FDA DRUG AND DEVICE PRODUCT APPROVALS

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

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

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

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

*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.

Volume 15 (1)
January 1992

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

18-776 01-03-92 (SUPPL)	NORCURON (INJECTABLE)	ORGANON W ORANGE, NJ 07082	VECURONIUM BROMIDE 20MG/VIAL (NEW STRENGTH)
19-614 01-09-92 (SUPPL)	VERELAN (CAPSULE, EXTENDED RELEASE)	ELAN GAINESVILLE, GA 30504	VERAPAMIL HYDROCHLORIDE 180MG (NEW STRENGTH)
19-962 01-10-92 (2 S**)	TOPROL XL (TABLET, EXTENDED RELEASE)	AB HASSLE MOLNDAL, SWEDEN	METOPROLOL SUCCINATE EQ 50MG TARTRATE EQ 100MG TARTRATE EQ 200MG TARTRATE (BETA ADRENERGIC BLOCKER)
19-710 01-22-92 (SUPPL)	OPTIRAY 300 (INJECTABLE)	MALLINCKRODT ST LOUIS, MO 63134	IOVERSOL 64% (NEW STRENGTH) [CEREBRAL AND PERIPHERAL ARTERIOGRAPHY; CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE HEAD]
19-710 01-22-92 (SUPPL)	OPTIRAY 350 (INJECTABLE)	MALLINCKRODT ST LOUIS, MO 63134	IOVERSOL 74% (NEW STRENGTH) [CORONARY ARTERIOGRAPHY AND LEFT VENTRICULOGRAPHY;

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

CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE BODY; INTRAVENOUS EXCRETORY UROGRAPHY; INTRAVENOUS DIGITAL SUBTRACTION ANGIOGRAPHY; VENOGRAPHY]

S** - Refers to Standard Review, Substantially Equivalent
New Therapeutic Potential Code Replaces Former "C" Code

20-098	MIVACRON	BURROUGHS WELLC	MIVACURIUM CHLORIDE
01-22-92	IN DEXTROSE 5%	RES TRIANGLE PK, NC	EQ 0.5MG BASE/ML
(1 P*)	IN PLASTIC CONTAINER	22709	EQ 50MG BASE/100ML
	(INJECTABLE)		(NONDEPOLARIZING SKELETAL MUSCLE RELAXANT)

20-098	MIVACRON	BURROUGHS WELLC	MIVACURIUM CHLORIDE
01-22-92	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 2MG BASE/ML
(1 P*)		22709	(NONDEPOLARIZING SKELETAL MUSCLE RELAXANT)

19-983	PROSTEP	ELAN	NICOTINE
01-28-92	(FILM,	GAINESVILLE, GA	11MG/24HR
(3 S**)	EXTENDED RELEASE)	30504	22MG/24HR
			(SMOKING DETERRENT)

19-775	MINIPRESS XL	PFIZER	PRAZOSIN HYDROCHLORIDE
01-29-92	(TABLET,	NEW YORK, NY	2.5MG
(3 S**)	EXTENDED RELEASE)	10017	5MG
			(ANTIHYPERTENSIVE)

19-261	PAREMYD	ALLERGAN	HYDROXYAMPHETAMINE
01-30-92	(SOLUTION/DROPS)	IRVINE, CA	HYDROBROMIDE
(4 S**)		92715	1%
			TROPICAMIDE
			0.25%
			(MYDRIATIC)

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

19-734	CARDENE	DUPONT MERCK	NICARDIPINE HYDROCHLORIDE
01-30-92	(INJECTABLE)	WILMINGTON, DE	2.5MG/ML
(3 S**)		19880	(CALCIUM ION INFLUX INHIBITOR) [HYPERTENSION]
20-043	OMNIFLOX	ABBOTT	TEMAFLOXACIN HYDROCHLORIDE
01-30-92	(TABLET)	ABBOTT PARK, IL	EQ 400MG BASE
(1 S**)		60064	EQ 600MG BASE (ANTIBACTERIAL)

P* - Refers to Priority Review, Therapeutic Gain
New Therapeutic Potential Code Replaces Former "A" and "B" Code
S** - Refers to Standard Review, Substantially Equivalent
New Therapeutic Potential Code Replaces Former "C" Code

19-651	ASACOL	NORWICH EATON	MESALAMINE
01-31-92	(TABLET,	NORWICH, NY	400MG
(3 P*)	DELAYED RELEASE)	13815	(NONSTEROIDAL ANTI-INFLAMMATORY) [ULCERATIVE COLITIS]
50-605	CEFTIN	GLAXO	CEFUROXIME AXETIL
01-31-92	(TABLET)	RES TRIANGLE PK, NC	EQ 125MG BASE
(SUPPL)		27709	EQ 250MG BASE EQ 500MG BASE (NEW INDICATION -- UNCOMPLICATED URETHRAL AND ENDOCERVICAL GONORRHEA)

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

P* - Refers to Priority Review, Therapeutic Gain
New Therapeutic Potential Code Replaces Former "A" and "B" Code

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.

20-005 01-23-92	CARDENE SR (CAPSULE, EXTENDED RELEASE)	SYNTEX PALO ALTO, CA 94304 (CALCIUM ION INFLUX INHIBITOR) [HYPERTENSION]	NICARDIPINE HYDROCHLORIDE 30MG 45MG 60MG

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

ORIGINAL ABBREVIATED NDAs

73-243*	LOPERAMIDE HCL	PERRIGO	LOPERAMIDE HYDROCHLORIDE
01-21-92	(SOLUTION)	ALLEGAN, MI	1MG/5ML
		49010	(ANTIDIARRHEAL)
			(OTC)
81-264	BENZTROPINE MESYLATE	MUTUAL PHARM	BENZTROPINE MESYLATE
01-23-92	(TABLET)	PHILADELPHIA, PA	1MG
		19124	(ANTIPARKINSON)
81-265	BENZTROPINE MESYLATE	MUTUAL PHARM	BENZTROPINE MESYLATE
01-23-92	(TABLET)	PHILADELPHIA, PA	2MG
		19124	(ANTIPARKINSON)
72-354	DESOWEN	OWEN GALDERMA	DESONIDE
01-24-92	(LOTION)	FORT WORTH, TX	0.05%
		76115	(CORTICOSTEROID)
73-308	TOLMETIN SODIUM	PUREPAC	TOLMETIN SODIUM
01-24-92	(CAPSULE)	ELIZABETH, NJ	EQ 400MG BASE
		07207	(NONSTEROIDAL
			ANTI-INFLAMMATORY)
73-392	TOLMETIN SODIUM	BAKER CUMMINS	TOLMETIN SODIUM
01-24-92	(CAPSULE)	MIAMI, FL	EQ 400MG BASE
		33178	(NONSTEROIDAL
			ANTI-INFLAMMATORY)
73-456	ATENOLOL	MYLAN	ATENOLOL
01-24-92	(TABLET)	MORGANTOWN, WV	50MG
		26505	(BETA ADRENERGIC BLOCKER)
73-457	ATENOLOL	MYLAN	ATENOLOL
01-24-92	(TABLET)	MORGANTOWN, WV	100MG

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

ORIGINAL ABBREVIATED NDAs

26505 (BETA ADRENERGIC BLOCKER)

81-189 HYDROCHLOROTHIAZIDE DANBURY HYDROCHLOROTHIAZIDE
01-24-92 (TABLET) DANBURY, CT 25MG
06813 (DIURETIC)

*First Time Product Available Generically

81-190 HYDROCHLOROTHIAZIDE DANBURY HYDROCHLOROTHIAZIDE
01-24-92 (TABLET) DANBURY, CT 100MG
06813 (DIURETIC)

72-292* MICROCOL JOHNSON AND JOHNSON CHLORHEXIDINE GLUCONATE
01-28-92 (SOLUTION) ARLINGTON, TX 0.5%
76004 (ANTIMICROBIAL)
(OTC)

73-398* K-LEASE ADRIA POTASSIUM CHLORIDE
01-28-92 (CAPSULE, COLUMBUS, OH 8MEQ
EXTENDED RELEASE) 43216 (ELECTROLYTE REPLENISHER)

73-428* CO-LAV COPLEY POLYETHYLENE GLYCOL 3350
01-28-92 (POWDER CANTON, MA 240GM/BOT
FOR RECONSTITUTION) 02021 POTASSIUM CHLORIDE
2.98GM/BOT
SODIUM BICARBONATE
6.72GM/BOT
SODIUM CHLORIDE 5.84GM/BOT
SODIUM SULFATE, ANHYDROUS
22.72GM/BOT
(GASTROINTESTINAL LAVAGE)

89-697 HYDROCODONE BITARTRATE MIKART ACETAMINOPHEN

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

ORIGINAL ABBREVIATED NDAs

01-28-92	AND ACETAMINOPHEN	ATLANTA, GA	500MG
	(TABLET)	30318	HYDROCODONE BITARTRATE
			5MG (ANALGESIC)
63-100	TOBRAMYCIN SULFATE	GENSIA	TOBRAMYCIN SULFATE
01-30-92	(INJECTABLE)	IRVINE, CA	EQ 40MG BASE/ML
		92718	(ANTIBIOTIC, AMINOGLYCOSIDE)
72-995*	METOCLOPRAMIDE	ROXANE	METOCLOPRAMIDE HYDROCHLORIDE
01-30-92	INTENSOL	COLUMBUS, OH	EQ 10MG BASE/ML
	(CONCENTRATE)	43216	(UPPER GI TRACT MOTILITY
			STIMULATOR)

*First Time Product Available Generically

73-529*	DOXAPRAM HCL	STERIS	DOXAPRAM HYDROCHLORIDE
01-30-92	(INJECTABLE)	PHOENIX, AZ	20MG/ML
		85043	(ANALEPTIC)
73-282*	CLEMASTINE FUMARATE	LEMMON	CLEMASTINE FUMARATE
01-31-92	(TABLET)	SELLERSVILLE, PA	1.34MG
		18960	(ANTIHISTAMINE)
73-283*	CLEMASTINE FUMARATE	LEMMON	CLEMASTINE FUMARATE
01-31-92	(TABLET)	SELLERSVILLE, PA	2.68MG
		18960	(ANTIHISTAMINE)

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

ORIGINAL ABBREVIATED NDAs

*First Time Product Available Generically

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-776	NORCURON	ORGANON	VECURONIUM BROMIDE
01-03-92	(INJECTABLE)	W ORANGE, NJ	10MG/VIAL
		07082	20MG/VIAL
			(REVISED LABELING --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			HOW SUPPLIED)
17-920	TAGAMET	SKF	CIMETIDINE
01-07-92	(TABLET)	PHILADELPHIA, PA	200MG
		19101	300MG
			400MG
			800MG
			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS;
OVERDOSAGE)			
17-924	TAGAMET	SKF	CIMETIDINE HYDROCHLORIDE
01-07-92	(SOLUTION)	PHILADELPHIA, PA	EQ 300MG BASE/5ML
		19101	(REVISED LABELING --
PRECAUTIONS;			
			ADVERSE REACTIONS;
OVERDOSAGE)			
17-939	TAGAMET	SKF	CIMETIDINE HYDROCHLORIDE
01-07-92	(INJECTABLE)	PHILADELPHIA, PA	EQ 300MG BASE/2ML
		19101	(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS;
OVERDOSAGE)			

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-434	TAGAMET HCL IN	SKF	CIMETIDINE HYDROCHLORIDE
01-07-92	SODIUM CHLORIDE 0.9%	PHILADELPHIA, PA	EQ 6MG BASE/ML
	IN PLASTIC CONTAINER	19101	(REVISED LABELING --
	(INJECTABLE)		PRECAUTIONS;
			ADVERSE REACTIONS;
OVERDOSAGE)			

19-614	VERELAN	ELAN	VERAPAMIL HYDROCHLORIDE
01-09-92	(CAPSULE,	GAINESVILLE, GA	120MG
	EXTENDED RELEASE)	30504	180MG
			240MG
			(REVISED LABELING --
			DESCRIPTION;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)

19-851	LOTENSIN	CIBA	BENAZEPRIL HYDROCHLORIDE
01-09-92	(TABLET)	SUMMIT, NJ	EQ 5MG BASE
		07901	EQ 10MG BASE
			EQ 20MG BASE
			EQ 40MG BASE
			(REVISED LABELING --
			ADVERSE REACTIONS)

20-037	VOLTAREN	CIBA	DICLOFENAC SODIUM
01-09-92	(SOLUTION/DROPS)	SUMMIT, NJ	0.1%
		07901	(REVISED LABELING --
			CLINICAL PHARMACOLOGY)

18-988	VASOCIDIN	IOLAB	PREDNISOLONE
01-10-92	(SOLUTION/DROPS)	CLAREMONT, CA	SODIUM PHOSPHATE
		91711	EQ 0.23% PHOSPHATE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			SULFACETAMIDE SODIUM 10% (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
16-363	LASIX	HOECHST ROUSSEL	FUROSEMIDE
01-15-92	(INJECTABLE)	SOMERVILLE, NJ	10MG/ML
		08876	(REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
12-193*	SER-AP-ES	CIBA	HYDRALAZINE HYDROCHLORIDE
01-16-92	(TABLET)	SUMMIT, NJ	25MG
		07901	HYDROCHLOROTHIAZIDE 15MG RESERPINE 0.1MG (REVISED LABELING -- ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
17-447	NORPACE	SEARLE	DISOPYRAMIDE PHOSPHATE
01-16-92	(CAPSULE)	SKOKIE, IL	EQ 100MG BASE
		60077	EQ 150MG BASE (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

18-655	NORPACE CR	SEARLE	DISOPYRAMIDE PHOSPHATE
01-16-92	(CAPSULE, EXTENDED RELEASE)	SKOKIE, IL 60077	EQ 100MG BASE EQ 150MG BASE (REVISED LABELING -- WARNINGS; PRECAUTIONS)
18-936	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
01-21-92	(CAPSULE)	INDIANAPOLIS, IN 46285	EQ 20MG BASE (REVISED LABELING -- CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)
20-101	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
01-21-92	(SOLUTION)	INDIANAPOLIS, IN 46285	EQ 20MG BASE/5ML (REVISED LABELING -- ADVERSE REACTIONS; OVERDOSAGE)

* Permitted

50-560	CEFIZOX	SKF	CEFTIZOXIME SODIUM
01-22-92	(INJECTABLE)	PHILADELPHIA, PA 19101	EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (REVISED LABELING -- CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-478	ADALAT	MILES	NIFEDIPINE
01-23-92	(CAPSULE)	W HAVEN, CT 06516	10MG 20MG (REVISED LABELING -- ADVERSE REACTIONS)
18-780	HUMULIN R	LILLY	INSULIN BIOSYNTHETIC HUMAN
01-27-92	(INJECTABLE) (OTC)	INDIANAPOLIS, IN 46285	100 UNITS/ML (REVISED LABELING -- PATIENT PACKAGE INSERT)
19-377	HUMULIN L	LILLY	INSULIN ZINC SUSP
01-27-92	(INJECTABLE) (OTC)	INDIANAPOLIS, IN 46285	BIOSYNTHETIC HUMAN 100 UNITS/ML (REVISED LABELING -- PATIENT PACKAGE INSERT)
19-529	HUMULIN BR	LILLY	INSULIN BIOSYNTHETIC HUMAN
01-27-92	(INJECTABLE) (OTC)	INDIANAPOLIS, IN 46285	100 UNITS/ML (REVISED LABELING -- PATIENT PACKAGE INSERT)
19-571	HUMULIN U	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

01-27-92	(INJECTABLE)	INDIANAPOLIS, IN 46285	EXTENDED BIOSYNTHETIC HUMAN 100 UNITS/ML (REVISED LABELING -- PATIENT PACKAGE INSERT) (OTC)
19-717	HUMULIN 70/30	LILLY	INSULIN BIOSYNTHETIC HUMAN
01-27-92	(INJECTABLE)	INDIANAPOLIS, IN 46285	30 UNITS/ML INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN 70 UNITS/ML (REVISED LABELING -- PATIENT PACKAGE INSERT) (OTC)
19-112	VENTOLIN	GLAXO	ALBUTEROL SULFATE
01-28-92	(TABLET)	RES TRIANGLE PK, NC 27709	EQ 2MG BASE EQ 4MG BASE (REVISED LABELING -- OVERDOSAGE)
19-309	VASOTEC	MSD	ENALAPRILAT
01-29-92	(INJECTABLE)	W POINT, PA 19486	1.25MG/ML (REVISED LABELING -- WARNINGS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-355	VAGISTAT-1	BRISTOL MYERS	TIOCONAZOLE
01-31-92	(OINTMENT)	EVANSVILLE, IN 47721	6.5% (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

50-605	CEFTIN	GLAXO	CEFUROXIME AXETIL
01-31-92	(TABLET)	RES TRIANGLE PK, NC 27709	EQ 125MG BASE EQ 250MG BASE EQ 500MG BASE (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1147 1-30-92	NONE (INJECTABLE)	WESTERN PATHOLOGY CONSULTANTS, PC SCOTTSBLUFF, NE 69361	RED BLOOD CELLS (TRANSFUSION) (A&B)
1147 1-30-92	NONE (INJECTABLE)	WESTERN PATHOLOGY CONSULTANTS, PC SCOTTSBLUFF, NE 69361	WHOLE BLOOD (TRANSFUSION) (A&B)
239 1-31-92	NONE (INJECTABLE)	HOUCHIN COMM BLOOD BANK BAKERSFIELD, CA 93301	CRYOPRECIPITATED AHF (TRANSFUSION) (B)
1131 1-31-92	NONE (INJECTABLE)	PERSONAL BLOOD STORAGE OF MEMPHIS MEMPHIS, TN 38118	PLATELETS (B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910012 01-06-92	HLA PHENOTYPING	ROCHE BIOMED LAB ELON COLLEGE, NC 27244	LEUKOCYTE TYPING TRAYS (C)
BK910019 01-16-92	PALL BPF4B LEUKOCYTE REMOVAL BLOOD PROCESSING FILTER WITH ATTACHED TUBING AND BLOOD BAG	PALL BIOMED GLEN COVE, NY 11542	LEUKOCYTE REMOVAL BLOOD PROCESSING FILTER WITH ATTACHED TUBING AND BLOOD BAG (C)
BK910022 01-21-92	DU PONT SORVALL RC 3B PLUS AND RC 3C PLUS CENTRIFUGES	DUPONT MED PRODS WILMINGTON, DE 19880	DU PONT SORVALL RC 3B PLUS AND RC 3C PLUS CENTRIFUGES
BK900034 01-27-92	PHLEBOTOMIST PROTECTION DEVICE	MILES BERKELEY, CA 94701	BLOOD BANK SUPPLIES (C)

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

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

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

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

P900032 01/31/92	AIS EXCIMER LASER ANGIOPLASTY SYSTEM	ADVANCED INTERNATIONAL SYSTEMS, INC. IRVINE, CA 92718	AIS EXCIMER LASER ANGIOPLASTY SYSTEM FOR THE PERCUTANEOUS TREATMENT OF CLINICALLY SIGNIFICANT OBSTRUCTIVE CORONARY ARTERY DISEASE
P900070 01/30/92	META DDDR PACING SYSTEM	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	META DDDR PACING SYSTEM FOR THE MAINTENANCE OF ATRIO-VENTRICULAR SYNCHRONY
P910056 01/17/92	CHIROFLEX II MODELS 32-C20SX/XX, 32-C21SX/XX, 32-C22SX/XX, 32-C23SX/XX, AND 32-C24SX/XX SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	CHIRON OPHTHALMICS, INC. IRVINE, CA 92718	MODELS FOR PRIMARY IMPLANTATION FOR THE USUAL CORRECTION OF APHAKIA IN PERSONS 60 YEARS OR OLDER WHO HAVE UNDERGONE EXTRACAPSULAR CATARACT EXTRACTION
P910058 01/17/92	CHIROFLEX MODEL 32-C10XX SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	CHIRON OPHTHALMICS, INC. IRVINE, CA 92718	FOR PRIMARY IMPLANTATION FOR THE VISUAL CORRECTION OF APHAKIA IN PERSONS 60 YEARS OF AGE OR OLDER

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

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

N17511/S09	HYSKON (32% DEXTRAN 70) HYSTEROSCOPY FLUID	KABI PHARMACIA PISCATAWAY, NJ 08855-1327	MANUFACTURE AND CONTROL OF HYSKON (32% DEXTRAN 70) HYSTEROSCOPY FLUID BY AFFILIATED COMPANY, KABI PHARMACIA, CLAYTON, NC	01/24/92
P800002/S08	NON-WOVEN WEB (NWW) HEMOSTAT (AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT OR AVITENE MCH)	MEDCHEM PRODUCTS, INC. WOBURN, MA 01801	CHANGE IN DEVICE PACKAGING THAT WOULD PROVIDE FOR THE MARKETING OF AN ENDOSCOPIC FORM OF THE DEVICE	01/07/92
P800022/S28	ZYDERM COLLAGEN IMPLANT NEW TRADE NAME: ZYDERM COLLAGEN IMPLANT WITH FINE GAUGE NEEDLE	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	MARKET PRODUCT WITH A 32 GAUGE NEEDLE UNDER A SEPARATE TRADE NAME	01/08/92
P810002/S22	ST. JUDE MEDICAL PYROLYTIC CARBON HEART VALVE	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	REVISION OF THE POSTAPPROVAL STUDY PROTOCOL FOR MONITORING VALVES FABRICATED FROM COMPONENTS MANUFACTURED BY ST. JUDE MEDICAL	01/09/92
P810046/S104	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, HARTZLER ACK 11 AND ACS PRISM CORONARY DILATATION CATHETERS	ADVANCED CARDIOVASCULAR SANTA CLARA, CA 95052-8167	ADDITIONAL BALLOON LENGTHS OF 10 MM, 15MM, 25 MM, 30 MM, 35MM, AND 40 MM FOR THE HARTZLER ACX II AND ACS PRISM CORONARY DILATATION CATHETERS	01/17/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P810046/S111	SIMPSON-ROBERT ADVANCED CORONARY BALLOON DILATATION CATHETER/ACS SLALOM CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SANTA CLARA, CA 95052-8167	ADDITION OF A TRACKING SHEATH TO THE ACS SLALOM CORONARY DILATATION CATHETER	01/16/92
P810046/S114	SIMPSON-ROBERT ADVANCED CORONARY BALLOON DILATATION CATHETER	ADVANCED CARDIOVASCULAR SANTA CLARA, CA 95052-8167	ADDITION OF AN ALTERNATE STERILIZATION SITE FOR THE STERILIZATION OF PTCA CATHETERS	01/17/92
P810046/S115	SIMPSON-ROBERT ADVANCED CORONARY BALLOON DILATATION CATHETER, ACS RX STREAK .014 CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SANTA CLARA, CA 95052-8167	ADDITION OF CAUTIONS AND NOTES TO THE INSTRUCTION FOR USE OF THE ACS RX STREAK .014 DILATATION CATHETER	01/16/92
P820021/S22	SOFTCON AND NEWVUES (VIFILCON A) SOFT (HYDROPHILIC), FOCUS VISITINT AND SOFTCOLORS AND FOCUS TORIC (VIFILCON A) (HYDROPHILIC) CONTACT LENSES	CIBA VISION CORPORATION ATLANTA, GA 30360	REVISED LABELING	01/14/92
P820065/S76	THE BOSTON LENS II (ITAFOCON A) AND THE BOSTON LENS IV (ITAFOCON B) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY	01/14/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P830026/S51 01/17/92	COSMOS PACING SYSTEM, NOVA II CARDIAC PULSE GENERATOR MODEL 282-04R	INTERMEDICS, INC. ANGLETON, TX 77515	LABELING ADDITIONS AND ADDRESS CHANGE TO THE PHYSICIAN'S MANUAL SUPPLEMENT
P830026/S52 01/21/92	COSMOS PACING SYSTEM, NOVA II CARDIAC PULSE GENERATOR MODEL 282-04Y	INTERMEDICS, INC. ANGLETON, TX 77515	LABELING ADDITIONS AND ADDRESS CHANGE TO THE PHYSICIAN'S MANUAL SUPPLEMENT
P840001/S22 01/17/92	ITREL TOTALLY IMPLANTABLE SPINAL CORD STIMULATION SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODEL 7455 VERSION QU02 SOFTWARE MODIFICATION FOR THE ITREL TOTALLY IMPLANTABLE SPINAL CORD STIMULATION SYSTEM
P840055/S24 01/14/92	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	ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY
P850021/S16 01/07/92	HYBRID PERCUTANEOUS TRANSLUMINAL	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA	CHANGE OF THE NAME OF THE EDGE PTCA CATHETER TO REACH .14

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CORONARY ANGIOPLASTY CATHETER, REACH .14 PTCA CATHETER	92711-1150	PTCA CATHETER	
P850064/S06	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR, LIFE PULSE HIGH-FREQUENCY JET VENTILATOR ADMINISTRATION SET	BUNNELL, INC. SALT LAKE CITY, UT 84115	LIFE PULSE HIGH-FREQUENCY JET VENTILATOR ADMINISTRATION SET FOR STERILE WATER HUMIDIFICATION	01/09/92
P850069/S08	KENNEDY LAD LIGAMENT AUGMENTATION DEVICE	3M HEALTH CARE ST. PAUL, MN 55144-1000	ADDITION OF AN EYELET WITH AN INTERNAL DIAMETER OF 3.5MM	01/28/92
P860019/S50	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, THE SHADOW P-14	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	CHANGE OF TRADE NAME	01/16/92
P860019/S51	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, TRAPPER EXCHANGE DEVICE	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	REVISED LABELING	01/16/92
P860022/S37	THE BOSTON EQUALENS (ITAFLUOROFOCON A)	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA	ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY	01/14/92

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTALS	
	AND THE BOSTON RXD (ITABIS-FLUOROFOCON A) CONTACT LENSES	01887	
P870043/S14 01/29/92	SPECTRAPROBE-PLR CATHETER AND MODEL 900 OPTILASE CONTACT LASER SOURCE SYSTEM, 2.5MM SPECTRAPROBE-MAX AND 2.5MM SPECTRAPROBE-MAX FLEX CATHETERS	TRIMEDYNE, INC. IRVINE, CA 92714	UPDATE THE INSTRUCTIONS FOR USE AND NAME CHANGE
P870050/S03 01/28/92	SEREINE CONTACT LENS CLEANER	WILSA, INC. DENVER, CO 80223	ADDITIONAL BOTTLE (CONTAINER) SIZE
P870051/S03 01/28/92	SEREINE CONTACT LENS WETTING AND SOAKING SOLUTION	WILSA, INC. DENVER, CO 80223	ADDITIONAL BOTTLE (CONTAINER) SIZE
P780007/S37 01/31/92	HYDRON (POLYMACON) SOFT (HYDROPHILIC)	ALLERGAN OPTICAL IRVINE, CA 92713-9534	MANUFACTURE AND MARKET TWO ADDITIONAL COLORS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CONTACT LENSES, ZERO 4 AND ZERO 6 (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES		
P870042/S07 01/31/92	STERISAL STERILE UNPRESERVED AEROSOL PRESSURIZED SPRAY	RADIATION STERILIZERS, INC. DECATUR, GA 30035-3808	ADDITIONAL BOTTLE (CONTAINER) SIZE
P880016/S03 01/23/92	ONCOR B/T GENE REARRANGEMENT TEST	ONCOR, INC. GAITHERSBURG, MD 20884	BT BLUE FOR DETECTING CLONAL POPULATIONS OF LYMPHOID CELLS IN MIXED CELL POPULATIONS
P880027/S17 01/24/92	SCHNEIDER MICROSOFTRAC PTCA CATHETER, SCHNEIDER MONORAIL PICCOLINO-FORTE 18 PTCA CATHETERS	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	MONORAIL PICCOLINO-FORTE 18 PTCA CATHETERS WITH OPTIONAL SILICONE FILM COATING
P880027/S19 01/30/92	SCHNEIDER MICROSOFTRAC PTCA CATHETER, SCHNEIDER MAGNARAIL PTCA CATHETERS: MODEL NUMBERS MR-020, MR-025, MR-030, MR-035, AND MR-040	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	MAGNARAIL PTCA CATHETERS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P880027/S20 01/24/92	SCHNEIDER MICROSOFTRAC PTCA CATHETER, SCHNEIDER MONORAIL PICCOLINO, XLP, MAGNUM-MEIER, AND MONORAIL PICCOLINO-FORTE PTCA CATHETERS	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	OPTIONAL APPLICATION OF A SILICONE FILM TO THE PET BALLOON SURFACE
P880027/S21 01/24/92	SCHNEIDER MICROSOFTRAC, XLP 30 AND MONORAIL PICCOLINO-FORTE 30 PTCA CATHETERS, MODEL NOS. XLP-025, 030, 035, P30-025, 030, 035, AND 040	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	ALTERNATE DESIGN CONFIGURATIONS TO BE MARKETED UNDER THE TRADE NAMES SCHNEIDER XLP 30 AND MONORAIL PICCOLINO-FORTE 30 PTCA CATHETERS
P880038/S19 01/21/92	META MV PACING SYSTEM, META II MODELS 1204 AND 1204H	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	REVISED LABELING FOR THE META II MODELS 1204 AND 1204H, AND INTRODUCTION OF SCAMP SOFTWARE VERSION V2.51
P890039/S01 01/21/92	MAESTRO SAVVI MODEL 305 PACING SYSTEM	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	POLYSAFE A-TRACK MODEL AT-332 ENDOCARDIAL PACING LEAD, RECONSTITUTION OF THE LEAD PACKAGE

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

			CONTENTS, AND APPLICATION OF THE 2000 V-DC HIPOT TEST
P890039/S03 01/21/92	MAESTRO SAVVI MODEL 305 PACING SYSTEM	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	INTRODUCTION OF POLYSAFE A-TRACK PACING LEADS: MODELS AT-343, AT-344, AT-443, AT-444, 425-04 AND 425-06
P890043/S14 01/16/92	SIMPSON CORONARY ATHEROCATH	DEVICES FOR VASCULAR INTERVENTION, INC. REDWOOD CITY, CA 94063	CHANGE IN STERILIZATION FACILITY
P890072/S04 01/28/92	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED) WITH AN ULTRAVIOLET LIGHT ABSORBER	PROGRESSIVE CHEMICAL RESEARCH, LTD. ALBERTA, CANADA TJ2 2V4	ADDITIONAL CONTACT LENS FINISHING LABORATORIES
P900001/S04 01/14/92	SGP 3 (UNIFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR, BLUE AND GREEN TINTED)	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NJ 07751	ADDITIONAL CONTACT LENS FINISHING LABORATORIES

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 JANUARY 1992.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR JANUARY 1992.

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) 295-8428

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

*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.

Volume 15 (2)
February 1992

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

20-166 02-14-92 (7* S**)	SODIUM THIOSULFATE (INJECTABLE) 21702	DEPT ARMY FORT DETRICK, MD	SODIUM THIOSULFATE 250MG/ML (ANTIDOTE) [TREATMENT OF CYANIDE POISONING]
19-548 02-19-92 (3 S**)	TORNALATE (SOLUTION/INHALATION) 19355	STERLING WINTHROP MALVERN, PA	BITOLTEROL MESYLATE 0.2% (BRONCHODILATOR)
20-013 02-21-92 (1 S**)	MAXAQUIN (TABLET) 60077	SEARLE SKOKIE, IL	LOMEFLOXACIN HYDROCHLORIDE EQ 400MG BASE (ANTIBACTERIAL)
20-005 02-21-92	CARDENE SR (CAPSULE,	SYNTEX PALO ALTO, CA	NICARDIPINE HYDROCHLORIDE 30MG

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**) EXTENDED RELEASE) 94304 45MG
60MG
(CALCIUM ION
INFLUX INHIBITOR)

18-828 ZOVIRAX BURROUGHS WELLC ACYCLOVIR
02-26-92 (CAPSULE) RES TRIANGLE PK, NC 200MG
(SUPPL) 27709 (NEW INDICATION --
VARICELLA INFECTIONS)
[CHICKENPOX]

7* - Refers to First Approved NDA For Drug Product Already Marketed
S** - Refers to Standard Review, Substantially Equivalent
(New Therapeutic Potential Code Replaces Former "C" Code)

19-909 ZOVIRAX BURROUGHS WELLC ACYCLOVIR
02-26-92 (SUSPENSION) RES TRIANGLE PK, NC 200MG/5ML
(SUPPL) 27709 (NEW INDICATION --
VARICELLA INFECTIONS)
[CHICKENPOX]

20-089 ZOVIRAX BURROUGHS WELLC ACYCLOVIR
02-26-92 (TABLET) RES TRIANGLE PK, NC 800MG
(SUPPL) 27709 (NEW INDICATION --
VARICELLA INFECTIONS)
[CHICKENPOX]

20-109 SYNAREL SYNTEX NAFARELIN ACETATE
02-26-92 (SPRAY, METERED) PALO ALTO, CA EQ 0.2MG BASE/INH
(6 S**, V***) 94304 (GONADOTROPIN RELEASING
HORMONE ANALOG)
[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

S** - Refers to Standard Review, Substantially Equivalent
New Therapeutic Potential Code Replaces Former "C" Code
V*** - Designated Orphan Drug

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.

THERE ARE NO APPROVABLE ORIGINAL NDAs FOR THE MONTH OF FEBRUARY 1992.

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

ORIGINAL ABBREVIATED NDAs

73-085	FLUOCINONIDE	NMC	FLUOCINONIDE
02-14-92	(CREAM)	GLENDALE, NY	0.05%
	11385	(CORTICOSTEROID)	

72-651	NIFEDIPINE	NOVOPHARM	NIFEDIPINE
02-19-92	(CAPSULE)	SCARBOROUGH	10MG
	ONTARIO, CANADA	(CALCIUM ION	
		INFLUX INHIBITOR)	

72-652*	ALBUTEROL SULFATE	DEY	ALBUTEROL SULFATE
02-21-92	(SOLUTION/INHALATION)	NAPA, CA	EQ 0.083% BASE
	94558	(BRONCHODILATOR)	

72-646	SILPHEN	SILARX	DIPHENHYDRAMINE HYDROCHLORIDE
02-27-92	(SYRUP)	SPRING VALLEY, NY	12.5MG/5ML
	10977	(ANTIHISTAMINE)	
		(OTC)	

72-761	METAPROTERENOL SULFATE	BIOCRAFT	METAPROTERENOL SULFATE
02-27-92	(SYRUP)	FAIR LAWN, NJ	10MG/5ML
	07410	(BRONCHODILATOR)	

73-043	BACLOFEN	BIOCRAFT	BACLOFEN
02-27-92	(TABLET)	FAIR LAWN, NJ	10MG
	07410	(SKELETAL MUSCLE RELAXANT)	

73-044	BACLOFEN	BIOCRAFT	BACLOFEN
02-27-92	(TABLET)	FAIR LAWN, NJ	20MG
	07410	(SKELETAL MUSCLE RELAXANT)	

72-692	GENCEPT 0.5/35-21	GENCON	ETHINYL ESTRADIOL
02-28-92	(TABLET)	DALLAS, TX	0.035MG
	75206	NORETHINDRONE	

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

ORIGINAL ABBREVIATED NDAs

0.5MG (HORMONAL CONTRACEPTIVE)

* First Time Product Available Generically

72-693 02-28-92	GENCEPT 1/35-21 (TABLET)	GENCON DALLAS, TX 75206	ETHINYL ESTRADIOL 0.035MG NORETHINDRONE 1MG (HORMONAL CONTRACEPTIVE)
72-694 02-28-92	GENCEPT 10/11-21 (TABLET)	GENCON DALLAS, TX 75206	ETHINYL ESTRADIOL 0.035MG NORETHINDRONE 0.5MG AND 1MG (HORMONAL CONTRACEPTIVE)
72-695 02-28-92	GENCEPT 0.5/35-28 (TABLET)	GENCON DALLAS, TX 75206	ETHINYL ESTRADIOL 0.035MG NORETHINDRONE 0.5MG (HORMONAL CONTRACEPTIVE)
72-696 02-28-92	GENCEPT 1/35-28 (TABLET)	GENCON DALLAS, TX 75206	ETHINYL ESTRADIOL 0.035MG NORETHINDRONE 1MG (HORMONAL CONTRACEPTIVE)
72-697 02-28-92	GENCEPT 10/11-28 (TABLET)	GENCON DALLAS, TX	ETHINYL ESTRADIOL 0.035MG

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
		ORIGINAL ABBREVIATED NDAs	
		75206	NORETHINDRONE 0.5MG AND 1MG (HORMONAL CONTRACEPTIVE)
72-972 02-28-92	SULINDAC (TABLET)	LEMMON SELLERSVILLE, PA 18960	SULINDAC 150MG (NONSTEROIDAL ANTI-INFLAMMATORY)
72-973 02-28-92	SULINDAC (TABLET)	LEMMON SELLERSVILLE, PA 18960	SULINDAC 200MG (NONSTEROIDAL ANTI-INFLAMMATORY)
73-005* 02-28-92	CINOXACIN (CAPSULE)	BIOCRAFT FAIR LAWN, NJ 07410	CINOXACIN 250MG (URINARY ANTI-INFECTIVE)
73-006* 02-28-92	CINOXACIN (CAPSULE)	BIOCRAFT FAIR LAWN, NJ 07410	CINOXACIN 500MG (URINARY ANTI-INFECTIVE)
81-034* 02-28-92	THEO-24 (CAPSULE, EXTENDED RELEASE)	SEARLE SKOKIE, IL 60077	THEOPHYLLINE 400MG (BRONCHODILATOR)

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

ORIGINAL ABBREVIATED NDAs

* First Time Product Available Generically

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-219	BETAGAN	ALLERGAN	LEVOBUNOLOL HYDROCHLORIDE
02-03-92	(SOLUTION)	IRVINE, CA	0.5%
		92715	(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-814	BETAGAN	ALLERGAN	LEVOBUNOLOL HYDROCHLORIDE
02-03-92	(SOLUTION)	IRVINE, CA	0.25%
		92715	(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
50-589	CEFIZOX	SKF	CEFTIZOXIME SODIUM
02-06-92	IN DEXTROSE 5%	PHILADELPHIA, PA	EQ 20MG BASE/ML
	IN PLASTIC CONTAINER	19101	EQ 40MG BASE/ML
	(INJECTABLE)		(REVISED LABELING -- DOSAGE AND ADMINISTRATION)
50-585	ROCEPHIN	ROCHE	CEFTRIAXONE SODIUM
02-11-92	(INJECTABLE)	NUTLEY, NJ	EQ 250MG BASE/VIAL
		07110	EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE)
50-670	ZITHROMAX	PFIZER	AZITHROMYCIN
02-11-92	(CAPSULE)	GROTON, CT	250MG
		06340	(REVISED LABELING --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

CLINICAL PHARMACOLOGY)

16-199	CORTENEMA	SOLVAY	HYDROCORTISONE
02-12-92	(ENEMA)	ATLANTA, GA 30308	100MG/60ML (REVISED LABELING -- HOW SUPPLIED)
18-298	TAVIST D	SANDOZ	CLEMASTINE FUMARATE
02-12-92	(TABLET, EXTENDED RELEASE)	E HANOVER, NJ 07936	EQ 1MG BASE PHENYLPROPANOLAMINE HYDROCHLORIDE 75MG (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
16-848	ANADROL-50	SYNTEX	OXYMETHOLONE
02-18-92	(TABLET)	PALO ALTO, CA 94304	50MG (REVISED LABELING -- PRECAUTIONS)
19-618	ROWASA	SOLVAY	MESALAMINE
02-19-92	(ENEMA)	MARIETTA, GA 30062	4GM/60ML (REVISED LABELING -- ADVERSE REACTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-919 02-19-92	ROWASA (SUPPOSITORY)	SOLVAY MARIETTA, GA 30062	MESALAMINE 500MG (REVISED LABELING -- ADVERSE REACTIONS)
12-885 02-27-92	WINSTROL (TABLET)	STERLING NEW YORK, NY 10016	STANOZOLOL 2MG (REVISED LABELING -- PRECAUTIONS)
19-962 02-27-92	TOPROL XL (TABLET, EXTENDED RELEASE)	AB HASSLE MOLNDAL, SWEDEN	METOPROLOL SUCCINATE EQ 50MG TARTRATE EQ 100MG TARTRATE EQ 200MG TARTRATE (REVISED LABELING -- CLINICAL PHARMACOLOGY)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

956	VIRONOSTIKA	ORGANON TEKNIKA	HUMAN T-LYMPHOTROPIC
02-04-92	HTLV-I	DURHAM, NC	VIRUS TYPE I (HTLV-I)
	MICROELISA	27704	(DETECTION OF ANTIBODIES
	SYSTEM		TO HTLV-I ANTIGEN IN
	(IN-VITRO TEST)		SERUM OR PLASMA)
			(B)
1148	NONE	HOWARD YOUNG MED	RED BLOOD CELLS
02-05-92	(INJECTABLE)	WOODRUFF, WI	(TRANSFUSION)
		54568	(A&B)
1148	NONE	HOWARD YOUNG MED	WHOLE BLOOD
02-05-92	(INJECTABLE)	WOODRUFF, WI	(TRANSFUSION)
		54568	(A&B)
1149	NONE	HRF	SOURCE PLASMA
02-05-92	(INJECTABLE)	BURLINGTON, NC	(FURTHER MANUFACTURING)
		27217	(A&B)
1150	FLUOROGNOST	WALDHEIM PHARMAZEUTIKA	HUMAN IMMUNODEFICIENCY
02-05-92	HIV-1 IFA	G.m.b.H.	VIRUS TYPE I
	(IN-VITRO TEST)	VIENNA, AUSTRIA	(DETECTION OF ANTIBODY
		A-1091	TO HUMAN IMMUNODEFICIENCY
			VIRUS TYPE I (HIV-1) IN
			HUMAN SERUM OR PLASMA)
			(A&B)
43	ABBOTT HIVAB	ABBOTT	HUMAN IMMUNODEFICIENCY
02-14-92	HIV-1/HIV-2	N CHICAGO, IL	VIRUS TYPE 1 AND 2
	(IN-VITRO TEST)	60064	(DETECTION OF HUMAN
			IMMUNODEFICIENCY VIRUS
			TYPE 1 AND 2 IN HUMAN
			SERUM OR PLASMA)
			(B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

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

467 NONE ALLERMED POSITIVE SKIN TEST
02-14-92 (INJECTABLE) SAN DIEGO, CA CONTROL-HISTAMINE
92111 (POSITIVE CONTROL IN
EVALUATION OF ALLERGENIC
SKIN TESTING)

361 NONE BLOOD BANK OF ALASKA SOURCE PLASMA
02-20-92 (INJECTABLE) ANCHORAGE, AK (FURTHER MANUFACTURING)
99508 (B)

1127 NONE HUNTER BLOOD PLASMA
02-26-92 (INJECTABLE) CLEARWATER, FL (TRANSFUSION)
34616 (B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

(B) Product License Issued

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910004 02-21-92	DUPACO BLOOD FLUID WARMING CUFF SET 92056 (C)	MPI DUPACO OCEANSIDE, CA	EMPTY CONTAINER FOR COLLECTION AND PROCESSING OF BLOOD AND BLOOD COMPONENTS

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 FEBRUARY 1992.

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P780010/S19 02/25/92	PERMALENS AND PERMALENS XL (PERFILCON A) HYDROPHILIC CONTACT LENSES	COOPERVISION, INC. ROCHESTER, NY 14623	CONSOLIDATED PACKAGE INSERT FOR PERMALENS AND PERMALENS XL (PERFILCON A) HYDROPHILIC CONTACT LENSES
P790018/S18 02/25/92	MEDTRONIC HALL PROSTHETIC HEART VALVE	MEDTRONIC, INC. MINNEAPOLIS, MN 55440	ADDITION OF A WARNING STATEMENT TO THE LABELING
P810020/S03 02/14/92	PALACOS R BONE CEMENT	EM INDUSTRIES, INC. HAWTHORNE, NY 10532	CHANGES IN PACKAGING MATERIALS
P810046/S106 02/10/92	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS XT 600 CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR ACS XT 600 CORONARY DILATATION CATHETER
P810046/S112 02/04/92	SIMPSON-ROBERTS CORONARY BALLOON DILATATION CATHETER	ADVANCED CARDIOVASCULAR TEMECULA, CA 92591-4628	ALTERNATIVE MATERIALS FOR APPLICATION AS PROXIMAL MARKERS ON VARIOUS ACS CORONARY DILATATION CATHETERS
P810046/S113 02/07/92	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETERS	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	ALTERNATE LINEAR LOW DENSITY POLYETHYLENE MATERIAL TO FORM THE BALLOON OF THE CATHETERS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P820003/S62 02/07/92	MEDTRONIC MODEL 7000 VERSATRAX PACING SYSTEM, MEDTRONIC MODEL 9710A PROGRAMMER, MEDTRONIC MODEL 9712 PRINTER, AND 9751B PRINTER	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	RELABELING OF PROGRAMMER AND PRINTERS TO ALLOW CARDIAC PACEMAKERS, INC. TO COMMERCIALLY DISTRIBUTE THEM UNDER ITS OWN BRAND NAME AND MODEL NUMBERS
P820056/S50 02/25/92	OPTACRYL 60 (KOLFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON OPTICAL, INC. MESA, AZ 85204	ADDITIONAL MANUFACTURING AND DISTRIBUTION SITE
P820063/S50 02/20/92	PARAPERM O_2 (PASIFOCON A) RIGID GAS PERMEABLE CONTACT LENSES	PARAGON OPTICAL, INC. MESA, AZ 85204	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P820065/S77 02/20/92	THE BOSTON LENS II (ITAFOCON A) AND THE BOSTON LENS IV (ITAFOCON B) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P820076/S13	DIPLOS-03	BIOTRONIK, INC.	SOFTWARE MODULE SWM

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	PULSE GENERATOR AND MODEL EPR-400 PROGRAMMER SOFTWARE MODULE SWM 600 VERSION C01U02	LAKE OSWEGO, OR 97035-5369	600 VERSION C01U02 FOR USE WITH THE PMS 600 PROGRAMMER	02/07/92
P830045/S36	AFP MODEL 283 PULSE GENERATOR WITH MODEL 370 PROGRAMMER, PHOENIX MODEL 2009M/S AND MODEL 2009K PULSE GENERATOR	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	SIEMENS PACESETTER PHOENIX MODEL 2009M/S AND MODEL 2009K PULSE GENERATOR	02/25/92
P830061/S17	CAPSURE AND CAPSURE SP PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55421-3576	ADDITION OF A WARNING TO THE LABELING WHICH INFORMS USERS OF POSSIBLE COMPLICATIONS WHICH CAN OCCUR WHEN LEAD IS INSERTED AND/OR REPOSITIONED	02/14/92
P840040/S27	HEART TRAK CORONARY BALLOON DILATATION CATHETER SYSTEM	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	COATING FOR THE DISTAL LUMEN OF GLIDER, SLIDER, AND NITECH CATHETERS	02/25/92
P850021/S17	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, SLINKY PTCA CATHETER	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	REVISED LABELING	02/14/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P850038/S17	PARAPERM EW (PASIFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON OPTICAL, INC. MESA, AZ 85204	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	02/18/92
P850077/S14	SUNSOFT (METHAFILCON A) SOFT (HYDROPHILIC) LENS, REVOLUTION (METHAFILCON A) SOFT (HYDROPHILIC) EXTENDED WEAR LENS	SUNSOFT CORPORATION ALBUQUERQUE, NM 87109	ALTERNATE MANUFACTURING SITE	02/18/92
P850088/S20	LENS PLUS OXYSEPT DISINFECTION SYSTEM, ULTRACARE DISINFECTANT/ NEUTRALIZER SYSTEM	ALLERGAN OPTICAL IRVINE, CA 92715-1599	MODIFICATION OF THE FORMULATION OF LENS PLUS OXYSEPT NEUTRALIZING TABLETS	02/21/92
P850089/S20	CAPSURE AND CAPSURE SP PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	ADDITION OF A WARNING TO THE LABELING WHICH INFORMS USERS OF POSSIBLE COMPLICATIONS WHICH CAN OCCUR WHEN LEAD IS INSERTED AND/OR REPOSITIONED	02/14/92
P860019/S42	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, SCIMED	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	NEW MODEL CATHETER WITH BALLOON DIAMETERS OF 1.5 MM, 2.0 MM, 2.5 MM, 3.0 MM AND 3.5 MM, TO BE	02/25/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	COBRA 10 CATHETER		MARKETED UNDER THE TRADE NAME COBRA 10	
P860019/S48	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, SCIMED ACE AND LONG ACE	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	MANUFACTURING PROCESS CHANGES	02/14/92
P860022/S38	THE BOSTON EQUALENS (ITAFLUOROFOCON A) AND THE BOSTON RXD (ITABISFLUOROFOCON A) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	02/20/92
P870007/S05	STERIDYNE SALINE SOLUTION, STERILE PRESERVED SALINE SOLUTION	OPTOPICS LABORATORIES CORPORATION FAIRTON, NJ 08320-0210	CHANGE THE PH FROM 7.2-7.5 TO 6.5-7.0	02/25/92
P870018/S05	SIEMENS LITHOSTAR LITHOTRIPTER	SIEMENS MEDICAL SYSTEMS, INC. ISELIN, NJ 08830	REVISED LABELING	02/05/92
P870024/S30	FLUOROPERM (PAFLUFOCON A), FLUOROPERM (PAFLUFOCON A, B, AND C) RIGID GAS PERMEABLE	PARAGON OPTICAL MESA, AZ 85204	COMBINE LABELING FOR FLUOROPERM RIGID GAS PERMEABLE CONTACT LENSES INTO A SINGLE FITTING GUIDE, PACKAGE INSERT, AND	02/25/92

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	CONTACT LENSES (CLEAR AND TINTED)		WEARER'S GUIDE	
P870024/S31	FLUOROPERM 92 (PAFLUFOCON A), FLUOROPERM 60 (PAFLUFOCON B), FLUOROPERM 30 (PAFLUFOCON C) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON OPTICAL, INC. MESA, AZ 85204	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	02/25/92
P870036/S14	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC 14K OVER-THE-WIRE CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	NEW PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER	02/13/92
P870045/S28	MODEL SP29UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	INTRAOPTICS, INC. BOCA RATON, FL 33429-1710	MODEL SP29UB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	02/21/92
P870048/S02	EBK, ETI-EBK	SORIN BIOMEDICA, S.P.A. STILLWATER, MN 55082	MODIFICATION IN THE DEVICE FROM A RADIOIMMUNOASSAY TO A MICROTITER ENZYME IMMUNOASSAY	02/10/92

APPLICATION NO. / APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P870049/S16 02/28/92	MICROSCAN RAPID PANELS	BAXTER DIAGNOSTIC INC. WEST SACRAMENTO, CA 95691	ADDITION OF MICROSCAN AS AN ALTERNATE VENDOR
P880001/S32 02/14/92	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	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P880006/S12 02/25/92	SENSOLOG MODEL 703 PULSE GENERATOR AND P700 PROGRAMMER, SENSOLOG III AND DIALOG II PULSE GENERATORS	PACESETTER SYSTEMS, INC. SYLMAR, CA 91342	PRODUCTION CHANGES (SILVER GLASS CHIP BONDING AND 100% X-RAY SCREENING) TO THE SENSOLOG III AND DIALOG II FAMILIES OF PULSE GENERATORS
P880011/S07 02/10/92	SONOLITH 2000 EXTRACORPOREAL SHOCK WAVE LITHOTRIPTER, SONOLITH 2000, 3000, 3000TM	TECHNOMED INTERNATIONAL, INC. DANVERS, MA 01923	LABELING CHANGES
P880029/S14 02/14/92	BAUSCH & LOMB B&L 70 (LIDOFILCON A) SOFT (HYDROPHILIC), BAUSCH & LOMB CW 79	BAUSCH & LOMB ROCHESTER, NY 14692-0450	REVISED BLISTER PACK AND CARTON LABELING

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	(LIDOFILCON B) SOFT, BAUSCH & LOMB MEDALIST TORIC (LIDOFILCON A) CONTACT LENSES			
P880031/S04	VITRAX OPHTHALMIC SURGICAL AID	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	TIGHTENED RELEASE SPECIFICATIONS FOR THE INTRAVITREAL ASSAY IN RABBITS FOR EACH NEW LOT	02/10/92
P880035/S01	VISTA OPTICS, OPTACRYL 18 (KOLFOCON A), AND OPTACRYL 32 (KOLFOCON B) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	VISTA OPTICS LIMITED STAPLEHURST, KENT, UK	ADDITIONAL MANUFACTURING FACILITY	02/20/92
P880038/S21	META MV PACING SYSTEM, META II MODELS 1204 AND 1204H	TELECTRONICS, INC. ENGLEWOOD, CO 80112	MODIFICATION TO THE LABELING FOR THE META II MODELS 1204 AND 1204H	02/28/92
P880078/S06	VH8500 HYPERTHERMIA TREATMENT SYSTEM	MED INSTITUTE, INC. WEST LAFAYETTE, IN 47906	OPTION OF IN-HOUSE CALIBRATION OF THE CATHETER TEMPERATURE SENSORS USED WITH THE HYPERTHERMIA SYSTEM	02/25/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890003/S13 02/28/92	SYNERGYST II MODELS 7070 AND 7071 PULSE GENERATORS, MODEL 9710 PROGRAMMER, MODEL 9739A MEMORYMOD, ELITE PULSE GENERATORS MODELS 7074, 7075, 7076	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFY AND RELABEL THE ELITE PULSE GENERATORS TO ALLOW CARDIAC PACEMAKERS, INC. TO COMMERCIALLY DISTRIBUTE THEM UNDER ITS OWN BRAND NAME AND MODEL NUMBERS
P890024/S02 02/25/92	TROPHOCAN CHORIONIC VILLUS SAMPLING CATHETER	CONCORD/PORTEX KEENE, NH 03431-0724	MARKETING OF PROCEDURE TRAYS FOR CHORIONIC VILLUS SAMPLING WITH A TWO YEAR TENTATIVE SHELF LIFE
P890032/S07 02/14/92	CORDIS ORION STEERABLE PTCA BALLOON CATHETER, CORDIS SOFT-WIRE ORION STEERABLE PTCA BALLOON CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	3.5 MM SOFT WIRE ORION STEERABLE PTCA BALLOON CATHETER
P890044/S19 02/06/92	BIS.45 (AMSILFOCON A) AND TRANS-AIRE (AMSILFOCON A)	BENTEC INCORPORATED SACRAMENTO, CA 95834	ADDITIONAL CONTACT LENS FINISHING LABORATORIES

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED)		
P890046/S15 02/06/92	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	IDEAL OPTICS, INC. ATLANTA, GA 30339	ADDITIONAL CONTACT LENS FINISHING LABORATORY
P890061/S01 02/10/92	VENTAK P MODEL 1600 AND AICD SOFTWARE MODULE 2830, VENTAK P MODEL 1600 PULSE GENERATOR	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	ALTERNATE MANUFACTURING SITE

NADA NUMBER / APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
		ORIGINAL VETERINARY NADAs		
140-921 11-08-91	PREDNISTAB (TABLET)	DOGS	VET-A-MIX SHENANDOAH, IA 51601	PREDNISOLONE 5MG
		SUPPLEMENTAL VETERINARY NADAs		
138-792 02-12-92	MGA 100-200/ RUMENSIN/TYLAN (PELLETS)	CATTLE	UPJOHN KALAMAZOO, MI 49001	MELENGESTROL ACETATE 0.0000276-0.00022% MONENSIN SODIUM 50-1200GM/TON TYLOSIN PHOSPHATE 90-360GM/TON
138-904 02-12-92	MGA 100-200/ BOVATEC/TYLAN (PELLETS)	CATTLE	UPJOHN KALAMAZOO, MI 49001	LASALOCID SODIUM 100-1440GM/TON MELENGESTROL ACETATE 0.0000276-0.00022% TYLOSIN PHOSPHATE 90-360GM/TON
138-995 02-12-92	MGA 100-200/ TYLAN (PELLETS)	CATTLE	UPJOHN KALAMAZOO, MI 49001	MELENGESTROL ACETATE 0.0000276-0.00022% TYLOSIN PHOSPHATE 90-360GM/TON
138-456 02-19-92	COBAN-BMD (PREMIX)	CHICKENS	AL LABS FORT LEE, NJ 07024	BACITRACIN METHYLENE DISALICYLATE 10GM/LB 25GM/LB 30GM/LB

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

ORIGINAL VETERINARY NADAs

40GM/LB
50GM/LB
60GM/LB
75GM/LB
MONENSIN SODIUM
45GM/LB
60GM/LB

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) 295-8428

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

*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.

Volume 15 (3)
March 1992

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

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-051 GLYNASE UPJOHN GLYBURIDE
03-04-92 (TABLET) KALAMAZOO, MI 1.5MG
(3 S**) 49001 3MG
(BLOOD GLUCOSE REGULATOR)

20-087 FLOXIN JOHNSON RW OFLOXACIN
03-31-92 (INJECTABLE) RARITAN, NJ 20MG/ML
(3 S**) 08869 40MG/ML
(ANTIBACTERIAL)

20-087 FLOXIN JOHNSON RW OFLOXACIN
03-31-92 IN DEXTROSE 5% RARITAN, NJ 400MG/100ML
(3 S**) (INJECTABLE) 08869 (ANTIBACTERIAL)

20-087 FLOXIN JOHNSON RW OFLOXACIN
03-31-92 IN DEXTROSE 5% RARITAN, NJ 4MG/ML
(3 S**) IN PLASTIC CONTAINER 08869 400MG/100ML

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

(INJECTABLE) (ANTIBACTERIAL)

S** - Refers to Standard Review, Substantially Equivalent
(New Therapeutic Potential Code Replaces Former "C" Code)

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.

50-671 03-24-92	VANCOCIN HCL IN PLASTIC CONTAINER (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	VANCOMYCIN HYDROCHLORIDE EQ 500MG BASE/100ML (ANTIBIOTIC, GLYCOPEPTIDE)
19-830 03-26-92	LIDOCAINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	LIDOCAINE HYDROCHLORIDE 200MG/100ML 400MG/100ML 800MG/100ML (ANTIARRHYTHMIC)
19-881 03-31-92	BUTOCONAZOLE NITRATE (CREAM)	SYNTEX PALO ALTO, CA 94304	BUTOCONAZOLE NITRATE 2% (ANTIFUNGAL)
50-683 03-31-92	ZEFAZONE IN PLASTIC CONTAINER (INJECTABLE)	UPJOHN KALAMAZOO, MI 49001	CEFMETAZOLE SODIUM EQ 20MG BASE/ML EQ 40MG BASE/ML (ANTIBIOTIC, CEPHEM)

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

ORIGINAL ABBREVIATED NDAs

87-561	DIPYRIDAMOLE	GENEVA	DIPYRIDAMOLE
02-25-92	(TABLET)	BROOMFIELD, CO	75MG
	80038	(PLATELET ADHESION INHIBITOR)	
87-562	DIPYRIDAMOLE	GENEVA	DIPYRIDAMOLE
02-25-92	(TABLET)	BROOMFIELD, CO	50MG
	80038	(PLATELET ADHESION INHIBITOR)	
63-009	MINOCYCLINE HCL	BIOCRAFT	MINOCYCLINE HYDROCHLORIDE
03-02-92	(CAPSULE)	FAIR LAWN, NJ	EQ 100MG BASE
	07410	(ANTIBIOTIC, TETRACYCLINE)	
63-011	MINOCYCLINE HCL	BIOCRAFT	MINOCYCLINE HYDROCHLORIDE
03-02-92	(CAPSULE)	FAIR LAWN, NJ	EQ 50MG BASE
	07410	(ANTIBIOTIC, TETRACYCLINE)	
73-443*	MEPERIDINE HCL	STERIS	MEPERIDINE HYDROCHLORIDE
03-17-92	(INJECTABLE)	PHOENIX, AZ	10MG/ML
	85063	(ANALGESIC)	
73-444	MEPERIDINE HCL	STERIS	MEPERIDINE HYDROCHLORIDE
03-17-92	(INJECTABLE)	PHOENIX, AZ	50MG/ML
	85063	(ANALGESIC)	
73-445	MEPERIDINE HCL	STERIS	MEPERIDINE HYDROCHLORIDE
03-17-92	(INJECTABLE)	PHOENIX, AZ	100MG/ML
	85063	(ANALGESIC)	
63-099	POLYMOX	BRISTOL MYERS	AMOXICILLIN
03-20-92	(CAPSULE)	SYRACUSE, NY	250MG
	13221	500MG	
		(ANTIBIOTIC, PENICILLIN)	

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

ORIGINAL ABBREVIATED NDAs

73-317	ATENOLOL	APOTHECON	ATENOLOL
03-20-92	(TABLET)	PRINCETON, NJ	50MG
	08543	(BETA ADRENERGIC BLOCKER)	

* First Time Product Available Generically

73-318	ATENOLOL	APOTHECON	ATENOLOL
03-20-92	(TABLET)	PRINCETON, NJ	100MG
	08543	(BETA ADRENERGIC BLOCKER)	

73-396	CLOFIBRATE	PHARMACAPS	CLOFIBRATE
03-20-92	(CAPSULE)	ELIZABETH, NJ	500MG
	07207	(ANTIHYPERLIPIDEMIC)	

72-218	ACEPHEN	G AND W	ACETAMINOPHEN
03-27-92	(SUPPOSITORY)	S PLAINFIELD, NJ	120MG
	07080	(ANALGESIC)	
		(OTC)	

72-237	ACEPHEN	G AND W	ACETAMINOPHEN
03-27-92	(SUPPOSITORY)	S PLAINFIELD, NJ	650MG
	07080	(ANALGESIC)	
		(OTC)	

72-344	ACEPHEN	G AND W	ACETAMINOPHEN
03-27-92	(SUPPOSITORY)	S PLAINFIELD, NJ	325MG
	07080	(ANALGESIC)	
		(OTC)	

72-155	METOCLOPRAMIDE HCL	CETUS BEN VENUE	METOCLOPRAMIDE HYDROCHLORIDE
03-30-92	(INJECTABLE)	EMERYVILLE, CA	EQ 10MG BASE/2ML
	94608	(UPPER GI TRACT	

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

ORIGINAL ABBREVIATED NDAs

		MOTILITY STIMULATOR)	
72-244	METOCLOPRAMIDE HCL	CETUS BEN VENUE	METOCLOPRAMIDE HYDROCHLORIDE
03-30-92	(INJECTABLE)	EMERYVILLE, CA	EQ 10MG BASE/2ML
	94608	(UPPER GI TRACT	
		MOTILITY STIMULATOR)	
73-340	PROMETA	MURO	METAPROTERENOL SULFATE
03-30-92	(SOLUTION/INHALATION)	TEWKSBURY, MA	5%
	01876	(BRONCHODILATOR)	
73-419*	ALBUTEROL SULFATE	LEMMON	ALBUTEROL SULFATE
03-30-92	(SYRUP)	SELLERSVILLE, PA	EQ 2MG BASE/5ML
	18960	(BRONCHODILATOR)	
73-465*	SODIUM NITROPRUSSIDE	GENSIA	SODIUM NITROPRUSSIDE
03-30-92	(INJECTABLE)	IRVINE, CA	25MG/ML
	92718	(ANTIHYPERTENSIVE)	
73-553*	NORTRIPTYLINE HCL	DANBURY	NORTRIPTYLINE HYDROCHLORIDE
03-30-92	(CAPSULE)	DANBURY, CT	EQ 10MG BASE
	06810	(ANTIDEPRESSANT)	
73-554*	NORTRIPTYLINE HCL	DANBURY	NORTRIPTYLINE HYDROCHLORIDE
03-30-92	(CAPSULE)	DANBURY, CT	EQ 25MG BASE
	06810	(ANTIDEPRESSANT)	
73-555*	NORTRIPTYLINE HCL	DANBURY	NORTRIPTYLINE HYDROCHLORIDE
03-30-92	(CAPSULE)	DANBURY, CT	EQ 50MG BASE

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

ORIGINAL ABBREVIATED NDAs

06810 (ANTIDEPRESSANT)

73-556*	NORTRIPTYLINE HCL	DANBURY	NORTRIPTYLINE HYDROCHLORIDE
03-30-92	(CAPSULE)	DANBURY, CT	EQ 75MG BASE
	06810	(ANTIDEPRESSANT)	

64-006*	PENTACEF	SMITHKLINE BEECHAM	CEFTAZIDIME
03-31-92	(INJECTABLE)	PHILADELPHIA, PA	(ARGININE FORMULATION)
	19101	1GM/VIAL	
		2GM/VIAL	
		(ANTIBIOTIC, CEPHEM)	

64-008*	PENTACEF	SMITHKLINE BEECHAM	CEFTAZIDIME
03-31-92	(INJECTABLE)	PHILADELPHIA, PA	(ARGININE FORMULATION)
	19101	6GM/VIAL	
		10GM/VIAL	
		(ANTIBIOTIC, CEPHEM)	

* First Time Product Available Generically

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

08-922	CALCIUM DISODIUM	3M	EDETATE CALCIUM DISODIUM
03-03-92	VERSENATE	ST PAUL, MN	200MG/ML
	(INJECTABLE)	55144	(REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
12-125	CARBOCAINE	COOK WAITE	MEPIVACAINE HYDROCHLORIDE
03-04-92	(INJECTABLE)	NEW YORK, NY	3%
		10016	(REVISED LABELING -- PRECAUTIONS)
12-125	CARBOCAINE	COOK WAITE	LEVONORDEFRIN
03-04-92	W/NEO-COBEFRIN	NEW YORK, NY	0.05MG/ML
	(INJECTABLE)	10016	MEPIVACAINE HYDROCHLORIDE 2% (REVISED LABELING -- PRECAUTIONS)
19-384	NOROXIN	MERCK	NORFLOXACIN
03-06-92	(TABLET)	WEST POINT, PA	400MG
		19486	(REVISED LABELING -- ADVERSE REACTIONS)
50-641	DOXYCYCLINE	MEDICOPHARMA	DOXYCYCLINE
03-06-92	MONOHYDRATE	CHARLOTTE, NC	EQ 100MG BASE
	(CAPSULE)	28206	(REVISED LABELING --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

CLINICAL PHARMACOLOGY)

20-035	ERGAMISOL	JANSSEN	LEVAMISOLE HYDROCHLORIDE
03-10-92	(TABLET)	PISCATAWAY, NJ	EQ 50MG BASE
	08855	(REVISED LABELING -- ADVERSE REACTIONS)	

50-627	RIFADIN	MERRELL DOW	RIFAMPIN
03-10-92	(INJECTABLE)	CINCINNATI, OH	600MG/VIAL
	45215	(REVISED LABELING -- DOSAGE AND ADMINISTRATION)	

50-484	CERUBIDINE	WYETH AYERST	DAUNORUBICIN HYDROCHLORIDE
03-11-92	(INJECTABLE)	RADNOR, PA	EQ 20MG BASE/VIAL
	19087	(REVISED LABELING -- WARNINGS)	

12-911	METOPIRONE	CIBA	METYRAPONE
03-13-92	(TABLET)	SUMMIT, NJ	250MG
	07901	(REVISED LABELING -- PRECAUTIONS)	

18-422	LOPID	PARKE DAVIS	GEMFIBROZIL
03-16-92	(TABLET)	MORRIS PLAINS, NJ	600MG
	07950	(REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)	

18-344	REGULAR ILETIN II	LILLY	INSULIN PURIFIED PORK

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

03-18-92 (PORK) INDIANAPOLIS, IN 100 UNITS/ML
(INJECTABLE) 46285 (REVISED LABELING --
PATIENT PACKAGE INSERT)
(OTC)

18-347 LENTE ILETIN II LILLY INSULIN ZINC SUSP
03-18-92 (PORK) INDIANAPOLIS, IN PURIFIED PORK
(INJECTABLE) 46285 100 UNITS/ML
(REVISED LABELING --
PATIENT PACKAGE INSERT)
(OTC)

18-477 LENTE ILETIN II LILLY INSULIN ZINC SUSP
03-18-92 (INJECTABLE) INDIANAPOLIS, IN PURIFIED BEEF
46285 100 UNITS/ML
(REVISED LABELING --
PATIENT PACKAGE INSERT)
(OTC)

18-478 REGULAR ILETIN II LILLY INSULIN PURIFIED BEEF
03-18-92 (INJECTABLE) INDIANAPOLIS, IN 100 UNITS/ML
46285 (REVISED LABELING --
PATIENT PACKAGE INSERT)
(OTC)

18-479 NPH ILETIN II LILLY INSULIN SUSP
03-18-92 (INJECTABLE) INDIANAPOLIS, IN ISOPHANE PURIFIED BEEF
46285 100 UNITS/ML
(REVISED LABELING --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

PATIENT PACKAGE INSERT)
(OTC)

19-640	HUMATROPE	LILLY	SOMATROPIN, BIOSYNTHETIC
03-18-92	(INJECTABLE)	INDIANAPOLIS, IN	5MG/VIAL
	46285	(REVISED LABELING -- PRECAUTIONS)	
50-370	ILOTYCIN GLUCEPTATE	DISTA	ERYTHROMYCIN GLUCEPTATE
03-18-92	(INJECTABLE)	INDIANAPOLIS, IN	EQ 1GM BASE/VIAL
	46206	(REVISED LABELING -- PRECAUTIONS; HOW SUPPLIED)	
17-364	AQUATENSEN	WALLACE	METHYCLOTHIAZIDE
03-20-92	(TABLET)	CRANBURY, NJ	5MG
	08512	(REVISED LABELING -- ADVERSE REACTIONS)	
05-264	HEPARIN LOCK FLUSH	ABBOTT	HEPARIN SODIUM
03-24-92	(INJECTABLE)	ABBOTT PARK, IL	10 UNITS/ML
	60064	100 UNITS/ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION)	
05-264	HEPARIN SODIUM	ABBOTT	HEPARIN SODIUM
03-24-92	(INJECTABLE)	ABBOTT PARK, IL	2,000 UNITS/ML
	60064	2,500 UNITS/ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION)	
50-590	TIMENTIN	BEECHAM	CLAVULANATE POTASSIUM
03-26-92	(INJECTABLE)	BRISTOL, TN	EQ 1GM ACID/VIAL
	37620	TICARCILLIN DISODIUM	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			EQ 30GM BASE/VIAL
			(REVISED LABELING --
			DESCRIPTION; WARNINGS;
			INDICATIONS AND USAGE;
			DOSAGE AND ADMINISTRATION)
50-649	MINOCIN	LEDERLE	MINOCYCLINE HYDROCHLORIDE
03-26-92	(CAPSULE)	PEARL RIVER, NY	EQ 50MG BASE
	10965		EQ 100MG BASE
			(REVISED LABELING --
			ADVERSE REACTIONS)
50-608	UNASYN	PFIZER	AMPICILLIN SODIUM
03-27-92	(INJECTABLE)	NEW YORK, NY	EQ 2GM BASE/VIAL
	10017		SULBACTAM SODIUM
			EQ 1GM BASE/VIAL
			(REVISED LABELING --
			HOW SUPPLIED)
50-608	UNASYN	PFIZER	AMPICILLIN SODIUM
03-27-92	(INJECTABLE)	NEW YORK, NY	EQ 1GM BASE/VIAL
	10017		SULBACTAM SODIUM
			EQ 500MG BASE/VIAL
			(REVISED LABELING --
			HOW SUPPLIED)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

THERE ARE NO PRODUCT LICENSES APPROVED FOR THE MONTH OF MARCH 1992.

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910006	QC-HEPATITIS	N AM BIOLS	BLOOD SCREENING/DIAGNOSTIC
03-12-92		MIAMI, FL 33169 (C)	SERUM CONTROLS
BK910018	RAD-SURE	GAF CHEM	BLOOD BANK SUPPLIES
03-12-92	BLOOD IRRADIATION LABEL	WAYNE, NJ 07470 (C)	
BK920003	FENWAL NEEDLE/	BAXTER HLTHCARE	BLOOD BANK SUPPLIES
03-12-92	TUBE SAMPLING PROTECTOR AND NEEDLE SAFETY COVER	ROUND LAKE, IL 60073 (C)	
BK920004	MGR ERB-5-0378	MGR EQUIPMENT	BLOOD STORAGE REFRIGERATOR
03-12-92		INWOOD, NY 11696 (C)	AND FREEZER
BK910007	MMED VAPOR	MECH AND MED	BLOOD PLASMA WARMING DEVICE
03-16-92	CONDENSATION AND BLOOD WARMER	ENGINEERED DESIGNS ROCHESTER, MN 55902 (C)	
BK910001	GAMMA PEG	GAMMA BIOLS	POTENTIATING MEDIA FOR IN-VITRO
03-24-92		HOUSTON, TX 77092 (C)	DIAGNOSTIC USE
BK900032	MP III	INSTA COOL OF N AM	BLOOD PLASMA FREEZER
03-30-92		RANCHO CORDOVA, CA 95742 (C)	
BK910016	COMPOMAT	NPBI	BLOOD BANK SUPPLIES/SYSTEM
03-30-92		EMMER-COMPACUUM, NETHERLANDS (C)	FOR BLOOD COMPONENT PREPARATION

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 MARCH 1992.

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

N16895/S79	SOFLENS (POLYMACON) CONTACT LENSES, BAUSCH & LOMB (POLYMACON) -EJ SERIES CONTACT LENSES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	MANUFACTURING PROCESS MODIFICATION	03/03/92
N16895/S80	SOFLENS (POLYMACON) CONTACT LENS, BAUSCH & LOMB SEEQUENCE 2 AND MEDALIST (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	REVISED BLISTER PACK LABEL AND CARTON LABEL	03/05/92
P780012/S06	IMX HAVAB	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	CHANGE IN THE SPECIFICATION RANGE FOR THE NEGATIVE CONTROL SAMPLE-TO-CUFF VALUES AND PERCENT INHIBITION	03/09/92
P810031/S14	HEALON	KABI PHARMACIA OPHTHALMICS INC. MONROVIA, CA 91017-7136	ALTERNATE PRODUCTION SITE OF SODIUM HYALURONATE BULK SUBSTANCE	03/09/92
P810046/S110	SIMPSON-ROBERT	ADVANCED	ALTERNATE	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

03/04/92	CORONARY BALLOON DILATATION CATHETER	CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	STERILIZATION SITE	
P810046/S116 03/24/92	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92390-1856	MODIFICATION OF THE STERILIZATION METHOD	
P810046/S123 03/24/92	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS RX STREAK .014 AND ACS RX STREAK .010 CORONARY BALLOON DILATATION CATHETERS	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	REVISED LABELING	
P820056/S52 03/30/92	OPTACRYL 60 (KOLFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES	
P820059/S18 03/05/92	CUSTOMEYES-38 (POLYMACON) HYDROPHILIC, AND NATURAL TOUCH (POLYMACON) CONTACT LENSES, CLEAR AND OPAQUE	SOLA/BARNES-HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING PROCEDURE	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	TINTED		
P820063/S52 03/30/92	PARAPERM 0_2 (PASIFOCON A) RIGID GAS PERMEABLE CONTACT LENS	PARAGON OPTICAL, INC. MESA, AZ 85204	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES
P830026/S53 03/20/92	COSMOS PACING SYSTEM, MODEL 370-08 WAND EXTENSION CABLE ACCESSORY	INTERMEDICS, INC. ANGLETON, TX 77515	MODEL 370-08 WAND EXTENSION CABLE ACCESSORY
P830033/S25 03/20/92	TIER B ADDITION OF MODEL SBUV20-23DO ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	SURGIDEV CORPORATION GOLETA, CA 93117	MODEL SBUV20-23DO ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS
P830040/S20 03/09/92	STYLE 58LE ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	3M VISION CARE ST. PAUL, MN 55144-1000	STYLE 58LE ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS
P830040/S21 03/09/92	REQUEST TO ADD MANUFACTURING STEP (SPECIAL SUPPLEMENT) AND TO CHANGE HAPTIC STAKING PROCEDURE	3M VISION CARE ST. PAUL, MN 55144-1000	REVISED MANUFACTURING PROCEDURE

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P840024/S29	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR POSTLINGUALLY DEAFENED ADULTS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	REVISED PACKAGE INSERT TO INCLUDE NEW CLAIM OF TELEPHONE BENEFIT	03/24/92
P840050/S44	OCUSIL (NEFOCON A) CONTACT LENS	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	03/23/92
P840051/S06	MAXON MONOFILAMENT POLYGLYCONATE ABSORBABLE SURGICAL SUTURE, MAXON CV MONOFILAMENT POLYGLYCONATE ABSORBABLE SURGICAL SUTURE	AMERICAN CYANAMID COMPANY DANBURY, CT 06810	EXPANDED INDICATIONS	03/24/92
P840060/S17	MODEL GR1A ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	MODEL GR1A ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	03/24/92
P840062/S03	COLLACOTE, COLLAPLUG, COLLATAPE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	COLLA-TEC, INC. PLAINSBORO, NJ 08536	REVISED LABELING	03/27/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P850010/S13	HELISTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT	COLLA-TEC, INC. PLAINSBORO, NJ 08536	REVISED LABELING	03/27/92
P850021/S15	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, MODIFICATION OF STERILIZATION METHOD FOR SLINKY PTCA CATHETER	BAXTER HEALTHCARE CORP. SANTA ANA, CA 92711-1150	MODIFICATION OF STERILIZATION METHOD	03/04/92
P850021/S19	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, REACH .14 PTCA CATHETER WITH 1.5 MM AND 4.0 MM BALLOONS	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	ADD 1.5 MM AND 4.0 MM BALLOON DIAMETERS TO THE REACH .14 PTCA CATHETER	03/13/92
P850038/S19	PARAPERM EW (PASIFOCON C) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON OPTICAL, INC. MESA, AZ 85204	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES	03/30/92
P850048/S08	TANDEM-R PSA IMMUNORADIOMETRIC ASSAY AND TANDEM-E PSA ENZYME IMMUNOASSAY	HYBRITECH, INC. SAN DIEGO, CA 92126-9006	REPLACING HUMAN SERUM WITH BOVINE SERUM ALBUMIN (BSA) AS THE PROTEIN MATRIX FOR THE ZERO DILUENT	03/24/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	(IMMUNOENZYMETRIC ASSAY)			
P850069/S09	KENNEDY LAD LIGAMENT AUGMENTATION DEVICE	3M HEALTHCARE GROUP ST. PAUL, MN 55144	NEW STERILIZATION VENDOR	03/13/92
P850088/S22	LENS PLUS OXYSEPT 1 DISINFECTING SOLUTION, LENS PLUS OXYSEPT 2 NEUTRALIZER (MULTIDOSE CONTAINER)	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ALTERNATE MANUFACTURING SITE	03/23/92
P850089/S18	STER TIP PACING LEAD MODELS 5025/5525, CAPSURE SP MODEL 5024M PACING LEAD	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFIED MANUFACTURING PROCEDURE	03/05/92
P860004/S23	MEDTRONIC SYNCHROMED INFUSION SYSTEM, SYNCHROMED INFUSION SYSTEM MODEL 8550 REFILL KIT	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MEMBRANE FILTER BEING ADDED TO THE MODEL 8550 REFILL KIT	03/24/92
P860007/S08	INTERTACH II MODELS 262-16 PACING SYSTEM, INTERTACH II MODELS 262-16 AND	INTERMEDICS, INC. ANGLETON, TX 77515	REVISED LABELING	03/03/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	262-16R			
P860059/S54	MODEL U370E ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MODEL U370E ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	03/27/92
P860059/S58	MODELS UB380E AND UB350ES ULTRAVIOLET-ABSORBING SURFACE MODIFIED POSTERIOR CHAMBER INTRAOCULAR LENSES	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MODELS UB380E AND UB350ES ULTRAVIOLET-ABSORBING SURFACE MODIFIED POSTERIOR CHAMBER INTRAOCULAR LENSES	03/27/92
P860059/S65	MODEL UPB380S ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MODEL UPB380S ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	03/03/92
P860059/S68	TIER A REQUEST FOR MODEL UB330F ULTRAVIOLET-ABSORBING POSTERIOR INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MODEL UB330F ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	03/09/92
P870024/S32	FLUOROPERM 92 (PAFLUFOCON A), FLUOROPERM 60 (PAFLUFOCON B) AND FLUOROPERM 30 (PAFLUFOCON C)	PARAGON OPTICAL, INC. MESA, AZ 85204	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES	03/30/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTS)		
P870043/S15 03/20/92	TRIMEDYNE'S SPECTRAPROBE-PLR CATHETER AND MODEL 900 OPTILASE CONTACT LASER SOURCE SYSTEM, 1.6 AND 2.0 MM HALOCATH CATHETERS	TRIMEDYNE, INC. IRVINE, CA 92714	ADDITION OF THE 1.6 AND 2.0 MM HALOCATH CATHETERS TO THEIR PRODUCT LINE
P880010/S13 03/24/92	MANUFACTURING SITE CHANGE	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	MANUFACTURING SITE CHANGE FROM BRENTWOOD, TN TO HUNTINGTON, WV
P880102/S01 03/05/92	LOMBART (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENS	JOHN M. SZABOCSIK, PH.D. CHICAGO, IL 60601	ALTERNATE MANUFACTURING SITE
P880102/S01 03/05/92	LOMBART (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES	LOMBART LENSES, LTD. NORFOLK, VA 23507	ALTERNATE MANUFACTURING SITE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P890003/S11 03/20/92	SYNERGYST II PULSE GENERATOR, MINUET PULSE GENERATOR MODELS 7107 AND 7108	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MINUET PULSE GENERATOR MODELS 7107 AND 7108
P890025/S03 03/18/92	TDX CYCLOSPORINE AND METABOLITES SERUM ASSAY, TDX CYCLOSPORINE MONOCLONAL WHOLE BLOOD ASSAY (LIST 9797)	ABBOTT LABORATORIES ABBOTT PARK, IL 60064-3500	USE OF MONOCLONAL INSTEAD OF POLYCLONAL ANTIBODY AND TO TRANSFER THE MANUFACTURING FACILITY FROM IRVING, TX TO BARCELONETA, PUERTO RICO
P890043/S12 03/20/92	SIMPSON CORONARY ATHEROCATH, SCA-EX, SCA-I, AND SCA-LP	DEVICES FOR VASCULAR INTERVENTION, INC. REDWOOD CITY, CA 94063	REVISED LABELING AND A NEW MODEL ATHERECTOMY CATHETER
P890066/S01 03/01/92	THERASONIC LITHOTRIPSY TREATMENT SYSTEM, THERASONIC LTS	DIASONICS, INC. MILPITAS, CA 95035	DEVICE MODIFICATIONS
P900022/S01 03/18/92	CHORUS MODELS 6003 AND 6033 DDD PACEMAKERS; PROGRAMMER MODELS CPR1 AND P2A, CHORUS MODELS 6004 AND 6034 DDD PACEMAKERS	ELA MEDICAL, INC. MINNETONKA, MN 55345	NEW PROGRAMMABLE PACE/SENSE POLARITY FEATURE

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P900022/S03 03/13/92	CHORUS MODELS 6001, 6003, AND 6033 DDD PACEMAKERS; PROGRAMMER MODELS CPR1 AND P2A	ELA MEDICAL, INC. MINNETONKA, MN 55345	NEW SOFTWARE SUBROUTINES IN THE CPR1 PROGRAMMER HEAD
P900048/S01 03/05/92	ELASTIMIDE MODELS AQ-2010 AND AQ-2000, CHIROFLEX MODELS 32-C31XX/SX AND 32-C30XX/SX SILICONE POSTERIOR CHAMBER IOLS	SOFLENSCO, INC. LOS ANGELES, CA 90071	ELASTIMIDE MODELS AQ-2010 AND AQ-2000, CHIROFLEX MODELS 32-C31XX/SX AND 32-C30XX/SX SILICONE POSTERIOR CHAMBER IOLS

THERE ARE NO ORIGINAL VETERINARY NADAs FOR THE MONTH OF MARCH 1992.

SUPPLEMENTAL VETERINARY NADAs

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

ORIGINAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR THE MONTH OF MARCH 1992.

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) 295-8428

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

*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.

Volume 15 (4)
April 1992

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

18-998 04-08-92 (SUPPL)	VASOTEC (TABLET)	MSD WEST POINT, PA 19486	ENALAPRIL MALEATE 2.5MG 5MG 10MG 20MG (EXPANDED INDICATION -- SURVIVAL BENEFIT EXPANDED TO ALL DEGREES OF HEART FAILURE)
19-830 04-08-92 (5 S**)	LIDOCAINE HCL 0.2% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	LIDOCAINE HYDROCHLORIDE 200MG/100ML (ANTIARRHYTHMIC)

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

19-830	LIDOCAINE HCL 0.4%	MCGAW	LIDOCAINE HYDROCHLORIDE
04-08-92	AND DEXTROSE 5%	IRVINE, CA	400MG/100ML
(5 S**)	IN PLASTIC CONTAINER	92713	(ANTIARRHYTHMIC)
	(INJECTABLE)		

19-830	LIDOCAINE HCL 0.8%	MCGAW	LIDOCAINE HYDROCHLORIDE
04-08-92	AND DEXTROSE 5%	IRVINE, CA	800MG/100ML
(5 S**)	IN PLASTIC CONTAINER	92713	(ANTIARRHYTHMIC)
	(INJECTABLE)		

S** - Refers to Standard Review, Substantially Equivalent
(New Therapeutic Potential Code Replaces Former "C" Code)

20-000	DEXTROSE 5%	MCGAW	CALCIUM CHLORIDE
04-17-92	IN RINGER'S	IRVINE, CA	33MG/100ML
(5 S**)	IN PLASTIC CONTAINTER	92713	DEXTROSE
	(INJECTABLE)		5GM/100ML
			POTASSIUM CHLORIDE
			30MG/100ML
			SODIUM CHLORIDE
			860MG/100ML
			(FLUID AND ELECTROLYTE
			REPLENISHER)

20-002	RINGER'S	MCGAW	CALCIUM CHLORIDE
04-17-92	IN PLASTIC CONTAINER	IRVINE, CA	33MG/100ML
(5 S**)	(INJECTABLE)	92713	POTASSIUM CHLORIDE
			30MG/100ML
			SODIUM CHLORIDE
			860MG/100ML
			(FLUID AND ELECTROLYTE

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

REPLENISHER)

20-055 GLUBATE HOECHST ROUSSEL GLYBURIDE
04-17-92 (TABLET) SOMERVILLE, NJ 1.5MG
(3 S**) 08876 3MG
(BLOOD GLUCOSE REGULATOR)

20-004 SODIUM LACTATE MCGAW SODIUM LACTATE
04-21-92 1/6 MOLAR IRVINE, CA 1.87GM/100ML
(5 S**) IN PLASTIC CONTAINER 92713 (ALKALINIZING AGENT/
(INJECTABLE) ELECTROLYTE REPLENISHER)

20-150 NICOTROL KABI NICOTINE
04-22-92 (FILM, PISCATAWAY, NJ 5MG/16HR
(3 S**) EXTENDED RELEASE) 08855 10MG/16HR
15MG/16HR
(SMOKING DETERRENT)

19-773 VENTOLIN GLAXO ALBUTEROL SULFATE
04-23-92 (SOLUTION/INHALATION) RES TRIANGLE PK, NC EQ 0.083% BASE
(3 S**) 27709 (BRONCHODILATOR)

S** - Refers to Standard Review, Substantially Equivalent
(New Therapeutic Potential Code Replaces Former "C" Code)

20-100 HUMULIN 50/50 LILLY INSULIN BIOSYNTHETIC HUMAN
04-29-92 (INJECTABLE) INDIANAPOLIS, IN 50 UNITS/ML
(3 S**) 46285 INSULIN SUSP ISOPHANE
BIOSYNTHETIC HUMAN
50 UNITS/ML
(BLOOD GLUCOSE REGULATOR)
(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

S** - Refers to Standard Review, Substantially Equivalent
(New Therapeutic Potential Code Replaces Former "C" Code)

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

APPROVABLE ORIGINAL NDAs

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

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

19-952 HEPARIN SODIUM MCGAW HEPARIN SODIUM
04-08-92 20,000 UNITS IRVINE, CA 4,000 UNITS/100ML
IN DEXTROSE 5% 92713 (ANTICOAGULANT)
IN PLASTIC CONTAINER
(INJECTABLE)

19-952 HEPARIN SODIUM MCGAW HEPARIN SODIUM
04-08-92 25,000 UNITS IRVINE, CA 5,000 UNITS/100ML
IN DEXTROSE 5% 92713 (ANTICOAGULANT)
IN PLASTIC CONTAINER
(INJECTABLE)

19-952 HEPARIN SODIUM MCGAW HEPARIN SODIUM
04-08-92 25,000 UNITS IRVINE, CA 10,000 UNITS/100ML
IN DEXTROSE 5% 92713 (ANTICOAGULANT)
IN PLASTIC CONTAINER
(INJECTABLE)

19-908 AMBIEN LOREX ZOLPIDEM TARTRATE
04-21-92 (TABLET) SKOKIE, IL 5MG
60077 10MG
(HYPNOTIC)

19-953 HEPARIN SODIUM MCGAW HEPARIN SODIUM
04-21-92 1000 UNITS IRVINE, CA 200 UNITS/100ML

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

APPROVABLE ORIGINAL NDAs

	IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	92713	(ANTICOAGULANT)
19-787	NORVASC	PFIZER	AMLODIPINE BESYLATE
04-22-92	(TABLET)	GROTON, CT 06340	EQ 2.5MG BASE EQ 5MG BASE EQ 10MG BASE (CALCIUM ION INFLUX INHIBITOR) [HYPERTENSION/ANGINA]
19-802	HEPARIN SODIUM	MCGAW	HEPARIN SODIUM
04-22-92	12,500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	IRVINE, CA 92713	5,000 UNITS/100ML (ANTICOAGULANT)
19-802	HEPARIN SODIUM	MCGAW	HEPARIN SODIUM
04-22-92	25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	IRVINE, CA 92713	1,000 UNITS/100ML (ANTICOAGULANT)
19-802	HEPARIN SODIUM	MCGAW	HEPARIN SODIUM
04-22-92	25,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	IRVINE, CA 92713	5,000 UNITS/100ML (ANTICOAGULANT)
19-802	HEPARIN SODIUM	MCGAW	HEPARIN SODIUM
04-22-92	25,000 UNITS IN	IRVINE, CA	5,000 UNITS/100ML

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

APPROVABLE ORIGINAL NDAs

SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	92713	(ANTICOAGULANT)	

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

ORIGINAL ABBREVIATED NDAs

81-271*	TEXACORT	GENDERM	HYDROCORTISONE
04-17-92	(SOLUTION)	LINCOLNSHIRE, IL 60069	2.5% (CORTICOSTEROID)
73-095*	CLEMASTINE FUMARATE	COPLEY	CLEMASTINE FUMARATE
04-21-92	(SYRUP)	CANTON, MA 02021	EQ 0.5MG BASE/5ML (ANTIHISTAMINE)
73-433	GO-EVAC	COPLEY	POLYETHYLENE GLYCOL 3350
04-28-92	(POWDER FOR RECONSTITUTION)	CANTON, MA 02021	236GM/BOT POTASSIUM CHLORIDE 2.97GM/BOT SODIUM BICARBONATE 6.74GM/BOT SODIUM CHLORIDE 5.86GM/BOT SODIUM SULFATE, ANHYDROUS 22.74GM/BOT (GASTROINTESTINAL LAVAGE)
74-099*	ATENOLOL	LEDERLE	ATENOLOL
04-28-92	(TABLET)	PEARL RIVER, NY 10965	25MG (BETA ADRENERGIC BLOCKER)
81-134	NIACIN	WOCKHARDT LTD	NIACIN
04-28-92	(TABLET)	BOMBAY, INDIA	500MG (VITAMIN)
63-206	AMPHOTERICIN B	PHARMA TEK	AMPHOTERICIN B
04-29-92	(INJECTABLE)	HUNTINGTON, NY 11743	50MG/VIAL (ANTIFUNGAL)
72-383	SULFAMETHOXAZOLE AND	CETUS BEN VENUE	SULFAMETHOXAZOLE

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

ORIGINAL ABBREVIATED NDAs

04-29-92	TRIMETHOPRIM	EMERYVILLE, CA	80MG/ML
	(INJECTABLE)	94608	TRIMETHOPRIM
			16MG/ML
			(ANTIBACTERIAL)

* First Time Product Available Generically

89-557*	HYDROCODONE BITARTRATE	MIKART	ACETAMINOPHEN
04-29-92	AND ACETAMINOPHEN	ATLANTA, GA	500MG/15ML
	(ELIXIR)	30318	HYDROCODONE BITARTRATE
			5MG/15ML
			(ANALGESIC)
72-323	ACETYLCYSTEINE	CETUS BEN VENUE	ACETYLCYSTEINE
04-30-92	(SOLUTION/INHALATION)	EMERYVILLE, CA	10%
		94608	(MUCOLYTIC)
72-324	ACETYLCYSTEINE	CETUS BEN VENUE	ACETYLCYSTEINE
04-30-92	(SOLUTION/INHALATION)	EMERYVILLE, CA	20%
		94608	(MUCOLYTIC)
73-079	LOPERAMIDE HCL	ROXANE	LOPERAMIDE HYDROCHLORIDE
04-30-92	(SOLUTION)	COLUMBUS, OH	1MG/5ML
		43216	(ANTIDIARRHEAL)
			(OTC)
73-192	LOPERAMIDE HCL	LEMMON	LOPERAMIDE HYDROCHLORIDE
04-30-92	(CAPSULE)	SELLERSVILLE, PA	2MG
		18960	(ANTIDIARRHEAL)
73-281*	TRIAMTERENE AND	GENEVA	HYDROCHLOROTHIAZIDE
04-30-92	HYDROCHLOROTHIAZIDE	BROOMFIELD, CO	25MG

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

ORIGINAL ABBREVIATED NDAs

	(TABLET)	80038	TRIAMTERENE 37.5MG (DIURETIC)
73-462 04-30-92	TOLMETIN SODIUM (CAPSULE)	GENEVA BROOMFIELD, CO 80038	TOLMETIN SODIUM EQ 400MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
73-552 04-30-92	BETAMETHASONE DIPROPIONATE (CREAM)	TARO DOWNSVIEW, ONTARIO	BETAMETHASONE DIPROPIONATE EQ 0.05% BASE (CORTICOSTEROID)

* First Time Product Available Generically

74-045 04-30-92	NIFEDIPINE (CAPSULE)	SCHERER ST. PETERSBURG, FL 33716	NIFEDIPINE 20MG (CALCIUM ION INFLUX INHIBITOR)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20-027	CARDIZEM	MARION MERRELL DOW	DILTIAZEM HYDROCHLORIDE
04-01-92	(INJECTABLE)	KANSAS CITY, MO	5MG/ML
		64134	(REVISED LABELING -- ADVERSE REACTIONS; OVERDOSAGE)
14-103	ONCOVIN	LILLY	VINCRISTINE SULFATE
04-02-92	(INJECTABLE)	INDIANAPOLIS, IN	1MG/ML
		46285	(REVISED LABELING -- CLINICAL PHARMACOLOGY; PRECAUTIONS)
20-038	FLUDARA	BERLEX	FLUDARABINE PHOSPHATE
04-02-92	(INJECTABLE)	ALAMEDA, CA	50MG/VIAL
		94501	(REVISED LABELING -- INDICATIONS AND USAGE; WARNINGS)
18-998	VASOTEC	MSD	ENALAPRIL MALEATE
04-08-92	(TABLET)	W POINT, PA	2.5MG
		19486	5MG
			10MG
			20MG
			(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
13-553	ESIMIL	CIBA	GUANETHIDINE MONOSULFATE
04-09-92	(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

ADVERSE REACTIONS)

17-563	COLESTID	UPJOHN	COLESTIPOL HYDROCHLORIDE
04-09-92	(GRANULE)	KALAMAZOO, MI	5GM/PACKET
	49001		500GM/BOTTLE
		(REVISED LABELING -- PRECAUTIONS)	
17-717	FEMCARE	SCHERING	CLOTRIMAZOLE
04-14-92	(TABLET)	KENILWORTH, NJ	100MG
	07033	(REVISED LABELING -- ADDITIONAL TRADE NAME) (OTC)	
18-052	FEMCARE	SCHERING	CLOTRIMAZOLE
04-14-92	(CREAM)	KENILWORTH, NJ	1%
	07033	(REVISED LABELING -- ADDITIONAL TRADE NAME) (OTC)	
10-895	NORLUTIN	PARKE DAVIS	NORETHINDRONE
04-16-92	(TABLET)	SANTURCE, PR	5MG
	00911	(REVISED LABELING -- WARNINGS; PATIENT PACKAGE INSERT)	
12-184	NORLUTATE	PARKE DAVIS	NORETHINDRONE ACETATE
04-16-92	(TABLET)	SANTURCE, PR	5MG
	00911	(REVISED LABELING -- WARNINGS; PATIENT PACKAGE INSERT)	
19-384	NOROXIN	MSD	NORFLOXACIN

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

04-17-92	(TABLET)	WEST POINT, PA	400MG
	19486	(REVISED LABELING -- ADVERSE REACTIONS)	
07-504	ACTHAR	ARMOUR	CORTICOTROPIN
04-20-92	(INJECTABLE)	KANKAKEE, IL	25 UNITS/VIAL
	60901	40 UNITS/VIAL	
		(REVISED LABELING -- DESCRIPTION)	
19-404	OCUFEN	ALLERGAN	FLURBIPROFEN SODIUM
04-21-92	(SOLUTION/DROPS)	IRVINE, CA	0.03%
	92715	(REVISED LABELING -- CONTRAINDICATIONS; PRECAUTIONS)	
08-372	H.P. ACTHAR GEL	ARMOUR	CORTICOTROPIN
04-22-92	(INJECTABLE)	KANKAKEE, IL	40 UNITS/ML
	60901	80 UNITS/ML	
		(REVISED LABELING -- DESCRIPTION)	
17-936	NPH ILETIN I	LILLY	INSULIN SUSP ISOPHANE
04-22-92	(BEEF-PORK)	INDIANAPOLIS, IN	BEEF/PORK
	(INJECTABLE)	46285	100 UNITS/ML
		(REVISED LABELING -- PATIENT PACKAGE INSERT)	
		(OTC)	
18-938	DDAVP	RHONE POULENC RORER	DESMOPRESSIN ACETATE
04-22-92	(INJECTABLE)	FORT WASHINGTON, PA	0.004MG/ML
	19034	(REVISED LABELING -- DESCRIPTION)	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-594	ACTIGALL	CIBA	URSODIOL
04-24-92	(CAPSULE)	SUMMIT, NJ	300MG
	07901	(REVISED LABELING -- PRECAUTIONS)	

19-698	TORADOL	SYNTEX	KETOROLAC TROMETHAMINE
04-24-92	(INJECTABLE)	PALO ALTO, CA	15MG/ML
	94304	30MG/ML	
		(REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	

19-726	ZOLADEX	IMPERIAL CHEM	GOSERELIN ACETATE
04-28-92	(IMPLANT)	CHESHIRE ENGLAND,	EQ 3.6MG BASE
	SK10	(REVISED LABELING -- ADVERSE REACTIONS)	

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

BIOLOGICAL PRODUCT LICENSES ISSUED

643 NONE ANDERSON MEMORIAL HOSP CRYOPRECIPITATED AHF
04-07-92 (INJECTABLE) ANDERSON, SC (TRANSFUSION)
29621 (B)

991 NONE AM-RHO LABS WHOLE BLOOD
04-07-92 (INJECTABLE) JACKSONVILLE, FL (TRANSFUSION)
32216 (B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

(B) Product License Issued

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

THERE ARE NO BIOLOGICAL PRODUCT DEVICE APPROVALS FOR APRIL 1992.

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 APRIL 1992.

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

P810046/S117 04/09/92	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	REVISED INSTRUCTIONS FOR REMOVING AIR FROM THE CATHETER
P820065/S78 04/06/92	THE BOSTON LENS II (ITAFOCON A) AND THE BOSTON LENS IV (ITAFOCON B) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P830006/S06 04/15/92	SOFTACT II (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENS	CONTACT LENS CORPORATION OF AMERICA MEMPHIS, TN 38118	BENZ RESEARCH AND DEVELOPMENT AS AN ALTERNATE SUPPLIER OF POLYMACON LENS BLANKS
P830045/S37 04/14/92	AFP MODEL 283 PULSE GENERATOR WITH MODEL 370 PROGRAMMER, MODEL 3038 FUNCTION PACK	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	MODEL 3038 FUNCTION PACK FOR USE WITH THE APS-II MODEL 3003 PROGRAMMER
P840039/S36 04/10/92	POSTERIOR CHAMBER INTRAOCULAR LENSES: TIER A MODIFICATION	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	MANUFACTURE OF ANY PMA-APPROVED IOL DESIGNS WITH SYMMETRICAL HAPTICS IN OPTIC DIAMETERS DOWN TO 5.0 MM

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P840055/S25	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	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	04/14/92
P850051/S35	ACTIVTRAX PACING SYSTEM, MEDTRONIC MICRO MINIX, LEGEND AND LEGEND II PULSE GENERATORS AND CPI TRIUMPH VR PULSE GENERATORS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	REVISED PACKAGE LABELING AND TECHNICAL MANUALS	04/10/92
P850089/S23	STERX TIP PACING LEAD MODELS 5025/5525, CPI DEXATIP MODEL 4262 PACING LEAD	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFIED MANUFACTURING PROCESS	04/09/92
P860015/S01	FLUORO-CEP ESTROGEN	ZEUS SCIENTIFIC INC. RARITAN, NJ 08869	"CONTRACT MANUFACTURER" AGREEMENT WITH SIN H. LEE, M.D. FOR OFF-SITE MANUFACTURING FOR INTERMEDIATES USED IN THE FORMULATION	04/21/92
P860015/S02	FLUORO-CEP ESTROGEN	ZEUS SCIENTIFIC INC. RARITAN, NJ 08869	APPROVAL FOR OFF-SITE QUALITY CONTROL PROCEDURES PERFORMED BY DR. PERTSCHUK ON FLUORO-CEP ESTROGEN	04/17/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P860022/S39	THE BOSTON EQUALENS (ITAFLUOROFOCON A) AND THE BOSTON RXD (ITABISFLUOROFOCON A) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	04/06/92
P870048/S05	ETI-EBK, MICROTRAK HBEAG/ANTI-HBE EIA	SORIN BIMEDICA S.P.A. STILLWATER, MN 55082	CHANGE TO THE LABELING TRADE NAME FOR SORIN'S ETI-EBK PRODUCT WHICH WILL ALSO BE DISTRIBUTED BY SYVA COMPANY	04/10/92
P870073/S09	POSTERIOR CHAMBER INTRAOCULAR LENSES: TIER A MODIFICATION	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	MANUFACTURE OF ANY PMA-APPROVED IOL DESIGNS WITH SYMMETRICAL HAPTICS IN OPTIC DIAMETERS DOWN TO 5.0 MM	04/10/92
P880001/S33	FLUOREX 700 (FLUSILFOCON A), FLUOREX 500 (FLUSILFOCON B), FLUOREX 300 (FLUSILFOCON C), RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	G.T. LABORATORIES CHICAGO, IL 60602	TWENTY-ONE ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTIION SITES	04/14/92
P880006/S13	SENSOLOG	SIEMENS PACESETTER, INC.	MODEL 3038 FUNCTION	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	MODEL 703 PULSE GENERATOR AND P700 PROGRAMMER, MODEL 3038 FUNCTION PACK	SYLMAR, CA 91392-9221	PACK FOR USE WITH THE APS-II MODEL 3003 PROGRAMMER	04/14/92
P880086/S15	SYNCHRONY MODEL 2020T PULSE GENERATOR AND APS-II MODEL 3000 PROGRAMMER, MODEL 3038 FUNCTION PACK	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	MODEL 3038 FUNCTION PACK FOR USE WITH THE APS-II MODEL 3003 PROGRAMMER	04/14/92
P890003/S12	SYNERGYST II PULSE GENERATOR, MODEL 9760 PROGRAMMER	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	NEW CABLE AND ADAPTERS IN THE MODEL 9760 PROGRAMMER	04/03/92
P890003/S14	MEDTRONIC MODEL 7070, 7071, AND 7071 SYNERGYST II PACEMAKER PULSE GENERATORS, 7074, 7076, AND 7077 ELITE, AND CPI 1226 AND 1229 PRELUDE PULSE GENERATORS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	ADDITIONAL INFORMATION TO THE PACKAGE LABELING AND TECHNICAL MANUALS	04/10/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890024/S03	TROPHOCAN CHORIONIC VILLUS SAMPLING (CVS) CATHETER	CONCORD/PORTEX KEENE, NH 03431-0724	REVISED DEVICE LABELING, PATIENT INFORMATION, "DEAR DOCTOR" LETTER AND MONITORING PROGRAM	04/21/92
P890024/S04	TROPHOCAN CHORIONIC VILLUS SAMPLING (CVS) CATHETER	CONCORD/PORTEX KEENE, NH 03431-0724	REVISED DEVICE LABELING, PATIENT INFORMATION, "DEAR DOCTOR" LETTER AND MONITORING PROGRAM	04/21/92
P890032/S13	CORDIS ORION STEERABLE PTCA BALLOON CATHETER, ORION STEERABLE PTCA BALLOON CATHETER WITH GLISSADE HYDROPHILIC COATING	CORDIS CORPORATION MIAMI, FL 33102-5700	USE OF A NEW FORMING TUBE MATERIAL	04/03/92
P890044/S20	BIS.45 AND TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND BLUE TINTED)	BENTEC ENGINEERING INC. SACRAMENTO, CA 95834	10 ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	04/14/92
P900001/S05	SGP 3 (UNIFOCON A) RIGID GAS PERMEABLE	PERMEABLE CONTACT LENSES, INC.	THREE ADDITIONAL CONTACT LENS	04/14/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CONTACT LENS FOR DAILY WEAR (CLEAR, BLUE AND GREEN TINTED)	MORGANVILLE, NJ 07751	FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	
P900025/S01	FLUORO-CEP PROGESTERONE 08869	ZEUS SCIENTIFIC INC. RARITAN, N.J.	"CONTRACT MANUFACTURER" AGREEMENT WITH SIN H. LEE, M.D. FOR OFF-SITE MANUFACTURING OF INTERMEDIATES USED IN THE FORMULATION	04/21/92
P900025/S02	FLUORO-CEP PROGESTERONE 08869	ZEUS SCIENTIFIC INC. RARITAN, NJ	APPROVAL FOR OFF-SITE QUALITY CONTROL PROCEDURES PERFORMED BY DR. PERTSCHUK ON FLUORO-CEP PROGESTERONE	04/17/92

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

ORIGINAL VETERINARY NADAs

140-939	LIQUID TYPE B	CATTLE	AGRI BEEF	MONENSIN SODIUM
04-07-92	MEDICATED CATTLE FEED		NAMPA, ID	400GM/TON
	R/T 400/150		83653	TYLOSIN PHOSPHATE
	(LIQUID)			150GM/TON
140-929	MICOTIL 300	CATTLE	ELANCO ANIMAL HLTH	TILMICOSIN PHOSPHATE
04-24-92	(LIQUID)		INDIANAPOLIS, IN 46285	300MG/ML

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR THE MONTH OF APRIL 1992.

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

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) 295-8428

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

*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.

Volume 15 (5)
May 1992

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

19-630 05-07-92 (SUPPL)	POTASSIUM CHLORIDE 0.075% IN DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 3.3GM/100ML POTASSIUM CHLORIDE 75MG/100ML SODIUM CHLORIDE 300MG/100ML (NEW STRENGTH)
19-630 05-07-92 (SUPPL)	POTASSIUM CHLORIDE 0.11% IN DEXTROSE 3.3% AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 3.3GM/100ML POTASSIUM CHLORIDE 110MG/100ML SODIUM CHLORIDE 300MG/100ML

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

			(NEW STRENGTH)
19-630	POTASSIUM CHLORIDE	MCGAW	DEXTROSE
05-07-92	0.15% IN DEXTROSE 3.3%	IRVINE, CA	3.3GM/100ML
(SUPPL)	AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE)	92713	POTASSIUM CHLORIDE 150MG/100ML SODIUM CHLORIDE 300MG/100ML (NEW STRENGTH)
19-630	POTASSIUM CHLORIDE	MCGAW	DEXTROSE
05-07-92	0.22% IN DEXTROSE 3.3%	IRVINE, CA	3.3GM/100ML
(SUPPL)	AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE)	92713	POTASSIUM CHLORIDE 220MG/100ML SODIUM CHLORIDE 300MG/100ML (NEW STRENGTH)
19-630	POTASSIUM CHLORIDE	MCGAW	DEXTROSE
05-07-92	0.3% IN DEXTROSE 3.3%	IRVINE, CA	3.3GM/100ML
(SUPPL)	AND SODIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE)	92713	POTASSIUM CHLORIDE 300MG/100ML SODIUM CHLORIDE 300MG/100ML (NEW STRENGTH)
20-057	CEREDASE	GENZYME	ALGLUCERASE
05-08-92	(INJECTABLE)	BOSTON, MA	10 UNITS/ML
(SUPPL)		02111	(NEW STRENGTH)
19-661	CYTOVENE	SYNTEX	GANCICLOVIR SODIUM
05-15-92	(INJECTABLE)	PALO ALTO, CA	EQ 500MG BASE/VIAL
(SUPPL)		94304	(NEW INDICATION -- PREVENTION OF CMV DISEASE

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

IN TRANSPLANT PATIENTS AT
RISK FOR CMV DISEASE)

18-703 ZANTAC GLAXO RANITIDINE HYDROCHLORIDE
05-19-92 (TABLET) RES TRIANGLE PK, NC EQ 150MG BASE
(SUPPL) 27709 EQ 300MG BASE
(NEW INDICATION --
TREATMENT OF ENDOSCOPICALLY
DIAGNOSED EROSIVE
ESOPHAGITIS)

19-675 ZANTAC GLAXO RANITIDINE HYDROCHLORIDE
05-19-92 (SYRUP) RES TRIANGLE PK, NC EQ 15MG BASE/ML
(SUPPL) 27709 (NEW INDICATION --
TREATMENT OF ENDOSCOPICALLY
DIAGNOSED EROSIVE
ESOPHAGITIS)

20-033 LOTENSIN HCT CIBA BENAZEPRIL HYDROCHLORIDE
05-19-92 (TABLET) SUMMIT, NJ 5MG
(4 S) 07901 HYDROCHLOROTHIAZIDE
6.25MG
(ANTIHYPERTENSIVE)

20-033 LOTENSIN HCT CIBA BENAZEPRIL HYDROCHLORIDE
05-19-92 (TABLET) SUMMIT, NJ 10MG
(4 S) 07901 HYDROCHLOROTHIAZIDE
12.5MG
(ANTIHYPERTENSIVE)

20-033 LOTENSIN HCT CIBA BENAZEPRIL HYDROCHLORIDE
05-19-92 (TABLET) SUMMIT, NJ 20MG
(4 S) 07901 HYDROCHLOROTHIAZIDE
12.5MG
(ANTIHYPERTENSIVE)

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

20-033	LOTENSIN HCT	CIBA	BENAZEPRIL HYDROCHLORIDE
05-19-92	(TABLET)	SUMMIT, NJ	20MG
(4 S)		07901	HYDROCHLOROTHIAZIDE
			25MG
			(ANTIHYPERTENSIVE)
16-636	NARCAN	DUPONT	NALOXONE HYDROCHLORIDE
05-29-92	(INJECTABLE)	WILMINGTON, DE	0.02MG/ML
(SUPPL)		19880	0.4MG/ML
			1MG/ML
			(NEW INDICATION --
			ADJUNCTIVE AGENT TO INCREASE
			BLOOD PRESSURE IN THE
			MANAGEMENT OF SEPTIC SHOCK)
20-092	DILACOR XR	RHONE POULENC RORER	DILTIAZEM HYDROCHLORIDE
05-29-92	(CAPSULE,	COLLEGEVILLE, PA	120MG*
(5 S)	EXTENDED RELEASE)	19426	180MG
			240MG
			(CALCIUM ION
			INFLUX INHIBITOR)

* - Not Marketed at This Time

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.

20-092 DILACOR XR RHONE POULENC RORER DILTIAZEM HYDROCHLORIDE
05-07-92 (CAPSULE, COLLEGEVILLE, PA 120MG
EXTENDED RELEASE) 19426 180MG
240MG
(CALCIUM ION
INFLUX INHIBITOR)

20-033 LOTENSIN HCT CIBA BENAZEPRIL HYDROCHLORIDE
05-15-92 (TABLET) SUMMIT, NJ 5MG
07901 HYDROCHLOROTHIAZIDE
6.25MG
(ANTIHYPERTENSIVE)

20-033 LOTENSIN HCT CIBA BENAZEPRIL HYDROCHLORIDE
05-15-92 (TABLET) SUMMIT, NJ 10MG
07901 HYDROCHLOROTHIAZIDE
12.5MG
(ANTIHYPERTENSIVE)

20-033 LOTENSIN HCT CIBA BENAZEPRIL HYDROCHLORIDE
05-15-92 (TABLET) SUMMIT, NJ 20MG
07901 HYDROCHLOROTHIAZIDE
12.5MG
(ANTIHYPERTENSIVE)

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

APPROVABLE ORIGINAL NDAs

20-033	LOTENSIN HCT	CIBA	BENAZEPRIL HYDROCHLORIDE
05-15-92	(TABLET)	SUMMIT, NJ	20MG
		07901	HYDROCHLOROTHIAZIDE
			25MG
			(ANTIHYPERTENSIVE)
20-125	ACCURETIC	PARKE DAVIS	HYDROCHLOROTHIAZIDE
05-15-92	(TABLET)	ANN ARBOR, MI	12.5MG
		48105	QUINAPRIL HYDROCHLORIDE
			EQ 10MG BASE
			(ANTIHYPERTENSIVE)
20-125	ACCURETIC	PARKE DAVIS	HYDROCHLOROTHIAZIDE
05-15-92	(TABLET)	ANN ARBOR, MI	12.5MG
		48105	QUINAPRIL HYDROCHLORIDE
			EQ 20MG BASE
			(ANTIHYPERTENSIVE)
20-125	ACCURETIC	PARKE DAVIS	HYDROCHLOROTHIAZIDE
05-15-92	(TABLET)	ANN ARBOR, MI	25MG
		48105	QUINAPRIL HYDROCHLORIDE
			EQ 20MG BASE
			(ANTIHYPERTENSIVE)
19-940	ACTINEX	BLOCK DRUG	MASOPROCOL
05-19-92	(CREAM)	JERSEY CITY, NJ	10%
		07302	(DERMATOLOGIC)
			[TREATMENT OF ACTINIC
			KERATOSES]

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

APPROVABLE ORIGINAL NDAs

20-045	SHADE UVAGUARD	PLOUGH	AVOBENZONE
05-29-92	(LOTION)	MEMPHIS, TN 38151	3% OCTYL METHOXYCINNAMATE 7.5% OXYBENZONE 3% (SUNSCREEN) (OTC)

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

ORIGINAL ABBREVIATED NDAs

74-052	ATENOLOL	GENEVA	ATENOLOL
05-01-92	(TABLET)	BROOMFIELD, CO	25MG
	80038	(BETA ADRENERGIC BLOCKER)	

81-235	METHOTREXATE	MYLAN	METHOTREXATE SODIUM
05-15-92	(TABLET)	MORGANTOWN, WV	EQ 2.5MG BASE
	26504	(ANTIMETABOLITE)	

63-116	TOBRAMYCIN SULFATE	ABBOTT	TOBRAMYCIN SULFATE
05-18-92	(INJECTABLE)	ABBOTT PARK, IL	EQ 40MG BASE/ML
	60064	(ANTIBIOTIC, AMINOGLYCOSIDE)	

63-274	AMIKACIN SULFATE	ELKINS SINN	AMIKACIN SULFATE
05-18-92	(INJECTABLE)	CHERRY HILL, NJ	EQ 50MG BASE/ML
	08003	(ANTIBIOTIC, AMINOGLYCOSIDE)	

63-275	AMIKACIN SULFATE	ELKINS SINN	AMIKACIN SULFATE
05-18-92	(INJECTABLE)	CHERRY HILL, NJ	EQ 250MG BASE/ML
	08003	(ANTIBIOTIC, AMINOGLYCOSIDE)	

72-247	METOCLOPRAMIDE HCL	CETUS BEN VENUE	METOCLOPRAMIDE HYDROCHLORIDE
05-18-92	(INJECTABLE)	EMERYVILLE, CA	EQ 10MG BASE/2ML
	94608	(UPPER GI TRACT MOTILITY STIMULATOR)	

63-282	CLINDAMYCIN PHOSPHATE	GENSIA	CLINDAMYCIN PHOSPHATE
05-29-92	(INJECTABLE)	IRVINE, CA	EQ 150MG BASE/ML
	92718	(ANTIBIOTIC, LINCOMYCIN)	

73-141	IBUPROFEN	TAG	IBUPROFEN
05-29-92	(TABLET)	SELLERSVILLE, PA	200MG
	18960	(NONSTEROIDAL	

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAs			
			ANTI-INFLAMMATORY) (OTC)
73-519 05-29-92	TOLMETIN SODIUM (CAPSULE)	LEMMON SELLERSVILLE, PA 18960	TOLMETIN SODIUM EQ 400MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
73-590 05-29-92	LACTULOSE (SYRUP)	ROXANE LABS COLUMBUS, OH 43216	LACTULOSE 10GM/15ML (LAXATIVE/AMMONIA DETOXICANT)
73-591 05-29-92	LACTULOSE (SYRUP)	ROXANE LABS COLUMBUS, OH 43216	LACTULOSE 10GM/15ML (LAXATIVE/AMMONIA DETOXICANT)
74-036 05-29-92	PIROXICAM (CAPSULE)	SCHIAPPARELLI SEARLE SKOKIE, IL 60077	PIROXICAM 10MG 20MG (NONSTEROIDAL ANTI-INFLAMMATORY)
81-223 05-29-92	HYDROCODONE BITARTRATE AND ACETAMINOPHEN (TABLET)	MIKART ATLANTA, GA 30318	ACETAMINOPHEN 650MG HYDROCODONE BITARTRATE 10MG (ANALGESIC)

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

72-837 DILTIAZEM HCL MYLAN DILTIAZEM HYDROCHLORIDE
03-16-92 (TABLET) MORGANTOWN, WV 90MG
26504 (CALCIUM ION
INFLUX INHIBITOR)

72-838 DILTIAZEM HCL MYLAN DILTIAZEM HYDROCHLORIDE
03-16-92 (TABLET) MORGANTOWN, WV 120MG
26504 (CALCIUM ION
INFLUX INHIBITOR)

73-185 DILTIAZEM HCL MYLAN DILTIAZEM HYDROCHLORIDE
03-16-92 (TABLET) MORGANTOWN, WV 30MG
26504 (CALCIUM ION
INFLUX INHIBITOR)

73-186 DILTIAZEM HCL MYLAN DILTIAZEM HYDROCHLORIDE
03-16-92 (TABLET) MORGANTOWN, WV 60MG
26504 (CALCIUM ION
INFLUX INHIBITOR)

73-466 GEMFIBROZIL MYLAN GEMFIBROZIL
03-27-92 (CAPSULE) MORGANTOWN, WV 300MG

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

ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

26504 (ANTIHYPERLIPIDEMIC)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-010	ILOSONE	LILLY	ERYTHROMYCIN ESTOLATE
04-03-92	(SUSPENSION)	INDIANAPOLIS, IN 46285	EQ 125MG BASE/5ML EQ 250MG BASE/5ML (REVISED LABELING -- PRECAUTIONS)
50-365	ILOSONE	LILLY	ERYTHROMYCIN ESTOLATE
04-03-92	(CAPSULE)	INDIANAPOLIS, IN 46285	EQ 250MG BASE (REVISED LABELING -- PRECAUTIONS)
50-426	ILOSONE	LILLY	ERYTHROMYCIN ESTOLATE
04-03-92	(TABLET)	INDIANAPOLIS, IN 46285	EQ 500MG BASE (REVISED LABELING -- PRECAUTIONS)
18-897	SODIUM CHLORIDE IN PLASTIC CONTAINER	ABBOTT ABBOTT PARK, IL 60064	SODIUM CHLORIDE 2.5MEQ/ML (REVISED LABELING -- WARNINGS)
04-08-92	(INJECTABLE)		
17-857	STADOL	BRISTOL	BUTORPHANOL TARTRATE
05-01-92	(INJECTABLE)	SYRACUSE, NY 13221	1MG/ML 2MG/ML (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; HOW SUPPLIED)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-769	CALCIMAR	RHONE POULENC RORER	CALCITONIN, SALMON
05-06-92	(INJECTABLE)	COLLEGEVILLE, PA	200IU/ML
	19426	(REVISED LABELING -- INDICATIONS AND USAGE)	
19-998	CHEMET	MCNEIL	SUCCIMER
05-06-92	(CAPSULE)	FORT WASHINGTON, PA	100MG
	19034	(REVISED LABELING -- WARNINGS)	
09-330	LANOXIN	BURROUGHS WELLCOME	DIGOXIN
05-07-92	(INJECTABLE)	RES TRIANGLE PK, NC	0.1MG/ML
	27709	0.25MG/ML	
		(REVISED LABELING -- PRECAUTIONS)	
12-151	ALDACTONE	SEARLE	SPIRONOLACTONE
05-07-92	(TABLET)	SAN JUAN, PR	25MG
	00936	50MG	
		100MG	
		(REVISED LABELING -- CLINICAL PHARMACOLOGY)	
18-118	LANOXICAPS	BURROUGHS WELLCOME	DIGOXIN
05-07-92	(CAPSULE)	RES TRIANGLE PK, NC	0.05MG
	27709	0.1MG	
		0.2MG	
		(REVISED LABELING -- PRECAUTIONS)	
18-998	VASOTEC	MERCK	ENALAPRIL MALEATE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

05-07-92	(TABLET)	WEST POINT, PA	2.5MG
	19486		5MG
			10MG
			20MG
			(REVISED LABELING --
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS)

19-221	VASERETIC	MERCK	ENALAPRIL MALEATE
05-07-92	(TABLET)	WEST POINT, PA	10MG
	19486		HYDROCHLOROTHIAZIDE
			25MG
			(REVISED LABELING --
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS)

19-309	VASOTEC	MERCK	ENALAPRILAT
05-07-92	(INJECTABLE)	WEST POINT, PA	1.25MG/ML
	19486		(REVISED LABELING --
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS)

19-558	PRINIVIL	MERCK	LISINOPRIL
05-07-92	(TABLET)	WEST POINT, PA	5MG
	19486		10MG
			20MG
			40MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-630	POTASSIUM CHLORIDE IN DEXTROSE AND SODIUM CHLORIDE IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE (MULTIPLE POTENCIES) POTASSIUM CHLORIDE (MULTIPLE POTENCIES) SODIUM CHLORIDE (MULTIPLE POTENCIES) (REVISED LABELING -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED; DIRECTIONS FOR USE)
05-07-92			
19-778	PRINZIDE 12.5 (TABLET)	MERCK WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 20MG (REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
05-07-92			
19-778	PRINZIDE 25 (TABLET)	MERCK WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 25MG LISINOPRIL 20MG
05-07-92			

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-885	ACCUPRIL	PARKE DAVIS	QUINAPRIL HYDROCHLORIDE
05-07-92	(TABLET)	ANN ARBOR, MI 48105	EQ 5MG BASE EQ 10MG BASE EQ 20MG BASE EQ 40MG BASE (REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
50-533	VIBRA-TABS	PFIZER	DOXYCYCLINE HYCLATE
05-07-92	(TABLET)	NEW YORK, NY 10017	EQ 100MG BASE (REVISED LABELING -- ADVERSE REACTIONS)
20-057	CEREDASE	GENZYME	ALGLUCERASE
05-08-92	(INJECTABLE)	BOSTON, MA 02111	10 UNITS/ML 80 UNITS/ML (REVISED LABELING -- HOW SUPPLIED)
50-006	VIBRAMYCIN	PFIZER	DOXYCYCLINE
05-11-92	(POWDER FOR RECONSTITUTION)	NEW YORK, NY 10017	EQ 25MG BASE/5ML (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
50-007	VIBRAMYCIN	PFIZER	DOXYCYCLINE HYCLATE
05-11-92	(CAPSULE)	NEW YORK, NY	EQ 50MG BASE
		10017	EQ 100MG BASE
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
50-442	VIBRAMYCIN	PFIZER	DOXYCYCLINE HYCLATE
05-11-92	(INJECTABLE)	NEW YORK, NY	EQ 100MG BASE/VIAL
		10017	EQ 200MG BASE/VIAL
			(REVISED LABELING --
			ADVERSE REACTIONS)
50-480	VIBRAMYCIN	PFIZER	DOXYCYCLINE CALCIUM
05-11-92	(SUSPENSION)	NEW YORK, NY	EQ 50MG BASE/5ML
		10017	(REVISED LABELING --
			ADVERSE REACTIONS)
50-533	VIBRA-TABS	PFIZER	DOXYCYCLINE HYCLATE
05-11-92	(TABLET)	NEW YORK, NY	EQ 100MG BASE
		10017	(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
18-052	GYNE-LOTRIMIN	SCHERING	CLOTRIMAZOLE
05-12-92	(CREAM)	KENILWORTH, NJ	1%

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		07033	(REVISED LABELING -- PATIENT INSTRUCTIONS)
50-444	MINOCIN	LEDERLE	MINOCYCLINE HYDROCHLORIDE
05-12-92	(INJECTABLE)	PEARL RIVER, NY	EQ 100MG BASE/VIAL
		10965	(REVISED LABELING -- ADVERSE REACTIONS)
50-445	MINOCIN	LEDERLE	MINOCYCLINE HYDROCHLORIDE
05-12-92	(SUSPENSION)	PEARL RIVER, NY	EQ 50MG BASE/5ML
		10965	(REVISED LABELING -- ADVERSE REACTIONS)
50-451	MINOCIN	LEDERLE	MINOCYCLINE HYDROCHLORIDE
05-12-92	(TABLET)	PEARL RIVER, NY	EQ 50MG BASE
		10965	EQ 100MG BASE (REVISED LABELING -- ADVERSE REACTIONS)
50-649	MINOCIN	LEDERLE	MINOCYCLINE HYDROCHLORIDE
05-12-92	(CAPSULE)	PEARL RIVER, NY	EQ 50MG BASE
		10965	EQ 100MG BASE (REVISED LABELING -- ADVERSE REACTIONS)
18-998	VASOTEC	MERCK	ENALAPRIL MALEATE
05-13-92	(TABLET)	WEST POINT, PA	2.5MG
		19486	5MG 10MG 20MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; 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

19-221	VASERETIC	MERCK	ENALAPRIL MALEATE
05-13-92	(TABLET)	WEST POINT, PA	10MG
	19486		HYDROCHLOROTHIAZIDE
			25MG
			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-309	VASOTEC	MERCK	ENALAPRILAT
05-13-92	(INJECTABLE)	WEST POINT, PA	1.25MG/ML
	19486		(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-558	PRINIVIL	MERCK	LISINOPRIL
05-13-92	(TABLET)	WEST POINT, PA	5MG
	19486		10MG
			20MG
			40MG
			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-778	PRINZIDE 12.5	MERCK	HYDROCHLOROTHIAZIDE
05-13-92	(TABLET)	WEST POINT, PA	12.5MG
	19486		LISINOPRIL
			20MG
			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS;
			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

19-778	PRINZIDE 25	MERCK	HYDROCHLOROTHIAZIDE
05-13-92	(TABLET)	WEST POINT, PA 19486	25MG LISINOPRIL 20MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-847	CIPRO	MILES	CIPROFLOXACIN
05-13-92	(INJECTABLE)	WEST HAVEN, CT 06516	10MG/ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-857	CIPRO IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MILES WEST HAVEN, CT 06516	CIPROFLOXACIN 200MG/100ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-858	CIPRO IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	MILES WEST HAVEN, CT 06516	CIPROFLOXACIN 200MG/100ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-661	CYTOVENE	SYNTEX	GANCICLOVIR SODIUM
05-15-92	(INJECTABLE)	PALO ALTO, CA 94304	EQ 500MG BASE/VIAL (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; 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; DOSAGE AND ADMINISTRATION)
50-588	CEFOTAN	STUART	CEFOTETAN DISODIUM
05-18-92	(INJECTABLE)	WILMINGTON, DE	EQ 1GM BASE/VIAL
		19897	EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (REVISED LABELING -- ADVERSE REACTIONS)
18-154	LONITEN	UPJOHN	MINOXIDIL
05-19-92	(TABLET)	KALAMAZOO, MI	2.5MG
		49001	10MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; PRECAUTIONS)
18-703	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
05-19-92	(TABLET)	RES TRIANGLE PK, NC	EQ 150MG BASE
		27709	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
18-703	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
05-19-92	(TABLET)	RES TRIANGLE PK, NC	EQ 300MG BASE
		27709	(REVISED LABELING -- CLINICAL PHARMACOLOGY;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
19-090	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
05-19-92	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 25MG BASE/ML
	27709		(REVISED LABELING -- HOW SUPPLIED)
19-675	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
05-19-92	(SYRUP)	RES TRIANGLE PK, NC	EQ 15MG BASE/ML
	27709		(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
16-851	FML	ALLERGAN	FLUOROMETHOLONE
05-20-92	(SUSPENSION/DROPS)	IRVINE, CA	0.1%
	92715		(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
18-086	TIMOPTIC	MSD	TIMOLOL MALEATE
05-20-92	(SOLUTION/DROPS)	WEST POINT, PA	EQ 0.25% BASE
	19486		EQ 0.5% BASE (REVISED LABELING --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
17-760	FML	ALLERGAN	FLUOROMETHOLONE
05-21-92	(OINTMENT)	IRVINE, CA 92715	0.1% (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
19-216	FML FORTE	ALLERGAN	FLUOROMETHOLONE
05-21-92	(SUSPENSION/DROPS)	IRVINE, CA 92715	0.25% (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
19-387	PROFENAL	ALCON	SUPROFEN
05-21-92	(SOLUTION/DROPS)	FORT WORTH, TX 76134	1% (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

19-463	TIMOPTIC IN OCUDOSE	MSD	TIMOLOL MALEATE	
05-21-92	(SOLUTION/DROPS)	WEST POINT, PA	EQ 0.25% BASE	
		19486	EQ 0.5% BASE	
			(REVISED LABELING -- DESCRIPTION; PRECAUTIONS; ADVERSE REACTIONS)	
19-489	VENTOLIN ROTACAPS	GLAXO	ALBUTEROL SULFATE	
05-21-92	(CAPSULE)	RES TRIANGLE PK, NC	EQ 0.2MG BASE	
		27709	(REVISED LABELING -- OVERDOSAGE)	
50-616	TOBRADEX	ALCON	DEXAMETHASONE	
05-21-92	(OINTMENT)	FORT WORTH, TX	0.1%	
		76134	TOBRAMYCIN	
			0.3%	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE)
11-977	DECADRON	MSD	DEXAMETHASONE	
05-26-92	(OINTMENT)	WEST POINT, PA	SODIUM PHOSPHATE	
		19486	EQ 0.05% PHOSPHATE	
			(REVISED LABELING -- PRECAUTIONS)	
20-035	ERGAMISOL	JANSSEN	LEVAMISOLE HYDROCHLORIDE	
05-26-92	(TABLET)	PISCATAWAY, NJ	EQ 50MG BASE	
		08855	(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

19-771 05-28-92	DIMETAPP SINUS (TABLET)	WHITEHALL NEW YORK, NY 10017	IBUPROFEN 200MG PSEUDOEPHEDRINE HYDROCHLORIDE 30MG (REVISED LABELING -- ALTERNATE TRADENAME)
16-636 05-29-92	NARCAN (INJECTABLE)	DUPONT WILMINGTON, DE 19880	NALOXONE HYDROCHLORIDE 0.02MG/ML 0.4MG/ML 1MG/ML (REVISED LABELING -- INDICATIONS)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1151 NONE DOMINION BIOLGS BLOOD GROUPING REAGENT
05-01-92 (IN-VITRO TEST) CANADA B3B 1M1 (ANTI-A, ANTI-B AND ANTI-A,B)
(A&B)

1106 PROLEUKIN CHIRON ALDESLEUKIN
05-05-92 (INJECTABLE) EMERYVILLE, CA (TREATMENT OF ADULTS [≥18
94608 YRS OLD] WITH METASTATIC
RENAL CELL CARCINOMA)
(B)

203 NONE SPOKANE & INLAND CRYOPRECIPITATED AHF
05-11-92 (INJECTABLE) EMPIRE BLOOD BANK (TRANSFUSION)
SPOKANE, WA (B)
99210

201 NONE SAN DIEGO BLOOD BANK PLATELETS
05-12-92 (INJECTABLE) SAN DIEGO, CA (TRANSFUSION)
92103 (B)

695 NONE COMM BLOOD BANK OF PLATELETS
05-12-92 (INJECTABLE) LANCASTER CNTY MED SOC (TRANSFUSION)
LINCOLN, NE (B)
68510

1152 SUDS HIV-1 MUREX HUMAN IMMUNODEFICIENCY VIRUS
05-22-92 (IN-VITRO TEST) NORCROSS, GA TYPE I
30071 (DETECTION OF ANTIBODIES
TO HIV-1 IN HUMAN SERUM
OR PLASMA)
(A&B)

1153 NONE PENINSULA LABS HUMAN IMMUNODEFICIENCY VIRUS
05-22-92 (IN-VITRO TEST) BELMONT, CA TYPE I
94002 (FOR FURTHER MANUFACTURING USE)
(A&B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910005 05-12-92	SAFE-T-VUE IRREVERSIBLE TEMPERATURE INDICATOR	WHITMAN MED CLOCK, NJ 07066	BLOOD BAG TEMPERATURE MONITOR (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

P910029	BLANCHARD SOFT (POLYMACON) SOFT CONTACT LENS	LES LABORATORIES BLANCHARD SHERBROOK, IL 60601	APPROVAL OF THE BLANCHARD SOFT (POLYMACON) CONTACT LENS FOR DAILY WEAR	05/22/92

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

P800049/S04 05/29/92	REQUEST TO MANUFACTURE MULTIPIECE LENSES (IOLS) AT HUNTINGTON, WEST VIRGINIA FACILITY	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MANUFACTURE MULTIPIECE IOLS AT HUNTINGTON, WEST VIRGINIA FACILITY
P810018/S30 05/29/92	REQUEST TO MANUFACTURE MULTIPIECE INTRAOCULAR LENSES (IOLS) AT HUNTINGTON, WEST VIRGINIA FACILITY	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MANUFACTURE MULTIPIECE IOLS AT HUNTINGTON, WEST VIRGINIA FACILITY
P810032/S42 05/29/92	REQUEST TO MANUFACTURE MULTIPIECE INTRAOCULAR LENSES (IOLS) AT HUNTINGTON, WEST VIRGINIA FACILITY	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MANUFACTURE MULTIPIECE IOLS AT HUNTINGTON, WEST VIRGINIA FACILITY
P820016/S01 05/29/92	REQUEST TO MANUFACTURE MULTIPIECE INTRAOCULAR LENSES (IOLS) AT HUNTINGTON, WEST	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MANUFACTURE MULTIPIECE IOLS AT HUNTINGTON, WEST VIRGINIA FACILITY

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

VIRGINIA FACILITY

P820047/S01	REQUEST TO MANUFACTURE MULTIPIECE INTRAOCULAR LENSES (IOLS) AT HUNTINGTON, WEST VIRGINIA FACILITY	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MANUFACTURE MULTIPIECE IOLS AT HUNTINGTON, WEST VIRGINIA FACILITY	05/29/92
P820053/S20	BARNES-HIND TITAN LIQUID CLEANER, BARNES-HIND WETTING AND SOAKING SOLUTION, COMFORTCARE GP WETTING AND SOAKING SOLUTION	SOLA BARNES HIND SUNNYVALE, CA 94086-5200	MODIFY THE BARNES HIND WETTING AND SOAKING SOLUTION LABELING	05/21/92
P830060/S30	VENTAK MODELS 1550 AND 1555 AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR SYSTEM	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	REMOVAL OF THE D-107 CIRCUIT DIODE FROM THE SYSTEM CIRCUIT IN THE VENTAK MODELS 1550 AND 1555	05/14/92
P840024/S37	NUCLEUS 22	COCHLEAR CORPORATION	ADDITION OF A 1000PF	

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	CHANNEL COCHLEAR IMPLANT	ENGLEWOOD, CO 80112	CAPACITOR TO THE LAPEL MICROPHONE CIRCUIT TO REDUCE THE RADIOFREQUENCY INTERFERENCE	05/21/92
P840033/S02	REQUEST TO MANUFACTURE MULTIPIECE INTRAOCULAR LENSES (IOLS) AT HUNTINGTON, WEST VIRGINIA FACILITY	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MANUFACTURE MULTIPIECE IOLS AT HUNTINGTON, WEST VIRGINIA FACILITY	05/29/92
P840040/S28	HEART TRAK CORONARY BALLOON DILATATION CATHETER SYSTEM, NITECH 018 PTCA CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	APPROVAL FOR THE NITECH 018 CORONARY BALLOON DILATATION CATHETER	05/29/92
P840060/S18	REQUEST TO MANUFACTURE MULTIPIECE INTRAOCULAR LENSES (IOLS) AT HUNTINGTON, WEST VIRGINIA FACILITY	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MANUFACTURE MULTIPIECE IOLS AT HUNTINGTON, WEST VIRGINIA FACILITY	05/29/92
P850048/S07	HYBRITECH TANDEM-R PSA IMMUNORADIOMETRIC	HYBRITECH, INC. SAN DIEGO, CA 92196-9006	MODIFICATIONS TO THE HYBRITECH TANDEM-R PSA IMMUNORADIOMETRIC	05/21/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	ASSAY		ASSAY, TO BE MARKETED UNDER THE TRADE NAME HYBRITECH STRATUS FLUOROMETRIC ENZYME IMMUNOASSAY	
P850088/S25	LENS PLUS OXYSEPT DISINFECTION SYSTEM, ULTRACARE DISINFECTANT/ NEUTRALIZER SYSTEM	ALLERGAN OPTICAL IRVINE, CA 92715-1599	REVISED LABELING TO INFORM USERS OF AN INCOMPATIBILITY OF THIS LENS CARE SYSTEM WITH ILLUSIONS (TEFILCON) SOFT (HYDROPHILIC) CONTACT LENS	05/05/92
P870015/S15	MEDSTONE STS EXTRACORPOREAL SHOCKWAVE LITHOTRIPTER	MEDSTONE INTERNATIONAL, INC. IRVINE, CA 92718	MODIFIED ULTRASOUND LOCALIZATION SYSTEM	05/19/92
P880001/S34	FLUOREX 700 (FLUSILFOCON A) AND FLUOREX 700, 500, AND 300 (FUSILFOCON A,B, AND C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	G.T. LABORATORIES, INC. CHICAGO, IL 60601	SIX ADDITIONAL LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	05/04/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P880053/S07	BARNES-HIND ENZYME + SURFACTANT CLEANER, COMFORTCARE GP DUAL ACTION DAILY CLEANER	SOLA BARNES HIND SUNNYVALE, CA 94086-5200	MODIFICATION OF THE FORMULATION FOR BARNES HIND ENZYME + SURFACTANT CLEANER BY LOWERING THE CONCENTRATION OF THE ENZYME, SUBTILISIN	05/21/92
P880078/S07	VH8500 HYPERTHERMIA TREATMENT SYSTEM	COOK, INCORPORATED BLOOMINGTON, IN 47402	REVISIONS TO THE VH8500 HYPERTHERMIA TREATMENT SYSTEM	05/21/92
P880078/S08	VH8500 HYPERTHERMIA TREATMENT SYSTEM	COOK, INCORPORATED BLOOMINGTON, IN 47402	CHANGE IN VENDOR FOR THE VIDEO GRAPHICS ARRAY (VGA) CARD	05/21/92
P880082/S14	REQUEST FOR 60 MONTH SHELF LIFE	EYE TECHNOLOGY, INC. ST. PAUL, MN 55117	APPROVAL FOR A 60 MONTH SHELF LIFE	05/15/92
P890003/S15	SYNERGYST II PULSE GENERATOR, ELITE PULSE GENERATOR MODELS 7074, 7075, 7076, AND 7077	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFICATION IN THE ELITE L58 IC	05/04/92
P890027/S08	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	ADDITION TO THE LAPEL MICROPHONE CIRCUIT TO REDUCE THE RADIOFREQUENCY INTERFERENCE	05/29/92
P890061/S03	VENTAK P MODEL 1600 AICD, SOFTWARE	CARDIAC PACEMAKERS, INC. ST. PAUL, MN	REMOVAL OF THE D-107 CIRCUIT DIODE FROM	05/14/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

MODULE MODEL 2830, VENTAK P MODEL 1600	55112-5798	THE SYSTEM CIRCUIT IN THE VENTAK P MODEL 1600

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

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR MAY 1992.

SUPPLEMENT VETERINARY NADAs

140-824 05-19-92	STENOROL (PREMIX)	TURKEYS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	HALOFUGINONE HYDROBROMIDE 2.7GM/LB

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) 295-8428

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

*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.

Volume 15 (6)
June 1992

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

20-066	NICORETTE DS	MERRELL DOW	NICOTINE POLACRILEX
06-08-92	(GUM, CHEWING)	CINCINNATI, OH	4MG
(5 S)	45215	(SMOKING DETERRENT)	

20-063	RBC-SCAN	CADEMA	TECHNETIUM TC-99M
06-11-92	(INJECTABLE)	MIDDLETOWN, NY	RED BLOOD CELL KIT
(3 S)	10940	N/A	
		(RADIOACTIVE DIAGNOSTIC)	

20-075	LIORESAL	MEDTRONIC	BACLOFEN
06-17-92	(INJECTABLE)	MINNEAPOLIS, MN	0.5MG/ML
(3 P, V*)	55432	2MG/ML	
		(MUSCLE RELAXANT/ANTISPASTIC)	

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

50-585	ROCEPHIN	ROCHE	CEFTRIAXONE SODIUM
06-17-92	(INJECTABLE)	NUTLEY, NJ	EQ 250MG BASE/VIAL
(SUPPL)		07110	EQ 500MG BASE/VIAL
			EQ 1GM BASE/VIAL
			EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(NEW INDICATION --
			SURGICAL PROPHYLAXIS
			FOR CHOLECYSTECTOMY)
20-180	PROSCAR	MSD	FINASTERIDE
06-19-92	(TABLET)	WEST POINT, PA	5MG
(1 P)		19486	(ENZYME INHIBITOR)
			[TREATMENT OF SYMPTOMATIC
			BENIGN PROSTATIC HYPERPLASIA]

V* - Designated Orphan Drug

20-199	HIVID	ROCHE	ZALCITABINE
06-19-92	(TABLET)	NUTLEY, NJ	0.375MG
(1 P, V*,		07110	0.75MG
AA**, E***)			(ANTIVIRAL)
50-560	CEFIZOX	SKF	CEFTIZOXIME SODIUM
06-23-92	(INJECTABLE)	PHILADELPHIA, PA	EQ 1GM BASE/VIAL
(SUPPL)		19101	EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(NEW INDICATION --
			PELVIC INFLAMMATORY
			DISEASE CAUSED BY
			NEISSERIA GONORRHOEAE,
			ESCHERICHIA COLI, OR

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

STREPTOCOCCUS AGALACTIAE)

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

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

APPROVABLE ORIGINAL NDAs

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

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

19-807 KERLEDEX LOREX BETAXOLOL HYDROCHLORIDE
06-04-92 (TABLET) SKOKIE, IL 5MG
60077 CHLORTHALIDONE
12.5MG
(ANTIHYPERTENSIVE)

19-807 KERLEDEX LOREX BETAXOLOL HYDROCHLORIDE
06-04-92 (TABLET) SKOKIE, IL 10MG
60077 CHLORTHALIDONE
12.5MG
(ANTIHYPERTENSIVE)

19-982 PROBETA LEDERLE BISOPROLOL FUMARATE
06-11-92 (TABLET) PEARL RIVER, NY 5MG
10965 10MG
(BETA ADRENERGIC BLOCKER)

50-680 CLEOCIN UPJOHN CLINDAMYCIN PHOSPHATE
06-23-92 (CREAM) KALAMAZOO, MI 2%
49001 (ANTIBIOTIC, LINCOMYCIN)

20-209 OXISTAT GLAXO OXICONAZOLE NITRATE
06-25-92 (LOTION) RES TRIANGLE PK, NC EQ 1% BASE

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

APPROVABLE ORIGINAL NDAs

27709			
	(ANTIFUNGAL)		

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

ORIGINAL ABBREVIATED NDAs

81-274	HEMSOL-HC	ABLE	HYDROCORTISONE ACETATE
06-19-92	(CREAM)	SOUTH PLAINFIELD, NJ	1%
		07080	(CORTICOSTEROID)
62-645	ULTRAGRIS-165	SIDMAK	GRISEOFULVIN,
06-30-92	(TABLET)	EAST HANOVER, NJ	ULTRAMICROCRYSTALLINE
		07936	165MG
			(ANTIFUNGAL)
62-646	ULTRAGRIS-330	SIDMAK	GRISEOFULVIN,
06-30-92	(TABLET)	EAST HANOVER, NJ	ULTRAMICROCRYSTALLINE
		07936	330MG
			(ANTIFUNGAL)
63-187	DOXYCYCLINE HYCLATE	SIDMAK	DOXYCYCLINE HYCLATE
06-30-92	(CAPSULE,	EAST HANOVER, NJ	EQ 100MG BASE
	COATED PELLETS)	07936	(ANTIBIOTIC TETRACYCLINE)
73-343	IBUPROFEN	LEMMON	IBUPROFEN
06-30-92	(TABLET)	SELLERSVILLE, PA	400MG
		18960	(NONSTEROIDAL
			ANTI-INFLAMMATORY)
73-344	IBUPROFEN	LEMMON	IBUPROFEN
06-30-92	(TABLET)	SELLERSVILLE, PA	600MG
		18960	(NONSTEROIDAL
			ANTI-INFLAMMATORY)
73-345	IBUPROFEN	LEMMON	IBUPROFEN
06-30-92	(TABLET)	SELLERSVILLE, PA	800MG
		18960	(NONSTEROIDAL
			ANTI-INFLAMMATORY)

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

ORIGINAL ABBREVIATED NDAs

73-479*	PENTAMIDINE	ABBOTT	PENTAMIDINE ISETHIONATE
06-30-92	ISETHIONATE	ABBOTT PARK, IL	300MG/VIAL
	(INJECTABLE)	60064	(ANTIPROTOZOAL)

* First Time Product Available Generically

73-488	FENTANYL CITRATE	STERIS	FENTANYL CITRATE
06-30-92	(INJECTABLE)	PHOENIX, AZ	EQ 0.05MG BASE/ML
		85063	(NARCOTIC ANALGESIC)
73-494	THIOTHIXENE HCL	ROXANE	THIOTHIXENE HYDROCHLORIDE
06-30-92	INTENSOL	COLUMBUS, OH	EQ 5MG BASE/ML
	(CONCENTRATE)	43216	(ANTIPSYCHOTIC)
73-527*	TOLMETIN SODIUM	PUREPAC	TOLMETIN SODIUM
06-30-92	(TABLET)	ELIZABETH, NJ	EQ 600MG BASE
		07207	(NONSTEROIDAL
			ANTI-INFLAMMATORY)
73-548*	DESONIDE	TARO	DESONIDE
06-30-92	(CREAM)	ONTARIO, CANADA	0.05%
			(CORTICOSTEROID)
81-319	PYRAZINAMIDE	MIKART	PYRAZINAMIDE
06-30-92	(TABLET)	ATLANTA, GA	500MG
		30318	(ANTIBACTERIAL)

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)	CLASSIFICATION(S)	STRENGTH(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.

73-666	METOPROLOL TARTRATE	MYLAN	METOPROLOL TARTRATE
06-29-92	(TABLET)	MORGANTOWN, WV 26504	50MG 100MG (BETA ADRENERGIC BLOCKER)
74-067	DILTIAZEM HCL	COPLEY	DILTIAZEM
06-30-92	(TABLET)	CANTON, MA 02021	HYDROCHLORIDE 30MG 60MG 90MG 120MG (CALCIUM ION INFLUX INHIBITOR)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-769	CALCIMAR	RHONE POULENC RORER	CALCITONIN, SALMON
06-01-92	(INJECTABLE)	COLLEGEVILLE, PA	200 IU/ML
	19426	(REVISED LABELING -- PRECAUTIONS)	
17-808	MIACALCIN	SANDOZ	CALCITONIN, SALMON
06-01-92	(INJECTABLE)	EAST HANOVER, NJ	100 IU/ML
	07936	200 IU/ML	
		(REVISED LABELING -- HOW SUPPLIED)	
19-507	KERLONE	LOREX	BETAXOLOL HYDROCHLORIDE
06-01-92	(TABLET)	SKOKIE, IL	10MG
	60077	20MG	
		(REVISED LABELING -- CLINICAL PHARMACOLOGY; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)	
17-450	MONISTAT 7	JOHNSON RW	MICONAZOLE NITRATE
06-03-92	(CREAM)	RARITAN, NJ	2%
	08869	(REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)	
18-520	MONISTAT 7	JOHNSON RW	MICONAZOLE NITRATE
06-03-92	(SUPPOSITORY)	RARITAN, NJ	100MG
	08869	(REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-440 06-09-92	M.V.C. 9+3 (INJECTABLE)	LYPHOMED MELROSE PARK, IL 60160	ASCORBIC ACID 10MG/ML BIOTIN 0.006MG/ML CYANOCOBALAMIN 0.5μGM/ML DEXPANTHENOL 1.5MG/ML ERGOCALCIFEROL 20 IU/ML FOLIC ACID 0.04MG/ML NIACINAMIDE 4MG/ML PYRIDOXINE HYDROCHLORIDE 0.4MG/ML RIBOFLAVIN PHOSPHATE SODIUM 0.36MG/ML THIAMINE HYDROCHLORIDE 0.3MG/ML VITAMIN A 330 IU/ML VITAMIN E 1 IU/ML (REVISED LABELING -- PRECAUTIONS)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-228	MANGANESE SULFATE	LYPHOMED	MANGANESE SULFATE
06-09-92	(INJECTABLE)	MELROSE PARK, IL 60160	EQ 0.1MG MANGANESE/ML (REVISED LABELING -- PRECAUTIONS)
19-229	ZINC SULFATE	LYPHOMED	ZINC SULFATE
06-09-92	(INJECTABLE)	MELROSE PARK, IL 60160	EQ 1MG ZINC/ML (REVISED LABELING -- PRECAUTIONS)
19-271	CHROMIC CHLORIDE	LYPHOMED	CHROMIC CHLORIDE
06-09-92	(INJECTABLE)	MELROSE PARK, IL 60160	EQ 0.004MG CHROMIUM/ML (REVISED LABELING -- PRECAUTIONS)
19-350	CUPRIC SULFATE	LYPHOMED	CUPRIC SULFATE
06-09-92	(INJECTABLE)	MELROSE PARK, IL 60160	EQ 0.4MG COPPER/ML (REVISED LABELING -- PRECAUTIONS)
11-529	PARAFON FORTE DSC	JOHNSON RW	CHLORZOXAZONE
06-10-92	(TABLET)	SPRING HOUSE, PA 19477	500MG (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
17-808	MIACALCIN	SANDOZ	CALCITONIN, SALMON
06-10-92	(INJECTABLE)	EAST HANOVER, NJ 07936	100 IU/ML 200 IU/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)

18-440 06-11-92	M.V.C. 9+3 (INJECTABLE)	LYPHOMED MELROSE PARK, IL 60160	ASCORBIC ACID 10MG/ML BIOTIN 0.006MG/ML CYANOCOBALAMIN 0.5UGM/ML DEXPANTHENOL 1.5MG/ML ERGOCALCIFEROL 20 IU/ML FOLIC ACID 0.04MG/ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			NIACINAMIDE 4MG/ML PYRIDOXINE HYDROCHLORIDE 0.4MG/ML RIBOFLAVIN PHOSPHATE SODIUM 0.36MG/ML THIAMINE HYDROCHLORIDE 0.3MG/ML VITAMIN A 330 IU/ML VITAMIN E 1 IU/ML (REVISED LABELING -- HOW SUPPLIED)
19-937	ADENOCARD	MEDCO	ADENOSINE
06-11-92	(INJECTABLE)	LOS ANGELES, CA	3MG/ML
		90048	(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
17-532	DIABETA	HOECHST ROUSSEL	GLYBURIDE
06-19-92	(TABLET)	SOMERVILLE, NJ	1.25MG
		08876	2.5MG 5MG (REVISED LABELING -- ADVERSE REACTIONS)
50-560	CEFIZOX	SKF	CEFTIZOXIME SODIUM
06-23-92	(INJECTABLE)	PHILADELPHIA, PA	EQ 1GM BASE/VIAL
		19101	EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

(REVISED LABELING --
CLINICAL PHARMACOLOGY;
INDICATIONS AND USAGE;
DOSAGE AND ADMINISTRATION)

07-409	BENTYL	MERRELL DOW	DICYCLOMINE HYDROCHLORIDE
06-24-92	(CAPSULE)	CINCINNATI, OH	10MG
	45215	(REVISED LABELING --	
		DESCRIPTION)	

07-409	BENTYL	MERRELL DOW	DICYCLOMINE HYDROCHLORIDE
06-24-92	(TABLET)	CINCINNATI, OH	20MG
	45215	(REVISED LABELING --	
		DESCRIPTION)	

18-538	LOZOL	RHONE POULENC RORER	INDAPAMIDE
06-24-92	(TABLET)	FORT WASHINGTON, PA	2.5MG
	19034	(REVISED LABELING --	
		ADVERSE REACTIONS)	

19-962	TOPROL XL	AB HASSLE	METOPROLOL SUCCINATE
06-24-92	(TABLET,	MOLNDAL, SWEDEN	EQ 50MG TARTRATE
	EXTENDED RELEASE)		EQ 100MG TARTRATE
			EQ 200MG TARTRATE
			(REVISED LABELING --
			WARNINGS;
			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

18-343 06-25-92	CAPOTEN (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	CAPTOPRIL 12.5MG 25MG 50MG 100MG (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
18-709 06-25-92	CAPOZIDE 25/15 (TABLET)	SQUIBB NEW BRUNSWICK, NJ 08903	CAPTOPRIL 25MG HYDROCHLOROTHIAZIDE 15MG (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
18-709 06-25-92	CAPOZIDE 25/25 (TABLET)	SQUIBB NEW BRUNSWICK, NJ 08903	CAPTOPRIL 25MG HYDROCHLOROTHIAZIDE 25MG (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
18-709 06-25-92	CAPOZIDE 50/15 (TABLET)	SQUIBB NEW BRUNSWICK, NJ	CAPTOPRIL 50MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		08903	HYDROCHLOROTHIAZIDE
			15MG
			(REVISED LABELING --
			DESCRIPTION; WARNINGS;
			PRECAUTIONS;
			ADVERSE REACTIONS)
18-709	CAPOZIDE 50/25	SQUIBB	CAPTOPRIL
06-25-92	(TABLET)	NEW BRUNSWICK, NJ	50MG
		08903	HYDROCHLOROTHIAZIDE
			25MG
			(REVISED LABELING --
			DESCRIPTION; WARNINGS;
			PRECAUTIONS;
			ADVERSE REACTIONS)
19-777	ZESTRIL	IMPERIAL CHEM	LISINOPRIL
06-25-92	(TABLET)	CHESHIRE, ENGLAND	5MG
			10MG
			20MG 40MG
			(REVISED LABELING --
			DESCRIPTION; WARNINGS;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			HOW SUPPLIED)
19-851	LOTENSIN	CIBA	BENAZEPRIL HYDROCHLORIDE
06-25-92	(TABLET)	SUMMIT, NJ	EQ 5MG BASE
		07901	EQ 10MG BASE
			EQ 20MG BASE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			EQ 40MG BASE (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-888 06-25-92	ZESTORETIC 20/12.5 (TABLET)	IMPERIAL CHEM CHESHIRE, ENGLAND	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 20MG (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-888 06-25-92	ZESTORETIC 20/25 (TABLET)	IMPERIAL CHEM CHESHIRE, ENGLAND	HYDROCHLOROTHIAZIDE 25MG LISINOPRIL 20MG (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-901 06-25-92	ALTACE (CAPSULE)	HOECHST ROUSSEL SOMERVILLE, NJ 08876	RAMIPRIL 1.25MG 2.5MG 5MG 10MG (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			
			WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-915 06-25-92	MONOPRIL (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	FOSINOPRIL SODIUM 10MG 20MG (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
50-580 06-25-92	AZACTAM (INJECTABLE)	SQUIBB NEW BRUNSWICK, NJ 08903	AZTREONAM 500MG/VIAL 1GM/VIAL 2GM/VIAL (REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)
50-632 06-25-92	AZACTAM (INJECTABLE)	SQUIBB NEW BRUNSWICK, NJ 08903	AZTREONAM 10MG/ML 20MG/ML 40MG/ML (REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)
17-029 06-26-92	HEPARIN SODIUM PRESERVATIVE FREE	LYPHOMED MELROSE PARK, IL	HEPARIN SODIUM 1,000 UNITS/ML

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
	(INJECTABLE)	60160	(REVISED LABELING -- HOW SUPPLIED)
17-029 06-26-92	HEPARIN SODIUM (INJECTABLE)	LYPHOMED MELROSE PARK, IL 60160	HEPARIN SODIUM 1,000 UNITS/ML 5,000 UNITS/ML 10,000 UNITS/ML 20,000 UNITS/ML (REVISED LABELING -- HOW SUPPLIED)
14-103 06-30-92	ONCOVIN (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	VINCRISTINE SULFATE 1MG/ML (REVISED LABELING -- WARNINGS; DOSAGE AND ADMINISTRATION)
50-514 06-30-92	NATACYN (SUSPENSION/DROPS)	ALCON FORT WORTH, TX 76115	NATAMYCIN 5% (REVISED LABELING -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1135 NONE ST JOHN CNTY PLATELETS
06-25-92 (INJECTABLE) BLOOD BANK (TRANSFUSION)
ST AUGUSTINE, FL (B)
32086

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

BIOLOGICAL PRODUCT LICENSES ISSUED

(B) Product License Issued

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910021	LIFESOURCE	LIFESOURCE ADVANCED	PLASMA/BLOOD STORAGE BAG
06-08-92	FLASH BAG	BLOOD BANK SYSTEMS ATLANTA, GA 30318	(C)
BK910013	GTI PEP ANTIBODY ENHANCEMENT SOLUTION	GENETIC TESTING INSTITUTE MILWAUKEE, WI 53237	POTENTIATING MEDIA FOR IN VITRO DIAGNOSTIC USE (C)
06-23-92			

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

P910020 06/15/92	RELAY/DASH/STRIDE/ DART PACING SYSTEM INCLUDING RELAY, DASH, AND STRIDE PULSE GENERATORS, AND THE DART PULSE GENERATOR WITH RX2000 GRAPHICS PROGRAMMER	INTERMEDICS, INC. ANGLETON, TX 77515	CARDIAC PACING
P910032 06/04/92	CUSTOM 67 (XYLOFILCON A) SOFT (HYDROPHILIC) CONTACT LENS	CUSTOM HYDROPHILICS MIAMI, FL 33173	LENS APPROVED FOR DAILY WEAR FOR CORRECTION OF VISUAL ACUITY IN NOT-APHAKIC PERSONS WITH NONDISEASED EYES THAT ARE MYOPIC OR HYPEROPIC

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

N16895/S76	SOFLENS (POLYMACON) BAUSCH & LOMB COMPACT DISINFECTING UNIT	BAUSCH & LOMB	RELOCATION OF MANUFACTURING SITE	06/26/92
	CONTACT LENS,	ROCHESTER, NY 14692-0450		
N50510/S46	VITEK SYSTEMS GENERAL SUSCEPTIBILITY CARD	VITEK SYSTEMS, INC. HAZELWOOD, MO 63042-2395	ADDITION OF OFLOXACIN (0.5 AND 2.0 MCG/ML) TO THE VITEK GRAM-NEGATIVE ANTIMICROBIAL PANELS	06/22/92
P820003/S61	VERSETRAX PACING SYSTEM, MEDTRONIC MODEL 5342 AND 5345 EXTERNAL PULSE GENERATORS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	LABELING ADDITION AND MANUFACTURING PROCESS REVISION	06/16/92
P800036/S29	INFUSAID IMPLANTABLE INFUSION PUMP - MODEL 400, CLINICIAN'S MANUAL AND REFILL KIT INSTRUCTIONS (MODEL 400)	INFUSAID, INC. NORWOOD, MA 02062	CHANGES TO THE CLINICIAN'S MANUAL AND REFILL KIT INSTRUCTIONS TO ADD ADDITIONAL CAUTIONS TO ENHANCE THE SAFE USE OF THE DEVICE	06/09/92
P820003/S63	MEDTRONIC MODEL 7000 VERSATRAX PACING SYSTEM, MEDTRONIC MODELS 5342 AND 5345	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MANUFACTURING PROCESS CHANGES	06/09/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

TEMPORARY
PULSE GENERATORS

P820056/S51 06/11/92	OPTACRYL 60 (KOLFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	MANUFACTURING AND MARKETING OF A BROWN TINT
P820063/S51 06/11/92	PARAPERM 0_2 (PASIFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	MANUFACTURING AND MARKETING OF LENS IN BROWN AND GRAY COLORS
P840050/S45 06/26/92	OCUSIL (NEFOCON A) CONTACT LENS	ALLERGAN OPTICAL IRVINE, CA 92713-9534	TWO ADDITIONAL LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P850038/S18 06/12/92	PARAPERM EW (PASIFOCON C) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	MANUFACTURING AND MARKETING OF A GRAY TINT
P850088/S27 06/26/92	LENS PLUS OXYSEPT DISINFECTION SYSTEM, ULTRACARE	ALLERGAN OPTICAL IRVINE, CA 92713-9534	REVISED LABELING TO REMIND PATIENTS TO USE A STERILE SALINE

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	DISINFECTANT/NEUT-RALIZER SYSTEM		SOLUTION TO RINSE LENSES	
P860002/S10	POSTERIOR CHAMBER INTRAOCULAR LENSES (IOL): 5.0 MM OPTICS	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	MANUFACTURE ANY PMA-APPROVED IOL DESIGN WITH SYMMETRICAL HAPTICS IN OPTIC DIAMETERS DOWN TO 5.0 MM	06/11/92
P860003/S21	UVAR PHOTOPHERESIS SYSTEM, TPS 102 PHOTOCEPTOR PHOTOACTIVATION CHAMBER	THERAKOS WEST CHESTER, PA 19380	CHANGES IN THE STERILIZATION PROCESS	06/19/92
P860003/S22	UVAR PHOTOPHERESIS SYSTEM, TPS 101 PHOTOPHERESIS BLOOD TUBING SET	THERAKOS WEST CHESTER, PA 19380	CHANGES IN THE STERILIZATION PROCESS	06/19/92
P870036/S15	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC 18K	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-1405	ADDITIONAL BALLOON DIAMETERS AND MODIFICATION TO DESIGN OF DISTAL TIP MARKER CONNECTION	06/22/92
P870045/S34	PACKAGING CHANGE	CHIRON INTRAOPTICS, INC.	MODIFIED PACKAGING	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

06/24/92	FOR POSTERIOR CHAMBER INTRAOCULAR LENSES	BOCA RATON, FL 33429	
P870048/S03 06/26/92	MICROTRAK II ANTI-HBE EIA	SORIN BIOMEDICA S.P.A. STILLWATER, MN 55082	A CHANGE TO A MICROTITER ENZYME IMMUNOASSAY FORMAT WHICH CONTAINS REAGENTS ONLY FOR THE DETECTION OF ANTI-HBE
P870048/S04 06/26/92	MICROTRAK II HBEAG EIA	SORIN BIOMEDICA S.P.A. STILLWATER, MN 55082	A CHANGE TO A MICROTITER ENZYME IMMUNOASSAY FORMAT WHICH CONTAINS REAGENTS ONLY FOR THE DETECTION OF HBEAG
P880001/S35 06/26/92	FLUOREX 700 (FLUSILFOCON A) AND FLUOREX 700, 500, AND 300 (FLUSILFOCON A, B, AND C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	G. T. LABORATORIES, INC. CHICAGO, IL 60601	FIVE ADDITIONAL LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P880003/S07 06/12/92	CORDIS PTCA DILATATION CATHETER, SLEUTH	CORDIS CORPORATION MIAMI, FL 33102-5700	MANUFACTURING MODIFICATIONS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	PTCA DILATATION CATHETER			
P890019/S03	ETI-AB-HAVK, MICROTRAK II TOTAL ANTI-HAV EIA	SORIN BIOMEDICA S.P.A. STILLWATER, MN 55082	MODIFICATION OF A MICROTITER ENZYME	06/26/92
P890032/S15	CORDIS ORION STEERABLE PTCA BALLOON CATHETER, ORION STEERABLE PTCA BALLOON CATHETER WITH GLISSADE HYDROPHILIC COATING	CORDIS CORPORATION MIAMI, FL 33102-5700	IMPLEMENTATION OF AN AUTOMATED LEAK (INFLATION/DEFLATION) TEST	06/22/92
P890040/S04	SOF-FORM 55 SPHERICAL (METHAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS	SALVATORI OPHTHALMICS SARASOTA, FL 34234	MODIFICATION OF INDICATIONS TO INCLUDE APHAKIC PERSONS AND TO EXPAND THE POWER RANGE FOR THE LENS	06/29/92
P890044/S21	BIS.45 (AMSILFOCON A) AND TRANS-AIRE (AMSILFOCON A), RIGID GAS PERMEABLE LENS FOR DAILY WEAR	BENTEC ENGINEERING, INC. SACRAMENTO, CA 95834	EIGHT ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND	06/26/92

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTALS	
	(CLEAR AND BLUE TINTED)		DISTRIBUTION SITES
P890046/S16 06/10/92	0-<PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	IDEAL OPTICS, INC. ATLANTA, GA 30339	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P890057/S02 06/22/92	3100 HIGH FREQUENCY OSCILLATORY VENTILATOR, MODEL 3100A HIGH FREQUENCY OSCILLATORY VENTILATOR	SENSORMEDICS CORPORATION YORBA LINDA, CA 92687	MANUFACTURING MODIFICATION

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

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR JUNE 1992.

ORIGINAL ABBREVIATED VETERINARY NADAs

200-046 05-15-92	NEOMYCIN SULFATE (POWDER)	CATTLE GOATS SHEEP SWINE	PFIZER NEW YORK, NY 10017	NEOMYCIN SULFATE 325GM/LB

SUPPLEMENTAL VETERINARY NADAs

95-735 05-04-92	RUMENSIN (PREMIX)	CATTLE GOATS	ELANCO ANIMAL HLTH INDIANAPOLIS, IN 46285	MONENSIN SODIUM 80GM/LB

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) 295-8428

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

*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.

Volume 15 (7)
July 1992

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

19-697 07-03-92 (3 S)	ORTHO TRI-CYCLEN (TABLET)	JOHNSON RW RARITAN, NJ 08869	ETHINYL ESTRADIOL 0.035MG NORGESTIMATE 0.18MG, 0.215MG, 0.25MG (HORMONAL CONTRACEPTIVE)
18-735 07-06-92 (SUPPL)	ISOVUE-250 (INJECTABLE)	SQUIBB PRINCETON, NJ 08543	IOPAMIDOL 51% (NEW STRENGTH)
19-710 07-09-92 (SUPPL)	OPTIRAY 240 (INJECTABLE)	MALLINCKRODT ST LOUIS, MO 63134	IOVERSOL 51% (NEW INDICATION -- CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE HEAD AND BODY AND INTRAVENOUS EXCRETORY UROGRAPHY)

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

20-119 07-14-92 (1 P, V*)	VUMON (INJECTABLE)	BRISTOL MYERS SQUIBB WALLINGFORD, CT 06492	TENIPOSIDE 10MG/ML (ANTINEOPLASTIC) [INDUCTION THERAPY IN PATIENTS WITH REFRACTORY CHILDHOOD ACUTE LYMPHOBLASTIC LEUKEMIA]
19-802 07-20-92 (5 S)	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 5,000 UNITS/100ML (ANTICOAGULANT)

V* - Designated Orphan Drug

19-802 07-20-92 (5 S)	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 5,000 UNITS/100ML (ANTICOAGULANT)
19-802 07-20-92 (5 S)	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 10,000 UNITS/100ML (ANTICOAGULANT)
19-802 07-20-92 (5 S)	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 5,000 UNITS/100ML (ANTICOAGULANT)
19-952	HEPARIN SODIUM	MCGAW	HEPARIN SODIUM

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

07-20-92	20,000 UNITS IN	IRVINE, CA	4,000 UNITS/100ML
(5 S)	5% DEXTROSE IN PLASTIC CONTAINER (INJECTABLE)	92713	(ANTICOAGULANT)
19-952	HEPARIN SODIUM	MCGAW	HEPARIN SODIUM
07-20-92	25,000 UNITS IN	IRVINE, CA	5,000 UNITS/100ML
(5 S)	5% DEXTROSE IN PLASTIC CONTAINER (INJECTABLE)	92713	(ANTICOAGULANT)
19-952	HEPARIN SODIUM	MCGAW	HEPARIN SODIUM
07-20-92	25,000 UNITS IN	IRVINE, CA	10,000 UNITS/100ML
(5 S)	5% DEXTROSE IN PLASTIC CONTAINER (INJECTABLE)	92713	(ANTICOAGULANT)
19-953	HEPARIN SODIUM	MCGAW	HEPARIN SODIUM
07-20-92	1,000 UNITS IN	IRVINE, CA	200 UNITS/100ML
(5 S)	0.9% SODIUM CHLORIDE IN PLASTIC CONTAINER (INJECTABLE)	92713	(ANTICOAGULANT)
20-250	HALFAN	SMITHKLINE BEECHAM	HALOFANTRINE HYDROCHLORIDE
07-24-92	(TABLET)	KING OF PRUSSIA, PA	250MG
(1 P, V*)		19406	(ANTIMALARIAL)
20-232	FIORICET	SANDOZ	ACETAMINOPHEN
07-30-92	WITH CODEINE	EAST HANOVER, NJ	325MG
(5 S)	(CAPSULE)	07936	BUTALBITAL 50MG CAFFEINE 40MG CODEINE PHOSPHATE 30MG

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

(ANALGESIC)

19-787	NORVASC	PFIZER	AMLODIPINE BESYLATE
07-31-92	(TABLET)	NEW YORK, NY	EQ 2.5MG BASE
(1 S)		10017	EQ 5MG BASE
			EQ 10MG BASE
			(CALCIUM ION
			INFLUX INHIBITOR)

19-982	ZEBETA	LEDERLE	BISOPROLOL FUMARATE
07-31-92	(TABLET)	PEARL RIVER, NY	5MG
(1 S)		10965	10MG
			(BETA ADRENERGIC BLOCKER)

V* - Designated Orphan Drug

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.

20-208 METROGEL CURATEK METRONIDAZOLE
07-27-92 (GEL) ELK GROVE VILLAGE, IL 0.75%
60007 (ANTIBACTERIAL)

19-287 DIAZEPAM KABI PHARMACIA DIAZEPAM
07-29-92 (INJECTABLE) CLAYTON, NC 5MG/ML
27520 (ANXIOLYTIC)

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

ORIGINAL ABBREVIATED NDAs

73-665	ATENOLOL AND	DANBURY	ATENOLOL
07-02-92	CHLORTHALIDONE	DANBURY, CT	50MG
	(TABLET)	06810	CHLORTHALIDONE
			25MG
			(BETA ADRENERGIC BLOCKER/
			DIURETIC)
73-665	ATENOLOL AND	DANBURY	ATENOLOL
07-02-92	CHLORTHALIDONE	DANBURY, CT	100MG
	(TABLET)	06810	CHLORTHALIDONE
			25MG
			(BETA ADRENERGIC BLOCKER/
			DIURETIC)
81-249	ACETAMINOPHEN AND	GENEVA	ACETAMINOPHEN
07-16-92	CODEINE PHOSPHATE	BROOMFIELD, CO	300MG
	(TABLET)	80020	CODEINE PHOSPHATE
			60MG
			(ANALGESIC)
81-250	ACETAMINOPHEN AND	GENEVA	ACETAMINOPHEN
07-16-92	CODEINE PHOSPHATE	BROOMFIELD, CO	300MG
	(TABLET)	80020	CODEINE PHOSPHATE
			30MG
			(ANALGESIC)
73-632	METAPROTERENOL SULFATE	SILARX	METAPROTERENOL SULFATE
07-22-92	(SYRUP)	SPRING VALLEY, NY	10MG/5ML
		10977	(BRONCHODILATOR)
73-524	EPITOL	LEMMON	CARBAMAZEPINE
07-29-92	(TABLET, CHEWABLE)	SELLERSVILLE, PA	100MG
		18960	(ANTICONVULSANT)

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

ORIGINAL ABBREVIATED NDAs

63-021	KANAMYCIN SULFATE	LOCH	KANAMYCIN SULFATE
07-31-92	(INJECTABLE)	BEDFORD, OH	EQ 75MG BASE/2ML
		44146	(ANTIBIOTIC, AMINOGLYCOSIDE)
63-022	KANAMYCIN SULFATE	LOCH	KANAMYCIN SULFATE
07-31-92	(INJECTABLE)	BEDFORD, OH	EQ 500MG BASE/2ML
		44146	(ANTIBIOTIC, AMINOGLYCOSIDE)
63-025	KANAMYCIN SULFATE	LOCH	KANAMYCIN SULFATE
07-31-92	(INJECTABLE)	BEDFORD, OH	EQ 1GM BASE/3ML
		44146	(ANTIBIOTIC, AMINOGLYCOSIDE)
73-168*	VERAPAMIL HCL	GENEVA	VERAPAMIL HYDROCHLORIDE
07-31-92	(TABLET)	BROOMFIELD, CO	40MG
		80020	(CALCIUM ION INFLUX INHIBITOR)
73-568*	VERAPAMIL HCL	BAKER CUMMINS	VERAPAMIL HYDROCHLORIDE
07-31-92	(TABLET, EXTENDED RELEASE)	MIAMI, FL 33178	240MG (CALCIUM ION INFLUX INHIBITOR)
73-588	TOLMETIN SODIUM	GENEVA	TOLMETIN SODIUM
07-31-92	(TABLET)	BROOMFIELD, CO	EQ 200MG BASE
		80020	(NONSTEROIDAL ANTI-INFLAMMATORY)
73-646	ATENOLOL	IPR	ATENOLOL
07-31-92	(TABLET)	CAROLINA, PR	25MG
		00628	(BETA ADRENERGIC BLOCKER)

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

ORIGINAL ABBREVIATED NDAs

73-673*	DIFLUNISAL	LEMMON	DIFLUNISAL
07-31-92	(TABLET)	SELLERSVILLE, PA	500MG
	18960	(NONSTEROIDAL	
		ANTI-INFLAMMATORY)	

73-679*	DIFLUNISAL	LEMMON	DIFLUNISAL
07-31-92	(TABLET)	SELLERSVILLE, PA	250MG
	18960	(NONSTEROIDAL	
		ANTI-INFLAMMATORY)	

* - First Time Product Available Generically

74-102	PIROXICAM	MYLAN	PIROXICAM
07-31-92	(CAPSULE)	MORGANTOWN, WV	10MG
	26505		20MG
		(NONSTEROIDAL	
		ANTI-INFLAMMATORY)	

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
TENTATIVE (DOSAGE FORM) STRENGTH(S)
APPROVAL DATE 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 Evaluations" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

THERE ARE NO ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVAL
FOR THE MONTH OF JULY 1992.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-440	M.V.C. 9+3	LYPHOMED	ASCORBIC ACID
07-01-92	(INJECTABLE)	MELROSE PARK, IL	10MG/ML
		60160	BIOTIN
			0.006MG/ML
			CYANOCOBALAMIN
			0.5μGM/ML
			DEXPANTHENOL
			1.5MG/ML
			ERGOCALCIFEROL
			20 IU/ML
			FOLIC ACID
			0.04MG/ML
			NIACINAMIDE
			4MG/ML
			PYRIDOXINE HYDROCHLORIDE
			0.4MG/ML
			RIBOFLAVIN PHOSPHATE SODIUM
			0.36MG/ML
			THIAMINE HYDROCHLORIDE
			0.3MG/ML
			VITAMIN A
			330 IU/ML
			VITAMIN E
			1 IU/ML
			(REVISED LABELING -- PRECAUTIONS)

19-129	MAXZIDE	MYLAN	HYDROCHLOROTHIAZIDE
07-01-92	(TABLET)	TAMPA, FL	50MG
		33602	TRIAMTERENE
			75MG
			(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

19-129 07-01-92	MAXZIDE-25 (TABLET)	MYLAN TAMPA, FL 33602	HYDROCHLOROTHIAZIDE 25MG TRIAMTERENE 37.5MG (REVISED LABELING -- PRECAUTIONS)
19-471 07-01-92	CARDIZEM SR (CAPSULE, EXTENDED RELEASE)	MARION MERRELL DOW KANSAS CITY, MO 64134	DILTIAZEM HYDROCHLORIDE 60MG 90MG 120MG (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; PRECAUTIONS)
17-659 07-02-92	ALUPENT (SOLUTION)	BOEHRINGER INGELHEIM RIDGEFIELD, CT 06877	METAPROTERENOL SULFATE 5% (REVISED LABELING -- HOW SUPPLIED)
09-766 07-06-92	METICORTEN (TABLET)	SCHERING KENILWORTH, NJ 07033	PREDNISONE 1MG (REVISED LABELING -- DESCRIPTION)
18-735 07-06-92	ISOVUE-200 (INJECTABLE)	SQUIBB PRINCETON, NJ 08543	IOPAMIDOL 41% (REVISED LABELING -- DESCRIPTION; ADVERSE REACTIONS; 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

			HOW SUPPLIED)
18-735	ISOVUE-300	SQUIBB	IOPAMIDOL
07-06-92	(INJECTABLE)	PRINCETON, NJ	61%
		08543	(REVISED LABELING --
			DESCRIPTION;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
18-735	ISOVUE-370	SQUIBB	IOPAMIDOL
07-06-92	(INJECTABLE)	PRINCETON, NJ	76%
		08543	(REVISED LABELING --
			DESCRIPTION;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
11-903	ZOLYSE	ALCON	CHYMOTRYPSIN
07-08-92	(POWDER	FORT WORTH, TX	750 UNITS/VIAL
	FOR RECONSTITUTION)	76134	(REVISED LABELING --
			CONTRAINDICATIONS;
			PRECAUTIONS)
19-710	OPTIRAY 160	MALLINCKRODT	IOVERSOL
07-09-92	(INJECTABLE)	ST LOUIS, MO	34%
		63134	(REVISED LABELING --
			INDICATIONS AND USAGE;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-710	OPTIRAY 240	MALLINCKRODT	IOVERSOL
07-09-92	(INJECTABLE)	ST LOUIS, MO	51%
		63134	(REVISED LABELING --
			INDICATIONS AND USAGE;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-710	OPTIRAY 320	MALLINCKRODT	IOVERSOL
07-09-92	(INJECTABLE)	ST LOUIS, MO	68%
		63134	(REVISED LABELING --
			INDICATIONS AND USAGE;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-710	OPTIRAY 350	MALLINCKRODT	IOVERSOL
07-09-92	(INJECTABLE)	ST LOUIS, MO	74%
		63134	(REVISED LABELING --
			INDICATIONS AND USAGE;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
50-461	ANCEF	SKF	CEFAZOLIN SODIUM
07-14-92	(INJECTABLE)	PHILADELPHIA, PA	EQ 500MG BASE/VIAL
		19101	EQ 1GM BASE/VIAL
			EQ 5GM BASE/VIAL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			EQ 10GM BASE/VIAL (REVISED LABELING -- HOW SUPPLIED)
17-576	OVCON-50	MEAD JOHNSON	ETHINYL ESTRADIOL
07-21-92	(TABLET)	EVANSVILLE, IN	0.05MG
	47721		NORETHINDRONE 1MG (REVISED LABELING -- WARNINGS; PATIENT PACKAGE INSERT)
17-716	OVCON-35	MEAD JOHNSON	ETHINYL ESTRADIOL
07-21-92	(TABLET)	EVANSVILLE, IN	0.035MG
	47721		NORETHINDRONE 0.4MG (REVISED LABELING -- WARNINGS; PATIENT PACKAGE INSERT)
18-087	RELEFACT TRH	FERRING	PROTIRELIN
07-21-92	(INJECTABLE)	SUFFERN, NY	0.5MG/ML
	10901		(REVISED LABELING -- PRECAUTIONS)
18-127	OVCON-35	MEAD JOHNSON	ETHINYL ESTRADIOL
07-21-92	(TABLET)	EVANSVILLE, IN	0.035MG
	47721		NORETHINDRONE 0.4MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(REVISED LABELING -- WARNINGS; PATIENT PACKAGE INSERT)
18-128	OVCON-50	MEAD JOHNSON	ETHINYL ESTRADIOL
07-21-92	(TABLET)	EVANSVILLE, IN	0.05MG
	47721		NORETHINDRONE 1MG (REVISED LABELING -- WARNINGS; PATIENT PACKAGE INSERT)
19-269	VENTOLIN	GLAXO	ALBUTEROL SULFATE
07-21-92	(SOLUTION)	RES TRIANGLE PK, NC	EQ 0.5% BASE
	27709		(REVISED LABELING -- HOW SUPPLIED)
20-036	AREDIA	CIBA GEIGY	PAMIDRONATE DISODIUM
07-21-92	(INJECTABLE)	SUMMIT, NJ	30MG/VIAL
	07901		(REVISED LABELING -- PRECAUTIONS)
50-564	AUGMENTIN '250'	BEECHAM	AMOXICILLIN
07-21-92	(TABLET)	BRISTOL, TN	250MG
	37620		CLAVULANATE POTASSIUM EQ 125MG ACID (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; ADVERSE REACTIONS)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-564	AUGMENTIN '500'	BEECHAM	AMOXICILLIN
07-21-92	(TABLET)	BRISTOL, TN	500MG
		37620	CLAVULANATE POTASSIUM
			EQ 125MG ACID
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; ADVERSE REACTIONS)
50-575	AUGMENTIN '125'	BEECHAM	AMOXICILLIN
07-21-92	(POWDER	BRISTOL, TN	125MG/5ML
	FOR RECONSTITUTION)	37620	CLAVULANATE POTASSIUM
			EQ 31.25MG ACID/5ML
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; ADVERSE REACTIONS)
50-575	AUGMENTIN '250'	BEECHAM	AMOXICILLIN
07-21-92	(POWDER	BRISTOL, TN	250MG/5ML
	FOR RECONSTITUTION)	37620	CLAVULANATE POTASSIUM
			EQ 62.5MG ACID/5ML
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; ADVERSE REACTIONS)
50-597	AUGMENTIN '125'	BEECHAM	AMOXICILLIN
07-21-92	(TABLET, CHEWABLE)	BRISTOL, TN	125MG
		37620	CLAVULANATE POTASSIUM
			EQ 31.25MG ACID
			(REVISED LABELING --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

CLINICAL PHARMACOLOGY;
INDICATIONS AND USAGE;
WARNINGS; ADVERSE REACTIONS)

50-597	AUGMENTIN '250'	BEECHAM	AMOXICILLIN
07-21-92	(TABLET, CHEWABLE)	BRISTOL, TN	250MG
	37620		CLAVULANATE POTASSIUM
			EQ 62.5MG ACID
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; ADVERSE REACTIONS)
17-661	TAVIST	DORSEY	CLEMASTINE FUMARATE
07-22-92	(TABLET)	LINCOLN, NE	2.68MG
	68501		(REVISED LABELING --
			HOW SUPPLIED)
17-661	TAVIST-1	DORSEY	CLEMASTINE FUMARATE
07-22-92	(TABLET)	LINCOLN, NE	1.34MG
	68501		(REVISED LABELING --
			HOW SUPPLIED)
18-948	CARNITOR	SIGMA TAU	LEVOCARNITINE
07-22-92	(TABLET)	GAITHERSBURG, MD	330MG
	20878		(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-948	CARNITOR	SIGMA TAU	LEVOCARNITINE
07-22-92	(SOLUTION)	GAITHERSBURG, MD	1GM/10ML
		20878	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE)
17-498	MICRONASE	UPJOHN	GLYBURIDE
07-27-92	(TABLET)	KALAMAZOO, MI	1.25MG
		49001	2.5MG
			5MG
			(REVISED LABELING -- PRECAUTIONS)
17-534	FIORINAL	SANDOZ	ASPIRIN
07-27-92	(CAPSULE)	EAST HANOVER, NJ	325MG
		07936	BUTALBITAL
			50MG
			CAFFEINE
			40MG
			(REVISED LABELING -- HOW SUPPLIED)
18-057	PLATINOL	BRISTOL MYERS	CISPLATIN
07-27-92	(INJECTABLE)	EVANSVILLE, IN	10MG/VIAL
		47721	(REVISED LABELING -- INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; OTHER TOXICITIES; 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

18-057	PLATINOL	BRISTOL MYERS	CISPLATIN
07-27-92	(INJECTABLE)	EVANSVILLE, IN	50MG/VIAL
		47721	(REVISED LABELING -- INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; OTHER TOXICITIES; DOSAGE AND ADMINISTRATION)
19-976	PHOSLO	BRAINTREE	CALCIUM ACETATE
07-27-92	(TABLET)	BRAINTREE, MA	EQ 169MG CALCIUM
		02184	(REVISED LABELING -- ADVERSE REACTIONS)
18-237	CALCIPARINE	DUPONT	HEPARIN CALCIUM
07-29-92	(INJECTABLE)	WILMINGTON, DE	25,000 UNITS/ML
		19880	(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
11-793	ESIDRIX	CIBA	HYDROCHLOROTHIAZIDE
07-30-92	(TABLET)	SUMMIT, NJ	25MG
		07901	50MG
			100MG
			(REVISED LABELING -- PRECAUTIONS)
12-665	VELBAN	LILLY	VINBLASTINE SULFATE
07-31-92	(INJECTABLE)	INDIANAPOLIS, IN	10MG/VIAL

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 --
		CLINICAL PHARMACOLOGY;
		WARNINGS; PRECAUTIONS;
		DOSAGE AND ADMINISTRATION)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1154 07-27-92	NONE (INJECTABLE)	DESERT PLASMA COLORADO SPRINGS, CO 80905	SOURCE PLASMA (TRANSFUSION) (A&B)
1155 07-27-92	NONE (INJECTABLE)	Rh ANTIBODY LABS HOLLY HILL, FL 32117	SOURCE PLASMA (TRANSFUSION) (A&B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910028 07-13-92	ASTO TUBE/ ASTO THERM 11777	NORTH AM TECH SERV PORT JEFFERSON, NY (C)	BLOOD AND PLASMA WARMING DEVICE
BK920006 07-17-92	CONTINENTAL REFRIGERATOR BLOOD BANK MODEL #C-BBRA-1S	NATL REFRIGERATION AND AIR CONDITIONING PRODS KING OF PRUSSIA, PA 19406	BLOOD STORAGE REFRIGERATORS AND FREEZERS (C)

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 JULY 1992.

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

P800022/S32	ZYPLAST COLLAGEN IMPLANT/HC 5000 PUMP	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	INCORPORATION OF HC 5000 HOMOGENIZER INTO THE MANUFACTURING PROCESS	07/07/92
P800022/S34	ZYDERM COLLAGEN IMPLANT AND ZYPLAST COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	REVISED PRODUCT LABELING	07/07/92
P840001/S25	MEDTRONIC ITREL II MODELS 7495, 7496, 7441 AND 7441NC	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MANUFACTURING MATERIAL CHANGES	07/09/92
P840024/S40	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	TRANSMITTER CABLES WITH LENGTHS UP TO 30 CM	07/07/92
P840024/S41	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	CHANGING OF TWO RESISTOR VALUES	07/07/92
P840024/S42	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATIONS	07/07/92
P840024/S43	NUCLEUS 22 CHANNEL COCHLEAR	COCHLEAR CORPORATION ENGLEWOOD, CO	MANUFACTURING MODIFICATIONS TO THE	07/07/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

IMPLANT	80112	MINI SPEECH PROCESSOR	
P840040/S30	HEART TRAK CORONARY BALLOON DILATATION CATHETER SYSTEM, THICKER BALLOON TUBING OF THE SLIDER 018 CORONARY DILATATION CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	THICKER BALLOON TUBING EXTRUSION FOR THE 2.0 MM X 20 MM BALLOON IN THE SLIDER 018 CATHETER	07/13/92
P840050/S46	OCUSIL (NEFOCON A) CONTACT LENS (CLEAR AND TINTED)	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	07/09/92
P850009/S05	CENTOCOR CA 125 RIA	CENTOCOR, INC. MALVERN, PA 19355-1307	LABELING CHANGES	07/15/92
P870015/S16	MEDSTONE STS EXTRACORPOREAL SHOCK WAVE LITHOTRIPTER	MEDSTONE INTERNATIONAL, INC. IRVINE, CA 92718	MANUFACTURING MODIFICATIONS	07/13/92
P880003/S09	HELIX PTCA	CORDIS CORPORATION	APPROVAL FOR THE 100	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

07/13/92	DILATATION CATHETERS AND HELIX PTCA DILATATION CATHETERS WITH Y-CONNECTOR	MIAMI, FL 33102-5700	PERCENT FUNCTIONAL INSPECTION OF THE BONDS AT FINAL ASSEMBLY
P890027/S11 07/07/92	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	TRANSMITTER CABLES WITH LENGTHS UP TO 30 CM
P890027/S12 07/07/92	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	CHANGE TWO RESISTOR VALUES
P890027/S13 07/07/92	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATION
P890027/S14 07/07/92	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATION

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

2 THROUGH 17 YEARS

P890046/S17 07/14/92	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	IDEAL OPTICS, INC. ATLANTA, GA 30339	ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
N17755/S40 07/27/92	ZIMMER BONE CEMENT	ZIMMER WARSAW, IN 46581-0708	REVISED LABELING
N18286/S06 07/21/92	GELFOAM STERILE SPONGE (ABSORBABLE GELATIN SPONGE, USP)	THE UPJOHN COMPANY KALAMAZOO, MI 49007	LABELING CHANGES IN THE WARNINGS AND PRECAUTIONS SECTIONS OF THE PACKAGE INSERT
P800022/S33 07/27/92	ZYPLAST COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	INCREASE THE FILL VOLUME FROM 1.5 CC TO 2.0 CC IN THE POLYPROPYLENE SYRINGE
P830066/S09 07/17/92	ABBOTT IMX CEA	ABBOTT LABORATORIES ABBOTT PARK, IL 60064-3500	APPROVAL OF THE IMX CEA KIT MANUFACTURED IN JAPAN AND INTENDED TO REPLACE THE IMX CEA KIT CURRENTLY

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

MANUFACTURED AND SOLD
IN THE UNITED STATES

P840008/S37	DORNIER LITHOTRIPTER, MODEL HM3, DORNIER MFL5000 MOBILE LITHOTRIPTER	DORNIER MEDICAL SYSTEMS,INC. KENNESAW, GA 30144	TWO NEW MANUFACTURERS OF TRUCKS/TRAILERS FOR THE MFL5000 MOBILE LITHOTRIPTER	07/29/92
P840040/S31	HEART TRAK CORONARY BALLOON DILATATION CATHETER SYSTEM, SLIDER ST CORONARY BALLOON DILATATION CATHETER WITH BALLOON SLEEVE MODIFICATION	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	MODIFICATION TO THE BALLOON SLEEVE OF THE SLIDER ST CATHETER	07/29/92
P870015/S17	MEDSTONE STS EXTRACORPOREAL SHOCK WAVE LITHOTRIPTER	MEDSTONE INTERNATIONAL, INC. IRVINE, CA 92718	MODIFICATION TO PORTION OF SOFTWARE THAT DETECTS ELECTRODE MISFIRE	07/27/92
P880001/S31	FLUOREX 700, 500, AND 300 AND	G.T. LABORATORIES CHICAGO, IL	COMBINE LABELING FOR THE SPHERICAL,	07/27/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	TANGENT STREAK BIFOCAL AND TRIFOCAL, (FLUSILFOCON A, B, AND C) RIGID GAS PERMEABLE CONTACT LENS	60601	BIFOCAL, AND TRIFOCAL VERSIONS OF THE FLUOREX 700, 500, AND 300 LENSES INTO A SINGLE PACKAGE INSERT AND WEARER'S GUIDE	
P880049/S02	EPCON SOFT (POLYMACON) HYDROPHILIC CONTACT LENS	EPCON LABORATORIES EL PASO, TX 79912	APPROVAL FOR A TORIC DESIGN CONFIGURATION OF THE LENS	07/23/92
P890032/S02	CORDIS ORION STEERABLE PTCA BALLOON CATHETER, CORDIS SOFT-WIRE ORION STEERABLE PTCA BALLOON CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	SOFT WIRE ORION STEERABLE PTCA BALLOON CATHETER FOR 2.0, 2.5 AND 3.0 MM BALLOON SIZES AND CHANGES TO THE MANUFACTURING PROCESS FOR THESE CATHETERS	07/23/92
P890072/S05	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	SEVEN ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	07/22/92

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

ORIGINAL VETERINARY NADAs

140-853 05-22-92	MONTEBAN-BMD (PREMIX)	BROILER CHICKENS	AL LABS FORT LEE, NJ 07024	NARASIN 36-92GM/LB BMD 25-75GM/LB

ORIGINAL ABBREVIATED VETERINARY NADAs

200-031 06-17-92	SULFADIMETHOXINE (POWDER)	BEEF CATTLE CHICKENS DAIRY CALVES DAIRY HEIFERS TURKEYS	AGRI LABS ST JOSEPH, MO 64503	SULFADIMETHOXINE 3.34OZ (94.6GM) OF SULFADIMETHOXINE AS SODIUM SALT AND DISODIUM EDETATE

SUPPLEMENTAL VETERINARY NADAs

65-010 07-16-92	PROCAINE PENICILLIN G (SUSPENSION)	CATTLE HORSES SHEEP SWINE	NORBROOK LABS NEWRY BT35 6JP NORTHERN IRELAND	PENICILLIN G PROCAINE 300,000 UNITS/ML

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

Volume 15 (8)
August 1992

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

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

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

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

*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

50-674	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
08-07-92	(TABLET)	KALAMAZOO, MI	EQ 100MG BASE
(1 S)		49001	EQ 200MG BASE
			(ANTIBIOTIC, CEPHEM)
50-675	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
08-07-92	(GRANULE,	KALAMAZOO, MI	EQ 50MG BASE/5ML
(3 S)	FOR RECONSTITUTION)	49001	EQ 100MG BASE/5ML
			(ANTIBIOTIC, CEPHEM)
50-687	BANAN	SANKYO	CEFPODOXIME PROXETIL
08-07-92	(TABLET)	NEW YORK, NY	EQ 100MG BASE
(3 S)		10017	EQ 200MG BASE
			(ANTIBIOTIC, CEPHEM)
50-688	BANAN	SANKYO	CEFPODOXIME PROXETIL
08-07-92	(GRANULE,	NEW YORK, NY	EQ 50MG BASE/5ML

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)	FOR RECONSTITUTION)	10017	EQ 100MG BASE/5ML
			(ANTIBIOTIC, CEPHEM)
20-062	CARDIZEM CD	MARION MERRELL DOW	DILTIAZEM HYDROCHLORIDE
08-10-92	(CAPSULE,	KANSAS CITY, MO	120MG
(SUPPL)	EXTENDED RELEASE)	64134	(NEW STRENGTH)
50-680	CLEOCIN	UPJOHN	CLINDAMYCIN PHOSPHATE
08-11-92	(CREAM)	KALAMAZOO, MI	EQ 2% BASE
(3 S)		49001	(ANTIBIOTIC, LINCOMYCIN)
19-826	THEOPHYLLINE 0.04%	MCGAW	THEOPHYLLINE
08-14-92	AND DEXTROSE 5%	IRVINE, CA	40MG/100ML
(5 S)	IN PLASTIC CONTAINER	92713	(BRONCHODILATOR)
	(INJECTABLE)		
19-826	THEOPHYLLINE 0.08%	MCGAW	THEOPHYLLINE
08-14-92	AND DEXTROSE 5%	IRVINE, CA	80MG/100ML
(5 S)	IN PLASTIC CONTAINER	92713	(BRONCHODILATOR)
	(INJECTABLE)		
19-826	THEOPHYLLINE 0.16%	MCGAW	THEOPHYLLINE
08-14-92	AND DEXTROSE 5%	IRVINE, CA	160MG/100ML
(5 S)	IN PLASTIC CONTAINER	92713	(BRONCHODILATOR)
	(INJECTABLE)		
19-826	THEOPHYLLINE 0.2%	MCGAW	THEOPHYLLINE
08-14-92	AND DEXTROSE 5%	IRVINE, CA	200MG/100ML
(5 S)	IN PLASTIC CONTAINER	92713	(BRONCHODILATOR)
	(INJECTABLE)		
19-826	THEOPHYLLINE 0.32%	MCGAW	THEOPHYLLINE
08-14-92	AND DEXTROSE 5%	IRVINE, CA	320MG/100ML
(5 S)	IN PLASTIC CONTAINER	92713	(BRONCHODILATOR)

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

	(INJECTABLE)		
19-826	THEOPHYLLINE 0.4%	MCGAW	THEOPHYLLINE
08-14-92	AND DEXTROSE 5%	IRVINE, CA	400MG/100ML
(5 S)	IN PLASTIC CONTAINER	92713	(BRONCHODILATOR)
	(INJECTABLE)		
20-208	METROGEL	CURATEK	METRONIDAZOLE
08-17-92	(GEL)	ELK GROVE VILLAGE, IL	0.75%
(3 S)		60007	(ANTIBACTERIAL)
20-171	DELFLEX W/	FRESENIUS	CALCIUM CHLORIDE
08-19-92	DEXTROSE 1.5%	CONCORD, CA	18.4MG/100ML
(5 S)	LOW MAGNESIUM	94520	DEXTROSE
	LOW CALCIUM		1.5GM/100ML
	(SOLUTION)		MAGNESIUM CHLORIDE
			5.08MG/100ML
			SODIUM CHLORIDE
			538MG/100ML
			SODIUM LACTATE
			448MG/100ML (PERITONEAL DIALYSATE)
20-171	DELFLEX W/	FRESENIUS	CALCIUM CHLORIDE
08-19-92	DEXTROSE 2.5%	CONCORD, CA	18.4MG/100ML
(5 S)	LOW MAGNESIUM	94520	DEXTROSE
	LOW CALCIUM		2.5GM/100ML
	(SOLUTION)		MAGNESIUM CHLORIDE
			5.08MG/100ML
			SODIUM CHLORIDE
			538MG/100ML
			SODIUM LACTATE
			448MG/100ML (PERITONEAL DIALYSATE)

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

20-171 08-19-92 (5 S)	DELFLEX W/ DEXTROSE 4.25% LOW MAGNESIUM LOW CALCIUM (SOLUTION)	FRESENIUS CONCORD, CA 94520	CALCIUM CHLORIDE 18.4MG/100ML DEXTROSE 4.25GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (PERITONEAL DIALYSATE)
17-661 08-21-92 (SUPPL)	TAVIST-1 (TABLET)	SANDOZ EAST HANOVER, NJ 07936	CLEMASTINE FUMARATE 1.34MG [RX TO OTC SWITCH] (OTC)
18-298 08-21-92 (SUPPL)	TAVIST D (TABLET, EXTENDED RELEASE)	SANDOZ EAST HANOVER, NJ 07936	CLEMASTINE FUMARATE 1.34MG PHENYLPROPANOLAMINE HYDROCHLORIDE 75MG [RX TO OTC SWITCH] (OTC)

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

APPROVABLE ORIGINAL NDAs

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

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

19-994 INHIBACE ROCHE CILAZAPRIL
08-13-92 (CAPSULE) NUTLEY, NJ 1.0MG
07110 2.5MG
5.0MG
(ANGIOTENSIN CONVERTING
ENZYME INHIBITOR)
[HYPERTENSION]

19-604 VOLMAX GLAXO ALBUTEROL SULFATE
08-26-92 (TABLET, RES TRIANGLE PK, NC EQ 4MG BASE
EXTENDED RELEASE) 27709 EQ 8MG BASE
(BRONCHODILATOR)

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

ORIGINAL ABBREVIATED NDAs

73-611 DIPHENHYDRAMINE HCL CUMBERLAND SWAN DIPHENHYDRAMINE HYDROCHLORIDE
08-20-92 (SYRUP) SMYRNA, TN 12.5MG/5ML
37167 (ANTIHISTAMINE)
(OTC)

72-029 LACTULOSE PACO LACTULOSE
08-25-92 (SYRUP) LAKEWOOD, NJ 10GM/15ML
08701 (LAXATIVE/AMMONIA DETOXICANT)

73-160 LACTULOSE PACO LACTULOSE
08-25-92 (SYRUP) LAKEWOOD, NJ 10GM/15ML
08701 (LAXATIVE/AMMONIA DETOXICANT)

73-178 VALPROIC ACID COPLEY VALPROIC ACID
08-25-92 (SYRUP) CANTON, MA 250MG/5ML
02021 (ANTICONVULSANT)

72-688 AMOXAPINE DANBURY AMOXAPINE
08-28-92 (TABLET) DANBURY, CT 25MG
06813 (ANTIDEPRESSANT)

72-689 AMOXAPINE DANBURY AMOXAPINE
08-28-92 (TABLET) DANBURY, CT 50MG
06813 (ANTIDEPRESSANT)

72-690 AMOXAPINE DANBURY AMOXAPINE
08-28-92 (TABLET) DANBURY, CT 100MG
06813 (ANTIDEPRESSANT)

72-691 AMOXAPINE DANBURY AMOXAPINE
08-28-92 (TABLET) DANBURY, CT 150MG
06813 (ANTIDEPRESSANT)

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

ORIGINAL ABBREVIATED NDAs

72-993	LOPERAMIDE HCL	GENEVA	LOPERAMIDE HYDROCHLORIDE
08-28-92	(CAPSULE)	BROOMFIELD, CO	2MG
	80020	(ANTIDIARRHEAL)	

73-589*	CARBIDOPA	LEMMON	CARBIDOPA
08-28-92	AND LEVODOPA	SELLERSVILLE, PA	25MG
	(TABLET)	18960	LEVODOPA
			100MG
			(ANTIPARKINSON)

73-607*	CARBIDOPA	LEMMON	CARBIDOPA
08-28-92	AND LEVODOPA	SELLERSVILLE, PA	25MG
	(TABLET)	18960	LEVODOPA
			250MG
			(ANTIPARKINSON)

73-618*	CARBIDOPA	LEMMON	CARBIDOPA
08-28-92	AND LEVODOPA	SELLERSVILLE, PA	10MG
	(TABLET)	18960	LEVODOPA
			100MG
			(ANTIPARKINSON)

74-103	PIROXICAM	COPLEY	PIROXICAM
08-28-92	(CAPSULE)	CANTON, MA	10MG
	02021		20MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)

81-051*	HYDROCODONE BITARTRATE	MIKART	ACETAMINOPHEN

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAs			
08-28-92	AND ACETAMINOPHEN (ELIXIR)	ATLANTA, GA 30318	500MG/15ML HYDROCODONE BITARTRATE 7.5MG/15ML (ANALGESIC)
73-314* 08-31-92	INDOMETHEGAN (SUPPOSITORY)	G AND W SOUTH PLAINFIELD, NJ 07080	INDOMETHACIN 50MG (NONSTEROIDAL ANTI-INFLAMMATORY)

* First Time Product Available Generically

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
TENTATIVE APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(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 Evaluations" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

74-019	PINDOLOL	MYLAN	PINDOLOL
08-25-92	(TABLET)	MORGANTOWN, WV 26505	5MG 10MG
			(BETA ADRENERGIC BLOCKER)

74-093	DILTIAZEM HCL	LEDERLE	DILTIAZEM HYDROCHLORIDE
08-25-92	(TABLET)	PEARL RIVER, NY 10965	30MG 60MG 90MG 120MG
			(CALCIUM ION INFLUX INHIBITOR)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

12-649	PERIACTIN	MSD	CYPROHEPTADINE HYDROCHLORIDE
08-05-92	(TABLET)	WEST POINT, PA 19486	4MG (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
13-220	PERIACTIN	MSD	CYPROHEPTADINE HYDROCHLORIDE
08-05-92	(SYRUP)	WEST POINT, PA 19486	2MG/5ML (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
18-240	TENORMIN	ICI	ATENOLOL
08-05-92	(TABLET)	WILMINGTON, DE 19897	25MG 50MG 100MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
18-760	TENORETIC 50	ICI	ATENOLOL
08-05-92	(TABLET)	WILMINGTON, DE 19897	50MG CHLORTHALIDONE 25MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
18-760	TENORETIC 100	ICI	ATENOLOL
08-05-92	(TABLET)	WILMINGTON, DE 19897	100MG CHLORTHALIDONE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			25MG
			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS;
			HOW SUPPLIED)
19-058	TENORMIN	ICI	ATENOLOL
08-05-92	(INJECTABLE)	WILMINGTON, DE	0.5MG/ML
	19897		(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS;
			HOW SUPPLIED)
17-532	DIABETA	HOECHST ROUSSEL	GLYBURIDE
08-06-92	(TABLET)	SOMERVILLE, NJ	1.25MG
	08876		2.5MG
			5MG
			(REVISED LABELING --
			PRECAUTIONS)
50-477	NEBCIN	LILLY	TOBRAMYCIN SULFATE
08-06-92	(INJECTABLE)	INDIANAPOLIS, IN	EQ 10MG BASE/ML
	46285		(REVISED LABELING --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			HOW SUPPLIED)
50-519	NEBCIN	LILLY	TOBRAMYCIN SULFATE
08-06-92	(INJECTABLE)	INDIANAPOLIS, IN	EQ 1.2GM BASE/VIAL
	46285		(REVISED LABELING --
			DESCRIPTION;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			CLINICAL PHARMACOLOGY;
			HOW SUPPLIED)
07-517	TAPAZOLE	LILLY	METHIMAZOLE
08-07-92	(TABLET)	INDIANAPOLIS, IN	5MG
		46285	10MG
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			WARNINGS; PRECAUTIONS)
19-758	CLOZARIL	SANDOZ	CLOZAPINE
08-10-92	(TABLET)	EAST HANOVER, NJ	25MG
		07936	100MG
			(REVISED LABELING --
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			OVERDOSAGE;
			DOSAGE AND ADMINISTRATION)
20-062	CARDIZEM CD	MARION MERRELL DOW	DILTIAZEM HYDROCHLORIDE
08-10-92	(CAPSULE,	KANSAS CITY, MO	120MG
	EXTENDED RELEASE)	64134	180MG
			240MG
			300MG
			(REVISED LABELING --
			HOW SUPPLIED)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-010	ILOSONE	LILLY	ERYTHROMYCIN ESTOLATE
08-10-92	(LIQUID)	INDIANAPOLIS, IN	EQ 125MG/5ML BASE
	46285		EQ 250MG/5ML BASE
		(REVISED LABELING -- PRECAUTIONS)	
50-365	ILOSONE	DISTA	ERYTHROMYCIN ESTOLATE
08-10-92	(CAPSULE)	INDIANAPOLIS, IN	EQ 250MG BASE
	46206	(REVISED LABELING -- PRECAUTIONS)	
50-370	ILOTYCIN GLUCEPTATE	DISTA	ERYTHROMYCIN GLUCEPTATE
08-10-92	(INJECTABLE)	INDIANAPOLIS, IN	EQ 1GM BASE/VIAL
	46206	(REVISED LABELING -- PRECAUTIONS)	
50-426	ILOSONE	DISTA	ERYTHROMYCIN ESTOLATE
08-10-92	(TABLET)	INDIANAPOLIS, IN	EQ 500MG BASE
	46206	(REVISED LABELING -- PRECAUTIONS)	
16-640	QUESTRAN	BRISTOL MYERS	CHOLESTYRAMINE
08-11-92	(POWDER)	EVANSVILLE, IN	EQ 4GM RESIN/PACKET
	47721		EQ 4GM RESIN/SCOOPFUL
		(REVISED LABELING -- DOSAGE AND ADMINISTRATION)	
18-067	CINOBAC	LILLY	CINOXACIN
08-11-92	(CAPSULE)	INDIANAPOLIS, IN	250MG
	46285		500MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-669	QUESTRAN LIGHT	BRISTOL MYERS	CHOLESTYRAMINE
08-11-92	(POWDER)	EVANSVILLE, IN	EQ 4GM RESIN/PACKET
	47721		EQ 4GM RESIN/SCOOPFUL
			(REVISED LABELING -- DOSAGE AND ADMINISTRATION)
16-680	EUTHROID-0.5	PARKE DAVIS	LIOTRIX (T4;T3)
08-12-92	(TABLET)	MORRIS PLAINS, NJ	0.03MG;0.0075MG
	07950		(REVISED LABELING -- HOW SUPPLIED)
16-680	EUTHROID-1	PARKE DAVIS	LIOTRIX (T4;T3)
08-12-92	(TABLET)	MORRIS PLAINS, NJ	0.06MG;0.015MG
	07950		(REVISED LABELING -- HOW SUPPLIED)
16-680	EUTHROID-2	PARKE DAVIS	LIOTRIX (T4;T3)
08-12-92	(TABLET)	MORRIS PLAINS, NJ	0.12MG;0.03MG
	07950		(REVISED LABELING -- HOW SUPPLIED)
16-680	EUTHROID-3	PARKE DAVIS	LIOTRIX (T4;T3)
08-12-92	(TABLET)	MORRIS PLAINS, NJ	0.18MG;0.045MG
	07950		(REVISED LABELING -- HOW SUPPLIED)
50-655	NALLPEN	BAXTER	NAFCILLIN SODIUM
08-12-92	(INJECTABLE)	ROUND LAKE, IL	EQ 20MG BASE/ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		60073	EQ 40MG BASE/ML
			(REVISED LABELING -- DESCRIPTION; WARNINGS;
			DIRECTIONS FOR USE;
			HOW SUPPLIED)
17-605	XYLO-PFAN	ADRIA	XYLOSE
08-17-92	(POWDER)	COLUMBUS, OH	25GM/BOTTLE
		43216	(REVISED LABELING --
			CONTRAINDICATIONS;
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)
17-031	OVRETTE	WYETH AYERST	NORGESTREL
08-19-92	(TABLET)	PHILADELPHIA, PA	0.075MG
		19101	(REVISED LABELING --
			INDICATIONS AND USAGE;
			CONTRAINDICATIONS;
			PRECAUTIONS; WARNINGS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			OTHER HEALTH BENEFITS;
			PATIENT PACKAGE INSERT)
18-285	VISKEN	SANDOZ	PINDOLOL
08-19-92	(TABLET)	EAST HANOVER, NJ	5MG
		07936	10MG
			(REVISED LABELING --
			DESCRIPTION; WARNINGS;
			PRECAUTIONS;
			CLINICAL LABORATORY)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-872	VISKAZIDE	SANDOZ	HYDROCHLOROTHIAZIDE
08-19-92	(TABLET)	EAST HANOVER, NJ	25MG
	07936		PINDOLOL
			5MG
			(REVISED LABELING --
			DESCRIPTION; WARNINGS;
			PRECAUTIONS;
			CLINICAL LABORATORY)

18-872	VISKAZIDE	SANDOZ	HYDROCHLOROTHIAZIDE
08-19-92	(TABLET)	EAST HANOVER, NJ	25MG
	07936		PINDOLOL
			10MG
			(REVISED LABELING --
			DESCRIPTION; WARNINGS;
			PRECAUTIONS;
			CLINICAL LABORATORY)

06-146	BENADRYL	PARKE DAVIS	DIPHENHYDRAMINE HYDROCHLORIDE
08-20-92	(INJECTABLE)	MORRIS PLAINS, NJ	10MG/ML
	07950		50MG/ML
			(REVISED LABELING --
			CONTRAINDICATIONS)

09-218	COUMADIN	DUPONT	WARFARIN SODIUM
08-20-92	(TABLET)	WILMINGTON, DE	1MG
	19880		2MG
			2.5MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			5MG
			7.5MG
			10MG
			(REVISED LABELING --
			CONTRAINDICATIONS)
09-486	BENADRYL	PARKE DAVIS	DIPHENHYDRAMINE HYDROCHLORIDE
08-20-92	(INJECTABLE)	MORRIS PLAINS, NJ	50MG/ML
	07950		(REVISED LABELING --
			CONTRAINDICATIONS)
18-936	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
08-20-92	(CAPSULE)	INDIANAPOLIS, IN	EQ 20MG BASE
	46285		(REVISED LABELING --
			ADVERSE REACTIONS)
19-758	CLOZARIL	SANDOZ	CLOZAPINE
08-20-92	(TABLET)	EAST HANOVER, NJ	25MG
	07936		100MG
			(HOW SUPPLIED)
20-101	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
08-20-92	(SOLUTION)	INDIANAPOLIS, IN	EQ 20MG BASE/5ML
	46285		(REVISED LABELING --
			ADVERSE REACTIONS)
20-180	PROSCAR	MSD	FINASTERIDE
08-20-92	(TABLET)	WEST POINT, PA	5MG
	19486		(REVISED LABELING --
			PATIENT PACKAGE INSERT)
18-452	SEPTRA	BURROUGHS WELLCOME	SULFAMETHOXAZOLE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

08-21-92	(INJECTABLE)	RES TRIANGLE PK, NC	80MG/ML
		27709	TRIMETHOPRIM
			16MG/ML
			(REVISED LABELING --
			WARNINGS)
19-243	PROVENTIL	SCHERING	ALBUTEROL SULFATE
08-26-92	(SOLUTION)	KENILWORTH, NJ	EQ 0.083% BASE
		07033	EQ 0.5% BASE
			(REVISED LABELING --
			HOW SUPPLIED)
50-405	KEFLEX	LILLY	CEPHALEXIN
08-27-92	(CAPSULE)	INDIANAPOLIS, IN	EQ 250MG BASE
		46285	EQ 500MG BASE
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE)
50-406	KEFLEX	LILLY	CEPHALEXIN
08-27-92	(POWDER	INDIANAPOLIS, IN	EQ 100MG BASE/ML
	FOR RECONSTITUTION)	46285	EQ 125MG BASE/5ML
			EQ 250MG BASE/5ML
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE)
19-621	VENTOLIN	GLAXO	ALBUTEROL SULFATE
08-28-92	(SYRUP)	RES TRIANGLE PK, NC	EQ 2MG BASE/5ML
		27709	(REVISED LABELING --
			OVERDOSAGE)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

244 08-18-92	NONE (INJECTABLE)	CTL TEXAS REG BLOOD CTR AUSTIN, TX 78756 (B)	PLASMA (TRANSFUSION)
258 08-18-92	NONE (INJECTABLE)	CTL TEXAS REG BLOOD CTR AUSTIN, TX 78756 (B)	CRYOPRECIPITATED AHF
711 08-19-92	TRIPEDIA (INJECTABLE)	OESTERREICHISCHES INSTITUT FUER HAEMODERIVATE G.m.b.H. VIENNA, AUSTRIA	FACTOR IX COMPLEX (B)
149 08-20-92	MONONINE (INJECTABLE)	ARMOUR PHARM COLLEGEVILLE, PA 80905 (B)	COAGULATION FACTOR IX (HUMAN)
1156 08-20-92	NONE (INJECTABLE)	RES FOUNDATION FOR MICROBIAL DISEASES OF OSAKA UNIV SUITA, OSAKA, JAPAN (A&B)	ACELLULAR PERTUSSIS VACCINE CONCENTRATE (FOR FURTHER MANUFACTURING USE)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

THERE ARE NO BIOLOGICAL PRODUCT DEVICE APPROVALS FOR AUGUST 1992.

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 AUGUST 1992.

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

P790018/S17 08/25/92	MEDTRONIC HALL PROSTHETIC HEART VALVE	MEDTRONIC HEART VALVES MINNEAPOLIS, MN 55440	DISCONTINUATION OF ANNUAL REPORT OF BLOOD AND REGURGITATION DATA ON THE MONTREAL COHORT AND 5 YEAR BLOOD DATA FROM ENTIRE COHORT
P800022/S37 08/18/92	ZYPLAST COLLAGEN IMPLANT AND ZYDERM COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	CHANGE IN MANUFACTURING PROCESS
P820065/S79 08/06/92	THE BOSTON LENS II (ITAFOCON A) AND THE BOSTON LENS IV (ITAFOCON B) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ADDITIONAL MANUFACTURING AND DISTRIBUTION SITE
P830034/S22 08/06/92	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	MODIFIED LABELING
P840008/S41	DORNIER	DORNIER MEDICAL SYSTEMS, INC.	REVISED WORDING OF

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	LITHOTRIPTER, MODEL HM3, DORNIER ELECTRODE S2000/18	KENNESSAW, GA 30144	THE PRECAUTION STATEMENT	08/06/92
P850023/S13	HEMOPAD FIBRILLAR ABSORBABLE COLLAGEN HEMOSTAT, AVITENE LFCH (LONG FIBER COLLAGEN HEMOSTAT)	BIOPLEX CORPORATION MONTVALE, NJ 07645	REVISED LABELING	08/26/92
P850079/S20	HYDRASOFT, HYDRASOFT XW, HYDRASOFT XW EZC, HYDRASOFT TORIC XW AND HYDRASOFT TORIC XW EZC SOFT (HYDROPHILIC) CONTACT LENSES	COASTVISION, INC. HUNTINGTON BEACH, CA 92648	APPROVAL FOR DAILY WEAR INDICATIONS FOR EXTENDED WEAR CONFIGURATIONS OF THE LENSES	08/06/92
P860002/S09	POSTERIOR CHAMBER INTRAOCULAR LENSES: LABELING CHANGES	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	REVISED LABELING	08/06/92
P860004/S11	SYNCHROMED INFUSION SYSTEM FOR ADMINISTRATION OF INTRATHECAL BACLOFEN (LIORESAL)	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN 55440-9087	INTRATHECAL ADMINISTRATION OF THE ANTISPASTICITY DRUG BACLOFEN (LIORESAL) USING THE SYNCHROMED INFUSION SYSTEM	08/12/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P860008/S11	ARZCO ARZCO TRANSESOPHAGEAL CARDIAC STIMULATOR, ARZCO TAPSCOPE	ARZCO MEDICAL SYSTEMS, INC. VERNON HILLS, IL 60061	ARZCO ESOPHAGEAL CARDIAC RECORDING AND PACING STETHOSCOPE WITH THERMISTOR	08/06/92
P860019/S56	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, SC SHADOW	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	NEW MODEL CATHETER	08/18/92
P860022/S41	BOSTON EQUALENS (ITAFLUOROFOCON A) CONTACT LENS, THE BOSTON RXD (ITABISFLUOROFOCON A) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ADDITIONAL CONTACT LENS FINISHING LABORATORY	08/06/92
P870015/S13	MEDSTONE STS EXTRACORPOREAL SHOCKWAVE LITHOTRIPTER	MEDSTONE INTERNATIONAL, INC. IRVINE, CA 92718	NEW LOCALIZATION METHOD USING THE INTENSIFIED RADIOGRAPHIC IMAGING SYSTEM (IRIS)	08/13/92
P870018/S06	SIEMENS LITHOSTAR LITHOTRIPTER FOR URINARY TRACT STONES	SIEMENS MEDICAL SYSTEMS, INC. ISELIN, NJ 08830	MANUFACTURING MODIFICATIONS	08/11/92
P870036/S16	VERSAFLEX	MEDTRONIC INTERVENTIONAL	ALTERNATE PACKAGING	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM	SAN DIEGO, CA 92121-2256	CONFIGURATION	08/03/92
P880086/S20	SYNCHRONY MODEL 2020T PULSE GENERATOR AND APS II MODEL 3000 PROGRAMMER, MODEL 3038 FUNCTION PACK	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	SOFTWARE MODIFICATIONS	08/11/92
P880098/S05	MENICON SF-P (MELAFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	MENICON CORPORATION NAKA-KU, JAPAN	REVISED LABELING	08/25/92
P890003/S17	SYNERGYST PACING SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	REVISED LABELING	08/18/92
P890039/S09	MAESTRO SAVVI MODEL 305 PACING SYSTEM/A-TRACK LEADS	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	MANUFACTURING MODIFICATIONS	08/03/92

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

ORIGINAL VETERINARY NADAs

140-818 07-24-92	PRODUCIL (PREMIX)	SWINE	MERCK RES LABS RANWAY, NJ 07065	EFROTOMYCIN 32GM/KG
140-954 08-05-92	SAFE-GUARD TYPE A MEDICATED ARTICLE/LINCOMIX TYPE A MEDICATED ARTICLE (PREMIX)	SWINE	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	FENBENDAZOLE 4% AND 8% LINCOMYCIN 20GM/LB AND 50GM/LB

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR AUGUST 1992.

SUPPLEMENTAL VETERINARY NADAs

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

ORIGINAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR AUGUST 1992.

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

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

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

Volume 15 (9)
September 1992

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

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

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

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

*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

19-912 09-03-92 (5 S)	BRONCHO SALINE (AEROSOL, METERED) 47716	BLAIREX EVANSVILLE, IN (DILUENT) (OTC)	SODIUM CHLORIDE 0.9%
19-978 09-03-92 (5 S)	BUPIVACAINE HCL KIT (INJECTABLE) 60064 0.23% (ANESTHETIC, LOCAL)	ABBOTT ABBOTT PARK, IL 0.114%	BUPIVACAINE HYDROCHLORIDE 0.075%
19-940 09-04-92 (1 S)	ACTINEX (CREAM) 07024	CHEMEX FORT LEE, NJ (DERMATOLOGIC)	MASOPROCOL 10%

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

			[TREATMENT OF ACTINIC KERATOSES]
84-499*	ESTRACE	MEAD JOHNSON	ESTRADIOL
09-08-92	(TABLET)	EVANSVILLE, IN	1MG
(SUPPL)		47721	(NEW INDICATION -- PREVENTION OF OSTEOPOROSIS)
84-500*	ESTRACE	MEAD JOHNSON	ESTRADIOL
09-08-92	(TABLET)	EVANSVILLE, IN	2MG
(SUPPL)		47721	(NEW INDICATION -- PREVENTION OF OSTEOPOROSIS)

* - Abbreviated NDA Supplement

19-785	CARDIOLITE	DUPONT MERCK	TECHNETIUM TC-99M
09-09-92	(INJECTABLE)	N BILLERICA, MA	SESTAMIBI KIT
(SUPPL)		01862	N/A (NEW INDICATION -- DIAGNOSIS AND LOCALIZATION OF ISCHEMIA AND CORONARY HEART DISEASE)
20-083	SPORANOX	JANSSEN	ITRACONAZOLE
09-11-92	(CAPSULE)	PISCATAWAY, NJ	100MG
(1 P, E**)		08855	(ANTIFUNGAL)
20-118	SUPRANE	ANAQUEST	DESFLURANE
09-18-92	(INHALATION)	LIBERTY CORNER, NJ	99.9%
(1 S)		07938	(ANESTHETIC, GENERAL)
20-154	VIDEX	BRISTOL MYERS SQUIBB	DIDANOSINE

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

09-25-92	(TABLET, CHEWABLE)	WALLINGFORD, CT	25MG
(SUPPL)		06492	50MG
			100MG
			150MG
			(NEW DOSAGE REGIMEN --
			LOWER RECOMMENDED
			STARTING DOSE GUIDELINES)

20-155	VIDEX	BRISTOL MYERS SQUIBB	DIDANOSINE
09-25-92	(POWDER	WALLINGFORD, CT	100MG/PACKET
(SUPPL)	FOR RECONSTITUTION)	06492	167MG/PACKET
			250MG/PACKET
			375MG/PACKET
			(NEW DOSAGE REGIMEN --
			LOWER RECOMMENDED
			STARTING DOSE GUIDELINES)

20-156	VIDEX	BRISTOL MYERS SQUIBB	DIDANOSINE
09-25-92	(POWDER	WALLINGFORD, CT	10MG/ML
(SUPPL)	FOR RECONSTITUTION)	06492	(NEW DOSAGE REGIMEN --
			LOWER RECOMMENDED
			STARTING DOSE GUIDELINES)

E** - Drug for Severely Debilitating/Life Threatening Illness

50-589	CEFIZOX	SKF	CEFTIZOXIME SODIUM
09-25-92	IN DEXTROSE 5%	PHILADELPHIA, PA	EQ 20MG BASE/ML
(SUPPL)	IN PLASTIC CONTAINER	19101	EQ 40MG BASE/ML
	(INJECTABLE)		(NEW INDICATION --
			PELVIC INFLAMMATORY DISEASE
			CAUSED BY NEISSERIA
			GONORRHOEAE, ESCHERICHIA
			COLI, OR STREPTOCOCCUS
			AGALACTIAE)

18-713	MYCELEX	MILES	CLOTRIMAZOLE
09-29-92	(TROCHE/LOZENGE)	WEST HAVEN, CT	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

(SUPPL) 06518 (NEW INDICATION -- PROPHYLAXIS IN DESIGNATED IMMUNOCOMPROMISED CONDITIONS TO REDUCE THE INCIDENCE OF OROPHARYNGEAL CANDIDIASIS)

50-529 PEDIAZOLE ROSS ERYTHROMYCIN ETHYLSUCCINATE
09-29-92 (GRANULE) COLUMBUS, OH EQ 200MG BASE/5ML
(SUPPL) 43215 SULFISOXAZOLE ACETYL EQ 600MG BASE/5ML (NEW DOSAGE REGIMEN -- TID OR QID DOSING)

50-637 ZEFAZONE UPJOHN CEFMETAZOLE SODIUM
09-29-92 (INJECTABLE) KALAMAZOO, MI EQ 1GM BASE/VIAL
(SUPPL) 49001 EQ 2GM BASE/VIAL (NEW INDICATION -- UNCOMPLICATED GONORRHEA)

18-828 OXISTAT GLAXO OXICONAZOLE NITRATE
09-30-92 (CREAM) RES TRIANGLE PK, NC EQ 1% BASE
(SUPPL) 27709 (NEW INDICATION -- DERMAL INFECTIONS-TINEA PEDIS, TINEA CRURIS, TINEA CORPORIS DUE TO EPIDERMOPHYTON FLOCCOSUM)

20-209 OXISTAT GLAXO OXICONAZOLE NITRATE
09-30-92 (LOTION) RES TRIANGLE PK, NC EQ 1% BASE
(3 S) 27709 (ANTIFUNGAL)

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

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

APPROVABLE ORIGINAL NDAs

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.

20-014 MAXAIR 3M PIRBUTEROL ACETATE
09-15-92 (AEROSOL, METERED) ST PAUL, MN EQ 0.2MG BASE/INH
55144 (BRONCHODILATOR)

20-049 PENTASA MARION MERRELL DOW MESALAMINE
09-25-92 (CAPSULE, KANSAS CITY, MO 250MG
EXTENDED RELEASE) 64114 (GASTROINTESTINAL
ANTI-INFLAMMATORY)

20-192 LAMISIL SANDOZ TERBINAFINE HYDROCHLORIDE
09-30-92 (CREAM) EAST HANOVER, NJ 1%
07936 (ANTIFUNGAL)

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

ORIGINAL ABBREVIATED NDAs

74-019*	PINDOLOL	MYLAN	PINDOLOL
09-03-92	(TABLET)	MORGANTOWN, WV 26505	5MG 10MG (BETA ADRENERGIC BLOCKER)
73-199	SULFAMETHOXAZOLE AND TRIMETHOPRIM	STERLING WINTHROP NEW YORK, NY 10016	SULFAMETHOXAZOLE 80MG/ML TRIMETHOPRIM 16MG/ML (ANTIBACTERIAL)
09-11-92	(INJECTABLE)		
73-187	LOPERAMIDE HCL	BARRE	LOPERAMIDE HYDROCHLORIDE
09-15-92	(SOLUTION)	BALTIMORE, MD 21207	1MG/5ML (ANTIDIARRHEAL) (OTC)
74-043	PIROXICAM	GENPHARM	PIROXICAM
09-22-92	(CAPSULE)	ETOBICOKE, ONTARIO	10MG 20MG (NONSTEROIDAL ANTI-INFLAMMATORY)
74-013	PINDOLOL	GENPHARM	PINDOLOL
09-24-92	(TABLET)	ETOBICOKE, ONTARIO	5MG (BETA ADRENERGIC BLOCKER)
74-018	PINDOLOL	GENPHARM	PINDOLOL
09-24-92	(TABLET)	ETOBICOKE, ONTARIO	10MG (BETA ADRENERGIC BLOCKER)
89-892*	PHENYTOIN	BARRE	PHENYTOIN
09-25-92	(SUSPENSION)	BALTIMORE, MD 21207	125MG/5ML (ANTICONVULSANT)

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

ORIGINAL ABBREVIATED NDAs

74-027	DESONIDE	COPLEY	DESONIDE
09-28-92	(CREAM)	CANTON, MA	0.05%
	02021	(CORTICOSTEROID)	

* - First Time Product Available Generically

73-120	ALBUTEROL SULFATE	MD PHARM	ALBUTEROL SULFATE
09-29-92	(TABLET)	SANTA ANA, CA	EQ 2MG BASE
	92704	(BRONCHODILATOR)	
73-121	ALBUTEROL SULFATE	MD PHARM	ALBUTEROL SULFATE
09-29-92	(TABLET)	SANTA ANA, CA	EQ 4MG BASE
	92704	(BRONCHODILATOR)	
63-329	CLINDA-DERM	PADDOCK	CLINDAMYCIN PHOSPHATE
09-30-92	(SOLUTION)	MINNEAPOLIS, MN	EQ 1% BASE
	55427	(ANTIBIOTIC, LINCOMYCIN)	
72-621	ACETYLCYSTEINE	ROXANE	ACETYLCYSTEINE
09-30-92	(SOLUTION/INHALATION)	COLUMBUS, OH	10%
	43216	(MUCOLYTIC)	
72-622	ACETYLCYSTEINE	ROXANE	ACETYLCYSTEINE
09-30-92	(SOLUTION/INHALATION)	COLUMBUS, OH	20%
	43216	(MUCOLYTIC)	
73-509	MORPHINE SULFATE	ABBOTT	MORPHINE SULFATE
09-30-92	(INJECTABLE)	ABBOTT PARK, IL	0.5MG/ML
	60064	(ANALGESIC)	
73-510	MORPHINE SULFATE	ABBOTT	MORPHINE SULFATE

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

ORIGINAL ABBREVIATED NDAs

09-30-92	(INJECTABLE)	ABBOTT PARK, IL	1MG/ML
		60064	(ANALGESIC)
74-138	LACTULOSE	UDL	LACTULOSE
09-30-92	(SYRUP)	LARGO, FL	10GM/15ML
		34641	(LAXATIVE/
			AMMONIA DETOXICANT)

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENT(S)
TENTATIVE (DOSAGE FORM) STRENGTH(S)
APPROVAL DATE 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 Evaluations" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

THERE ARE NO ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVAL FOR THE MONTH OF SEPTEMBER 1992.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

13-400	ALDOMET	MSD	METHYLDOPA
09-03-92	(TABLET)	WEST POINT, PA	125MG
		19486	250MG
			500MG
			(REVISED LABELING -- PRECAUTIONS)
16-016	ALDOCLOR	MSD	METHYLDOPA
09-03-92	(TABLET)	WEST POINT, PA	250MG
		19486	CHLOROTHIAZIDE
			150MG
			(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
16-016	ALDOCLOR	MSD	METHYLDOPA
09-03-92	(TABLET)	WEST POINT, PA	250MG
		19486	CHLOROTHIAZIDE
			250MG
			(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-343	CAPOTEN	BRISTOL MYERS SQUIBB	CAPTOPRIL
09-03-92	(TABLET)	PRINCETON, NJ	12.5MG
		08543	25MG
			50MG
			100MG
			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
18-389	ALDOMET	MSD	METHYLDOPA
09-03-92	(SUSPENSION)	WEST POINT, PA	250MG/5ML
		19486	(REVISED LABELING --
			PRECAUTIONS)
19-152	ISOPTIN SR	KNOLL	VERAPAMIL HYDROCHLORIDE
09-03-92	(TABLET,	WHIPPANY, NJ	120MG
	EXTENDED RELEASE)	07981	180MG
			240MG
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			OVERDOSAGE)
11-210	TESSALON	FOREST LABS	BENZONATATE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

09-04-92	(CAPSULE)	NEW YORK, NY	100MG
	10155	(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)	
19-785	CARDIOLITE	DUPONT MERCK	TECHNETIUM TC-99M
09-09-92	(INJECTABLE)	N BILLERICA, MA	SESTAMIBI KIT
	01862	N/A	
		(REVISED LABELING -- INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS)	
10-374	MEDIHALER-EPI	3M	EPINEPHRINE BITARTRATE
09-10-92	(AEROSOL)	ST PAUL, MN	7MG/ML
	55144	(REVISED LABELING -- PATIENT PACKAGE INSERT)	
		(OTC)	
18-200	MIDAMOR	MSD	AMILORIDE HYDROCHLORIDE
09-16-92	(TABLET)	WEST POINT, PA	5MG
	19486	(REVISED LABELING -- ADVERSE REACTIONS; HOW SUPPLIED)	
18-257	TONOCARD	MERCK	TOCAINIDE HYDROCHLORIDE
09-16-92	(TABLET)	WEST POINT, PA	400MG
	19486		600MG
		(REVISED LABELING -- INDICATIONS AND USAGE; WARNINGS; HOW SUPPLIED)	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-753	ETHMOZINE	DUPONT	MORICIZINE HYDROCHLORIDE	
09-16-92	(TABLET)	WILMINGTON, DE	200MG	
		19880	250MG	
			300MG	
			(REVISED LABELING --	
			CLINICAL ACTIONS;	
			INDICATIONS AND USAGE;	
			WARNINGS; PRECAUTIONS)	
11-145*	DIURIL	MSD	CHLOROTHIAZIDE	
09-17-92	(TABLET)	WEST POINT, PA	250MG	
		19486	500MG	
			(REVISED LABELING --	
			PRECAUTIONS;	
			ADVERSE REACTIONS;	
			HOW SUPPLIED)	

* - Permitted

11-635	DIUPRES-250	MSD	CHLOROTHIAZIDE	
09-17-92	(TABLET)	WEST POINT, PA	250MG	
		19486	RESERPINE	
			0.125MG	(REVISED LABELING --
			PRECAUTIONS;	
			ADVERSE REACTIONS)	
11-635	DIUPRES-500	MSD	CHLOROTHIAZIDE	
09-17-92	(TABLET)	WEST POINT, PA	500MG	
		19486	RESERPINE	
			0.125MG	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
11-835*	HYDRODIURIL	MSD	HYDROCHLOROTHIAZIDE
09-17-92	(TABLET)	WEST POINT, PA 19486	25MG 50MG 100MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
11-870*	DIURIL	MSD	CHLOROTHIAZIDE
09-17-92	(SUSPENSION)	WEST POINT, PA 19486	250MG/5ML (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)

* - Permitted

11-958	HYDROPRES 25	MSD	HYDROCHLOROTHIAZIDE
09-17-92	(TABLET)	WEST POINT, PA 19486	25MG RESERPINE 0.125MG (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; ADVERSE REACTIONS; HOW SUPPLIED)
11-958	HYDROPRES 50	MSD	HYDROCHLOROTHIAZIDE
09-17-92	(TABLET)	WEST POINT, PA	50MG
		19486	RESERPINE 0.125MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
13-402	ALDORIL 15	MSD	HYDROCHLOROTHIAZIDE
09-17-92	(TABLET)	WEST POINT, PA	15MG
		19486	METHYLDOPA 250MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
13-402	ALDORIL 25	MSD	HYDROCHLOROTHIAZIDE
09-17-92	(TABLET)	WEST POINT, PA	25MG
		19486	METHYLDOPA 250MG (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

13-402	ALDORIL D30	MSD	HYDROCHLOROTHIAZIDE
09-17-92	(TABLET)	WEST POINT, PA	30MG
	19486		METHYLDOPA
			500MG
			(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
13-402	ALDORIL D50	MSD	HYDROCHLOROTHIAZIDE
09-17-92	(TABLET)	WEST POINT, PA	50MG
	19486		METHYLDOPA
			500MG
			(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
16-016	ALDOCLOR-150	MSD	CHLOROTHIAZIDE
09-17-92	(TABLET)	WEST POINT, PA	150MG
	19486		METHYLDOPA
			250MG
			(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
16-016	ALDOCLOR-250	MSD	CHLOROTHIAZIDE
09-17-92	(TABLET)	WEST POINT, PA	250MG
	19486		METHYLDOPA
			250MG
			(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
18-201	MODURETIC 5-50	MSD	AMILORIDE HYDROCHLORIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

09-17-92	(TABLET)	WEST POINT, PA	EQ 5MG ANHYDROUS
		19486	HYDROCHLOROTHIAZIDE
			50MG
			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS)
19-011	GOLYTELY	BRAINTREE	POLYETHYLENE GLYCOL 3350
09-17-92	(POWDER	BRAINTREE, MA	236GM/BOTTLE
	FOR RECONSTITUTION)	02184	POTASSIUM CHLORIDE
			2.97GM/BOTTLE
			SODIUM BICARBONATE
			6.74GM/BOTTLE
			SODIUM CHLORIDE
			5.86GM/BOTTLE
			SODIUM SULFATE, ANHYDROUS
			22.74GM/BOTTLE
			(REVISED LABELING --
			CONTRAINDICATIONS)
18-509	BAROS	LAFAYETTE	SODIUM BICARBONATE
09-21-92	(GRANULE,	LAFAYETTE, IN	460MG/GM
	EFFERVESCENT)	47902	TARTARIC ACID
			420MG/GM
			(REVISED LABELING --
			PRECAUTIONS)
19-501	ROGAINE	UPJOHN	MINOXIDIL
09-24-92	(SOLUTION)	KALAMAZOO, MI	2%
		49001	(REVISED LABELING --
			PATIENT INFORMATION)
20-154	VIDEX	BRISTOL MYERS SQUIBB	DIDANOSINE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

09-25-92	(TABLET, CHEWABLE)	WALLINGFORD, CT	25MG
		06492	50MG
			100MG
			150MG
			(REVISED LABELING --
			INDICATIONS AND USAGE;
			WARNINGS; ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)

20-155	VIDEX	BRISTOL MYERS SQUIBB	DIDANOSINE
09-25-92	(POWDER	WALLINGFORD, CT	100MG/PACKET
	FOR RECONSTITUTION)	06492	167MG/PACKET
			250MG/PACKET
			375MG/PACKET
			(REVISED LABELING --
			INDICATIONS AND USAGE;
			WARNINGS; ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)

20-156	VIDEX	BRISTOL MYERS SQUIBB	DIDANOSINE
09-25-92	(POWDER	WALLINGFORD, CT	10MG/ML
	FOR RECONSTITUTION)	06492	(REVISED LABELING --
			INDICATIONS AND USAGE;
			WARNINGS; ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)

50-589	CEFIZOX	SKF	CEFTIZOXIME SODIUM
09-25-92	IN DEXTROSE 5%	PHILADELPHIA, PA	EQ 20MG BASE/ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

	IN PLASTIC CONTAINER	19101	EQ 40MG BASE/ML
	(INJECTABLE)		(REVISED LABELING -- INDICATIONS AND USAGE)
50-285	MYCIFRADIN	UPJOHN	NEOMYCIN SULFATE
09-28-92	(SOLUTION)	KALAMAZOO, MI	EQ 87.5MG BASE/5ML
		49001	(REVISED LABELING -- INDICATIONS AND USAGE; CONTRAINDICATIONS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
18-713	MYCELEX	MILES	CLOTRIMAZOLE
09-29-92	(TROCHE/LOZENGE)	WEST HAVEN, CT	10MG
		06516	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; HOW SUPPLIED)
50-529	PEDIAZOLE	ROSS	ERYTHROMYCIN ETHYLSUCCINATE
09-29-92	(GRANULE)	COLUMBUS, OH	EQ 200MG BASE/5ML
		43215	SULFISOXAZOLE ACETYL EQ 600MG BASE/5ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
50-588	CEFOTAN	STUART	CEFOTETAN DISODIUM
09-29-92	(INJECTABLE)	WILMINGTON, DE	EQ 1GM BASE/VIAL
		19897	EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (REVISED LABELING --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

ADVERSE REACTIONS)

50-637	ZEFAZONE	UPJOHN	CEFMETAZOLE SODIUM
09-29-92	(INJECTABLE)	KALAMAZOO, MI	EQ 1GM BASE/VIAL
		49001	EQ 2GM BASE/VIAL
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
06-343	WYDASE	WYETH AYERST	HYALURONIDASE
09-30-92	(INJECTABLE)	PHILADELPHIA, PA	150 UNITS/ML
		19101	150 UNITS/VIAL
			1,500 UNITS/VIAL
			(REVISED LABELING --
			HOW SUPPLIED)
18-735	ISOVUE-200	SQUIBB	IOPAMIDOL
09-30-92	(INJECTABLE)	PRINCETON, NJ	41%
		08543	(REVISED LABELING --
			HOW SUPPLIED)
18-735	ISOVUE-250	SQUIBB	IOPAMIDOL
09-30-92	(INJECTABLE)	PRINCETON, NJ	51%
		08543	(REVISED LABELING --
			HOW SUPPLIED)
18-735	ISOVUE-300	SQUIBB	IOPAMIDOL
09-30-92	(INJECTABLE)	PRINCETON, NJ	61%
		08543	(REVISED LABELING --
			HOW SUPPLIED)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-735	ISOVUE-370	SQUIBB	IOPAMIDOL
09-30-92	(INJECTABLE)	PRINCETON, NJ	76%
		08543	(REVISED LABELING -- HOW SUPPLIED)

18-998	VASOTEC	MERCK	ENALAPRIL MALEATE
09-30-92	(TABLET)	WEST POINT, PA	2.5MG
		19486	5MG
			10MG
			20MG
			(REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)

19-221	VASERETIC	MERCK	ENALAPRIL MALEATE
09-30-92	(TABLET)	WEST POINT, PA	10MG
		19486	HYDROCHLOROTHIAZIDE
			25MG
			(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)

19-309	VASOTEC	MERCK	ENALAPRILAT
09-30-92	(INJECTABLE)	WEST POINT, PA	1.25MG/ML
		19486	(REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)

19-558	PRINIVIL	MERCK	LISINOPRIL
09-30-92	(TABLET)	WEST POINT, PA	5MG
		19486	10MG
			20MG
			40MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(REVISED LABELING -- WARNINGS)
19-778	PRINZIDE 12.5	MERCK	HYDROCHLOROTHIAZIDE
09-30-92	(TABLET)	WEST POINT, PA	12.5MG
		19486	LISINOPRIL 20MG
			(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-778	PRINZIDE 25	MERCK	HYDROCHLOROTHIAZIDE
09-30-92	(TABLET)	WEST POINT, PA	25MG
		19486	LISINOPRIL 20MG
			(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-828	OXISTAT	GLAXO	OXICONAZOLE NITRATE
09-30-92	(CREAM)	RES TRIANGLE PK, NC	EQ 1% BASE
		27709	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1158 09-14-92	ORTHOCLONE OKT3 (INJECTABLE) 78756	ORTHO BIOTECH RARITAN, NJ	MUROMONAB-CD3 (TREATMENT OF ACUTE ALLOGRAFT REJECTION IN RENAL TRANSPLANT PATIENTS) (A&B)
1157 09-23-92	NONE (INJECTABLE) 21205	JOHNS HOPKINS HOSP BALTIMORE, MD	PLATELETS (TRANSFUSION) (A&B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK920012	705 FTSPP 790F	HAEMONETICS	EMPTY CONTAINER FOR
09/16/92		BRAINTREE, MA 02184	COLLECTION OF BLOOD COMPONENTS (C)
BK920002	ETHOX TRANSFER PACK	ETHOX BUFFALO, NY 14204	EMPTY CONTAINER COLLECTION AND BLOOD COMPONENTS (C)
09/17/92			
BK920008	VIROTROL	BLACKHAWK BIOSYS SAN RAMON, CA 94583	QUALITY CONTROL KITS FOR BLOOD BANKING REAGENTS (C)
09/17/92			

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

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 SEPTEMBER 1992.

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

N18286/S07	GELFOAM STERILE SPONGE (ABSORBABLE GELATIN SPONGE, USP), GELFOAM STERILE POWDER FOR GENERAL HEMOSTASIS	THE UPJOHN COMPANY KALAMAZOO, MI 49001-0199	MARKETING OF A POWDERED FORM OF GELFOAM	09/10/92
P790018/S20	MEDTRONIC HALL VALVE PROSTHESIS	MEDTRONIC HEART VALVES MINNEAPOLIS, MN 55432	USE OF ECHODOPPLER TO MEET CONDITION OF APPROVAL WHICH REQUIRED CATHETERIZATION DATA ON ASYMPTOMATIC PATIENTS	09/03/92
P800022/S36	ZYPLAST COLLAGEN IMPLANT AND ZYDERM COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	EXPANSION OF THE PRESCRIPTION RESTRICTION TO INCLUDE ORAL AND MAXILLOFACIAL SURGEONS IN ADDITION TO LICENSED PHYSICIANS	09/02/92
P820051/S14	OCU-FLEX (OCUFILCON B) SOFT (HYDROPHILIC) LENS AQUA-SPHERE 53 AND AQUA-CYL TORIC (OCUFILCON B) SOFT HYDROPHILIC CONTACT LENS	OCU-EASE OPTICAL PRODUCTS, INC. PINOLE, CA 94564	ALTERNATE MANUFACTURER AND PRIVATE LABEL DISTRIBUTOR FOR THE LENSES	09/11/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P830060/S32	VENTAK MODELS 1550/1555 CARDIOVERTER DEFIBRILLATOR	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	MODIFICATIONS TO THE PATIENT'S MANUAL	09/24/92
P840024/S36	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATIONS	09/14/92
P840055/S26	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	FOUR ADDITIONAL CONTACT LENS FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	09/30/92
P870002/S11	APPLIED LABORATORIES STERILE SALINE SOLUTION	APPLIED LABORATORIES, INC. COLUMBUS, IN 47202-0448	LOWERING THE MINIMUM REQUIRED IRRADIATION DOSAGE FOR STERILIZING THE SALINE SOLUTION FROM 2.5 TO 2.16 MEGARADS	09/01/92
P880001/S36	FLUOREX 700 (FLUSILFOCON A), FLUOREX 500 (FLUSILFOCON B) AND FLUOREX 300 (FLUSILFOCON C) RIGID GAS PERMEABLE	G.T. LABORATORIES CHICAGO, IL 60601	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	09/30/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CONTACT LENS (CLEAR AND TINTED)		
P890027/S07 09/14/92	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATIONS
P890029/S03 09/11/92	CIBA 2000 SPHERICAL (ATLAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES	CIBA VISION CORPORATION ATLANTA, GA 30360	EXPAND INDICATIONS OF CLEAR CIBA 2000 SPHERICAL SOFT CONTACT LENSES FROM DAILY WEAR USE TO INCLUDE EXTENDED WEAR
P890039/S06 09/14/92	MAESTRO SAVVI MODEL 305 PACING SYSTEM/A-TRACK LEADS	CARDIAC CONTROL SYSTEMS INC. PALM COAST, FL 32137	MANUFACTURING MODIFICATIONS
P890044/S22 09/01/92	BIS.45 (AMSILFOCON A) AND TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED)	BENTEC ENGINEERING INC. SACRAMENTO, CA 95834	12 ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P890044/S23 09/30/92	BIS.45 (AMSILFOCON A) AND TRANS-AIRE (AMSILFOCON A)	BENTEC ENGINEERING INC. SACRAMENTO, CA 95834	SIX ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
	RIGID GAS PERMEABLE CONTACT LENSES FOR DAILY WEAR (CLEAR AND TINTED)		BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P890061/S05 09/24/92	VENTAK P MODEL 1600 (AICD) AND SOFTWARE MODULE MODEL 2830/VENTAK P MODEL 1600 PULSE GENERATOR	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	MODIFICATIONS TO THE PATIENT'S MANUAL

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

ORIGINAL VETERINARY NADAs

140-989 07-31-92	PARASITE-S (LIQUID)	FISH (SALMON, TROUT, CATFISH, LARGEMOUTH BASS, BLUEGILL, SUNFISH)	WESTERN CHEMICAL FERNDALE, WA 98248	FORNALIN 37% W/W

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR SEPTEMBER 1992.

SUPPLEMENTAL VETERINARY NADAs

140-338 08-04-92	NAXCEL (POWDER)	SWINE CHICKENS	UPJOHN KALAMAZOO, MI 49001	CEFTIOFUR SODIUM 50MG/ML

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

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) 295-8428

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

*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.

Volume 15 (10)
October 1992

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

20-062 10-15-92 (SUPPL)	CARDIZEM CD (CAPSULE, EXTENDED RELEASE)	MARION MERRELL DOW KANSAS CITY, MO 64134	DILTIAZEM HYDROCHLORIDE 120MG 180MG 240MG 300MG (NEW INDICATION -- MANAGEMENT OF CHRONIC STABLE ANGINA AND ANGINA DUE TO CORONARY ARTERY SPASM)
11-835 10-28-92 (SUPPL)	HYDRODIURIL (TABLET)	MSD WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 25MG 50MG 100MG

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

(NEW DOSAGE REGIMEN --
DECREASE STARTING DOSE TO
25MG FOR THE TREATMENT OF
OF EDEMA AND CONTROL OF
HYPERTENSION)

18-841	DAYPRO	SEARLE	OXAPROZIN
10-29-92	(TABLET)	SKOKIE, IL	600MG
(1 S)		60077	(NONSTEROIDAL ANTI-INFLAMMATORY)
20-246	DEPO-PROVERA	UPJOHN	MEDROXYPROGESTERONE ACETATE
10-29-92	(INJECTABLE)	KALAMAZOO, MI	150MG/ML
(6 P)		49001	(HORMONAL CONTRACEPTIVE)
19-807	KERLEDEX	LOREX	BETAXOLOL HYDROCHLORIDE
10-30-92	(TABLET)	SKOKIE, IL	5MG
(4 S)		60077	CHLORTHALIDONE 12.5MG (ANTIHYPERTENSIVE)
19-807	KERLEDEX	LOREX	BETAXOLOL HYDROCHLORIDE
10-30-92	(TABLET)	SKOKIE, IL	10MG
(4 S)		60077	CHLORTHALIDONE 12.5MG (ANTIHYPERTENSIVE)
19-865	BETAPACE	BERLEX	SOTALOL HYDROCHLORIDE
10-30-92	(TABLET)	WAYNE, NJ	80MG
(1 P, V*)		07470	160MG 240MG 320MG** (ANTIARRHYTHMIC)
19-916	MORPHINE SULFATE	ABBOTT	MORPHINE SULFATE
10-30-92	(INJECTABLE)	ABBOTT PARK, IL	1MG/ML
(5 S)		60064	(ANALGESIC)
19-917	MORPHINE SULFATE	ABBOTT	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

10-30-92	(INJECTABLE)	ABBOTT PARK, IL	0.5MG/ML
(5 S)		60064	(ANALGESIC)

ERRATA

19-828***	OXISTAT	GLAXO	OXICONAZOLE NITRATE
09-30-92	(CREAM)	RES TRIANGLE PK, NC	EQ 1% BASE
		27709	(NEW INDICATION -- DERMAL INFECTIONS-TINEA PEDIS, TINEA CRURIS, TINEA CORPORIS DUE TO EPIDERMOPHYTON FLOCCOSUM)

* - Designated Orphan Drug
** - Not Marketed At This Time
*** - Corrected NDA Number

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

APPROVABLE ORIGINAL NDAs

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

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

20-107	NOVAMINE	BAXTER	AMINO ACIDS
10-23-92	(INJECTABLE)	ROUND LAKE, IL	15%
		60073	(NUTRIENT REPLENISHER)

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

ORIGINAL ABBREVIATED NDAs

89-987	BUTAPAP	MIKART	ACETAMINOPHEN
10-26-92	(TABLET)	ATLANTA, GA	325MG
	30318		BUTALBITAL
			50MG
			(ANALGESIC/ANXIOLYTIC)
89-988*	BUTAPAP	MIKART	ACETAMINOPHEN
10-26-92	(TABLET)	ATLANTA, GA	650MG
	30318		BUTALBITAL
			50MG
			(ANALGESIC/ANXIOLYTIC)
73-680	METOCLOPRAMIDE HCL	SILARX	METOCLOPRAMIDE HYDROCHLORIDE
10-27-92	(SOLUTION)	SPRING VALLEY, NY	EQ 5MG BASE/5ML
	10977		(UPPER GI TRACT
			MOTILITY STIMULATOR)
81-226	HYDROCODONE BITARTRATE	MIKART	ACETAMINOPHEN
10-27-92	AND ACETAMINOPHEN	ATLANTA, GA	500MG/15ML
	(ELIXIR)	30318	HYDROCODONE BITARTRATE
			5MG/15ML
			(ANALGESIC)
89-450	ACETAMINOPHEN AND	MIKART	ACETAMINOPHEN
10-27-92	CODEINE PHOSPHATE	ATLANTA, GA	120MG/5ML
	(ELIXIR)	30318	CODEINE PHOSPHATE
			12MG/5ML
			(ANALGESIC)
62-931	VANCOMYCIN HCL	ABBOTT	VANCOMYCIN HYDROCHLORIDE
10-29-92	(INJECTABLE)	ABBOTT PARK, IL	EQ 500MG BASE/VIAL
	60064		(ANTIBIOTIC, GLYCOPEPTIDE)

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

ORIGINAL ABBREVIATED NDAs

62-933	VANCOMYCIN HCL	ABBOTT	VANCOMYCIN HYDROCHLORIDE
10-29-92	(INJECTABLE)	ABBOTT PARK, IL	EQ 1GM BASE/VIAL
	60064	(ANTIBIOTIC, GLYCOPEPTIDE)	

* - First Time Product Available Generically

73-676	ATENOLOL	SCHIAPPARELLI SEARLE	ATENOLOL
10-30-92	(TABLET)	SKOKIE, IL	50MG
	60077		100MG
		(BETA ADRENERGIC BLOCKER)	

74-030*	MICONAZOLE NITRATE	COPLEY	MICONAZOLE NITRATE
10-30-92	(CREAM)	CANTON, MA	2%
	02021	(ANTIFUNGAL)	
		(OTC)	

74-110*	NAPROXEN	HAMILTON	NAPROXEN
10-30-92	(TABLET)	PALO ALTO, CA	250MG
	94304		375MG
			500MG
		(NONSTEROIDAL	
		ANTI-INFLAMMATORY)	

74-194*	LOPERAMIDE HCL	PERRIGO	LOPERAMIDE HYDROCHLORIDE
10-30-92	(TABLET)	ALLEGAN, MI	2MG
	49010	(ANTIDIARRHEAL)	
		(OTC)	

81-239*	CYCRIN	WYETH AYERST	MEDROXYPROGESTERONE ACETATE
10-30-92	(TABLET)	PHILADELPHIA, PA	2.5MG
	19101	(PROGESTIN)	

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

ORIGINAL ABBREVIATED NDAs

81-240*	CYCRIN	WYETH AYERST	MEDROXYPROGESTERONE ACETATE
10-30-92	(TABLET)	PHILADELPHIA, PA 19101	5MG (PROGESTIN)

* - First Time Product Available Generically

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
TENTATIVE APPROVAL DATE	(DOSAGE FORM)		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 Evaluations" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

74-195*	NAPROXEN SODIUM	DANBURY	NAPROXEN SODIUM
10-28-92	(TABLET)	DANBURY, CT 06810	275MG 550MG (NONSTEROIDAL ANTI-INFLAMMATORY)
74-097*	ISOFLURANE	ABBOTT	ISOFLURANE
10-30-92	(LIQUID, INHALATION)	ABBOTT PARK, IL 60064	99.9% (ANESTHETIC, GENERAL)

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

ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

* - First Time Product Available Generically

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

10-571*	COMPAZINE	SMITHKLINE BEECHAM	PROCHLORPERAZINE MALEATE
09-30-92	(TABLET)	PHILADELPHIA, PA 19101	EQ 5MG BASE EQ 10MG BASE EQ 25MG BASE (REVISED LABELING -- DESCRIPTION; ADVERSE REACTIONS; DOSAGE ADMINISTRATION; HOW SUPPLIED)
10-742*	COMPAZINE	SMITHKLINE BEECHAM	PROCHLORPERAZINE EDISYLATE
09-30-92	(INJECTABLE)	PHILADELPHIA, PA 19101	EQ 5MG BASE/ML (REVISED LABELING -- DESCRIPTION; ADVERSE REACTIONS; DOSAGE ADMINISTRATION; HOW SUPPLIED)
11-000*	COMPAZINE	SKF	PROCHLORPERAZINE MALEATE
09-30-92	(CAPSULE, EXTENDED RELEASE)	PHILADELPHIA, PA 19101	EQ 10MG BASE EQ 15MG BASE EQ 30MG BASE (REVISED LABELING -- DESCRIPTION; ADVERSE REACTIONS; DOSAGE ADMINISTRATION; HOW SUPPLIED)
11-127*	COMPAZINE	SMITHKLINE BEECHAM	PROCHLORPERAZINE
09-30-92	(SUPPOSITORY)	PHILADELPHIA, PA 19101	2.5MG 5MG 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

DESCRIPTION;
ADVERSE REACTIONS;
DOSAGE ADMINISTRATION;
HOW SUPPLIED)

* - Permitted

11-188*	COMPAZINE	SKF	PROCHLORPERAZINE EDISYLATE
09-30-92	(SYRUP)	PHILADELPHIA, PA	EQ 5MG BASE/5ML
	19101	(REVISED LABELING --	
		DESCRIPTION;	
		ADVERSE REACTIONS;	
		DOSAGE ADMINISTRATION;	
		HOW SUPPLIED)	
11-958	HYDROPRES 25	MSD	HYDROCHLOROTHIAZIDE
10-01-92	(TABLET)	WEST POINT, PA	25MG
	19486	RESERPINE	
		0.125MG	
		(REVISED LABELING --	
		PRECAUTIONS)	
11-958	HYDROPRES 50	MSD	HYDROCHLOROTHIAZIDE
10-01-92	(TABLET)	WEST POINT, PA	50MG
	19486	RESERPINE	
		0.125MG	
		(REVISED LABELING --	
		PRECAUTIONS)	
18-201	MODURETIC 5-50	MSD	AMILORIDE HYDROCHLORIDE
10-01-92	(TABLET)	WEST POINT, PA	EQ 5MG ANHYDROUS
	19486	HYDROCHLOROTHIAZIDE	
		50MG	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(REVISED LABELING -- PRECAUTIONS; HOW SUPPLIED)
20-092	DILACOR XR	RHONE POULENC RORER	DILTIAZEM HYDROCHLORIDE
10-02-92	(CAPSULE, EXTENDED RELEASE)	COLLEGEVILLE, PA 19426	180MG 240MG (REVISED LABELING -- PRECAUTIONS)

* - Permitted

08-922	CALCIUM DISODIUM VERSENATE (INJECTABLE)	3M ST PAUL, MN 55144	EDETATE CALCIUM DISODIUM 200MG/ML (REVISED LABELING -- WARNINGS; DOSAGE AND ADMINISTRATION)
17-381	SILVADENE (CREAM)	MARION MERRELL DOW KANSAS CITY, MO 64137	SILVER SULFADIAZINE 1% (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)
18-115	TRIAMINIC-12	SANDOZ	CHLORPHENIRAMINE MALEATE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

10-05-92	(TABLET, EXTENDED RELEASE)	E HANOVER, NJ 07936	12MG	
			PHENYLPROPANOLAMINE HYDROCHLORIDE	75MG
			(REVISED LABELING -- OTC LABELING)	
18-831	TRACRIUM	BURROUGHS WELLCOME	ATRACURIUM BESYLATE	
10-06-92	(INJECTABLE)	RES TRIANGLE PK, NC 27709	10MG/ML	
			(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	
17-395	INTROPIN	DUPONT	DOPAMINE HYDROCHLORIDE	
10-07-92	(INJECTABLE)	WILMINGTON, DE 19880	40MG/ML	
			80MG/ML	
			160MG/ML	
			(REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; HOW SUPPLIED)	
19-915	MONOPRIL	BRISTOL MYERS SQUIBB	FOSINOPRIL SODIUM	
10-07-92	(TABLET)	PRINCETON, NJ 08543	10MG	
			20MG	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

(REVISED LABELING --
PRECAUTIONS;
ADVERSE REACTIONS;
OVERDOSAGE;
DOSAGE AND ADMINISTRATION)

17-450	MONISTAT 7	JOHNSON RW	MICONAZOLE NITRATE
10-08-92	(CREAM)	RARITAN, NJ	2%
	08869	(REVISED LABELING -- PATIENT PACKAGE INSERT)	

17-717	GYNE-LOTRIMIN	SCHERING	CLOTRIMAZOLE
10-08-92	(TABLET)	LIBERTY CORNER, NJ	100MG
	07938	(REVISED LABELING -- PATIENT PACKAGE INSERT)	

18-052	GYNE-LOTRIMIN	SCHERING	CLOTRIMAZOLE
10-08-92	(CREAM)	KENILWORTH, NJ	1%
	07033	(REVISED LABELING -- PATIENT PACKAGE INSERT)	

18-182	MYCELEX-7	MILES	CLOTRIMAZOLE
10-08-92	(TABLET)	W HAVEN, CT	100MG
	06516	(REVISED LABELING -- PATIENT PACKAGE INSERT)	

18-230	MYCELEX-7	MILES	CLOTRIMAZOLE
10-08-92	(CREAM)	W HAVEN, CT	1%
	06516	(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

18-520	MONISTAT 7	JOHNSON RW	MICONAZOLE NITRATE
10-08-92	(SUPPOSITORY)	RARITAN, NJ	100MG
		08869	(REVISED LABELING -- PATIENT PACKAGE INSERT)
50-608	UNASYN	PFIZER	AMPICILLIN SODIUM
10-08-92	(INJECTABLE)	NEW YORK, NY	EQ 1GM BASE/VIAL
		10017	SULBACTAM SODIUM EQ 500MG BASE/VIAL (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; WARNINGS; ADVERSE REACTIONS)
50-608	UNASYN	PFIZER	AMPICILLIN SODIUM
10-08-92	(INJECTABLE)	NEW YORK, NY	EQ 2GM BASE/VIAL
		10017	SULBACTAM SODIUM EQ 1GM BASE/VIAL (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; WARNINGS; ADVERSE REACTIONS)
18-473	VENTOLIN	GLAXO	ALBUTEROL
10-09-92	(AEROSOL, METERED)	RES TRIANGLE PK, NC	0.09MG/INH
		27709	(REVISED LABELING -- PRECAUTIONS; OVERDOSAGE)
19-112	VENTOLIN	GLAXO	ALBUTEROL SULFATE
10-13-92	(TABLET)	RESEARCH TRIANGLE, NC	EQ 2MG BASE
		27709	EQ 4MG BASE (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;
			OVERDOSAGE)
50-504	MANDOL	LILLY	CEFAMANDOLE NAFATE
10-14-92	(INJECTABLE)	INDIANAPOLIS, IN	EQ 1GM BASE/VIAL
	46285		EQ 2GM BASE/VIAL
			(REVISED LABELING --
			STABILITY)
18-686	NORMODYNE	SCHERING	LABETALOL HYDROCHLORIDE
10-15-92	(INJECTABLE)	KENILWORTH, NJ	5MG/ML
	07033		(REVISED LABELING --
			DESCRIPTION;
			CONTRAINDICATIONS;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS)
18-687	NORMODYNE	SCHERING	LABETALOL HYDROCHLORIDE
10-15-92	(TABLET)	KENILWORTH, NJ	100MG
	07033		200MG
			300MG
			(REVISED LABELING --
			DESCRIPTION;
			CONTRAINDICATIONS;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS)
18-709	CAPOZIDE 25/15	SQUIBB	CAPTOPRIL
10-15-92	(TABLET)	NEW BRUNSWICK, NJ	25MG
	08903		HYDROCHLOROTHIAZIDE
			15MG
			(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

ADVERSE REACTIONS;
DOSAGE AND ADMINISTRATION)

18-709	CAPOZIDE 25/25	SQUIBB	CAPTOPRIL
10-15-92	(TABLET)	NEW BRUNSWICK, NJ	25MG
		08903	HYDROCHLOROTHIAZIDE
			25MG

(REVISED LABELING --
PRECAUTIONS;
ADVERSE REACTIONS;
DOSAGE AND ADMINISTRATION)

18-709	CAPOZIDE 50/15	SQUIBB	CAPTOPRIL
10-15-92	(TABLET)	NEW BRUNSWICK, NJ	50MG
		08903	HYDROCHLOROTHIAZIDE
			15MG

(REVISED LABELING --
PRECAUTIONS;
ADVERSE REACTIONS;
DOSAGE AND ADMINISTRATION)

18-709	CAPOZIDE 50/25	SQUIBB	CAPTOPRIL
10-15-92	(TABLET)	NEW BRUNSWICK, NJ	50MG
		08903	HYDROCHLOROTHIAZIDE
			25MG

(REVISED LABELING --

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
			PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-574 10-15-92	THALITONE (TABLET)	HORUS ROCHESTER, NY 14623	CHLORTHALIDONE 15MG (REVISED LABELING -- PRECAUTIONS)
20-062 10-15-92	CARDIZEM CD (CAPSULE, EXTENDED RELEASE)	MARION MERRELL DOW KANSAS CITY, MO 64134	DILTIAZEM HYDROCHLORIDE 120MG 180MG 240MG 300MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
20-092 10-15-92	DILACOR XR (CAPSULE, EXTENDED RELEASE)	RHONE POULENC RORER COLLEGEVILLE, PA 19426	DILTIAZEM HYDROCHLORIDE 120MG 180MG 240MG (REVISED LABELING -- DESCRIPTION;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
11-835	HYDRODIURIL	MSD	HYDROCHLOROTHIAZIDE
10-28-92	(TABLET)	WEST POINT, PA	25MG
		19486	50MG
			100MG
			(REVISED LABELING --
			PRECAUTIONS; OVERDOSAGE;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
13-553	ESIMIL	CIBA	GUANETHIDINE MONOSULFATE
10-28-92	(TABLET)	SUMMIT, NJ	10MG
		07901	HYDROCHLOROTHIAZIDE
			25MG
			(REVISED LABELING --
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)
19-489	VENTOLIN ROTACAPS	GLAXO	ALBUTEROL SULFATE
10-28-92	(CAPSULE)	RES TRIANGLE PK, NC	EQ 0.2MG BASE
		27709	(REVISED LABELING --
			PRECAUTIONS; OVERDOSAGE)
20-038	FLUDARA	BERLEX	FLUDARABINE PHOSPHATE
10-28-92	(INJECTABLE)	ALAMEDA, CA	50MG/VIAL
		94501	(REVISED LABELING --

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
			PRECAUTIONS; WARNINGS; ADVERSE REACTIONS)
05-264 10-29-92	HEPARIN SODIUM (INJECTABLE)	ABBOTT ABBOTT PARK, IL 60064	HEPARIN SODIUM 2,000 UNITS/ML 2,500 UNITS/ML (REVISED LABELING -- PRECAUTIONS)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1159 10-06-92	NONE (INJECTABLE)	CENTRAL PENINSULA GENERAL HOSP SOLDOTNA, AK 99669	WHOLE BLOOD (TRANSFUSION) (A&B)
659 10-16-92	NONE (INJECTABLE)	COMM BLOOD BANK OF LANCASTER CNTY MED SOCIETY LINCOLN, NE 68510	CRYOPRECIPITATED AHF (TRANSFUSION) (B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK920023	LEUKOCYTE	PALL BIOMED PROD	PALL AUTOSTOP LEUKOCYTE
10/26/92	REMOVAL PLATELET	GLEN COVE, NY	REMOVAL PLATELET FILTER
	FILTER	11542	WITH ATTACHED TUBING
			(C)

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

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

BIOLOGICAL PRODUCT ABBREVIATED NDA APPROVALS

72-562	LMD 10% IN	ABBOTT	DEXTRAN 40
10-30-92	SODIUM CHLORIDE 0.9%	ABBOTT PARK, IL	10GM/100ML
	IN PLASTIC CONTAINER	60064	(PLASMA EXPANDER)
	(INJECTABLE)		

72-563	LMD 10%	ABBOTT	DEXTRAN 40
10-30-92	IN DEXTROSE 5%	ABBOTT PARK, IL	10GM/100ML
	IN PLASTIC CONTAINER	60077	(PLASMA EXPANDER)
	(INJECTABLE)		

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

P860005 10/29/92	PRO OSTEON IMPLANT 500 CORALLINE HYDROXYAPATITE BONE VOID FILLER (FORMERLY INTERPORE 500)	INTERPORE ORTHOPAEDICS, INC. WEST CALDWELL, NJ 07006	PRO OSTEON IMPLANT 500 CORALLINE HYDROXYAPATITE BONE VOID FILLER INDICATED FOR THE REPAIR OF ACUTE METAPHYSEAL FRACTURE DEFECTS
P910016 10/30/92	UNICOMPARTMENTAL DEVICE CONFIGURATION OF THE NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY WARSAW, IN 46581-0988	UNICOMPARTMENTAL DEVICE CONFIGURATION OF THE NEW JERSEY LCS TOTAL KNEE SYSTEM INDICATED FOR UNCEMENTED USE IN CERTAIN PATIENTS

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

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

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/S03	SURGICAL SIMPLEX P RADIOPAQUE BONE CEMENT, SURGICAL SIMPLEX P BONE CEMENT	HOWMEDICA RUTHERFORD, NJ 07070-2584	ALTERNATE FACILITY FOR FILLING AMPOULES WITH MONOMER	10/01/92
N17004/S03	SURGICAL SIMPLEX P RADIOPAQUE BONE CEMENT, SURGICAL SIMPLEX P BONE CEMENT	HOWMEDICA RUTHERFORD, NJ 07070-2584	ALTERNATE FACILITY FOR FILLING AMPOULES WITH MONOMER	10/01/92
N17755/S39	ZIMMER BONE CEMENT	ZIMMER, INC. WARSAW, IN 46580-0708	ADJUSTMENT IN THE MANUFACTURING TOLERANCES OF THE LIQUID MONOMER WEIGHT TO FALL WITHIN THE TOLERANCES OF ASTM F 451	10/22/92
P790017/S41	USCI GRUNTZIG DILACA CORONARY ARTERY BALLOON DILATATION CATHETER, USCI SOLO BALLOON DILATATION CATHETER WITH PRO/PEL COATING	C.R. BARD, INC. BILLERICA, MA 01821	NEW MODEL CATHETER	10/20/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P810002/S24	ST. JUDE MEDICAL PYROLYTIC CARBON HEART VALVE	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	HEMODYNAMIC PLUS SERIES OF VALVES (MITRAL SIZES 17, 19, AND 21 MM) AND CORRESPONDING SIZERS	10/27/92
P810046/S118	SIMPSON-ROBERT ADVANCED CORONARY BALLOON DILATATION CATHETER, ACS RX FLOWTRACK 40 CORONARY DILATATION CATHETER	CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	ACS RX FLOWTRACK 40 CORONARY DILATATION CATHETER	10/29/92
P810046/S132	SIMPSON-ROBERT ADVANCED CORONARY BALLOON DILATATION CATHETER, ACS RX STREAK .014 CORONARY DILATATION CATHETER	CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	MODIFIED ACS RX STREAK CORONARY DILATATION CATHETER	10/01/92
P830060/S28	VENTAK MODEL 1550, AND 1555 PULSE GENERATORS	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	ALTERNATE STERILIZATION SITE	10/30/92
P840008/S39	DORNIER LITHOTRIPTER, MODEL HM3, DORNIER MULTIPURPOSE	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	MANUFACTURING MODIFICATIONS	10/29/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	LITHOTRIPTER MPL9000			
P840050/S47	OCUSIL (NEFOCON A)	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ADDITIONAL MANUFACTURING AND DISTRIBUTION SITE	10/29/92
P860019/S45	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, NC SHADOW CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	NEW MODEL CATHETER	10/01/92
P860059/S56	MODEL UPB380 ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2096	MODEL UPB380 ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	10/02/92
P860059/S61	MODEL UPB385 ULTRAVIOLET-ABSORBING SURFACE MODIFIED POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MODEL UPB385 ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	10/02/92
P860059/S63	MODEL UPB365 ULTRAVIOLET-ABSORBING SURFACE MODIFIED POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MODEL UPB365 ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	10/01/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P860059/S71	POSTERIOR CHAMBER INTRAOCULAR LENS (IOLS): 5.0MM OPTICS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	MANUFACTURE OF ANY PMA-APPROVED IOL DESIGN W/SYMMETRICAL HAPTICS IN OPTIC DIAMETERS DOWN TO 5.0MM	10/01/92
P870018/S07	SIEMENS LITHOSTAR LITHOTRIPTER POSTAPPROVAL STUDY	SIEMENS MEDICAL SYSTEMS, INC. ISELIN, NJ 08830	USE OF A NEW SHOCK TUBE (SHOCK TUBE C) AT WELLESLEY HOSPITAL, TORONTO, ONTARIO, CANADA	10/05/92
P880027/S22	SCHNEIDER MICROSOFTRAC PTCA CATHETER, SCHNEIDER MONGOOSE PTCA CATHETERS	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	DESIGN CHANGE	10/29/92
P890066/S03	THERASONIC LITHOTRIPSY TREATMENT SYSTEM	DIASONICS, INC. MILPITAS, CA 95035	CONTACT ULTRASOUND PROBE INTENDED TO REPLACE THE STATIONARY IN-LINE PROBE IN THE THERASONIC LITHOTRIPSY TREATMENT SYSTEM	10/29/92
P900001/S06	SGP 3 (UNIFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NJ	THREE ADDITIONAL MANUFACTURING AND DISTRIBUTION	10/02/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

DAILY WEAR (CLEAR, BLUE AND GREEN TINTED)	07751	FACILITIES

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

ORIGINAL VETERINARY NADAs

140-830	COBAN/ALBAC	CHICKENS	AL LABS	BACITRACIN
09-01-92	(PREMIX)		FT LEE, NJ	50GM/LB
		07024		MONENSIN SODIUM
				40GM/LB
140-830	COBAN/ALBAC	CHICKENS	AL LABS	BACITRACIN
09-01-92	(PREMIX)		FT LEE, NJ	50GM/LB
		07024		MONENSIN SODIUM
				60GM/LB

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR OCTOBER 1992.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR OCTOBER 1992.

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

ORIGINAL VETERINARY NADAs

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

ORIGINAL VETERINARY NADAs

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

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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

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

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

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

*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.

Volume 15 (11)
November 1992

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

19-700 11-09-92 (3 S)	ACULAR (DROPS/OPHTHALMIC)	SYNTEX PALO ALTO, CA 94304	KETOROLAC TROMETHAMINE 0.5% (NONSTEROIDAL ANTI-INFLAMMATORY)
83-220* 11-10-92 (SUPPL)	OGEN (TABLET)	ABBOTT ABBOTT PARK, IL 60064	ESTROPIPATE 0.75MG 1.5MG 3MG (NEW INDICATION -- PREVENTION OF OSTEOPOROSIS)
20-131 11-16-92	PROHANCE (INJECTABLE)	SQUIBB PRINCETON, NJ	GADOTERIDOL 279.3MG/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

(1 S) 08543 (MRI CONTRAST MEDIUM)

20-207	ALKERAN	BURROUGHS WELLCOME	MELPHALAN HYDROCHLORIDE
11-18-92	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 50MG BASE/VIAL
(3 P, V**)		27709	(ANTINEOPLASTIC)
			[PALLIATIVE TREATMENT
			OF MULTIPLE MYELOMA]

19-151	RYTHMOL	KNOLL	PROPAFENONE HYDROCHLORIDE
11-20-92	(TABLET)	WHIPPANY, NJ	225MG
(SUPPL)		07981	(NEW STRENGTH)

20-205	PSORCON	DERMIK	DIFLORASONE DIACETATE
11-20-92	(CREAM)	COLLEGEVILLE, PA	0.05%
(5 S)		19426	(CORTICOSTEROID)

* - Abbreviated NDA Supplement

19-487	IMODIUM A-D	MCNEIL	LOPERAMIDE HYDROCHLORIDE
11-23-92	(SOLUTION)	FORT WASHINGTON, PA	1MG/5ML
(SUPPL)		19034	(NEW INDICATION --
			TRAVELERS' DIARRHEA)
			(OTC)

19-591	LARIAM	ROCHE	MEFLOQUINE HYDROCHLORIDE
11-23-92	(TABLET)	NUTLEY, NJ	250MG
(SUPPL)		07110	(NEW DOSAGE REGIMEN --
			NEW MALARIA PROPHYLAXIS
			GUIDELINES)

19-860	IMODIUM A-D	MCNEIL	LOPERAMIDE HYDROCHLORIDE
11-23-92	(TABLET)	FORT WASHINGTON, PA	2MG
(SUPPL)		19034	(NEW INDICATION --
			TRAVELERS' DIARRHEA)
			(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

20-259	MEPRON	BURROUGHS WELLCOME	ATOVAQUONE
11-25-92	(TABLET)	RES TRIANGLE PK, NC	250MG
(1 P, AA***,V**)		27709	(ANTIPROTOZOAL)
			[TREATMENT OF MILD TO MODERATE PNEUMOCYSTIS CARINII PNEUMONIA IN PATIENTS WHO ARE INTOLERANT TO TRIMETHOPRIM-SULFAMETHOXAZOLE]
19-882	TECHNESCAN MAG3	MALLINCKRODT	TECHNETIUM TC-99M
11-27-92	(INJECTABLE)	SAINT LOUIS, MO	MERTIATIDE KIT
(SUPPL)		63134	N/A
			(NEW INDICATION -- RENAL IMAGING AGENT FOR USE IN CHILDREN)
20-014	MAXAIR	3M	PIRBUTEROL ACETATE
11-30-92	(AEROSOL, METERED)	SAINT PAUL, MN	EQ 0.2MG BASE/INH
(3 S)		55144	(BRONCHODILATOR)

V** - Designated Orphan Drug
AA*** - Priority Classification for AIDS Drug

20-161	POTASSIUM CHLORIDE	ABBOTT	POTASSIUM CHLORIDE
11-30-92	10MEQ	ABBOTT PARK, IL	745MG/100ML
(3 S)	IN PLASTIC CONTAINER (INJECTABLE)	60064	(ELECTROLYTE REPLENISHER)

20-161	POTASSIUM CHLORIDE	ABBOTT	POTASSIUM CHLORIDE
11-30-92	10MEQ	ABBOTT PARK, IL	14.9MG/ML
(3 S)	IN PLASTIC CONTAINER (INJECTABLE)	60064	(ELECTROLYTE REPLENISHER)

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-161 POTASSIUM CHLORIDE ABBOTT POTASSIUM CHLORIDE
11-30-92 20MEQ ABBOTT PARK, IL 1.49GM/100ML
(3 S) IN PLASTIC CONTAINER 60064 (ELECTROLYTE REPLENISHER)
(INJECTABLE)

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.

20-161 POTASSIUM CHLORIDE ABBOTT POTASSIUM CHLORIDE
11-05-92 10MEQ ABBOTT PARK, IL 745MG/100ML
IN PLASTIC CONTAINER 60064 (ELECTROLYTE REPLENISHER)
(INJECTABLE)

20-161 POTASSIUM CHLORIDE ABBOTT POTASSIUM CHLORIDE
11-05-92 10MEQ ABBOTT PARK, IL 14.9MG/ML
IN PLASTIC CONTAINER 60064 (ELECTROLYTE REPLENISHER)
(INJECTABLE)

20-161 POTASSIUM CHLORIDE ABBOTT POTASSIUM CHLORIDE
11-05-92 20MEQ ABBOTT PARK, IL 1.49MG/100ML
IN PLASTIC CONTAINER 60064 (ELECTROLYTE REPLENISHER)
(INJECTABLE)

20-186 ZIAC LEDERLE BISOPROLOL FUMARATE
11-18-92 (TABLET) PEARL RIVER, NY 5MG
10965 HYDROCHLOROTHIAZIDE
6.25MG
(ANTIHYPERTENSIVE)

20-186 ZIAC LEDERLE BISOPROLOL FUMARATE
11-18-92 (TABLET) PEARL RIVER, NY 10MG
10965 HYDROCHLOROTHIAZIDE

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

APPROVABLE ORIGINAL NDAs

			6.25MG
			(ANTIHYPERTENSIVE)
20-164	ENOXAPARIN	RHONE POULENC RORER	ENOXAPARIN SODIUM
11-20-92	(INJECTABLE)	FORT WASHINGTON, PA 19034	30MG/0.3ML
			(ANTICOAGULANT)
19-843	ISOLYTE S	MCGAW	DEXTROSE
11-30-92	W/DEXTROSE 5%	IRVINE, CA	5GM/100ML
	IN PLASTIC CONTAINER	92713	MAGNESIUM CHLORIDE
	(INJECTABLE)		30MG/100ML
			POTASSIUM CHLORIDE
			37MG/100ML
			SODIUM ACETATE
			370MG/100ML
			SODIUM CHLORIDE
			530MG/100ML
			SODIUM GLUCONATE
			500MG/100ML
			(ELECTROLYTE REPLENISHER)
19-844	ISOLYTE H	MCGAW	DEXTROSE
11-30-92	W/DEXTROSE 5%	IRVINE, CA	5GM/100ML
	IN PLASTIC CONTAINER	92713	MAGNESIUM CHLORIDE
	(INJECTABLE)		30MG/100ML
			POTASSIUM CHLORIDE
			97MG/100ML
			SODIUM ACETATE
			220MG/100ML
			SODIUM CHLORIDE
			140MG/100ML

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

APPROVABLE ORIGINAL NDAs

(ELECTROLYTE REPLENISHER)

19-864	ISOLYTE R	MCGAW	CALCIUM CHLORIDE
11-30-92	W/DEXTROSE 5%	IRVINE, CA	37MG/100ML
	IN PLASTIC CONTAINER	92713	DEXTROSE
	(INJECTABLE)		5GM/100ML
			MAGNESIUM CHLORIDE
			31MG/100ML
			POTASSIUM CHLORIDE
			120MG/100ML
			SODIUM ACETATE
			330MG/100ML
			SODIUM CHLORIDE
			88MG/100ML
			(ELECTROLYTE REPLENISHER)
19-870	ISOLYTE M	MCGAW	DEXTROSE
11-30-92	W/DEXTROSE 5%	IRVINE, CA	5GM/100ML
	IN PLASTIC CONTAINER	92713	POTASSIUM CHLORIDE
	(INJECTABLE)		150MG/100ML
			POTASSIUM PHOSPHATE, DIBASIC
			130MG/100ML
			SODIUM ACETATE

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

APPROVABLE ORIGINAL NDAs

			280MG/100ML
			SODIUM CHLORIDE
			91MG/100ML
			(ELECTROLYTE REPLENISHER)
19-873	ISOLYTE P	MCGAW	DEXTROSE
11-30-92	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 REPLENISHER)
20-080	IMITREX	GLAXO	SUMATRIPTAN SUCCINATE
11-30-92	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 12MG BASE/ML
		27709	(SEROTONIN AGONIST)
			[ACUTE TREATMENT
			OF MIGRAINE ATTACKS]

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

ORIGINAL ABBREVIATED NDAs

73-185*	DILTIAZEM HCL	MYLAN	DILTIAZEM HYDROCHLORIDE
11-05-92	(TABLET)	MORGANTOWN, WV	30MG
		26504	(CALCIUM ION
			INFLUX INHIBITOR)
73-186*	DILTIAZEM HCL	MYLAN	DILTIAZEM HYDROCHLORIDE
11-05-92	(TABLET)	MORGANTOWN, WV	60MG
		26504	(CALCIUM ION
			INFLUX INHIBITOR)
72-837*	DILTIAZEM HCL	MYLAN	DILTIAZEM HYDROCHLORIDE
11-05-92	(TABLET)	MORGANTOWN, WV	90MG
		26504	(CALCIUM ION
			INFLUX INHIBITOR)
72-838*	DILTIAZEM HCL	MYLAN	DILTIAZEM HYDROCHLORIDE
11-05-92	(TABLET)	MORGANTOWN, WV	120MG
		26504	(CALCIUM ION
			INFLUX INHIBITOR)
74-067*	DILTIAZEM HCL	COPLEY	DILTIAZEM HYDROCHLORIDE
11-05-92	(TABLET)	CANTON, MA	30MG
		02021	60MG
			90MG
			120MG
			(CALCIUM ION
			INFLUX INHIBITOR)
74-093*	DILTIAZEM HCL	LEDERLE	DILTIAZEM HYDROCHLORIDE
11-05-92	(TABLET)	PEARL RIVER, NY	30MG
		10965	60MG
			90MG
			120MG

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

ORIGINAL ABBREVIATED NDAs

(CALCIUM ION
INFLUX INHIBITOR)

* - First Time Product Available Generically

81-236*	THEOPHYLLINE	SIDMAK	THEOPHYLLINE
11-09-92	(TABLET, EXTENDED RELEASE)	EAST HANOVER, NJ 07936	450MG (BRONCHODILATOR)

73-562	DIFLUNISAL	ROXANE	DIFLUNISAL
11-27-92	(TABLET)	COLUMBUS, OH 43216	250MG (NONSTEROIDAL ANTI-INFLAMMATORY)

73-563	DIFLUNISAL	ROXANE	DIFLUNISAL
11-27-92	(TABLET)	COLUMBUS, OH 43216	500MG (NONSTEROIDAL ANTI-INFLAMMATORY)

89-779	PHENYTOIN SODIUM	MARSAM	PHENYTOIN SODIUM
11-27-92	(INJECTABLE)	CHERRY HILL, NJ 08034	50MG/ML (ANTICONVULSANT)

81-266	METHYLPREDNISOLONE SODIUM SUCCINATE	GENSIA	METHYLPREDNISOLONE SODIUM SUCCINATE
11-30-92	(INJECTABLE)	IRVINE, CA 92718	EQ 125MG BASE/VIAL (CORTICOSTEROID)

81-267	METHYLPREDNISOLONE	GENSIA	METHYLPREDNISOLONE
11-30-92	SODIUM SUCCINATE	IRVINE, CA	SODIUM SUCCINATE

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

ORIGINAL ABBREVIATED NDAs

	(INJECTABLE)	92718	EQ 500MG BASE/VIAL
			(CORTICOSTEROID)
81-268	METHYLPREDNISOLONE	GENSIA	METHYLPREDNISOLONE
11-30-92	SODIUM SUCCINATE	IRVINE, CA	SODIUM SUCCINATE
	(INJECTABLE)	92718	EQ 1GM BASE/VIAL
			(CORTICOSTEROID)

* - First Time Product Available Generically

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 Evaluations" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

74-032*	METOPROLOL TARTRATE	STERIS	METOPROLOL TARTRATE
11-13-92	(INJECTABLE)	PHOENIX, AZ	1MG/ML
	85063	(BETA ADRENERGIC BLOCKER)	

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

ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-763	IFEX	BRISTOL MYERS SQUIBB	IFOSFAMIDE
11-10-92	(INJECTABLE)	BUFFALO, NY	1GM/VIAL
		14213	3GM/VIAL
			(REVISED LABELING -- HOW SUPPLIED)
11-145*	DIURIL	MSD	CHLOROTHIAZIDE SODIUM
11-13-92	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
		19486	(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
16-273	LASIX	HOECHST ROUSSEL	FUROSEMIDE
11-13-92	(TABLET)	SOMERVILLE, NJ	20MG
		08876	40MG
			80MG
			(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
16-363	LASIX	HOECHST ROUSSEL	FUROSEMIDE
11-13-92	(INJECTABLE)	SOMERVILLE, NJ	10MG/ML
		08876	(REVISED LABELING -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
17-688	LASIX	HOECHST ROUSSEL	FUROSEMIDE
11-13-92	(SOLUTION)	SOMERVILLE, NJ	10MG/ML
		08876	(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
18-237	CALCIPARINE	DUPONT	HEPARIN CALCIUM

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

11-16-92	(INJECTABLE)	WILMINGTON, DE	25,000 UNITS/ML
		19880	(REVISED LABELING --
			PRECAUTIONS)

* Permitted

18-814	HEPARIN SODIUM 20,000	BAXTER	HEPARIN SODIUM
11-19-92	UNITS AND DEXTROSE 5%	ROUND LAKE, IL	4,000 UNITS/100ML
	IN PLASTIC CONTAINER	60073	(REVISED LABELING --
	(INJECTABLE)		DESCRIPTION; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)

18-814	HEPARIN SODIUM 25,000	BAXTER	HEPARIN SODIUM
11-19-92	UNITS AND DEXTROSE 5%	ROUND LAKE, IL	5,000 UNITS/100ML
	IN PLASTIC CONTAINER	60073	(REVISED LABELING --
	(INJECTABLE)		DESCRIPTION; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)

18-814	HEPARIN SODIUM 25,000	BAXTER	HEPARIN SODIUM
11-19-92	UNITS AND DEXTROSE 5%	ROUND LAKE, IL	10,000 UNITS/100ML
	IN PLASTIC CONTAINER	60073	(REVISED LABELING --
	(INJECTABLE)		DESCRIPTION; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)

19-151	RYTHMOL	KNOLL	PROPAFENONE HYDROCHLORIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

11-20-92	(TABLET)	WHIPPANY, NJ	150MG
		07981	225MG
			300MG
			(REVISED LABELING --
			DESCRIPTION;
			INDICATIONS AND USAGE;
			WARNINGS;
			ADVERSE REACTIONS;
			HOW SUPPLIED)

19-851	LOTENSIN	CIBA	BENAZEPRIL HYDROCHLORIDE
11-20-92	(TABLET)	SUMMIT, NJ	EQ 5MG BASE
		07901	EQ 10MG BASE
			EQ 20MG BASE
			EQ 40MG BASE
			(REVISED LABELING --
			PRECAUTIONS;
			ADVERSE REACTIONS;
			OVERDOSAGE;
			DOSAGE AND ADMINISTRATION)

19-487	IMODIUM A-D	MCNEIL	LOPERAMIDE HYDROCHLORIDE
11-23-92	(SOLUTION)	FORT WASHINGTON, PA	1MG/5ML
		19034	(REVISED LABELING --
			OTC LABELING - INDICATIONS)

19-591	LARIAM	ROCHE	MEFLOQUINE HYDROCHLORIDE
11-23-92	(TABLET)	NUTLEY, NJ	250MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		07110	(REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
19-860	IMODIUM A-D	MCNEIL	LOPERAMIDE HYDROCHLORIDE
11-23-92	(TABLET)	FORT WASHINGTON, PA	2MG
		19034	(REVISED LABELING -- OTC LABELING - INDICATIONS)
50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
11-23-92	(INJECTABLE)	WEST POINT, PA	EQ 250MG BASE/VIAL
		19486	IMIPENEM 250MG/VIAL (REVISED LABELING -- ADVERSE REACTIONS)
50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
11-23-92	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
		19486	IMIPENEM 500MG/VIAL (REVISED LABELING -- ADVERSE REACTIONS)
50-630	PRIMAXIN	MSD	CILASTATIN SODIUM
11-23-92	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
		19486	IMIPENEM 500MG/VIAL (REVISED LABELING -- 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

50-630	PRIMAXIN	MSD	CILASTATIN SODIUM
11-23-92	(INJECTABLE)	WEST POINT, PA	EQ 750MG BASE/VIAL
	19486		IMIPENEM
			750MG/VIAL
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			ADVERSE REACTIONS)
18-163	RESTORIL	SANDOZ	TEMAZEPAM
11-25-92	(CAPSULE)	EAST HANOVER, NJ	7.5MG
	07936		15MG
			30MG
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS;
			PATIENT PACKAGE INSERT)
17-247	SANOREX	SANDOZ	MAZINDOL
11-27-92	(TABLET)	EAST HANOVER, NJ	1MG
	07936		2MG
			(REVISED LABELING --
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DRUG ABUSE AND DEPENDENCE;
			OVERDOSAGE;
			DOSAGE AND ADMINISTRATION)
19-643	MEVACOR	MERCK	LOVASTATIN
11-27-92	(TABLET)	WEST POINT, PA	10MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		19486	20MG 40MG (REVISED LABELING -- PRECAUTIONS)
19-766	ZOCOR	MERCK	SIMVASTATIN
11-27-92	(TABLET)	WEST POINT, PA	5MG
		19486	10MG 20MG 40MG (REVISED LABELING -- PRECAUTIONS)
19-882	TECHNESCAN MAG3	MALLINCKRODT	TECHNETIUM TC-99M
11-27-92	(INJECTABLE)	SAINT LOUIS, MO	MERTIATIDE KIT
		63134	N/A (REVISED LABELING -- INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
18-353	FLAGYL I.V.	SCHIAPPARELLI SEARLE	METRONIDAZOLE HYDROCHLORIDE
11-30-92	(INJECTABLE)	SKOKIE, IL	EQ 500MG BASE/VIAL
		60077	(REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)
18-353	FLAGYL I.V. RTU	SCHIAPPARELLI SEARLE	METRONIDAZOLE
11-30-92	IN PLASTIC CONTAINER	SKOKIE, IL	500MG/100ML
	(INJECTABLE)	60077	(REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1162	NONE	LORAIN CNTY BLOOD BANK	PLASMA
11-13-92	(INJECTABLE)	ELYRIA, OH 44035	(TRANSFUSION) (A&B)
1162	NONE	LORAIN CNTY BLOOD BANK	PLATELETS
11-13-92	(INJECTABLE)	ELYRIA, OH 44035	(TRANSFUSION) (A&B)
1162	NONE	LORAIN CNTY BLOOD BANK	RED BLOOD CELLS
11-13-92	(INJECTABLE)	ELYRIA, OH 44035	(TRANSFUSION) (A&B)
1162	NONE	LORAIN CNTY BLOOD BANK	WHOLE BLOOD
11-13-92	(INJECTABLE)	ELYRIA, OH 44035	(TRANSFUSION) (A&B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910020	COBE SPECTRATHERM	COBE BCT	BLOOD AND PLASMA
11/02/92		LAKEWOOD, CO 80215 (C)	WARMING DEVICE
BK900015	INVERNESS BLOOD	IBG SYS	AUTOMATED BLOOD GROUPING
11/05/92	GROUPING SYSTEMS FOR "PATIENT" & "PRE-NATAL" GROUPING	LAYTONSVILLE, MD 20882 (C)	& ANTIBODY TEST SYSTEMS
BK910024	SEBRA MODEL 2100	ENGINEERING AND	HEAT SEALING DEVICE
11/05/92	TUBE SEALER	RES ASSOC (C) TUCSON, AZ 85716	
BK910025	SEBRA MODEL 1440	ENGINEERING AND	BLOOD BANK SUPPLIES
11/05/92	BLOOD SHAKER/ WEIGHT MONITOR	RES ASSOC (C) TUCSON, AZ 85716	
BK910026	SEBRA MODEL 2590	ENGINEERING AND	HEAT SEALING DEVICE
11/05/92	HAND HELD TUBE SEALER	RES ASSOC (C) TUCSON, AZ 85716	

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

P900023 11/20/92	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	APPROVAL FOR THE ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM

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

N17755/S41	ZIMMER DOUGH TYPE & L.V.C. BONE CEMENT	ZIMMER, INC. WARSAW, IN 46581-0708	ADDITION OF SCHOTT-WEST GLASS AS ANOTHER VENDOR FOR GLASS AMPULES	11/25/92
N50510/S51	VITEK SYSTEMS GENERAL SUSCEPTIBILITY CARD	BIOMERIEUX VITEK, INC. HAZELWOOD, MO 63042-2395	SOFTWARE COEFFICIENT CHANGES	11/19/92
P790018/S19	MEDTRONIC HALL PROSTHETIC HEART VALVE, 22 MM AORTIC VALVE	MEDTRONIC HEART VALVES MINNEAPOLIS, MN 55440	22 MM AORTIC MEDTRONIC HALL VALVE AND CORRESPONDING VALVE SIZER	11/06/92
P800041/S12	SIEMENS-ELEMA ENDOCARDIAL CARBON TIPPED LEADS	PACESETTER SYSTEMS, INC. SYLMAR, CA 91392-9221	ALTERNATIVE TRAY MATERIAL	11/18/92
P810046/S133	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS RX PERFUSION CORONARY DILATATION CATHETER WITH QUARTER SIZE BALLOONS	ADVANCED CARDIOVASCULAR SANTA CLARA, CA 95052-8167	MODIFIED ACS RX PERFUSION CORONARY DILATATION CATHETER WITH QUARTER SIZE BALLOONS	11/05/92
P810055/S44	ULTRAVIOLET-ABSORBING MODEL 720M	KABI PHARMACIA OPHTHALMICS INC. MONROVIA, CA	MODEL 720M LENS TO BE MANUFACTURED ENTIRELY AT PHARMACIA	11/06/92

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	POSTERIOR CHAMBER INTRAOCULAR LENS	91017-7136	PRODUCTION B.V., CRONINGEN, THE NETHERLANDS	
P820003/S64	MEDTRONIC MODELS 9710/9710A PROGRAMMING SYSTEM AND CPI MODEL 2038 PROGRAMMING SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	PRODUCTION MODIFICATION	11/16/92
P820049/S54	ETHYLENE OXIDE STERILIZATION OF INTRAOCULAR LENSES	ALLERGAN MEDICAL OPTICS SANTA ANA, CA 92799-5155	ALTERNATIVE ETHYLENE OXIDE STERILIZATION PROCESS AND STERILIZING IN THE FINAL PACKAGE ASSEMBLY	11/09/92
P820049/S55	INTRAOCULAR LENSES (IOLS): ALTERNATE STERILIZATION PROCESSES	ALLERGAN MEDICAL OPTICS SANTA ANA, CA 92799-5155	ALTERNATIVE ETHYLENE OXIDE STERILIZATION PROCESS AND STERILIZING IN THE FINAL PACKAGING ASSEMBLY	11/09/92
P820056/S53	OPTACRYL 60 (KOLFOCON A) RIGID GAS PERMEABLE CONTACT LENS	PARAGON OPTICAL MESA, AZ 85204	THREE ADDITIONAL LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND	11/25/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

DISTRIBUTION SITES

P830045/S39	AFP PACING SYSTEMS	PACESETTER SYSTEMS, INC. SYLMAR, CA 91392-9221	ALTERNATIVE TRAY MATERIAL	11/18/92
P840040/S33	HEART TRAK CORONARY BALLOON DILATATION CATHETER SYSTEM, SLIDER LONG BALLOON DILATATION CATHETER WITH 2.0MM BALLOON	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	ADDITION OF THE 2.0MM BALLOON TO THE SLIDER LONG BALLOON DILATATION CATHETER	11/20/92
P840055/S27	SGP (TELEFOCON A) AND SGPII (TELEFOCON B) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR, BLUE AND GREEN TINTED)	PERMEABLE TECHNOLOGIES, INC. MORGANVILLE, NJ 07751	FOUR ADDITIONAL LENS FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	11/30/92
P850023/S10	HEMAFLEX ABSORBABLE COLLAGEN HEMOSTAT	BIOPLEX CORPORATION MONTVALE, NJ 07645	HEMAFLEX ABSORBABLE COLLAGEN HEMOSTAT TO BE USED AS AN ADJUNCT TO HEMOSTASIS WHEN CONTROL OF BLEEDING BY OTHER METHODS IS INEFFECTIVE OR IMPRACTICAL	11/16/92
P850038/S20	PARAPERM EW	PARAGON OPTICAL	THREE ADDITIONAL LENS	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	(PASIFOCON C) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	MESA, AZ 85204	FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	11/25/92
P850051/S36	ACTIVITRAX PACING SYSTEM/MICRO MINIX AND LEGEND PULSE GENERATORS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	INCORPORATION OF A SPOT WELD BETWEEN THE MULTI-BEAM CONTACT AND THE BARREL IT LIES WITHIN	11/05/92
P860022/S36	BOSTON EQUALENS (ITAFLUOROFOCON A) RIGID GAS PERMEABLE CONTACT LENS, BOSTON RXD (ITABISFLUOROFOCON A) BIFOCAL RIGID GAS PERMEABLE CONTACT LENS	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	FOR SIX BIFOCAL LENS DESIGNS MANUFACTURED FROM THE BOSTON RXD (ITABISFLUOROFOCON A) CONTACT LENS MATERIAL	11/05/92
P860034/S09	ETHYLENE OXIDE STERILIZATION OF INTRAOCULAR LENSES	ALLERGAN MEDICAL OPTICS SANTA ANA, CA 92799-5155	ALTERNATIVE ETHYLENE OXIDE STERILIZATION PROCESS AND STERILIZING IN THE FINAL PACKAGE ASSEMBLY	11/09/92
P860034/S10	INTRAOCULAR LENSES (IOLS): ALTERNATE	ALLERGAN MEDICAL OPTICS SANTA ANA, CA 92799-5155	ALTERNATIVE ETHYLENE OXIDE STERILIZATION PROCESS AND	11/09/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	STERILIZATION PROCESSES		STERILIZING IN THE FINAL PACKAGING ASSEMBLY
P860059/S67 11/06/92	TIER A REQUEST FOR MODEL UPB350FS ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	APPROVAL FOR MODEL UPB350FS ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS
P870024/S34 11/25/92	FLUOROPERM 92 (PAFLUFOCON A), FLUOROPERM 60 (PAFLUFOCON B), FLUOROPERM 30 (PAFLUFOCON C) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	THREE ADDITIONAL LENS FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P880006/S14 11/18/92	SENSOLOG PACING SYSTEMS	PACESETTER SYSTEMS, INC. SYLMAR, CA 91392-9221	ALTERNATIVE TRAY MATERIAL
P880081/S13 11/09/92	ETHYLENE OXIDE STERILIZATION OF INTRAOCULAR LENSES	ALLERGAN MEDICAL OPTICS SANTA ANA, CA 92799-5155	ALTERNATIVE ETHYLENE OXIDE STERILIZATION PROCESS AND STERILIZING IN THE FINAL PACKAGE ASSEMBLY
P880081/S14 11/09/92	INTRAOCULAR LENSES (IOLS):	ALLERGAN MEDICAL OPTICS SANTA ANA, CA	ALTERNATIVE ETHYLENE OXIDE STERILIZATION

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	ALTERNATE STERILIZATION PROCESSES	92799-5155	PROCESS AND STERILIZING IN THE FINAL PACKAGING ASSEMBLY
P880086/S18 11/18/92	SYNCHRONY II AND SOLUS PACING SYSTEMS	PACESETTER SYSTEMS, INC. SYLMAR, CA 91392-9221	ALTERNATIVE TRAY MATERIAL
P890003/S18 11/05/92	SYNERGYST PACING SYSTEM/ELITE MINUET AND PRELUDE DR PULSE GENERATORS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	INCORPORATION OF A SPOT WELD BETWEEN THE MULTI-BEAM CONTACT AND THE BARREL IT LIES WITHIN
P890032/S16 11/06/92	CORDIS ORION STEERABLE PTCA BALLOON CATHETER, CORDIS SOFT-WIRE ORION STEERABLE PTCA BALLOON CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	FOR A NEW FORMING TUBE MATERIAL, OPTIONAL HYDROMER COATING, REVISED LABELING AND IMPLEMENTATION OF A SEMI-AUTOMATED BALLOON FOLDING

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

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR NOVEMBER 1992.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR NOVEMBER 1992.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR NOVEMBER 1992.

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) 295-8428

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

*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.

Volume 15 (12)
December 1992

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

20-163 12-04-92 (5 S)	DIANEAL PD-2 W/DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION)	BAXTER MCGAW PARK, IL 60085	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 1.5GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (PERITONEAL DIALYSATE)
20-163 12-04-92 (5 S)	DIANEAL PD-2 W/DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION)	BAXTER MCGAW PARK, IL 60085	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 2.5GM/100ML MAGNESIUM CHLORIDE

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

			5.08MG/100ML
			SODIUM CHLORIDE
			538MG/100ML
			SODIUM LACTATE
			448MG/100ML
			(PERITONEAL DIALYSATE)
20-163	DIANEAL PD-2	BAXTER	CALCIUM CHLORIDE
12-04-92	W/DEXTROSE 4.25%	MCGAW PARK, IL	25.7MG/100ML
(5 S)	IN PLASTIC CONTAINER	60085	DEXTROSE
	(SOLUTION)		4.25GM/100ML
			MAGNESIUM CHLORIDE
			5.08MG/100ML
			SODIUM CHLORIDE
			538MG/100ML
			SODIUM LACTATE
			448MG/100ML
			(PERITONEAL DIALYSATE)
20-183	DIANEAL LOW CALCIUM	BAXTER	CALCIUM CHLORIDE
12-04-92	W/DEXTROSE 1.5%	MCGAW PARK, IL	18.3MG/100ML
(5 S)	IN PLASTIC CONTAINER	60085	DEXTROSE
	(SOLUTION)		1.5GM/100ML
			MAGNESIUM CHLORIDE
			5.08MG/100ML

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

			SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (PERITONEAL DIALYSATE)
20-183 12-04-92 (5 S)	DIANEAL LOW CALCIUM W/DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION)	BAXTER MCGAW PARK, IL 60085	CALCIUM CHLORIDE 18.3MG/100ML DEXTROSE 2.5GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (PERITONEAL DIALYSATE)
20-183 12-04-92 (5 S)	DIANEAL LOW CALCIUM W/DEXTROSE 3.5% IN PLASTIC CONTAINER (SOLUTION)	BAXTER MCGAW PARK, IL 60085	CALCIUM CHLORIDE 18.3MG/100ML DEXTROSE 3.5GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (PERITONEAL DIALYSATE)

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

20-183	DIANEAL LOW CALCIUM	BAXTER	CALCIUM CHLORIDE
12-04-92	W/DEXTROSE 4.25%	MCGAW PARK, IL	18.3MG/100ML
(5 S)	IN PLASTIC CONTAINER	60085	DEXTROSE
	(SOLUTION)		4.25GM/100ML
			MAGNESIUM CHLORIDE
			5.08MG/100ML
			SODIUM CHLORIDE
			538MG/100ML
			SODIUM LACTATE
			448MG/100ML
			(PERITONEAL DIALYSATE)
19-891	DILAUDID	KNOLL	HYDROMORPHONE HYDROCHLORIDE
12-07-92	(SOLUTION)	WHIPPANY, NJ	5MG/5ML
(3 S)		07981	(ANALGESIC)
19-892	DILAUDID	KNOLL	HYDROMORPHONE HYDROCHLORIDE
12-07-92	(TABLET)	WHIPPANY, NJ	8MG
(3 S)		07981	(ANALGESIC)
20-045	SHADE UVAGUARD	PLOUGH	AVOBENZONE
12-07-92	(LOTION)	MEMPHIS, TN	3%
(4 S)		38151	OCTYL METHOXYCINNAMATE
			7.5%
			OXYBENZONE
			3%
			(SUNSCREEN)
			(OTC)
20-178	SODIUM CHLORIDE 0.9%	BAXTER	SODIUM CHLORIDE
12-07-92	IN PLASTIC CONTAINER	ROUND LAKE, IL	9MG/ML
(5 S)	(INJECTABLE)	60073	900MG/100ML
			(ELECTROLYTE REPLENISHER)
20-179	DEXTROSE 5%	BAXTER	DEXTROSE

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

12-07-92	IN PLASTIC CONTAINER	ROUND LAKE, IL	50MG/ML
(5 S)	(INJECTABLE)	60073	5GM/100ML
			(FLUID AND NUTRIENT REPLENISHER)
19-617	PREPIDIL	UPJOHN	DINOPROSTONE
12-09-92	(GEL)	KALAMAZOO, MI	0.5MG/3GM
(3 S)		49001	(PROSTAGLANDIN) [CERVICAL RIPENING]
20-071	DESOGEN	ORGANON	DESOGESTREL
12-10-92	(TABLET-21 DAY)	WEST ORANGE, NJ	0.15MG
(1, 4 S)		07052	ETHINYL ESTRADIOL 0.03MG (HORMONAL CONTRACEPTIVE)
20-071	DESOGEN	ORGANON	DESOGESTREL
12-10-92	(TABLET-28 DAY)	WEST ORANGE, NJ	0.15MG
(1, 4 S)		07052	ETHINYL ESTRADIOL 0.03MG (HORMONAL CONTRACEPTIVE)
19-710	OPTIRAY 320	MALLINCKRODT	IOVERSOL
12-11-92	(INJECTABLE)	SAINT LOUIS, MO	68%
(SUPPL)		63134	(NEW INDICATION -- ANGIOCARDIOGRAPHY, CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE HEAD AND BODY, AND INTRAVENOUS EXCRETORY UROGRAPHY IN CHILDREN)
20-301	ORTHO-CEPT	JOHNSON RW	DESOGESTREL
12-14-92	(TABLET-21 DAY)	RARITAN, NJ	0.15MG
(5 S)		08869	ETHINYL ESTRADIOL 0.03MG (HORMONE CONTRACEPTIVE)

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

20-301	ORTHO-CEPT	JOHNSON RW	DESOGESTREL
12-14-92	(TABLET-28 DAY)	RARITAN, NJ	0.15MG
(5 S)		08869	ETHINYL ESTRADIOL
			0.03MG
			(HORMONE CONTRACEPTIVE)
20-021	PSEUDOEPHEDRINE HCL	ALZA	PSEUDOEPHEDRINE
12-15-92	(TABLET,	PALO ALTO, CA	HYDROCHLORIDE
(3 S)	EXTENDED RELEASE)	94304	240MG
			(DECONGESTANT)
			(OTC)
50-006	VIBRAMYCIN	PFIZER	DOXYCYCLINE
12-15-92	(POWDER	NEW YORK, NY	EQ 25MG BASE/5ML
(SUPPL)	FOR RECONSTITUTION)	10017	(NEW INDICATION --
			PROPHYLAXIS OF MALARIA)
50-007	VIBRAMYCIN	PFIZER	DOXYCYCLINE HYCLATE
12-15-92	(CAPSULE)	NEW YORK, NY	EQ 50MG BASE
(SUPPL)		10017	EQ 100MG BASE
			(NEW INDICATION --
			PROPHYLAXIS OF MALARIA)
50-480	VIBRAMYCIN	PFIZER	DOXYCYCLINE CALCIUM
12-15-92	(SUSPENSION)	NEW YORK, NY	EQ 50MG BASE/5ML
(SUPPL)		10017	(NEW INDICATION --
			PROPHYLAXIS OF MALARIA)
50-533	VIBRA-TABS	PFIZER	DOXYCYCLINE HYCLATE
12-15-92	(TABLET)	NEW YORK, NY	EQ 100MG BASE
(SUPPL)		10017	(NEW INDICATION --
			PROPHYLAXIS OF MALARIA)
18-948	CARNITOR	SIGMA TAU	LEVOCARNITINE
12-16-92	(TABLET)	GAITHERSBURG, MD	330MG
(SUPPL)		20878	(NEW INDICATION --
			TREATMENT OF SECONDARY

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

			CARNITINE DEFICIENCY)
18-948	CARNITOR	SIGMA TAU	LEVOCARNITINE
12-16-92	(SOLUTION)	GAITHERSBURG, MD	1GM/10ML
(SUPPL)		20878	(NEW INDICATION -- TREATMENT OF SECONDARY CARNITINE DEFICIENCY)
19-908	AMBIEN	LOREX	ZOLPIDEM TARTRATE
12-16-92	(TABLET)	SKOKIE, IL	5MG
(1 S)		60077	10MG
			(HYPNOTIC)
20-182	CARNITOR	SIGMA TAU	LEVOCARNITINE
12-16-92	(INJECTABLE)	GAITHERSBURG, MD	200MG/ML
(3 P, V*)		20878	(CARNITINE REPLENISHER) [TREATMENT OF SECONDARY CARNITINE DEFICIENCY]
19-386	BREVIBLOC	DUPONT	ESMOLOL HYDROCHLORIDE
12-18-92	(INJECTABLE)	WILMINGTON, DE	10MG/ML
(SUPPL)		19880	250MG/ML
			(NEW INDICATION -- INTRAOPERATIVE AND POSTOPERATIVE TACHYCARDIA AND/OR HYPERTENSION)
19-386	BREVIBLOC	DUPONT	ESMOLOL HYDROCHLORIDE
12-18-92	(INJECTABLE)	WILMINGTON, DE	10MG/ML
(SUPPL)		19880	250MG/ML
			(NEW DOSAGE REGIMEN -- BOLUS DOSING)

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

18-651	MARINOL	UNIMED	DRONABINOL
12-22-92	(CAPSULE)	SOMERVILLE, NJ	2.5MG
(SUPPL, V*)		08876	5MG
			10MG
			(NEW INDICATION -- TREATMENT OF ANOREXIA ASSOCIATED WITH WEIGHT LOSS IN PATIENTS WITH AIDS)

V* - Designated Orphan Drug

19-604	VOLMAX	GLAXO	ALBUTEROL SULFATE
12-23-92	(TABLET,	RES TRIANGLE PK, NC	EQ 4MG BASE
(3 S)	EXTENDED RELEASE)	27709	EQ 8MG BASE
			(BRONCHODILATOR)

50-689	MYCOBUTIN	ADRIA	RIFABUTIN
12-23-92	(CAPSULE)	COLUMBUS, OH	150MG
(1 P, V*)		43216	(ANTIMYCOBACTERIAL)
			[PREVENTION OF DISSEMINATED MYCOBACTERIUM AVIUM COMPLEX DISEASE IN PATIENTS WITH ADVANCED HIV INFECTIONS]

20-080	IMITREX	GLAXO	SUMATRIPTAN SUCCINATE
12-28-92	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 6MG/0.5ML
(1 P)		27709	(SEROTONIN AGONIST)
			[ACUTE TREATMENT OF MIGRAINE ATTACKS]

20-031	PAXIL	SMITHKLINE BEECHAM	PAROXETINE HYDROCHLORIDE
12-29-92	(TABLET)	KING OF PRUSSIA, PA	EQ 10MG BASE
(1 S)		19406	EQ 20MG BASE
			EQ 30MG BASE
			EQ 40MG BASE
			EQ 50MG 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

			(ANTIDEPRESSANT)
20-262	TAXOL	BRISTOL MYERS SQUIBB	PACLITAXEL
12-29-92	(INJECTABLE)	WALLINGFORD, CT	6MG/ML
(1 P)		06492	(ANTINEOPLASTIC)
			[METASTATIC CARCINOMA OF THE OVARY AFTER FAILURE OF FIRST-LINE CHEMOTHERAPY]
50-683	ZEFAZONE	UPJOHN	CEFMETAZOLE SODIUM
12-29-92	IN PLASTIC CONTAINER	KALAMAZOO, MI	EQ 20MG BASE/ML
(3 S)	(INJECTABLE)	49001	EQ 40MG BASE/ML
			(ANTIBIOTIC, CEPHEM)

V* - Designated Orphan Drug

19-660	TILADE	FISONS	NEDOCROMIL SODIUM
12-30-92	(AEROSOL, METERED)	ROCHESTER, NY	1.75MG/INH
(1 S)		14603	(ANTI-INFLAMMATORY)
			[MAINTENANCE THERAPY IN THE MANAGEMENT OF MILD TO MODERATE BRONCHIAL ASTHMA]
19-941	EMLA	ASTRA	LIDOCAINE
12-30-92	(CREAM)	WESTBOROUGH, MA	2.5%
(3 S)		01581	PRILOCAINE
			2.5%
			(TOPICAL ANESTHETIC)
19-960	MANOPLAX	BOOTS	FLOSEQUINAN
12-30-92	(TABLET)	SHREVEPORT, LA	50MG
(1 S)		71106	75MG
			100MG
			125MG*

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

(VASODILATOR)
[MANAGEMENT OF CONGESTIVE
HEART FAILURE]

20-192 LAMISIL SANDOZ TERBINAFINE HYDROCHLORIDE
12-30-92 (CREAM) EAST HANOVER, NJ 1%
(1 S) 07936 (ANTIFUNGAL)

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

20-103 ZOFRAN GLAXO ONDANSETRON HYDROCHLORIDE
12-31-92 (TABLET) RES TRIANGLE PK, NC EQ 4MG/BASE
(3 P) 27709 EQ 8MG/BASE
(ANTIEMETIC)

* - Not Marketed at This Time
50-664 CEFZIL BRISTOL MYERS SQUIBB CEFPROZIL
12-31-92 (TABLET) WALLINGFORD, CT 250MG
(SUPPL) 06492 500MG
(EXPANDED INDICATION --
PHARYNGITIS/TONSILLITIS
CAUSED BY STREPTOCOCCUS
PYOGENES INDICATION
EXPANDED TO INCLUDE PEDIATRIC
PATIENTS AGE
2 YEARS TO 12 YEARS)

50-665 CEFZIL BRISTOL MYERS SQUIBB CEFPROZIL
12-31-92 (SUSPENSION) WALLINGFORD, CT 125MG/5ML

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)	06492	250MG/5ML (EXPANDED INDICATION -- PHARYNGITIS/TONSILLITIS CAUSED BY STREPTOCOCCUS PYOGENES INDICATION EXPANDED TO INCLUDE	PEDIATRIC PATIENTS AGE 2 YEARS TO 12 YEARS)

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.

19-891 11-20-92	DILAUDID (LIQUID)	KNOLL WHIPPANY, NJ 07981	HYDROMORPHONE HYDROCHLORIDE 1MG/ML (ANALGESIC)
50-694 12-16-92	CEFOTAN IN PLASTIC CONTAINER (INJECTABLE)	ICI WILMINGTON, DE 19897	CEFOTETAN DISODIUM 20MG/ML 40MG/ML (ANTIBIOTIC, CEPHEM)
19-960 12-23-92	MANOPLAX (TABLET)	BOOTS SHREVEPORT, LA 71106	FLOSEQUINAN 50MG 75MG 100MG 125MG (VASODILATOR) [MANAGEMENT OF CONGESTIVE HEART FAILURE]
19-921 12-30-92	OCUFLOX (SOLUTION)	ALLERGAN IRVINE, CA 92713	OFLOXACIN 0.3% (ANTIBACTERIAL)

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

ORIGINAL ABBREVIATED NDAs

74-091	LOPERAMIDE HCL	OHM	LOPERAMIDE HYDROCHLORIDE
12-10-92	(TABLET)	FRANKLIN PARK, NJ	2MG
		08823	(ANTIDIARRHEAL)
			(OTC)
74-131	PIROXICAM	LEMMON	PIROXICAM
12-11-92	(CAPSULE)	SELLERSVILLE, PA	10MG
		18960	20MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
64-013	AMOXICILLIN	BIOCRAFT	AMOXICILLIN
12-22-92	(TABLET, CHEWABLE)	FAIR LAWN, NJ	250MG
		07410	(ANTIBIOTIC, PENICILLIN)
73-515*	KETOPROFEN	BIOCRAFT	KETOPROFEN
12-22-92	(CAPSULE)	FAIR LAWN, NJ	25MG
		07410	(NONSTEROIDAL
			ANTI-INFLAMMATORY)
73-516*	KETOPROFEN	BIOCRAFT	KETOPROFEN
12-22-92	(CAPSULE)	FAIR LAWN, NJ	50MG
		07410	(NONSTEROIDAL
			ANTI-INFLAMMATORY)
73-517*	KETOPROFEN	BIOCRAFT	KETOPROFEN
12-22-92	(CAPSULE)	FAIR LAWN, NJ	75MG
		07410	(NONSTEROIDAL
			ANTI-INFLAMMATORY)
73-696*	NITROFURANTOIN,	DANBURY	NITROFURANTOIN
12-31-92	MACROCRYSTALLINE	DANBURY, CT	25MG
	(CAPSULE)	06813	50MG

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
		ORIGINAL ABBREVIATED NDAs	
			100MG (ANTIBACTERIAL)
* - First Time Product Available Generically			
74-054 12-31-92	NORTRIPTYLINE HCL (CAPSULE)	GENEVA BROOMFIELD, CO 80038	NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE EQ 25MG BASE EQ 50MG BASE EQ 75MG BASE (ANTIDEPRESSANT)

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.

20-201	DOBUTAMINE	ABBOTT	DOBUTAMINE
12-18-92	IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT PK, IL 60064	50MG/100ML 100MG/100ML 200MG/100ML (VASODILATOR, INOTROPIC, ADRENERGIC)
20-269	DOBUTAMINE	ABBOTT	DOBUTAMINE
12-18-92	IN DEXTROSE 5% (INJECTABLE)	ABBOTT PK, IL 60064	50MG/100ML 100MG/100ML 200MG/100ML (VASODILATOR, INOTROPIC, ADRENERGIC)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

16-151	UREX	3M	METHENAMINE HIPPURATE
11-10-92	(TABLET)	SAINT PAUL, MN	1GM
		55144	(REVISED LABELING -- CLINICAL PHARMACOLOGY; PRECAUTIONS)
18-276	XANAX	UPJOHN	ALPRAZOLAM
12-01-92	(TABLET)	KALAMAZOO, MI	0.25MG
		49001	0.5MG
			1MG
			2MG
			(REVISED LABELING -- ADVERSE REACTIONS; HOW SUPPLIED)
18-422	LOPID	PARKE DAVIS	GEMFIBROZIL
12-02-92	(TABLET)	MORRIS PLAINS, NJ	600MG
		07950	(REVISED LABELING -- PRECAUTIONS)
50-624	ROCEPHIN W/ DEXTROSE	ROCHE	CEFTRIAXONE SODIUM
12-04-92	IN PLASTIC CONTAINER	NUTLEY, NJ	EQ 20MG BASE/ML
	(INJECTABLE)	07110	EQ 40MG BASE/ML
			(REVISED LABELING -- INDICATIONS AND USAGE)
11-838	TOFRANIL	GEIGY	IMIPRAMINE HYDROCHLORIDE
12-08-92	(INJECTABLE)	ARDSLEY, NY	12.5MG/ML
		10502	(REVISED LABELING -- PRECAUTIONS)
17-090	TOFRANIL-PM	GEIGY	IMIPRAMINE PAMOATE
12-08-92	(CAPSULE)	ARDSLEY, NY	EQ 75MG HCL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		10502	EQ 100MG HCL EQ 125MG HCL EQ 150MG HCL (REVISED LABELING -- PRECAUTIONS)
16-118	TESLAC	SQUIBB	TESTOLACTONE
12-09-92	(TABLET)	NEW BRUNSWICK, NJ 08903	50MG (REVISED LABELING -- USP REQUIREMENTS STATEMENT)
19-979	TICLID	SYNTEX	TICLOPIDINE HYDROCHLORIDE
12-10-92	(TABLET)	PALO ALTO, CA 94304	250MG (REVISED LABELING -- WARNINGS; PRECAUTIONS)
17-422	BICNU	BRISTOL	CARMUSTINE
12-11-92	(INJECTABLE)	SYRACUSE, NY 13221	100MG/VIAL (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
18-632	STERILE WATER FOR INJECTION IN PLASTIC CONTAINER	BAXTER	WATER FOR INJECTION, STERILE
12-11-92	(INJECTABLE)	ROUND LAKE, IL 60073	100% (REVISED LABELING -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
18-684	BRANCHAMIN 4% IN PLASTIC CONTAINER	BAXTER	AMINO ACIDS
12-11-92	(INJECTABLE)	ROUND LAKE, IL 60073	4% (REVISED LABELING -- DESCRIPTION;

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
			DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
18-931 12-11-92	TRAVASOL 5.5% IN PLASTIC CONTAINER (INJECTABLE)	BAXTER ROUND LAKE, IL 60073	AMINO ACIDS 5.5% (REVISED LABELING -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
18-931 12-11-92	TRAVASOL 8.5% IN PLASTIC CONTAINER (INJECTABLE)	BAXTER ROUND LAKE, IL 60073	AMINO ACIDS 8.5% (REVISED LABELING -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
18-931 12-11-92	TRAVASOL 10% IN PLASTIC CONTAINER (INJECTABLE)	BAXTER ROUND LAKE, IL 60073	AMINO ACIDS 10% (REVISED LABELING -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-710 12-11-92	OPTIRAY 160 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	IOVERSOL 34% (REVISED LABELING -- INDICATIONS AND USAGE; 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;
			DOSAGE AND ADMINISTRATION)
19-710	OPTIRAY 240	MALLINCKRODT	IOVERSOL
12-11-92	(INJECTABLE)	SAINT LOUIS, MO	51%
		63134	(REVISED LABELING --
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-710	OPTIRAY 320	MALLINCKRODT	IOVERSOL
12-11-92	(INJECTABLE)	SAINT LOUIS, MO	68%
		63134	(REVISED LABELING --
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
19-757	CHIBROXIN	MERCK	NORFLOXACIN
12-11-92	(SOLUTION/DROPS)	WEST POINT, PA	0.3%
		19486	(REVISED LABELING --
			ADDITIONAL CAUTIONARY
			INFORMATION)
08-107	LEUCOVORIN CALCIUM	LEDERLE	LEUCOVORIN CALCIUM
12-15-92	(INJECTABLE)	PEARL RIVER, NY	EQ 3MG BASE/ML
		10965	EQ 50MG BASE/VIAL
			EQ 100MG BASE/VIAL
			EQ 350MG BASE/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	
			CLINICAL PHARMACOLOGY; WARNINGS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
20-073 12-15-92	MAZICON (INJECTABLE)	ROCHE NUTLEY, NJ 07110	FLUMAZENIL 0.1MG/ML (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
50-006 12-15-92	VIBRAMYCIN (POWDER FOR RECONSTITUTION)	PFIZER NEW YORK, NY 10017	DOXYCYCLINE EQ 25MG BASE/5ML (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
50-007 12-15-92	VIBRAMYCIN (CAPSULE)	PFIZER NEW YORK, NY 10017	DOXYCYCLINE HYCLATE EQ 50MG BASE EQ 100MG BASE (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
50-480 12-15-92	VIBRAMYCIN (SUSPENSION)	PFIZER NEW YORK, NY 10017	DOXYCYCLINE CALCIUM EQ 50MG BASE/5ML (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-533	VIBRA-TABS	PFIZER	DOXYCYCLINE HYCLATE
12-15-92	(TABLET)	NEW YORK, NY	EQ 100MG BASE
	10017	(REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	
18-948	CARNITOR	SIGMA TAU	LEVOCARNITINE
12-16-92	(TABLET)	GAITHERSBURG, MD	330MG
	20878	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE)	
18-948	CARNITOR	SIGMA TAU	LEVOCARNITINE
12-16-92	(SOLUTION)	GAITHERSBURG, MD	1GM/10ML
	20878	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE)	
19-979	TICLID	SYNTEX	TICLOPIDINE HYDROCHLORIDE
12-16-92	(TABLET)	PALO ALTO, CA	250MG
	94303	(REVISED LABELING -- PATIENT PACKAGE INSERT)	
07-529	QUINIDINE GLUCONATE	LILLY	QUINIDINE GLUCONATE
12-17-92	(INJECTABLE)	INDIANAPOLIS, IN	80MG/ML
	46285	(REVISED LABELING -- DOSAGE AND ADMINISTRATION)	
09-766	METICORTEN	SCHERING	PREDNISONE
12-17-92	(TABLET)	KENILWORTH, NJ	1MG
	07033	(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

12-657	CELESTONE	SCHERING	BETAMETHASONE
12-17-92	(TABLET)	KENILWORTH, NJ	0.6MG
		07033	(REVISED LABELING -- WARNINGS; PRECAUTIONS)
14-215	CELESTONE	SCHERING	BETAMETHASONE
12-17-92	(SYRUP)	KENILWORTH, NJ	0.6MG/5ML
		07033	(REVISED LABELING -- WARNINGS; PRECAUTIONS)
14-602	CELESTONE SOLUSPAN	SCHERING	BETAMETHASONE ACETATE
12-17-92	(INJECTABLE)	KENILWORTH, NJ	3MG/ML
		07033	BETAMETHASONE SODIUM PHOSPHATE EQ 3MG BASE/ML (REVISED LABELING -- WARNINGS; PRECAUTIONS)
17-561	CELESTONE	SCHERING	BETAMETHASONE
12-17-92	(INJECTABLE)	KENILWORTH, NJ	SODIUM PHOSPHATE
		07033	EQ 3MG BASE/ML (REVISED LABELING -- WARNINGS; PRECAUTIONS)
11-559	BREVITAL	LILLY	METHOHEXITAL SODIUM
12-18-92	(INJECTABLE)	INDIANAPOLIS, IN	500MG/VIAL
		46285	2.5GM/VIAL 5GM/VIAL (REVISED LABELING -- ADVERSE REACTIONS; 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			
			COMPATIBILITY INFORMATION; HOW SUPPLIED)
13-402 12-18-92	ALDORIL 15 (TABLET)	MSD WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 15MG METHYLDOPA 250MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
13-402 12-18-92	ALDORIL 25 (TABLET)	MSD WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 25MG METHYLDOPA 250MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; 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

			HOW SUPPLIED)
13-402	ALDORIL D30	MSD	HYDROCHLOROTHIAZIDE
12-18-92	(TABLET)	WEST POINT, PA	30MG
	19486		METHYLDOPA
			500MG
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			OVERDOSAGE;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
13-402	ALDORIL D50	MSD	HYDROCHLOROTHIAZIDE
12-18-92	(TABLET)	WEST POINT, PA	50MG
	19486		METHYLDOPA
			500MG
			(REVISED LABELING --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			OVERDOSAGE;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
19-386	BREVIBLOC	DUPONT	ESMOLOL HYDROCHLORIDE
12-18-92	(INJECTABLE)	WILMINGTON, DE	10MG/ML
	19880		250MG/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

			INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
17-697 12-22-92	KINEVAC (INJECTABLE)	SQUIBB PRINCETON, NJ 08543	SINCALIDE 0.005MG/VIAL (REVISED LABELING -- WARNINGS; PRECAUTIONS)
18-651 12-22-92	MARINOL (CAPSULE)	UNIMED SOMERVILLE, NJ 08876	DRONABINOL 2.5MG 5MG 10MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; CLINICAL TRIALS; INDIVIDUALIZATION OF DOSAGES; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)
19-802 12-22-92	HEPARIN SODIUM 12500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 5,000 UNITS/100ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
19-802 12-22-92	HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45%	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 10,000 UNITS/100ML (REVISED LABELING --

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
	LABELING SUPPLEMENTS TO ORIGINAL NDAs		
	IN PLASTIC CONTAINER (INJECTABLE)		DOSAGE AND ADMINISTRATION)
19-802 12-22-92	HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 5,000 UNITS/100ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
19-802 12-22-92	HEPARIN SODIUM 25000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 5,000 UNITS/100ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
19-952 12-22-92	HEPARIN SODIUM 20000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 4,000 UNITS/100ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
19-952 12-22-92	HEPARIN SODIUM 25000 UNITS IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 5,000 UNITS/100ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
19-952 12-22-92	HEPARIN SODIUM 25000 UNITS IN	MCGAW IRVINE, CA	HEPARIN SODIUM 10,000 UNITS/100ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

	DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	92713	(REVISED LABELING -- DOSAGE AND ADMINISTRATION)
19-953 12-22-92	HEPARIN SODIUM 1000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	HEPARIN SODIUM 200 UNITS/100ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
20-180 12-22-92	PROSCAR (TABLET)	MSD WEST POINT, PA 19486	FINASTERIDE 5MG (REVISED LABELING -- PRECAUTIONS)
18-333 12-28-92	CARAFATE (TABLET)	BLUE RIDGE KANSAS CITY, MO 64137	SUCRALFATE 1GM (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
18-533 12-28-92	NIZORAL (TABLET)	JANSSEN PISCATAWAY, NJ 08854	KETOCONAZOLE 200MG (REVISED LABELING -- BOXED WARNING; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; PRECAUTIONS; ADVERSE REACTIONS; 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

20-083	SPORANOX	JANSSEN	ITRACONAZOLE
12-28-92	(CAPSULE)	PISCATAWAY, NJ	100MG
		08855	(REVISED LABELING -- BOXED WARNINGS; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-998	CHEMET	MCNEIL	SUCCIMER
12-29-92	(CAPSULE)	FORT WASHINGTON, PA	100MG
		19034	(REVISED LABELING -- HOW SUPPLIED)
50-497	TICAR	BEECHAM	TICARCILLIN DISODIUM
12-30-92	(INJECTABLE)	BRISTOL, TN	EQ 1GM BASE/VIAL
		37620	EQ 3GM BASE/VIAL EQ 6GM BASE/VIAL (REVISED LABELING -- WARNINGS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
50-667	LORABID	LILLY	LORACARBEF
12-30-92	(POWDER FOR RECONSTITUTION)	INDIANAPOLIS, IN	100MG/5ML
		46285	200MG/5ML (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			
			INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
50-668 12-30-92	LORABID (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	LORACARBEF 200MG (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
50-504 12-31-92	MANDOL (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	CEFAMANDOLE NAFATE EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL (REVISED LABELING -- STABILITY)
50-558	ZINACEF	GLAXO	CEFUROXIME SODIUM

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

12-31-92	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 750MG BASE/VIAL
		27709	EQ 1.5GM BASE/VIAL
			(REVISED LABELING -- HOW SUPPLIED; INSTRUCTIONS FOR CONSTITUTION)
50-578	FORTAZ	GLAXO	CEFTAZIDIME
12-31-92	(INJECTABLE)	RES TRIANGLE PK, NC	500MG/VIAL
		27709	1GM/VIAL
			2GM/VIAL
			6GM/VIAL
			(REVISED LABELING -- HOW SUPPLIED; INSTRUCTIONS FOR CONSTITUTION)
50-664	CEFZIL	BRISTOL MYERS SQUIBB	CEFPROZIL
12-31-92	(TABLET)	WALLINGFORD, CT	250MG
		06492	500MG
			(REVISED LABELING -- CLINICAL PHARMACOLOGY; DOSAGE AND ADMINISTRATION)
50-665	CEFZIL	BRISTOL MYERS SQUIBB	CEFPROZIL
12-31-92	(SUSPENSION)	WALLINGFORD, CT	125MG/5ML
		06492	250MG/5ML
			(REVISED LABELING -- CLINICAL PHARMACOLOGY; DOSAGE AND ADMINISTRATION)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1160 NONE BIO COMPONENTS SOURCE LEUKOCYTES
12-04-92 (NONE) DAYTONA BEACH, FL (FURTHER MANUFACTURING)
32114 (A&B)

1160 NONE BIO COMPONENTS SOURCE PLASMA
12-04-92 (NONE) DAYTONA BEACH, FL (FURTHER MANUFACTURING)
32114 (A&B)

1161 NONE KNOXVILLE PLASMA SOURCE PLASMA
12-04-92 (NONE) MARYVILLE, TN (FURTHER MANUFACTURING)
37801 (A&B)

140 RECOMBINATE BAXTER HLTHCARE ANTIHEMOPHILIC FACTOR
12-10-92 (INJECTABLE) GLENDALE, CA (RECOMBINANT)
91203 (TREATMENT OF HEMOPHILIA A)
(B)

1156 JE VAX RES FOUNDATION FOR JAPANESE ENCEPHALITIS
12-10-92 (INJECTABLE) MICROBIAL DISEASES VIRUS VACCINE INACTIVATED
OF OSAKA UNIV (PREVENTION OF JAPANESE
OSAKA, 565, JAPAN ENCEPHALITIS)
(B)

1163 NONE GENETICS INSTITUTE ANTIHEMOPHILIC FACTOR
12-10-92 (NONE) ANDOVER, MA CONCENTRATE
01810 (RECOMBINANT)
(FOR FURTHER MANUFACTURING USE)
(A&B)

244 NONE CNTRL TEXAS REGIONAL PLATELETS
12-28-92 (INJECTABLE) BLOOD CTR (TRANSFUSION)
AUSTIN, TX (B)
78756

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1162 NONE LORIAN CNTY BLOOD BANK CRYOPRECIPITATED AHF
12-28-92 (INJECTABLE) ELYRIA, OH (TRANSFUSION)
44035 (B)

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

947 NONE CELLTECH LIMITED SATUMOMAB CONCENTRATE
12-29-92 (NONE) SLOUGH, BERKSHIRE, (FOR FURTHER MANUFACTURING USE)
UNITED KINGDOM (B)

1164 ONCOSCINT CYTOGEN SATUMOMAB PENDETIDE
12-29-92 CR/OV PRINCETON, NJ (IMAGING COLORECTAL CANCER)
(INJECTABLE) 08540 (B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

(B) Product License Issued

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK920007	LAMBDA	ONE LAMBDA	HLA
12-28-92	MONOCLONAL TRAY	CANOGA PARK, CA	(C)
	CLASS I AND II	91303	

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

P910006	AIA-PACK AFP	TOSOH MEDICS, INC. SAN FRANCISCO, CA 94080	AIA-PACK TO BE USED FOR THE QUANTITATIVE MEASUREMENT OF AFP IN SERUM TO AID IN THE MANAGEMENT OF PATIENTS WITH NON-SEMINOMATOUS TESTICULAR CARCINOMA	12/18/92

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

P820053/S12 12/31/92	BARNES-HIND TITAN LIQUID CLEANER AND BARNES-HIND WETTING AND SOAKING SOLUTION COMFORTCARE GP DAILY CLEANER	SOLA BARNES HIND SUNNYVALE, CA 94086-5200	FORMULATION MODIFICATION TO INCLUDE A SUSPENSION OF MICROFINE DISSOLVING PARTICLES TO THE DAILY CLEANER
P830026/S54 12/29/92	COSMOS PACING SYSTEM	INTERMEDICS, INC. ANGLETON, TX 77515	CHANGE THE MANUFACTURING SITE FROM FREEPORT TO ANGLETON, TEXAS
P830055/S22 12/03/92	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY INC. WARSAW, IN 46581-0988	ADDITION OF NEW SIZES OF BOTH POROUS COATED AND TEXTURED IMPLANTS
P840008/S38 12/04/92	DORNIER LITHOTRIPTER, MODEL HM3, DORNIER MULTIFUNCTIONAL LITHOTRIPTER MFL 5000	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	MODIFICATION TO THE OPERATION OF THE MFL 5000 LITHOTRIPTER TO ALLOW THE USER TO CHANGE THE KV SETTING WHILE SHOCK WAVES ARE BEING DELIVERED
P840008/S42 12/08/92	DORNIER LITHOTRIPTER, MODEL HM3, DORNIER LITHOTRIPTER, MODEL HM4	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	MODIFICATION TO THE OPERATION OF THE HM4 LITHOTRIPTER TO ALLOW THE USER TO CHANGE THE KV SETTING WHILE SHOCK WAVES ARE BEING

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

DELIVERED

P840040/S34 12/30/92	MANSFIELD CORONARY BALLOON DILATATION CATHETER SYSTEM, 3.4F NITECH 8 CORONARY BALLOON DILATATION CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	INCREASE THE CATHETER SHAFT O.D. OF THE EXISTING NITECH 8 CATHETER TO 3.4F
P840040/S35 12/30/92	HEART TRAK CORONARY BALLOON DILATATION CATHETER SYSTEM, SLIDER STRETCH CORONARY BALLOON DILATATION CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172-2414	EXTENSION OF THE USABLE SHAFT LENGTH TO 155 CM FOR THE SLIDER AND SLIDER LONG BALLOON CATHETERS
P840055/S29 12/04/92	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	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P850049/S01 12/08/92	COOK BIRD'S NEST VENA CAVA FILTER, GIANTURCO-ROEHM	COOK INCORPORATED BLOOMINGTON, IN 47402	PUSH-BUTTON RELEASE MECHANISM FOR THE DEPLOYMENT OF THE

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	BIRD'S NEST VENA CAVA FILTER WITH MODIFIED PUSH-BUTTON RELEASE MECHANISM	GIANTURCO-ROEHM	BIRD'S NEST FILTER
P850069/S06	EM KENNEDY LAD LIGAMENT AUGMENTATION DEVICE	3M HEALTH CARE ST. PAUL, MN 55144-1000	KENNEDY LAD LIGAMENT AUGMENTATION DEVICE
12/31/92			
P850089/S24	STER TIP PACING LEAD MODELS 5025 AND 5525, MEDTRONIC MODEL 5023M, 5523, 5024M AND 5524M, CAPTURE SP PACING LEADS AND CARDIAC PACEMAKERS MODEL 4162 AND 4262	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFICATIONS TO THE GENERIC TECHNICAL MANUAL FOR PACING LEADS
12/17/92			
P860007/S09	INTERTACH PACING SYSTEM	INTERMEDICS, INC. ANGLETON, TX 77515	CHANGE THE MANUFACTURING SITE FROM FREEPORT TO ANGLETON, TX
12/29/92			
P870024/S33	FLUOROPERM 92 (PAFLUFOCON A) FLUOROPERM 60 (PAFLUFOCON B) AND FLUOROPERM 30	PARAGON OPTICAL, INC. MESA, AZ 85204	USE OF A SMALLER PERCENTAGE OF D&C VIOLET NO. 2 COLOR ADDITIVE IN VIOLET TINTED CONTACT LENSES
12/30/92			

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	(PAFLUFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (VIOLET TINT)			
P870026/S04	DURACLEAN DAILY CLEANER, RESOLVE/GP DAILY CLEANER	ALLERGAN OPTICAL IRVINE, CA 92715-1599	USE OF RESOLVE/GP DAILY CLEANER WITH FLUOROSILICONE ACRYLATE AND ALLERGAN ADVENT (FLUROFOCON A) RIGID GAS PERMEABLE CONTACT LENSES	12/30/92
P870036/S17	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, THRUFLEX II	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	NEW MODEL CATHETER	12/24/92
P870036/S18	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC 14K OVER-THE-WIRE CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	MEDTRONIC 14K OVER-THE-WIRE CORONARY BALLOON DILATATION CATHETER 3.0 MM BALLOON TO BE MOUNTED ON A 3.1 FRENCH CATHETER SHAFT	12/29/92
P880003/S08	HELIX PTCA DILATATION CATHETER, OLYMPIX AND SLEUTH XT PTCA	CORDIS CORPORATION MIAMI, FL 33102-5700	OLYMPIX AND SLEUTH XT PTCA DILATATION CATHETERS	12/18/92

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

DILATATION CATHETERS

P880027/S23 12/30/92	SCHNEIDER MICROSOFTRAC PTCA CATHETER	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	REVISED MANUFACTURING PROCESS
P890003/S07 12/29/92	SYNERGYST II MODELS 7070 AND 7071, MODEL 9760 PROGRAMMING SYSTEM WITH MODEL 9852 SOFTWARE	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	ALTERNATE MANUFACTURING SITE
P890003/S16 12/04/92	SYNERGYST II PULSE GENERATOR, ELITE II PULSE GENERATOR MODELS 7084, 7085 AND 7086; MODEL 9857E SOFTWARE AND MODEL 9748 MEMORYMOD	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	ELITE II PULSE GENERATOR MODELS 7084, 7085, AND 7086, MODEL 9857 SOFTWARE, AND MODEL 9748 MEMORYMOD
P890017/S02 12/11/92	PALMAZ BALLOON-EXPANDABLE STENT	JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS WARREN, NJ 07059	LABELING AND REPACKAGING OF THE FINAL PRODUCT AT EITHER THE WARREN, NJ OR THE READINGTON, NJ FACILITY

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890025/S04	TDX CYCLOSPORINE AND METABOLITES SERUM ASSAY	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	INCORPORATION OF LABELING CHANGES	12/17/92
P890025/S05	TDX CYCLOSPORINE AND METABOLITES SERUM ASSAY, TDX/TDXFLX CYCLOSPORINE AND METABOLITES SERUM ASSAY	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	USE OF CYCLOSPORINE AND METABOLITES SERUM ASSAY ON THE TDXFLX AS AN AID IN THE MANAGEMENT OF CARDIAC AND RENAL TRANSPLANT PATIENTS	12/17/92
P890025/S06	TDX CYCLOSPORINE AND METABOLITES SERUM ASSAY, TDX/TDXFLX CYCLOSPORINE AND METABOLITES WHOLE BLOOD ASSAY	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	USE OF THE ASSAY ON THE TDXFLX ANALYZER	12/15/92
P890025/S07	TDX CYCLOSPORINE MONOCLONAL WHOLE BLOOD ASSAY, TDX/TDXFLX CYCLOSPORINE MONOCLONAL WHOLE BLOOD ASSAY	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	USE OF CYCLOSPORINE MONOCLONAL WHOLE BLOOD ASSAY ON THE TDXFLX ANALYZER	12/15/92
P890043/S15	SIMPSON CORONARY ATHEROCATH	DEVICES FOR VASCULAR INTERVENTION, INC. REDWOOD CITY, CA 94063	ALTERNATE STERILIZATION PROCESS	12/07/92

APPLICATION NO. / APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P890046/S18 12/04/92	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	IDEAL OPTICS, INC. ATLANTA, GA 30339	ADDITIONAL CONTACT LENS FINISHING LABORATORY
P900001/S07 12/04/92	SGP 3 (UNIFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR, BLUE AND GREEN TINTED)	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NJ 07751	THREE ADDITIONAL CONTACT LENS FINISHING LABORATORIES
P900001/S08 12/04/92	SGP 3 (UNIFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR BLUE AND GREEN TINTED)	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NJ 07751	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES
P910020/S01 12/29/92	RELAY/DASH PACING SYSTEM	INTERMEDICS, INC. ANGLETON, TX 77515	CHANGE THE MANUFACTURING SITE FROM FREEPORT TO ANGLETON, TEXAS

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

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR DECEMBER 1992.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR DECEMBER 1992.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR DECEMBER 1992.