CLEANER	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SITE
N18078/S48 05/18/93	SOFT MATE SALINE SOLUTION FOR SENSITIVE EYES	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SITE
P780013/S07 05/19/93	GBF V/X ASPHERIC (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENS	GBF CONTACT LENSES, INC. VIRGINIA BEACH, VA 23452	TWO SITES TO DO ADDITIONAL MANUFACTURING PROCEDURES
P790017/S46 05/20/93	USCI SOLITAIRE RAPID EXCHANGE BALLOON DILATATION CATHETER WITH PRO/PEL COATING	C.R. BARD, INC. BILLERICA, MA 01821	NEW MODEL CATHETER
P790017/S47 05/20/93	USCI GRUNTZIG DILACA CORONARY ARTERY BALLOON DILATATION CATHETER, USCI XPRT BALLOON DILATATION CATHETER WITH PRO/PEL COATING	C.R. BARD, INC. BILLERICA, MA 01821	NEW MODEL CATHETER

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P800022/S42 05/13/93	ZYPLAST COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	ASSIST DEVICE AND ITS ASSOCIATED LABELING TO BE MADE AVAILABLE FOR USE WITH THE ZYPLAST COLLAGEN IMPLANT SYRINGE
P810006/S17 05/13/93	COLLASTAT MICROFIBRILLAR COLLAGEN, INSTAT MCH MICROFIBRILLAR COLLAGEN HEMOSTAT	VITAPHORE CORPORATION MENLO PARK, CA 94025	JOHNSON AND JOHNSON MEDICAL, INC. AS DISTRIBUTOR OF COLLASTAT MICROFIBRILLAR HEMOSTAT
P810039/S17 05/28/93	BAUSCH & LOMB SENSITIVE EYES DROPS	BAUSCH & LOMB ROCHESTER, NY 14692-0450	2 ML PROFESSIONAL SAMPLE SIZE IN A 7.5 ML LOW DENSITY POLYETHYLENE CONTAINER TO BE INCLUDED IN KITS DISTRIBUTED BY EYE CARE PRACTITIONERS
P810046/S138 05/04/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS RX PERFUSION CATHETER .30 MM BALLOON AND MODIFIED DISTAL JUNCTION	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	ADDITIONAL BALLOON LENGTH FOR THE ACS RX PERFUSION CATHETER AND MODIFICATION TO THE LUMEN JUNCTION UNDER THE BALLOON
P820053/S21 05/18/93	BARNES-HIND GAS PERMEABLE DAILY CLEANER	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SITE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P820060/S07 05/13/93	ABBOTT AFP-EIA	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	REVISED PACKAGE INSERT
P840004/S06 05/13/93	SATURN II (SYNERGICON A) CONTACT LENS	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	STABILITY TESTING PROTOCOL TO EXTEND THE EXPIRATION DATING
P840024/S35 05/20/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATIONS
P840024/S39 05/20/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MODIFICATION OF THE MAGNET OPTION LABELING AND DISTRIBUTION OF THE NEW MAGNET OPTION
P840029/S04 05/17/93	HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	100 CM LENGTH OF THE SIZES 6, 8, AND 10 MM DIAMETER STRAIGHT SIZES OF THE HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT
P840029/S05 05/11/93	HEMASHIELD WOVEN DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	ADDITION OF THE HEMASHIELD WOVEN DOUBLE VELOUR GRAFT TO THE HEMASHIELD PRODUCT LINE
P840029/S06 05/17/93	HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	12 X 6 MM BIFURCATED SIZE OF THE HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P840029/S07 05/17/93	HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	7 MM X 100 CM SIZE OF THE HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT
P840029/S08 05/11/93	HEMASHIELD WOVEN DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	MODIFICATION OF THE LENGTH OF THE BIFURCATED SIZES OF THE HEMASHIELD WOVEN DOUBLE VELOUR GRAFT
P840029/S09 05/11/93	HEMASHIELD WOVEN DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	ADDITIONAL PACKAGE FOR THE 60 CM LENGTHS OF THE HEMASHIELD WOVEN DOUBLE VELOUR GRAFT
P840029/S10 05/11/93	HEMASHIELD WOVEN DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	MODIFICATION OF THE ACCEPTABLE LIMITS FOR THE SHRINK TEMPERATURE
P840029/S11 05/17/93	HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	MODIFICATION OF THE ACCEPTABLE LIMITS FOR THE SHRINK TEMPERATURE FOR THE HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT
P840029/S14 05/17/93	HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	ALTERNATE METHOD (AIR POROSITY) TO MEASURE POROSITY OF THE HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT
P840029/S15 05/11/93	HEMASHIELD WOVEN DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	USE OF AN ALTERNATE METHOD TO MEASURE POROSITY

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P840055/S31 05/27/93	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	ADDITIONAL CONTACT LENS FINISHING LABORATORY AS AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P850051/S38 05/18/93	ACTIVITRAX PACING SYSTEM, INTEGRATED CIRCUIT REVISION ON MEDTRONIC LEGEND AND CPI TRIUMPH VR PULSE GENERATORS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	REVISIONS TO THE L74 INTEGRATED CIRCUIT IN THE LEGEND PULSE GENERATOR MODELS 8416-8418, AND THE CPI TRIUMPH VR PULSE GENERATOR MODELS 1123-1125
P860019/S60 05/04/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER, RALLY PTCA CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	NEW MODEL EXCHANGE CATHETER TO BE MARKETED UNDER THE TRADE NAME RALLY
P860019/S61 05/04/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER, TRAPPER EXCHANGE DEVICE	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	REVISED LABELING
P870002/S10 05/11/93	APPLIED BUFFERED STERILE SALINE SOLUTION (AEROSOL)	APPLIED LABORATORIES, INC. COLUMBUS, IN 47202-0448	15 FL. OZ. SIZE AEROSOL PEERLESS CONTAINER WITH AN ARMITAGE 203 LINER

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P870036/S20 05/04/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC 14K AND 18K PTCA CATHETERS	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	MANUFACTURING MODIFICATION
P880001/S38 05/11/93	FLUOREX 700 (FLUSILFOCON A), FLUOREX 500 (FLUSILFOCON B) AND FLUOREX 300 (FLUSILFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	G.T. LABORATORIES, INC. CHICAGO, IL 60602	THREE ALTERNATE MANUFACTURING AND DISTRIBUTING SITES
P880003/S07 05/04/93	HELIX PTCA DILATATION CATHETER, SLEUTH PTCA DILATATION CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	FINAL LABELING
P880009/S05 05/17/93	VIRAPAP HUMAN PAPILLOMAVIRUS DNA DETECTION KIT	DIGENE DIAGNOSTICS, INC. SILVER SPRING, MD 20904	CHANGE IN MANUFACTURING SITE
P880035/S02 05/19/93	VISTA OPTICS, OPTACRYL 18 (KOLFOCON A) AND VISTA OPTICS, OPTACRYL 32 (KOLFOCON B) RIGID GAS PERMEABLE CONTACT LENSES	VISTA OPTICS LIMITED BRADBURY, UK	ADDITION OF 17 FINISHING LABORATORIES AS ALTERNATE MANUFACTURERS AND DISTRIBUTORS

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P880078/S10 05/21/93	VH8500 HYPERTHERMIA TREATMENT SYSTEM	COOK INCORPORATED BLOOMINGTON, IN 47402	SOFTWARE REVISION
P880102/S02 05/05/93	LOMBART (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES, LL-38 (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES	LOMBART LENSES LTD. NORFOLK, VA 23507	ALTERNATE MANUFACTURING SITE
P890001/S05 05/04/93	LEOCOR PTCA CATHETER, MODEL 5S, LEOCOR PTCA CATHETER MODEL PICO-ST (COATED)	LEOCOR, INC. HOUSTON, TX 77058	ADDITION OF A SILICONE COATING TO THE LEOCOR PICOCATH PTCA CATHETER
P890001/S07 05/04/93	LEOCOR PTCA CATHETER, MODEL 5S, LEOCOR PTCA CATHETER CORFLO MODEL 7.5PT (COATED)	LEOCOR, INC. HOUSTON, TX 77058	ADDITION OF A SILICONE COATING TO THE LEOCOR PTCA CATHETER CORFLO MODEL 7.5PT
P890027/S06 05/20/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATIONS

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P890027/S10 05/20/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MODIFICATION OF THE MAGNET OPTION LABELING AND DISTRIBUTION OF THE NEW MAGNET OPTION
P890043/S17 05/04/93	SIMPSON CORONARY ATHEROCATH, SCA-LP AND SCA-EX DEVICES	DEVICES FOR VASCULAR INTERVENTION, INC. REDWOOD CITY, CA 94063	MANUFACTURING MODIFICATION
P890044/S26 05/27/93	TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	BENTEC INCORPORATED SACRAMENTO, CA 95834	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P890064/S01 05/17/93	VIRATYPE HUMAN PAPILLOMAVIRUS DNA TYPING KIT	DIGENE DIAGNOSTICS, INC. SILVER SPRING, MD 20904	CHANGE IN MANUFACTURING SITE
P890072/S08 05/27/93	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED WITH AN ULTRAVIOLET LIGHT ABSORBER)	PROGRESSIVE OPTICAL RESEARCH, LTD. ALBERTA, CANADA	THREE ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTING SITES

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P900001/S09 05/27/93	SGP 3 (UNIFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR, BLUE AND GREEN TINTED)	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NJ 07751	ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY AS AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE

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

ORIGINAL VETERINARY NADAs

140-958	EQUIPHEN	HORSES	LUITPOLD PHARM	PHENYLBUTAZONE
05-14-93	(PASTE)		SHIRLEY, NY	6GM/30GM
			11967	12GM/60GM

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR MAY 1993.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR MAY 1993.

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

FDA DRUG AND DEVICE PRODUCT APPROVALS

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

Center for Devices and Radiological Health
Mary Jo Robinson (301) 594-21

Center for Biologics Evaluation and Research
Joseph Wilczek (301) 594-2012

Center for Veterinary Medicin
Melanie R. Berson, D.V.M.
(301) 594-1643

*To whom general inquiries should be directed.

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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			
19-777 09-JUN-93 (SUPPL)	ZESTRIL (TABLET)	ZENECA WILMINGTON, DE 19897	LISINOPRIL 2.5MG 5MG 10MG 20MG 40MG (NEW INDICATION -- ADJUNCTIVE THERA MANAGEMENT OF HI
19-844 10-JUN-93 (5 S)	ISOLYTE H IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML MAGNESIUM CHLOR 30MG/100ML POTASSIUM CHLORI 97MG/100ML SODIUM ACETATE 220MG/100ML SODIUM CHLORIDE 140MG/100ML (NUTRITION/ELECTR REPLENISHER)

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

ORIGINAL VETERINARY NADAs

19-864 10-JUN-93 (5 S)	ISOLYTE R IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	CALCIUM CHLORIDE 37MG/100ML DEXTROSE 5GM/100ML MAGNESIUM CHLOR 31MG/100ML POTASSIUM CHLORI 120MG/100ML SODIUM ACETATE 330MG/100ML SODIUM CHLORIDE 88MG/100ML (NUTRITION/ELECTR REPLENISHER)
19-870 10-JUN-93 (5 S)	ISOLYTE M IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML POTASSIUM CHLORIDE 150MG/100ML POTASSIUM PHOSPHATE, DIBA 130MG/100ML SODIUM ACETATE 280MG/100ML SODIUM CHLORIDE 91MG/100ML (NUTRITION/ELECTROLYTE REPLENISHER)

NUMBER OVAL DATE SSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
	ORIGINAL AND SUPPLEMENTAL NDAs FOR NEW DRUG PRODUCTS		
19-873 10-JUN-93 (5 S)	ISOLYTE P IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 31MG/100ML POTASSIUM CHLORIDE 130MG/100ML POTASSIUM PHOSPHATE, DIBA 26MG/100ML SODIUM ACETATE 320MG/100ML (NUTRITION/ELECTROLYTE REPLENISHER)
18-155 11-JUN-93 (SUPPL)	OPTICROM (SOLUTION/DROPS)	FISONS ROCHESTER, NY 14603	CROMOLYN SODIUM 4% (REMOVAL OF INDICATION -- GIANT PAPILLARY CONJUNCTIVITIS)
19-558 14-JUN-93 (SUPPL)	PRINIVIL (TABLET)	MERCK WEST POINT, PA 19486	LISINOPRIL 5MG 10MG 20MG 40MG (NEW INDICATION -- ADJUNCTIVE THERAPY IN THE MANAGEMENT OF HEART FAIL
19-287 18-JUN-93 (3 S)	DIZAC (INJECTABLE)	KABI PHARMACIA CLAYTON, NC 27520	DIAZEPAM 5MG/ML (ANTI-ANXIETY AGENTS/ ANXIOLYTICS)
20-134 18-JUN-93 (1 P)	METASTRON (INJECTABLE)	MEDI PHYSICS ARLINGTON HEIGHTS, IL 60005	STRONTIUM CHLORIDE, SR-89 1MCI/ML (RADIOPHARMACEUTICALS) [RELIEF OF BONE PAIN IN PATIENTS WITH PAINFUL SKELETAL METASTASES]

NUMBER OVAL DATE SSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
*****ORIGINAL AND SUPPLEMENTAL NDAs*** FOR NEW DRUG PRODUCTS**			
20-215 30-JUN-93 (5 S)	MONOKET (TABLET)	SCHWARZ PHARMA MILWAUKEE, WI 53201	ISOSORBIDE MONONITRATE 10MG 20MG (VASODILATORS)
50-617 30-JUN-93 (SUPPL)	ERYGEL (GEL)	ALLERGAN IRVINE, CA 92713	ERYTHROMYCIN 2% (NEW DOSAGE REGIMEN -- ONCE OR TWICE DAILY APPLICATION)

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.

20-136 07-JUN-93	DEMADEX (TABLET)	BOEHRINGER MANNHEIM ROCKVILLE, MD 20850	TORSEMIDE 5MG 10MG 20MG 100MG (DIURETICS AND RENAL TUBULE INHIBITORS) [HYPERTENSION/EDEMA]
20-137 07-JUN-93	DEMADEX (INJECTABLE)	BOEHRINGER MANNHEIM ROCKVILLE, MD 20850	TORSEMIDE 10MG/ML (DIURETICS AND RENAL TUBULE INHIBITORS) [HYPERTENSION/EDEMA]
20-330 24-JUN-93	TIMOPTIC-XE (SOLUTION/DROPS)	MERCK WEST POINT, PA 19486	TIMOLOL MALEATE EQ 0.25% BASE EQ 0.5% BASE (BETA BLOCKERS)
19-746 30-JUN-93	CHLORPHENIRAMINE MALEATE (TABLET, EXTENDED RELEASE)	ALZA PALO ALTO, CA 94303	CHLORPHENIRAMINE MALEATE 16MG (ANTIHISTAMINE) (OTC)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
		ORIGINAL ABBREVIATED NDAS	
72-801 15-JUN-93	METOCLOPRAMIDE HCL (TABLET)	BIOCRAFT FAIR LAWN, NJ 07410	METOCLOPRAMIDE HYDROCHLOR EQ 5MG BASE (MOTILITY STIMULANTS)
74-116 15-JUN-93	PIROXICAM (CAPSULE)	MEPHA AG SWITZERLAND	PIROXICAM 10MG (NSAID)
74-118 15-JUN-93	PIROXICAM (CAPSULE)	MEPHA AG SWITZERLAND	PIROXICAM 20MG (NSAID)
72-648 16-JUN-93	TIMOLOL MALEATE (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	TIMOLOL MALEATE 5MG (BETA BLOCKERS)
72-649 16-JUN-93	TIMOLOL MALEATE (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	TIMOLOL MALEATE 10MG (BETA BLOCKERS)
72-650 16-JUN-93	TIMOLOL MALEATE (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	TIMOLOL MALEATE 20MG (BETA BLOCKERS)
73-038 22-JUN-93	SULINDAC (TABLET)	MYLAN MORGANTOWN, WV 26504	SULINDAC 150MG (NSAID)
73-039 22-JUN-93	SULINDAC (TABLET)	MYLAN MORGANTOWN, WV 26504	SULINDAC 200MG (NSAID)
71-402 25-JUN-93	METOCLOPRAMIDE HCL (SOLUTION)	LIQUIPHARM LOS ANGELES, CA 90034	METOCLOPRAMIDE HYDROCHLOR EQ 5MG BASE/5ML (MOTILITY STIMULANTS)
72-779 25-JUN-93	ALBUTEROL SULFATE (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	ALBUTEROL SULFATE EQ 2MG BASE (BETA-2 AGONIST)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
		ORIGINAL ABBREVIATED NDAS	
72-780 25-JUN-93	ALBUTEROL SULFATE (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	ALBUTEROL SULFATE EQ 4MG BASE (BETA-2 AGONIST)
74-028 28-JUN-93	AMANTADINE HCL (SYRUP)	MIKART ATLANTA, GA 30318	AMANTADINE HYDROCHLORIDE 50MG/5ML (ANTIVIRAL - ANTI-INFLUENZA)
72-923 29-JUN-93	VERAPAMIL HCL (TABLET)	WATSON LABS CORONA, CA 91720	VERAPAMIL HYDROCHLORIDE 40MG (CALCIUM CHANNEL BLOCKERS)
72-924 29-JUN-93	VERAPAMIL HCL (TABLET)	WATSON LABS CORONA, CA 91720	VERAPAMIL HYDROCHLORIDE 40MG (CALCIUM CHANNEL BLOCKERS)
73-484 29-JUN-93	VALPROIC ACID (CAPSULE)	PHARMACAPS ELIZABETH, NJ 07207	VALPROIC ACID 250MG (ANTICONVULSANTS)
40-001* 30-JUN-93	METHAZOLAMIDE (TABLET)	COPLEY PHARM CANTON, MA 02021	METHAZOLAMIDE 25MG 50MG (CARBONIC ANHYDRASE INHIBITO
40-036* 30-JUN-93	METHAZOLAMIDE (TABLET)	GENEVA BROOMFIELD, CO 80038	METHAZOLAMIDE 25MG 50MG (CARBONIC ANHYDRASE INHIBITO
71-315 30-JUN-93	METOCLOPRAMIDE HCL (SOLUTION)	LEMMON SELLERSVILLE, PA 18960	METOCLOPRAMIDE HYDROCHLOR EQ 5MG BASE/5ML (MOTILITY STIMULANTS)
81-295* 30-JUN-93	ESTRACE (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	ESTRADIOL 0.5MG (ESTROGENS)

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

ORIGINAL ABBREVIATED NDAS

* - First Time Product Available Generically

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

ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

A ***tentative approval*** indicates that FDA has given an abbreviated new drug application (ANDA) provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Generic drug products that are the subjects of tentative approvals ***may not be*** legally ***marketed*** until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the ANDA receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluation" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

74-198 22-JUN-93	NAPROXEN SODIUM (TABLET)	LEMMON SELLERSVILLE, PA 18960	NAPROXEN SODIUM 275MG 550MG (NSAID)
74-162 29-JUN-93	NAPROXEN SODIUM (TABLET)	GENEVA BROOMFIELD, CO 80038	NAPROXEN SODIUM 275MG 550MG (NSAID)
74-140 30-JUN-93	NAPROXEN (TABLET)	GENEVA BROOMFIELD, CO 80038	NAPROXEN 250MG 375MG 500MG (NSAID)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
20-036 06-MAY-93	AREDIA (INJECTABLE)	CIBA SUMMIT, NJ 07901	PAMIDRONATE DISODIUM 30MG/VIAL 60MG/VIAL 90MG/VIAL (LABELING REVISION -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
17-694 01-JUN-93	IMODIUM (CAPSULE)	JANSSEN PISCATAWAY, NJ 08854	LOPERAMIDE HYDROCHLORIDE 2MG (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; DRUG ABUSE AND DEPENDENCE)
18-760 04-JUN-93	TENORETIC 50 (TABLET)	ICI PHARMS WILMINGTON, DE 19897	ATENOLOL 50MG CHLORTHALIDONE 25MG (LABELING REVISION -- ADVERSE REACTIONS; POTENTIAL ADVERSE EFFECTS)
18-760 04-JUN-93	TENORETIC 100 (TABLET)	ICI PHARMS WILMINGTON, DE 19897	ATENOLOL 100MG CHLORTHALIDONE 25MG (LABELING REVISION -- ADVERSE REACTIONS; POTENTIAL ADVERSE EFFECTS)
17-831 07-JUN-93	DIDRONEL (TABLET)	P AND G NORWICH, NY 13815	ETIDRONATE DISODIUM 200MG 400MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
09-218 08-JUN-93	COUMADIN (TABLET)	DUPONT WILMINGTON, DE 19880	WARFARIN SODIUM 1MG 2MG 2.5MG 5MG 7.5MG 10MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; ADVERSE REACTIONS DOSAGE AND LABORATORY CONT
18-469 08-JUN-93	BSS PLUS (SOLUTION)	ALCON LABS FORT WORTH, TX 76134	CALCIUM CHLORIDE 0.154MG/ML 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 (LABELING REVISION -- WARNINGS; PRECAUTIONS; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
19-777 09-JUN-93	ZESTRIL (TABLET)	ZENECA PHARMS WILMINGTON, DE 19897	LISINOPRIL 2.5MG 5MG 10MG 20MG 40MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
20-036 09-JUN-93	AREDIA (INJECTABLE)	CIBA GEIGY SUMMIT, NJ 07901	PAMIDRONATE DISODIUM 30MG/VIAL 60MG/VIAL 90MG/VIAL (LABELING REVISION -- ADVERSE REACTIONS)
18-155 11-JUN-93	OPTICROM (SOLUTION/DROPS)	FISONS BEDFORD, MA 01730	CROMOLYN SODIUM 4% (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
19-558 14-JUN-93	PRINIVIL (TABLET)	MERCK WEST POINT, PA 19486	LISINOPRIL 5MG 10MG 20MG 40MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
50-420 18-JUN-93	RIFADIN (CAPSULE)	MERRELL DOW PHARMS CINCINNATI, OH 45215	RIFAMPIN 300MG (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; ADVERSE REACTIONS)
50-504 18-JUN-93	MANDOL (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	CEFAMANDOLE NAFATE EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL (LABELING REVISION -- INDICATIONS AND USAGE)
50-627 18-JUN-93	RIFADIN (INJECTABLE)	MERRELL DOW PHARMS CINCINNATI, OH 45215	RIFAMPIN 600MG/VIAL (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; ADVERSE REACTIONS)
18-401 25-JUN-93	BUPRENEX (INJECTABLE)	RECKITT AND COLMAN RICHMOND, VA 23235	BUPRENORPHINE HYDROCHLORID EQ 0.3MG BASE/ML (LABELING REVISION -- PRECAUTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
18-484 26-JUN-93	PROSTIN VR PEDIATRIC (INJECTABLE)	UPJOHN KALAMAZOO, MI 49001	ALPROSTADIL 0.5MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
19-574 26-JUN-93	THALITONE (TABLET)	HORUS ROCHESTER, NY 14623	CHLORTHALIDONE 15MG (LABELING REVISION -- PRECAUTIONS; DOSAGE AND ADMINISTRATION)
50-614 28-JUN-93	KEFTAB (TABLET)	LILLY INDIANAPOLIS, IN 46285	CEPHALEXIN HYDROCHLORIDE EQ 250MG BASE EQ 500MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS)
19-384 29-JUN-93	NOROXIN (TABLET)	MERCK WEST POINT, PA 19486	NORFLOXACIN 400MG (LABELING REVISION -- ADVERSE REACTIONS)
50-606 30-JUN-93	VANCOCIN HCL (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	VANCOMYCIN HYDROCHLORIDE EQ 125MG/BASE EQ 250MG/BASE (LABELING REVISION -- ADVERSE REACTIONS)
50-617 30-JUN-93	ERYGEL (GEL)	ALLERGAN HERBERT IRVINE, CA 92713	ERYTHROMYCIN 2% (LABELING REVISION -- DOSAGE AND ADMINISTRATION)

LICENCE NUMBER LICENCE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT LICENCES ISSUED

0202 07-JUN-93	NONE (INJECTABLE)	TACOMA PIERCE CNTY BLOOD BANK TACOMA, WA 98405	CRYOPRECIPITATED AHF (TRANSFUSION) (B)
1106 22-JUN-93	CHIRON RIBA HCV 2.0 SIA (IN VITRO TEST)	CHIRON EMERYVILLE, CA 94608	HEPATITIS C VIRUS ENCODED ANTIGEN RECOMBINANT (RIBA) (QUALITATIVE STRIP IMMUNOBLOT ASSAY) (B)

LICENCE NUMBER LICENCE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT LICENCES ISSUED

(B) Product License Issued

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910032 07-JUN-93	OPTIPRESS	BAXTER HLTHCARE ROUND LAKE, IL 60073	BLOOD BANK SUPPLIES (C)
BK920022 07-JUN-93	RCM-MB-30 PLASMA STORAGE BAG	STERICON BROADVIEW, IL 60153	TRANSFER SETS (C)
BK920024 07-JUN-93	MUREX PEG POTENTIATOR FOR ANTIBODY DETECTION	MUREX BIOLGS CONROE, TX 77305	POTENTIATING MEDIA FOR IN VITRO DIAGNOSTIC USE (C)
BK920028 07-JUN-93	VIROTROL HIV-2	BLACKHAWK BIOSYSTEMS SAN RAMON, CA 94583	QUALITY CONTROL KITS FOR BLOOD BANKING REAGENTS (C)
BK920032 07-JUN-93	SEPACELL PRE-STORAGE LEUKOCYTE DEPLETION SET FOR RED CELL	BAXTER HLTHCARE ROUND LAKE, IL 60073	EMPTY CONTAINERS FOR COLLECTIVE PROCESSING OF BLOOD AND BLOOD COMPONENTS (C)

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPLICATION NO. 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 JUNE 1993.****

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

N17003/S04 06/08/93	SURGICAL SIMPLEX P BONE CEMENT	HOWMEDICA, INC. RUTHERFORD, NJ 07070-2584	ALTERNATE FACILITY TO MANUFACTURE THE POWDER COMPONENT OF THE SURGICAL SIMPLEX P BONE CEMENT
N17987/S24 06/22/93	CSI COLOURS (CROFILCON A) CONTACT LENS	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	STABILITY TESTING PROTOCOL TO EXTEND THE EXPIRATION DATING THE CSI COLOURS (CROFILCON A) CONTACT LENS
N18020/S38 06/29/93	ALLERGAN PRESERVED SALINE SOLUTION	ALLERGAN OPTICAL IRVINE, CA 92713-9534	MODIFIED SPECIFICATIONS FOR SODIUM CHLORIDE AND OSMOLAL FOR THE ALLERGAN PRESERVED SALINE SOLUTION
N50510/S52 06/24/93	VITEK SYSTEMS GENERAL SUSCEPTIBILITY CARD	BIOMERIEUX VITEK, INC. HAZELWOOD, MO 63042	ADDITION OF OFLOXACIN (1, 2, AND 8 MCG/ML) TO THE VITEK GRAM-POSITIVE ANTIMICROBIAL SUSCEPTIBILITY PANELS
P790002/S14 06/14/93	EBI BI-OSTEOGEN BONE HEALING SYSTEM	ELECTRO-BIOLOGY, INC. PARSIPPANY, NJ 07054-1079	MODIFIED VERSION OF THE EBI BO HEALING SYSTEM, MODEL 1020 TO DESIGNATED THE EBI BONE HEAL SYSTEM MODEL 123
P790017/S43 06/04/93	USCI GRUNTZIG DILACA CORONARY ARTERY BALLOON DILATATION CATHETER, USCI SPRINT BALLOON DILATATION CATHETER	C.R. BARD, INC. BILLERICA, MA 01821	TAPERED BALLOON CATHETER INDICATED FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY
P800036/S29 06/17/93	MODEL 400 IMPLANTABLE PUMP	INFUSAID INC. NORWOOD, MA 02062	RESUMPTION OF COMMERCIAL DISTRIBUTION OF THE MODEL 400 IMPLANTABLE PUMP WITH SEPTU MATERIAL P/N 36290

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS			
P820018/S58 06/18/93	AUTIMA MODEL 2251 PULSE GENERATOR AND MODEL 2600 PROGRAMMER, MODEL 9600 NETWORK PROGRAMMER SOFTWARE VERSION 4.50UE	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	APPROVAL FOR THE MODEL 9600 NETWORK PROGRAMMER SOFTW VERSION 4.5UE
P830045/S42 06/04/93	AFP MODEL 283 PULSE GENERATOR W/MODEL 370 PROGRAMMER, PARAGON MODELS 2010/2011, PARAGON II MODEL 2016, PHOENIX MODELS 2005/2008/2009	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	APPROVAL FOR AN ADDITIONAL QUARTZ CRYSTAL COMPONENT TEST
P830055/S23 06/08/93	POSTERIOR CRUCIATE RETAINING DEVICE, CONFIGURATION OF THE LCS TOTAL KNEE SYSTEM WITH POROCOAT	DEPUY INC. WARSAW, IN 46581-0988	CHANGE IN THE POST APPROVAL STUDY; REDUCTION FROM 350 TO OF THE NUMBER OF CASES ENTE THE STUDY
P830055/S25 06/04/93	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	CHANGE IN THE RADIUS OF THE SULCUS ANGLE OF THE FEMORAL COMPONENTS
P830055/S27 06/04/93	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	ADDITION OF TIBIAL TRAYS
P830055/S28 06/04/93	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	ADDITION OF TIBIAL TRAYS
P830055/S29 06/04/93	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	ADDITIONAL SUPPLIER OF LIDSTOCK PACKAGING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS			
P840062/S04 06/24/93	COLLACOTE, COLLATAPE, COLLAPLUG, ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	COLLA-TEC, INC. PLAINSBORO, NJ 08536	CHANGE OF DISTRIBUTOR
P850010/S14 06/08/93	HELISTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT AND HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENT--FIBRILLAR FORM	COLLA-TEC, INC. PLAINSBORO, NJ 08536	CALGON VESTAL LABORATORIES DISTRIBUTOR
P850088/S26 06/09/93	ULTRACARE NEUTRALIZING TABLETS	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ALTERNATE SITE FOR PLACING NEUTRALIZING TABLETS INTO "CHECKBOOKS" BEFORE FINAL ASSEMBLY INTO COMBINATION CARTONS
P860019/S56 06/15/93	SC SHADOW	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A "PATENTED TAP TECHNOLOGY" LABEL
P860019/S66 06/15/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, NC COBRA 14	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	NEW MODEL CATHETER
P860019/S67 06/14/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, ACE, QUANTUM, GRAFT ACE, EXPRESS, RALLY AND COBRA 10	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	REVISED LABELING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS			
P860027/S09 06/03/93	MAESTRO SERIES 500 PULSE GENERATOR, MODELS 501, 505, 509, MAESTRO MODEL 1006/1006P PROGRAMMER RELEASE III SOFTWARE	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	APPROVAL FOR THE MAESTRO MO 1006/1006P PROGRAMMER RELEAS SOFTWARE
P870024/S29 06/22/93	FLUOROPERM (PAFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS, FLUOROPERM ST BIFOCAL (PAFLUFOCON B) RIGID GAS PERMEABLE CONTACT LENS	PARAGON OPTICAL MESA, AZ 85204	MANUFACTURING MODIFICATIONS
P880003/S10 06/17/93	CORDIS PTCA DILATATION CATHETERS, CORDIS SLEEK PTCA DILATATION CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR CORDIS SLEEK PT DILATATION CATHETERS
P880003/S11 06/17/93	CORDIS PTCA DILATATION CATHETERS, OLYMPIX AND SLEUTH XT PTCA DILATATION CATHETERS (WITH 3 CM LONG BALLOONS)	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR A 3 CM LONG BAL
P880003/S12 06/17/93	CORDIS PTCA DILATATION CATHETERS, OLYMPIX AND SLEUTH XT PTCA DILATATION CATHETERS (WITH 4 CM LONG BALLOONS)	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR A 4 CM LONG BAL

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS			
P880038/S23 06/18/93	META-MV CARDIAC PACING SYSTEM, MODEL 9600 NETWORK PROGRAMMER SOFTWARE VERSION 4.50UE	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	APPROVAL FOR THE MODEL 9600 NETWORK PROGRAMMER SOFTW VERSION 4.50UE
P880086/S21 06/04/93	SYNCHRONY MODEL 2020T, SOLUS MODELS 2002/2003, SOLUS II MODELS 2006/2007, SYNCHRONY II MODELS 2022/2023, SYNCHRONY III MODELS 2028/2029 PULSE GENERATORS	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	APPROVAL FOR AN ADDITIONAL QUARTZ CRYSTAL COMPONENT T
P890003/S20 06/03/93	SYNERGYST II MODELS 7070 AND 7071, MODEL 9858A SOFTWARE DISKETTES FOR USE WITH THE MODEL 9760 PROGRAMMER SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MODEL 9858A SOFTWARE DISKETTES FOR USE W THE MODEL 9760 PROGRAMMER SYSTEM
P890032/S14 06/17/93	CORDIS ORION STEERABLE PTCA BALLOON CATHETER, CORDIS LIGHTNING STEERABLE PTCA BALLOON CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR THE ORION II STEERABLE PTCA BALLOON CATH
P890039/S08 06/24/93	MAESTRO II SAVVI MODEL 333 PACING SYSTEM	CARDIAC CONTROL SYSTEM, INC. PALM COAST, FL 32137	APPROVAL FOR THE MAESTRO II S MODEL 333 VDD PACING SYSTEM
P900032/S01 06/22/93	DYMER 200+ EXCIMER LASER SYSTEM, LAIS MODEL PC4010 MULTIFIBER LASER CATHETER	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA 92718	APPROVAL FOR THE MODEL PC40 (1.3MM) LASER CATHETER
P900032/S02 06/22/93	DYMER 200+ EXCIMER LASER SYSTEM, LAIS MODEL PC4021 MULTIFIBER LASER CATHETER	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA 92718	APPROVAL FOR THE MODEL PC40 (1.6MM) LASER CATHETER

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS			
P900050/S01 06/14/93	ACCESS MOBILITY SYSTEM	QUEST TECHNOLOGIES CORPORATION SUNNYVALE, CA 94086-9716	ADDITION OF THE ACCESS MOBILI SYSTEM ATTENDANT CONTROL
P900070/S01 06/29/93	META DDDR PACING SYSTEM MODELS 1250H AND 1254 WITH MODEL 9600 PROGRAMMER SOFTWARE VERSION 4.5	TELECTRONICS PACING SYSTEMS ENGLEWOOD, CO 80112	INTRODUCTION OF THE META DDDR MODEL 1254 PULSE GENERA AND A MODIFIED VERSION OF THE MODEL 1250H AND 9600 PROGRAMMER SOFTWARE VERSION 4.5
P910016/S02 06/08/93	NEW JERSEY UNICOMPARTMENTAL LCS KNEE	DEPUY WARSAW, IN 46580	ADDITION OF PAPER MANUFACTU COMPANY AS A SUPPLIER OF TYV LIDSTOCK PACKAGING
P910029/S01 06/29/93	BLANCHARD SOFT (POLYMACON) CONTACT LENS, ESSTECH PS ASPHERIC (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENS	LES LABORATORIES BLANCHARD QUEBEC, CANADA	APPROVAL TO MANUFACTURE AND DISTRIBUTE AN ALTERNATE DESIGN CONFIGURATION OF THE BLANCHARD SOFT LENS

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

ORIGINAL VETRINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR JUNE 1993.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR JUNE 1993.

SUPPLEMENTAL VETERINARY NADAs

065-269 29-JUN-93	POLYOTIC SOLUBLE (POWDER)	CALVES, SWINE	AM CYANAMID WAYNE, NJ 07470	TETRACYCLINE HYDROCHLORIDE 25GM/LB
065-441 29-JUN-93	POLYOTIC SOLUBLE CONCENTRATE (POWDER)	CALVES, SWINE	AM CYANAMID WAYNE, NJ 07470	TETRACYCLINE HYDROCHLORIDE 102.4GM/LB

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

ORIGINAL VETRINARY NADAs

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

ORIGINAL VETRINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

VOLUME 16 (07)
JULY 1993

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

Center for Devices and Radiological Health
Mary Jo Robinson (301) 594-21

Center for Biologics Evaluation and Research
Joseph Wilczek (301) 594-2012

Center for Veterinary Medicin
Norman Turner
(301) 594-1623

*To whom general inquiries should be directed.

This report is compiled by the Division of Drug Information Resources, OM, CDER.
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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

18-602 01-JUL-93 (SUPPL)	CARDIZEM (TABLET)	MARION MERRELL DOW KANSAS CITY, MO 64137	DILTIAZEM HYDROCHLORIDE 30MG 60MG 90MG 120MG (INDICATION CHANGE -- REMOVAL OF SECOND LINE RESTRICTIONS FOR USE IN ANGINA PATIENTS; REFERENCE TO STUDIES DELE

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		ORIGINAL VETRINARY NADAs	
20-315 09-JUL-93 (1 P, V*)	ORLAAM (CONCENTRATE)	BIOMETRIC RES ARLINGTON, VA 22209	LEVOMETHADYL ACETATE HYDROCHLORIDE 10MG/ML (OPIATE AGONIST) [MANAGEMENT OF OPIATE DEPENDENCE]
18-956 13-JUL-93 (SUPPL)	OMNIPAQUE 180 (INJECTABLE)	STERLING NEW YORK, NY 10016	IOHEXOL 38.8% (NEW ROUTE -- ORAL OR RECTAL USE IN CHILDREN FOR THE EXAMINAT OF THE GASTROINTESTINAL TR
18-956 13-JUL-93 (SUPPL)	OMNIPAQUE 240 (SOLUTION)	STERLING NEW YORK, NY 10016	IOHEXOL 51.8% (NEW ROUTE -- ORAL OR RECTAL USE IN CHILDREN FOR THE EXAMINAT OF THE GASTROINTESTINAL TR
V* - Designated Orphan Drug			
18-956 13-JUL-93 (SUPPL)	OMNIPAQUE 300 (SOLUTION)	STERLING NEW YORK, NY 10016	IOHEXOL 64.7% (NEW ROUTE -- ORAL OR RECTAL USE IN CHILDREN FOR THE EXAMINAT OF THE GASTROINTESTINAL TR
18-473 20-JUL-93 (SUPPL)	VENTOLIN (AEROSOL, METERED)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL 0.09MG/INH (NEW INDICATION -- PREVENTION OF EXERCISE - INDUCED BRONCHOSPASM IN CHILDREN AGES 4-11 YEARS)
19-489 20-JUL-93 (SUPPL)	VENTOLIN ROTACAPS (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL SULFATE EQ 0.2MG BASE (NEW INDICATION -- PREVENTION OF EXERCISE - INDUCED BRONCHOSPASM IN CHILDREN AGES 4-11 YEARS)
20-006 26-JUL-93 (5 S)	MANNITOL 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	MANNITOL 5GM/100ML (OSMOTIC DIURETICS)

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**		
20-006 26-JUL-93 (5 S)	MANNITOL 10% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	MANNITOL 10GM/100ML (OSMOTIC DIURETICS)
20-006 26-JUL-93 (5 S)	MANNITOL 15% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	MANNITOL 15GM/100ML (OSMOTIC DIURETICS)
20-006 26-JUL-93 (5 S)	MANNITOL 20% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	MANNITOL 20GM/100ML (OSMOTIC DIURETICS)
19-710 27-JUL-93 (SUPPL)	OPTIRAY 350 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	IOVERSOL 74% (NEW INDICATION -- PEDIATRIC ANGIOCARDIOGRA
20-189 29-JUL-93 (1 P, V*)	FELBATOL (SUSPENSION)	WALLACE LABS CRANBURY, NJ 08512	FELBAMATE 600MG/5ML (ANTICONVULSANTS)
20-189 29-JUL-93 (1 P, V*)	FELBATOL (TABLET)	WALLACE LABS CRANBURY, NJ 08512	FELBAMATE 400MG 600MG (ANTICONVULSANTS)
20-210 29-JUL-93 (1 S)	PROPULSID (TABLET)	JANSSEN PISCATAWAY, NJ 08855	CISAPRIDE MONOHYDRATE EQ 10MG BASE EQ 20MG BASE (UPPER GI TRACT MOTILITY STIMULATOR) [SYMPTOMATIC TREATMENT O PATIENTS WITH NOCTURNAL HEARTBURN DUE TO GERD]
19-921 30-JUL-93 (3 S)	OCUFLOX (SOLUTION, DROPS)	ALLERGAN IRVINE, CA 92713	OFLOXACIN 0.3% (OPHTHALMIC-QUINOLONE ANTIBACTERIALS)

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**			
20-258 30-JUL-93 (3 P)	IOPIDINE (SOLUTION, DROPS)	ALCON FORT WORTH, TX 76134	APRACLONIDINE HYDROCHLOI EQ O.5% BASE (ALPHA ADRENERGIC AGONIST [SHORT-TERM ADJUNCTIVE THERAPY FOR INTRA-OCULAR PRESSUR REDUCTION]
50-694 30-JUL-93 (5 S)	CEFOTAN IN PLASTIC CONTAINER (INJECTABLE)	ZENECA PHARMS WILMINGTON, DE 19897	CEFOTETAN DISODIUM EQ 20MG BASE/ML EQ 40MG BASE/ML (ANTIBIOTIC, CEPHALOSPORIN

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.

20-304 01-JUL-93	TRASYLOL (INJECTABLE)	MILES PHARM WEST HAVEN, CT 06516	APROTININ BOVINE 10,000 UNITS/ML (FIBRINOLYTICS/ ANTIFIBRINOLYTICS)
20-225 15-JUL-93	IMDUR (EXTENDED RELEASE, TABLET)	SCHERING KENILWORTH, NJ 07033	ISOSORBIDE MONONITRATE 30MG 60MG (VASODILATOR)
50-657 26-JUL-93	MINOCYCLINE HCL (CAPSULE, COATED PELLETS)	FAULDING SALISBURY SOUTH AUSTRALIA	MINOCYCLINE HYDROCHLORIDE EQ 50MG BASE EQ 100MG BASE (TETRACYCLINES - SYSTEMIC)
20-322 30-JUL-93	DIFLUCAN (TABLET)	PFIZER CENTRAL RES GROTON, CT 06340	FLUCONAZOLE 150MG (ANTIFUNGAL-VAGINAL) [VAGINAL CANDIDA INFECTIONS]

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
		ORIGINAL ABBREVIATED NDAS	
62-797 12-JUL-93	AMPICILLIN SODIUM (INJECTABLE)	IBI APRILIA, ITALY	AMPICILLIN SODIUM EQ 125MG BASE/VIAL EQ 2GM BASE/VIAL (PENICILLINS)
74-165* 16-JUL-93	CLOTRIMAZOLE (CREAM)	NMC GLENDALE, NY 11385	CLOTRIMAZOLE 1% (FUNGICIDES) (OTC)
63-295* 26-JUL-93	MONOCID (INJECTABLE)	SMITHKLINE BEECHAM PHILADELPHIA, PA 19101	CEFONICID SODIUM EQ 1GM BASE/VIAL (CEPHALOSPORINS)
74-234 26-JUL-93	NORTRIPTYLINE HCL (CAPSULE)	MYLAN MORGANTOWN, WV 26505	NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE EQ 25MG BASE EQ 50MG BASE EQ 75MG BASE (ANTIDEPRESSANTS)
62-751 30-JUL-93	C-SOLVE-2 (SWAB)	SYOSSET LABS SYOSSET, NY 11791	ERYTHROMYCIN 2% (ANTIBIOTIC, MACROLIDE)
63-253 30-JUL-93	ERYTHROMYCIN LACTOBIONATE (INJECTABLE)	GENSIA IRVINE, CA 92718	ERYTHROMYCIN LACTOBIONATE EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL (ANTIBIOTIC, MACROLIDE)
63-350 30-JUL-93	AMIKACIN SULFATE (INJECTABLE)	DUPONT MERCK GARDEN CITY, NY 11530	AMIKACIN SULFATE EQ 50MG BASE/ML EQ 250MG BASE/ML (AMINOGLYCOSIDES)

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

ORIGINAL ABBREVIATED NDAS

* - First Time Product Available Generically

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAS			
72-781 30-JUL-93	NIFEDIPINE (CAPSULE)	FLEMINGTON FLEMINGTON, NJ 08822	NIFEDIPINE 10MG (CALCIUM CHANNEL BLOCKERS)
73-254 30-JUL-93	LOPERAMIDE HCL (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	LOPERAMIDE HYDROCHLORIDE 2MG (ANTIDIARRHEAL) (OTC)
81-002 30-JUL-93	MEPERIDINE HCL (INJECTABLE)	ASTRA USA WESTBOROUGH, MA 01581	MEPERIDINE HYDROCHLORIDE 10MG/ML (NARCOTIC ANALGESICS)
81-306 30-JUL-93	ETHOSUXIMIDE (SYRUP)	COPLEY PHARM CANTON, MA 02021	ETHOSUXIMIDE 250MG/5ML (ANTICONVULSANTS)

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

ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

A ***tentative approval*** indicates that FDA has given an abbreviated new drug application (ANDA) provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Generic drug products that are the subjects of tentative approvals ***may not be*** legally ***marketed*** until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the ANDA receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluation" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

74-174 09-JUL-93	ALPRAZOLAM (TABLET)	LEDERLE PEARL RIVER, NY 10965	ALPRAZOLAM 0.25MG 0.5MG 1MG 2MG (ANXIOLYTIC)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
18-602 01-JUL-93	CARDIZEM (TABLET)	MARION MERRELL DOW KANSAS CITY, MO 64137	DILTIAZEM HYDROCHLORIDE 30MG 60MG 90MG 120MG (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS)
18-998 01-JUL-93	VASOTEC (TABLET)	MERCK WEST POINT, PA 19486	ENALAPRIL MALEATE 2.5MG 5MG 10MG 20MG (LABELING REVISION -- CLINICAL PHARMACOLOGY)
19-386 01-JUL-93	BREVIBLOC (INJECTABLE)	ANAQUEST LIBERTY CORNER, NJ 07938	ESMOLOL HYDROCHLORIDE 10MG/ML 250MG/ML (LABELING REVISION -- PRECAUTIONS)
17-769 06-JUL-93	CALCIMAR (INJECTABLE)	RHONE POULENC RORER COLLEGEVILLE, PA 19426	CALCITONIN, SALMON 200 IU/ML (LABELING REVISION -- PRECAUTIONS)
18-883 07-JUL-93	DELFLEX W/DEXTROSE 1.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION)	FRESENIUS WALNUT CREEK, CA 94598	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 1.5GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
18-883	DELFLEX	FRESENIUS	CALCIUM CHLORIDE

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
	LABELING SUPPLEMENTS TO ORIGINAL NDAS		
07-JUL-93	W/DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION)	WALNUT CREEK, CA 94598	25.7MG/100ML DEXTROSE 1.5GM/100ML MAGNESIUM CHLORIDE 15.2MG/100ML SODIUM CHLORIDE 567MG/100ML SODIUM LACTATE 392MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
18-883 07-JUL-93	DELFLEX W/DEXTROSE 2.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION)	FRESENIUS WALNUT CREEK, CA 94598	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 2.5GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
18-883 07-JUL-93	DELFLEX W/DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION)	FRESENIUS WALNUT CREEK, CA 94598	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 2.5GM/100ML MAGNESIUM CHLORIDE 15.2MG/100ML SODIUM CHLORIDE 567MG/100ML SODIUM LACTATE 392MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
18-883 07-JUL-93	DELFLEX W/DEXTROSE 4.25% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION)	FRESENIUS WALNUT CREEK, CA 94598	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 4.25GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
18-883 07-JUL-93	DELFLEX W/DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION)	FRESENIUS WALNUT CREEK, CA 94598	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 4.25GM/100ML MAGNESIUM CHLORIDE 15.2MG/100ML SODIUM CHLORIDE 567MG/100ML SODIUM LACTATE 392MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
17-063 13-JUL-93	ISMOTIC (SOLUTION)	ALCON LABS FORT WORTH, TX 76134	ISOSORBIDE 100GM/220ML (LABELING REVISION -- DESCRIPTION; ADVERSE REACTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
18-956 13-JUL-93	OMNIPAQUE 180 (SOLUTION)	STERLING NEW YORK, NY 10016	IOHEXOL 38.8% (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
18-956 13-JUL-93	OMNIPAQUE 240 (SOLUTION)	STERLING NEW YORK, NY 10016	IOHEXOL 51.8% (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
18-956 13-JUL-93	OMNIPAQUE 300 (SOLUTION)	STERLING NEW YORK, NY 10016	IOHEXOL 64.7% (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
50-368 14-JUL-93	ILOTYCIN (OINTMENT)	LILLY INDIANAPOLIS, IN 46285	ERYTHROMYCIN 5MG/GM (LABELING REVISION -- CLINICAL PHARMACOLOGY)
18-719 16-JUL-93	MODRASTANE (CAPSULE)	STERLING NEW YORK, NY 10016	TRILOSTANE 30MG 60MG (LABELING REVISION -- PRECAUTIONS)
18-473 20-JUL-93	VENTOLIN (AEROSOL, METERED)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL 0.09MG/INH (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
19-489 20-JUL-93	VENTOLIN ROTACAPS (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL SULFATE EQ 0.2MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
17-078 21-JUL-93	DEXEDRINE (CAPSULE, EXTENDED RELEASE)	SMITHKLINE BEECHAM PHILADELPHIA, PA 19101	DEXTROAMPHETAMINE SULFATE 5MG 10MG 15MG (LABELING REVISION -- ADVERSE REACTIONS)
20-013 21-JUL-93	MAXAQUIN (TABLET)	SEARLE SKOKIE, IL 60077	LOMEFLOXACIN HYDROCHLORIDE EQ 400MG BASE (LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
18-768 23-JUL-93	VEPESID (INJECTABLE)	BRISTOL SYRACUSE, NY 13221	ETOPOSIDE 20MG/ML (LABELING REVISION -- DESCRIPTION; CONTRAINDICATIONS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
19-557 23-JUL-93	VEPESID (CAPSULE)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	ETOPOSIDE 50MG (LABELING REVISION -- DESCRIPTION; CONTRAINDICATIONS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
20-198 23-JUL-93	ADALAT CC (TABLET, EXTENDED RELEASE)	MILES PHARM WEST HAVEN, CT 06516	NIFEDIPINE 30MG 60MG 90MG (LABELING REVISION -- PATIENT INSTRUCTIONS)
20-262 23-JUL-93	TAXOL (INJECTABLE)	BRISTOL MYERS SQUIBB WALLINGFORD, CT 06492	PACLITAXEL 6MG/ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
17-532 27-JUL-93	DIABETA (TABLET)	HOECHST ROUSSEL SOMERVILLE, NJ 08876	GLYBURIDE 1.25MG 2.5MG 5MG (LABELING REVISION -- WARNINGS; DOSAGE AND ADMINISTRATION)
18-202 27-JUL-93	CYTADREN (TABLET)	CIBA PHARM SUMMIT, NJ 07901	AMINOGLUTETHIMIDE 250MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-710 27-JUL-93	OPTIRAY 160 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	IOVERSOL 34% (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
19-710 27-JUL-93	OPTIRAY 240 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	IOVERSOL 51% (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
19-710 27-JUL-93	OPTIRAY 320 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	IOVERSOL 68% (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
19-710 27-JUL-93	OPTIRAY 350 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	IOVERSOL 74% (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
17-954 28-JUL-93	BRETYLOL (INJECTABLE)	DUPONT WILMINGTON, DE 19880	BRETYLIUM TOSYLATE 50MG/ML (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-501 28-JUL-93	ROGAINE (SOLUTION)	UPJOHN KALAMAZOO, MI 49001	MINOXIDIL 2% (LABELING REVISION -- CLINICAL TRIAL EXPERIENCE-MAL PRECAUTIONS; HOW SUPPLIED; PATIENT INFORMATION; INSTRUCTIONS FOR USE)
19-813 28-JUL-93	DURAGESIC (FILM, EXTENDED RELEASE)	ALZA PALO ALTO, CA 94303	FENTANYL 0.6MG/24HR 1.2MG/24HR 1.8MG/24HR 2.4MG/24HR (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; DOSAGE AND ADMINISTRATION)
50-370 30-JUL-93	ILOTYCIN GLUCEPTATE (INJECTABLE)	DISTA PRODS INDIANAPOLIS, IN 46206	ERYTHROMYCIN GLUCEPTATE EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL (LABELING REVISION -- PRECAUTIONS)
50-588 30-JUL-93	CEFOTAN (INJECTABLE)	STUART PHARMS WILMINGTON, DE 19897	CEFOTETAN DISODIUM EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
50-637 30-JUL-93	ZEFAZONE (INJECTABLE)	UPJOHN KALAMAZOO, MI 49001	CEFMETAZOLE SODIUM EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

LICENCE NUMBER LICENCE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
BIOLOGICAL PRODUCT LICENCES ISSUED			
1106 07-23-93	BETASERON (INJECTABLE)	CHIRON EMERYVILLE, CA 94608	INTERFERON BETA-1B (TREATMENT OF MULTIPLE SCLEROSIS) (B)
1166 07-26-93	NONE (INJECTABLE)	NATIONAL HLTH GUARD FORT LAUDERDALE, FL 33309	RED BLOOD CELLS (TRANSFUSION) (A&B)
1166 07-26-93	NONE (INJECTABLE)	NATIONAL HLTH GUARD FORT LAUDERDALE, FL 33309	WHOLE BLOOD (TRANSFUSION) (A&B)

LICENCE NUMBER LICENCE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT LICENCES ISSUED

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

BK910034 07-29-93	QWICK 1 BLOOD AND PLASMA WARMER	MICROWAVE MED SYS LITTLETON, MA 01460	BLOOD AND PLASMA WARMING DEVICE (C)
BK920026 07-30-93	SDP MICROPLATE ASSAY MANAGEMENT	GENETIC SYS SEATTLE, WA 98121	MICROPLATE ASSAY MANAGEMENT (C)

DEVICE NUMBER APPROVABLE 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

P910013 07/09/93	WESLEY-JESSEN HS-16 CLEANING SOLUTION	WESLEY-JESSEN CORPORATION CHICAGO, IL 60610-3496	WESLEY-JESSEN HS-16 CLEANING SOLUTION FOR USE TO CLEAN SO (HYDROPHILIC) CONTACT LENSES BEFORE RINSING AND DISINFECTI
P910065 07/17/93	AIA-PACK PA	TOSOH MEDICS, INC. TOKYO, JAPAN	APPROVAL FOR THE TOSOH AIA P PA

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

MEDICAL DEVICE - PMA SUPPLEMENTS

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

N17676/S24 07/02/93	NATURVUE (HEFILCON A) SOFT (HYDROPHILIC) CONTACT LENS, BAUSCH & LOMB (HEFILCON C) VISIBILITY TINTED CONTACT LENSES	BAUSCH & LOMB HEALTHCARE AND OPTICS ROCHESTER, NY 14692-0450	TINTED WITH C.I. REACTIVE BLUE 246 IN ACCORDANCE WITH 21 CFR 73.3106
P790007/S11 07/02/93	HANCOCK MODIFIED ORIFICE AORTIC BIOPROSTHESIS (MODELS 250 AND 150)	MEDTRONIC HEALTH VALVES MINNEAPOLIS, MN 55440	REVISED LABELING
P790032/S03 07/23/93	CLINICAL ASSAYS GAMMADAB [125I], ALPHA FETOPROTEIN RADIOIMMUNOASSAY KIT	BAXTER HEALTHCARE CORPORATION MIAMI, FL 33152-0672	KITS TO BE MANUFACTURED AT FACILITIES LOCATED IN STILLWATER, MN
P810046/S122 07/29/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, STACK PERFUSION IV CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE ACS STACK PERFUSION IV CORONARY DILATA CATHETER
P810046/S125 07/07/93	SIMPSON-ROBERT CORONARY DILATATION CATHETER, ACS RX STREAK .014 CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	ADDITIONAL BALLOON LENGTHS F THE ACS RX STREAK .014 CORONA DILATATION CATHETER
P810046/S126 07/21/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS PINKERTON 18-PRELOAD, AND ACS OMEGA 010-PRELOAD CORONARY DILATATION	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	TO PREPACKAGE AN ACS GUIDEW WITHIN THE GUIDEWIRE LUMEN O ACS PINKERTON AND OMEGA CORONARY DILATATION CATHETE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTS	
P810046/S130 07/23/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS EDGE CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE ACS EDGE CORONARY DILATATION CATHETE
P820053/S22 07/28/93	COMFORTCARE GP WETTING AND SOAKING SOLUTION	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SIT
P820060/S06 07/01/93	ABBOTT AFP-EIA, ABBOTT IMX-AFP	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	MODIFIED MANUFACTURING PROC TO PROVIDE AN ADDITIONAL PURIFICATION STEP
P820083/S13 07/01/93	GORE-TEX EXPANDED PTFE SUTURE	W.L. GORE & ASSOCIATES, INC. FLAGSTAFF, AZ 86003-2300	ALTERNATIVE MANUFACTURING FACILITY FOR BOXING OPERATION
P840008/S44 07/19/93	MODEL MFL5000 MOBILE LITHOTRIPTER	DORNIER MEDICAL SYSTEMS KENNESAW, GA 30144	ALTERNATE TRANSPORT DEVICE DESIGN THAT SECURES THE SHOC WAVE GENERATOR FOR BOTH VERSIONS OF THE MFL5000 MOBIL LITHOTRIPTER
P840040/S37 07/08/93	HEART TRAK CORONARY BALLOON DILATATION CATHETER SYSTEM, 3.4 F SLIDER 40 MM LONG BALLOON DILATATION CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	APPROVAL FOR THE 3.4 F SLIDER 40 MM LONG BALLOON DILATATION CATHETER
P840055/S30 07/12/93	SGP II (TELEFOCON B) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PERMEABLE TECHNOLOGIES, INC. MORGANVILLE, NJ 07751	APPROVAL OF THE LENSES IN SPHERICAL AND ASPHERICAL SINGLE VISION AND SPHERICAL AND ASPHERICAL MULTIFOCAL CONFIGURATIONS
P850007/S13 07/29/93	SPINAL-STIM	AMERICAN MEDICAL ELECTRONICS, INC. RICHARDSON, TX 75081	MODIFIED LABELING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTS	
P850021/S22 07/01/93	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, LONG REACH 40 MM PTCA CATHETER	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	APPROVAL FOR THE LONG REACH 40 MM PTCA CATHETER
P850051/S39 07/02/93	ACTIVITRAX PACING SYSTEM, MODEL 8360 MICRO MINIX IMPLANTABLE PULSE GENERATOR	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFIED LABELING
P860019/S52 07/21/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER, SCIMED QUANTUM PTCA DILATATION CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A NEW MODEL PTCA CATHETER
P860019/S68 07/01/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, NC RALLY	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A NEW MODEL CATHETER
P860019/S74 07/29/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A CHANGE IN THE TRADE NAME FOR THE QUANTUM CATHETER
P860058/S01 07/29/93	ENZYMUN-TEST CEA	BOEHRINGER MANNHEIM INDIANAPOLIS, IN 46250-0100	APPROVAL FOR A CHANGE IN KIT CONFIGURATION
P870078/S03 07/02/93	HANCOCK STANDARD PORCINE BIOPROSTHESIS (MODELS 242, 342, 342R, AND 342C)	MEDTRONIC HEART VALVES MINNEAPOLIS, MN 55440	MODIFIED LABELING
P880003/S13 07/07/93	SLEEK PTCA DILATATION CATHETERS WITH 3 AND 4 CM BALLOONS	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR CORDIS SLEEK PT DILATATION CATHETERS WITH 3 A CM BALLOONS

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTS			
P880003/S14 07/21/93	CORDIS PTCA DILATATION CATHETERS, PREDATOR PTCA DILATATION CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR THE PREDATOR P DILATATION CATHETER
P880003/S18 07/29/93	CORDIS PTCA DILATATION CATHETERS, CORDIS SLEEK PTCA DILATATION CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	MANUFACTURING MODIFICATION
P890047/S01 07/20/93	PROVISC	ALCON LABORATORIES, INC. FORT WORTH, TX 76134	MODIFIED MANUFACTURING PROC
P900023/S01 07/12/93	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	APPROVAL FOR THE ADDITION OF ALARM MUTE SWITCH
P910064/S02 07/09/93	REALITY FEMALE CONDOM	WISCONSIN PHARMACAL COMPANY CHICAGO, IL 60611	REVISED PATIENT DEVICE LABELI

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
ORIGINAL VETRINARY NADAs			
140-896 09-JUN-93	OTOMAX (OINTMENT)	DOGS SCHERING PLOUGH KENILWORTH, NJ 07033	GENTAMICIN SULFATE 3MG/GM BETAMETHASONE VALERATE 1MG/GM CLOTRIMAZOLE 10MG/GM
140-892 29-JUN-93	SYNANTHIC BOVINE DEWORMER (PASTE)	CATTLE SYNTEX AN HLTH PALO ALTO, CA 94303	OXFENDAZOLE 18.5%
ORIGINAL ABBREVIATED VETERINARY NADAs			
200-038 05-25-93	SULFADIMETHOXINE (LIQUID)	CATTLE AGRI LABS ST JOSEPH, MO 64503	SULFADIMETHOXINE 400MG/ML
200-033 06-11-93	UNIPRIM (POWDER)	HORSES MACLEOD PHARMA FT COLLINS, CO 80525	TRIMETHOPRIM 67MG/GM SULFADIAZINE 333MG/GM
200-113 06-28-93	BLOSOL (LIQUID)	CATTLE, UPJOHN SWINE, KALAMAZOO,MI SHEEP, 49001 GOATS	NEOMYCIN SULFATE 200MG/ML (EQUIVALENT TO 140MG NEOMYCIN PER ML)
SUPPLEMENTAL VETERINARY NADAs			
THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR JULY 1993.			

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

ORIGINAL VETRINARY NADAs

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

ORIGINAL VETRINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

VOLUME 16 (08)
AUGUST 1993

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

Center for Devices and Radiological Health
Mary Jo Robinson (301) 594-21

Center for Biologics Evaluation and Research
Joseph Wilczek (301) 594-2012

Center for Veterinary Medicin
Norman Turner
(301) 594-1623

*To whom general inquiries should be directed.

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.

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

19-843 09-AUG-93 (5 S)	ISOLYTE S IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 30MG/100ML POTASSIUM CHLORIDE 37MG/100ML SODIUM ACETATE 370MG/100ML SODIUM CHLORIDE 530MG/100ML SODIUM GLUCONATE 500MG/100ML (NUTRITION/ELECTROLYTE REPLENISHER)
20-225 12-AUG-93 (3 S)	IMDUR (TABLET, EXTENDED RELEASE)	SCHERING PLOUGH KENILWORTH, NJ 07033	ISOSORBIDE MONONITRATE 30MG* 60MG (VASODILATORS)
20-007 13-AUG-93 (SUPPL)	ZOFRAN (INJECTABLE)	GLAXO RES TRIANGLE PK, NC 27709	ONDANSETRON HYDROCHLOR EQ 2MG BASE/ML (NEW OR MODIFIED INDICATIO PREVENTION OF POSTOPERAT NAUSEA AND/OR VOMITING)

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

ORIGINAL VETRINARY NADAs

* - Not Marketed at This Time

20-091 13-AUG-93 (1 S)	IMAGENT (LIQUID)	ALLIANCE PHARM SAN DIEGO, CA 92121	PERFLUBRON 100% (DIAGNOSTIC) [USE WITH MR IMAGING TO ENHANCE DELINEATION OF TH BOWEL]
19-596 17-AUG-93 (SUPPL)	MAGNEVIST (INJECTABLE)	BERLEX LABS WAYNE, NJ 07470	GADOPENTETATE DIMEGLUMI 469.01MG/ML (NEW OR MODIFIED INDICATIO USE WITH MRI IN ADULTS TO PROVIDE CONTRAST ENHANCEMENT AND FACILITAT VISUALIZATION OF LESIONS IN BODY [EXCLUDING THE HEART
20-136 23-AUG-93 (1 S)	DEMADEX (TABLET)	BOEHRINGER MANNHEIM ROCKVILLE, MD 20850	TORSEMIDE 5MG 10MG 20MG 100MG (DIURETICS AND RENAL TUBUL INHIBITORS)
20-137 23-AUG-93 (3 S)	DEMADEX (INJECTABLE)	BOEHRINGER MANNHEIM ROCKVILLE, MD 20850	TORSEMIDE 10MG/ML (DIURETICS AND RENAL TUBUL INHIBITORS)
09-218 24-AUG-93 (SUPPL)	COUMADIN (TABLET)	DUPONT WILMINGTON, DE 19880	WARFARIN SODIUM 4MG (NEW STRENGTH)

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.

****THERE ARE NO APPROVABLE ORIGINAL NDAs FOR THE MONTH OF AUGUST 1993.****

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAS			
87-771 06-AUG-93	CETAPRED (OINTMENT)	ALCON LABS FORT WORTH, TX 76134	PREDNISOLONE ACETATE 0.25% SULFACETAMIDE SODIUM 10% (CORTICOSTEROID/ANTI-INFECTIV
63-239 13-AUG-93	ROCEPHIN (INJECTABLE)	ROCHE LABS NUTLEY, NJ 07110	CEFTRIAXONE SODIUM EQ 250MG BASE/VIAL* EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL (CEPHALOSPORINS)
81-309 30-AUG-93	MEPERIDINE HCL (INJECTABLE)	INTL MEDICATION SOUTH EL MONTE, CA 91733	MEPERIDINE HYDROCHLORIDE 10MG/ML (NARCOTIC ANALGESICS)
72-640* 31-AUG-93	CLOTRIMAZOLE (CREAM)	TARO PHARMS DOWNSVIEW, ONTARIO CANADA	CLOTRIMAZOLE 1% (FUNGICIDES) (RX/OTC)
73-098 31-AUG-93	PEG-LYTE (POWDER FOR RECONSTITUTION)	INVAMED FAIRFIELD, NJ 07004	POLYETHYLENE GLYCOL 3350 236GM/BOT POTASSIUM CHLORIDE 2.97GM/BOT SODIUM BICARBONATE 6.74GM/BOT SODIUM CHLORIDE 5.86GM/BOT SODIUM SULFATE, ANHYDROUS 22.74GM/BOT (LAXATIVES)
74-106* 31-AUG-93	NAPROXEN SODIUM (TABLET)	HAMILTON HUMACAO, PR 00791	NAPROXEN SODIUM 275MG 550MG (NSAID)

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

ORIGINAL ABBREVIATED NDAS

* - First Time Product Available Generically

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

ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

A ***tentative approval*** indicates that FDA has given an abbreviated new drug application (ANDA) provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Generic drug products that are the subjects of tentative approvals ***may not be*** legally ***marketed*** until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the ANDA receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluation" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

74-105 30-AUG-93	NAPROXEN (TABLET)	LEDERLE PEARL RIVER, NY 10965	NAPROXEN 250MG 375MG 500MG (NSAID)
74-121 31-AUG-93	NAPROXEN (TABLET)	MYLAN MORGANTOWN, WV 26504	NAPROXEN 250MG 375MG 500MG (NSAID)

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

ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
06-525 04-AUG-93	GANTRISIN (TABLET)	ROCHE NUTLEY, NJ 07110	SULFISOXAZOLE 500MG (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS
09-182 04-AUG-93	GANTRISIN (SUSPENSION)	ROCHE NUTLEY, NJ 07110	SULFISOXAZOLE ACETYL EQ 500MG BASE/5ML (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS
09-182 04-AUG-93	GANTRISIN (SYRUP)	ROCHE NUTLEY, NJ 07110	SULFISOXAZOLE ACETYL EQ 500MG BASE/5ML (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS
09-218 06-AUG-93	COUMADIN (TABLET)	DUPONT WILMINGTON, DE 19880	WARFARIN SODIUM 1MG 2MG 2.5MG 5MG 7.5MG 10MG (LABELING REVISION -- CLINICAL PHARMACOLOGY)
06-536 09-AUG-93	URECHOLINE (TABLET)	MSD WEST POINT, PA 19486	BETHANECHOL CHLORIDE 5MG 10MG 25MG 50MG (LABELING REVISION -- ADVERSE REACTIONS; HOW SUPPLIED)
06-536 09-AUG-93	URECHOLINE (INJECTABLE)	MSD WEST POINT, PA 19486	BETHANECHOL CHLORIDE 5MG/ML (LABELING REVISION -- ADVERSE REACTIONS; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		*****LABELING SUPPLEMENTS TO ORIGINAL NDAs*****	
18-596 09-AUG-93	INTAL (SOLUTION)	FISONS BEDFORD, MA 01730	CROMOLYN SODIUM 10MG/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; HOW SUPPLIED)
12-708* 12-AUG-93	DIUTENSIN-R (TABLET)	WALLACE LABS CRANBURY, NJ 08512	METHYCHLOTHIAZIDE 2.5MG RESERPINE 0.1MG (LABELING REVISION -- LABELING FORMAT REVISION PROGRAM)
20-007 13-AUG-93	ZOFRAN (INJECTABLE)	GLAXO RES TRIANGLE PK, NC 27709	ONDANSETRON HYDROCHLORIDE EQ 2MG BASE/ML (LABELING REVISION -- CLINICAL TRIALS; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-596 17-AUG-93	MAGNEVIST (INJECTABLE)	BERLEX LABS WAYNE, NJ 07470	GADOPENTETATE DIMEGLUMINE 469.01MG/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS)
06-460 18-AUG-93	PROTAMINE SULFATE (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	PROTAMINE SULFATE 10MG/ML (LABELING REVISION -- PRECAUTIONS; OVERDOSAGE; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
18-936 18-AUG-93	PROZAC (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	FLUOXETINE HYDROCHLORIDE EQ 10MG BASE EQ 20MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
* - Permitted			
20-101 18-AUG-93	PROZAC (SOLUTION)	LILLY INDIANAPOLIS, IN 46285	FLUOXETINE HYDROCHLORIDE EQ 20MG BASE/5ML (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
09-218 24-AUG-93	COUMADIN (TABLET)	DUPONT WILMINGTON, DE 19880	WARFARIN SODIUM 1MG 2MG 2.5MG 4MG 5MG 7.5MG 10MG (LABELING REVISION -- DESCRIPTION, HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
19-655 24-AUG-93	RETROVIR (CAPSULE)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709	ZIDOVUDINE 100MG (LABELING REVISION -- BOXED WARNINGS; DESCRIPTION CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-910 24-AUG-93	RETROVIR (SYRUP)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709	ZIDOVUDINE 50MG/5ML (LABELING REVISION -- BOXED WARNINGS; DESCRIPTION CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
11-664 25-AUG-93	DECADRON (TABLET)	MSD WEST POINT, PA 19486	DEXAMETHASONE 0.25MG 0.5MG 0.75MG 1.5MG 4MG 6MG (LABELING REVISION -- WARNINGS; PRECAUTIONS; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
*****LABELING SUPPLEMENTS TO ORIGINAL NDAs*****			
17-029 25-AUG-93	HEPARIN SODIUM (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	HEPARIN SODIUM 1,000 UNITS/ML 5,000 UNITS/ML 10,000 UNITS/ML 20, 000 UNITS/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
17-029 25-AUG-93	HEPARIN LOCK FLUSH (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	HEPARIN SODIUM 10 UNITS/ML 100 UNITS/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
17-651 25-AUG-93	HEPARIN SODIUM (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	HEPARIN SODIUM 5,000 UNITS/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
17-651 25-AUG-93	HEPFLUSH-10 (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	HEPARIN LOCK FLUSH SOLUTION 10 UNITS/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
07-110 26-AUG-93	CORTONE (INJECTABLE)	MSD WEST POINT, PA 19486	CORTISONE ACETATE 50MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
10-562 26-AUG-93	HYDELTRA-TBA (INJECTABLE)	MSD WEST POINT, PA 19486	PREDNISOLONE TEBUTATE 20MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		*****LABELING SUPPLEMENTS TO ORIGINAL NDAs*****	
11-583 26-AUG-93	HYDELTRASOL (INJECTABLE)	MSD WEST POINT, PA 19486	PREDNISOLONE SODIUM PHOSPH EQ 20MG PHOSPHATE/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
12-052 26-AUG-93	HYDROCORTONE (INJECTABLE)	MSD WEST POINT, PA 19486	HYDROCORTISONE SODIUM PHOSPHATE EQ 50MG BASE/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
12-071 26-AUG-93	DECADRON (INJECTABLE)	MSD WEST POINT, PA 19486	DEXAMETHASONE SODIUM PHOSP EQ 4MG PHOSPHATE/ML EQ 24MG PHOSPHATE/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
17-979 26-AUG-93	HEPARIN SODIUM (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	HEPARIN SODIUM 1,000 UNITS/ML 10,000 UNITS/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		*****LABELING SUPPLEMENTS TO ORIGINAL NDAs*****	
07-750 27-AUG-93	CORTONE (TABLET)	MSD WEST POINT, PA 19486	CORTISONE ACETATE 25MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
08-506 27-AUG-93	HYDROCORTONE (TABLET)	MSD WEST POINT, PA 19486	HYDROCORTISONE 10MG 20MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
08-228 27-AUG-93	HYDROCORTONE (INJECTABLE)	MSD WEST POINT, PA 19486	HYDROCORTISONE ACETATE 25MG/ML 50MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
12-376 27-AUG-93	DECADRON (ELIXIR)	MSD WEST POINT, PA 19486	DEXAMETHASONE 0.5MG/5ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
13-334 27-AUG-93	DECADRON W/XYLOCAINE (INJECTABLE)	MSD WEST POINT, PA 19486	DEXAMETHASONE SODIUM PHOSP EQ 4MG PHOSPHATE/ML LIDOCAINE HYDROCHLORIDE 10MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
16-675 27-AUG-93	DECADRON-LA (INJECTABLE)	MERCK WEST POINT, PA 19486	DEXAMETHASONE ACETATE EQ 8MG BASE/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)

LICENCE NUMBER LICENCE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT LICENCES ISSUED

NO BIOLOGICAL PRODUCT LICENSES ISSUED FOR THE MONTH OF AUGUST 1993.

DEVICE NUMBER APPROVABLE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
BIOLOGICAL PRODUCT DEVICE APPROVALS			
BK920025 08/05/93	FETAL CELLS SCREENING KIT	BAXTER DIAGS MIAMI, FL 33172	DADE FETAL-CYTE SCREENING KIT (C)
BK920031 08/20/92	LEUKOCYTE TYPING TRAY	MEDICAL MARKETING CONSULTANTS BETHESDA, MD 20814	sHLA-STAT B27 ELISA FOR HLA-B27 TYPING (C)

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

P910073 08/26/93	0060 SERIES ENDOTAK LEAD SYSTEM	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	APPROVAL OF THE 0060 SERIES ENDOTAK LEAD SYSTEM

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

*****MEDICAL DEVICE - PMA SUPPLEMENTS*****

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

P790024/S23 08/11/93	LC-65 DAILY CONTACT LENS CLEANER WITHOUT THIMEROSAL	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ADDITIONAL CONTAINER SIZE FOR LENS PLUS DAILY CLEANER FORMULATION AND TRADE NAME CHANGE TO LC-65 DAILY CONTACT LENS CLEANER
P810046/S139 08/09/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ALTERNATE STERILIZATION METHOD (E-BEAM RADIATION) FOR ACS PTCA CATHETERS	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	ADDITION OF AN ALTERNATE STERILIZATION METHOD
P810046/S141 08/24/93	SIMPSON-ROBERT BALLOON DILATATION CATHETER, ACS RX FLOWTRACK 40 CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	ADDITION OF A WARNING TO THE INSTRUCTIONS FOR USE
P820003/S65 08/04/93	VERSATRAX PACING SYSTEM, MEDTRONIC MODEL 5346 TEMPORARY PULSE GENERATOR	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR MEDTRONIC MODEL 5346 TEMPORARY PULSE GENERATOR
P820003/S67 08/10/93	VERSATRAX PACING SYSTEM, MEDTRONIC MODEL 5423 ELECTROCARDIOGRAM CABLE	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MEDTRONIC MODEL 5423 ELECTROCARDIOGRAM CABLE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		*****MEDICAL DEVICE - PMA SUPPLEMENTS*****	
P820049/S53 08/11/93	MODELS PC-37NB, PC-63CNB, AND PC-64CNB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	APPROVAL FOR MODELS PC-37NB PC-63CNB, AND PC-64CNB ULTRAVIOLET-ABSORBING POSTE CHAMBER INTRAOCULAR LENSES
P830026/S58 08/04/93	COSMOS PACING SYSTEM, COSMOS II MODELS 284-05 AND 283-03 PULSE GENERATORS	INTERMEDICS, INC. ANGLETON, TX 77515	MODIFIED MANUFACTURING
P840008/S46 08/04/93	DORNIER MFL5000 LITHOTRIPTER	DORNIER MEDICAL SYSTEMS KENNESAW, GA 30144	MODIFIED LABELING
P840040/S39 08/17/93	MANSFIELD CORONARY BALLOON DILATATION CATHETER SYSTEM, SYNERGY CONVERTIBLE RAPID EXCHANGE PTCA CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	MANUFACTURING MODIFICATION
P850022/S08 08/06/93	ORTHOPAK BONE GROWTH STIMULATOR	BIOLECTRON, INC. HACKENSAK, NJ 07601	APPROVAL TO DISTRIBUTE BONE GROWTH STIMULATING SYSTEM W NEW ELECTRODE GEL
P860007/S12 08/04/93	INTERTACH PACING SYSTEM, INTERTACH II PULSE GENERATORS MODELS 262-16 AND 262-16R	INTERMEDICS, INC. ANGLETON, TX 77515	MODIFIED MANUFACTURING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTS	
P870023/S03 08/24/93	DE.STAT 3 CLEANING/DISINFECTING STORAGE SOLUTION, ULTRA 3 CLEANING. DISINFECTING. STORAGE SOLUTION	SHERMAN PHARMACEUTICALS, INC. MANDEVILLE, LA 70470-1377	MANUFACTURING MODIFICATION
P870036/S21 08/27/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC 14K LONG CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	APPROVAL OF A NEW MODEL CATHETER WITH A 30MM BALLOO LENGTH AND ONE RADIOPAQUE MARKER BAND UNDER THE BALLO
P870036/S23 08/06/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC SPIRIT CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	NEW MODEL CATHETER TO BE MARKETED UNDER THE TRADE NA MEDTRONIC SPIRIT CORONARY BALLOON DILATATION CATHETER
P870036/S24 08/09/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC 14K CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	MODIFIED SPECIFICATIONS FOR THE GUIDEWIRE LUMEN TUBING EXTRUSION
P880003/S15 08/20/93	CORDIS PTCA DILATATION CATHETERS, PREDATOR PTCA DILATATION CATHETER (WITH 3 AND 4 CM) LONG BALLOONS	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR 3 AND 4 CM LONG BALLOONS FOR THE PREDATOR P DILATATION CATHETER

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTS	
P880003/S19 08/02/93	CORDIS PTCA DILATATION CATHETERS, CORDIS OLYMPIX AND SLEUTH XT DILATATION CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	MANUFACTURING MODIFICATION
P880013/S02 08/11/93	HFV INFANT STAR VENTILATOR	INFRASONICS, INC. SAN DIEGO, CA 92121	NEW MANUFACTURING FACILITY
P880027/S26 08/12/93	SCHNEIDER MICROSOFTRAC PTCA CATHETER	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	ALTERNATIVE PACKAGING AND LABELING
P880035/S06 08/11/93	VISTA OPTICS, VISTACRYL 18 (KOLFOCON A) AND VISTA OPTICS, VISTACRYL 32 (KOLFOCON B) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	VISTA OPTICS LIMITED UNITED KINGDOM 14396-86	ELEVEN ADDITIONAL RIGID GAS PERMEABLE CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AN DISTRIBUTING SITES
P880090/S07 08/11/93	ANTERIOR CHAMBER INTRAOCULAR LENSES: PRIVATE DISTRIBUTION REQUEST	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	APPROVAL FOR OPTICAL RADIATION CORPORATION TO DISTRIBUTE MODELS 121UV AND S121UV AS ORC MODELS UV15L A UV15S ULTRAVIOLET-ABSORBING ANTERIOR CHAMBER IOLS
P880090/S08 08/11/93	ANTERIOR CHAMBER INTRAOCULAR LENSES: PRIVATE DISTRIBUTION REQUEST	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	APPROVAL FOR WORLD OPTICS, I TO DISTRIBUTE MODELS 121UV AN S121UV AS WORLD OPTICS MODELS W221UV AND WS221UV ULTRAVIOLET-ABSORBING ANTER CHAMBER IOLS

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		*****MEDICAL DEVICE - PMA SUPPLEMENTS*****	
P890003/S23 08/10/93	SYNERGYST PACING SYSTEM, MEDTRONIC MODEL 5424 ELECTROCARDIOGRAM CABLE	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MEDTRONIC MODEL 5424 ELECTROCARDIOGRAM CABLE
P890029/S02 08/02/93	CIBA 2000 SPHERICAL (ATLAFILCON A) SOFT (HYDROPHILIC) LENS, CIBA 2000 (ATLAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS	CIBA VISION CORPORATION DULUTH, GA 30136-1518	APPROVAL FOR THE TINTED VERSION OF THE ATLAFILCON A CONTACT LENSES
P890039/S11 08/26/93	MAESTRO SAVVI MODEL 305 PACING SYSTEM, MAESTRO SAVVI MODEL 325 PULSE GENERATOR	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	APPROVAL FOR THE MAESTRO SAVVI MODEL 325 PULSE GENERATOR
P900023/S04 08/20/93	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	CHANGE TO THE POWER SUPPLY PRINTED CIRCUIT BOARD IN THE ABIOMED BVS 5000 CONSOLE
P900032/S06 08/12/93	DYMER 200+ EXCIMER LASER SYSTEM	ADVANCED INTERVENTIONAL IRVINE, CA 92718	APPROVAL FOR THE MODEL PC40 LASER CATHETER
P900039/S02 08/05/93	COLLAGRAFT BONE GRAFT MATRIX	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	MODIFIED SPECIFICATIONS FOR A COMPONENT OF THE COLLAGRAF BONE GRAFT MATRIX
P900048/S02 08/23/93	ELASTIMIDE SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES, CHIROFLEX SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES	SOFLENSCO, INC. IRVINE, CA 92718-1903	REVISED LABELING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
*****MEDICAL DEVICE - PMA SUPPLEMENTS*****			
P910030/S01 08/30/93	GIANTURCO-ROUBIN FLEX-STENT CORONARY STENT	COOK, INC. BLOOMINGTON, IN 47402	MANUFACTURING MODIFICATION

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

ORIGINAL VETRINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR AUGUST 1993.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ABBREVIATED VETERINARY NADAs FOR AUGUST 1993.

SUPPLEMENTAL VETERINARY NADAs

12-123 30-JUN-93	GALLIMYCIN (INJECTABLE)	CATTLE	SANOFI AN HLTH OVERLAND PK, KS 66210	ERYTHROMYCIN 200MG/ML
8-622 09-JUL-93	TERRAMYCIN (POWDER)	BEES, CALVES, CATTLE, CHICKENS, SHEEP, SWINE, TURKEYS	PFIZER NEW YORK, NY 10017	OXYTETRACYCLINE HYDROCHLORIDE 1GM/1.32GM 1GM/2.73GM 1GM/4.43GM 1GM/18.14GM

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
ORIGINAL VETRINARY NADAs			
38-200 09-JUL-93	OXY WS MEDAMYCIN (POWDER)	CHICKENS,FERMENTA AN TURKEYS HLTH KANSAS CITY, MO 64153	OXYTETRACYCLINE HYDROCHLORIDE 1GM/4.2GM
111-607 16-JUL-93	DRONCIT (SOLUTION)	CATS, MILES DOGS AGRICULTURE DIV AN HLTH PRODS SHAWNEE MISSION, KS 66201	PRAZIQUANTEL 5.68%
111-798 16-JUL-93	DRONCIT (TABLET)	DOGS MILES AGRICULTURE DIV AN HLTH PRODS SHAWNEE MISSION, KS 66201	PRAZIQUANTEL 34MG
96-298 17-AUG-93	BOVATEC (LIQUID)	CATTLE HOFFMAN LA ROCHE NUTLEY, NJ 07110	LASALOCID SODIUM 90.8GM/LB

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

ORIGINAL VETRINARY NADAs

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

ORIGINAL VETRINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

VOLUME 16 (09)
SEPTEMBER 1993

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

Center for Devices and Radiological Health
Mary Jo Robinson (301) 594-21

Center for Biologics Evaluation and Research
Joseph Wilczek (301) 594-2012

Center for Veterinary Medicin
Norman Turner
(301) 594-1623

*To whom general inquiries should be directed.

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.

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			
20-070 09-SEP-93 (1 P)	COGNEX (CAPSULE)	PARKE DAVIS ANN ARBOR, MI 48105	TACRINE HYDROCHLORIDE EQ 10MG BASE EQ 20MG BASE EQ 30MG BASE EQ 40MG BASE (REVERSIBLE CHOLINESTERAS INHIBITOR) [DEMENTIA OF THE ALZHEIMER TYPE]
20-264 10-SEP-93 (3 S, V*)	MEGACE (SUSPENSION)	BRISTOL MYERS SQUIBB EVANSVILLE, IN 47721	MEGESTROL ACETATE 40MG/ML (PROGESTERONE DERIVATIVE [TREATMENT OF ANOREXIA, CACHEXIA, OR UNEXPLAINED WEIGHT LOSS IN PATIENTS WITH AIDS]
19-649 17-SEP-93 (1 P)	FLUMADINE (TABLET)	FOREST LABS NEW YORK, NY 10155	RIMANTADINE HYDROCHLORID 100MG (ANTIVIRAL - ANTI-INFLUENZA)
19-650 17-SEP-93 (3 P)	FLUMADINE (SYRUP)	FOREST LABS NEW YORK, NY 10155	RIMANTADINE HYDROCHLORID 10MG/ML (ANTIVIRAL - ANTI-INFLUENZA)

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

ORIGINAL VETRINARY NADAs

V* - Designated Orphan Drug

19-508 21-SEP-93 (SUPPL)	AXID (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	NIZATIDINE 150MG 300MG (NEW INDICATION -- TREATMENT OF ACTIVE BENIG GASTRIC ULCER UP TO 8 WEEI
20-213 22-SEP-93 (3 S)	MIOCHOL-E (POWDER FOR RECONSTITUTION)	IOLAB CLAREMONT, CA 91711	ACETYLCHOLINE CHLORIDE 20MG/VIAL (PARASYMPATHOMIMETIC) [MIOSIS OF THE IRIS]
18-343 23-SEP-93 (SUPPL)	CAPOTEN (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	CAPTOPRIL 12.5MG 25MG 50MG 100MG (NEW INDICATION -- TREATMENT OF LEFT VENTRIC DYSFUNCTION FOLLOWING MYOCARDIAL INFARCTION)
20-191 23-SEP-93 (1 S, V*)	ALOMIDE (SOLUTION/DROPS)	ALCON FORT WORTH, TX 76115	LODOXAMIDE TROMETHAMINE EQ 0.1% BASE (MAST CELL STABILIZER) [VERNAL KERATOCONJUNCTIV VERNAL CONJUNCTIVITIS, VERNAL KERATITIS]
19-816 24-SEP-93 (3 S)	ORUVAIL (CAPSULE, EXTENDED RELEASE)	WYETH AYERST RADNOR, PA 19087	KETOPROFEN 200MG (NSAID) [RHEUMATOID ARTHRITIS, OSTEOARTHRITIS]
20-051 24-SEP-93 (SUPPL)	GLYNASE (TABLET)	UPJOHN KALAMAZOO, MI 49001	GLYBURIDE 4.5MG 6MG (NEW STRENGTHS)

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

V* - Designated Orphan Drug

20-201** 27-SEP-93 (5 S)	DOBUTAMINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT LABS ABBOTT PARK, IL 60064	DOBUTAMINE HYDROCHLORID EQ 50MG BASE/100ML EQ 100MG BASE/100ML EQ 200MG BASE/100ML (SYMPATHOMIMETIC/BETA-1 ADRENERGIC AGONIST)
20-255** 27-SEP-93 (5 S)	DOBUTAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	BAXTER ROUND LAKE, IL 60073	DOBUTAMINE HYDROCHLORID EQ 50MG BASE/100ML EQ 100MG BASE/100ML EQ 200MG BASE/100ML EQ 400MG BASE/100ML (SYMPATHOMIMETIC/BETA-1 ADRENERGIC AGONIST)
20-269** 27-SEP-93 (5 S)	DOBUTAMINE IN DEXTROSE 5% (INJECTABLE)	ABBOTT LABS ABBOTT PARK, IL 60064	DOBUTAMINE HYDROCHLORID EQ 50MG BASE/100ML EQ 100MG BASE/100ML EQ 200MG BASE/100ML (SYMPATHOMIMETIC/BETA-1 ADRENERGIC AGONIST)
19-057 29-SEP-93 (SUPPL)	HYTRIN (TABLET)	ABBOTT LABS ABBOTT PARK, IL 60064	TERAZOSIN HYDROCHLORIDE EQ 1MG BASE EQ 2MG BASE EQ 5MG BASE EQ 10MG BASE (NEW CLAIM FOR ALREADY MARKETED DRUG PRODUCT -- TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLA
20-122 29-SEP-93 (SUPPL)	NIPENT (INJECTABLE)	PARKE DAVIS ANN ARBOR, MI 48105	PENTOSTATIN 10MG/VIAL (NEW INDICATION -- SINGLE AGENT TREATMENT FO UNTREATED HAIRY CELL LEUK

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

** - Effectiveness of the approval is delayed until October 19, 1993

20-223 29-SEP-93 (6 S)	HYTRIN (TABLET)	ABBOTT LABS ABBOTT PARK, IL 60064	TERAZOSIN HYDROCHLORIDE EQ 1MG BASE EQ 2MG BASE EQ 5MG BASE EQ 10MG BASE (ALPHA-1 ADRENORECEPTOR BLOCKER) [NEW CLAIM FOR ALREADY MARKETED DRUG PRODUCT -- TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLA
20-228 29-SEP-93 (3 P)	ATROVENT (SOLUTION)	BOEHRINGER INGELHEIM RIDGEFIELD, CT 06877	IPRATROPIUM BROMIDE 0.02% (BRONCHODILATOR)

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.

20-095 09-SEP-93	ZANTAC 150 (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 150MG BASE (HISTAMINE H2-RECEPTOR ANTAGONIST)
20-095 09-SEP-93	ZANTAC 300 (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE 300MG (HISTAMINE H2-RECEPTOR ANTAGONIST)
20-251 14-SEP-93	ZANTAC (GRANULE, EFFERVESCENT)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 150MG BASE/PACKET (HISTAMINE H2-RECEPTOR ANTAGONIST)
20-251 14-SEP-93	ZANTAC (TABLET, EFFERVESCENT)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 150MG BASE (HISTAMINE H2-RECEPTOR ANTAGONIST)
20-249 15-SEP-93	PEPCID IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	MERCK WEST POINT, PA 19486	FAMOTIDINE 0.4MG/ML (HISTAMINE H2-RECEPTOR ANTAGONIST)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
	ORIGINAL ABBREVIATED NDAS		
74-260 03-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	PUREPAC ELIZABETH, NJ 07207	CARBIDOPA 10MG LEVODOPA 100MG (ANTI-PARKINSON DRUGS)
74-260 03-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	PUREPAC ELIZABETH, NJ 07207	CARBIDOPA 25MG LEVODOPA 100MG (ANTI-PARKINSON DRUGS)
74-260 03-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	PUREPAC ELIZABETH, NJ 07207	CARBIDOPA 25MG LEVODOPA 250MG (ANTI-PARKINSON DRUGS)
73-449 23-SEP-93	TRIAMTERENE AND HYDROCHLOROTHIAZIDE (TABLET)	WATSON LABS CORONA, CA 91720	HYDROCHLOROTHIAZIDE 25MG TRIAMTERENE 37.5MG (DIURETICS AND RENAL TUBULE INHIBITORS)
81-213 23-SEP-93	ESTROPIPATE (TABLET)	WATSON LABS CORONA, CA 91720	ESTROPIPATE 0.75MG (ESTROGENS)
81-214 23-SEP-93	ESTROPIPATE (TABLET)	WATSON LABS CORONA, CA 91720	ESTROPIPATE 1.5MG (ESTROGENS)
81-215 23-SEP-93	ESTROPIPATE (TABLET)	WATSON LABS CORONA, CA 91720	ESTROPIPATE 3MG (ESTROGENS)
81-216 23-SEP-93	ESTROPIPATE (TABLET)	WATSON LABS CORONA, CA 91720	ESTROPIPATE 6MG (ESTROGENS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
	ORIGINAL ABBREVIATED NDAS		
73-485 27-SEP-93	VERAPAMIL HCL (INJECTABLE)	MARSAM CHERRY HILL, NJ 08034	VERAPAMIL HYDROCHLORIDE 2.5MG/ML (CALCIUM CHANNEL BLOCKERS)
74-002 27-SEP-93	TOLMETIN SODIUM (TABLET)	GENEVA BROOMFIELD, CO 80038	TOLMETIN SODIUM EQ 600MG BASE (NSAID)
74-270* 27-SEP-93	GEMFIBROZIL (TABLET)	LEDERLE PEARL RIVER, NY 10965	GEMFIBROZIL 600MG (LIPID ALTERING AGENTS)
64-045 28-SEP-93	AMIKACIN SULFATE (INJECTABLE)	GENSIA IRVINE, CA 92718	AMIKACIN SULFATE EQ 50MG BASE/ML EQ 250MG BASE/ML (AMINOGLYCOSIDES)
73-364 28-SEP-93	HALOPERIDOL (CONCENTRATE)	SILARX SPRING VALLEY, NY 10977	HALOPERIDOL LACTATE EQ 2MG BASE/ML (ANTIPSYCHOTICS)
73-381 28-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	WATSON LABS CORONA, CA 91720	CARBIDOPA 10MG LEVODOPA 100MG (ANTI-PARKINSON DRUGS)
73-382 28-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	WATSON LABS CORONA, CA 91720	CARBIDOPA 25MG LEVODOPA 100MG (ANTI-PARKINSON DRUGS)
73-383 28-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	WATSON LABS CORONA, CA 91720	CARBIDOPA 25MG LEVODOPA 250MG (ANTI-PARKINSON DRUGS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAS			
81-277 28-SEP-93	LEUCOVORIN CALCIUM (INJECTABLE)	GENSIA IRVINE, CA 92718	LEUCOVORIN CALCIUM EQ 100MG BASE/VIAL (FOLIC ACID ANTAGONIST ANTIDO
81-278 28-SEP-93	LEUCOVORIN CALCIUM (INJECTABLE)	GENSIA IRVINE, CA 92718	LEUCOVORIN CALCIUM EQ 50MG BASE/VIAL (FOLIC ACID ANTAGONIST ANTIDO

* - First Time Product Available Generically

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

ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

A ***tentative approval*** indicates that FDA has given an abbreviated new drug application (ANDA) provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Generic drug products that are the subjects of tentative approvals ***may not be*** legally ***marketed*** until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the ANDA receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluation" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

74-046 28-SEP-93	ALPRAZOLAM (TABLET)	ALPHAPHARM PTY LTD BRISBANE, AUSTRALIA	ALPRAZOLAM 0.25MG 0.5MG 1MG (ANXIOLYTIC)
74-257 28-SEP-93	NAPROXEN SODIUM (TABLET)	ROXANE COLUMBUS, OH 43216	NAPROXEN SODIUM 275MG 550MG (NSAID)
74-263 28-SEP-93	NAPROXEN (TABLET)	PUREPAC PHARM ELIZABETH, NJ 07207	NAPROXEN 250MG 375MG 500MG (NSAID)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
07-842 17-AUG-93	FLAXEDIL (INJECTABLE)	DAVIS AND GECK PEARL RIVER, NY 10965	GALLAMINE TRIETHIODIDE 20MG/ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
06-325 02-SEP-93	TUBOCURARINE CHLORIDE (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	TUBOCURARINE CHLORIDE 3MG/ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
09-766 07-SEP-93	METICORTEN (TABLET)	SCHERING KENILWORTH, NJ 07033	PREDNISONE 1MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
11-161 07-SEP-93	ARISTOCORT (TABLET)	LEDERLE LABS PEARL RIVER, NY 10965	TRIAMCINOLONE 1MG 2MG 4MG 8MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
11-283 07-SEP-93	KENACORT (TABLET)	SQUIBB NEW BRUNSWICK, NJ 08903	TRIAMCINOLONE DIACETATE 4MG 8MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
11-685 07-SEP-93	ARISTOCORT (INJECTABLE)	LEDERLE LABS PEARL RIVER, NY 10965	TRIAMCINOLONE DIACETATE 25MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
12-515 07-SEP-93	KENACORT (SYRUP)	SQUIBB NEW BRUNSWICK, NJ 08903	TRIAMCINOLONE DIACETATE EQ 4MG BASE/5ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
12-657 07-SEP-93	CELESTONE (TABLET)	SCHERING KENILWORTH, NJ 07033	BETAMETHASONE 0.6MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
12-665 07-SEP-93	VELBAN (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	VINBLASTINE SULFATE 10MG/VIAL (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
12-802 07-SEP-93	ARISTOCORT (INJECTABLE)	LEDERLE LABS PEARL RIVER, NY 10965	TRIAMCINOLONE DIACETATE 40MG/ML (LABELING REVISION -- WARNING; PRECAUTIONS)
14-215 07-SEP-93	CELESTONE (SYRUP)	SCHERING KENILWORTH, NJ 07033	BETAMETHASONE 0.6MG/5ML (LABELING REVISION -- WARNING; PRECAUTIONS)
14-602 07-SEP-93	CELESTONE SOLUSPAN (INJECTABLE)	SCHERING KENILWORTH, NJ 07033	BETAMETHASONE ACETATE 3MG/ML BETAMETHASONE SODIUM PHOSPHATE EQ 3MG BASE/ML (LABELING REVISION -- WARNING; PRECAUTIONS)
16-466 07-SEP-93	ARISTOSPAN (INJECTABLE)	LEDERLE LABS PEARL RIVER, NY 10965	TRIAMCINOLONE HEXACETONIDE 5MG/ML (LABELING REVISION -- WARNING; PRECAUTIONS)
17-561 07-SEP-93	CELESTONE (INJECTABLE)	SCHERING KENILWORTH, NJ 07033	BETAMETHASONE SODIUM PHOSP EQ 3MG BASE/ML (LABELING REVISION -- WARNING; PRECAUTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
18-949 07-SEP-93	SELDANE (TABLET)	MERRELL DOW CINCINNATI, OH 45215	TERFENADINE 60MG (LABELING REVISION -- BOXED WARNING; DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; PATIENT PACKAGE INSERT)
19-243 07-SEP-93	PROVENTIL (SOLUTION)	SCHERING KENILWORTH, NJ 07033	ALBUTEROL SULFATE EQ 0.083% BASE EQ 0.5% BASE (LABELING REVISION -- HOW SUPPLIED)
19-664 07-SEP-93	SELDANE-D (TABLET, EXTENDED RELEASE)	MERRELL DOW CINCINNATI, OH 45215	PSEUDOEPHEDRINE HYDROCHLO 120MG TERFENADINE 60MG (LABELING REVISION -- BOXED WARNING; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; PATIENT PACKAGE INSERT)
50-542 13-SEP-93	AMOXIL (TABLET, CHEWABLE)	SMITHKLINE BEECHAM PHILADELPHIA, PA 19101	AMOXICILLIN 125MG 250MG (LABELING REVISION -- WARNINGS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
17-892 14-SEP-93	HALCION (TABLET)	UPJOHN KALAMAZOO, MI 49001	TRIAZOLAM 0.125MG 0.25MG (LABELING REVISION -- OVERDOSAGE; HOW SUPPLIED)
18-276 14-SEP-93	XANAX (TABLET)	UPJOHN KALAMAZOO, MI 49001	ALPRAZOLAM 0.25MG 0.5MG 1MG 2MG (LABELING REVISION -- OVERDOSAGE; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-658 17-SEP-93	CLARITIN (TABLET)	SCHERING KENILWORTH, NJ 07033	LORATADINE 10MG (LABELING REVISION -- ADVERSE REACTIONS)
19-508 21-SEP-93	AXID (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	NIZATIDINE 150MG 300MG (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
19-478 22-SEP-93	ADALAT (CAPSULE)	MILES PHARM WEST HAVEN, CT 06516	NIFEDIPINE 10MG 20MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
19-834 22-SEP-93	PLENDIL (TABLET, EXTENDED RELEASE)	MERCK WEST POINT, PA 19486	FELODIPINE 5MG 10MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
50-138 22-SEP-93	BICILLIN C-R (INJECTABLE)	WYETH AYERST PHILADELPHIA, PA 19101	PENICILLIN G BENZATHINE 300,000 UNITS/ML PENICILLIN G PROCAINE 300,000 UNITS/ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
50-138 22-SEP-93	BICILLIN C-R 900/300 (INJECTABLE)	WYETH AYERST PHILADELPHIA, PA 19101	PENICILLIN G BENZATHINE 900,000 UNITS/2ML PENICILLIN G PROCAINE 300,000 UNITS/2ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
50-141 22-SEP-93	BICILLIN L-A (INJECTABLE)	WYETH AYERST PHILADELPHIA, PA 19101	PENICILLIN G BENZATHINE 300,000 UNITS/ML 600,000 UNITS/ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
18-343 23-SEP-93	CAPOTEN (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	CAPTOPRIL 12.5MG 25MG 37.5MG 50MG 100MG (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
18-731 23-SEP-93	BUSPAR (TABLET)	BRISTOL SYRACUSE, NY 13221	BUSPIRONE HYDROCHLORIDE 5MG 10MG (LABELING REVISION -- PRECAUTIONS)
19-558 23-SEP-93	PRINIVIL (TABLET)	MERCK WEST POINT, PA 19486	LISINOPRIL 5MG 10MG 20MG 40MG (LABELING REVISION -- ADVERSE REACTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
19-777 23-SEP-93	ZESTRIL (TABLET)	ZENECA PHARMS WILMINGTON, DE 19897	LISINOPRIL 5MG 10MG 20MG 40MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; HOW SUPPLIED)
19-778 23-SEP-93	PRINZIDE 12.5 (TABLET)	MERCK WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 20MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
19-778 23-SEP-93	PRINZIDE 25 (TABLET)	MERCK WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 25MG LISINOPRIL 20MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
19-888 23-SEP-93	ZESTORETIC 20/12.5 (TABLET)	ZENECA PHARMS WILMINGTON, DE 19897	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 20MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
19-888 23-SEP-93	ZESTORETIC 20/25 (TABLET)	ZENECA PHARMS WILMINGTON, DE 19897	HYDROCHLOROTHIAZIDE 25MG LISINOPRIL 20MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)
19-960 23-SEP-93	MANOPLAX (TABLET)	BOOTS SHREVEPORT, LA 71136	FLOSEQUINAN 50MG 75MG 100MG (LABELING REVISION -- WARNINGS; DOSAGE AND ADMINISTRATION)
20-051 24-SEP-93	GLYNASE (TABLET)	UPJOHN KALAMAZOO, MI 49001	GLYBURIDE 4.5MG 6MG (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; HOW SUPPLIED)
20-210 27-SEP-93	PROPULSID (TABLET)	JANSSEN PISCATAWAY, NJ 08855	CISAPRIDE MONOHYDRATE EQ 10MG BASE (LABELING REVISION -- PRECAUTIONS; HOW SUPPLIED)
19-545 28-SEP-93	DIDRONEL (INJECTABLE)	MGI MINNEAPOLIS, MN 55343	ETIDRONATE DISODIUM 50MG/ML (LABELING REVISION -- PRECAUTIONS)
19-961 28-SEP-93	GANITE (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	GALLIUM NITRATE 25MG/ML (LABELING REVISION -- ADVERSE REACTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
50-344 28-SEP-93	STATROL (OINTMENT)	ALCON LABS FORT WORTH, TX 76134	NEOMYCIN SULFATE EQ 3.5MG BASE/GM POLYMYXIN B SULFATE 10,000 UNITS/GM (LABELING REVISION -- DESCRIPTION; PRECAUTIONS)
50-456 28-SEP-93	STATROL (SOLUTION/DROPS)	ALCON LABS FORT WORTH, TX 76134	NEOMYCIN SULFATE EQ 3.5MG BASE/ML POLYMYXIN B SULFATE 16,250 UNITS/ML (LABELING REVISION -- DESCRIPTION; PRECAUTIONS)
19-057 29-SEP-93	HYTRIN (TABLET)	ABBOTT LABS ABBOTT PARK, IL 60064	TERAZOSIN HYDROCHLORIDE EQ 1MG BASE EQ 2MG BASE EQ 5MG BASE EQ 10MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; DOSAGE AND ADMINISTRATION)
20-122 29-SEP-93	NIPENT (INJECTABLE)	PARKE DAVIS ANN ARBOR, MI 48105	PENTOSTATIN 10MG/VIAL (LABELING REVISION -- CLINICAL STUDIES; INDICATIONS AND USAGE; ADVERSE EVENTS; DOSAGE AND ADMINISTRATION)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-653 30-SEP-93	ORTHO CYCLEN-21 (TABLET)	JOHNSON RW RARITAN, NJ 08869	ETHINYL ESTRADIOL 0.035MG NORGESTIMATE 0.25MG (LABELING REVISION -- CLINICAL PHARMACOLOGY)
19-653 30-SEP-93	ORTHO CYCLEN-28 (TABLET)	JOHNSON RW RARITAN, NJ 08869	ETHINYL ESTRADIOL 0.035MG NORGESTIMATE 0.25MG (LABELING REVISION -- CLINICAL PHARMACOLOGY)

LICENCE NUMBER LICENCE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
BIOLOGICAL PRODUCT LICENCES ISSUED			
1167 15-SEP-93	NONE (INJECTABLE)	NIH WARREN GRANT MAGNUSON CLINICAL CTR BETHESDA, MD 20892	PLASMA (TRANSFUSION) (A&B)
1167 15-SEP-93	NONE (INJECTABLE)	NIH WARREN GRANT MAGNUSON CLINICAL CTR BETHESDA, MD 20892	RED BLOOD CELLS (TRANSFUSION) (A&B)
1167 15-SEP-93	NONE (INJECTABLE)	NIH WARREN GRANT MAGNUSON CLINICAL CTR BETHESDA, MD 20892	WHOLE BLOOD (TRANSFUSION) (A&B)

LICENCE NUMBER LICENCE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)

BIOLOGICAL PRODUCT LICENCES ISSUED

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

DEVICE NUMBER APPROVABLE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
BIOLOGICAL PRODUCT DEVICE APPROVALS			
BK920039 02-SEP-93	PLASMA COLLECTION SYSTEM PCS 2	HAEMONETICS BRAINTREE, MA 02184	AUTOMATED BLOOD CELL SEPARA (C)
BK930010 09-SEP-93	HLA-B27 SCREENING SYSTEM	BECKTON DICKINSON IMMUNOCYTOMETRY SYS SAN JOSE, CA 95131	HLA TYPING SYSTEM (C)
BK930001 20-SEP-93	PLASMA SAMPLE VIAL	MILES BERKELEY, CA 94701	EMPTY CONTAINERS FOR THE COLLECTION AND PROCESSING O BLOOD AND BLOOD COMPONENTS (C)
BK920033 21-SEP-93	pHIX	IMMUCOR NORCROSS, GA 30091	POTENTIATING MEDIA FOR IN-VITRO DIAGNOSTIC USE (C)
BK920013 29-SEP-93	MTS DILUENT 2	MICRO TYPING SYS POMPANO BEACH, FL 33069	POTENTIATING MEDIA FOR IN-VITRO DIAGNOSTIC USE (C)
BK920014 29-SEP-93	MTS CENTRIFUGE	MICRO TYPING SYS POMPANO BEACH, FL 33069	BLOOD BANK CENTRIFUGE FOR IN-VITRO DIAGNOSTIC USE (C)
BK920016 29-SEP-93	MTS BUFFERED GEL CARD	MICRO TYPING SYS POMPANO BEACH, FL 33069	BLOOD BANK CENTRIFUGE FOR IN-VITRO DIAGNOSTIC USE (C)
BK920030 29-SEP-93	MTS DILUENT 1	MICRO TYPING SYS POMPANO BEACH, FL 33069	STABILIZED ENZYME SOLUTION (C)

DEVICE NUMBER APPROVABLE 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

P870076 09/29/93	FALOPE-RING BAND AND APPLICATOR SYSTEMS	CABOT MEDICAL CORPORATION LANGHORNE, PA 19047	APPROVAL FOR THE FALOPE-RING BAND AND APPLICATOR SYSTEMS
P890059 09/30/93	PD 1343 DISINFECTING TABLET WITH UNISOL SALINE	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL FOR THE PD 1343 DISINFECTING TABLET WITH UNISO SALINE
P900030 09/30/93	CONTIGEN BARD COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	APPROVAL FOR THE CONTIGEN BA COLLAGEN IMPLANT
P900060 09/29/93	CARBOMEDICS PROSTHETIC HEART VALVE	CARBOMEDICS, INC. AUSTIN, TX 78752-1793	APPROVAL FOR THE CARBOMEDIC PROSTHETIC HEART VALVE

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

MEDICAL DEVICE - PMA SUPPLEMENTS

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

N17600/S11 09/29/93	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT (MCH), SYRINGEAVITENE	MEDCHEM PRODUCTS,INC. WOBURN, MA 01801	MANUFACTURING MODIFICATION
P800022/S39 09/30/93	ZYDERM COLLAGEN IMPLANT AND ZYPLAST COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	CHANGE IN THE QUALITY CONTRO TEST METHOD FOR DETERMINING LIDOCAINE CONCENTRATIONS IN FINAL PRODUCT
P810002/S26 09/23/93	ST. JUDE MEDICAL PYROLYTIC CARBON HEART VALVE, HEMODYNAMIC PLUS SERIES	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	REVISED LABELING
P810046/S124 09/30/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, 1.5 MM BALLOON ACS SLALOM CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	APPROVAL FOR THE ACS SLALOM CORONARY DILATATION CATHETE WITH 1.5 MM BALLOON
P810046/S127 09/14/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, RX ELIPSE .014 DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE RX ELIPSE .0 DILATATION CATHETER
P810046/S142 09/02/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS CORONARY DILATATION CATHETERS LISTED IN THE SUBMISSION	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	MANUFACTURING MODIFICATION

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

MEDICAL DEVICE - PMA SUPPLEMENTS

P820059/S19 09/30/93	CUSTOMEYES-38 (POLYMACON) HYDROPHILIC CONTACT LENSES, NATURAL TOUCH (POLYMACON) CONTACT LENSES, CLEAR AND OPAQUE TINTED	SOLA BARNES HIND SUNNYVALE, CA 94086-5200	APPROVAL FOR ONE ALTERNATE MANUFACTURING SITE
P820065/S80 09/07/93	THE BOSTON LENS II (ITAFOCON A) AND THE BOSTON LENS IV (ITAFOCON B) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ONE ADDITIONAL FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AN DISTRIBUTION SITE
P820065/S81 09/07/93	THE BOSTON LENS II (ITAFOCON A) AND THE BOSTON LENS IV (ITAFOCON B) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ONE ADDITIONAL FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AN DISTRIBUTION SITE
P830045/S45 09/02/93	AFP MODEL 203 PULSE GENERATOR WITH MODEL 370 PROGRAMMER, MODEL 3070 AND MODEL 4553 TEMPORARY CARDIAC PACERS	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	REVISED LABELING
P850049/S03 09/23/93	COOK BIRD'S NEST VENA CAVA FILTER, GIANTURCO-ROEHM BIRD'S NEST VENA CAVA FILTER WITH PUSH-BUTTON HANDLE RELEASE	COOK INCORPORATED BLOOMINGTON, IN 47402	APPROVAL FOR THE PUSH-BUTTO HANDLE RELEASE MECHANISM

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTS	
P860019/S69 09/03/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER LONG RALLY	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A NEW MODEL CATHETER
P860019/S73 09/13/93	SCIMED CORONARY BALLOON DILATATION CATHETER, ACE 1CM TIP AND FLEXIBLE TIP PTCA CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	APPROVAL FOR TWO NEW MODEL CATHETERS
P860022/S43 09/07/93	THE BOSTON EQUALENS (ITAFLUOROFOCON A) AND THE BOSTON RXD (ITABISFLUOROFOCON A) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ONE ADDITIONAL FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AN DISTRIBUTION SITE
P860022/S44 09/07/93	THE BOSTON EQUALENS (ITAFLUOROFOCON A) AND THE BOSTON RXD (ITABISFLUOROFOCON A) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ONE ADDITIONAL FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AN DISTRIBUTION SITE
P870026/S05 09/28/93	RESOLVE/GP DAILY CLEANER	ALLERGAN OPTICAL IRVINE, CA 92713-9534	MANUFACTURING MODIFICATION
P870029/S07 09/29/93	STAY-WET 3 LUBRICATING AND WETTING SOLUTION, ULTRA 3 WETTING, LUBRICATING, REWETTING DROPS	SHERMAN PHARMACEUTICALS, INC. MANDEVILLE, LA 70470-1377	APPROVAL TO MODIFY THE PREVIOUSLY APPROVED STAY-WE LUBRICATING AND WETTING SOLU
P870077/S01 09/24/93	CARPENTIER EDWARDS DURAFLEX BIOPROSTHESIS	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	APPROVAL TO STOP COLLECTING YEARLY ECHO-DOPPLER DATA IN POSTAPPROVAL STUDY

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTS	
P880001/S39 09/15/93	FLUOREX 700 (FLUSILFOCON A), FLUOREX 500 (FLUSILFOCON B), AND FLUOREX 300 (FLUSILFOCON C) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	G.T. LABORATORIES CHICAGO, IL 60602	THREE ADDITIONAL CONTACT LEN FINISHING LABORATORIES TO BEC ALTERNATE MANUFACTURING AN DISTRIBUTION SITES
P880003/S16 09/23/93	OLYMPIX, SLEUTH XT, SLEEK AND PREDATOR PTCA DILATATION CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	MANUFACTURING MODIFICATIONS
P880027/S27 09/23/93	SCHNEIDER MICROSOFTRAC PTCA CATHETER, AND FREEHAND PTCA CATHETER MODELS: FH20-020, FH20-025, FH20-030, FH20-035, AND FH20-040	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	ALTERNATIVE DESIGN TO THE CURRENTLY MARKETED MONGOO PTCA CATHETER TO BE MARKETE UNDER THE TRADE NAME FREEHA PTCA CATHETER
P890034/S01 09/10/93	MODEL APT 1010 ULTRAHIGH FREQUENCY VENTILATOR	INFRASONICS, INC. ROCKY HILL, CT 06067-3440	SOFTWARE MODIFICATION
P890046/S20 09/20/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	APPROVAL FOR ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AN DISTRIBUTION SITE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTS	
P890046/S21 09/20/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	APPROVAL FOR ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AN DISTRIBUTION SITE
P890046/S22 09/20/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	APPROVAL FOR ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AN DISTRIBUTION SITE
P890046/S23 09/30/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	APPROVAL FOR ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AN DISTRIBUTION SITE
P890058/S10 09/02/93	NOVALENS (ROSIFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OCUTEC CORPORATION MORRISVILLE, NC 27560	APPROVAL FOR PRINCETON POLY LABS AS A SUB-CONTRACT MANUFACTURING FACILITY FOR T MANUFACTURE OF BUTTONS USE MFG
P890072/S09 09/07/93	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED) WITH AN ULTRAVIOLET LIGHT ABSORBER	PROGRESSIVE OPTICAL RESEARCH, LTD. ALBERTA, CANADA	THREE ADDITIONAL CONTACT LEN FINISHING LABORATORIES TO BE ALTERNATE MANUFACTURING AN DISTRIBUTING SITES
P910001/S02 09/23/93	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM MODEL 4	SPECTRANETICS CORPORATION COLORADO SPRINGS, CO 80907-5159	APPROVAL FOR THE CVX-300 EXC LASER SYSTEM, MODEL 4

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

MEDICAL DEVICE - PMA SUPPLEMENTS

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

ORIGINAL VETRINARY NADAs

141-014 13-AUG-93	SUPER-OV (POWDER)	COWS	AUSA INTL TYLER, TX 75703	FOLLICLE STIMULATING HORMONE 75 UNITS/VIAL

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ABBREVIATED VETERINARY NADAs FOR SEPTEMBER 1993.

SUPPLEMENTAL VETERINARY NADAs

065-252 05-AUG-93	STREP SOL (SOLUTION)	CALVES, VETERINARY CHICKENS, SVCS SWINE	MEDESTO, CA 95354	STREPTOMYCIN SULFATE 250MG/ML

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

ORIGINAL VETRINARY NADAs

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

ORIGINAL VETRINARY NADAs

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

ORIGINAL VETRINARY NADAs

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) 594-2186

Center for Biologics Evaluation and Research
Joseph Wilczek (301) 594-2012

Center for Veterinary Medicine
Norman Turner
(301) 594-1623

*To whom general inquiries should be directed.

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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

20-195 04-OCT-93 (5 S)	FENTANYL (TROCHE/LOZENGE)	ANESTA SALT LAKE CITY, UT 84103	FENTANYL CITRATE EQ 0.2MG BASE EQ 0.3MG BASE EQ 0.4MG BASE (NARCOTIC ANALGESIC)
19-762 12-OCT-93 (3 S)	TESTODERM (FILM, EXTENDED RELEASE)	ALZA PALO ALTO, CA 94303	TESTOSTERONE 4MG/24HR 6MG/24HR (ANDROGEN)
50-684 22-OCT-93 (1, 4 S)	ZOSYN (INJECTABLE)	LEDERLE LABS PEARL RIVER, NY 10965	PIPERACILLIN SODIUM EQ 2GM BASE/VIAL (ANTIBIOTIC, PENICILLIN) TAZOBACTAM SODIUM EQ 250MG BASE/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

(BETA LACTAMASE INHIBITOR)

50-684	ZOSYN	LEDERLE LABS	PIPERACILLIN SODIUM
22-OCT-93	(INJECTABLE)	PEARL RIVER, NY	EQ 3GM BASE/VIAL
(1, 4 S)	10965	(ANTIBIOTIC, PENICILLIN)	
		TAZOBACTAM SODIUM	
		EQ 375MG BASE/VIAL	
		(BETA LACTAMASE INHIBITOR)	

50-684	ZOSYN	LEDERLE LABS	PIPERACILLIN SODIUM
22-OCT-93	(INJECTABLE)	PEARL RIVER, NY	EQ 4GM BASE/VIAL
(1, 4 S)	10965	(ANTIBIOTIC, PENICILLIN)	
		TAZOBACTAM SODIUM	
		EQ 500MG BASE/VIAL	
		(BETA LACTAMASE INHIBITOR)	

50-684	ZOSYN	LEDERLE LABS	PIPERACILLIN SODIUM
22-OCT-93	(INJECTABLE)	PEARL RIVER, NY	EQ 36GM BASE/VIAL
(1, 4 S)	10965	(ANTIBIOTIC, PENICILLIN)	
		TAZOBACTAM SODIUM	
		EQ 4.5GM BASE/VIAL	
		(BETA LACTAMASE INHIBITOR)	

19-627	DIPRIVAN	ZENECA	PROPOFOL
26-OCT-93	(INJECTABLE)	WILMINGTON, DE	10MG/ML
(SUPPL)	19897	(NEW INDICATION --	
		PEDIATRIC ANESTHESIA IN	
		CHILDREN 3 YEARS AND OLDER)	

19-885	ACCUPRIL	PARKE DAVIS	QUINAPRIL HYDROCHLORIDE
29-OCT-93	(TABLET)	ANN ARBOR, MI	EQ 5MG BASE
(SUPPL)	48106	EQ 10MG BASE	
		EQ 20MG BASE	

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

			EQ 40MG BASE (NEW INDICATION -- ADJUNCTIVE THERAPY IN THE MANAGEMENT OF HEART FAILURE)
20-279	DERMATOP	HOECHST ROUSSEL	PREDNICARBATE
29-OCT-93	(CREAM)	SOMERVILLE, NJ	0.1%
(3 S)		08876	(CORTICOSTEROID)

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.

20-126	ZONALON	GENDERM	DOXEPIN HYDROCHLORIDE
15-OCT-93	(CREAM)	LINCOLNSHIRE, IL	5%
	60069	(ANTIPRURITIC)	
20-296	MEGACE	BRISTOL MYERS SQUIBB	MEGESTROL ACETATE
20-OCT-93	(TABLET)	EVANSVILLE, IN	250MG
	47721	(PROGESTERONE DERIVATIVE)	
19-183	CARAFATE	MARION MERRELL DOW	SUCRALFATE
25-OCT-93	(SUSPENSION)	KANSAS CITY, MO	500MG/5ML
	64134	(ANTIULCER)	

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

ORIGINAL ABBREVIATED NDAs

63-321	VANCOLED	LEDERLE	VANCOMYCIN HYDROCHLORIDE
15-OCT-93	(POWDER FOR RECONSTITUTION)	CAROLINA, PR 00630	EQ 250MG BASE/5ML EQ 500MG BASE/6ML (ANTIBIOTIC, GLYCOPEPTIDE)
74-046*	ALPRAZOLAM	ALPHAPHARM	ALPRAZOLAM
19-OCT-93	(TABLET)	BRISBANE, AUSTRALIA	0.25MG 0.5MG 1MG (ANXIOLYTIC)
74-174*	ALPRAZOLAM	LEDERLE	ALPRAZOLAM
19-OCT-93	(TABLET)	PEARL RIVER, NY 10965	0.25MG 0.5MG 1MG 2MG (ANXIOLYTIC)
74-199*	ALPRAZOLAM	ROXANE	ALPRAZOLAM
19-OCT-93	(TABLET)	COLUMBUS, OH 43216	0.25MG 0.5MG 1MG (ANXIOLYTIC)
74-206*	DOBUTAMINE HCL	GENSIA	DOBUTAMINE HYDROCHLORIDE
19-OCT-93	(INJECTABLE)	IRVINE, CA 92718	EQ 12.5MG BASE/ML (SYMPATHOMIMETIC/ BETA-1 ADRENERGIC AGONIST)
64-032	TAZICEF	SMITHKLINE BEECHAM	CEFTAZIDIME
31-OCT-93	(INJECTABLE)	PHILADELPHIA, PA 19101	1GM/VIAL 2GM/VIAL (ANTIBIOTIC, CEPHEM)

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

ORIGINAL ABBREVIATED NDAs

64-033	CEFAZOLIN SODIUM	SMITHKLINE BEECHAM	CEFAZOLIN SODIUM
31-OCT-93	(INJECTABLE)	PHILADELPHIA, PA	EQ 1GM BASE/VIAL
	19101	(ANTIBIOTIC, CEPHEM)	

* - First Time Product Available Generically

73-458	CLEMASTINE FUMARATE	GENEVA	CLEMASTINE FUMARATE
31-OCT-93	(TABLET)	BROOMFIELD, CO	1.34MG
	80020	(ANTIHISTAMINE)	

73-459	CLEMASTINE FUMARATE	GENEVA	CLEMASTINE FUMARATE
31-OCT-93	(TABLET)	BROOMFIELD, CO	2.68MG
	80020	(ANTIHISTAMINE)	

73-661	PINDOLOL	NOVOPHARM	PINDOLOL
31-OCT-93	(TABLET)	SCARBOROUGH, ONTARIO	5MG
	CANADA		10MG
		(BETA ADRENERGIC BLOCKER)	

74-075	CLEMASTINE FUMARATE	BARRE	CLEMASTINE FUMARATE
31-OCT-93	(SYRUP)	BALTIMORE, MD	EQ 0.5MG BASE/5ML
	21207	(ANTIHISTAMINE)	

74-172*	NADOLOL	MYLAN	NADOLOL
31-OCT-93	(TABLET)	MORGANTOWN, WV	20MG
	26505		40MG
			80MG
		(BETA ADRENERGIC BLOCKER)	

74-203	ATENOLOL AND	MYLAN	ATENOLOL
31-OCT-93	CHLORTHALIDONE	MORGANTOWN, WV	50MG
(TABLET)	26505	CHLORTHALIDONE	

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

ORIGINAL ABBREVIATED NDAs

			25MG
			(ANTIHYPERTENSIVE)
74-203	ATENOLOL AND	MYLAN	ATENOLOL
31-OCT-93	CHLORTHALIDONE	MORGANTOWN, WV	100MG
	(TABLET)	26505	CHLORTHALIDONE
			25MG
			(ANTIHYPERTENSIVE)
74-256	GEMFIBROZIL	LEMMON	GEMFIBROZIL
31-OCT-93	(TABLET)	SELLERSVILLE, PA	600MG
		18960	(LIPID ALTERING AGENTS)

* - First Time Product Available Generically

74-312*	ALPRAZOLAM	ROXANE	ALPRAZOLAM
31-OCT-93	(CONCENTRATE)	COLUMBUS, OH	1MG/ML
		43216	(ANXIOLYTIC)
74-314*	ALPRAZOLAM	ROXANE	ALPRAZOLAM
31-OCT-93	(SOLUTION)	COLUMBUS, OH	0.5MG/5ML
		43216	(ANXIOLYTIC)
74-342	ALPRAZOLAM	PUREPAC PHARM	ALPRAZOLAM
31-OCT-93	(TABLET)	ELIZABETH, NJ	0.25MG
		07207	0.5MG
			1MG
			2MG
			(ANXIOLYTIC)

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 INGREDIENT(S)
TENTATIVE APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S) CLASSIFICATION(S)

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

74-246	CIMETIDINE	MYLAN	CIMETIDINE
22-OCT-93	(TABLET)	MORGANTOWN, WV 26504	200MG 300MG 400MG 800MG (HISTAMINE H2-RECEPTOR ANTAGONIST)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
17-769 24-SEP-93	CALCIMAR (INJECTABLE) 19034	RHONE POULENC RORER FT WASHINGTON, PA	CALCITONIN, SALMON 200IU/ML (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS)
19-190 04-OCT-93	TRIPHASIL-28 (TABLET) 19101	WYETH AYERST PHILADELPHIA, PA	ETHINYL ESTRADIOL 0.03MG,0.04MG,0.03MG LEVONORGESTREL 0.05MG,0.075MG,0.125MG (LABELING REVISION -- DESCRIPTION; INDICATIONS AND USAGE; PRECAUTIONS; PATIENT PACKAGE INSERT)
50-012 05-OCT-93	GARAMYCIN (INJECTABLE) 07033	SCHERING KENILWORTH, NJ	GENTAMICIN SULFATE EQ 40MG BASE/ML (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS)
50-437 05-OCT-93	GARAMYCIN (INJECTABLE) 07033	SCHERING KENILWORTH, NJ	GENTAMICIN SULFATE EQ 10MG BASE/ML (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS)
20-062 06-OCT-93	CARDIZEM CD (CAPSULE, EXTENDED RELEASE)	CARDERM THALWIL, SWITZERLAND	DILTIAZEM HYDROCHLORIDE 120MG 180MG 240MG 300MG (LABELING REVISION -- 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

50-585	ROCEPHIN	ROCHE	CEFTRIAXONE SODIUM
07-OCT-93	(INJECTABLE)	NUTLEY, NJ	EQ 250MG BASE/VIAL
		07110	EQ 500MG BASE/VIAL
			EQ 1GM BASE/VIAL
			EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(LABELING REVISION --
			ADVERSE REACTIONS)
50-624	ROCEPHIN W/ DEXTROSE	ROCHE	CEFTRIAXONE SODIUM
07-OCT-93	IN PLASTIC CONTAINER	NUTLEY, NJ	EQ 20MG BASE/ML
	(INJECTABLE)	07110	EQ 40MG BASE/ML
			(LABELING REVISION --
			ADVERSE REACTIONS)
50-675	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
12-OCT-93	(GRANULE,	KALAMAZOO, MI	EQ 50MG BASE/5ML
	FOR RECONSTITUTION)	49001	EQ 100MG BASE/5ML
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			DOSAGE AND ADMINISTRATION)
50-605	CEFTIN	GLAXO	CEFUROXIME AXETIL
18-OCT-93	(TABLET)	RES TRIANGLE PK, NC	EQ 125MG BASE
		27709	EQ 250MG BASE
			EQ 500MG BASE
			(LABELING REVISION --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			CLINICAL PHARMACOLOGY;
			DOSAGE AND ADMINISTRATION)
50-624	ROCEPHIN W/ DEXTROSE	ROCHE	CEFTRIAXONE SODIUM
20-OCT-93	IN PLASTIC CONTAINER	NUTLEY, NJ	EQ 20MG BASE/ML
	(INJECTABLE)	07110	EQ 40MG BASE/ML
			(LABELING REVISION --
			DOSAGE AND ADMINISTRATION)
50-675	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
20-OCT-93	(GRANULE,	KALAMAZOO, MI	EQ 50MG BASE/5ML
	FOR RECONSTITUTION)	49001	EQ 100MG BASE/5ML
			(LABELING REVISION --
			INDICATIONS AND USAGE)
18-225	BUMEX	ROCHE	BUMETANIDE
21-OCT-93	(TABLET)	NUTLEY, NJ	0.5MG
		07110	1MG
			2MG
			(LABELING REVISION --
			PRECAUTIONS)
18-226	BUMEX	ROCHE	BUMETANIDE
21-OCT-93	(INJECTABLE)	NUTLEY, NJ	0.25MG/ML
		07110	(LABELING REVISION --
			PRECAUTIONS)
18-998	VASOTEC	MERCK	ENALAPRIL MALEATE
21-OCT-93	(TABLET)	WEST POINT, PA	2.5MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		19486	5MG 10MG 20MG (LABELING REVISION -- ADVERSE REACTIONS)
19-221	VASERETIC	MERCK	ENALAPRIL MALEATE
21-OCT-93	(TABLET)	WEST POINT, PA	10MG
		19486	HYDROCHLOROTHIAZIDE 25MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
19-309	VASOTEC	MERCK	ENALAPRILAT
21-OCT-93	(INJECTABLE)	WEST POINT, PA	1.25MG/ML
		19486	(LABELING REVISION -- ADVERSE REACTIONS)
19-851	LOTENSIN	CIBA PHARM	BENAZEPRIL HYDROCHLORIDE
21-OCT-93	(TABLET)	SUMMIT, NJ	EQ 5MG BASE
		07901	EQ 10MG BASE EQ 20MG BASE EQ 40MG BASE (LABELING REVISION -- WARNINGS; PRECAUTIONS)
20-033	LOTENSIN HCT	CIBA PHARM	BENAZEPRIL HYDROCHLORIDE
21-OCT-93	(TABLET)	SUMMIT, NJ	5MG
		07901	HYDROCHLOROTHIAZIDE 6.25MG (LABELING REVISION --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

WARNINGS; PRECAUTIONS)

20-033	LOTENSIN HCT	CIBA PHARM	BENAZEPRIL HYDROCHLORIDE
21-OCT-93	(TABLET)	SUMMIT, NJ	10MG
		07901	HYDROCHLOROTHIAZIDE
			12.5MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
20-033	LOTENSIN HCT	CIBA PHARM	BENAZEPRIL HYDROCHLORIDE
21-OCT-93	(TABLET)	SUMMIT, NJ	20MG
		07901	HYDROCHLOROTHIAZIDE
			12.5MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
20-033	LOTENSIN HCT	CIBA PHARM	BENAZEPRIL HYDROCHLORIDE
21-OCT-93	(TABLET)	SUMMIT, NJ	20MG
		07901	HYDROCHLOROTHIAZIDE
			25MG
			(LABELING REVISION -- WARNINGS; PRECAUTIONS)

20-209	OXISTAT	GLAXO	OXICONAZOLE NITRATE
21-OCT-93	(LOTION)	RES TRIANGLE PK, NC	EQ 1% BASE
		27709	(LABELING REVISION --
			CLINICAL PHARMACOLOGY)

18-080	DEXTROSE 10%	ABBOTT LABS	DEXTROSE
25-OCT-93	IN PLASTIC CONTAINER	ABBOTT PARK, IL	10GM/100ML
	(INJECTABLE)	60064	(LABELING REVISION --
			DESCRIPTION; PRECAUTIONS;
			HOW SUPPLIED)

18-090	SODIUM CHLORIDE 0.45%	ABBOTT LABS	SODIUM CHLORIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

25-OCT-93	IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT PARK, IL 60064	450MG/100ML (LABELING REVISION -- DESCRIPTION; PRECAUTIONS; HOW SUPPLIED)
18-887 25-OCT-93	INTAL (AEROSOL, METERED)	FISONS BEDFORD, MA 01730	CROMOLYN SODIUM 0.8MG/INH (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-813 25-OCT-93	DURAGESIC (FILM, EXTENDED RELEASE)	ALZA PALO ALTO, CA 94303	FENTANYL 0.6MG/24HR 1.2MG/24HR 1.8MG/24HR 2.4MG/24HR (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
19-627 26-OCT-93	DIPRIVAN (INJECTABLE)	ZENECA LTD WILMINGTON, DE 19897	PROPOFOL 10MG/ML (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; 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

18-663	CHYMODIACTIN	BOOTS PHARMS	CHYMOPAPAIN
28-OCT-93	(INJECTABLE)	LINCOLNSHIRE, IL	4,000 UNITS/VIAL
		60069	(LABELING REVISION -- BOXED WARNINGS; DESCRIPTION; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-885	ACCUPRIL	PARKE DAVIS	QUINAPRIL HYDROCHLORIDE
29-OCT-93	(TABLET)	ANN ARBOR, MI	EQ 5MG BASE
		48106	EQ 10MG BASE EQ 20MG BASE EQ 40MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
50-010	ILOSONE	LILLY	ERYTHROMYCIN ESTOLATE
29-OCT-93	(SUSPENSION)	INDIANAPOLIS, IN	125MG/5ML
		46285	(LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)
50-365	ILOSONE	LILLY	ERYTHROMYCIN ESTOLATE
29-OCT-93	(TABLET)	INDIANAPOLIS, IN	500MG
		46285	(LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-426	ILOSONE	LILLY	ERYTHROMYCIN ESTOLATE
29-OCT-93	(CAPSULE)	INDIANAPOLIS, IN 46285	250MG
		(LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)	

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

BIOLOGICAL PRODUCT LICENSES ISSUED

THERE ARE NO BIOLOGICAL PRODUCT LICENSES ISSUED FOR THE MONTH OF OCTOBER 1993.

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK920037	PEG (PLUS)	ORGANON TEKNIKA	POLYETHYLENE GLYCOL ENHANCEMENT
21-OCT-93		DURHAM, NC	ADDITIVE FOR ADDITIVE ANTIBODY
		27704	DETECTION TEST
			(C)
BK930014	GTI REDUCED WASH	GENETIC TESTING INST	ELUTION KIT FOR RAPID ELUTION
28-OCT-93	ELUTION KIT	BROOKVILLE, WI	OF ANTIBODIES FROM RBC
		53045	(C)
BK930025	KELSEA CLAMP	ICU MED	NEEDLE PROTECTOR
28-OCT-93	NEEDLE COVER	IRVINE, CA	(C)
	AND GUIDE	92718	

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 APPROVAL APPLICATIONS FOR THE MONTH OF OCTOBER 1993.

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

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

N12159/S12	SURGICEL/SURGICEL ABSORBABLE HEMOSTAT	JOHNSON AND JOHNSON MEDICAL, INC. ARLINGTON, VA 76004-3130	APPROVAL TO MARKET A 1 INCH X 3.5 INCH SIZE SURGICEL NU-KNIT ABSORBABLE HEMOSTAT	10/13/93
N18033/S24	HYDRO-MARC (ETAFILCON A) HYDROPHILIC CONTACT LENS, ACUVUE (ETAFILCON A) HYDROPHILIC CONTACT LENS	VISTAKON, INC. JACKSONVILLE, FL 32247-0157	REVISED LABELING	10/27/93
P810046/S140	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE RX ELLIPSE .014 DILATATION CATHETER	10/21/93
P810046/S145	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS SPECTRUM CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	ADDITION OF A WARNING TO THE INSTRUCTIONS FOR USE AND TO THE PACKAGE LABELS FOR THE ACS SPECTRUM CORONARY DILATATION CATHETER	10/13/93
P820083/S14	GORE-TEX EPTFE SUTURE	W.L. GORE & ASSOCIATES, INC. FLAGSTAFF, AZ 86003-2300	APPROVAL FOR AN ALTERNATIVE STERILIZATION	10/15/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
P840004/S07	SATURN II (SYNERGICON A) CONTACT LENSES, SOFTPERM (SYNERGICON A) CONTACT LENSES	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	REVISED LABELING	10/14/93
P840040/S38	BSC/MANSFIELD PTCA CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172-2414	MANUFACTURING MODIFICATIONS	10/21/93
P850021/S24	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETERS, THE SLINKY AND REACH .14 PTCA CATHETERS	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	MANUFACTURING MODIFICATIONS	10/25/93
P880013/S03	HFV INFANT STAR VENTILATOR	INFRASONICS, INC. SAN DIEGO, CA 92121	PACKAGE COLOR CHANGE	10/26/93
P890068/S01	ULTRAVIOLET-ABSORBING	CHIRON INTRAOPTICS, INC. IRVINE, CA	APPROVAL FOR ULTRAVIOLET-ABSORBING	10/22/93

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
		MEDICAL DEVICE - PMA SUPPLEMENTALS		
	POSTERIOR CHAMBER INTRAOCULAR LENSES	92718-1903	POSTERIOR CHAMBER INTRAOCULAR LENSES APPROVED UNDER DGS INC.'S PMAS P880072 AND P880072/S7, WHICH DGS LICENSED TO CII	
P900032/S15	DYMER 200+ EXCIMER LASER SYSTEM	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA 92718	MANUFACTURING MODIFICATIONS	10/25/93

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 THE MONTH OF OCTOBER 1993.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR THE MONTH OF OCTOBER 1993.

SUPPLEMENTAL VETERINARY NADAs

140-856	PG 600	SWINE	INTERVET	CHORIONIC
08-30-93	(POWDER FOR RECONSTITUTION)		MILLSBORO, DE 19966	GONADOTROPIN 200 IU/VIAL SERUM GONADOTROPIN 400 IU/VIAL
115-581	RUMENSIN	CATTLE	MOORMAN MANUFACTURING NORTH LITTLE ROCK, AR 72119	MONENSIN 300GM/TON
09-20-93	(BLOCKS)			
44-581	FLAVOMYCIN	CATTLE	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	BAMBERMYCINS 2GM/LB 4GM/LB 10GM/LB
09-21-93	(POWDER)			

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 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
*George R. Scott (301) 443-3910

Center for Devices and Radiological Health
Mary Jo Robinson (301) 594-2186

Center for Biologics Evaluation and Research
Joseph Wilczek (301) 594-2012

Center for Veterinary Medicine
Norman Turner
(301) 594-1623

*To whom general inquiries should be directed.

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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

18-998 VASOTEC MERCK ENALAPRIL MALEATE
04-NOV-93 (TABLET) WEST POINT, PA 2.5MG
(SUPPL) 19486 5MG
10MG
20MG
(NEW INDICATION --
ASYMPTOMATIC LEFT
VENTRICULAR DYSFUNCTION)

20-330 TIMOPTIC-XE MERCK TIMOLOL MALEATE
04-NOV-93 (SOLUTION/DROPS) WEST POINT, PA EQ 0.25% BASE
(3 S) 19486 EQ 0.5% BASE
(BETA ADRENERGIC BLOCKER)

19-516 MS CONTIN PURDUE FREDERICK MORPHINE SULFATE

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

08-NOV-93	(TABLET,	NORWALK, CT	200MG
(SUPPL)	EXTENDED RELEASE)	06850	(NEW STRENGTH)
20-219	LIVOSTIN	IOLAB	LEVOCABASTINE HYDROCHLORIDE
10-NOV-93	(SUSPENSION/DROPS)	CLAREMONT, CA	EQ 0.05% BASE
(1 P)		91711	(ANTIHISTAMINE)
20-168	NUTROPIN	GENENTECH	SOMATROPIN, BIOSYNTHETIC
17-NOV-93	(INJECTABLE)	SAN FRANCISCO, CA	5MG/VIAL
(5 S)		94080	10MG/VIAL
			(HUMAN GROWTH HORMONE)
19-778	PRINZIDE 10-12.5	MERCK	HYDROCHLOROTHIAZIDE
18-NOV-93	(TABLET)	WEST POINT, PA	12.5MG
(SUPPL)		19486	LISINOPRIL
			10MG
			(NEW DOSAGE REGIMEN --
			DOSING REGIMEN OF 10MG
			LISINOPRIL AND 12.5MG
			HYDROCHLOROTHIAZIDE)
			[NEW STRENGTH]
19-778	PRINZIDE 20-12.5	MERCK	HYDROCHLOROTHIAZIDE
18-NOV-93	(TABLET)	WEST POINT, PA	12.5MG
(SUPPL)		19486	LISINOPRIL
			20MG
			(NEW DOSAGE REGIMEN --
			DOSING REGIMEN OF 10MG
			LISINOPRIL AND 12.5MG
			HYDROCHLOROTHIAZIDE)
19-778	PRINZIDE 20-25	MERCK	HYDROCHLOROTHIAZIDE
18-NOV-93	(TABLET)	WEST POINT, PA	25MG
(SUPPL)		19486	LISINOPRIL
			20MG
			(NEW DOSAGE REGIMEN --
			DOSING REGIMEN OF 10MG

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

LISINOPRIL AND 12.5MG
HYDROCHLOROTHIAZIDE)

19-888 ZESTORETIC 10-12.5 ZENECA HYDROCHLOROTHIAZIDE
18-NOV-93 (TABLET) WILMINGTON, DE 12.5MG
(SUPPL) 19897 LISINOPRIL
10MG
(NEW DOSAGE REGIMEN --
DOSING REGIMEN OF 10MG
LISINOPRIL AND 12.5MG
HYDROCHLOROTHIAZIDE)
[NEW STRENGTH]

19-888 ZESTORETIC 20-12.5 ZENECA HYDROCHLOROTHIAZIDE
18-NOV-93 (TABLET) WILMINGTON, DE 12.5MG
(SUPPL) 19897 LISINOPRIL
20MG
(NEW DOSAGE REGIMEN --
DOSING REGIMEN OF 10MG
LISINOPRIL AND 12.5MG
HYDROCHLOROTHIAZIDE)

19-888 ZESTORETIC 20-25 ZENECA HYDROCHLOROTHIAZIDE
18-NOV-93 (TABLET) WILMINGTON, DE 25MG
(SUPPL) 19897 LISINOPRIL
20MG
(NEW DOSAGE REGIMEN --
DOSING REGIMEN OF 10MG
LISINOPRIL AND 12.5MG
HYDROCHLOROTHIAZIDE)

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

19-353	ALFENTA	JANSSEN	ALFENTANIL HYDROCHLORIDE
22-NOV-93	(INJECTABLE)	PISCATAWAY, NJ	EQ 0.5MG BASE/ML
(SUPPL)		08854	(NEW INDICATION -- ANALGESIC COMPONENT FOR MONITORED ANESTHESIA CARE)
20-142	CATAFLAM	GEIGY	DICLOFENAC POTASSIUM
24-NOV-93	(TABLET)	SUMMIT, NJ	25MG
(3 S)		07901	50MG (NONSTEROIDAL ANTI-INFLAMMATORY)

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.

20-187	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
02-NOV-93	(CAPSULE)	INDIANAPOLIS, IN	EQ 10MG BASE
	46285		EQ 20MG BASE
			(ANTIDEPRESSANT)
			[OBSESSIVE COMPULSIVE
			DISORDER]
20-187	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
02-NOV-93	(SOLUTION)	INDIANAPOLIS, IN	EQ 20MG BASE/5ML
	46285		(ANTIDEPRESSANT)
			[OBSESSIVE COMPULSIVE
			DISORDER]
20-151	EFFEXOR	WYETH AYERST	VENLAFAXINE HYDROCHLORIDE
08-NOV-93	(TABLET)	PHILADELPHIA, PA	EQ 12.5MG BASE
	19101		EQ 25MG BASE
			EQ 37.5MG BASE
			EQ 50MG BASE
			EQ 75MG BASE
			EQ 100MG BASE
			(ANTIDEPRESSANT)

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

ORIGINAL ABBREVIATED NDAs

73-507*	MICONAZOLE NITRATE	ABLE	MICONAZOLE NITRATE
19-NOV-93	(SUPPOSITORY)	SOUTH PLAINFIELD, NJ	100MG
	07080	(ANTIFUNGAL)	
		(OTC)	
73-508*	MICONAZOLE NITRATE	ABLE	MICONAZOLE NITRATE
19-NOV-93	(SUPPOSITORY)	SOUTH PLAINFIELD, NJ	200MG
	07080	(ANTIFUNGAL)	
40-058*	PROCHLORPERAZINE	G AND W	PROCHLORPERAZINE
24-NOV-93	(SUPPOSITORY)	SOUTH PLAINFIELD, NJ	25MG
	07080	(ANTIEMETIC, ANTIPSYCHOTIC)	
64-052	TOBRAMYCIN	BAUSCH AND LOMB	TOBRAMYCIN
29-NOV-93	(SOLUTION/DROPS)	TAMPA, FL	0.3%
	33637	(ANTIBIOTIC, AMINOGLYCOSIDE)	
74-086	DOBUTAMINE HCL	ABBOTT	DOBUTAMINE HYDROCHLORIDE
29-NOV-93	(INJECTABLE)	ABBOTT PARK, IL	EQ 12.5MG BASE/ML
	60064	(SYMPATHOMIMETIC/	
		BETA-1 ADRENERGIC AGONIST)	
73-528	LOPERAMIDE HCL	ABLE	LOPERAMIDE HYDROCHLORIDE
30-NOV-93	(TABLET)	SOUTH PLAINFIELD, NJ	2MG
	07080	(ANTIDIARRHEAL)	
		(OTC)	
74-079*	DILTIAZEM HCL	PROGRAPHARM	DILTIAZEM HYDROCHLORIDE
30-NOV-93	(CAPSULE,	SELLERSVILLE, PA	60MG
	EXTENDED RELEASE)	18960	90MG
			120MG
		(CALCIUM ION	
		INFLUX INHIBITOR)	

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAs			
74-114 30-NOV-93	DOBUTAMINE HCL (INJECTABLE)	STERIS PHOENIX, AZ 85043	DOBUTAMINE HYDROCHLORIDE EQ 12.5MG BASE/ML (SYMPATHOMIMETIC/ BETA-1 ADRENERGIC AGONIST)

* First Time Product Available Generically

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

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

74-142 30-NOV-93	NAPROXEN SODIUM (TABLET)	NOVOPHARM LTD SCARBOROUGH, ONTARIO CANADA	NAPROXEN SODIUM 275MG 550MG (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

09-458	CORTISONE ACETATE	RICHLYN LABS	CORTISONE ACETATE
06-OCT-93	(TABLET)	PHILADELPHIA, PA	25MG
	19124	(LABELING REVISION -- WARNINGS; PRECAUTIONS)	
17-351	CORTIFOAM	REED AND CARNRICK	HYDROCORTISONE ACETATE
15-OCT-93	(AEROSOL)	JERSEY CITY, NJ	10%
	07302	(LABELING REVISION -- WARNINGS; PRECAUTIONS)	
08-453	ANECTINE	BURROUGHS WELLCOME	SUCCINYLCHOLINE CHLORIDE
29-OCT-93	(INJECTABLE)	RES TRIANGLE PK, NC	20MG/ML
	27709	500MG/VIAL 1GM/VIAL (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)	
07-073	AZULFIDINE	KABI	SULFASALAZINE
02-NOV-93	(TABLET)	PISCATAWAY, NJ	500MG
	08855	(LABELING REVISION -- ADVERSE REACTIONS)	
11-960	ARISTOCORT	LEDERLE	TRIAMCINOLONE DIACETATE
02-NOV-93	(SYRUP)	PEARL RIVER, NY	2MG/5ML
	10965	(LABELING REVISION -- DESCRIPTION; ADVERSE REACTIONS)	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-591	LARIAM	ROCHE	MEFLOQUINE HYDROCHLORIDE
02-NOV-93	(TABLET)	NUTLEY, NJ 07110	250MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
50-674	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
02-NOV-93	(TABLET)	KALAMAZOO, MI 49001	EQ 100MG BASE EQ 200MG BASE (LABELING REVISION -- PRECAUTIONS)
50-675	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
02-NOV-93	(GRANULE, FOR RECONSTITUTION)	KALAMAZOO, MI 49001	EQ 50MG BASE/5ML EQ 100MG BASE/5ML (LABELING REVISION -- PRECAUTIONS)
07-073	AZULFIDINE EN-TABS	KABI	SULFASALAZINE
03-NOV-93	(TABLET, DELAYED RELEASE)	PISCATAWAY, NJ 08855	500MG (LABELING REVISION -- ADVERSE REACTIONS)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20-145*	NITRO-DUR	SCHERING	NITROGLYCERIN
03-NOV-93	(FILM, EXTENDED RELEASE)	KENILWORTH, NJ 07033	2.4MG/24HR 4.8MG/24HR 7.2MG/24HR 9.6MG/24HR 14.4MG/24HR (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS)

* - Permitted

18-343	CAPOTEN	BRISTOL MYERS SQUIBB	CAPTOPRIL
04-NOV-93	(TABLET)	PRINCETON, NJ 08543	12.5MG 25MG 50MG 100MG (LABELING REVISION -- WARNINGS)
18-998	VASOTEC	MERCK	ENALAPRIL MALEATE
04-NOV-93	(TABLET)	WEST POINT, PA 19486	2.5MG 5MG 10MG 20MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
04-NOV-93	(INJECTABLE)	WEST POINT, PA	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

		19486	IMIPENEM
			250MG/VIAL
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			COMPATIBILITY AND STABILITY)
50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
04-NOV-93	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
		19486	IMIPENEM
			500MG/VIAL
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			COMPATIBILITY AND STABILITY)
50-630	PRIMAXIN	MSD	CILASTATIN SODIUM
04-NOV-93	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
		19486	IMIPENEM
			500MG/VIAL
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			PREPARATION
			FOR ADMINISTRATION)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-630	PRIMAXIN	MSD	CILASTATIN SODIUM
04-NOV-93	(INJECTABLE)	WEST POINT, PA	EQ 750MG BASE/VIAL
		19486	IMIPENEM
			750MG/VIAL
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			PREPARATION
			FOR ADMINISTRATION)

50-608	UNASYN	PFIZER	AMPICILLIN SODIUM
05-NOV-93	(INJECTABLE)	NEW YORK, NY	EQ 1GM BASE/VIAL
		10017	SULBACTAM SODIUM
			EQ 500MG BASE/VIAL
			(LABELING REVISION -- ADVERSE REACTIONS)

50-608	UNASYN	PFIZER	AMPICILLIN SODIUM
05-NOV-93	(INJECTABLE)	NEW YORK, NY	EQ 2GM BASE/VIAL
		10017	SULBACTAM SODIUM
			EQ 1GM BASE/VIAL
			(LABELING REVISION -- ADVERSE REACTIONS)

19-516	MS CONTIN	PURDUE FREDERICK	MORPHINE SULFATE
08-NOV-93	(TABLET,	NORWALK, CT	15MG
	EXTENDED RELEASE)	06850	30MG
			60MG
			100MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			200MG (LABELING REVISION -- DESCRIPTION; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
50-634	FORTAZ	GLAXO	CEFTAZIDIME SODIUM
08-NOV-93	IN PLASTIC CONTAINER	RES TRIANGLE PK, NC	EQ 20MG BASE/ML
	(INJECTABLE)	27709	EQ 40MG BASE/ML (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
11-694	DIMETANE-DC	ROBINS	BROMPHENIRAMINE MALEATE
09-NOV-93	(SYRUP)	RICHMOND, VA	2MG/5ML
		23220	CODEINE PHOSPHATE 10MG/5ML PHENYLPROPANOLAMINE HYDROCHLORIDE 12.5MG/5ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
20-083	SPORANOX	JANSSEN	ITRACONAZOLE
09-NOV-93	(CAPSULE)	PISCATAWAY, NJ	100MG
		08855	(LABELING REVISION -- ADVERSE REACTIONS)
19-640	HUMATROPE	LILLY	SOMATROPIN, BIOSYNTHETIC
18-NOV-93	(INJECTABLE)	INDIANAPOLIS, IN	5MG/VIAL
		46285	(LABELING REVISION -- DESCRIPTION)

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 10-12.5	MERCK	HYDROCHLOROTHIAZIDE
18-NOV-93	(TABLET)	WEST POINT, PA	12.5MG
	19486		LISINOPRIL
			10MG
			(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
19-778	PRINZIDE 20-12.5	MERCK	HYDROCHLOROTHIAZIDE
18-NOV-93	(TABLET)	WEST POINT, PA	12.5MG
	19486		LISINOPRIL
			20MG
			(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
19-778	PRINZIDE 20-25	MERCK	HYDROCHLOROTHIAZIDE
18-NOV-93	(TABLET)	WEST POINT, PA	25MG
	19486		LISINOPRIL
			20MG
			(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
19-888	ZESTORETIC 10-12.5	ZENECA	HYDROCHLOROTHIAZIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-NOV-93	(TABLET)	WILMINGTON, DE	12.5MG
	19897		LISINOPRIL
			10MG
			(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)

19-888	ZESTORETIC 20-12.5	ZENECA	HYDROCHLOROTHIAZIDE
18-NOV-93	(TABLET)	WILMINGTON, DE	12.5MG
	19897		LISINOPRIL
			20MG
			(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)

19-888	ZESTORETIC 20-25	ZENECA	HYDROCHLOROTHIAZIDE
18-NOV-93	(TABLET)	WILMINGTON, DE	25MG
	19897		LISINOPRIL
			20MG
			(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)

18-153	BECLOVENT	GLAXO	BECLOMETHASONE DIPROPIONATE
19-NOV-93	(AEROSOL, METERED)	RES TRIANGLE PK, NC	0.042MG/INH
	27709		(LABELING REVISION --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			WARNINGS; PRECAUTIONS)
18-584	BECONASE	GLAXO	BECLOMETHASONE DIPROPIONATE
19-NOV-93	(AEROSOL, METERED)	RES TRIANGLE PK, NC	0.042MG/INH
	27709	(LABELING REVISION --	
		WARNINGS; PRECAUTIONS)	
19-389	BECONASE AQ	GLAXO	BECLOMETHASONE
19-NOV-93	(SPRAY, METERED)	RES TRIANGLE PK, NC	DIPROPIONATE MONOHYDRATE
	27709	EQ 0.042MG DIPROP/INH	
		(LABELING REVISION --	
		WARNINGS; PRECAUTIONS)	
50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
19-NOV-93	(INJECTABLE)	WEST POINT, PA	EQ 250MG BASE/VIAL
	19486	IMIPENEM	
		250MG/VIAL	
		(LABELING REVISION --	
		COMPATIBILITY AND STABILITY)	
50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
19-NOV-93	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
	19486	IMIPENEM	
		500MG/VIAL	
		(LABELING REVISION --	
		COMPATIBILITY AND STABILITY)	
19-009	MAXAIR	3M	PIRBUTEROL ACETATE
22-NOV-93	(AEROSOL, METERED)	SAINT PAUL, MN	EQ 0.2MG BASE/INH
	55144	(LABELING REVISION --	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			HOW SUPPLIED)
19-157	PEDIAPRED	FISONS	PREDNISOLONE SODIUM
22-NOV-93	(SOLUTION)	ROCHESTER, NY	PHOSPHATE
	14603		EQ 5MG BASE/5ML
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
19-353	ALFENTA	JANSSEN	ALFENTANIL HYDROCHLORIDE
22-NOV-93	(INJECTABLE)	PISCATAWAY, NJ	EQ 0.5MG BASE/ML
	08854		(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-618	ROWASA	SOLVAY	MESALAMINE
22-NOV-93	(ENEMA)	MARIETTA, GA	4GM/60ML
	30062		(LABELING REVISION --
			PRECLINICAL TOXICOLOGY;
			PRECAUTIONS)
19-643	MEVACOR	MERCK	LOVASTATIN
22-NOV-93	(TABLET)	WEST POINT, PA	20MG
	19486		40MG
			(LABELING REVISION --

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)
19-583	RELAFEN	SMITHKLINE BEECHAM	NABUMETONE
23-NOV-93	(TABLET)	KING OF PRUSSIA, PA	500MG
		19406	750MG
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			INDIVIDUALIZATION OF DOSING;
			WARNINGS;
			ADVERSE REACTIONS)
19-643	MEVACOR	MERCK	LOVASTATIN
23-NOV-93	(TABLET)	WEST POINT, PA	10MG
		19486	20MG
			40MG
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY)
19-643	MEVACOR	MERCK	LOVASTATIN
24-NOV-93	(TABLET)	WEST POINT, PA	10MG
		19486	20MG
			40MG
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY)
19-111	TUSSIONEX	FISONS	CHLORPHENIRAMINE POLISTIREX
26-NOV-93	(SUSPENSION,	BEDFORD, MA	EQ 8MG MALEATE/5ML
	EXTENDED RELEASE)	01730	HYDROCODONE POLISTIREX

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
			EQ 10MG BITARTRATE/5ML (LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)
19-621 26-NOV-93	VENTOLIN (SYRUP)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL SULFATE EQ 2MG BASE/5ML (LABELING REVISION -- DESCRIPTION; PRECAUTIONS; OVERDOSAGE)
06-146 29-NOV-93	BENADRYL (INJECTABLE)	PARKE DAVIS MORRIS PLAINS, NJ 07950	DIPHENHYDRAMINE HYDROCHLORIDE 10MG/ML 50MG/ML (LABELING REVISION -- HOW SUPPLIED)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1062 NONE BIOSCOT BLOOD GROUPING REAGENT
08-NOV-93 (IN VITRO TEST) LIVINGSTON, UK (MONOCLONAL)
(FOR FURTHER
MANUFACTURING USE)
(B)

228 NONE SW FLORIDA BLOOD BANK SOURCE LEUKOCYTES
16-NOV-93 (INJECTABLE) TAMPA, FL (B)
33601

457 NONE PALM BEACH BLOOD BANK SOURCE LEUKOCYTES
16-NOV-93 (INJECTABLE) WEST PALM BEACH, FL (B)
33407

1168 NONE PLANK STREET LAB SOURCE PLASMA
23-NOV-93 (INJECTABLE) FORT SMITH, AR (A&B)
72903

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

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

BK930007	EXTENDED STORAGE PLATELET COLLECTION SET	HAEMONETICS BRAINTREE, MA 02184	EMPTY CONTAINERS FOR THE COLLECTION AND PROCESSING OF BLOOD COMPONENTS (C)	16-NOV-93
BK930008	FRESH FROZEN PLASMA COLLECTION SET (LATHAM BOWL)	HAEMONETICS BRAINTREE, MA 02184	EMPTY CONTAINERS FOR THE COLLECTION AND PROCESSING OF BLOOD COMPONENTS (C)	16-NOV-93
BK930009	FRESH FROZEN PLASMA COLLECTION SET (BLOW MOLDED BOWL)	HAEMONETICS BRAINTREE, MA 02184	EMPTY CONTAINERS FOR THE COLLECTION AND PROCESSING OF BLOOD COMPONENTS (C)	16-NOV-93
BK930016	VITROL I REAGENTS (CMV)	BLACKHAWK BIOSYS SAN RAMON, CA 94583	QUALITY CONTROL KITS FOR BLOOD BANKING REAGENTS (C)	16-NOV-93
BK930021	SAMPLINK	MIGADAS SYLVAN CLIFFS, NY 07632	BLOOD SAMPLING DEVICE (C)	16-NOV-93
BK930026	GAMMA RQC KIT	GAMMA BIOLOGS HOUSTON, TX 77092	QUALITY CONTROL KITS FOR BLOOD BANKING REAGENTS (C)	16-NOV-93

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

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

P920036	S-38 SOFT (POLYMACON) CONTACT LENS	NISSEL LIMITED HERTFORDSHIRE, UK	APPROVAL FOR THE S-38 SOFT (POLYMACON) CONTACT LENS	11/26/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

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

N17679/S27 11/23/93	VANTAGE (TETRAPHILCON A) SOFT AND VANTAGE TORIC (TETRAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS (CLEAR AND TINTED)	COOPERVISION, INC. SCOTTSVILLE, NY 14546	ALTERNATE DESIGN CONFIGURATION FOR THE TETRAFILCON A MATERIAL
N18033/S26 11/04/93	ACUVUE (ETAFILCON A) CONTACT LENS AND SUREVUE (ETAFILCON A) CONTACT LENS	VISTAKON JACKSONVILLE, FL 32247	MODIFIED MANUFACTURING PROCESS
P780007/S39 11/23/93	HYDRON (POLYMACON) HYDROPHILIC CONTACT LENS, HYDRON BIOMEDICS HYDROPHILIC CONTACT LENSES	OCULAR SCIENCES AMERICAN HYDRON SO. SAN FRANCISCO, CA 94080	REVISED LABELING
P790027/S56 11/17/93	POSTERIOR CHAMBER INTRAOCULAR LENSES (IOLS) WITH HAPTIC	IOLAB CORPORATION CLAREMONT, CA 91711	APPROVAL FOR ANY PMA-APPROVED INTRAOCULAR LENS DESIGN WITH

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	DIAMETERS OF 5.0MM	SYMMETRICAL HAPTICS IN OPTIC DIAMETERS DOWN TO 5.0MM		
P800022/S40	ZYPLAST AND ZYDERM COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94230	APPROVAL FOR A 24 MONTH EXPIRATION DATE	11/01/93
P800022/S41	ZYPLAST AND ZYDERM COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94230	APPROVAL FOR SCALE-UP OF EQUIPMENT USED	11/01/93
P800022/S44	ZYPLAST AND ZYDERM COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94230	APPROVAL FOR A LARGE SCALE COLLAGEN HOMOGENIZATION SYSTEM	11/01/93
P810006/S16	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	VITAPHORE CORPORATION MENLO PARK, CA 94025	ALTERNATIVE PACKAGING CONFIGURATIONS IN SINGLE OR DOUBLE TYVEK POUCHES	11/01/93
P810046/S146	ACS RX ELIPSE .014 CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	ADDITION OF A QUALITY CONTROL TEST TO THE MANUFACTURING PROCESS	11/08/93
P820059/S20	POLYMACON CONTACT LENSES	SOLA BARNES HIND SUNNYVALE, CA 94086-5200	APPROVAL FOR AN EXPIRATION DATING OF FIVE YEARS	11/23/93
P820086/S11	CIBASOFT, CIBASOFT STD, CIBATHIN, TORISOFT, AND	CIBA VISION CORPORATION DULUTH, GA 30136-1518	MODIFICATION OF THE LENSES BY INCORPORATING "LISTED" COLOR	11/23/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	BI-SOFT (TEFILCON) SOFT (HYDROPHILIC) CONTACT LENS WITH CIBATINT		ADDITIVES USING THE CIBATINT PROCESS	
P840066/S31	SOFT MATE CONSEPT-2 NEUTRALIZING AND RINSING SOLUTION	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	REVISED STABILITY SPECIFICATION FOR THE PRESERVATIVE FOR THE SOLUTION	11/04/93
P850002/S08	UNILENS SOFT ASPHERIC CONTACT LENS, SIMULVUE SOFT BIFOCAL, AND ALGES (HEFILCON A) SOFT (HYDROPHILIC) BIFOCAL CONTACT LENS	UNILENS CORP. U.S.A. LARGO, FL 34647-1511	REVISED LABELING	11/17/93
P850002/S09	UNILENS SOFT ASPHERIC CONTACT LENS, SIMULVUE SOFT BIFOCAL, AND ALGES (HEFILCON A) SOFT (HYDROPHILIC) BIFOCAL CONTACT	UNILENS CORP. U.S.A. LARGO, FL 34647-1511	REVISED LABELING	11/17/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	LENS		
P850035/S10 11/15/93	SPF IMPLANTABLE SPINAL FUSION STIMULATOR	ELECTRO-BIOLOGY, INC. PARSIPPANY, NJ 07054-1079	APPROVAL FOR THE SPF IMPLANTABLE SPINAL FUSION STIMULATOR
P860005/S02 11/17/93	INTERPORE PRO OSTEON IMPLANT 500 CORALLINE HYDROXYAPATITE	INTERPORE INTERNATIONAL IRVINE, CA 92718-2402	MANUFACTURING DEVICE IN NEW SIZES AND CONFIGURATIONS
P860019/S71 11/08/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, SCIMED STRIKER PTCA CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A NEW MODEL CATHETER
P870024/S36 11/23/93	FLUOROPERM (PAFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS, FLUOROPERM 151 (PAFLUFOCON D) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON VISION SCIENCES PHOENIX, AZ 85022	MODIFIED VERSION OF LENS MATERIAL

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P870036/S26	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC RAIDER CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	ALTERNATIVE MODIFIED VERSION OF MEDTRONIC 14K PTCA CATHETER	11/04/93
P870036/S27	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC PANTHER CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	APPROVAL FOR A MODIFIED, UPDATED VERSION OF THE MEDTRONIC 14K PTCA CATHETER	11/05/93
P870045/S29	REQUEST FOR AN ALTERNATE MANUFACTURING PROCEDURE	CHIRON INTRAOPTICS, INC. IRVINE, CA 92718-1903	APPROVAL FOR AN ALTERNATE HAPTIC STAKING PROCESS	11/17/93
P880001/S40	FLUOREX 700 (FLUSILFOCON A),	G.T. LABORATORIES CHICAGO, IL	APPROVAL FOR THREE ADDITIONAL CONTACT	11/23/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	FLUOREX 500 (FLUSILFOCON B), AND FLUOREX 300 (FLUSILFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	60601	LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	
P890003/S21	SYNERGYST PACING SYSTEM, ELITE II PULSE GENERATOR MODELS 7084, 7085 AND 7086; MODEL 9857E SOFTWARE AND MODEL 9748 MEMORYMOD	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MANUFACTURING MODIFICATION	11/08/93
P890046/S24	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	11/04/93
P900023/S05	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	APPROVAL TO INCREASE THE STERILIZATION LOAD SIZE FOR THE BVS 5000 BLOOD PUMP SET FROM 20 TO 30 UNITS	11/23/93
P900023/S06	BVS 5000 BI-VENTRICULAR	ABIOMED, INC. DANVERS, MA	APPROVAL TO REPLACE THE CURRENT	11/23/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	SUPPORT SYSTEM	01923	DIFFERENTIAL PRESSURE TRANSDUCER WITH ANOTHER MODEL DUE TO UNAVAILABILITY IN THE NEAR FUTURE	
P900032/S20	DYMER 200+ EXCIMER LASER SYSTEM	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA 92718	APPROVAL FOR THE MODEL PC4016 LASER CATHETER	11/23/93
P910029/S02	BLANCHARD SOFT (POLYMACON) CONTACT LENS, ESSTECH PC ASPHERIC (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENS	LES LABORATORIES BLANCHARD RESEARCH AND DEVELOPMENT, QUEBEC, CANADA SARASOTA, FL AS AN ALTERNATE SUPPLIER OF POLYMACON LENS BLANKS	APPROVAL FOR BENZ	11/23/93
N17679/S27	VANTAGE (TETRAPHILCON A) SOFT AND VANTAGE TORIC (TETRAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS (CLEAR AND TINTED)	COOPERVISION, INC. SCOTTSVILLE, NY 14546	ALTERNATE DESIGN CONFIGURATION FOR THE TETRAFILCON A MATERIAL	11/23/93
N18033/S26	ACUVUE (ETAFILCON A) CONTACT LENS AND SUREVUE	VISTAKON JACKSONVILLE, FL 32247	MODIFIED MANUFACTURING PROCESS	11/04/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	(ETAFILCON A) CONTACT LENS			
P780007/S39	HYDRON (POLYMACON) HYDROPHILIC CONTACT LENS, HYDRON BIOMEDICS HYDROPHILIC CONTACT LENSES	OCULAR SCIENCES AMERICAN HYDRON SO. SAN FRANCISCO, CA 94080	REVISED LABELING	11/23/93
P790027/S56	POSTERIOR CHAMBER INTRAOCULAR LENSES (IOLS) WITH HAPTIC DIAMETERS OF 5.0MM	IOLAB CORPORATION CLAREMONT, CA 91711	APPROVAL FOR ANY PMA-APPROVED INTRAOCULAR LENS DESIGN WITH SYMMETRICAL HAPTICS IN OPTIC DIAMETERS DOWN TO 5.0MM	11/17/93
P800022/S40	ZYPLAST AND ZYDERM COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94230	APPROVAL FOR A 24 MONTH EXPIRATION DATE	11/01/93
P800022/S41	ZYPLAST AND ZYDERM COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94230	APPROVAL FOR SCALE-UP OF EQUIPMENT USED	11/01/93
P800022/S44	ZYPLAST AND ZYDERM COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94230	APPROVAL FOR A LARGE SCALE COLLAGEN HOMOGENIZATION SYSTEM	11/01/93

APPLICATION NO. / APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P810006/S16 11/01/93	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	VITAPHORE CORPORATION MENLO PARK, CA 94025	ALTERNATIVE PACKAGING CONFIGURATIONS IN SINGLE OR DOUBLE TYVEK POUCHES
P810046/S146 11/08/93	ACS RX ELIPSE .014 CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	ADDITION OF A QUALITY CONTROL TEST TO THE MANUFACTURING PROCESS
P820059/S20 11/23/93	POLYMACON CONTACT LENSES	SOLA BARNES HIND SUNNYVALE, CA 94086-5200	APPROVAL FOR AN EXPIRATION DATING OF FIVE YEARS
P820086/S11 11/23/93	CIBASOFT, CIBASOFT STD, CIBATHIN, TORISOFT, AND BI-SOFT (TEFILCON) SOFT (HYDROPHILIC) CONTACT LENS WITH CIBATINT	CIBA VISION CORPORATION DULUTH, GA 30136-1518	MODIFICATION OF THE LENSES BY INCORPORATING "LISTED" COLOR ADDITIVES USING THE CIBATINT PROCESS
P840066/S31 11/04/93	SOFT MATE CONSEPT-2 NEUTRALIZING	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	REVISED STABILITY SPECIFICATION FOR THE PRESERVATIVE FOR THE

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	AND RINSING SOLUTION		SOLUTION	
P850002/S08	UNILENS SOFT ASPHERIC CONTACT LENS, SIMULVUE SOFT BIFOCAL, AND ALGES (HEFILCON A) SOFT (HYDROPHILIC) BIFOCAL CONTACT LENS	UNILENS CORP. U.S.A. LARGO, FL 34647-1511	REVISED LABELING	11/17/93
P850002/S09	UNILENS SOFT ASPHERIC CONTACT LENS, SIMULVUE SOFT BIFOCAL, AND ALGES (HEFILCON A) SOFT (HYDROPHILIC) BIFOCAL CONTACT LENS	UNILENS CORP. U.S.A. LARGO, FL 34647-1511	REVISED LABELING	11/17/93
P850035/S10	SPF IMPLANTABLE SPINAL FUSION STIMULATOR	ELECTRO-BIOLOGY, INC. PARSIPPANY, NJ 07054-1079	APPROVAL FOR THE SPF IMPLANTABLE SPINAL FUSION STIMULATOR	11/15/93
P860005/S02	INTERPORE PRO OSTEON IMPLANT 500 CORALLINE HYDROXYAPATITE	INTERPORE INTERNATIONAL IRVINE, CA 92718-2402	MANUFACTURING DEVICE IN NEW SIZES AND CONFIGURATIONS	11/17/93
P860019/S71	SCIMED	SCIMED LIFE SYSTEMS,	APPROVAL FOR A NEW	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, SCIMED STRIKER PTCA CATHETER	INC. MAPLE GROVE, MN 55311-3648	MODEL CATHETER	11/08/93
P870024/S36	FLUOROPERM (PAFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS, FLUOROPERM 151 (PAFLUFOCON D) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON VISION SCIENCES PHOENIX, AZ 85022	MODIFIED VERSION OF LENS MATERIAL	11/23/93
P870036/S26	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC RAIDER CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	ALTERNATIVE MODIFIED VERSION OF MEDTRONIC 14K PTCA CATHETER	11/04/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P870036/S27	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC PANTHER CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	APPROVAL FOR A MODIFIED, UPDATED VERSION OF THE MEDTRONIC 14K PTCA CATHETER	11/05/93
P870045/S29	REQUEST FOR AN ALTERNATE MANUFACTURING PROCEDURE	CHIRON INTRAOPTICS, INC. IRVINE, CA 92718-1903	APPROVAL FOR AN ALTERNATE HAPTIC STAKING PROCESS	11/17/93
P880001/S40	FLUOREX 700 (FLUSILFOCON A), FLUOREX 500 (FLUSILFOCON B), AND FLUOREX 300 (FLUSILFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	G.T. LABORATORIES CHICAGO, IL 60601	APPROVAL FOR THREE ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	11/23/93
P890003/S21	SYNERGYST PACING SYSTEM, ELITE II PULSE GENERATOR MODELS 7084, 7085 AND 7086; MODEL 9857E SOFTWARE AND MODEL 9748 MEMORYMOD	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MANUFACTURING MODIFICATION	11/08/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890046/S24 11/04/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P900023/S05 11/23/93	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	APPROVAL TO INCREASE THE STERILIZATION LOAD SIZE FOR THE BVS 5000 BLOOD PUMP SET FROM 20 TO 30 UNITS
P900023/S06 11/23/93	BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	APPROVAL TO REPLACE THE CURRENT DIFFERENTIAL PRESSURE TRANSDUCER WITH ANOTHER MODEL DUE TO UNAVAILABILITY IN THE NEAR FUTURE
P900032/S20 11/23/93	DYMER 200+ EXCIMER LASER SYSTEM	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA 92718	APPROVAL FOR THE MODEL PC4016 LASER CATHETER
P910029/S02 11/23/93	BLANCHARD SOFT (POLYMACON) CONTACT LENS, ESSTECH PC ASPHERIC (POLYMACON) SOFT	LES LABORATORIES BLANCHARD QUEBEC, CANADA	APPROVAL FOR BENZ RESEARCH AND DEVELOPMENT, SARASOTA, FL AS AN ALTERNATE SUPPLIER OF POLYMACON LENS BLANKS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

(HYDROPHILIC)
CONTACT LENS

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

ORIGINAL VETERINARY NADAs

141-036 09-10-93	PIRSUE (GEL)	CATTLE	UPJOHN KALAMAZOO, MI 49001	PIRLIMYCIN HYDROCHLORIDE 5MG/ML
140-974 09-23-93	IVOMEC (PREMIX)	SWINE	MERCK RAHWAY, NJ 07065	IVERMECTIN 0.6% W/W
141-008 09-29-93	DRONTAL (TABLET)	CATS KITTENS	MILES SHANNEE MISSION, KS 66201	PRAZIQUANTEL 18.2MG PYRANTEL PAMOATE 72.6MG
140-872 11-05-93	POSILAC (SUSPENSION)	COWS	MONSANTO ST LOUIS, MO 63167	RECOMBINANT DNA DERIVED METHIONYL BOVINE SOMATOTROPIN 500MG/VIAL

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR NOVEMBER 1993.

SUPPLEMENTAL VETERINARY NADAs

140-989	PARASITE-S	SHRIMP	WESTERN CHEMICAL	FORMALIN

NADA NUMBER / APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
ORIGINAL VETERINARY NADAs				
09-30-93	(SOLUTION)		FERNDALE, WA 98248	37%
65-256 10-15-93	CHLORTET SOLUBLE-O (POWDER)	CHICKENS SWINE TURKEYS	FEED SPECIALTIES DES MOINES, IA 50313	CHLORTETRACYCLINE HYDROCHLORIDE 25.6GM/PACKET 102.4GM/PACKET

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
*George R. Scott (301) 443-3910

Center for Devices and Radiological Health
Mary Jo Robinson (301) 594-2186

Center for Biologics Evaluation and Research
Joseph Wilczek (301) 594-2012

Center for Veterinary Medicine
Norman Turner
(301) 594-1623

*To whom general inquiries should be directed.

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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

18-150 THALLOUS MALLINCKRODT THALLOUS CHLORIDE, TL-201
16-DEC-93 CHLORIDE TL 201 SAINT LOUIS, MO 1MCI/ML
(SUPPL) (INJECTABLE) 63134 (NEW DOSAGE REGIMEN -- INCREASE IN PATIENT DOSE WHEN USE OF SINGLE PHOTON EMISSION TOMOGRAPHY (SPECT) IS INTENDED)

19-183 CARAFATE MARION MERRELL DOW SUCRALFATE
16-DEC-93 (SUSPENSION) KANSAS CITY, MO 1GM/10ML
(3 S) 64134 (ANTIULCER)

20-326 NEUTREXIN US BIOSCIENCE TRIMETREXATE GLUCURONATE
17-DEC-93 (INJECTABLE) WEST CONSHOHOCKEN, PA EQ 25MG BASE/VIAL
(1P, AA*, 19428 (FOLATE ANTAGONIST)

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**, E***)			[PNEUMOCYSTIS CARINII PNEUMONIA]

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

19-867	ISOLYTE E	MCGAW	CALCIUM CHLORIDE
20-DEC-93	IN DEXTROSE 5%	IRVINE, CA	35MG/100ML
(5 S)	IN PLASTIC CONTAINER	92713	DEXTROSE
	(INJECTABLE)		5GM/100ML
			MAGNESIUM CHLORIDE
			30MG/100ML
			POTASSIUM CHLORIDE
			74MG/100ML
			SODIUM ACETATE
			640MG/100ML
			SODIUM CHLORIDE
			500MG/100ML
			SODIUM CITRATE
			74MG/100ML
			(FLUID AND

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

ELECTROLYTE REPLENISHER)

20-090	DIFLUCAN	PFIZER	FLUCONAZOLE
23-DEC-93	(POWDER,	NEW YORK, NY	50MG/5ML
(3 S)	FOR RECONSTITUTION)	10017	200MG/5ML
		(ANTIFUNGAL)	

50-662	BIAXIN	ABBOTT	CLARITHROMYCIN
23-DEC-93	(TABLET)	ABBOTT PARK, IL	250MG
(SUPPL)		60064	500MG
		(NEW INDICATION -- TREATMENT OF DISSEMINATED MYCOBACTERIAL INFECTIONS DUE TO MYCOBACTERIUM AVIUM AND MYCOBACTERIUM INTRACELLULARE)	

50-697	BIAXIN	ABBOTT	CLARITHROMYCIN
23-DEC-93	(TABLET)	ABBOTT PARK, IL	250MG
(6 S, AA*, E***)		60064	500MG
		(ANTIBIOTIC, MACROLIDE) [TREATMENT OF DISSEMINATED MYCOBACTERIAL INFECTIONS DUE TO MYCOBACTERIUM AVIUM AND MYCOBACTERIUM INTRACELLULARE]	

AA* - Priority Classification AIDS Drug
E*** - Drug for Severely Debilitating/Life Threatening Illness

50-698	BIAXIN	ABBOTT	CLARITHROMYCIN
23-DEC-93	(GRANULE,	ABBOTT PARK, IL	125MG/5ML
(3 S)	FOR RECONSTITUTION)	60064	250MG/5ML
		(ANTIBIOTIC, MACROLIDE) [TREATMENT OF DISSEMINATED MYCOBACTERIAL INFECTIONS DUE TO MYCOBACTERIUM AVIUM AND MYCOBACTERIUM	

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

INTRACELLULARE]

20-151	EFFEXOR	WYETH AYERST	VENLAFAXINE HYDROCHLORIDE
28-DEC-93	(TABLET)	PHILADELPHIA, PA	EQ 12.5MG BASE*
(1 S)		19101	EQ 25MG BASE
			EQ 37.5MG BASE
			EQ 50MG BASE
			EQ 75MG BASE
			EQ 100MG BASE
			(ANTIDEPRESSANT)
18-467	HEPATOLITE	DUPONT	TECHNETIUM TC-99M
29-DEC-93	(INJECTABLE)	WILMINGTON, DE	DISOFENIN KIT
(SUPPL)		19880	N/A
			(NEW INDICATION -- DIAGNOSIS AND EVALUATION OF ACUTE CHOLECYSTITIS WHEN PERFORMED WITH MORPHINE SULFATE AUGMENTATION)

* - Not Marketed at This Time

20-176	KABIVITE PED F+W KIT	KABI	ASCORBIC ACID

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

29-DEC-93	(INJECTABLE)	CLAYTON, NC	80MG/VIAL
(3 P)	27520		BIOTIN 0.02MG/VIAL CYANOCOBALAMIN 0.001MG/VIAL FOLIC ACID 0.14MG/VIAL NIACINAMIDE 17MG/VIAL PANTOTHENIC ACID 5MG/VIAL PYRIDOXINE 1MG/VIAL RIBOFLAVIN 1.4MG/VIAL THIAMINE 1.2MG/VIAL [WATER SOLUBLE VIAL] ERGOCALCIFEROL 400IU/10ML PHYTONADIONE 0.2MG/10ML VITAMIN A PALMITATE EQ 2,300 UNITS BASE/10ML VITAMIN E 7IU/10ML [FAT SOLUBLE VIAL] (PEDIATRIC MULTIVITAMIN)
20-239	KYTRIL	SMITHKLINE BEECHAM	GRANISETRON HYDROCHLORIDE
29-DEC-93	(INJECTABLE)	KING OF PRUSSIA, PA	EQ 3MG BASE/ML
(1 S)	19406		(ANTIEMETIC)
20-272	RISPERDAL	JANSSEN	RISPERIDONE
29-DEC-93	(TABLET)	TITUSVILLE, NJ	1MG
(1 P)	08560		2MG

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

3MG
4MG
5MG*
(ANTIPSYCHOTIC)

* - Not Marketed At This Time

20-273 DOVONEX BRISTOL MYERS SQUIBB CALCIPOTRIENE
29-DEC-93 (OINTMENT) BUFFALO, NY 0.005%
(1 S) 14213 (ANTIPSORIATIC)

20-304 TRASYLOL MILES PHARM APROTININ
29-DEC-93 (INJECTABLE) WEST HAVEN, CT 10,000 KIU/ML***
(1P, V**) 06516 (FIBRINOLYTICS/
ANTIFIBRINOLYTICS)
[PROPHYLACTIC USE TO REDUCE
PERIOPERATIVE BLOOD LOSS/
NEED FOR TRANSFUSION IN
SELECT CORONARY PATIENTS]

19-942 INTRALIPID KABI SOYBEAN OIL
30-DEC-93 (INJECTABLE) CLAYTON, NC 30%
(5 S) 27520 (CALORIE AND ESSENTIAL
FATTY ACID REPLENISHER)

19-949 DIFLUCAN PFIZER FLUCONAZOLE
30-DEC-93 (TABLET) GROTON, CT 50MG
(SUPPL) 06340 100MG
200MG
(NEW INDICATION --
TO DECREASE THE INCIDENCE
OF CANDIDIASIS IN PATIENTS
UNDERGOING BONE MARROW
TRANSPLANTATION WHO RECEIVE
CYTOTOXIC CHEMOTHERAPY
AND/OR RADIATION THERAPY)

19-950 DIFLUCAN PFIZER FLUCONAZOLE
30-DEC-93 (INJECTABLE) NEW YORK, NY 2MG/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

(SUPPL) 10017 (NEW INDICATION --
TO DECREASE THE INCIDENCE
OF CANDIDIASIS IN PATIENTS
UNDERGOING BONE MARROW
TRANSPLANTATION WHO RECEIVE
CYTOTOXIC CHEMOTHERAPY
AND/OR RADIATION THERAPY)

V** - Designated Orphan Drug
*** - Kallikrein Inhibitor Units

20-184 ACEON JOHNSON RW PERINDOPRIL ERBUMINE
30-DEC-93 (TABLET) SPRING HOUSE, PA 2MG
(1 S) 19477 4MG
8MG
(ANGIOTENSIN CONVERTING
ENZYME INHIBITOR)

20-235 NEURONTIN PARKE DAVIS GABAPENTIN
30-DEC-93 (CAPSULE) ANN ARBOR, MI 100MG
(1 P) 48105 300MG
400MG
(ANTICONVULSANT)

19-304 LIPIDIL FOURNIER FENOFIBRATE
31-DEC-93 (CAPSULE) CHENOVE, FRANCE 100MG
(1 S) (LIPID REGULATING AGENT)

20-261 LESCOL SANDOZ FLUVASTATIN SODIUM
31-DEC-93 (CAPSULE) EAST HANOVER, NJ EQ 20MG BASE
(1 S) 07936 EQ 40MG BASE
(CHOLESTEROL LOWERING
AGENT)

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

ERRATA

20-195	FENTANYL	ANESTA	FENTANYL CITRATE
04-OCT-93	(TROCHE/LOZENGE)	SALT LAKE CITY, UT	EQ 0.2MG BASE
(3 P)*		84103	EQ 0.3MG BASE
			EQ 0.4MG BASE
			(NARCOTIC ANALGESIC)

* - Revised Classification code

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.

20-059 13-DEC-93	ADENOSCAN (INJECTABLE)	MEDCO RES TRIANGLE PK, NC 27709	ADENOSINE 3MG/ML (NUCLEOSIDE) [ADJUNCT TO THALLIUM-201 MYOCARDIAL PERFUSION SCINTIGRAPHY IN PATIENTS UNABLE TO EXERCISE ADEQUATELY]
20-239 13-DEC-93	KYTRIL (INJECTABLE)	SMITHKLINE BEECHAM KING OF PRUSSIA, PA 19406	GRANISETRON HYDROCHLORIDE EQ 3MG BASE/ML (ANTIEMETIC)
20-334 14-DEC-93	METRONIDAZOLE (CAPSULE)	SEARLE SKOKIE, IL 60077	METRONIDAZOLE 375MG (ANTIPROTOZOAL)
20-337 16-DEC-93	TEMOVATE (GEL)	GLAXO RES TRIANGLE PK, NC 27709	CLOBETASOL PROPIONATE 0.05% (CORTICOSTEROID)
19-754	CONCENTRATED	ABBOTT	DEXTROSE

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

APPROVABLE ORIGINAL NDAs

17-DEC-93	DEXTROSE AND SODIUM CHLORIDE IN PLASTIC CONTAINER (SOLUTION)	ABBOTT PARK, IL 60064	0.2GM/100ML SODIUM CHLORIDE 0.9GM/100ML (RED BLOOD CELL PROCESSOR)
19-755	CONCENTRATED	ABBOTT	CALCIUM CHLORIDE
17-DEC-93	LACTATED RINGERS IN PLASTIC CONTAINER (SOLUTION)	ABBOTT PARK, IL 60064	0.02GM/100ML POTASSIUM CHLORIDE 0.03GM/100ML SODIUM CHLORIDE 0.6GM/100ML SODIUM LACTATE 0.31GM/100ML (FLUID AND ELECTROLYTE REPLENISHER)
19-756	CONCENTRATED	ABBOTT	SODIUM CHLORIDE
17-DEC-93	SODIUM CHLORIDE IN PLASTIC CONTAINER (SOLUTION)	ABBOTT PARK, IL 60064	0.9GM/100ML (FLUID AND ELECTROLYTE REPLENISHER)
20-184	ACEON	JOHNSON RW	PERINDOPRIL ERBUMINE
17-DEC-93	(TABLET)	SPRING HOUSE, PA 19477	2MG 4MG 8MG (ANGIOTENSIN CONVERTING ENZYME INHIBITOR) [HYPERTENSION]

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

APPROVABLE ORIGINAL NDAs

20-233	RHINOCORT	BESSELAAR	BUDESONIDE
17-DEC-93	(AEROSOL, METERED)	PRINCETON, NJ	0.032MG/INH
		08540	(GLUCOCORTICOSTEROID)
			[MANAGEMENT OF SYMPTOMS
			OF RHINITIS]
20-235	NEURONTIN	PARKE DAVIS	GABAPENTIN
21-DEC-93	(CAPSULE)	ANN ARBOR, MI	100MG
		48105	300MG
			400MG
			(ANTICONVULSANT)
20-340	TEMOVATE	GLAXO	CLOBETASOL PROPIONATE
22-DEC-93	(CREAM)	RES TRIANGLE PK, NC	0.05%
		27709	(CORTICOSTEROID)
50-673	CECLOR CD	LILLY	CEFACLOR
22-DEC-93	(TABLET)	INDIANAPOLIS, IN	EQ 375MG BASE
		46285	(ANTIBIOTIC, CEPHEM)
20-237	SALAGEN	MGI	PILOCARPINE HYDROCHLORIDE
28-DEC-93	(TABLET)	MINNEAPOLIS, MN	5MG
		55343	10MG
			(CHOLINERGIC AGONIST)
			[TREATMENT OF SYMPTOMS OF
			XEROSTOMIA DUE TO SALIVARY
			GLAND HYPOFUNCTION
			RESULTING FROM RADIOTHERAPY
			FOR CANCER OF THE HEAD

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

APPROVABLE ORIGINAL NDAs

AND NECK]

19-671	TRIAMCINOLONE	WHITBY	TRIAMCINOLONE ACETONIDE
30-DEC-93	ACETONIDE	RICHMOND, VA	0.05%
	(CREAM)	23261	(CORTICOSTEROID)

20-336	DYNACIRC CR	SANDOZ	ISRADIPINE
30-DEC-93	(TABLET,	EAST HANOVER, NJ	5MG
	EXTENDED RELEASE)	07936	10MG
			(CALCIUM ION INFLUX
			INHIBITOR)
			[HYPERTENSION]

20-343	PRIMACOR	STERLING WINTHROP	MILRINONE LACTATE
30-DEC-93	IN DEXTROSE 5%	COLLEGEVILLE, PA	EQ 0.1MG BASE/ML
	IN PLASTIC CONTAINER	19426	EQ 0.15MG BASE/ML
	(INJECTABLE)		EQ 0.2MG BASE/ML
			(INOTROPIC/VASODILATOR)
			[CONGESTIVE HEART FAILURE]

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

ORIGINAL ABBREVIATED NDAs

73-592*	LEVORA 0.15/30-21	SYNTEX	ETHINYL ESTRADIOL
13-DEC-93	(TABLET)	PALO ALTO, CA	0.03MG
	94304		LEVONORGESTREL
			0.15MG
			(HORMONAL CONTRACEPTIVE)
73-594*	LEVORA 0.15/30-28	SYNTEX	ETHINYL ESTRADIOL
13-DEC-93	(TABLET)	PALO ALTO, CA	0.03MG
	94304		LEVONORGESTREL
			0.15MG
			(HORMONAL CONTRACEPTIVE)
40-059	FLUOCINOLONE	BAUSCH AND LOMB	FLUOCINOLONE ACETONIDE
20-DEC-93	ACETONIDE	TAMPA, FL	0.01%
	(SOLUTION)	33637	(CORTICOSTEROID)
73-653*	METOPROLOL TARTRATE	MUTUAL PHARM	METOPROLOL TARTRATE
21-DEC-93	(TABLET)	PHILADELPHIA, PA	50MG
	19124		(BETA ADRENERGIC BLOCKER)
73-654*	METOPROLOL TARTRATE	MUTUAL PHARM	METOPROLOL TARTRATE
21-DEC-93	(TABLET)	PHILADELPHIA, PA	100MG
	19124		(BETA ADRENERGIC BLOCKER)
73-666*	METOPROLOL TARTRATE	MYLAN	METOPROLOL TARTRATE
21-DEC-93	(TABLET)	MORGANTOWN, WV	50MG
	26504		100MG
			(BETA ADRENERGIC BLOCKER)
74-032*	METOPROLOL TARTRATE	STERIS	METOPROLOL TARTRATE
21-DEC-93	(INJECTABLE)	PHOENIX, AZ	1MG/ML
	85043		(BETA ADRENERGIC BLOCKER)

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

ORIGINAL ABBREVIATED NDAs

74-105 21-DEC-93	NAPROXEN (TABLET)	LEDERLE PEARL RIVER, NY 10965	NAPROXEN 250MG 375MG 500MG (NONSTEROIDAL ANTI-INFLAMMATORY)

* - First Time Product Available Generically

74-121 21-DEC-93	NAPROXEN (TABLET)	MYLAN MORGANTOWN, WV 26504	NAPROXEN 250MG 375MG 500MG (NONSTEROIDAL ANTI-INFLAMMATORY)
74-129 21-DEC-93	NAPROXEN (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	NAPROXEN 250MG 375MG 500MG (NONSTEROIDAL ANTI-INFLAMMATORY)
74-133* 21-DEC-93	METOPROLOL TARTRATE (INJECTABLE)	STERLING WINTHROP NEW YORK, NY 10016	METOPROLOL TARTRATE 1MG/ML (BETA ADRENERGIC BLOCKER)
74-140 21-DEC-93	NAPROXEN (TABLET)	GENEVA BROOMFIELD, CO 80038	NAPROXEN 250MG 375MG 500MG (NONSTEROIDAL ANTI-INFLAMMATORY)
74-142	NAPROXEN SODIUM	NOVOPHARM	NAPROXEN SODIUM

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

ORIGINAL ABBREVIATED NDAs

21-DEC-93	(TABLET)	SCARBOROUGH, ONTARIO CANADA	EQ 250MG BASE EQ 500MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
74-162 21-DEC-93	NAPROXEN SODIUM (TABLET)	GENEVA BROOMFIELD, CO 80038	NAPROXEN SODIUM EQ 250MG BASE EQ 500MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)

* - First Time Product Available Generically

74-195 21-DEC-93	NAPROXEN SODIUM (TABLET)	DANBURY DANBURY, CT 06810	NAPROXEN SODIUM EQ 250MG BASE EQ 500MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
74-198 21-DEC-93	NAPROXEN SODIUM (TABLET)	LEMMON SELLERSVILLE, PA 18960	NAPROXEN SODIUM EQ 250MG BASE EQ 500MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
74-201 21-DEC-93	NAPROXEN (TABLET)	LEMMON SELLERSVILLE, PA 18960	NAPROXEN 250MG 375MG 500MG (NONSTEROIDAL ANTI-INFLAMMATORY)

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

ORIGINAL ABBREVIATED NDAs

74-207	NAPROXEN	COPLEY	NAPROXEN
21-DEC-93	(TABLET)	CANTON, MA	250MG
		02021	375MG
			500MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
74-257	NAPROXEN SODIUM	ROXANE	NAPROXEN SODIUM
21-DEC-93	(TABLET)	COLUMBUS, OH	EQ 250MG BASE
		43216	EQ 500MG BASE
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
74-263	NAPROXEN	PUREPAC	NAPROXEN
21-DEC-93	(TABLET)	ELIZABETH, NJ	250MG
		07207	375MG
			500MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
81-066	FOLIC ACID	LOCH PHARMS	FOLIC ACID
29-DEC-93	(INJECTABLE)	BEDFORD, OH	5MG/ML
		44146	(VITAMIN)
81-298	CHLORZOXAZONE	OHM	CHLORZOXAZONE
29-DEC-93	(TABLET)	FRANKLIN PARK, NJ	250MG
		08823	(SKELETAL MUSCLE RELAXANT)
81-299	CHLORZOXAZONE	OHM	CHLORZOXAZONE
29-DEC-93	(TABLET)	FRANKLIN PARK, NJ	500MG
		08823	(SKELETAL MUSCLE RELAXANT)

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

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDA TENTATIVE APPROVALS FOR DECEMBER 1993.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-759	SODIUM CHLORIDE 0.45%	ABBOTT	SODIUM CHLORIDE
01-DEC-93	IN PLASTIC CONTAINER	ABBOTT PARK, IL	450MG/100ML
	(INJECTABLE)	60064	(LABELING REVISION -- HOW SUPPLIED)

11-958	HYDROPRES 25	MSD	HYDROCHLOROTHIAZIDE
02-DEC-93	(TABLET)	WEST POINT, PA	25MG
	19486		RESERPINE 0.125MG (LABELING REVISION -- PRECAUTIONS)

11-958	HYDROPRES 50	MSD	HYDROCHLOROTHIAZIDE
02-DEC-93	(TABLET)	WEST POINT, PA	50MG
	19486		RESERPINE 0.125MG (LABELING REVISION -- PRECAUTIONS)

19-687	LUTREPULSE PUMP KIT	FERRING	GONADORELIN ACETATE
02-DEC-93	(INJECTABLE)	SUFFERN, NY	0.8MG/VIAL
	10901		3.2MG/VIAL (LABELING REVISION -- DESCRIPTION; WARNINGS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

17-563	FLAVORED COLESTID	UPJOHN	COLESTIPOL HYDROCHLORIDE
06-DEC-93	(GRANULE)	KALAMAZOO, MI	5GM/PACKET
	49001		5GM/SCOOP (LABELING REVISION -- DESCRIPTION)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-614	VERELAN	ELAN	VERAPAMIL HYDROCHLORIDE
06-DEC-93	(CAPSULE, EXTENDED RELEASE)	GAINESVILLE, GA 30504	120MG 180MG 240MG (LABELING REVISION -- HOW SUPPLIED)
20-014	MAXAIR	3M	PIRBUTEROL ACETATE
06-DEC-93	(AEROSOL, METERED)	SAINT PAUL, MN 55144	EQ 0.2MG BASE/INH (LABELING REVISION -- HOW SUPPLIED; PATIENT PACKAGE INSERT)
20-092	DILACOR XR	RHONE POULENC RORER	DILTIAZEM HYDROCHLORIDE
06-DEC-93	(CAPSULE, EXTENDED RELEASE)	COLLEGEVILLE, PA 19426	120MG 180MG 240MG (LABELING REVISION -- PRECAUTIONS)
50-370	ILOTYCIN GLUCEPTATE	LILLY	ERYTHROMYCIN GLUCEPTATE
07-DEC-93	(INJECTABLE)	INDIANAPOLIS, IN 46285	EQ 1GM BASE/VIAL (LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)
19-715	DIPENTUM	KABI	OLSALAZINE SODIUM
08-DEC-93	(CAPSULE)	PISCATAWAY, NJ 08855	250MG (LABELING REVISION -- ADVERSE REACTIONS)
18-086	TIMOPTIC	MERCK	TIMOLOL MALEATE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

09-DEC-93	(SOLUTION/DROPS)	WEST POINT, PA	EQ 0.25% BASE
	19486		EQ 0.5% BASE
		(LABELING REVISION --	
		CLINICAL PHARMACOLOGY;	
		INDICATIONS AND USAGE;	
		PRECAUTIONS)	
18-201	MODURETIC 5-50	MSD	AMILORIDE HYDROCHLORIDE
09-DEC-93	(TABLET)	WEST POINT, PA	EQ 5MG ANHYDROUS
	19486		HYDROCHLOROTHIAZIDE
			50MG
		(LABELING REVISION --	
		PRECAUTIONS)	
19-463	TIMOPTIC IN OCUDOSE	MERCK	TIMOLOL MALEATE
09-DEC-93	(SOLUTION/DROPS)	WEST POINT, PA	EQ 0.25% BASE
	19486		EQ 0.5% BASE
		(LABELING REVISION --	
		INDICATIONS AND USAGE)	
19-888	ZESTORETIC 10-12.5	ZENECA	HYDROCHLOROTHIAZIDE
09-DEC-93	(TABLET)	WILMINGTON, DE	12.5MG
	19897		LISINOPRIL
			10MG
		(LABELING REVISION --	
		PRECAUTIONS;	
		ADVERSE REACTIONS)	
19-888	ZESTORETIC 20-12.5	ZENECA	HYDROCHLOROTHIAZIDE
09-DEC-93	(TABLET)	WILMINGTON, DE	12.5MG
	19897		LISINOPRIL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			20MG
			(LABELING REVISION --
			PRECAUTIONS;
			ADVERSE REACTIONS)
19-888	ZESTORETIC 20-25	ZENECA	HYDROCHLOROTHIAZIDE
09-DEC-93	(TABLET)	WILMINGTON, DE	25MG
	19897		LISINOPRIL
			20MG
			(LABELING REVISION --
			PRECAUTIONS;
			ADVERSE REACTIONS)
19-080	PROSOM	ABBOTT	ESTAZOLAM
13-DEC-93	(TABLET)	ABBOTT PARK, IL	1MG
	60064		2MG
			(LABELING REVISION --
			OVERDOSAGE)
18-164	ANAPROX	SYNTEX	NAPROXEN SODIUM
15-DEC-93	(TABLET)	HUMACAO, PR	EQ 250MG BASE
	00661		(LABELING REVISION --
			DESCRIPTION)
18-164	ANAPROX DS	SYNTEX	NAPROXEN SODIUM
15-DEC-93	(TABLET)	HUMACAO, PR	EQ 500MG BASE
	00661		(LABELING REVISION --
			DESCRIPTION)
18-150	THALLOUS	MALLINCKRODT	THALLOUS CHLORIDE, TL-201
16-DEC-93	CHLORIDE TL 201	SAINT LOUIS, MO	1MCI/ML
	(INJECTABLE) 63134		(LABELING REVISION --
			DOSAGE AND ADMINISTRATION)
20-035	ERGAMISOL	JANSSEN	LEVAMISOLE HYDROCHLORIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-DEC-93	(TABLET)	PISCATAWAY, NJ	EQ 50MG BASE
	08855	(LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)	
07-942	SUS-PHRINE	FOREST LABS	EPINEPHRINE
20-DEC-93	(INJECTABLE)	NEW YORK, NY	5MG/ML
	10155	(LABELING REVISION -- DESCRIPTION; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)	
20-033	LOTENSIN HCT	CIBA	BENAZEPRIL HYDROCHLORIDE
20-DEC-93	(TABLET)	SUMMIT, NJ	5MG
	07901	HYDROCHLOROTHIAZIDE 6.25MG (LABELING REVISION -- PRECAUTIONS)	
20-033	LOTENSIN HCT	CIBA	BENAZEPRIL HYDROCHLORIDE
20-DEC-93	(TABLET)	SUMMIT, NJ	10MG
	07901	HYDROCHLOROTHIAZIDE 12.5MG (LABELING REVISION -- PRECAUTIONS)	
20-033	LOTENSIN HCT	CIBA	BENAZEPRIL HYDROCHLORIDE
20-DEC-93	(TABLET)	SUMMIT, NJ	20MG
	07901	HYDROCHLOROTHIAZIDE	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			12.5MG
			(LABELING REVISION --
			PRECAUTIONS)
20-033	LOTENSIN HCT	CIBA	BENAZEPRIL HYDROCHLORIDE
20-DEC-93	(TABLET)	SUMMIT, NJ	20MG
		07901	HYDROCHLOROTHIAZIDE
			25MG
			(LABELING REVISION --
			PRECAUTIONS)
16-131	CLOMID	MARION MERRELL DOW	CLOMIPHENE CITRATE
21-DEC-93	(TABLET)	KANSAS CITY, MO	50MG
		64134	(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			CONTRAINDICATIONS;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			OVERDOSAGE;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
11-860	HUMORSOL	MSD	DEMECARIUM BROMIDE
22-DEC-93	(SOLUTION/DROPS)	WEST POINT, PA	0.125%
		19486	0.25%
			(LABELING REVISION --
			PRECAUTIONS)
19-757	CHIBROXIN	MERCK	NORFLOXACIN
22-DEC-93	(SOLUTION/DROPS)	WEST POINT, PA	0.3%
		19486	(LABELING REVISION --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

PRECAUTIONS)

04-782	PREMARIN	WYETH AYERST	ESTROGENS, CONJUGATED
23-DEC-93	(TABLET)	PHILADELPHIA, PA	0.3MG
	19101		0.625MG
			0.9MG
			1.25MG
			2.5MG
			(LABELING REVISION --
			INDICATIONS AND USAGE)
16-619	SUBLIMAZE	JANSSEN	FENTANYL CITRATE
23-DEC-93	(INJECTABLE)	PISCATAWAY, NJ	EQ 0.05MG BASE/ML
	08854		(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
20-210	PROPULSID	JANSSEN	CISAPRIDE MONOHYDRATE
23-DEC-93	(TABLET)	PISCATAWAY, NJ	EQ 10MG BASE
	08855		EQ 20MG BASE
			(LABELING REVISION --
DESCRIPTION;			
			HOW SUPPLIED)
50-662	BIAXIN	ABBOTT	CLARITHROMYCIN
23-DEC-93	(TABLET)	ABBOTT PARK, IL	250MG
	60064		500MG
			(LABELING REVISION --
DESCRIPTION;			
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			PRECAUTIONS;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
18-841 27-DEC-93	DAYPRO (TABLET) 60077	SEARLE SKOKIE, IL	OXAPROZIN 600MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
08-126 28-DEC-93	CORTISONE ACETATE (TABLET) 49001	UPJOHN KALAMAZOO, MI	CORTISONE ACETATE 5MG 10MG 25MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
08-697 28-DEC-93	CORTEF (TABLET) 49001	UPJOHN KALAMAZOO, MI	HYDROCORTISONE 5MG 10MG 20MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
09-866 28-DEC-93	SOLU-CORTEF (INJECTABLE) 49001	UPJOHN KALAMAZOO, MI	HYDROCORTISONE SODIUM SUCCINATE EQ 100MG BASE/VIAL EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL (LABELING REVISION -- WARNINGS;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

PRECAUTIONS)				
09-900	CORTEF	UPJOHN	HYDROCORTISONE CYPIONATE	
28-DEC-93	(SUSPENSION)	KALAMAZOO, MI	EQ 10MG BASE/5ML	
	49001	(LABELING REVISION --		
WARNINGS; PRECAUTIONS)				
09-986	DELTASONE	UPJOHN	PREDNISONE	
28-DEC-93	(TABLET)	KALAMAZOO, MI	2.5MG	49001
5MG				
			10MG	
			20MG	
			50MG	(LABELING REVISION
--			WARNINGS; PRECAUTIONS)	
11-153	MEDROL	UPJOHN	METHYLPREDNISOLONE	
28-DEC-93	(TABLET)	KALAMAZOO, MI	2MG	
	49001		4MG	
			8MG	
			16MG	
			24MG	
			32MG	
			(LABELING REVISION --	
			WARNINGS; PRECAUTIONS)	
18-467	HEPATOLITE	DUPONT	TECHNETIUM TC-99M	
29-DEC-93	(INJECTABLE)	WILMINGTON, DE	DISOFENIN KIT	
	19880		N/A	
			(LABELING REVISION --	
			CLINICAL PHARMACOLOGY;	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			INDICATIONS AND USAGE; PRECAUTIONS; RADIATION DOSIMETRY)
19-949 30-DEC-93	DIFLUCAN (TABLET)	PFIZER GROTON, CT 06340	FLUCONAZOLE 50MG 100MG 200MG (LABELING REVISION -- DESCRIPTION; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-950 30-DEC-93	DIFLUCAN (INJECTABLE)	PFIZER NEW YORK, NY 10017	FLUCONAZOLE 2MG/ML (LABELING REVISION -- DESCRIPTION; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
20-144* 30-DEC-93	TRANSDERM-NITRO (FILM, EXTENDED RELEASE)	CIBA GEIGY SUMMIT, NJ 07901	NITROGLYCERIN 0.1MG/HR 0.2MG/HR 0.4MG/HR 0.6MG/HR 0.8MG/HR (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			[NEW STRENGTH]
20-145* 30-DEC-93	NITRO-DUR (FILM, EXTENDED RELEASE)	KEY KENILWORTH, NJ 07033	NITROGLYCERIN 0.1MG/HR 0.2MG/HR 0.3MG/HR 0.4MG/HR 0.6MG/HR 0.8MG/HR (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED) [NEW STRENGTH]

* - Permitted

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

BIOLOGICAL PRODUCT LICENSES ISSUED

938 NONE CHAMPLAIN VALLEY PLATELETS
02-DEC-93 (INJECTABLE) PHYS HOSP MED CTR (TRANSFUSION)
PLATTSBURGH, NY (B)
12901

203 NONE INLAND NW BLOOD CTR PLATELETS
08-DEC-93 (INJECTABLE) SPOKANE, WA (TRANSFUSION)
99210 (B)

1048 PULMOZYME GENENTECH DORNASE ALFA
30-DEC-93 (SOLUTION) S SAN FRANCISCO, CA (TREATMENT OF CYSTIC
94080 FIBROSIS)
(B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

(B) Product License Issued

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

THERE ARE NO BIOLOGICAL PRODUCT DEVICE APPROVALS FOR DECEMBER 1993.

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 DECEMBER 1993.

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

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

N16420/S04	POLYTEF PASTE FOR INJECTION	MENTOR CORPORATION SANTA BARBARA, CA 93111	NEW SECONDARY CONTRACT STERILIZATION FACILITY	12/08/93
N18331/S23	PDS II (POLYDIOXANONE) SUTURE, DYED & UNDYED	ETHICON, INC. SOMERVILLE, NJ 08876-0151	USE OF AN ALTERNATE DILUENT IN THE STERILIZATION PROCESS	12/09/93
P790007/S12	HANCOCK MODIFIED ORIFICE (M.O.) AORTIC BIOPROSTHESIS (MODEL 250)	MEDTRONIC HEART VALVES MINNEAPOLIS, MN 55440	MANUFACTURING MODIFICATIONS	12/08/93
P790020/S54	PERMAFLEX UV NATURALS (VASURFILCON A) SOFT CONTACT LENSES	PILKINGTON BARNES HIND, USA SUNNYVALE, CA 94086-5200	RELOCATION OF THE MANUFACTURE AND PREPARATION OF THE MOLDS AND THE POLYMERIZATION OF THE DRY CONTACT LENSES	12/22/93
P810006/S18	COLLASTAT COLLAGEN ABSORBABLE HEMOSTATIC SPONGE, OTOFOAM ABSORBABLE HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION PLAINSBORO, NJ 08536	DISTRIBUTION OF SPONGE BY SMITH & NEPHEW RICHARDS, INC.	12/21/93
P820076/S15	DIPLOS CARDIAC	BIOTRONIK, INC.	APPROVAL TO	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	PACING SYSTEM, GEMNOS 04-A CARDIAC PACEMAKER	LAKE OSWEGO, OR 97035-5369	COMMERCIALLY DISTRIBUTE THE GEMNOS 04-A CARDIAC PACEMAKER	12/08/93
P830034/S23	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 MODIFY THE EYECARE PROFESSIONALS' TRIAL LENS DISINFECTION INSTRUCTIONS TO REDUCE THE RECOMMENDED STORAGE TIME	12/02/93
P830060/S33	VENTAK MODEL 6910 LEAD ADAPTER	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	APPROVAL FOR THE MODEL 6910 LEAD ADAPTER	12/14/93
P830061/S19	STER TIP PACING LEAD MODELS 4003 AND 4503, CAPSURE AND CAPSURE SP PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFICATIONS TO THE GENERIC TECHNICAL MANUAL	12/21/93
P840001/S29	MEDTRONIC ITREL AND ITREL II SPINAL CORD STIMULATION SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55440-9087	MODIFICATIONS TO PHYSICIAN AND HOSPITAL STAFF MANUAL AND PATIENT MANUAL	12/07/93
P850007/S10	PHYSIO-STIM	AMERICAN MEDICAL	CONCURRENCE WITH	

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
		ELECTRONICS, INC. RICHARDSON, TX 75081	CONDITIONS OF APPROVAL IN FDA'S FEBRUARY 8, 1991 APPROVABLE LETTER	12/06/93
P850088/S29	ULTRACARE DISINFECTING SOLUTION/NEUTRALIZER SYSTEM	ALLERGAN OPTICAL IRVINE, CA 92713-9534	APPROVAL TO INTRODUCE A 4 FL. OZ./12 TABLET CONFIGURATION THAT INCLUDES THE ALLERGAN CUP	12/15/93
P850089/S27	STER TIP PACING LEAD MODELS 5025 AND 5525, MEDTRONIC 5023M, 5523, 5024M AND 5524M CAPSURE SP PACING LEADS AND PACEMAKERS MODEL 4162 AND 4262 PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFICATIONS TO THE GENERIC TECHNICAL MANUAL FOR THE PACING LEADS	12/06/93
P850093/S10	BAUSCH & LOMB FIZZICLEAN AND THERMA-ZYME PROTEIN REMOVER, BAUSCH & LOMB RENU 1 STEP ENZYMATIC CLEANER	BAUSCH & LOMB HEALTHCARE AND OPTICS ROCHESTER, NY 14692-0450	APPROVAL TO COMBINE BAUSCH & LOMB RENU ENZYMATIC CLEANER WITH RENU MULTI-PURPOSE SOLUTION FOR SIMULTANEOUS ENZYMATIC CLEANING	12/22/93

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P860003/S20	UVAR	THERAKOS, INC.	MANUFACTURING	12/07/93
	PHOTOPHERESIS SYSTEM	WEST CHESTER, PA 19380	MODIFICATION	
P860061/S06	ULTRAZYME	ALLERGAN OPTICAL	REVISED LABELING	12/15/93
	ENZYMATIC CLEANER	IRVINE, CA 92713-9534		
P880027/S29	SCHNEIDER	SCHNEIDER (USA) INC.	REVISED LABELING	12/07/93
	MICROSOFTRAC PTCA CATHETER	PLYMOUTH, MN 55442		
P890045/S03	GELSEAL TRIAXIAL	CARBOMEDICS	REVISED LABELING	12/07/93
	VASCULAR GRAFT	AUSTIN, TX 78752-1793		
P890061/S06	VENTAK MODEL 6910	CARDIAC PACEMAKERS, INC.	APPROVAL FOR THE	12/14/93
	LEAD ADAPTER	ST. PAUL, MN 55112-5798	MODEL 6910 LEAD ADAPTER	
P900039/S03	COLLAGRAFT BONE	COLLAGEN CORPORATION	APPROVAL FOR THE	12/09/93
	GRAFT MATRIX	PALO ALTO, CA 94303-3308	MEDICAL HISTORY FORM TO BE USED IN THE POST-APPROVAL STUDY	
P900056/S05	ROTABLATOR	HEART TECHNOLOGY, INC.	REVISED OPERATIONS	12/07/93
	ROTATIONAL ANGIOPLASTY SYSTEM	BELLEVUE, WA 98005-1887	MANUAL	
P900060/S02	CARBOMEDICS	CARBOMEDICS, INC.	REVISED LABELING	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

12/21/93	PROSTHETIC HEART VALVE	AUSTIN, TX 78752-1793	

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

ORIGINAL VETERINARY NADAs

65-506 11-08-93	COMBICILLIN (SUSPENSION)	CATTLE DOGS HORSES	ANTHONY PRDTS ARCADIA, CA 91006	PENICILLIN G BENZATHINE 150,000 UNITS/ML PENICILLIN G PROCAINE 150,000 UNITS/ML
65-506 11-08-93	COMBICILLIN-AG (SUSPENSION)	CATTLE DOGS HORSES	ANTHONY PRDTS ARCADIA, CA 91006	PENICILLIN G BENZATHINE 150,000 UNITS/ML PENICILLIN G PROCAINE 150,000 UNITS/ML

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR DECEMBER 1993.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR DECEMBER 1993.