FDA DRUG AND DEVICE PRODUCT APPROVALS

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

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

18-754 06-JAN-94 (SUPPL)	ORUDIS (CAPSULE)	WYETH AYERST PHILADELPHIA, PA 19101	KETOPROFEN 25MG 50MG 75MG (NEW INDICATION -- MANAGEMENT OF PAIN)
17-376 07-JAN-94 (SUPPL)	SEPTRA (TABLET)	BURROUGHS WELLC RES TRIANGLE PK, NC 27709	SULFAMETHOXAZOLE 400MG TRIMETHOPRIM 80MG (NEW INDICATION -- PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOSUPPRESSED AND CONSIDERED TO BE AT AN INCREASED RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA)
17-376 07-JAN-94 (SUPPL)	SEPTRA DS (TABLET)	BURROUGHS WELLC RES TRIANGLE PK, NC 27709	SULFAMETHOXAZOLE 800MG TRIMETHOPRIM 160MG (NEW INDICATION --

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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

			PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOSUPPRESSED AND CONSIDERED TO BE AT AN INCREASED RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA)
17-377	BACTRIM	ROCHE	SULFAMETHOXAZOLE
07-JAN-94	(TABLET)	NUTLEY, NJ	400MG
(SUPPL)		07110	TRIMETHOPRIM
			80MG
			(NEW INDICATION -- PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOSUPPRESSED AND CONSIDERED TO BE AT AN INCREASED RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA)
17-377	BACTRIM DS	ROCHE	SULFAMETHOXAZOLE
07-JAN-94	(TABLET)	NUTLEY, NJ	800MG
(SUPPL)		07110	TRIMETHOPRIM
			160MG
			(NEW INDICATION -- PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOSUPPRESSED AND CONSIDERED TO BE AT AN INCREASED RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA)

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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

17-560	BACTRIM PEDIATRIC	ROCHE	SULFAMETHOXAZOLE
07-JAN-94	(SUSPENSION)	NUTLEY, NJ	200MG/5ML
(SUPPL)		07110	TRIMETHOPRIM
			40MG/5ML
			(NEW INDICATION --
			PROPHYLAXIS AGAINST
			PNEUMOCYSTIS CARINII
			PNEUMONIA IN INDIVIDUALS
			WHO ARE IMMUNOSUPPRESSED
			AND CONSIDERED TO BE AT AN
			INCREASED RISK OF
			DEVELOPING PNEUMOCYSTIS
			CARINII PNEUMONIA)
17-598	SEPTRA	BURROUGHS WELLC	SULFAMETHOXAZOLE
07-JAN-94	(SUSPENSION)	RES TRIANGLE PK, NC	200MG/5ML
(SUPPL)		27709	TRIMETHOPRIM
			40MG/5ML
			(NEW INDICATION --
			PROPHYLAXIS AGAINST
			PNEUMOCYSTIS CARINII
			PNEUMONIA IN INDIVIDUALS
			WHO ARE IMMUNOSUPPRESSED
			AND CONSIDERED TO BE AT AN
			INCREASED RISK OF
			DEVELOPING PNEUMOCYSTIS
			CARINII PNEUMONIA)
17-598	SEPTRA GRAPE	BURROUGHS WELLC	SULFAMETHOXAZOLE
07-JAN-94	(SUSPENSION)	RES TRIANGLE PK, NC	200MG/5ML
(SUPPL)		27709	TRIMETHOPRIM
			40MG/5ML
			(NEW INDICATION --
			PROPHYLAXIS AGAINST

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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

PNEUMOCYSTIS CARINII
PNEUMONIA IN INDIVIDUALS
WHO ARE IMMUNOSUPPRESSED
AND CONSIDERED TO BE AT AN
INCREASED RISK OF
DEVELOPING PNEUMOCYSTIS
CARINII PNEUMONIA)

20-283	SEPTRA GRAPE	BURROUGHS WELLC	SULFAMETHOXAZOLE
07-JAN-94	(SUSPENSION)	RES TRIANGLE PK, NC	200MG/5ML
(6 S)		27709	TRIMETHOPRIM
			40MG/5ML
			(ANTIBACTERIAL)
			[PROPHYLAXIS AGAINST
			PNEUMOCYSTIS CARINII
			PNEUMONIA IN INDIVIDUALS
			WHO ARE IMMUNOSUPPRESSED
			AND CONSIDERED TO BE AT AN
			INCREASED RISK OF
			DEVELOPING PNEUMOCYSTIS
			CARINII PNEUMONIA]

20-283	SEPTRA	BURROUGHS WELLC	SULFAMETHOXAZOLE
07-JAN-94	(SUSPENSION)	RES TRIANGLE PK, NC	200MG/5ML
(6 S)		27709	TRIMETHOPRIM
			40MG/5ML
			(ANTIBACTERIAL)
			[PROPHYLAXIS AGAINST
			PNEUMOCYSTIS CARINII
			PNEUMONIA IN INDIVIDUALS
			WHO ARE IMMUNOSUPPRESSED
			AND CONSIDERED TO BE AT AN
			INCREASED RISK OF
			DEVELOPING PNEUMOCYSTIS
			CARINII PNEUMONIA]

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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-284	SEPTRA	BURROUGHS WELLC	SULFAMETHOXAZOLE
07-JAN-94	(TABLET)	RES TRIANGLE PK, NC	400MG
(6 S)		27709	TRIMETHOPRIM
			80MG
			(ANTIBACTERIAL)
			[PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOSUPPRESSED AND CONSIDERED TO BE AT AN INCREASED RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA]

20-284	SEPTRA DS	BURROUGHS WELLC	SULFAMETHOXAZOLE
07-JAN-94	(TABLET)	RES TRIANGLE PK, NC	800MG
(6 S)		27709	TRIMETHOPRIM
			160MG
			(ANTIBACTERIAL)
			[PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII PNEUMONIA IN INDIVIDUALS WHO ARE IMMUNOSUPPRESSED AND CONSIDERED TO BE AT AN INCREASED RISK OF DEVELOPING PNEUMOCYSTIS CARINII PNEUMONIA]

20-299	BACTRIM	ROCHE	SULFAMETHOXAZOLE
07-JAN-94	(TABLET)	NUTLEY, NJ	400MG
(6 S)		07110	TRIMETHOPRIM
			80MG
			(ANTIBACTERIAL)
			[PROPHYLAXIS AGAINST PNEUMOCYSTIS CARINII

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

PNEUMONIA IN INDIVIDUALS
WHO ARE IMMUNOSUPPRESSED
AND CONSIDERED TO BE AT AN
INCREASED RISK OF
DEVELOPING PNEUMOCYSTIS
CARINII PNEUMONIA]

20-299 BACTRIM DS ROCHE SULFAMETHOXAZOLE
07-JAN-94 (TABLET) NUTLEY, NJ 800MG
(6 S) 07110 TRIMETHOPRIM
160MG
(ANTIBACTERIAL)
[PROPHYLAXIS AGAINST
PNEUMOCYSTIS CARINII
PNEUMONIA IN INDIVIDUALS
WHO ARE IMMUNOSUPPRESSED
AND CONSIDERED TO BE AT AN
INCREASED RISK OF
DEVELOPING PNEUMOCYSTIS
CARINII PNEUMONIA]

20-300 BACTRIM PEDIATRIC ROCHE SULFAMETHOXAZOLE
07-JAN-94 (SUSPENSION) NUTLEY, NJ 200MG/5ML
(6 S) 07110 TRIMETHOPRIM
40MG/5ML
(ANTIBACTERIAL)
[PROPHYLAXIS AGAINST
PNEUMOCYSTIS CARINII
PNEUMONIA IN INDIVIDUALS
WHO ARE IMMUNOSUPPRESSED
AND CONSIDERED TO BE AT AN
INCREASED RISK OF
DEVELOPING PNEUMOCYSTIS
CARINII PNEUMONIA]

20-204 ALEVE HAMILTON PHARMS NAPROXEN SODIUM

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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

11-JAN-94	(TABLET)	PALO ALTO, CA	EQ 200MG BASE
(3 S)	94304	(NONSTEROIDAL ANTI-INFLAMMATORY) (OTC)	
18-343	CAPOTEN	BRISTOL MYERS SQUIBB	CAPTOPRIL
28-JAN-94	(TABLET)	PRINCETON, NJ	12.5MG
(SUPPL)	08543		25MG
			50MG
			100MG
			(NEW INDICATION -- TREATMENT OF DIABETIC NEPHROPATHY IN PATIENTS WITH TYPE I INSULIN-DEPENDENT DIABETES MELLITUS AND RETINOPATHY)

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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

ERRATA

20-142*	CATAFLAM	CIBA GEIGY	DICLOFENAC POTASSIUM
24-NOV-93	(TABLET)	SUMMIT, NJ	25MG
(2 S)		07901	50MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
20-210**	PROPULSID	JANSSEN	CISAPRIDE MONOHYDRATE
23-DEC-93	(TABLET)	TITUSVILLE, NJ	EQ 20MG BASE
(SUPPL)		08560	(NEW STRENGTH)
20-304***	TRASYLOL	MILES PHARM	APROTININ BOVINE
29-DEC-93	(INJECTABLE)	WEST HAVEN, CT	10,000 KIU/ML****
(1P, V**)		06516	(FIBRINOLYTICS/
			ANTIFIBRINOLYTICS)
			[PROPHYLACTIC USE TO REDUCE
			PERIOPERATIVE BLOOD LOSS/
			NEED FOR TRANSFUSION IN
			SELECT CORONARY PATIENTS]

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

* - Revised Classification Code.
** - Previously Published as approved July 29, 1993. Corrected approval date December 23, 1993.
*** - Previously published as APROTININ - correction to APROTININ BOVINE
**** - Kallikrein Inhibitor Units
V** - Designated Orphan Drug

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

APPROVABLE ORIGINAL NDAs

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

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

20-374 23-DEC-93	INPERSOL-LC W/DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION)	ABBOTT ABBOTT PARK, IL 60064	CALCIUM CHLORIDE 18.4MG/100ML DEXTROSE 1.5GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (PERITONEAL DIALYSATE)
20-374 23-DEC-93	INPERSOL-LC W/DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION)	ABBOTT ABBOTT PARK, IL 60064	CALCIUM CHLORIDE 18.4MG/100ML DEXTROSE 2.5GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
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			CLASSIFICATION(S)

APPROVABLE ORIGINAL NDAs

(PERITONEAL DIALYSATE)

20-374	INPERSOL-LC	ABBOTT	CALCIUM CHLORIDE
23-DEC-93	W/DEXTROSE 3.5%	ABBOTT PARK, IL	18.4MG/100ML
	IN PLASTIC CONTAINER	60064	DEXTROSE
	(SOLUTION)		3.5GM/100ML
			MAGNESIUM CHLORIDE
			5.08MG/100ML
			SODIUM CHLORIDE
			538MG/100ML
			SODIUM LACTATE
			448MG/100ML
			(PERITONEAL DIALYSATE)
20-374	INPERSOL-LC	ABBOTT	CALCIUM CHLORIDE
23-DEC-93	W/DEXTROSE 4.25%	ABBOTT PARK, IL	18.4MG/100ML
	IN PLASTIC CONTAINER	60064	DEXTROSE
	(SOLUTION)		4.25GM/100ML
			MAGNESIUM CHLORIDE
			5.08MG/100ML
			SODIUM CHLORIDE
			538MG/100ML
			SODIUM LACTATE
			448MG/100ML
			(PERITONEAL DIALYSATE)
20-287	FRAGMIN	KABI	DALTEPARIN SODIUM
10-JAN-94	(INJECTABLE)	UPPSALA, SWEDEN	2,500 UNITS/0.2ML
			5,000 UNITS/0.2ML

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APPROVABLE ORIGINAL NDAs

(ANTICOAGULANT)

20-214	ZEMURON	ORGANON	ROCURONIUM BROMIDE
11-JAN-94	(INJECTABLE)	W ORANGE, NJ 07052	10MG/ML (NON-DEPOLARIZING NEUROMUSCULAR BLOCKING AGENT)

20-095	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
24-JAN-94	(CAPSULE)	RES TRIANGLE PK, NC 27709	EQ 150MG BASE (HISTAMINE H-2 RECEPTOR ANTAGONIST)

20-095	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
24-JAN-94	(CAPSULE)	RES TRIANGLE PK, NC 27709	EQ 300MG BASE (HISTAMINE H-2 RECEPTOR ANTAGONIST)

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

ORIGINAL ABBREVIATED NDAs

73-695*	PERIOGARD	COLGATE PALMOLIVE	CHLORHEXIDINE GLUCONATE
14-JAN-94	(SOLUTION)	PISCATAWAY, NJ 08855	0.12% (ANTIMICROBIAL)
40-062	METHAZOLAMIDE	MIKART	METHAZOLAMIDE
27-JAN-94	(TABLET)	ATLANTA, GA 30318	25MG 50MG (CARBONIC ANHYDRASE INHIBITOR)
64-039	ERYTHROMYCIN	BAUSCH AND LOMB	ERYTHROMYCIN
27-JAN-94	(SOLUTION)	TAMPA, FL 33637	2% (ANTIBIOTIC, MACROLIDE)
74-063	PINDOLOL	MUTUAL PHARM	PINDOLOL
27-JAN-94	(TABLET)	PHILADELPHIA, PA 19124	5MG 10MG (BETA ADRENERGIC BLOCKER)
74-215	ALPRAZOLAM	MYLAN	ALPRAZOLAM
27-JAN-94	(TABLET)	MORGANTOWN, WV 26505	0.25MG 0.5MG 1MG 2MG (ANXIOLYTIC)
74-258	METOPROLOL TARTRATE	APOTHECON	METOPROLOL TARTRATE
27-JAN-94	(TABLET)	PRINCETON, NJ 08543	50MG 100MG (BETA ADRENERGIC BLOCKER)
74-289	NAPROXEN SODIUM	COPLEY PHARM	NAPROXEN SODIUM
27-JAN-94	(TABLET)	CANTON, MA	EQ 250MG BASE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
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ORIGINAL ABBREVIATED NDAs

	02021		EQ 500MG BASE
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)

* - First Time Product Available Generically

74-333	METOPROLOL TARTRATE	COPLEY PHARM	METOPROLOL TARTRATE
27-JAN-94	(TABLET)	CANTON, MA	50MG
	02021		100MG
			(BETA ADRENERGIC BLOCKER)
73-092	BACLOFEN	ROYCE LABS	BACLOFEN
28-JAN-94	(TABLET)	MIAMI, FL	10MG
	33014		(SKELETAL MUSCLE RELAXANT)
73-093	BACLOFEN	ROYCE LABS	BACLOFEN
28-JAN-94	(TABLET)	MIAMI, FL	20MG
	33014		(SKELETAL MUSCLE RELAXANT)
73-637	PIROXICAM	NOVOPHARM	PIROXICAM
28-JAN-94	(CAPSULE)	SCARBOROUGH, CANADA	10MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
73-638	PIROXICAM	NOVOPHARM	PIROXICAM
28-JAN-94	(CAPSULE)	SCARBOROUGH, CANADA	20MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
74-330*	VERAPAMIL HCL	BAKER NORTON	VERAPAMIL HYDROCHLORIDE
31-JAN-94	(TABLET,	MIAMI, FL	180MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
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ORIGINAL ABBREVIATED NDAs

EXTENDED RELEASE)	33178	(CALCIUM ION	
		INFLUX INHIBITOR)	

* - First Time Product Available Generically

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

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

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

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDA TENTATIVE APPROVALS FOR JANUARY 1994.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-926	INSULIN	NOVO NORDISK PHARMS	INSULIN PORK
03-JAN-94	(INJECTABLE)	PRINCETON, NJ	100 UNITS/ML
		08540	(LABELING REVISION -- SYRINGES; NEEDLE-FREE INJECTORS) (OTC)
17-929	NPH INSULIN	NOVO NORDISK PHARMS	INSULIN SUSP ISOPHANE BEEF
03-JAN-94	(INJECTABLE)	PRINCETON, NJ	100 UNITS/ML
		08540	(LABELING REVISION -- SYRINGES; NEEDLE-FREE INJECTORS) (OTC)
17-996	SEMILENTE INSULIN	NOVO NORDISK PHARMS	INSULIN ZINC SUSP
03-JAN-94	(INJECTABLE)	PRINCETON, NJ	PROMPT BEEF
		08540	100 UNITS/ML (LABELING REVISION -- SYRINGES; NEEDLE-FREE INJECTORS) (OTC)
17-997	ULTRALENTE INSULIN	NOVO NORDISK PHARMS	INSULIN ZINC SUSP
03-JAN-94	(INJECTABLE)	PRINCETON, NJ	EXTENDED BEEF
		08540	100 UNITS/ML (LABELING REVISION -- SYRINGES; NEEDLE-FREE INJECTORS) (OTC)
17-998	LENTE INSULIN	NOVO NORDISK PHARMS	INSULIN ZINC SUSP BEEF
03-JAN-94	(INJECTABLE)	PRINCETON, NJ	100 UNITS/ML
		08540	(LABELING REVISION --

NDA NUMBER TRADE NAME APPLICANT ACTIVE INGREDIENTS(S)
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LABELING SUPPLEMENTS TO ORIGINAL NDAs

SYRINGES; NEEDLE-FREE
INJECTORS)
(OTC)

18-193 VELOSULIN NOVO NORDISK PHARMS INSULIN PURIFIED PORK
03-JAN-94 (INJECTABLE) PRINCETON, NJ 100 UNITS/ML
08540 (LABELING REVISION --
SYRINGES; NEEDLE-FREE
INJECTORS)
(OTC)

18-194 INSULIN INSULATARD NOVO NORDISK PHARMS INSULIN SUSP ISOPHANE
03-JAN-94 NPH NORDISK PRINCETON, NJ PURIFIED PORK
(INJECTABLE) 08540 100 UNITS/ML
(LABELING REVISION --
SYRINGES; NEEDLE-FREE
INJECTORS)
(OTC)

18-195 INSULIN NORDISK NOVO NORDISK PHARMS INSULIN PURIFIED PORK
03-JAN-94 MIXTARD (PORK) PRINCETON, NJ 30 UNITS/ML
(INJECTABLE) 08540 INSULIN SUSP ISOPHANE
PURIFIED PORK
70 UNITS/ML
(LABELING REVISION --
SYRINGES; NEEDLE-FREE
INJECTORS)
(OTC)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
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LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-381	REGULAR PURIFIED	NOVO NORDISK PHARMS	INSULIN PURIFIED PORK
03-JAN-94	PORK INSULIN	PRINCETON, NJ	100 UNITS/ML
	(INJECTABLE)	08540	(LABELING REVISION -- SYRINGES; NEEDLE-FREE INJECTORS) (OTC)
18-383	LENTE	NOVO NORDISK PHARMS	INSULIN ZINC SUSP
03-JAN-94	(INJECTABLE)	PRINCETON, NJ	PURIFIED PORK
	08540		100 UNITS/ML (LABELING REVISION -- SYRINGES; NEEDLE-FREE INJECTORS) (OTC)
18-623	NPH PURIFIED PORK	NOVO NORDISK PHARMS	INSULIN SUSP
03-JAN-94	ISOPHANE INSULIN	PRINCETON, NJ	ISOPHANE PURIFIED PORK
	(INJECTABLE)	08540	100 UNITS/ML (LABELING REVISION -- SYRINGES; NEEDLE-FREE INJECTORS) (OTC)
18-985	ORTHO-NOVUM 7/7/7-21	JOHNSON RW	ETHINYL ESTRADIOL
03-JAN-94	(TABLET)	RARITAN, NJ	0.035MG
	08869		NORETHINDRONE 0.5MG, 0.75MG AND 1MG (LABELING REVISION -- PRECAUTIONS; PATIENT PACKAGE INSERT)
18-985	ORTHO-NOVUM 7/7/7-28	JOHNSON RW	ETHINYL ESTRADIOL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
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LABELING SUPPLEMENTS TO ORIGINAL NDAs

03-JAN-94	(TABLET)	RARITAN, NJ	0.035MG
	08869		NORETHINDRONE
			0.5MG, 0.75MG AND 1MG
			(LABELING REVISION --
			PRECAUTIONS;
			PATIENT PACKAGE INSERT)
19-449	INSULATARD NPH HUMAN	NOVO NORDISK PHARMS	INSULIN SUSP ISOPHANE
03-JAN-94	(INJECTABLE)	PRINCETON, NJ	SEMISYNTHETIC PURIFIED HUMAN
	08540		100 UNITS/ML
			(LABELING REVISION --
			SYRINGES; NEEDLE-FREE
			INJECTORS)
			(OTC)
19-450	VELOSULIN HUMAN	NOVO NORDISK PHARMS	INSULIN SEMISYNTHETIC
03-JAN-94	(INJECTABLE)	PRINCETON, NJ	PURIFIED HUMAN
	08540		100 UNITS/ML
			(LABELING REVISION --
			SYRINGES; NEEDLE-FREE
			INJECTORS)
			(OTC)
19-585	MIXTARD HUMAN 70/30	NOVO NORDISK PHARMS	INSULIN SEMISYNTHETIC
03-JAN-94	(INJECTABLE)	PRINCETON, NJ	PURIFIED HUMAN
	08540		30 UNITS/ML
			INSULIN SUSP ISOPHANE
			SEMISYNTHETIC PURIFIED HUMAN
			70 UNITS/ML
			(LABELING REVISION --
			SYRINGES; NEEDLE-FREE
			INJECTORS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
			(OTC)
19-938 03-JAN-94	NOVOLIN R (INJECTABLE)	NOVO NORDISK PHARMS PRINCETON, NJ 08540	INSULIN BIOSYNTHETIC HUMAN 100 UNITS/ML (LABELING REVISION -- SYRINGES; NEEDLE-FREE INJECTORS) (OTC)
19-959 03-JAN-94	NOVOLIN N (INJECTABLE)	NOVO NORDISK PHARMS PRINCETON, NJ 08540	INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN 100 UNITS/ML (LABELING REVISION -- SYRINGES; NEEDLE-FREE INJECTORS) (OTC)
19-965 03-JAN-94	NOVOLIN L (INJECTABLE)	NOVO NORDISK PHARMS PRINCETON, NJ 08540	INSULIN ZINC SUSP BIOSYNTHETIC HUMAN 100 UNITS/ML (LABELING REVISION -- SYRINGES; NEEDLE-FREE INJECTORS) (OTC)
19-991 03-JAN-94	NOVOLIN 70/30 (INJECTABLE)	NOVO NORDISK PHARMS PRINCETON, NJ	INSULIN BIOSYNTHETIC HUMAN 30 UNITS/ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		08540	INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN 70 UNITS/ML (LABELING REVISION -- SYRINGES; NEEDLE-FREE INJECTORS) (OTC)
17-735	MODICON 28	JOHNSON RW	ETHINYL ESTRADIOL
04-JAN-94	(TABLET)	RARITAN, NJ	0.035MG
		08869	NORETHINDRONE 0.5MG (LABELING REVISION -- PRECAUTIONS; PATIENT PACKAGE INSERT)
17-919	ORTHO-NOVUM 1/35-28	JOHNSON RW	ETHINYL ESTRADIOL
04-JAN-94	(TABLET)	RARITAN, NJ	0.035MG
		08869	NORETHINDRONE 1MG (LABELING REVISION -- PRECAUTIONS; PATIENT PACKAGE INSERT)
20-207	ALKERAN	BURROUGHS WELLC	MELPHALAN HYDROCHLORIDE
05-JAN-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 50MG BASE/VIAL
		27709	(LABELING REVISION -- DOSAGE AND ADMINISTRATION)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-754	ORUDIS	WYETH AYERST	KETOPROFEN
06-JAN-94	(CAPSULE)	PHILADELPHIA, PA 19101	25MG 50MG 75MG (LABELING REVISION -- DESCRIPTION; CLINICAL TRIALS; INDICATIONS AND USAGE; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)
17-376	SEPTRA	BURROUGHS WELLC	SULFAMETHOXAZOLE
07-JAN-94	(TABLET)	RES TRIANGLE PK, NC 27709	400MG TRIMETHOPRIM 80MG (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
17-376	SEPTRA DS	BURROUGHS WELLC	SULFAMETHOXAZOLE
07-JAN-94	(TABLET)	RES TRIANGLE PK, NC 27709	800MG TRIMETHOPRIM 160MG (LABELING REVISION -- INDICATIONS AND USAGE; 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

17-377 07-JAN-94	BACTRIM (TABLET)	ROCHE NUTLEY, NJ 07110	SULFAMETHOXAZOLE 400MG TRIMETHOPRIM 80MG (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
17-377 07-JAN-94	BACTRIM DS (TABLET)	ROCHE NUTLEY, NJ 07110	SULFAMETHOXAZOLE 800MG TRIMETHOPRIM 160MG (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
17-560 07-JAN-94	BACTRIM PEDIATRIC (SUSPENSION)	ROCHE NUTLEY, NJ 07110	SULFAMETHOXAZOLE 200MG/5ML TRIMETHOPRIM 40MG/5ML (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
17-598 07-JAN-94	SEPTRA (SUSPENSION)	BURROUGHS WELLC RES TRIANGLE PK, NC 27709	SULFAMETHOXAZOLE 200MG/5ML TRIMETHOPRIM 40MG/5ML (LABELING REVISION --

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)
17-598 07-JAN-94	SEPTRA GRAPE (SUSPENSION)	BURROUGHS WELLC RES TRIANGLE PK, NC 27709	SULFAMETHOXAZOLE 200MG/5ML TRIMETHOPRIM 40MG/5ML (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
17-926 07-JAN-94	INSULIN (INJECTABLE)	NOVO NORDISK PHARMS PRINCETON, NJ 08540	INSULIN PORK 100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
17-929 07-JAN-94	NPH INSULIN (INJECTABLE)	NOVO NORDISK PHARMS PRINCETON, NJ 08540	INSULIN SUSP ISOPHANE BEEF 100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
17-996 07-JAN-94	SEMILENTE INSULIN (INJECTABLE)	NOVO NORDISK PHARMS PRINCETON, NJ 08540	INSULIN ZINC SUSP PROMPT BEEF 100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
17-997 07-JAN-94	ULTRALENTE INSULIN (INJECTABLE)	NOVO NORDISK PHARMS PRINCETON, NJ	INSULIN ZINC SUSP EXTENDED BEEF

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		08540	100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
17-998	LENTE INSULIN	NOVO NORDISK PHARMS	INSULIN ZINC SUSP BEEF
07-JAN-94	(INJECTABLE)	PRINCETON, NJ	100 UNITS/ML
		08540	(LABELING REVISION -- PRECAUTIONS) (OTC)
18-193	VELOSULIN	NOVO NORDISK PHARMS	INSULIN PURIFIED PORK
07-JAN-94	(INJECTABLE)	PRINCETON, NJ	100 UNITS/ML
		08540	(LABELING REVISION -- PRECAUTIONS) (OTC)
18-194	INSULIN INSULATARD	NOVO NORDISK PHARMS	INSULIN SUSP ISOPHANE
07-JAN-94	NPH NORDISK	PRINCETON, NJ	PURIFIED PORK
	(INJECTABLE)	08540	100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
18-195	INSULIN NORDISK	NOVO NORDISK PHARMS	INSULIN PURIFIED PORK
07-JAN-94	MIXTARD (PORK)	PRINCETON, NJ	30 UNITS/ML
	(INJECTABLE)	08540	INSULIN SUSP ISOPHANE PURIFIED PORK 70 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
18-381	REGULAR PURIFIED	NOVO NORDISK PHARMS	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

07-JAN-94	PORK INSULIN (INJECTABLE)	PRINCETON, NJ 08540	100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
18-383	LENTE	NOVO NORDISK PHARMS	INSULIN ZINC SUSP
07-JAN-94	(INJECTABLE)	PRINCETON, NJ 08540	PURIFIED PORK 100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
18-623	NPH PURIFIED PORK	NOVO NORDISK PHARMS	INSULIN SUSP ISOPHANE
07-JAN-94	ISOPHANE INSULIN (INJECTABLE)	PRINCETON, NJ 08540	PURIFIED PORK 100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
19-449	INSULATARD NPH HUMAN	NOVO NORDISK PHARMS	INSULIN SUSP ISOPHANE
07-JAN-94	(INJECTABLE)	PRINCETON, NJ 08540	SEMISYNTHETIC PURIFIED HUMAN 100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
19-450	VELOSULIN HUMAN	NOVO NORDISK PHARMS	INSULIN SEMISYNTHETIC
07-JAN-94	(INJECTABLE)	PRINCETON, NJ 08540	PURIFIED HUMAN 100 UNITS/ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(LABELING REVISION -- PRECAUTIONS) (OTC)
19-585	MIXTARD HUMAN 70/30	NOVO NORDISK PHARMS	INSULIN SEMISYNTHETIC
07-JAN-94	(INJECTABLE)	PRINCETON, NJ 08540	PURIFIED HUMAN 30 UNITS/ML INSULIN SUSP ISOPHANE SEMISYNTHETIC PURIFIED HUMAN 70 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
19-938	NOVOLIN R	NOVO NORDISK PHARMS	INSULIN BIOSYNTHETIC HUMAN
07-JAN-94	(INJECTABLE)	PRINCETON, NJ 08540	100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
19-959	NOVOLIN N	NOVO NORDISK PHARMS	INSULIN SUSP ISOPHANE
07-JAN-94	(INJECTABLE)	PRINCETON, NJ 08540	BIOSYNTHETIC HUMAN 100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)
19-965	NOVOLIN L	NOVO NORDISK PHARMS	INSULIN ZINC SUSP
07-JAN-94	(INJECTABLE)	PRINCETON, NJ 08540	BIOSYNTHETIC HUMAN 100 UNITS/ML (LABELING REVISION -- PRECAUTIONS) (OTC)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-991	NOVOLIN 70/30	NOVO NORDISK PHARMS	INSULIN BIOSYNTHETIC HUMAN
07-JAN-94	(INJECTABLE)	PRINCETON, NJ	30 UNITS/ML
		08540	INSULIN SUSP ISOPHANE
			BIOSYNTHETIC HUMAN
			70 UNITS/ML
			(LABELING REVISION --
			PRECAUTIONS)
			(OTC)
18-938	DDAVP	RHONE POULENC RORER	DESMOPRESSIN ACETATE
11-JAN-94	(INJECTABLE)	FORT WASHINGTON, PA	0.004MG/ML
		19034	(LABELING REVISION --
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS)
19-813	DURAGESIC	ALZA	FENTANYL
11-JAN-94	(FILM,	PALO ALTO, CA	0.6MG/24HR
	EXTENDED RELEASE)	94303	1.2MG/24HR
			1.8MG/24HR
			2.4MG/24HR
			(LABELING REVISION --
			BOX WARNING;
			CONTRAINDICATIONS;
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)
17-386	ZAROXOLYN	FISONS	METOLAZONE
13-JAN-94	(TABLET)	ROCHESTER, NY	2.5MG
		14603	5MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			10MG (LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DRUG INTERACTIONS)
18-662	ACCUTANE	ROCHE	ISOTRETINOIN
13-JAN-94	(CAPSULE)	NUTLEY, NJ 07110	10MG 20MG 40MG (LABELING REVISION -- BOX WARNING; DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINSTRATION; HOW SUPPLIED; PATIENT INFORMATION/CONSENT; PATIENT INFORMATION BROCHURE)
19-532	MYKROX	FISONS	METOLAZONE
13-JAN-94	(TABLET)	ROCHESTER, NY 14603	0.5MG (LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DRUG INTERACTIONS)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-773	VENTOLIN	GLAXO	ALBUTEROL SULFATE
13-JAN-94	(SOLUTION)	RES TRIANGLE PK, NC	EQ 0.083% BASE
	27709	(LABELING REVISION -- PRECAUTIONS)	

18-998	VASOTEC	MERCK	ENALAPRIL MALEATE
14-JAN-94	(TABLET)	WEST POINT, PA	2.5MG
	19486		5MG
			10MG
			20MG
		(LABELING REVISION -- WARNINGS)	

19-221	VASERETIC	MERCK	ENALAPRIL MALEATE
14-JAN-94	(TABLET)	WEST POINT, PA	10MG
	19486		HYDROCHLOROTHIAZIDE
			25MG
		(LABELING REVISION -- WARNINGS)	

19-309	VASOTEC	MERCK	ENALAPRILAT
14-JAN-94	(INJECTABLE)	WEST POINT, PA	1.25MG/ML
	19486	(LABELING REVISION -- WARNINGS)	

19-558	PRINIVIL	MERCK	LISINOPRIL
14-JAN-94	(TABLET)	WEST POINT, PA	5MG
	19486		10MG

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
			20MG 40MG (LABELING REVISION -- WARNINGS)
19-778 14-JAN-94	PRINZIDE 20-12.5 (TABLET)	MERCK WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 20MG (LABELING REVISION -- WARNINGS)
19-778 14-JAN-94	PRINZIDE 20-25 (TABLET)	MERCK WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 25MG LISINOPRIL 20MG (LABELING REVISION -- WARNINGS)
19-901 14-JAN-94	ALTACE (CAPSULE)	HOECHST ROUSSEL SOMERVILLE, NJ 08876	RAMIPRIL 1.25MG 2.5MG 5MG 10MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-837	BRETYLIUM TOSYLATE	BAXTER	BRETYLIUM TOSYLATE
19-JAN-94	IN DEXTROSE 5%	ROUND LAKE, IL	200MG/100ML
	IN PLASTIC CONTAINER	60073	400MG/100ML
	(INJECTABLE)		(LABELING REVISION -- WARNINGS; ADVERSE REACTIONS)
19-415	METRODIN	SERONO LABS	UROFOLLITROPIN
24-JAN-94	(INJECTABLE)	NORWELL, MA	75IU/AMP
		02061	(LABELING REVISION -- WARNINGS; ADVERSE REACTIONS; HOW SUPPLIED)
19-489	VENTOLIN ROTACAPS	GLAXO	ALBUTEROL SULFATE
27-JAN-94	(CAPSULE)	RES TRIANGLE PK, NC	EQ 0.2MG BASE
		27709	(LABELING REVISION -- WARNINGS; PRECAUTIONS)
12-594	METAHYDRIN	MERRELL DOW PHARMS	TRICHLORMETHIAZIDE
28-JAN-94	(TABLET)	CINCINNATI, OH	2MG
		45215	4MG
			(LABELING REVISION -- LABELING FORMAT REVISION PROGRAM)
16-672	OVRAL	WYETH AYERST	ETHINYL ESTRADIOL
28-JAN-94	(TABLET)	PHILADELPHIA, PA	0.05MG
		19101	NORGESTREL
			0.5MG
			(LABELING REVISION -- PRECAUTIONS; PATIENT PACKAGE INSERT)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

16-806	OVRAL-28	WYETH AYERST	ETHINYL ESTRADIOL
28-JAN-94	(TABLET)	PHILADELPHIA, PA	0.05MG
		19101	NORGESTREL
			0.5MG
			(LABELING REVISION --
			PRECAUTIONS;
			PATIENT PACKAGE INSERT)
17-557	DANOCRINE	STERLING WINTHROP	DANAZOL
28-JAN-94	(CAPSULE)	NEW YORK, NY	50MG
		10016	100MG
			200MG
			(LABELING REVISION --
			ADVERSE REACTIONS)
17-612	LO/OVRAL	WYETH AYERST	ETHINYL ESTRADIOL
28-JAN-94	(TABLET)	PHILADELPHIA, PA	0.03MG
		19101	NORGESTREL
			0.3MG
			(LABELING REVISION --
			PRECAUTIONS;
			PATIENT PACKAGE INSERT)
17-802	LO/OVRAL-28	WYETH AYERST	ETHINYL ESTRADIOL
28-JAN-94	(TABLET)	PHILADELPHIA, PA	0.03MG
		19101	NORGESTREL
			0.3MG
			(LABELING REVISION --
			PRECAUTIONS;
			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

18-343	CAPOTEN	BRISTOL MYERS SQUIBB	CAPTOPRIL
28-JAN-94	(TABLET)	PRINCETON, NJ	12.5MG
		08543	25MG
			50MG
			100MG
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)
18-668	NORDETTE-21	WYETH AYERST	ETHINYL ESTRADIOL
28-JAN-94	(TABLET)	PHILADELPHIA, PA	0.03MG
		19101	LEVONORGESTREL
			0.15MG
			(LABELING REVISION --
			PRECAUTIONS;
			PATIENT PACKAGE INSERT)
18-782	NORDETTE-28	WYETH AYERST	ETHINYL ESTRADIOL
28-JAN-94	(TABLET)	PHILADELPHIA, PA	0.03MG
		19101	LEVONORGESTREL
			0.15MG
			(LABELING REVISION --
			PRECAUTIONS;
			PATIENT PACKAGE INSERT)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1170 NONE PLASMA CTR OF SOURCE PLASMA
26-JAN-94 (INJECTABLE) EAST NEW ORLEANS (FURTHER MANUFACTURING)
NEW ORLEANS, LA (A&B)
70127

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

BIOLOGICAL PRODUCT LICENSES ISSUED

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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK930013 12-JAN-94	MCS PLUS AND DISPOSABLE SETS No LIST 890, 790 791A, 791	HAEMONETICS BRAINTREE, MA 02184	AUTOMATED BLOOD CELL SEPARATOR (C)
BK930030 12-JAN-94	MTS DILUENT 2 PLUS	MICRO TYPING SYS POMPANO BEACH, FL 33069	POTENTIATING MEDIA FOR IN VITRO DIAGNOSTIC USE (C)
BK930024 26-JAN-94	OLYMPUS PK7200 BLOOD GROUPING ANALYZER	OLYMPUS AM LAKE SUCCESS, NY 11042	AUTOMATED BLOOD GROUPING ANALYZER (C)

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

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

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

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

P900029 01/10/94	NDS SYSTEM	CIBA VISION CORPORATION DULUTH, GA 30136-1518	APPROVAL FOR THE NDS SYSTEM WHICH IS INDICATED FOR THE CLEANING, DISINFECTING, RINSING, SOAKING AND STORING OF SOFT (HYDROPHILIC) LENSES
P900042 01/18/94	AWARE TEST SYSTEM	BIOMETRIC RESEARCH INSTITUTE, INC. ARLINGTON, VA 22209-2306	APPROVAL FOR THE AWARE TEST SYSTEM
P920045 01/24/94	OP-3 (LOTIFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	STELLAR CONTACT LENS, INC. BUFFALO GROVE, IL 60089	APPROVAL FOR THE OP-3 (LOTIFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)

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

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

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

P790017/S44 01/07/94	USCI GRUNTZIG DILACA CORONARY ARTERY BALLOON DILATATION CATHETERS, USCI SILK AND AGIL BALLOON DILATATION CATHETERS WITH PRO/PEL COATING	C.R. BARD, INC. BILLERICA, MA 01821	TWO NEW CATHETER MODELS
P790017/S45 01/07/94	USCI GRUNTZIG DILACA CORONARY ARTERY BALLOON DILATATION CATHETERS	C.R. BARD, INC. BILLERICA, MA 01821	CONSOLIDATION OF MANUFACTURING OPERATIONS SITES
P810046/S143 01/27/94	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS CORONARY DILATATION CATHETERS	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	MANUFACTURING MODIFICATIONS
P810055/S54 01/27/94	ULTRAVIOLET-ABSORBING MODEL 722D POSTERIOR CHAMBER INTRAOCULAR LENS	PHARMACIA OPHTHALMICS INC. MONROVIA, CA 91017-7136	APPROVAL TO MANUFACTURE MODEL 722D LENS ENTIRELY AT GRONINGEN, NETHERLANDS FACILITY
P820003/S66 01/26/94	VERSATRAX PACING SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	INTRODUCTION OF NEW STERILIZATION SYSTEM AT PUERTO RICO AND

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

NETHERLANDS FACILITIES

P820056/S55	OPTACRYL (KOLFOCON A) RIGID GAS PERMEABLE CONTACT LENSES	PARAGON VISION SCIENCES MESA, AZ 85204	ONE CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	01/04/94
P820056/S56	OPTACRYL (KOLFOCON A) RIGID GAS PERMEABLE CONTACT LENSES	PARAGON VISION SCIENCES MESA, AZ 85204	ONE CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	01/04/94
P820063/S54	PARAPERM 02 (PASIFOCON A) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON VISION SCIENCES MESA, AZ 85204	ONE CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	01/04/94
P820063/S55	PARAPERM O2 (PASIFOCON A) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON VISION SCIENCES MESA, AZ 85204	ONE CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	01/04/94
P820083/S16	GORE-TEX EXPANDED PTFE SUTURE	W. L. GORE & ASSOCIATES FLAGSTAFF, AZ 86002	MODIFICATION OF SUTURE LABELING WITH REGARD TO STERILIZATION INSTRUCTIONS	01/10/94
P830037/S33	DURASOFT 3 COLORS (PHEMFILCON A) HYDROPHILIC	WESLEY-JESSEN CORPORATION DES PLAINES, IL 60018	MODIFIED MANUFACTURING PROCESS	01/31/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	CONTACT LENSES, FRESHLOOK COLORS AND LITETINT (PHEMFILCON A) SOFT (HYDROPHILIC) CONTACT LENS			
P830037/S34	FRESHLOOK COLORS (PHEMFILCON A) SOFT (HYDROPHILIC) CONTACT LENS AND FRESHLOOK LITETINT (PHEMFILCON A) SOFT (HYDROPHILIC)	WESLEY-JESSEN CORPORATION DES PLAINS, IL 60618	ALTERNATE STERILIZATION SITE	01/31/94
P840002/S01	STAT-PACE IIA PULSE GENERATOR, PACESCOPE ESOPHAGEAL PACING STETHOSCOPE	SEECOR, INC. TAMPA, FL 33624	MODIFIED PACING SYSTEM WHICH INCLUDES BOTH THE STAT-PACE IIA PULSE GENERATOR AND THE PACESCOPE ESOPHAGEAL PACING STETHOSCOPE	01/11/94
P840019/S11	TANDEM-R CEA IMMUNORADIOMETRIC ASSAY	HYBRITECH INCORPORATED SAN DIEGO, CA 92126-9006	MANUFACTURING MODIFICATIONS	01/13/94
P840055/S28	SGP (TELEFOCON A) AND SGP II (TELEFOCON B) SILICONE ACRYLATE RIGID GAS PERMEABLE CONTACT LENSES	PERMEABLE TECHNOLOGIES, INC. MORGANVILLE, NJ 07751	APPROVAL FOR SGP (TELEFOCON A) AND SGP II (TELEFOCON B) RIGID GAS PERMEABLE CONTACT LENSES IN BROWN AND GRAY TINTS	01/31/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	(CLEAR, BLUE, GREEN, BROWN AND GRAY TINTS)		
P850038/S22 01/04/94	PARAPERM EW (PASIFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON VISION SCIENCES MESA, AZ 85204	ONE CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P850038/S23 01/04/94	PARAPERM EW (PASIFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON VISION SCIENCES MESA, AZ 85204	ONE ALTERNATE LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P850051/S40 01/26/94	ACTIVITRAX PACING SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	INTRODUCTION OF NEW STERILIZATION SYSTEM AT PUERTO RICO AND NETHERLANDS FACILITIES
P860019/S70 01/04/94	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETERS	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	PACKAGING CHANGE
P860019/S72 01/04/94	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETERS	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	LABELING CHANGES TO ALL SCIMED PTCA CATHETER INSTRUCTIONS FOR USE MANUALS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P860019/S75	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANTIOPLASTY CATHETER, CRUISE PTCA CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	NEW MODEL CATHETER	01/27/94
P860019/S76	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, BIOSLIDE PC HYDROPHILIC COATING	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	ALTERNATE COATING CONFIGURATION	01/27/94
P860023/S06	BAUSCH & LOMB RENU MULTI-PURPOSE SOLUTION	BAUSCH & LOMB ROCHESTER, NY 14692-0450	ALTERNATE FORMULATION FOR THE APPROVED BAUSCH & LOMB RENU MULTI-PURPOSE SOLUTION	01/24/94
P860040/S12	SPHERICAL AND TORIC (METHAFILCON A) SOFT (HYDROPHILIC) CONTACT LENSES	CAL BIONICS NOVATO, CA 94947	ALTERNATE MANUFACTURING FACILITY RELOCATION	01/27/94
P870023/S05	DE STAT 3R, LOBOB C/D/S SOLUTION	SHERMAN PHARMACEUTICALS, INC. MANDEVILLE, LA 70470-1377	APPROVAL FOR LOBOB LABORATORIES, INC. TO PACKAGE, PRIVATE LABEL, AND DISTRIBUTE	01/04/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P870024/S39	FLUOROPERM 92, 60, AND 30 (PAFLUFOCON A, B, AND C) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED) SOLUTION	PARAGON VISION SCIENCES MESA, AZ 85204	ONE CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	01/04/94
P870024/S40	FLUOROPERM 92, 60, AND 30 (PAFLUFOCON A, B, AND C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED) SOLUTION	PARAGON VISION SCIENCES MESA, AZ 85204	ONE CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	01/04/94
P870029/S09	STAY WET 3R, LOBOB W/RW SOLUTION	SHERMAN PHARMACEUTICALS, INC. MANDEVILLE, LA 70470-1377	APPROVAL FOR LOBOB LABORATORIES, INC. TO PACKAGE, PRIVATE LABEL, AND DISTRIBUTE SOLUTION	01/04/94
P880003/S17	OLYMPIX AND SLEUTH XT PTCA DILATATION CATHETERS WITH A MODIFIED Y-CONNECTOR	CORDIS CORPORATION MIAMI, FL 33102-5700	MODIFIED Y-CONNECTOR	01/12/94
P880003/S20	CORDIS PTCA DILATATION CATHETERS, CORDIS OLYMPIX AND SLEUTH XT PTCA	CORDIS CORPORATION MIAMI, FL 33102-5700	CONSOLIDATED SET OF INSTRUCTIONS FOR USE FOR THE OLYMPIX AND SLEUTH XT PTCA	01/07/94

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
CATHETERS		CATHETERS		
P880003/S21	CORDIS PTCA DILATATION CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	REVISED SHELF-LIFE TESTING PROTOCOL	01/27/94
P880031/S05	AMO VITRAX (SODIUM HYALURONATE)	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	NEW FILL VOLUME AND LABELING CHANGES	01/10/94
P880031/S06	AMO VITRAX (SODIUM HYALURONATE)	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	ALTERNATE SUPPLIER OF ROOSTER COMBS	01/10/94
P880031/S07	AMO VITRAX (SODIUM HYALURONATE)	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	MODIFIED PACKAGING	01/10/94
P880078/S11	VH8500 HYPERTHERMIA TREATMENT SYSTEM, VOLUMETRIC HYPERTHERMIA OPEN LUMEN CATHETER (VHOC)	COOK, INC. BLOOMINGTON, IN 47402	MANUFACTURING MODIFICATION	01/26/94
P890003/S22	SYNERGIST II PACING SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	INTRODUCTION OF NEW STERILIZATION SYSTEM AT PUERTO RICO AND NETHERLANDS FACILITIES	01/26/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890043/S21 01/12/94	SIMPSON CORONARY ATHEROCATH GTO DEVICE	DEVICES FOR VASCULAR INTERVENTIONS, INC. REDWOOD CITY, CA 94063	APPROVAL FOR THE ATHEROCATH GTO DEVICE
P890044/S27 01/26/94	BIS.45 AND TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED)	BENTEC INCORPORATED SACRAMENTO, CA 95834	ONE CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P890046/S25 01/13/94	0-> PERM F60R (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY
P890058/S12 01/04/94	NOVALENS (ROSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND BLUE TINTED)	OCUTEC CORPORATION MORRISVILLE, NC 27560	ONE ALTERNATE MANUFACTURER AND DISTRIBUTOR OF THE NOVALENS (ROSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS
P890063/S03 01/31/94	GENESIS HOME UTERINE ACTIVITY	CARELINK CORPORATION SANTA ANA, CA	ADDITION OF A SECOND MANUFACTURING

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	MONITORING SYSTEM	92705	FACILITY	
P890072/S10	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED) WITH AN ULTRAVIOLET LIGHT ABSORBER	PROGRESSIVE OPTICAL RESEARCH, LTD. ALBERTA, CANADA	THREE FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES	01/07/94
P900023/S08	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	MANUFACTURING MODIFICATION	01/24/94
P900039/S01	COLLAGRAFT BONE GRAFT MATRIX STRIP	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	APPROVAL FOR THE COLLAGRAFT BONE MATRIX STRIP	01/27/94
P900056/S02	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM	HEART TECHNOLOGY, INC. BELLEVUE, WA 98005-1887	MANUFACTURING MODIFICATION	01/10/94
P900056/S03	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM	HEART TECHNOLOGY, INC. BELLEVUE, WA 98005-1887	TWO ADDITIONAL SUPPLIERS FOR THE STERILE PACKAGING POUCH	01/07/94
P910030/S02	GIANTURCO-ROUBIN FLEX-STENT CORONARY STENT	COOK, INC. BLOOMINGTON, IN 47402	LABELING CHANGES IN THE TECHNICAL INSTRUCTIONS FOR USE BOOKLET	01/27/94

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 JANUARY 1994.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR JANUARY 1994.

SUPPLEMEMTAL VETERINARY NADAs

130-435 12-10-93	OXYTET SOLUBLE (POWDER)	SWINE	ID RUSSELL LONGMONT, CO 80501	OXYTETRACYCLINE HYDROCHLORIDE 2.46OZ 9.87OZ 3.09LB/PAIL

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

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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

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

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

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

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-236 SEREVENT GLAXO SALMETEROL XINAFOATE
04-FEB-94 (AEROSOL, METERED) RES TRIANGLE PK, NC EQ 0.021MG BASE/INH
(1 P) 27709 (BETA ADRENERGIC AGONIST)

20-233 RHINOCORT ASTRA USA BUDESONIDE
14-FEB-94 (AEROSOL, METERED) WESTBOROUGH, MA 0.05MG/INH
(1 S) 01581 (CORTICOSTEROID)
[MANAGEMENT OF SYMPTOMS OF RHINITIS]

20-249 PEPCID MERCK FAMOTIDINE
18-FEB-94 (INJECTABLE) WEST POINT, PA 0.4MG/ML
(3 S) 19486 (HISTAMINE H2-RECEPTOR ANTAGONIST)

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

18-703	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
28-FEB-94	(TABLET)	RES TRIANGLE PK, NC	EQ 150MG BASE
(SUPPL)		27709	(ALTERNATIVE DOSING SCHEDULE -- AFTER THE EVENING MEAL FOR THE 300MG ONCE DAILY DOSE)
18-703	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
28-FEB-94	(TABLET)	RES TRIANGLE PK, NC	EQ 300MG BASE
(SUPPL)		27709	(ALTERNATIVE DOSING SCHEDULE -- AFTER THE EVENING MEAL FOR THE 300MG ONCE DAILY DOSE)
19-675	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
28-FEB-94	(SYRUP)	RES TRIANGLE PK, NC	EQ 15MG BASE/ML
(SUPPL)		27709	(ALTERNATIVE DOSING SCHEDULE -- AFTER THE EVENING MEAL FOR THE 300MG ONCE DAILY DOSE)
20-187	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
28-FEB-94	(CAPSULE)	INDIANAPOLIS, IN	EQ 10MG BASE
(6 S)		46285	EQ 20MG BASE (ANTIDEPRESSANT) [OBSESSIVE-COMPULSIVE DISORDER]

ERRATA

20-142	CATAFLAM	GEIGY	DICLOFENAC POTASSIUM
24-NOV-93	(TABLET)	SUMMIT, NJ	25MG
(2 S*)		07901	50MG (NONSTEROIDAL ANTI-INFLAMMATORY)

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

* - Revised Classification 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.

THERE ARE NO APPROVABLE ORIGINAL NDAs FOR FEBRUARY 1994.

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

ORIGINAL ABBREVIATED NDAs

74-284	ETOPOSIDE	GENSIA	ETOPOSIDE
10-FEB-94	(INJECTABLE)	IRVINE, CA	20MG/ML
		92718	(ANTINEOPLASTIC)

40-052	THEOPHYLLINE	INWOOD LABS	THEOPHYLLINE
14-FEB-93	(CAPSULE, EXTENDED	NEW YORK, NY	100MG
	RELEASE)	10155	125MG
			200MG
			300MG
			(BRONCHODILATOR)

74-085	ALPRAZOLAM	NOVOPHARM	ALPRAZOLAM
16-FEB-94	(TABLET)	SCARBOROUGH, CANADA	0.25MG
			0.5MG
			1MG
			(ANXIOLYTIC)

74-087*	CLOBETASOL	COPLEY PHARM	CLOBETASOL PROPIONATE
16-FEB-94	PROPIONATE	CANTON, MA	0.05%
	(CREAM)	02021	(CORTICOSTEROID)

74-089*	CLOBETASOL	COPLEY PHARM	CLOBETASOL PROPIONATE
16-FEB-94	PROPIONATE	CANTON, MA	0.05%
	(OINTMENT)	02021	(CORTICOSTEROID)

40-063	ACETIC ACID 2%	BAUSCH AND LOMB	ACETIC ACID, GLACIAL
25-FEB-94	IN AQUEOUS	TAMPA, FL	2%
	ALUMINUM ACETATE	33637	ALUMINUM ACETATE
	(SOLUTION/DROPS)		0.79%
			(ASTRINGENT/ANTIMICROBIAL)

73-691	IBUPROFEN	PRIVATE FMLTNS	IBUPROFEN
25-FEB-94	(TABLET)	EDISON, NJ	200MG
		08818	(NONSTEROIDAL

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

ORIGINAL ABBREVIATED NDAs

ANTI-INFLAMMATORY)

* - First Time Product Available Generically

74-084	DILTIAZEM HCL	NOVOPHARM	DILTIAZEM HYDROCHLORIDE
25-FEB-94	(TABLET)	SCARBOROUGH, CANADA	30MG
			60MG
			(CALCIUM ION
			INFLUX INHIBITOR)
64-042	NYSTATIN	BAUSCH AND LOMB	NYSTATIN
28-FEB-94	(SUSPENSION)	TAMPA, FL	100,000 UNITS/ML
		33637	(ANTIFUNGAL)
72-945	CYTARABINE	BULL LABS	CYTARABINE
28-FEB-94	(INJECTABLE)	MULGRAVE VICTORIA,	20MG/ML
		AUSTRIA	(ANTINEOPLASTIC)
74-025*	GUANABENZ ACETATE	WATSON LABS	GUANABENZ ACETATE
28-FEB-94	(TABLET)	CORONA, CA	EQ 4MG BASE
		91720	EQ 8MG BASE
			(ANTIHYPERTENSIVE)
74-211	NAPROXEN	ROXANE LABS	NAPROXEN
28-FEB-94	(TABLET)	COLUMBUS, OH	250MG
		43216	375MG
			500MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
74-265	ATENOLOL	INVAMED	ATENOLOL
28-FEB-94	(TABLET)	FAIRFIELD, NJ	25MG

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

ORIGINAL ABBREVIATED NDAs

07004		50MG
		100MG
		(BETA ADRENERGIC BLOCKER)

* - First Time Product Available Generically

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

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

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

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDA TENTATIVE APPROVALS FOR FEBRUARY 1994.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-473	VENTOLIN	GLAXO	ALBUTEROL
02-FEB-94	(AEROSOL, METERED)	RES TRIANGLE PK, NC	0.09MG/INH
	27709	(LABELING REVISION -- PRECAUTIONS; PATIENT'S INSTRUCTIONS FOR USE)	
19-548	TORNALATE	STERLING WINTHROP	BITOLTEROL MESYLATE
02-FEB-94	(SOLUTION)	MALVERN, PA	0.2%
	19355	(LABELING REVISION -- WARNINGS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; PRECAUTIONS)	
16-659	NORINYL 1+50 28-DAY	SYNTEX (FP)	MESTRANOL
04-FEB-94	(TABLET)	HUMACAO, PR	0.05MG
	00661	NORETHINDRONE 1MG (LABELING REVISION -- PATIENT PACKAGE INSERTS; PRECAUTIONS; DOSAGE AND ADMINISTRATION; INFORMATION FOR THE PATIENT)	
17-565	NORINYL 1+35 28-DAY	SYNTEX (FP)	ETHINYL ESTRADIOL
04-FEB-94	(TABLET)	HUMACAO, PR	0.035MG
	00661	NORETHINDRONE 1MG (LABELING REVISION -- PATIENT PACKAGE INSERTS; PRECAUTIONS; DOSAGE AND ADMINISTRATION; INFORMATION FOR THE PATIENT)	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-565	NORINYL 1+35 21-DAY	SYNTEX (FP)	ETHINYL ESTRADIOL
04-FEB-94	(TABLET)	HUMACAO, PR	0.035MG
	00661		NORETHINDRONE
			1MG
			(LABELING REVISION --
			PATIENT PACKAGE INSERTS;
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			INFORMATION FOR THE PATIENT)
17-566	BREVICON 21-DAY	SYNTEX (FP)	ETHINYL ESTRADIOL
04-FEB-94	(TABLET)	HUMACAO, PR	0.035MG
	00661		NORETHINDRONE
			0.5MG
			(LABELING REVISION --
			PATIENT PACKAGE INSERTS;
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			INFORMATION FOR THE PATIENT)
17-743	BREVICON 28-DAY	SYNTEX (FP)	ETHINYL ESTRADIOL
04-FEB-94	(TABLET)	HUMACAO, PR	0.035MG
	00661		NORETHINDRONE
			0.5MG
			(LABELING REVISION --
			PATIENT PACKAGE INSERTS;
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			INFORMATION FOR THE PATIENT)
18-977	TRI-NORINYL 21-DAY	SYNTEX (FP)	ETHINYL ESTRADIOL
04-FEB-94	(TABLET)	HUMACAO, PR	0.035MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		00661	NORETHINDRONE
			0.5MG AND 1MG
			(LABELING REVISION --
			PATIENT PACKAGE INSERTS;
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			INFORMATION FOR THE PATIENT)
18-977	TRI-NORINYL 28-DAY	SYNTEX (FP)	ETHINYL ESTRADIOL
04-FEB-94	(TABLET)	HUMACAO, PR	0.035MG
		00661	NORETHINDRONE
			0.5MG AND 1MG
			(LABELING REVISION --
			PATIENT PACKAGE INSERTS;
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			INFORMATION FOR THE PATIENT)
19-898	PRAVACHOL	BRISTOL MYERS SQUIBB	PRAVASTATIN SODIUM
08-FEB-94	(TABLET)	PRINCETON, NJ	10MG
		08543	20MG
			40MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)
18-017	BLOCADREN	MSD	TIMOLOL MALEATE
09-FEB-94	(TABLET)	WEST POINT, PA	5MG
		19486	10MG
			20MG
			(LABELING REVISION --
			DESCRIPTION; PRECAUTIONS;
			OVERDOSAGE)
18-061	TIMOLIDE 10-25	MSD	HYDROCHLOROTHIAZIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

09-FEB-94	(TABLET)	WEST POINT, PA	25MG
	19486		TIMOLOL MALEATE
			10MG
			(LABELING REVISION --
			PRECAUTIONS; OVERDOSAGE)
20-154	VIDEX	BRISTOL MYERS SQUIBB	DIDANOSINE
10-FEB-94	(TABLET, CHEWABLE)	WALLINGFORD, CT	25MG
	06492		50MG
			100MG
			150MG
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY)
20-155	VIDEX	BRISTOL MYERS SQUIBB	DIDANOSINE
10-FEB-94	(POWDER FOR	WALLINGFORD, CT	100MG/PACKETT
	RECONSTITUTION)	06492	167MG/PACKETT
			250MG/PACKETT
			375MG/PACKETT
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY)
20-156	VIDEX	BRISTOL MYERS SQUIBB	DIDANOSINE
10-FEB-94	(POWDER FOR	WALLINGFORD, CT	10MG/ML
	RECONSTITUTION)	06492	(LABELING REVISION --
			CLINICAL PHARMACOLOGY)
11-145	DIURIL	MERCK	CHLOROTHIAZIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

16-FEB-94	(TABLET)	WEST POINT, PA	250MG
	19486		500MG
		(LABELING REVISION --	
		PRECAUTIONS;	
		DOSAGE AND ADMINISTRATION)	
11-835	HYDRODIURIL	MERCK	HYDROCHLOROTHIAZIDE
16-FEB-94	(TABLET)	WEST POINT, PA	25MG
	19486		50MG
			100MG
		(LABELING REVISION --	
		PRECAUTIONS)	
11-870	DIURIL	MERCK	CHLOROTHIAZIDE
16-FEB-94	(SUSPENSION)	WEST POINT, PA	EQ 250MG/5ML
	19486		(LABELING REVISION --
		PRECAUTIONS;	
		DOSAGE AND ADMINISTRATION)	
12-148	ORETICYL 25	ABBOTT LABS	DESERPIDINE
16-FEB-94	(TABLET)	ABBOTT PARK, IL	0.125MG
	60064		HYDROCHLOROTHIAZIDE
			25MG
		(LABELING REVISION --	
		LABELING FORMAT	
		REVISION PROGRAM)	
12-148	ORETICYL 50	ABBOTT LABS	DESERPIDINE
16-FEB-94	(TABLET)	ABBOTT PARK, IL	0.125MG
	60064		HYDROCHLOROTHIAZIDE
			50MG
		(LABELING REVISION --	
		LABELING FORMAT	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			REVISION PROGRAM)
12-148	ORETICYL FORTE	ABBOTT LABS	DESERPIDINE
16-FEB-94	(TABLET)	ABBOTT PARK, IL	0.25MG
		60064	HYDROCHLOROTHIAZIDE
			25MG
			(LABELING REVISION --
			LABELING FORMAT
			REVISION PROGRAM)
12-462	LOMOTIL	SEARLE	ATROPINE SULFATE
18-FEB-94	(TABLET)	SAN JUAN, PR	0.025MG
		00936	DIPHENOXYLATE HYDROCHLORIDE
			2.5MG
			(LABELING REVISION --
			DESCRIPTION)
12-541	DEPO-PROVERA	UPJOHN	MEDROXYPROGESTERONE ACETATE
18-FEB-94	(INJECTABLE)	KALAMAZOO, MI	400MG/ML
		49001	(LABELING REVISION --
			WARNINGS; PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)
12-699	LOMOTIL	SEARLE	ATROPINE SULFATE
18-FEB-94	(SOLUTION)	SAN JUAN, PR	0.025MG/5ML
		00936	DIPHENOXYLATE HYDROCHLORIDE
			2.5MG/5ML
			(LABELING REVISION --
			DESCRIPTION)
12-836	PERSANTINE	BOEHRINGER INGELHEIM	DIPYRIDAMOLE
18-FEB-94	(TABLET)	RIDGEFIELD, CT	25MG
		06877	50MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			75MG
			(LABELING REVISION --
			PRECAUTIONS; OVERDOSAGE)
18-998	VASOTEC	MERCK	ENALAPRIL MALEATE
18-FEB-94	(TABLET)	WEST POINT, PA	2.5MG
	19486		5MG
			10MG
			20MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
19-221	VASERETIC	MERCK	ENALAPRIL MALEATE
18-FEB-94	(TABLET)	WEST POINT, PA	10MG
	19486		HYDROCHLOROTHIAZIDE
			25MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
19-309	VASOTEC	MERCK	ENALAPRILAT
18-FEB-94	(INJECTABLE)	WEST POINT, PA	1.25MG/ML
	19486		(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
18-123	FACTREL	WYETH AYERST LABS	GONADORELIN HYDROCHLORIDE
22-FEB-94	(INJECTABLE)	NEW YORK, NY	EQ 0.1MG BASE/VIAL
	12979		EQ 0.5MG BASE/VIAL
			(LABELING REVISION --
			PRECAUTIONS)
19-766	ZOCOR	MERCK	SIMVASTATIN
22-FEB-94	(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

			(LABELING REVISION -- CLINICAL PHARMACOLOGY; ADVERSE REACTIONS; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
13-296	DUO-MEDIHALER	3M	ISOPROTERENOL HYDROCHLORIDE
23-FEB-94	(AEROSOL, METERED)	SAINT PAUL, MN 55144	0.16MG/INH PHENYLEPHRINE BITARTRATE 0.24MG/INH (LABELING REVISION -- PATIENT INSTRUCTIONS)
18-703	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
28-FEB-94	(TABLET)	RES TRIANGLE PK, NC 27709	EQ 150MG BASE (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
18-703	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
28-FEB-94	(TABLET)	RES TRIANGLE PK, NC 27709	EQ 300MG BASE (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
19-675	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
28-FEB-94	(SYRUP)	RES TRIANGLE PK, NC 27709	EQ 15MG BASE/ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1169 NONE *CELLTECH BIOLGCS PLC SATUMOMAB CONCENTRATE
01-FEB-94 (NONE) SLOUGH, BERKSHIRE (FOR FURTHER MANUFACTURING USE)
SLI 4EN, UK (A&B)

1169 NONE *CELLTECH BIOLGCS PLC BLOOD GROUPING REAGENT
01-FEB-94 (IN VITRO) SLOUGH, BERKSHIRE (MONOCLONAL)
SL1 4EN, UK (FOR FURTHER MANUFACTURING USE)
(B)

1171 ONCASPAR ENZON PEGASPARGASE
01-FEB-94 (INJECTABLE) PISCATAWAY, NJ (FOR TREATMENT OF PATIENTS WITH
08854 ACUTE LYMPHOBLASTIC LEUKEMIA)
(A&B)

0201 NONE SAN DIEGO BLOOD BANK CRYOPRECIPITATED AHF
03-FEB-94 (INJECTABLE) SAN DIEGO, CA (TRANSFUSION)
92103 (B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

* - Formerly Celltech Limited
(A) Established License Issued
(B) Product License Issued

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK930023	LITTLE PIG	NU QUEST	BLOOD SAMPLE
24-FEB-94	STICKER	WEBB CITY, MO	SEGMENT EVACUATION
	64870	(C)	
BK930031	EXPRESSO	GENECTIC SYS CORP	SOFTWARE FOR BLOOD
24-FEB-94	CARTRIDGE FOR	REDMOND, WA	VIRUS APPLICATIONS
	BLOOD	98052	(C)
	APPLICATIONS		
BK940003	QWIK-1	MICROWAVE MED SYS	BLOOD AND PLASMA
24-FEB-94		LITTLETON, MA	WARNING DEVICE
	01460	(C)	

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

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

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

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

P930005 02/28/94	K-C STERILE PRESERVED SALINE SOLUTION	KC PHARMACEUTICALS, INC. POMONA, CA 91768	APPROVAL FOR THE K-C STERILE PRESERVED SALINE SOLUTION

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

N18466 /S15	CMW ORTHOPAEDIC BONE CEMENT	DENTSPLY INTERNATIONAL YORK, PA 17405-0872	MANUFACTURING MODIFICATIONS	02/15/94
P810002/S27	ST. JUDE MEDICAL PROSTHETIC HEART VALVE	ST. JUDE MEDICAL ST. PAUL, MN 55117	APPROVAL TO MARKET THE COATED AORTIC VALVED GRAFT PROSTHESIS (MODEL CVAG-304) IN SIZES 21, 23, 25, 27, 29, 31, AND 33 MM	02/10/94
P820018/S60	AUTIMA MODEL 2251 AND 2600	TELECTRONICS PACING SYSTEMS ENGLEWOOD, CO 80112	ISOMEDIX, INC. OF SPARTANBURG, SOUTH CAROLINA AS THE NEW CONTRACT STERILIZATION COMPANY	02/24/94
P880038/S25	META-MV PACING SYSTEM	TELECTRONICS PACING SYSTEMS ENGLEWOOD, CO 80112	ISOMEDIX, INC. OF SPARTANBURG, SOUTH CAROLINA AS THE NEW CONTRACT STERILIZATION COMPANY	02/24/94
P900070/S05	META DDDR PACING SYSTEM	TELECTRONICS PACING SYSTEMS ENGLEWOOD, CO 80112	ISOMEDIX, INC. OF SPARTANBURG, SOUTH CAROLINA AS THE NEW CONTRACT STERILIZATION COMPANY	02/24/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P820065/S82 02/16/94	THE BOSTON LENS II (ITAFOCON A) AND THE BOSTON LENS IV (ITAFOCON B) CONTACT LENSES	WILMINGTON PARTNERS LP WILMINGTON, MA 01887	ONE FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P860022/S45 02/16/94	THE BOSTON EQUALENS (ITAFLUOROFOCON A) AND THE BOSTON RXD (ITABISFLUOROFOCON A) CONTACT LENSES	WILMINGTON PARTNERS L.P. WILMINGTON, MA 01887	ONE FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P830055/S17 02/24/94	ROTATING PLATFORM CONFIGURATION OF THE N.J. LCS TOTAL KNEE SYSTEM	DEPUY INC. WARSAW, IN 46581-0988	APPROVAL FOR THE ROTATING PLATFORM CONFIGURATION OF THE N.J. LCS TOTAL KNEE SYSTEM
P830071/S04 02/16/94	PERM-WET WETTING AND SOAKING SOLUTION, PERM-CLEAN DAILY CLEANER, AND PD 1413 WETTING, SOAKING, AND DISINFECTION SOLUTION	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	PACO PHARMACEUTICAL SERVICES, INC. AS AN ALTERNATE MANUFACTURING SITE
P840055/S3 02/04/94	SGP (TELEFOCON A) AND SGP II (TELEFOCON B) SILICONE-ACRYLATE RIGID GAS PERMEABLE	PERMEABLE TECHNOLOGIES, INC. MORGANVILLE, NJ 07751	MANUFACTURING MODIFICATIONS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

CONTACT LENSES

P850021/S21 02/04/94	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER READY .14 PTCA CATHETER	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	APPROVAL FOR THE READY .14 PTCA CATHETER
P850021/S23 02/10/94	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, QUICK .14 PTCA CATHETER	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	MANUFACTURING MODIFICATIONS
P860061/S07 02/22/94	HYDROZYME (SUBTILISIN A) WEEKLY ENZYMATIC CLEANER	ALLERGAN OPTICAL IRVINE, CA 92713-9534	REVISED LABELING
P880024/S02 02/24/94	N-18 (KOLFOCON A) AND N-32 (KOLFOCON B) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	NEEFE OPTICAL SUPPLY BIG SPRING, TX 79721-2196	PROTOCOL TO ALLOW CONTACT LENS FINISHING LABORATORIES TO MANUFACTURE AND MARKET RIGID GAS PERMEABLE (RGP) CONTACT LENSES

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890001/S02 02/15/94	CORFLO MODELS 5S, 7.5S AND 7.5PT PTCA CATHETER AND HEMOPERFUSION PUMP	LEOCOR, INC. HOUSTON, TX 77058	APPROVAL FOR THE CORFLO MODEL 5S, 7.5S AND 7.5PT PTCA CATHETER AND HEMOPERFUSION PUMP
P920045/S01 02/24/94	OP-3 (LOTIFOCON A) RIGID GAS PERMEABLE CONTACT LENS	STELLAR CONTACT LENS, INC. CHICAGO, IL 60611	PROTOCOL FOR ADDING LENS FINISHING LABORATORIES FOR MANUFACTURING AND MARKETING RIGID GAS PERMEABLE (RGP) CONTACT LENSES FROM OP-3 MATERIAL

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 FEBRUARY 1994.

ORIGINAL ABBREVIATED VETERINARY NADAs

200-075 23-FEB-94	SACOX (POWDER)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	SALINOMYCIN SODIUM 30GM/LB
200-071 24-FEB-94	EUTHASOL (SOLUTION)	DOGS	DELMARVA LABS MIDLOTHIAN, VA 23113	PENTOBARBITAL SODIUM 390MG/ML PHENYTOIN SODIUM 50MG/ML
200-088 24-FEB-94	SEDAZINE (SOLUTION)	HORSES, CERVIDAE	FORT DODGE LABS FORT DODGE, IA 50501	XYLAZINE HYDROCHLORIDE 100MG/ML

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR FEBRUARY 1994.

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

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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

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

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

16-042 DYAZIDE SMITHKLINE BEECHAM HYDROCHLOROTHIAZIDE
03-MAR-94 (CAPSULE) KING OF PRUSSIA, PA 25MG
(SUPPL) 19406 TRIAMTERENE
37.5MG
(NEW STRENGTH)

20-355 DESMOPRESSIN ACETATE RHONE POULENC RORER DESMOPRESSIN ACETATE
07-MAR-94 (SPRAY, METERED) COLLEGEVILLE, PA 0.15MG/INH
(3 P, V*) 19426 (HEMOSTASIS AGENT)
[TREATMENT OF PATIENTS WITH
HEMOPHILIA A OR VON
WILLEBRAND'S DISEASE
(TYPE I) WHOSE FACTOR VIII
COAGULANT ACTIVITY IS
GREATER THAN 5%]

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

20-095	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
08-MAR-94	(CAPSULE)	RES TRIANGLE PK, NC	EQ 150MG BASE
(3 S)		27709	(HISTAMINE H-2 RECEPTOR ANTAGONIST)

20-095	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
08-MAR-94	(CAPSULE)	RES TRIANGLE PK, NC	EQ 300MG BASE
(3 S)		27709	(HISTAMINE H-2 RECEPTOR ANTAGONIST)

V* - Designated Orphan Drug

19-676	NUTROPIN	GENENTECH	SOMATROPIN
09-MAR-94	(INJECTABLE)	SAN FRANCISCO, CA	5MG/VIAL
(5 S, V*)		94080	10MG/VIAL
			(HUMAN GROWTH HORMONE) [LONG TERM TREATMENT OF CHILDREN WHO HAVE GROWTH FAILURE DUE TO A LACK OF ENDOGENOUS GROWTH HORMONE SECRETION]

20-214	ZEMURON	ORGANON	ROCURONIUM BROMIDE
17-MAR-94	(INJECTABLE)	WEST ORANGE, NJ	10MG/ML
(1 S)		07052	(NONDEPOLARIZING NEUROMUSCULAR BLOCKING AGENT)

20-214	ZEMURON (P/F)	ORGANON	ROCURONIUM BROMIDE
17-MAR-94	(INJECTABLE)	WEST ORANGE, NJ	10MG/ML

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

(1 S)	07052		(NONDEPOLARIZING NEUROMUSCULAR BLOCKING AGENT)
17-970	NOLVADEX	ZENECA	TAMOXIFEN CITRATE
21-MAR-94	(TABLET)	WILMINGTON, DE	EQ 20MG BASE**
(SUPPL)	19897		(NEW STRENGTH) (NEW DOSAGE REGIMEN -- ONCE OR TWICE DAILY DOSING WITH A 20MG TABLET)
20-237	SALAGEN	MGI	PILOCARPINE HYDROCHLORIDE
22-MAR-94	(TABLET)	MINNEAPOLIS, MN	5MG
(3 P, V*)	55343		(CHOLINERGIC AGONIST) [TREATMENT OF SYMPTOMS OF XEROSTOMIA FROM SALIVARY GLAND HYPOFUNCTION CAUSED BY RADIOTHERAPY FOR CANCER OF THE HEAD AND NECK]

V* - Designated Orphan Drug
** - Not Marketed At This Time

19-806	SEMPREX	BURROUGHS WELLCOME	ACRIVASTINE
25-MAR-94	(CAPSULE)	RES TRIANGLE PK, NC	8MG
(1, 4 S)	27709		(ANTIHISTAMINE) PSEUDOEPHEDRINE HYDROCHLORIDE 60MG (DECONGESTANT)
20-084	IOBENGUANE	CIS	M-IODOBENZYL
25-MAR-94	SULFATE I 131	BEDFORD, MA	GUANIDINE SULFATE, I-131
(1 P)	(INJECTABLE)	01730	2.3mCi/ML (RADIOACTIVE DIAGNOSTIC) [ADJUNCTIVE DIAGNOSTIC AGENT

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

			IN THE LOCALIZATION OF PRIMARY OR METASTATIC PHEOCHROMOCYTOMAS AND NEUROBLASTOMAS]
50-653	ACTISITE	ON SITE	TETRACYCLINE HYDROCHLORIDE
25-MAR-94	(FIBER,	WAYLAND, MA	12.7MG/FIBER
(3 S)	EXTENDED RELEASE)	01778	(ANTIBIOTIC, TETRACYCLINE) [ADJUNCT TO SCALING AND ROOT PLANING FOR REDUCTION OF POCKET DEPTH AND BLEEDING ON PROBING IN PATIENTS WITH ADULT PERIODONTITIS]
20-083	SPORANOX	JANSSEN	ITRACONAZOLE
29-MAR-94	(CAPSULE)	PISCATAWAY, NJ	100MG
(SUPPL)		08855	(NEW INDICATION -- TREATMENT OF PULMONARY AND EXTRAPULMONARY ASPERGILLOSIS IN PATIENTS WHO ARE INTOLERANT OF OR WHO ARE REFRACTORY TO AMPHOTERICIN B THERAPY)
09-218	COUMADIN	DUPONT MERCK	WARFARIN SODIUM
31-MAR-94	(TABLET)	WILMINGTON, DE	1MG
(SUPPL)		19880	2MG 2.5MG 4MG 5MG 7.5MG 10MG

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

(NEW INDICATION --
PROPHYLAXIS AND/OR
TREATMENT OF THROMBOEMBOLIC
COMPLICATIONS ASSOCIATED
WITH PROSTHETIC HEART VALVE
REPLACEMENT)

18-780 31-MAR-94 (SUPPL)	HUMULIN R (INJECTABLE) 46285	LILLY INDIANAPOLIS, IN	INSULIN BIOSYNTHETIC HUMAN 500 UNITS/ML (NEW STRENGTH)
20-251 31-MAR-94 (3 S)	ZANTAC 150 (GRANULE, EFFERVESCENT)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 150MG BASE/PACKET (HISTAMINE H-2 RECEPTOR ANTAGONIST)
20-251 31-MAR-94 (3 S)	ZANTAC 150 (TABLET, EFFERVESCENT)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 150MG BASE (HISTAMINE H-2 RECEPTOR ANTAGONIST)

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.

20-389	MYCELEX 7	MILES	CLOTRIMAZOLE
22-MAR-94	COMBINATION PACK	WEST HAVEN, CT	1%-CREAM
	(SUPPOSITORY AND CREAM)	06516	100MG-SUPPOSITORY
			(ANTIFUNGAL)
			(OTC)
20-323	ESTRADIOL	NOVEN	ESTRADIOL
24-MAR-94	(FILM, EXTENDED RELEASE)	MIAMI, FL 33186	0.0375MG/24HR
			0.05MG/24HR
			0.075MG/24HR
			0.10MG/24HR
			(ESTROGEN)
50-703	BACTROBAN	SMITHKLINE BEECHAM	MUPIROCIN CALCIUM
28-MAR-94	(OINTMENT)	KING OF PRUSSIA, PA 19406	EQ 2% BASE
			(ANTIBACTERIAL)

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

APPROVABLE ORIGINAL NDAs

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

ORIGINAL ABBREVIATED NDAs

74-307*	LEVOBUNOLOL HCL	BAUSCH AND LOMB	LEVOBUNOLOL HYDROCHLORIDE
04-MAR-94	(SOLUTION/DROPS)	TAMPA, FL	0.25%
	33637		(BETA ADRENERGIC BLOCKER)
74-326*	LEVOBUNOLOL HCL	BAUSCH AND LOMB	LEVOBUNOLOL HYDROCHLORIDE
04-MAR-94	(SOLUTION/DROPS)	TAMPA, FL	0.5%
	33637		(BETA ADRENERGIC BLOCKER)
81-149	HYDROXYZINE HCL	ROYCE LABS	HYDROXYZINE HYDROCHLORIDE
18-MAR-94	(TABLET)	MIAMI, FL	10MG
	33014		(ANXIOLYTIC/ANTIPRURITIC)
81-150	HYDROXYZINE HCL	ROYCE LABS	HYDROXYZINE HYDROCHLORIDE
18-MAR-94	(TABLET)	MIAMI, FL	25MG
	33014		(ANXIOLYTIC/ANTIPRURITIC)
81-151	HYDROXYZINE HCL	ROYCE LABS	HYDROXYZINE HYDROCHLORIDE
18-MAR-94	(TABLET)	MIAMI, FL	50MG
	33014		(ANXIOLYTIC/ANTIPRURITIC)
74-126	ATENOLOL	GENPHARM	ATENOLOL
23-MAR-94	(TABLET)	ETOBICOKE, CANADA	50MG
			100MG
			(BETA ADRENERGIC BLOCKER)
73-288	METOPROLOL TARTRATE	GENEVA PHARM	METOPROLOL TARTRATE
25-MAR-94	(TABLET)	BROOMFIELD, CO	50MG
	80038		(BETA ADRENERGIC BLOCKER)
73-289	METOPROLOL TARTRATE	GENEVA PHARM	METOPROLOL TARTRATE
25-MAR-94	(TABLET)	BROOMFIELD, CO	100MG
	80038		(BETA ADRENERGIC BLOCKER)
74-031*	TRIAZOLAM	ALPHAPHARM PTY	TRIAZOLAM

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

ORIGINAL ABBREVIATED NDAs

25-MAR-94	(TABLET)	BRISBANE, AUSTRALIA	0.125MG 0.25MG (SEDATIVE/HYPNOTIC)

* - First Time Product Available Generically

74-080	CARBIDOPA AND	SCS PHARMS	CARBIDOPA
25-MAR-94	LEVODOPA	SKOKIE, IL	10MG
	(TABLET)	60077	LEVODOPA 100MG (ANTIPARKINSON)

74-080	CARBIDOPA AND	SCS PHARMS	CARBIDOPA
25-MAR-94	LEVODOPA	SKOKIE, IL	25MG
	(TABLET)	60077	LEVODOPA 100MG (ANTIPARKINSON)

74-080	CARBIDOPA AND	SCS PHARMS	CARBIDOPA
25-MAR-94	LEVODOPA	SKOKIE, IL	25MG
	(TABLET)	60077	LEVODOPA 250MG (ANTIPARKINSON)

73-019	IBUPROFEN	MCNEIL CONSUMER	IBUPROFEN
30-MAR-94	(TABLET)	FORT WASHINGTON, PA	200MG
	19034		(NONSTEROIDAL ANTI-INFLAMMATORY)

74-190*	NAPROXEN	ROXANE LABS	NAPROXEN
30-MAR-94	(SUSPENSION)	COLUMBUS, OH	25MG/ML
	43216		(NONSTEROIDAL ANTI-INFLAMMATORY)

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

ORIGINAL ABBREVIATED NDAs

63-294 31-MAR-94	CEFIZOX (INJECTABLE)	FUJISAWA USA DEERFIELD, IL 60015	CEFTIZOXIME SODIUM EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL (ANTIBIOTIC, CEPHEM)

* - First Time Product Available Generically

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

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

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

74-300 28-MAR-94	LORAZEPAM (INJECTABLE)	STERLING NEW YORK, NY 10016	LORAZEPAM 2MG/ML (ANXIOLYTIC)
74-243 31-MAR-94	LORAZEPAM (INJECTABLE)	STERLING NEW YORK, NY 10016	LORAZEPAM 2MG/ML 4MG/ML (ANXIOLYTIC)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

06-327 ISUPREL STERLING ISOPROTERENOL HYDROCHLORIDE
07-FEB-94 (SOLUTION) NEW YORK, NY 0.5%
10016 1%
(LABELING REVISION --
DESCRIPTION;
CLINICAL PHARMACOLOGY;
INDICATIONS AND USAGE;
CONTRAINDICATIONS;
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS;
OVERDOSAGE;
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED)

19-085 ATROVENT BOEHRINGER INGELHEIM IPRATROPIUM BROMIDE
25-FEB-94 (AEROSOL, METERED) RIDGEFIELD, CT 0.018MG/INH
06877 (LABELING REVISION --
HOW SUPPLIED)

16-796 INAPSINE JANSSEN DROPERIDOL
02-MAR-94 (INJECTABLE) PISCATAWAY, NJ 2.5MG/ML
08854 (LABELING REVISION --
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS;
OVERDOSAGE)

19-453 DRIXORAL PLUS SCHERING PLOUGH ACETAMINOPHEN
02-MAR-94 (TABLET, LIBERTY CORNER, NJ 500MG
EXTENDED RELEASE) 07938 DEXBROMPHENIRAMINE MALEATE
3MG
PSEUDOEPHEDRINE SULFATE
60MG
(LABELING REVISION --
ALTERNATE NAME --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

	DRIXORAL ALLERGY SINUS)		
	(OTC)		
19-898	PRAVACHOL	BRISTOL MYERS SQUIBB	PRAVASTATIN SODIUM
02-MAR-94	(TABLET)	PRINCETON, NJ	10MG
	08543		20MG
			40MG
		(LABELING REVISION --	
		OVERDOSAGE)	
20-098	MIVACRON	BURROUGHS WELLCOME	MIVACURIUM CHLORIDE
02-MAR-94	IN DEXTROSE 5%	RES TRIANGLE PK, NC	EQ 0.5MG BASE/ML
	IN PLASTIC CONTAINER	27709	EQ 50MG BASE/100ML
	(INJECTABLE)	(LABELING REVISION --	
		DOSAGE AND ADMINISTRATION)	
20-098	MIVACRON	BURROUGHS WELLCOME	MIVACURIUM CHLORIDE
02-MAR-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 2MG BASE/100ML
	27709	(LABELING REVISION --	
		DOSAGE AND ADMINISTRATION)	
20-189	FELBATOL	WALLACE	FELBAMATE
02-MAR-94	(SUSPENSION)	CRANBURY, NJ	600MG/5ML
	08512	(LABELING REVISION --	
		CLINICAL PHARMACOLOGY;	
		CLINICAL STUDIES;	
		PRECAUTIONS)	
20-189	FELBATOL	WALLACE	FELBAMATE
02-MAR-94	(TABLET)	CRANBURY, NJ	400MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		08512	600MG
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			CLINICAL STUDIES;
			PRECAUTIONS)
16-042	DYAZIDE	SMITHKLINE BEECHAM	HYDROCHLOROTHIAZIDE
03-MAR-94	(CAPSULE)	KING OF PRUSSIA, PA	25MG
		19406	TRIAMTERENE
			37.5MG
			(LABELING REVISION --
			DESCRIPTION;
			ADVERSE REACTIONS;
			HOW SUPPLIED)
19-008	BRETYLIUM TOSYLATE	ABBOTT	BRETYLIUM TOSYLATE
04-MAR-94	IN DEXTROSE 5%	ABBOTT PARK, IL	200MG/100ML
	(INJECTABLE)	60064	400MG/100ML
			(LABELING REVISION --
			DESCRIPTION; WARNINGS;
			PRECAUTIONS;
			ADVERSE REACTIONS)
19-030	BRETYLIUM TOSYLATE	ABBOTT	BRETYLIUM TOSYLATE
04-MAR-94	(INJECTABLE)	ABBOTT PARK, IL	50MG/ML
		60064	(LABELING REVISION --
			DESCRIPTION; WARNINGS;

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; HOW SUPPLIED)
19-033 04-MAR-94	BRETYLIUM TOSYLATE (INJECTABLE) 60064	ABBOTT ABBOTT PARK, IL	BRETYLIUM TOSYLATE 50MG/ML (LABELING REVISION -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
07-529 07-MAR-94	QUINIDINE GLUCONATE (INJECTABLE) 46285	ELI LILLY INDIANAPOLIS, IN	QUINIDINE GLUCONATE 80MG/ML (LABELING REVISION -- DESCRIPTION; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
13-402 07-MAR-94	ALDORIL 15 (TABLET) 19486	MERCK WEST POINT, PA	HYDROCHLOROTHIAZIDE 15MG METHYLDOPA 250MG (LABELING REVISION --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			PRECAUTIONS; HOW SUPPLIED)
13-402	ALDORIL 25	MERCK	HYDROCHLOROTHIAZIDE
07-MAR-94	(TABLET)	WEST POINT, PA	25MG
	19486		METHYLDOPA
			250MG
			(LABELING REVISION --
			PRECAUTIONS; HOW SUPPLIED)
13-402	ALDORIL D30	MERCK	HYDROCHLOROTHIAZIDE
07-MAR-94	(TABLET)	WEST POINT, PA	30MG
	19486		METHYLDOPA
			500MG
			(LABELING REVISION --
			PRECAUTIONS; HOW SUPPLIED)
13-402	ALDORIL D50	MERCK	HYDROCHLOROTHIAZIDE
07-MAR-94	(TABLET)	WEST POINT, PA	50MG
	19486		METHYLDOPA
			500MG
			(LABELING REVISION --
			PRECAUTIONS; HOW SUPPLIED)
18-485	ISOPTIN	KNOLL PHARM	VERAPAMIL HYDROCHLORIDE
07-MAR-94	(INJECTABLE)	WHIPPANY, NJ	2.5MG/ML
	07981		(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			OVERDOSAGE)
50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
07-MAR-94	(INJECTABLE)	WEST POINT, PA	EQ 250MG BASE/VIAL
	19486		IMIPENEM
			250MG/VIAL
			(LABELING REVISION --

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)
50-587 07-MAR-94	PRIMAXIN (INJECTABLE) 19486	MSD WEST POINT, PA	CILASTATIN SODIUM EQ 500MG BASE/VIAL IMIPENEM 500MG/VIAL (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
19-558 10-MAR-94	PRINIVIL (TABLET) 19486	MERCK WEST POINT, PA	LISINOPRIL 5MG 10MG 20MG 40MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
19-778 10-MAR-94	PRINZIDE 10-12.5 (TABLET) 19486	MERCK WEST POINT, PA	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 10MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
19-778 10-MAR-94	PRINZIDE 20-12.5 (TABLET) 19486	MERCK WEST POINT, PA	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 20MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
19-778	PRINZIDE 20-25	MERCK	HYDROCHLOROTHIAZIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

10-MAR-94	(TABLET)	WEST POINT, PA	25MG
	19486	LISINOPRIL	
			20MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
20-164	LOVENOX	RHONE POULENC RORER	ENOXAPARIN SODIUM
14-MAR-94	(INJECTABLE)	COLLEGEVILLE, PA	30MG/0.3ML
	19426		(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			WARNINGS; PRECAUTIONS)
18-671	SODIUM IODIDE I 123	NORTH AM CHEM	SODIUM IODIDE, I-123
17-MAR-94	(CAPSULE)	GOLDEN, CO	100 UCI
	80401		200 UCI
			(LABELING REVISION --
			RADIATION DOSIMETRY)
17-970	NOLVADEX	ZENECA PHARMS	TAMOXIFEN CITRATE
21-MAR-94	(TABLET)	WILMINGTON, DE	EQ 10MG BASE
	19897		(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			WARNINGS; PRECAUTIONS)
18-533	NIZORAL	JANSSEN	KETOCONAZOLE
22-MAR-94	(TABLET)	PISCATAWAY, NJ	200MG
	08854		(LABELING REVISION --
			DRUG INTERACTIONS;
			HOW SUPPLIED)
20-090	DIFLUCAN	PFIZER	FLUCONAZOLE
22-MAR-94	(POWDER	NEW YORK, NY	50MG/5ML
	FOR RECONSTITUTION)	10017	200MG/5ML

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
			(LABELING REVISION -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
16-126 24-MAR-94	PRIMATENE MIST (AEROSOL, METERED) 10017	WHITEHALL NEW YORK, NY	EPINEPHRINE 0.2MG/INH (LABELING REVISION -- PATIENT INSTRUCTIONS) (OTC)
16-126 24-MAR-94	BRONITIN MIST (AEROSOL, METERED) 10017	WHITEHALL NEW YORK, NY	EPINEPHRINE BITARTRATE 0.3MG/INH (LABELING REVISION -- PATIENT INSTRUCTIONS) (OTC)
10-379 28-MAR-94	CYTOMEL (TABLET) 19428	SMITHKLINE BEECHAM CONSHOHOCKEN, PA	LIOTHYRONINE SODIUM EQ 0.005MG BASE EQ 0.025MG BASE EQ 0.05MG BASE (LABELING REVISION -- DESCRIPTION; PRECAUTIONS; DOSAGE AND ADMINISTRATION; OVERDOSAGE)
19-415 28-MAR-94	METRODIN (INJECTABLE) 02061	SERONO NORWELL, MA	UROFOLLITROPIN 75IU/AMP (LABELING REVISION -- INDICATIONS AND USAGE)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-726 29-MAR-94	ZOLADEX (IMPLANT)	ZENECA MACCLESFIELD, UNITED KINGDOM	GOSERELIN ACETATE EQ 3.6MG BASE (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-813 29-MAR-94	DURAGESIC (FILM, EXTENDED RELEASE)	ALZA PALO ALTO, CA 94303	FENTANYL 0.6MG/24HR 1.2MG/24HR 1.8MG/24HR 2.4MG/24HR (LABELING REVISION -- PATIENT INSTRUCTIONS)
20-083 29-MAR-94	SPORANOX (CAPSULE)	JANSSEN PISCATAWAY, NJ 08855	ITRACONAZOLE 100MG (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
11-145 31-MAR-94	DIURIL (INJECTABLE)	MERCK WEST POINT, PA 19486	CHLOROTHIAZIDE SODIUM EQ 500MG BASE/VIAL (LABELING REVISION -- HOW SUPPLIED)
18-343 31-MAR-94	CAPOTEN (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ	CAPTOPRIL 12.5MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

08543		25MG 50MG 100MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)

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

BIOLOGICAL PRODUCT LICENCES ISSUED

1172 01-MAR-94	NONE (NONE)	UNIV PLASMA OPELOUSAS, LA 70571	SOURCE PLASMA (FOR FURTHER MANUFACTURING USE) (A&B)
1151 16-MAR-94	NONE (IN VITRO)	DOMINION BIOLGS LTD DARTMOUTH, NOVA SCOTIA CANADA, B3B 1M1	REAGENT RED CELLS (BLOOD GROUPING) (B)
1173 24-MAR-94	NONE (NONE)	SIMI BIOLOG FORT SMITH, AR 72903	SOURCE PLASMA (FOR FURTHER MANUFACTURING USE) (A&B)

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

BIOLOGICAL PRODUCT LICENCES ISSUED

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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

THERE ARE NO BIOLOGICAL PRODUCT DEVICE APPROVALS FOR MARCH 1994.

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

P910066 03/04/94	ORTHOLOGIC 1000 BONE GROWTH STIMULATOR	ORTHOLOGIC CORPORATION PHOENIX, AZ 85034	APPROVAL FOR THE ORTHOLOGIC 100O BONE GROWTH STIMULATOR
P920008 03/07/94	UCL-55 AND UCL-55 TORIC (OCUFILCON C) SOFT (HYDROPHILIC) CONTACT LENSES	UNITED CONTACT LENS, INC. LYNNWOOD, WA 98036	APPROVAL FOR THE UCL-55 AND UCL-55 TORIC (OCUFILCON C) SOFT (HYDROPHILIC) CONTACT LENSES
P920032 03/10/94	MODEL 4553 MICRO-PACE DUAL-CHAMBER, DDD, TEMPORARY CARDIAC PACEMAKER	PACE MEDICAL, INC. WALTHAM, MA 02154	APPROVAL FOR THE MODEL 4553 MICRO-PACE DUAL-CHAMBER DDD TEMPORARY CARDIAC PACEMAKER

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

P810002/S25 03/31/94	SAINT JUDE MEDICAL PROSTHETIC HEART VALVE	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	MODIFICATION OF POST APPROVAL STUDY BEING CONDUCTED AS A CONDITION OF APPROVAL OF P810002
P830006/S07 03/01/94	SOFTACT (POLYMACON) HYDROPHILIC CONTACT LENS, SOFTACT II ASPHERIC (POLYMACON) HYDROPHILIC CONTACT LENS	CONTACT LENS CORPORATION OF AMERICA MEMPHIS, TN 38118	ALTERNATE DESIGN CONFIGURATION OF THE SOFTACT POLYMACON HYDROPHILIC CONTACT LENS
P830034/S19 03/14/94	OPTI-FREE RINSING, DISINFECTING AND STORAGE SOLUTION, OPTI-ONE MULTI-PURPOSE SOLUTION	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	REVISED LABELING
P830055/S30 03/17/94	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	MANUFACTURING MODIFICATION
P830055/S31 03/17/94	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	MANUFACTURING MODIFICATIONS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P830061/S21 03/17/94	STER TIP PACING LEAD MODELS 4003 AND 4503, CAPSURE AND CAPSURE SP PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MANUFACTURING MODIFICATIONS
P830061/S22 03/17/94	STER TIP PACING LEAD MODELS 4003 AND 4503, CAPSURE AND CAPSURE SP PACING LEAD MODELS 4003M, 4503M, 4504M AND 4523	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MANUFACTURING MODIFICATIONS
P840019/S10 03/17/94	TANDEM-R CEA, HYBRITECH STRATUS CEA FLUOROMETRIC ENZYME IMMUNOASSAY	HYBRITECH, INC. SAN DIEGO, CA 92196-9006	MANUFACTURING MODIFICATIONS
P840024/S34 03/09/94	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATIONS
P840024/S45 03/09/94	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATION
P840024/S49 03/30/94	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT SYSTEM	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	UPGRADED SPEECH PROCESSOR
P840024/S50 03/09/94	NUCLEUS 22 CHANNEL COCHLEAR	COCHLEAR CORPORATION ENGLEWOOD, CO	ADDITION OF RADIOPAQUE LABELING

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	IMPLANT	80112		
P840024/S51	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	NEW LAPEL MICROPHONE CABLE LENGTHS	03/09/94
P840039/S32	POSTERIOR CHAMBER INTRAOCULAR LENSES: PRIVATE DISTRIBUTION REQUEST	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	APPROVAL FOR WORLD OPTICS, INC., WESTLAKE VILLAGE, CA, TO DISTRIBUTE STORZ' POSTERIOR CHAMBER INTRAOCULAR LENSES	03/28/94
P870073/S06	POSTERIOR CHAMBER INTRAOCULAR LENSES: PRIVATE DISTRIBUTION REQUEST	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	APPROVAL FOR WORLD OPTICS, INC., WESTLAKE VILLAGE, CA, TO DISTRIBUTE STORZ' POSTERIOR CHAMBER INTRAOCULAR LENSES	03/28/94
P840039/S37	MODEL P434UV ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	APPROVAL FOR THE MODEL P434UV ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	03/28/94
P840040/S36	HEART TRAK CORONARY BALLOON DILATATION CATHETER SYSTEM, SYNERGY II CONVERTIBLE RAPID EXCHANGE PTCA CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	APPROVAL FOR THE SYNERGY II CONVERTIBLE RAPID EXCHANGE PTCA CATHETER	03/17/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P840066/S28	SOFTMATE PEROXIDE SYSTEM, SOFTMATE CONSEPT-2 NEUTRALIZING AND RINSING SPRAY AND SOFTMATE CONSEPT CLEANING AND DISINFECTING SYSTEM	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SITE AND LABELING REVISIONS TO THE PACKAGE INSERT	03/31/94
P850009/S06	CENTOCOR CA 125 RIA	CENTOCOR, INC. NALVERN, PA 19355	REVISED LABELING	03/23/94
P850022/S07	ORTHOPAK BONE GROWTH STIMULATOR	BIOLECTRON, INC. HACKENSACK, NJ 07601	REVISED LABELING	03/09/94
P850035/S13	SPF IMPLANTABLE SPINAL FUSION STIMULATOR, SPF-XL IMPLANTABLE SPINAL FUSION STIMULATOR	ELECTRO-BIOLOGY, INC. PARSIPPANY, NJ 07054-1079	MODIFIED VERSION OF THE SPF 2T IMPLANTABLE SPINAL FUSION STIMULATOR	03/09/94
P850064/S05	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL INCORPORATED SALT LAKE CITY, UT 84115	EXPANSION OF THE INDICATIONS OF THE MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	03/17/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P850089/S26 03/17/94	STER TIP PACING LEAD MODELS 5025 AND 5525, CAPSURE AND CAPSURE SP PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MANUFACTURING MODIFICATIONS
P850089/S28 03/04/94	STER TIP PACING LEAD MODELS 5025 AND 5525, MEDTRONIC CAPSURE SP MODEL 5024M AND CPI DEXATIP MODEL 4262 PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	DESIGN, MANUFACTURING AND LABELING CHANGES TO THE PACING LEADS
P860005/S01 03/17/94	PRO OSTEON IMPLANT 500 CORALLINE HYDROXYAPATITE BONE VOID FILLER	INTERPORE ORTHOPAEDICS, INC. IRVINE, CA 92718-2402	NEW MANUFACTURING SITE
P860005/S03 03/17/94	PRO OSTEON IMPLANT 500 CORALLINE HYDROXYAPATITE BONE VOID FILLER	INTERPORE INTERNATIONAL IRVINE, CA 92718-2402	APPROVAL FOR CHANGING THE POST-MARKET STUDY BY SENDING A QUESTIONNAIRE DIRECTLY TO EACH PATIENT ENROLLED IN THE STUDY

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P860019/S82	SCIMED PTCA CATHETERS	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	REVISED PACKAGING	03/18/94
P860022/S40	THE BOSTON EQUALENS II (ITAFLUOROFOCON B) RIGID GAS PERMEABLE CONTACT LENS	WILMINGTON PARTNERS L.P. WILMINGTON, MA 01887	APPROVAL FOR A THERAPEUTIC SCLERAL LENS DESIGN	03/01/94
P860042/S26	LASERPROBE-PLR FLEX AND LASERPROBE-PLR PLUS CATHETERS AND OPTILASE MODEL 900 CONTACT LASER SYSTEM, MODEL 1210 OMNIPULSE HOLMIUM:YAG LASER	TRIMEDYNE, INC. IRVINE, CA 92714	MODIFICATION OF THE MAXIMUM OUTPUT OF THE MODEL 1210 OMNIPULSE HOLMIUM:YAG LASER ENERGY SOURCE	03/17/94
P860042/S27	LASERPROBE-PLR FLEX AND LASERPROBE-PLR PLUS CATHETERS AND OPTILASE MODEL 900 CONTACT LASER SYSTEM, MODEL 1210 OMNIPULSE HOLMIUM:YAG LASER	TRIMEDYNE, INC. IRVINE, CA 92714	REVISED STERILIZATION PROCESS AND VALIDATION PROTOCOL	03/01/94
P860059/S62	ULTRAVIOLET-ABSORBING	IOPTEX RESEARCH INC. IRWINDALE, CA	NEW MODEL UPB350NS POSTERIOR CHAMBER	03/28/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	MODEL UPB350NS	91706-2094	INTRAOCULAR LENS POSTERIOR CHAMBER INTRAOCULAR LENS
P870043/S16 03/17/94	TRIMEDYNE'S SPECTRAPROBE-PLR CATHETER AND MODEL 900 OPTILASE CONTACT LASER SOURCE SYSTEM, MODEL 1210 OMNIPULSE HOLMIUM:YAG LASER ENERGY SOURCE	TRIMEDYNE, INC. IRVINE, CA 92714	MODIFICATION OF THE MAXIMUM OUTPUT OF THE MODEL 1210 OMNIPULSE HOLMIUM:YAG LASER ENERGY SOURCE
P880024/S03 03/04/94	N-18 (KOLFOCON A) AND N-32 (KOLFOCON B) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	NEEFE OPTICAL SUPPLY BIG SPRING, TX 79721-2196	MANUFACTURING MODIFICATIONS
P890025/S08 03/31/94	TDX/TDXFLX CYCLOSPORINE AND METABOLITES SERUM/PLASMA AND WHOLE BLOOD, TDX/TDXFLX CYCLOSPORINE MONOCLONAL WHOLE BLOOD	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	REVISED LABELING
P890027/S05 03/09/94	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATIONS

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

			IN CHILDREN AGES 2 THROUGH 17 YEARS
P890027/S16 03/09/94	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATION
P890027/S19 03/30/94	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT SYSTEM	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATIONS
P890027/S20 03/09/94	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	ADDITION OF RADIOPAQUE LABELING TO THE IMPLANT
P890027/S21 03/09/94	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	NEW LAPEL MICROPHONE CABLE LENGTHS
P890034/S02 03/28/94	APT 1010 ULTRAHIGH FREQUENCY VENTILATOR	INFRASONICS, INC. SAN DIEGO, CA 92121	MANUFACTURE OF THE APT 1010 ULTRAHIGH FREQUENCY VENTILATOR AT THE INFRASONICS, INC. MANUFACTURING FACILITY, SORRENTO VALLEY BLVD., SAN DIEGO, CA

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P890046/S26	O-> PERM F6O (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	03/01/94
P890046/S27	O-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE	03/01/94
P900030/S01	CONTIGEN BARD COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303	ALTERNATE METHOD OF STERILIZATION	03/28/94
P910023/S02	CADENCE TIERED THERAPY DEFIBRILLATOR SYSTEM, CADENCE MODEL V-100D PULSE GENERATOR AND MODELS DP-3219 AND DP-3238 EPICARDIAL LEADS	VENTRITEX, INC. SUNNYVALE, CA 94086-6527	APPROVAL FOR THE CADENCE MODEL V-100D PULSE GENERATOR AND MODELS DP-3219 AND DP-3238 EPICARDIAL DEFIBRILLATION LEADS	03/25/94
P900056/S01	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM	HEART TECHNOLOGY, INC. BELLEVUE, WA 98005-1997	ADDITIONAL CONTRACT STERILIZATION FACILITY	03/17/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P900061/S02 03/31/94	MEDTRONIC MODEL 7217 PCD TACHYARRHYTHMIA CONTROL DEVICE AND MODEL 6721 S/M/L EPICARDIAL PATCH LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MODEL 7217D PCD TACHYARRHYTHMIA CONTROL DEVICE AND THE MODEL 6721 S/M/L EPICARDIAL PATCH LEAD
P910023/S05 03/28/94	CADENCE TIERED THERAPY DEFIBRILLATOR SYSTEM	VENTRITEX, INC. SUNNYVALE, CA 94086-6527	REVISED LABELING
P910056/S02 03/28/94	CHIROFLEX II MODELS 32-C30SX/XX AND 32-C31SX/XX SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES	CHIRON VISION CORPORATION IRVINE, CA 92718-1903	APPROVAL FOR THE CHIROFLEX II MODELS 32-C30SX/XX AND 32-C31SX/XX SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES
P830037/S35 03/03/94	DURASOFT 3 COLORS, FRESHLOOK COLORS, AND FRESHLOOK LITETINT (PHEMFILCON A) OPTIFIT TORIC SOFT (HYDROPHILIC) CONTACT LENS	WESLEY-JESSEN CORPORATION DES PLAINES, IL 60018	ALTERNATE MANUFACTURING PROCESS

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

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR MARCH 1994.

ORIGINAL ABBREVIATED VETERINARY NADAs

NADA NUMBER / APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
200-080 28-MAR-94	SACOX (POWDER)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	SALINOMYCIN SODIUM 40-60GM/TON ROXARSONE 45.4GM/TON BAMBENMYCINS 1-2 GM/TON

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR MARCH 1994.

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

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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

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

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

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

*To whom general inquiries should be directed.

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

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

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-126 ZONALON GENDERM DOXEPIN HYDROCHLORIDE
01-APR-94 (CREAM) LINCOLNSHIRE, IL 5%
(3 S) 60069 (ANTIPRURITIC)

50-708 PROGRAF FUJISAWA TACROLIMUS
08-APR-94 (CAPSULE) DEERFIELD, IL EQ 1MG BASE
(1 P, E*) 60015 EQ 5MG BASE
(IMMUNOSUPPRESSANT)
[PROPHYLAXIS OF ORGAN REJECTION IN PATIENTS RECEIVING ALLOGENEIC LIVER TRANSPLANTS]

50-709 PROGRAF FUJISAWA TACROLIMUS

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

08-APR-94	(INJECTABLE)	DEERFIELD, IL	EQ 5MG/ML BASE
(3 P, E*)	60015		(IMMUNOSUPPRESSANT) [PROPHYLAXIS OF ORGAN REJECTION IN PATIENTS RECEIVING ALLOGENEIC LIVER TRANSPLANTS]
20-262	TAXOL	BRISTOL MYERS SQUIBB	PACLITAXEL
13-APR-94	(INJECTABLE)	BUFFALO, NY	6MG/ML
(SUPPL)	14213		(NEW INDICATION -- TREATMENT OF METASTATIC CARCINOMA OF THE BREAST AFTER FAILURE OF FIRST-LINE OR SUBSEQUENT CHEMOTHERAPY)

E* - Drug for Severely Debilitating /Life Threatening Illness

19-640	HUMATROPE	LILLY	SOMATROPIN, BIOSYNTHETIC
15-APR-94	(INJECTABLE)	INDIANAPOLIS, IN	5MG/VIAL
(SUPPL)	46285		(NEW DOSAGE REGIMEN -- INCREASE MAXIMUM DOSE AND VARIATIONS IN THE DOSING REGIMEN)
20-036	AREDIA	CIBA GEIGY	PAMIDRONATE DISODIUM
15-APR-94	(INJECTABLE)	SUMMIT, NJ	30MG/VIAL
(SUPPL)	07901		60MG/VIAL 90MG/VIAL (NEW DOSAGE REGIMEN -- REDUCTION IN INFUSION TIME FROM 24 TO 4 HOURS FOR THE 60MG DOSE)
19-865	BETAPACE	BERLEX	SOTALOL HYDROCHLORIDE

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-APR-94	(TABLET)	WAYNE, NJ	120MG
(SUPPL)		07470	(NEW STRENGTH)

18-654	VERSED	ROCHE	MIDAZOLAM HYDROCHLORIDE
26-APR-94	(INJECTABLE)	NUTLEY, NJ	EQ 1MG BASE/ML
(SUPPL)		07110	EQ 5MG BASE/ML
			(NEW INDICATION -- EXPANSION OF CONSCIOUS SEDATION INDICATION TO INCLUDE SHORT THERAPEUTIC PROCEDURES)

20-329	GLUCOTROL XL	PFIZER	GLIPIZIDE
26-APR-94	(TABLET,	NEW YORK, NY	5MG
(3 S)	EXTENDED RELEASE)	10017	10MG
			(BLOOD GLUCOSE REGULATOR)

20-337	TEMOVATE	GLAXO	CLOBETASOL PROPIONATE
29-APR-94	(GEL)	RES TRIANGLE PK, NC	0.05%
(3 S)		27709	(CORTICOSTEROID)

ERRATA

19-806	SEMPREX-D*	BURROUGHS WELLCOME	ACRIVASTINE

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

25-MAR-94	(CAPSULE)	RES TRIANGLE PK, NC	8MG
(1, 4 S)	27709	(ANTIHISTAMINE)	PSEUDOEPHEDRINE HYDROCHLORIDE 60MG (DECONGESTANT)

* - Corrected Trade Name

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

APPROVABLE ORIGINAL NDAs

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

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

20-286 20-APR-94	MONOPRIL HCT (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	FOSINOPRIL SODIUM 20MG HYDROCHLOROTHIAZIDE 12.5MG (ANTIHYPERTENSIVE)

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

ORIGINAL ABBREVIATED NDAs

63-313	AMIKACIN	BEDFORD	AMIKACIN SULFATE
11-APR-94	(INJECTABLE)	BEDFORD, OH	EQ 50MG BASE/ML
	44146	(ANTIBIOTIC, AMINOGLYCOSIDE)	
63-315	AMIKACIN	BEDFORD	AMIKACIN SULFATE
11-APR-94	(INJECTABLE)	BEDFORD, OH	EQ 250MG BASE/ML
	44146	(ANTIBIOTIC, AMINOGLYCOSIDE)	
74-243*	LORAZEPAM	STERLING WINTHROP	LORAZEPAM
12-APR-94	(INJECTABLE)	NEW YORK, NY	2MG/ML
	10016		4MG/ML
		(ANXIOLYTIC)	
74-300*	LORAZEPAM	STERLING WINTHROP	LORAZEPAM
12-APR-94	(INJECTABLE)	NEW YORK, NY	2MG/ML
	10016	(ANXIOLYTIC)	
74-276	LORAZEPAM	STERIS	LORAZEPAM
15-APR-94	(INJECTABLE)	PHOENIX, AZ	2MG/ML
	85063		4MG/ML
		(ANXIOLYTIC)	
74-209*	CROMOLYN SODIUM	DEY	CROMOLYN SODIUM
26-APR-94	(SOLUTION)	NAPA, CA	10MG/ML
	94558	(ASTHMA PROPHYLACTIC)	
73-403*	QUESTRAN	BRISTOL MYERS SQUIBB	CHOLESTYRAMINE
28-APR-94	(TABLET)	PRINCETON, NJ	EQ 1GM RESIN
	08548	(ANTIHYPERLIPIDEMIC)	
73-447	PENTACARINAT	RHONE POULENC RORER	PENTAMIDINE ISETHIONATE
28-APR-94	(INJECTABLE)	COLLEGEVILLE, PA	300MG/VIAL
	19426	(ANTIPROTOZOAL)	

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

ORIGINAL ABBREVIATED NDAs

40-075	PENTOLAIR	BAUSCH AND LOMB	CYCLOPENTOLATE HYDROCHLORIDE
29-APR-94	(SOLUTION/DROPS)	TAMPA, FL	1%
		33637	(CYCLOPLEGIC MYDRIATIC)

* - First Time Product Available Generically

64-054	GENTAMICIN SULFATE	BAUSCH AND LOMB	GENTAMICIN SULFATE
29-APR-94	(OINTMENT)	TAMPA, FL	EQ 0.1% BASE
		33637	(ANTIBIOTIC, AMINOGLYCOSIDE)

64-056	GENTAMICIN SULFATE	BAUSCH AND LOMB	GENTAMICIN SULFATE
29-APR-94	(CREAM)	TAMPA, FL	EQ 0.1% BASE
		33637	(ANTIBIOTIC, AMINOGLYCOSIDE)

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

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

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

74-151	CIMETIDINE	NOVOPHARM	CIMETIDINE
29-APR-94	(TABLET)	SCARBOROUGH, ONTARIO CANADA	200MG 300MG 400MG (HISTAMINE H2-RECEPTOR ANTAGONIST)
74-281	CIMETIDINE	DUPONT MERCK	CIMETIDINE
29-APR-94	(TABLET)	GARDEN CITY, NY 11530	200MG 300MG 400MG (HISTAMINE H2-RECEPTOR ANTAGONIST)
74-463	CIMETIDINE	NOVOPHARM	CIMETIDINE
29-APR-94	(TABLET)	SCARBOROUGH, ONTARIO CANADA	800MG (HISTAMINE H2-RECEPTOR ANTAGONIST)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20-095 04-APR-94	ZANTAC 150 (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 150MG BASE (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
20-095 04-APR-94	ZANTAC 300 (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 300MG BASE (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
18-154 08-APR-94	LONITEN (TABLET)	UPJOHN KALAMAZOO, MI 49001	MINOXIDIL 2.5MG 10MG (LABELING REVISION -- PRECAUTIONS)
19-501 08-APR-94	ROGAINE (SOLUTION)	UPJOHN KALAMAZOO, MI 49001	MINOXIDIL 2% (LABELING REVISION -- PRECAUTIONS; HOW SUPPLIED)
19-574 08-APR-94	THALITONE (TABLET)	HORUS ROCHESTER, NY 14623	CHLORTHALIDONE 15MG (LABELING REVISION -- CLINICAL PHARMACOLOGY)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-941	EMLA	ASTRA	LIDOCAINE
11-APR-94	(CREAM)	WESTBOROUGH, MA	2.5%
	01581		PRILOCAINE
			2.5%
			(LABELING REVISION --
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)
09-766	METICORTEN	SCHERING	PREDNISONE
13-APR-94	(TABLET)	KENILWORTH, NJ	1MG
	07033		(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
12-657	CELESTONE	SCHERING	BETAMETHASONE
13-APR-94	(TABLET)	KENILWORTH, NJ	0.6MG
	07033		(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
14-215	CELESTONE	SCHERING	BETAMETHASONE
13-APR-94	(SYRUP)	KENILWORTH, NJ	0.6MG/5ML
	07033		(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
14-602	CELESTONE SOLUSPAN	SCHERING	BETAMETHASONE ACETATE
13-APR-94	(INJECTABLE)	KENILWORTH, NJ	3MG/ML
	07033		BETAMETHASONE
			SODIUM PHOSPHATE
			EQ 3MG BASE/ML
			(LABELING REVISION --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			WARNINGS; PRECAUTIONS)
17-441	INFED	SCHEIN PHARM	IRON DEXTRAN
13-APR-94	(INJECTABLE)	PHOENIX, AZ	EQ 50MG IRON/ML
	85043	(LABELING REVISION --	
		DESCRIPTION;	
		CLINICAL PHARMACOLOGY;	
		WARNINGS; PRECAUTIONS;	
		ADVERSE REACTIONS;	
		OVERDOSAGE;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	
17-561	CELESTONE	SCHERING	BETAMETHASONE
13-APR-94	(INJECTABLE)	KENILWORTH, NJ	SODIUM PHOSPHATE
	07033	EQ 3MG BASE/ML	
		(LABELING REVISION --	
		WARNINGS; PRECAUTIONS)	
19-906	ANAFRANIL	BASEL PHARMS	CLOMIPRAMINE HYDROCHLORIDE
13-APR-94	(CAPSULE)	SUMMIT, NJ	25MG
	07901	50MG	
		75MG	
		(LABELING REVISION --	
		PRECAUTIONS)	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20-262	TAXOL	BRISTOL MYERS SQUIBB	PACLITAXEL
13-APR-94	(INJECTABLE)	BUFFALO, NY	6MG/ML
	14213	(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)	
18-603	ZOVIRAX	BURROUGHS WELLCOME	ACYCLOVIR SODIUM
14-APR-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 500MG BASE/VIAL
	27709	EQ 1GM BASE/VIAL (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)	
18-828	ZOVIRAX	BURROUGHS WELLCOME	ACYCLOVIR
14-APR-94	(CAPSULE)	RES TRIANGLE PK, NC	200MG
	27709	(LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS)	
18-972	CORDARONE	WYETH AYERST LABS	AMIODARONE HYDROCHLORIDE
14-APR-94	(TABLET)	NEW YORK, NY	200MG
	12979	(LABELING REVISION -- WARNINGS; PRECAUTIONS)	
19-909	ZOVIRAX	BURROUGHS WELLCOME	ACYCLOVIR
14-APR-94	(SUSPENSION)	RES TRIANGLE PK, NC	200MG/5ML
	27709	(LABELING REVISION -- 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

20-089	ZOVIRAX	BURROUGHS WELLCOME	ACYCLOVIR
14-APR-94	(TABLET)	RES TRIANGLE PK, NC	800MG
		27709	(LABELING REVISION --
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			ADVERSE REACTIONS)
19-640	HUMATROPE	LILLY	SOMATROPIN, BIOSYNTHETIC
15-APR-94	(INJECTABLE)	INDIANAPOLIS, IN	5MG/VIAL
		46285	(LABELING REVISION --
			OVERDOSAGE;
			DOSAGE AND ADMINISTRATION)
20-036	AREDIA	CIBA GEIGY	PAMIDRONATE DISODIUM
15-APR-94	(INJECTABLE)	SUMMIT, NJ	30MG/VIAL
		07901	60MG/VIAL
			90MG/VIAL
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			WARNINGS;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
09-470	XYLOCAINE VISCOUS	ASTRA	LIDOCAINE HYDROCHLORIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-APR-94	(SOLUTION)	WESTBOROUGH, MA	2%
	01581	(LABELING REVISION -- DOSAGE AND ADMINISTRATION)	
16-099	ATROMID-S	WYETH AYERST	CLOFIBRATE
19-APR-94	(CAPSULE)	NEW YORK, NY	500MG
	12979	(LABELING REVISION -- WARNINGS)	
16-927	DEMULEN 1/50-21	SEARLE	ETHINYL ESTRADIOL
20-APR-94	(TABLET)	SAN JUAN, PR	0.05MG
	00936	ETHYNODIOL DIACETATE 1MG (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; PATIENT PACKAGE INSERT)	
16-936	DEMULEN 1/50-28	SEARLE	ETHINYL ESTRADIOL
20-APR-94	(TABLET)	SAN JUAN, PR	0.05MG
	00936	ETHYNODIOL DIACETATE 1MG (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; PATIENT PACKAGE INSERT)	
17-820	DOBUTREX	LILLY	DOBUTAMINE HYDROCHLORIDE
20-APR-94	(INJECTABLE)	INDIANAPOLIS, IN	EQ 12.5MG BASE/ML
	46285	(LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)	
18-160	DEMULEN 1/35-28	SEARLE	ETHINYL ESTRADIOL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20-APR-94	(TABLET)	SAN JUAN, PR	0.035MG
	00936		ETHYNODIOL DIACETATE
			1MG
			(LABELING REVISION --
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			PATIENT PACKAGE INSERT)
18-168	DEMULEN 1/35-21	SEARLE	ETHINYL ESTRADIOL
20-APR-94	(TABLET)	SAN JUAN, PR	0.035MG
	00936		ETHYNODIOL DIACETATE
			1MG
			(LABELING REVISION --
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			PATIENT PACKAGE INSERT)
19-192	TRIPHASIL-21	WYETH AYERST	ETHINYL ESTRADIOL
20-APR-94	(TABLET)	NEW YORK, NY	0.03MG,0.04MG,0.03MG
	12979		LEVONORGESTREL
			0.05MG,0.075MG,0.125MG
			(LABELING REVISION --
			DESCRIPTION;
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			PATIENT PACKAGE INSERT)
19-425	TRANDATE	GLAXO	LABETALOL HYDROCHLORIDE
20-APR-94	(INJECTABLE)	RES TRIANGLE PK, NC	5MG/ML
	27709		(LABELING REVISION --
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
19-865	BETAPACE	BERLEX	SOTALOL HYDROCHLORIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20-APR-94	(TABLET)	WAYNE, NJ	80MG
	07470		120MG
			160MG
			240MG
			(LABELING REVISION -- CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS; OVERDOSAGE; HOW SUPPLIED)
06-035	METHERGINE	SANDOZ	METHYLERGONOVINE MALEATE
25-APR-94	(TABLET)	EAST HANOVER, NJ	0.2MG
	07936		(LABELING REVISION -- ADVERSE REACTIONS)
06-035	METHERGINE	SANDOZ	METHYLERGONOVINE MALEATE
25-APR-94	(INJECTABLE)	EAST HANOVER, NJ	0.2MG/ML
	07936		(LABELING REVISION -- ADVERSE REACTIONS)
18-654	VERSED	ROCHE	MIDAZOLAM HYDROCHLORIDE
26-APR-94	(INJECTABLE)	NUTLEY, NJ	EQ 1MG BASE/ML
	07110		EQ 5MG BASE/ML
			(LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
19-732	LUPRON DEPOT	TAP	LEUPROLIDE ACETATE
26-APR-94	(INJECTABLE)	DEERFIELD, IL	7.5MG/VIAL
	60015		(LABELING REVISION -- DESCRIPTION)
20-011	LUPRON DEPOT	TAP	LEUPROLIDE ACETATE
26-APR-94	(INJECTABLE)	DEERFIELD, IL	3.75MG/VIAL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		60015	(LABELING REVISION -- DESCRIPTION)
50-585	ROCEPHIN	ROCHE	CEFTRIAXONE SODIUM
26-APR-94	(INJECTABLE)	NUTLEY, NJ	EQ 250MG BASE/VIAL
		07110	EQ 500MG BASE/VIAL
			EQ 1GM BASE/VIAL
			EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(LABELING REVISION -- PRECAUTIONS; WARNINGS)
50-619	MYCOSTATIN	SQUIBB	NYSTATIN
26-APR-94	(PASTILLE)	NEW BRUNSWICK, NJ	200,000 UNITS
		08903	(LABELING REVISION -- ADVERSE REACTIONS)
50-624	ROCEPHIN W/ DEXTROSE	ROCHE	CEFTRIAXONE SODIUM
26-APR-94	(INJECTABLE)	NUTLEY, NJ	EQ 20MG BASE/ML
		07110	EQ 40MG BASE/ML
			(LABELING REVISION -- PRECAUTIONS; WARNINGS)
20-007	ZOFRAN	GLAXO	ONDANSETRON HYDROCHLORIDE
27-APR-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 2MG BASE/ML
		27709	(LABELING REVISION -- ADVERSE REACTIONS)
20-103	ZOFRAN	GLAXO	ONDANSETRON HYDROCHLORIDE
27-APR-94	(TABLET)	RES TRIANGLE PK, NC	EQ 4MG BASE
		27709	EQ 8MG BASE
			(LABELING REVISION -- ADVERSE REACTIONS)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-118 28-APR-94	LANOXICAPS (CAPSULE)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709	DIGOXIN 0.05MG 0.1MG 0.2MG (LABELING REVISION -- PRECAUTIONS)
18-565 28-APR-94	DURAMORPH PF (INJECTABLE)	ELKINS SINN CHERRY HILL, NJ 08003	MORPHINE SULFATE 0.5MG/ML 1MG/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DRUG ABUSE AND DEPENDENCE; OVERDOSAGE; HOW SUPPLIED)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1127	NONE	HUNTER BLOOD CTR	CRYOPRECIPITATED AHF
05-APR-94	(INJECTABLE)	CLEARWATER, FL 34618	(TRANSFUSION) (B)
1174	NONE	LEESVILLE PLASMA CTR	SOURCE PLASMA
07-APR-94	(NONE)	OPELOUSAS, LA 70571	(FOR FURTHER MANUFACTURING USE) (A&B)
1175	NONE	UNIV PLASMA	SOURCE PLASMA
07-APR-94	(NONE)	OPELOUSAS, LA 70571	(FOR FURTHER MANUFACTURING USE) (A&B)
0274	NONE	BERGEN COMM REG BLOOD CTR	CRYOPRECIPITATED AHF
12-APR-94	(INJECTABLE)	PARAMUS, NJ 07652	(TRANSFUSION) (B)
1176	NONE	BOWLING GREEN BIOLS	SOURCE PLASMA
20-APR-94	(NONE)	GALLUP, NM 87301	(FOR FURTHER MANUFACTURING USE) (A&B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK940004	SEROMAX	INTL EQUIPMENT	CELL WASHER
08-APR-94		NEEDHAM HEIGHTS, MA 02194	(C)

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

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

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

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

P900038 04/20/94	PARASTEP I SYSTEM	SIGMEDICS, INC. NORTHFIELD, IL 60093-3016	TO ENABLE APPROPRIATELY SELECTED SKELETALLY MATURE SPINAL CORD INJURED PERSONS (LEVELS C6-T12) TO STAND AND ATTAIN LIMITED AMBULATION

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

N18073/S022	SOFT MATE DAILY CLEANER FOR SENSITIVE EYES AND SOFT MATE HANDS OFF DAILY CLEANER	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE STERILIZATION SITE	04/13/94
N18078/S047	SOFT MATE SALINE SOLUTION FOR SENSITIVE EYES	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE STERILIZATION SITE	04/13/94
P790018/S023	MEDTRONIC HEART VALVE	MEDTRONIC, INC. MINNEAPOLIS, MN 55440	MODIFY POSTAPPROVAL STUDY	04/12/94
P790029/S023	SOFT MATE DISINFECTING SOLUTION	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE STERILIZATION SITE	04/13/94
P800018/S017	SOFT MATE COMFORT DROPS AND BARNES-HIND GAS PERMEABLE COMFORT DROPS	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE STERILIZATION SITE	04/13/94
P810002/S029	SAINT JUDE MEDICAL PROSTHETIC HEART VALVE	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	MODIFY POSTAPPROVAL STUDY	04/08/94
P810002/S030	ST. JUDE MEDICAL	ST JUDE MEDICAL, INC.	DESIGN MODIFICATION	

APPLICATION NO. / APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
04/13/94	PROSTHETIC HEART VALVE	ST. PAUL, MN 55117	
P810017/S020 04/13/94	SOFT MATE PROTEIN REMOVER, SOFT MATE WEEKLY CLEANER, AND GAS PERMEABLE PROTEIN REMOVER SOLUTION	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE STERILIZATION SITE
P810031/S017 04/28/94	HEALON GV	PHARMACIA OPHTHALMICS, INC. MONROVIA, CA 91017-7136	PRECAUTIONS AND OTHER LABELING MODIFIED
P810046/S147 04/04/94	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER	ADVANCED CARDIOVASCULAR SANTA CLARA, CA 95052-8167	REVISED INSTRUCTIONS FOR USE
P820053/S018 04/13/94	BARNES-HIND GAS PERMEABLE DAILY CLEANER AND GAS PERMEABLE WETTING AND SOAKING SOLUTION	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE STERILIZATION SITE
P820083/S015 04/08/94	GORE-TEX EXPANDED PTFE SUTURE	W.L. GORE & ASSOCIATES FLAGSTAFF, AZ 86003-2300	REVISED EXPIRATION DATE
P830013/S005	BAUSCH & LOMB	BAUSCH & LOMB	NEW SIZE CONTAINER

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	SENSITIVE EYES DAILY CLEANER	ROCHESTER, NY 14692-0450		04/13/94
P830037/S036	WESLEY-JESSEN FRESHLOOK COLORS AND FRESHLOOK LITETINT HYDROPHILIC CONTACT LENSES	WESSLEY-JESSEN CHICAGO, IL 60610-3496	REVISED INSTRUCTIONS FOR USE	04/28/94
P840024/S048	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	DEVICE DESIGN CHANGES	04/28/94
P840041/S005	VASCUFIL COATED MONOFILAMENT POLYBUTESTER NON ABSORBABLE SURGICAL SUTURE, U.S.P. (CLEAR OR BLUE)	DAVIS+GECK DANBURY, CT 06810	NEW TRADE NAME, VASCUFIL; DEVICE DESIGN CHANGE	04/20/94
P840066/S027	SOFT MATE CONSEPT-1 CLEANING AND DISINFECTING SOLUTION AND SOFT MATE CONSEPT-2 NEUTRALIZING AND RINSING SOLUTION	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE STERILIZATION SITE	04/13/94
P860019/S077	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	NEW TRADE NAME, CLIPIT; DEVICE DESIGN CHANGE	04/29/94

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
P860019/S079	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	NEW TRADE NAME, NC CRUISE PTCA DEVICE DESIGN CHANGE	04/14/94
P860019/S080	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	NEW TRADE NAME, SCIMED COBRA PTCA CATHETERS; DEVICE DESIGN CHANGE	04/29/94
P870015/S020	MEDSTONE STS EXTRACORPOREAL SHOCKWAVE LITHOTRIPTER	MEDSTONE INTERNATIONAL INC. ALISO VIEJO, CA 92656	MODIFIED POSTAPPROVAL STUDY	04/19/94
P880003/S024	SLEEK PLUS PTCA DILATATION CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	NEW TRADE NAME, SLEEK PLUS PTCA CATHETER; DEVICE DESIGN CHANGE	04/20/94
P880011/S008	TECHNOMED SONOLITH 3000 LITHOTRIPTER FOR RENAL STONES	TECHNOMED INTERNATIONAL DANVERS, MA 01923	MODIFIED POSTAPPROVAL STUDY	04/18/94
P880027/S028	SCHNEIDER MICROSOFTRACK PTCA CATHETER	SCHNEIDER (USA) INC. MINNEAPOLIS, MN 55442	NEW TRADE NAMES, MCRAIL20, MCRAIL30, AND MCRAIL40; DEVICE DESIGN MODIFICATION	04/29/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P880042/S001	EDAP LT.01 LITHOTRIPTER FOR FRAGMENTATION OF RENAL CALCULI	EDAP INTERNATIONAL CORPORATION AMHERST, MA 01002	MODIFIED POSTAPPROVAL STUDY	04/18/94
P880056/S002	MURINE LUBRICATING AND REWETTING DROPS	ROSS PRODUCT DIVISION ROSS LABORATORIES COLUMBUS,OH 43215	CHANGE OF TRADE NAME TO CLEAR EYES CLR SOOTHING DROPS; OTHER LABELING REVISIONS	04/14/94
P890003/S024	ELITE II PULSE GENERATOR	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	DEVICE DESIGN CHANGE	04/29/94
P890027/S018	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	DEVICE DESIGN CHANGES	04/28/94
P890032/S017	CORDIS ORION STEERABLE PTCA BALLOON CATHETER, ORION SOFT-WIRE AND LIGHTNING STEERABLE PTCA BALLOON CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	MODIFIED MANUFACTURING PROCESS	04/28/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	WITH OPTIONAL GLISSADE HYDROPHILIC		
P890039/S013 04/29/94	MAESTRO II SAVVI PACING SYSTEM, MODELS 231, 232, 325, AND 333	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	DEVICE DESIGN CHANGE
P890043/S022 04/13/94	SIMPSON CORONARY ATHEROCATH	DEVICES FOR VASCULAR INTERVENTIONS, INC. REDWOOD CITY, CA 94063	NEW TRADE NAME, SCA-EX 7F GRAFT
P890066/S005 04/18/94	THERASONIC LTS FOCAL SURGERY LITHOTRIPTER FOR RENAL STONES	MILPITAS, CA 95035	MODIFIED POSTAPPROVAL STUDY
P890067/S005 04/13/94	STERIDYNE STERILE PRESERVED SALINE SOLUTION	STERIDYNE LABORATORIES, INC. EAST BRUNSWICK, NJ 08816	NEW CONTAINER SIZE
P900047/S002 04/05/94	WET-N-SOAK REWETTING DROPS	ALLERGAN OPTICAL IRVINE, CA 92713-9534	DEVICE DESIGN CHANGE
P900060/S001 04/13/94	CARBOMEDICS PROSTHETIC HEART VALVE	CARBOMEDICS, INC. AUSTIN, TX 78752-1793	DEVICE DESIGN CHANGES
P900060/S004 04/13/94	CARBOMEDICS PROSTHETIC HEART VALVE	CARBOMEDICS, INC. AUSTIN, TX 78752-1793	DEVICE DESIGN CHANGES

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P900061/S003	MEDTRONIC MODEL 7217B PCD TACHYRHYTHMIA CONTROL SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	REVISED LABELING	04/04/94
P910060/S001	ELASTIMIDE MODELS AQ2000, AQ2003, AQ2010, AND AQ2013 SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES	STAAR SURGICAL COMPANY MONROVIA, CA 91016	LICENSING AGREEMENT WITH SOFTLENSCO, FOR ELASTIMIDE MODELS AQ2000, AQ2003, AQ2010, AND AQ2013	04/20/94
P910064/S005	REALITY FEMALE CONDOM	WISCONSIN PHARMACAL COMPANY CHICAGO, IL 60611	NEW MANUFACTURING SITE	04/13/94
P920015/S001	MEDTRONIC TRANSVENE DF-1 LEAD	MEDTRONIC, INC MINNEAPOLIS, MN 55432-3576	NEW TRADE NAMES, MEDTRONIC TRANSVENE DF-1 LEAD MODELS 6933, 6936, AND 6939; DEVICE DESIGN CHANGES	04/20/94
P930005/S001	KC STERILE PRESERVED SALINE SOLUTION	STERIDYNE LABORATORIES, INC. EAST BRUNSWICK, NJ 08816	NEW CONTAINER SIZE	04/13/94

NADA NUMBER / APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
ORIGINAL VETERINARY NADAs				
141-015 24-FEB-94	ENACARD (TABLET)	DOGS	MERCK RAHWAY, NJ 07065	ENALAPRIL MALEATE 1MG 2.5MG 5MG 10MG 20MG
141-025 04-MAR-94	CATTLYST (PREMIX)	CATTLE	SYNTEX AN HLTH DIV OF SYNTEX AGRIBUSINESS PALO ALTO, CA 94304	LAIDLOMYCIN PROPIONATE POTASSIUM 50GM/LB
141-034 04-MAR-94	FLAVOMYCIN (POWDER)	CATTLE	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	BAMBERMYCINS 2GM/LB 4GM/LB 10GM/LB
140-940 10-MAR-94	AVIAX (PREMIX)	CHICKENS	PFIZER NEW YORK, NY 10017	SEMDURAMICIN SODIUM 5.13%

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

ORIGINAL ABBREVIATED VETERINARY NADAs

200-049 30-SEP-93	TETRACYCLINE HYDROCHLORIDE (POWDER)	CALVES, SWINE, TURKEYS	AGRI LABS LTD JOSEPH, MO 64503	TETRACYCLINE HYDROCHLORIDE 324GM/LB
200-082 18-MAR-94	SACOX BMD (POWDER)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	BACITRACIN METHYLENE DISALICYLATE 30GM/LB 50GM/LB 60GM/LB 75GM/LB SALINOMYCIN SODIUM 30GM/LB
200-083 18-MAR-94	SACOX FLAVOMYCIN (POWDER)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	BAMBERMYCINS 2GM/LB 4GM/LB 10GM/LB SALINOMYCIN SODIUM 30GM/LB
200-081 01-APR-94	SACOX 3-NITRO, BMD (POWDER)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	BACITRACIN METHYLENE DISALICYLATE 30GM/LB 50GM/LB 60GM/LB 75GM/LB

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
				ROXARSONE 10% 20% 50% SALINOMYCIN SODIUM 30GM/LB

ORIGINAL ABBREVIATED VETERINARY NADAs

200-086 28-APR-94	SACOX ALBAC 3 NITRO (POWDER)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	BACITRACIN ZINC 50GM/LB ROXARSONE 10% 20% 50% SALINOMYCIN SODIUM 30GM/LB

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

SUPPLEMENTAL VETERINARY NADAs

65-140 09-15-93	TET SOL 324 (POWDER)	CALVES, CHICKENS, SWINE, TURKEYS	WADE JONES LOWELL, AR 72745	TETRACYCLINE HYDROCHLORIDE 324GM/LB
65-123 03-18-94	TETRACYCLINE SOLUBLE (POWDER)	CHICKENS, TURKEYS	PFIZER NEW YORK, NY 10017	TETRACYCLINE HYDROCHLORIDE 10GM/6.4 OZ PACKET
38-233 03-30-94	RALGRO (IMPLANT)	CATTLE	PITMAN MOORE MUNDELEIN, IL 60060	ZERANOL 36MG/IMPLANT

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)
92-444	RUMANTEL 88	GOATS	PFIZER	MORANTEL TARTRATE
04-15-94	(POWDER)		NEW YORK, NY 10017	88GM/LB

FDA DRUG AND DEVICE PRODUCT APPROVALS

Center for Drug Evaluation and Research
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Center for Devices and Radiological Health
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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

19-558 PRINIVIL MERCK LISINOPRIL
28-JAN-94 (TABLET) WEST POINT, PA 2.5MG
(SUPPL) 19486 (NEW STRENGTH)

19-667 SANDOSTATIN SANDOZ OCTREOTIDE ACETATE
03-MAY-94 (INJECTABLE) EAST HANOVER, NJ EQ 0.05MG BASE/ML
(SUPPL) 07936 EQ 0.1MG BASE/ML
EQ 0.2MG BASE/ML
EQ 0.5MG BASE/ML
EQ 1MG BASE/ML
(NEW INDICATION --
TREATMENT OF ACROMEGALY)

18-680 COPPER T POPULATION COUNCIL COPPER
19-MAY-94 MODEL TCU 380A NEW YORK, NY APPROX 309MG COPPER
(SUPPL) (INTRAUTERINE DEVICE) 10021 (NEW DOSAGE REGIMEN --

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

EXTENSION OF THE PERIOD
OF USE FROM EIGHT TO
TEN YEARS)

20-367	CEREZYME	GENZYME	IMIGLUCERASE
23-MAY-94	(INJECTABLE)	CAMBRIDGE, MA	200 UNITS/VIAL
(1 P, V*, E**)		02139	(ENZYME REPLENISHER)
			[TREATMENT OF TYPE 1 GAUCHER DISEASE]

V* - Designated Orphan Drug
E** - Drug for Severely Debilitating/Life Threatening Illness

50-705	RIFATER	MARION MERRELL DOW	ISONIAZID
31-MAY-94	(TABLET)	KANSAS CITY, MO	50MG
(4 S,V*)		64137	PYRAZINAMIDE
			300MG
			RIFAMPIN
			120MG
			(ANTIBACTERIAL)
			[SHORT-COURSE TREATMENT OF PULMONARY TUBERCULOSIS]

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

V* - Designated Orphan Drug

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.

20-286	MONOPRIL HCT	BRISTOL MYERS SQUIBB	FOSINOPRIL SODIUM
20-APR-94	(TABLET)	PRINCETON, NJ	10MG
		08543	HYDROCHLOROTHIAZIDE
			12.5MG

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

(ANTIHYPERTENSIVE)

20-286	MONOPRIL HCT	BRISTOL MYERS SQUIBB	FOSINOPRIL SODIUM
20-APR-94	(TABLET)	PRINCETON, NJ	20MG
		08543	HYDROCHLOROTHIAZIDE
			12.5MG
			(ANTIHYPERTENSIVE)
20-312	MOEXIPRIL HCL	BESSELAAR	MOEXIPRIL HYDROCHLORIDE
20-MAY-94	(TABLET)	PRINCETON, NJ	7.5MG
		08540	15MG
			(ANTIHYPERTENSIVE)

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

ORIGINAL ABBREVIATED NDAs

74-226*	GLIPIZIDE	MYLAN	GLIPIZIDE
10-MAY-94	(TABLET)	MORGANTOWN, WV	5MG
	26505		10MG
		(BLOOD GLUCOSE REGULATOR)	
64-048	GENTAMICIN SULFATE	BAUSCH AND LOMB	GENTAMICIN SULFATE
11-MAY-94	(SOLUTION/DROPS)	TAMPA, FL	EQ 0.3% BASE
	33637	(ANTIBIOTIC, AMINOGLYCOSIDE)	
74-151*	CIMETIDINE	NOVOPHARM	CIMETIDINE
17-MAY-94	(TABLET)	SCARBOROUGH, ONTARIO	200MG
	CANADA		300MG
			400MG
			(HISTAMINE H2-RECEPTOR ANTAGONIST)
74-246*	CIMETIDINE	MYLAN	CIMETIDINE
17-MAY-94	(TABLET)	MORGANTOWN, WV	200MG
	26505		300MG
			400MG
			800MG
			(HISTAMINE H2-RECEPTOR ANTAGONIST)
74-281*	CIMETIDINE	ENDO LABS	CIMETIDINE
17-MAY-94	(TABLET)	GARDEN CITY, NY	200MG
	11530		300MG
			400MG
			(HISTAMINE H2-RECEPTOR ANTAGONIST)
74-329*	CIMETIDINE	ENDO LABS	CIMETIDINE
17-MAY-94	(TABLET)	GARDEN CITY, NY	800MG
	11530		(HISTAMINE H2-RECEPTOR

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

ORIGINAL ABBREVIATED NDAs

ANTAGONIST)

* - First Time Product Available Generically

74-463* CIMETIDINE NOVOPHARM CIMETIDINE
17-MAY-94 (TABLET) SCARBOROUGH, ONTARIO 800MG
CANADA (HISTAMINE H2-RECEPTOR
ANTAGONIST)

40-073 NAFAZAIR BAUSCH AND LOMB NAPHAZOLINE HYDROCHLORIDE
25-MAY-94 (SOLUTION/DROPS) TAMPA, FL 0.1%
33637 (OCULAR VASOCONSTRICTOR)

63-176 TOBRAMYCIN STERIS TOBRAMYCIN
25-MAY-94 (SOLUTION/DROPS) PHOENIX, AZ 0.3%
85043 (ANTIBIOTIC, AMINOGLYCOSIDE)

74-171* HYDROCORTISONE COPLEY PHARM HYDROCORTISONE
27-MAY-94 (ENEMA) CANTON, MA 100MG/60ML
02021 (CORTICOSTEROID)

74-217 METOPROLOL TARTRATE WATSON LABS METOPROLOL TARTRATE
27-MAY-94 (TABLET) CORONA, CA 50MG
91720 100MG
(BETA ADRENERGIC BLOCKER)

74-280 LORAZEPAM ABBOTT LORAZEPAM
27-MAY-94 (INJECTABLE) ABBOTT PARK, IL 2MG/ML
60064 4MG/ML
(ANXIOLYTIC)

74-282 LORAZEPAM ABBOTT LORAZEPAM

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

ORIGINAL ABBREVIATED NDAs

27-MAY-94	(INJECTABLE)	ABBOTT PARK, IL	2MG/ML
		60064	4MG/ML
		(ANXIOLYTIC)	
64-021	TOBRAMYCIN SULFATE	APOTHECON	TOBRAMYCIN SULFATE
31-MAY-94	(INJECTABLE)	PRINCETON, NJ	EQ 10MG BASE/ML
		08543	EQ 40MG BASE/ML
		(ANTIBIOTIC, AMINOGLYCOSIDE)	

* - First Time Product Available Generically

64-026	TOBRAMYCIN SULFATE	APOTHECON	TOBRAMYCIN SULFATE
31-MAY-94	(INJECTABLE)	PRINCETON, NJ	EQ 40MG BASE/ML
		08543	(ANTIBIOTIC, AMINOGLYCOSIDE)

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

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

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

74-329	CIMETIDINE	ENDO	CIMETIDINE
03-MAY-94	(TABLET)	GARDEN CITY, NY 11530	800MG (HISTAMINE H2-RECEPTOR ANTAGONIST)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20-103 04-APR-94	ZOFRAN (TABLET)	GLAXO RES TRIANGLE PK, NC 27709	ONDANSETRON HYDROCHLORIDE EQ 4MG BASE EQ 8MG BASE (LABELING REVISION -- HOW SUPPLIED)
19-773 21-APR-94	VENTOLIN (SOLUTION)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL SULFATE EQ 0.083% BASE (LABELING REVISION -- PRECAUTIONS)
17-055 02-MAY-94	A.P.L. (INJECTABLE)	WYETH AYERST LABS NEW YORK, NY 12979	GONADOTROPIN, CHORIONIC 5,000 UNITS/VIAL 10,000 UNITS/VIAL 20,000 UNITS/VIAL (LABELING REVISION -- ADVERSE REACTIONS; PRECAUTIONS)
17-557 02-MAY-94	DANOCRINE (CAPSULE)	STERLING WINTHROP NEW YORK, NY 10016	DANAZOL 50MG 100MG 200MG (LABELING REVISION -- CLINICAL PHARMACOLOGY)
19-621 02-MAY-94	VENTOLIN (SYRUP)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL SULFATE EQ 2MG BASE/5ML (LABELING REVISION -- PRECAUTIONS)
13-413 03-MAY-94	DECADRON (AEROSOL)	MSD WEST POINT, PA 19486	DEXAMETHASONE SODIUM PHOSPHATE EQ 0.1MG PHOSPHATE/INH

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(LABELING REVISION --
			ADVERSE REACTIONS)
14-242	DECADRON	MSD	DEXAMETHASONE
03-MAY-94	(AEROSOL)	WEST POINT, PA	SODIUM PHOSPHATE
	19486		EQ 0.1MG PHOSPHATE/INH
			(LABELING REVISION --
			ADVERSE REACTIONS)
19-667	SANDOSTATIN	SANDOZ	OCTREOTIDE ACETATE
03-MAY-94	(INJECTABLE)	EAST HANOVER, NJ	EQ 0.05MG BASE/ML
	07936		EQ 0.1MG BASE/ML
			EQ 0.2MG BASE/ML
			EQ 0.5MG BASE/ML
			EQ 1MG BASE/ML
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			OVERDOSAGE;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
18-240	TENORMIN	ZENECA	ATENOLOL
04-MAY-94	(TABLET)	WILMINGTON, DE	25MG
	19897		50MG
			100MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS;

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
			ADVERSE REACTIONS; HOW SUPPLIED)
18-760 04-MAY-94	TENORETIC 50 (TABLET) 19897	ZENECA WILMINGTON, DE	ATENOLOL 50MG CHLORTHALIDONE 25MG (LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
18-760 04-MAY-94	TENORETIC 100 (TABLET) 19897	ZENECA WILMINGTON, DE	ATENOLOL 100MG CHLORTHALIDONE 25MG (LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
19-058 04-MAY-94	TENORMIN (INJECTABLE) 19897	ZENECA WILMINGTON, DE	ATENOLOL 0.5MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; HOW SUPPLIED)
17-831 05-MAY-94	DIDRONEL (TABLET) 13815	P AND G NORWICH, NY	ETIDRONATE DISODIUM 200MG 400MG (LABELING REVISION -- 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;
			CONTRAINDICATIONS;
			WARNINGS;
			ADVERSE REACTIONS)
19-798	NASACORT	RHONE POULENC RORER	TRIAMCINOLONE ACETONIDE
06-MAY-94	(AEROSOL)	FORT WASHINGTON, PA	0.055MG/INH
	19034		(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
16-049	INNOVAR	JANSSEN	DROPERIDOL
09-MAY-94	(INJECTABLE)	TITUSVILLE, NJ	2.5MG/ML
	08980		FENTANYL CITRATE
			EQ 0.05MG BASE/ML
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			OVERDOSAGE)
18-123	FACTREL	WYETH AYERST	GONADORELIN HYDROCHLORIDE
09-MAY-94	(INJECTABLE)	NEW YORK, NY	EQ 0.1MG BASE/VIAL
	12979		EQ 0.5MG BASE/VIAL
			(LABELING REVISION --
			ADVERSE REACTIONS)
19-627	DIPRIVAN	ZENECA	PROPOFOL
09-MAY-94	(INJECTABLE)	CHESHIRE, ENGLAND	10MG/ML
			(LABELING REVISION --
			HOW SUPPLIED)
18-998	VASOTEC	MERCK	ENALAPRIL MALEATE
11-MAY-94	(TABLET)	WEST POINT, PA	2.5MG
	19486		5MG
			10MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			20MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
19-221	VASERETIC	MERCK	ENALAPRIL MALEATE
11-MAY-94	(TABLET)	WEST POINT, PA	10MG
	19486		HYDROCHLOROTHIAZIDE
			25MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
19-309	VASOTEC	MERCK	ENALAPRILAT
11-MAY-94	(INJECTABLE)	WEST POINT, PA	1.25MG/ML
	19486		(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
19-558	PRINIVIL	MERCK	LISINOPRIL
11-MAY-94	(TABLET)	WEST POINT, PA	2.5MG
	19486		5MG
			10MG
			20MG
			40MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
19-778	PRINZIDE 10-12.5	MERCK	HYDROCHLOROTHIAZIDE
11-MAY-94	(TABLET)	WEST POINT, PA	12.5MG
	19486		LISINOPRIL
			10MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS)
19-778	PRINZIDE 20-12.5	MERCK	HYDROCHLOROTHIAZIDE
11-MAY-94	(TABLET)	WEST POINT, PA	12.5MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

	19486	LISINOPRIL	20MG
		(LABELING REVISION -- WARNINGS; PRECAUTIONS)	
19-778	PRINZIDE 20-25	MERCK	HYDROCHLOROTHIAZIDE
11-MAY-94	(TABLET)	WEST POINT, PA	25MG
	19486	LISINOPRIL	
		20MG	
		(LABELING REVISION -- WARNINGS; PRECAUTIONS)	
12-209	FLUOROURACIL	ROCHE	FLUOROURACIL
12-MAY-94	(INJECTABLE)	NUTLEY, NJ	50MG/ML
	07110	(LABELING REVISION -- WARNINGS)	
18-998	VASOTEC	MERCK	ENALAPRIL MALEATE
16-MAY-94	(TABLET)	WEST POINT, PA	2.5MG
	19486	5MG	
		10MG	
		20MG	
		(LABELING REVISION -- DOSAGE AND ADMINISTRATION)	
19-643	MEVACOR	MERCK	LOVASTATIN
17-MAY-94	(TABLET)	WEST POINT, PA	10MG
	19486	20MG	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			40MG
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			ADVERSE REACTIONS;
			INDICATIONS AND USAGE;
			DOSAGE AND ADMINISTRATION)
20-180	PROSCAR	MSD	FINASTERIDE
18-MAY-94	(TABLET)	WEST POINT, PA	5MG
	19486		(LABELING REVISION --
			ADVERSE REACTIONS;
			PATIENT PACKAGE INSERT)
18-680	COPPER T	POPULATION COUNCIL	COPPER
19-MAY-94	MODEL TCU 380A	NEW YORK, NY	APPROX 309MG COPPER
(INTRAUTERINE DEVICE)	10021		(LABELING REVISION --
			CLINICAL STUDIES;
			PATIENT PACKAGE INSERT)
19-915	MONOPRIL	BRISTOL MYERS SQUIBB	FOSINOPRIL SODIUM
19-MAY-94	(TABLET)	PRINCETON, NJ	10MG
	08543		20MG
			(WARNINGS; PRECAUTIONS)
20-201	DOBUTAMINE HCL	ABBOTT	DOBUTAMINE HYDROCHLORIDE
19-MAY-94	IN DEXTROSE 5%	ABBOTT PARK, IL	EQ 50MG BASE/100ML
	(INJECTABLE) 60064		EQ 100MG BASE/100ML
			EQ 200MG BASE/100ML (LABELING REVISION --
			PRECAUTIONS)
20-269	DOBUTAMINE HCL	ABBOTT	DOBUTAMINE HYDROCHLORIDE
19-MAY-94	IN DEXTROSE 5%	ABBOTT PARK, IL	EQ 50MG BASE/100ML
	(INJECTABLE) 60064		EQ 100MG BASE/100ML

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
			EQ 200MG BASE/100ML (LABELING REVISION -- PRECAUTIONS)
19-758 20-MAY-94	CLOZARIL (TABLET)	SANDOZ EAST HANOVER, NJ 07936	CLOZAPINE 25MG 100MG (LABELING REVISION -- CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)
09-768 26-MAY-94	PLAQUENIL (TABLET)	STERLING WINTHROP NEW YORK, NY 10016	HYDROXYCHLOROQUINE SULFATE 200MG (LABELING REVISION -- ADVERSE REACTIONS)
19-978 26-MAY-94	BUPIVACAINE HCL KIT (INJECTABLE)	ABBOTT ABBOTT PARK, IL 60064	BUPIVACAINE HYDROCHLORIDE 0.075% 0.114% 0.23% (LABELING REVISION -- DOSAGE AND ADMINISTRATION; INSTRUCTIONS FOR USE)
17-854 31-MAY-94	REGLAN (TABLET)	ROBINS RICHMOND, VA 23220	METOCLOPRAMIDE HYDROCHLORIDE EQ 5MG BASE EQ 10MG BASE (LABELING REVISION -- PRECAUTIONS; OVERDOSAGE)
17-862	REGLAN	ROBINS	METOCLOPRAMIDE HYDROCHLORIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

31-MAY-94	(INJECTABLE)	RICHMOND, VA	EQ 10MG BASE/2ML
	23220	(LABELING REVISION -- PRECAUTIONS; OVERDOSAGE)	

18-821	REGLAN	ROBINS	METOCLOPRAMIDE HYDROCHLORIDE
31-MAY-94	(SOLUTION)	RICHMOND, VA	EQ 5MG BASE/5ML
	23220	(LABELING REVISION -- PRECAUTIONS; OVERDOSAGE)	

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

BIOLOGICAL PRODUCT LICENSES ISSUED

0913 11-MAY-94	NONE (INJECTABLE)	COMM BLOOD CTRS OF S FLORIDA LAUDERHILL, FL (B) 33313	SOURCE LEUKOCYTES (TRANSFUSION)

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				
BK920029 06-MAY-94	NONE	BAXTER HLTHCARE ROUND LAKE, IL (C)	COLLECTION CHAMBER FOR CS-3000 PLUS BLOOD CELL SEPARATOR	60073
BK940005 18-MAY-94	NONE	BAXTER HLTHCARE ROUND LAKE, IL 60073 (C)	FENWAL BONE MARROW COLLECTION KIT	
BK940009 18-MAY-94	OPTIPRESS	BAXTER HLTHCARE ROUND LAKE, IL 60073 (C)	AUTOMATED BLOOD COMPONENT EXTRACTOR	

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

DATA UNAVAILABLE FOR THE MONTH OF MAY 1994

APPLICATION NO. TRADE NAME APPROVAL DATE	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

DATA UNAVAILABLE FOR THE MONTH OF MAY 1994

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 MAY 1994.

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

ORIGINAL ABBREVIATED VETERINARY NADAs

200-089 06-APR-94	SACOX, BACIFERM (PREMIX)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	BACITRACIN ZINC 10GM/LB 25GM/LB 40GM/LB 50GM/LB SALINOMYCIN SODIUM 30GM/LB
200-092 06-APR-94	SACOX, STAFAC (PREMIX)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	SALINOMYCIN SODIUM 30GM/LB VIRGINIAMYCIN 10% 20% 50%
200-093 06-APR-94	SACOX, LINCOMIX (PREMIX)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	LINCOMYCIN 20GM/LB 50GM/LB SALINOMYCIN SODIUM 30GM/LB
200-090 20-MAY-94	SACOX, LINCOMIX, 3-NITR0 (PREMIX)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	LINCOMYCIN 20GM/LB 50GM/LB ROXARSONE 10%

NADA NUMBER / APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
				20% 50% SALINOMYCIN SODIUM 30GM/LB

ORIGINAL ABBREVIATED VETERINARY NADAs

200-094 20-MAY-94	SACOX, STAFAC, 3-NITRO (PREMIX)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	ROXARSONE 10% 20% 50% SALINOMYCIN SODIUM 30GM/LB VIRGINIAMYCIN 10% 20% 50%
200-097 20-MAY-94	SACOX, 3-NITRO (PREMIX)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	ROXARSONE 10% 20% 50% SALINOMYCIN SODIUM 30GM/LB
200-143	SACOX, 3-NITRO,	CHICKENS	HOECHST ROUSSEL	BACITRACIN ZINC

NADA NUMBER / APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
25-MAY-94	BACIFERM (PREMIX)		AGRI VET SOMERVILLE, NJ 08876	10GM/LB 25GM/LB 40GM/LB 50GM/LB ROXARSONE 10% 20% 50% SALINOMYCIN SODIUM 30GM/LB

***SUPPLEMENTAL VETERINARY NADAs

128-620 25-APR-94	PANACUR (SUSPENSION)	GOATS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	FENBENDAZOLE 100MG/ML
132-337 25-APR-94	PROBAN (TABLET)	DOGS	MILES SHAWNEE MISSION, KS 66201	CYTHIOATE 90MG

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

FDA DRUG AND DEVICE PRODUCT APPROVALS

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This report is compiled by the Division of Drug Information Resources, OM, CDER.
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-336 01-JUN-94 (3 S)	DYNACIRC CR (TABLET, EXTENDED RELEASE)	SANDOZ EAST HANOVER, NJ 07936	ISRADIPINE 5MG 10MG (CALCIUM ION INFLUX INHIBITOR) [HYPERTENSION]
20-314 02-JUN-94 (1 S)	OCTREOSCAN (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	INDIUM IN-111 PENTETREOTIDE KIT 3MCI/ML (RADIOACTIVE DIAGNOSTIC) [SCINTIGRAPHIC LOCALIZATION OF PRIMARY AND METASTATIC NEUROENDOCRINE TUMORS BEARING SOMATOSTATIN RECEPTORS]

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

18-831	TRACRIUM	BURROUGHS WELLC	ATRACURIUM BESYLATE
06-JUN-94	(INJECTABLE)	RES TRIANGLE PK, NC	10MG/ML
(SUPPL-019)		27709	(EXPANDED USE -- ICU PATIENTS UNDERGOING LONG-TERM INFUSION DURING MECHANICAL VENTILATION)
19-872	TYLENOL	MCNEIL	ACETAMINOPHEN
08-JUN-94	(TABLET,	FORT WASHINGTON, PA	650MG
(3 S)	EXTENDED RELEASE)	19034	(ANALGESIC) (OTC)
20-065	OPCON-A	BAUSCH AND LOMB	NAPHAZOLINE HYDROCHLORIDE
08-JUN-94	(SOLUTION/DROPS)	ROCHESTER, NY	0.027%
(5 S)		14692	(OCULAR VASOCONSTRICTOR) PHENIRAMINE MALEATE 0.315% (ANTIHISTAMINE) (OTC)
20-226	NAPHCON-A	ALCON	NAPHAZOLINE HYDROCHLORIDE
08-JUN-94	(SOLUTION/DROPS)	FORT WORTH, TX	0.025%
(4 S)		76115	(OCULAR VASOCONSTRICTOR) PHENIRAMINE MALEATE 0.3% (ANTIHISTAMINE) (OTC)
20-340	TEMOVATE	GLAXO	CLOBETASOL PROPIONATE
17-JUN-94	(CREAM)	RES TRIANGLE PK, NC	0.05%
(3 S)		27709	(CORTICOSTEROID)
20-262	TAXOL	BRISTOL MYERS SQUIBB	PACLITAXEL
22-JUN-94	(INJECTABLE)	WALLINGFORD, CT	6MG/ML
(SUPPL-003)		06492	(NEW DOSAGE REGIMEN -- FOR OVARIAN CANCER THE RECOMMENDED REGIMEN IS

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

			135MG/M^2 OR 175MG/M^2 INTRAVENOUSLY OVER THREE HOURS EVERY THREE WEEKS)
20-389 23-JUN-94 (5 S)	MYCELEX-7 COMBINATION PACK (SUPPOSITORY AND CREAM)	MILES WEST HAVEN, CT 06516	CLOTRIMAZOLE 100MG-SUPPOSITORY 1%-CREAM (ANTIFUNGAL) (OTC)
20-309 24-JUN-94 (5 S)	MAGNESIUM SULFATE IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT ABBOTT PARK, IL 60064	MAGNESIUM SULFATE 80MG/ML 4GM/100ML (MINERAL REPLENISHER/ ANTICONVULSANT)
20-412 24-JUN-94 (1 P, AA*, E**, H***)	ZERIT (CAPSULE)	BRISTOL MYERS SQUIBB WALLINGFORD, CT 06492	STAVUDINE 5MG**** 15MG 20MG 30MG 40MG (ANTIVIRAL) [TREATMENT OF ADULTS WITH ADVANCED HIV INFECTION - ALTERNATIVE THERAPY]

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

20-363	FAMVIR	SMITHKLINE BEECHAM	FAMCICLOVIR
29-JUN-94	(TABLET)	PHILADELPHIA, PA	500MG
(1 S)	19101	(ANTIVIRAL)	
		[MANAGEMENT OF ACUTE	
		HERPES ZOSTER (SHINGLES)]	
20-322	DIFLUCAN	PFIZER	FLUCONAZOLE
30-JUN-94	(TABLET)	GROTON, CT	150MG
(6 P)	06340	(NEW STRENGTH)	
		(ANTIFUNGAL)	
		[VAGINAL CANDIDIASIS]	
50-672	CEFTIN	GLAXO	CEFUROXIME AXETIL
30-JUN-94	(POWDER	RES TRIANGLE PK, NC	EQ 125MG BASE/5ML
(3 S)	FOR RECONSTITUTION)	27709	(ANTIBIOTIC, CEPHEM)

AA* - Priority Classification AIDS Drug
E** - Drug for Severely Debilitating/Life Threatening Illness
H*** - Accelerated Approval - Approved Under the Provisions of 21 CFR 314 Subpart H
**** - 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.

THERE ARE NO APPROVABLE ORIGINAL NDAs FOR JUNE 1994.

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

ORIGINAL ABBREVIATED NDAs

74-176*	CIMETIDINE HCL	BARRE	CIMETIDINE HYDROCHLORIDE
01-JUN-94	(SOLUTION)	BALTIMORE, MD	EQ 300MG BASE/5ML
	21224		(HISTAMINE H2-RECEPTOR ANTAGONIST)
74-224	TRIAZOLAM	ROXANE	TRIAZOLAM
01-JUN-94	(TABLET)	COLUMBUS, OH	0.125MG
	43216		0.25MG
			(SEDATIVE/HYPNOTIC)
74-267	GUANABENZ ACETATE	COPLEY PHARM	GUANABENZ ACETATE
01-JUN-94	(TABLET)	CANTON, MA	EQ 4MG BASE
	02021		EQ 8MG BASE
			(ANTIHYPERTENSIVE)
81-224	LEUCOVORIN CALCIUM	ELKINS SINN	LEUCOVORIN CALCIUM
03-JUN-94	(INJECTABLE)	CHERRY HILL, NJ	EQ 100MG BASE/VIAL
	08003		(FOLIC ACID ANTAGONIST ANTIDOTE)
20-374*	INPERSOL-LC/LM	ABBOTT	CALCIUM CHLORIDE
13-JUN-94	W/ DEXTROSE 4.25%	ABBOTT PARK, IL	18.4MG/100ML
	IN PLASTIC CONTAINER	60064	DEXTROSE
	(SOLUTION)		4.25GM/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(S)	

ORIGINAL ABBREVIATED NDAs

* - First Time Product Available Generically

20-374*	INPERSOL-LC/LM	ABBOTT	CALCIUM CHLORIDE
13-JUN-94	W/ DEXTROSE 3.5%	ABBOTT PARK, IL	18.4MG/100ML
	IN PLASTIC CONTAINER	60064	DEXTROSE
	(SOLUTION)		3.5GM/100ML
			MAGNESIUM CHLORIDE
			5.08MG/100ML
			SODIUM CHLORIDE
			538MG/100ML
			SODIUM LACTATE
			448MG/100ML
			(PERITONEAL DIALYSATE)
20-374*	INPERSOL-LC/LM	ABBOTT	CALCIUM CHLORIDE
13-JUN-94	W/ DEXTROSE 2.5%	ABBOTT PARK, IL	18.4MG/100ML
	IN PLASTIC CONTAINER	60064	DEXTROSE
	(SOLUTION)		2.5GM/100ML
			MAGNESIUM CHLORIDE
			5.08MG/100ML
			SODIUM CHLORIDE
			538MG/100ML
			SODIUM LACTATE
			448MG/100ML
			(PERITONEAL DIALYSATE)
20-374*	INPERSOL-LC/LM	ABBOTT	CALCIUM CHLORIDE
13-JUN-94	W/ DEXTROSE 1.5%	ABBOTT PARK, IL	18.4MG/100ML
	IN PLASTIC CONTAINER	60064	DEXTROSE
	(SOLUTION)		1.5GM/100ML

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

ORIGINAL ABBREVIATED NDAs

MAGNESIUM CHLORIDE
5.08MG/100ML
SODIUM CHLORIDE
538MG/100ML
SODIUM LACTATE
448MG/100ML
(PERITONEAL DIALYSATE)

* - First Time Product Available Generically

74-358*	FLURBIPROFEN	MYLAN	FLURBIPROFEN
20-JUN-94	(TABLET)	MORGANTOWN, WV	50MG
	26505		100MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)

40-045*	QUINIDINE SULFATE	COPLEY PHARM	QUINIDINE SULFATE
30-JUN-94	(TABLET,	CANTON, MA	300MG
	EXTENDED RELEASE)	02021	(ANTIARRHYTHMIC)

63-163	CLINDAMYCIN PHOSPHATE	BEDFORD LABS	CLINDAMYCIN PHOSPHATE
30-JUN-94	(INJECTABLE)	BEDFORD, OH	EQ 150MG BASE/ML
	44146		(ANTIBIOTIC, LINCOMYCIN)

73-399	CLEMASTINE FUMARATE	LEMMON	CLEMASTINE FUMARATE
30-JUN-94	(SYRUP)	SELLERSVILLE, PA	EQ 0.5MG BASE/5ML
	18960		(ANTIHISTAMINE)

73-636*	DIPIVEFRIN HCL	ALCON	DIPIVEFRIN HYDROCHLORIDE
30-JUN-94	(SOLUTION/DROPS)	FORT WORTH, TX	0.1%
	76115		(ANTI-GLAUCOMA)

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

ORIGINAL ABBREVIATED NDAs

74-017	FUROSEMIDE	MARSAM	FUROSEMIDE
30-JUN-94	(INJECTABLE)	CHERRY HILL, NJ 08034	10MG/ML (DIURETIC)
74-346*	PASER	JACOBUS	AMINOSALICYLIC ACID
30-JUN-94	(GRANULE, DELAYED RELEASE)	PRINCETON, NJ 08540	4GM/PACKET (ANALGESIC)

* - First Time Product Available Generically

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

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

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

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS FOR JUNE 1994.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-831	TRACRIUM	BURROUGHS WELLC	ATRACURIUM BESYLATE
01-JUN-94	(INJECTABLE)	RES TRIANGLE PK, NC 27709	10MG/ML
			(LABELING REVISION -- CLINICAL PHARMACOLOGY; PRECAUTIONS)

19-843	ISOLYTE S IN	MCGAW	DEXTROSE
01-JUN-94	DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	IRVINE, CA 92713	5GM/100ML
			MAGNESIUM CHLORIDE 30MG/100ML
			POTASSIUM CHLORIDE 37MG/100ML
			SODIUM ACETATE 370MG/100ML
			SODIUM CHLORIDE 530MG/100ML
			SODIUM GLUCONATE 500MG/100ML
			(LABELING REVISION -- INDICATIONS AND USAGE)

19-844	ISOLYTE H IN	MCGAW	DEXTROSE
01-JUN-94	DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	IRVINE, CA 92713	5GM/100ML
			MAGNESIUM CHLORIDE 30MG/100ML
			POTASSIUM CHLORIDE 97MG/100ML
			SODIUM ACETATE 220MG/100ML
			SODIUM CHLORIDE 140MG/100ML
			(LABELING REVISION -- INDICATIONS AND USAGE)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-864 01-JUN-94	ISOLYTE R IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	CALCIUM CHLORIDE 37MG/100ML DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 31MG/100ML POTASSIUM CHLORIDE 120MG/100ML SODIUM ACETATE 330MG/100ML SODIUM CHLORIDE 88MG/100ML (LABELING REVISION -- INDICATIONS AND USAGE)
19-870 01-JUN-94	ISOLYTE M IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML POTASSIUM CHLORIDE 150MG/100ML POTASSIUM PHOSPHATE, DIBASIC 130MG/100ML SODIUM ACETATE 280MG/100ML SODIUM CHLORIDE 91MG/100ML (LABELING REVISION -- INDICATIONS AND USAGE)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-873 01-JUN-94	ISOLYTE P IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 31MG/100ML POTASSIUM CHLORIDE 130MG/100ML POTASSIUM PHOSPHATE, DIBASIC 26MG/100ML SODIUM ACETATE 320MG/100ML (LABELING REVISION -- INDICATIONS AND USAGE)
19-904 01-JUN-94	POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE)	BAXTER ROUND LAKE, IL 60073	POTASSIUM CHLORIDE 14.9MG/ML 746MG/100ML (LABELING REVISION -- INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-904 01-JUN-94	POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE)	BAXTER ROUND LAKE, IL 60073	POTASSIUM CHLORIDE 29.8MG/ML 1.49GM/100ML (LABELING REVISION -- INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
19-904 01-JUN-94	POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE)	BAXTER ROUND LAKE, IL 60073	POTASSIUM CHLORIDE 2.24GM/100ML (LABELING REVISION -- INDICATIONS AND USAGE;

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)
19-904 01-JUN-94	POTASSIUM CHLORIDE 40MEQ IN PLASTIC CONTAINER (INJECTABLE)	BAXTER ROUND LAKE, IL 60073	POTASSIUM CHLORIDE 2.98GM/100ML (LABELING REVISION -- INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
18-831 06-JUN-94	TRACRIUM (INJECTABLE)	BURROUGHS WELLC RES TRIANGLE PK, NC 27709	ATRACURIUM BESYLATE 10MG/ML (LABELING REVISION -- PRECAUTIONS; DOSAGE AND ADMINISTRATION)
19-085 13-JUN-94	ATROVENT (AEROSOL, METERED)	BOEHRINGER INGELHEIM RIDGEFIELD, CT 06877	IPRATROPIUM BROMIDE 0.018MG/INH (LABELING REVISION -- CONTRAINDICATIONS; ADVERSE REACTIONS; HOW SUPPLIED)
19-489 14-JUN-94	VENTOLIN ROTACAPS (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL SULFATE EQ 0.2MG BASE (LABELING REVISION -- PRECAUTIONS)
18-484	PROSTIN VR PEDIATRIC	UPJOHN	ALPROSTADIL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

15-JUN-94	(INJECTABLE)	KALAMAZOO, MI	0.5MG/ML
	49001	(LABELING REVISION -- DOSAGE AND ADMINISTRATION)	
19-465	SODIUM CHLORIDE 0.9%	ABBOTT LABS	SODIUM CHLORIDE
21-JUN-94	(INJECTABLE)	ABBOTT PARK, IL	900MG/100ML
	60064	(LABELING REVISION -- DESCRIPTION; INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED; INSTRUCTIONS FOR USE)	
20-262	TAXOL	BRISTOL MYERS SQUIBB	PACLITAXEL
22-JUN-94	(INJECTABLE)	WALLINGFORD, CT	6MG/ML
	06492	(LABELING REVISION -- CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)	
18-087	RELEFACT TRH	FERRING LABS	PROTIRELIN
23-JUN-94	(INJECTABLE)	SUFFERN, NY	0.5MG/ML
	10901	(LABELING REVISION -- NEW TRADE NAME -- THYREL TRH)	
50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
24-JUN-94	(INJECTABLE)	WEST POINT, PA	EQ 250MG BASE/VIAL
	19486	IMIPENEM 250MG/VIAL (LABELING REVISION -- DESCRIPTION; ADVERSE REACTIONS)	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
24-JUN-94	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
	19486	IMIPENEM	
		500MG/VIAL	
		(LABELING REVISION --	
		DESCRIPTION;	
		ADVERSE REACTIONS)	
50-630	PRIMAXIN	MSD	CILASTATIN SODIUM
24-JUN-94	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
	19486	IMIPENEM	
		500MG/VIAL	
		(LABELING REVISION --	
		DESCRIPTION;	
		ADVERSE REACTIONS)	
50-630	PRIMAXIN	MSD	CILASTATIN SODIUM
24-JUN-94	(INJECTABLE)	WEST POINT, PA	EQ 750MG BASE/VIAL
	19486	IMIPENEM	
		750MG/VIAL	
		(LABELING REVISION --	
		DESCRIPTION;	
		ADVERSE REACTIONS)	
12-728	ORTHO-NOVUM 1/50 21	JOHNSON RW	MESTRANOL
28-JUN-94	(TABLET)	RARITAN, NJ	0.05MG
	08869	NORETHINDRONE	
		1MG	
		(LABELING REVISION --	
		PRECAUTIONS;	
		PATIENT PACKAGE INSERT)	
16-954	MICRONOR	JOHNSON RW	NORETHINDRONE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

28-JUN-94	(TABLET)	RARITAN, NJ	0.35MG
	08869	(LABELING REVISION --	
		PRECAUTIONS;	
		PATIENT PACKAGE INSERT)	
17-488	MODICON 21	JOHNSON RW	ETHINYL ESTRADIOL
28-JUN-94	(TABLET)	RARITAN, NJ	0.035MG
	08869	NORETHINDRONE	
		0.5MG	
		(LABELING REVISION --	
		PRECAUTIONS;	
		PATIENT PACKAGE INSERT)	
17-489	ORTHO-NOVUM 1/35-21	JOHNSON RW	ETHINYL ESTRADIOL
28-JUN-94	(TABLET)	RARITAN, NJ	0.035MG
	08869	NORETHINDRONE	
		1MG	
		(LABELING REVISION --	
		PRECAUTIONS;	
		PATIENT PACKAGE INSERT)	
19-653	ORTHO CYCLEN-21	JOHNSON RW	ETHINYL ESTRADIOL
28-JUN-94	(TABLET)	RARITAN, NJ	0.035MG
	08869	NORGESTIMATE	
		0.25MG	
		(LABELING REVISION --	
		PRECAUTIONS;	
		DOSAGE AND ADMINISTRATION;	
		PATIENT PACKAGE INSERT)	
19-653	ORTHO CYCLEN-28	JOHNSON RW	ETHINYL ESTRADIOL
28-JUN-94	(TABLET)	RARITAN, NJ	0.035MG
	08869	NORGESTIMATE	
		0.25MG	
		(LABELING REVISION --	
		PRECAUTIONS;	
		DOSAGE AND ADMINISTRATION;	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

PATIENT PACKAGE INSERT)

19-697	ORTHO TRI-CYCLEN	JOHNSON RW	ETHINYL ESTRADIOL
28-JUN-94	(21-DAY)	RARITAN, NJ	0.035MG
	(TABLET)	08869	NORGESTIMATE
			0.18MG,0.215MG,0.25MG
			(LABELING REVISION --
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			PATIENT PACKAGE INSERT)
19-697	ORTHO TRI-CYCLEN	JOHNSON RW	ETHINYL ESTRADIOL
28-JUN-94	(28-DAY)	RARITAN, NJ	0.035MG
	(TABLET)	08869	NORGESTIMATE
			0.18MG,0.215MG,0.25MG
			(LABELING REVISION --
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			PATIENT PACKAGE INSERT)
11-835	HYDRODIURIL	MERCK	HYDROCHLOROTHIAZIDE
29-JUN-94	(TABLET)	WEST POINT, PA	25MG
		19486	50MG
			100MG
			(LABELING REVISION --
			DOSAGE AND ADMINISTRATION)
18-830	TAMBOCOR	3M	FLECAINIDE ACETATE
29-JUN-94	(TABLET)	SAINT PAUL, MN	50MG
		55144	100MG
			150MG
			(LABELING REVISION --
			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

19-004	ORTHO-NOVUM 7/14-21	JOHNSON RW	ETHINYL ESTRADIOL
29-JUN-94	(TABLET)	RARITAN, NJ	0.035MG
	08869		NORETHINDRONE
			0.5MG, 1MG
			(LABELING REVISION --
			PRECAUTIONS;
			PATIENT PACKAGE INSERT)
19-004	ORTHO-NOVUM 7/14-28	JOHNSON RW	ETHINYL ESTRADIOL
29-JUN-94	(TABLET)	RARITAN, NJ	0.035MG
	08869		NORETHINDRONE
			0.5MG, 1MG
			(LABELING REVISION --
			PRECAUTIONS;
			PATIENT PACKAGE INSERT)
19-970	NITROGLYCERIN	BAXTER	NITROGLYCERIN
29-JUN-94	IN DEXTROSE 5%	ROUND LAKE, IL	10MG/100ML
	(INJECTABLE)	60073	20MG/100ML
			40MG/100ML
			(LABELING REVISION --
			DESCRIPTION;
			CONTRAINDICATIONS;
			HOW SUPPLIED)
16-016	ALDOCLOR-150	MSD	CHLOROTHIAZIDE
30-JUN-94	(TABLET)	WEST POINT, PA	150MG
	19486		METHYLDOPA
			250MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(LABELING REVISION --
			PRECAUTIONS;
			HOW SUPPLIED)
16-016	ALDOCLOR-250	MSD	CHLOROTHIAZIDE
30-JUN-94	(TABLET)	WEST POINT, PA	250MG
	19486		METHYLDOPA
			250MG
			(LABELING REVISION --
			PRECAUTIONS;
			HOW SUPPLIED)
19-949	DIFLUCAN	PFIZER	FLUCONAZOLE
30-JUN-94	(TABLET)	GROTON, CT	50MG
	06340		100MG
			200MG
			(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
19-950	DIFLUCAN	PFIZER	FLUCONAZOLE
30-JUN-94	(INJECTABLE)	NEW YORK, NY	2MG/ML
	10017		(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			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			
			HOW SUPPLIED)
20-090 30-JUN-94	DIFLUCAN (POWDER FOR RECONSTITUTION)	PFIZER NEW YORK, NY 10017	FLUCONAZOLE 50MG/5ML 200MG/5ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
50-605 30-JUN-94	CEFTIN (TABLET)	GLAXO RES TRIANGLE PK, NC 27709	CEFUROXIME AXETIL EQ 125MG BASE EQ 250MG BASE EQ 500MG BASE (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

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

BIOLOGICAL PRODUCT LICENSES ISSUED

THERE ARE NO BIOLOGICAL PRODUCT LICENSES ISSUED FOR JUNE 1994.

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK930029	ACCESS	BAXTER HLTHCARE	ACCESS MANAGEMENT SYSTEM (AMS)
06-20-94		ROUND LAKE, IL 91203	(C)
BK930032	GTI ACE	GENETIC TESTING INST	DETECTION OF IgG
06-20-94	CAPTURE ELISA	BROOKFIELD, WI 53045	ANTIBODIES TO PLATELET-SPECIFIC ANTIBODIES (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

P890056	MODEL PC-28LB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	APPROVAL FOR THE PC28LB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	05/26/94
P910075	WESLEY-JESSEN MULTI-PURPOSE SOLUTION	WESLEY-JESSEN DES PLAINES, IL 60018	APPROVAL FOR USE IN THE CHEMICAL (NOT HEAT) DISINFECTION, CLEANING, RINSING AND STORAGE OF SOFT (HYDROPHILIC) CONTACT LENSES	06/01/94
P910077	VENTAK PRX MODEL 1700 AND MODEL 1705 AICD SYSTEM, MODEL 2850 PRESCRIPTOR PROGRAMMER AND MODEL 2860 PROGRAM DISK	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	APPROVAL FOR THE TREATMENT OF PATIENTS WITH VENTRICULAR FIBRILLATION AND/OR VENTRICULAR TACHYARRHYTHMIAS WHO ARE AT HIGH RISK OF SUDDEN CARDIAC DEATH	06/17/94
P910054	INOUE BALLOON CATHETER	TORAY INDUSTRIES (AMERICA), INC. NEW YORK, NY 10016-1901	APPROVAL FOR THE PERCUTANEOUS TRANSVENOUS MITRAL COMMISSUROTOMY IN PATIENTS WITH HEMODYNAMICALLY SIGNIFICANT MITRAL VALVULAR STENOSIS	06/28/94

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

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

P920021	OPUS CEA	PB DIAGNOSTIC SYSTEMS, INC. WESTWOOD, MA 02090	QUANTITATIVE MEASUREMENT OF CARCINOEMBRYONIC ANTIGEN IN SERUM USED IN MANAGEMENT AND PROGNOSIS OF CANCER PATIENTS IN WHOM CHANGING CEA ARE OBSERVED	06/20/94
P930024	GRIESHABER SCLERAL BUCKLING BALLOON CATHETER	GRIESHABER & CO., INC. KENNESAW, GA 30144	TEMP IMPLANT TO BUCKLE SCLERA TO FACILITATE RETINAL REATTACHMENTS WHERE ANTERIOR BREAKS IN TWO-THIRDS OF GLOBE DON'T SUBTEND RETINAL ARC MORE 1 HR (6 MM)	06/02/94

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

N17/679/S28 05/10/94	PREFERENCE, (TETRAFILCON A) SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENS (CLEAR & TINTED) COOPERCLEAR (TETRAFILCON A) SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENS VANTAGE THIN & VANTAGE THIN ACCENTS (TETRAFILCON A) SOFT (HYDROPHILIC) EXTENDED WEAR CONTACT LENS (CLEAR & TINTED)	COOPERVISION, INC SCOTTSVILLE, NY 14546	CHANGE IN STERILIZATION PROCESS
P790018/S22 05/09/94	MEDTRONIC HALL PROSTHETIC HEART VALVE	MEDTRONIC, INC. MINNEAPOLIS, MN 55440	DEVICE DESIGN CHANGE TO MODEL Z7700 FOR 21,23,25,27,29,31, AND 33MM SIZES
P800041/S11 05/25/94	CARBON TIP LEAD MODELS 1085S, 1085M, 1085K	PACESETTER SYSTEMS, INC. SYLMER, CA 91342	ALTERNATE MANUFACTURING FACILITY AT SYLMER, CA
P810002/S28 05/10/94	ST.JUDE MEDICAL PROSTHETIC HEART VALVE	ST.JUDE MEDICAL, INC. ST. PAUL, MN 55117	ALTERNATE STERILIZATION SITE AT LIBERTYVILLE, IL

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P810018/S32	POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	CHANGES IN DEVICE DESIGN	05/05/94
P810032/S44	POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	CHANGES IN DEVICE DESIGN	05/05/94
P830026/S56	COSMOS PACING SYSTEM NOVA III, QUANTUM III, SUPRIMA III PULSE GENERATORS	INTERMEDICS, INC. ANGLETON, TX 77515	DEVICE DESIGN AND LABELING CHANGES IN VARIOUS MODELS	05/06/94
P830026/S59	COSMOS PACING SYSTEM COSMOS II, NOVA II, QUANTUM II PULSE GENERATORS	INTERMEDICS, INC. ANGLETON, TX 77515	DEVICE DESIGN CHANGES TO COSMOS II, NOVA II, AND QUANTUM II PACING SYSTEMS	05/17/94
P830026/S60	COSMOS PACING SYSTEM COSMOS II MODELS 284-05 AND 283-03 II PULSE GENERATORS	INTERMEDICS, INC. ANGLETON, TX 77515	DEVICE DESIGN CHANGES TO COSMOS II, NOVA II, AND QUANTUM II PACING SYSTEMS	05/17/94
P830037/S37	WESLEY-JESSEN FRESHLOOK OPTIFIT TORIC COLORS AND FRESHLOOK OPTIFIT	WESLEY-JESSEN CHICAGO, IL 60610-3496	REVISED LABELING FOR MONOVISION FITTING TECHNIQUE	05/27/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	TORIC LITETINT HYDROPHILIC CONTACT LENSES		
P830056/S74 05/17/94	ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES: STERILIZATION FACILITY CHANGE	OPTICAL RADIATION CORPORATION AZUSA, CA 91702	ALTERNATE STERILIZATION SITE AT SALINAS, PUERTO RICO
P840001/S30 05/25/94	MEDTRONIC ITREL SPINAL CORD STIMULATION SYSTEM	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN 55440-9087	CHANGE IN STERILIZATION PROCESS
P840008/S48 05/04/94	DORNIER LITHOTRIPTER, MODELS HM3, HM4, MPL9000 AND MFL5000	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	CHANGE IN POSTAPPROVAL PROTOCOL
P840033/S4 05/05/94	POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	CHANGES IN DEVICE DESIGN
P850045/S15 05/27/94	BLAIREX BUFFERED STERILE SALINE SOLUTION	BLAIREX LABORATORIES, INC. EVANSVILLE, IN 47716-0190	APPROVAL OF A SHELFLIFE PROTOCOL AND SHELFLIFE EXTENSION
P850045/S16 05/27/94	BLAIREX BUFFERED STERILE SALINE SOLUTION	BLAIREX LABORATORIES, INC. EVANSVILLE, IN 47716-0190	ALTERNATE MANUFACTURING SITE AT COLUMBUS, IN

APPLICATION NO. / APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P850069/S10 05/19/94	KENNEDY LAD LIGAMENT AUGMENTATION DEVICE	3M HEALTH CARE ST. PAUL, MN 55133	CHANGE IN BIOLOGICAL TESTS PERFORMED
P860004/S29 05/04/94	MEDTRONIC SYNCHROMED INFUSION SYSTEM MODEL 8502s ACCESS PORT WITH SCREENED SEPTUM	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN 55440-9087	APPROVAL OF MODEL 8502s ACCESS PORT WITH SCREENED SEPTUM FOR USE WITH SYNCHROMED PUMPS
P860007/S13 05/17/94	INTERTACH PACING SYSTEM INTERTACH II PULSE GENERATORS MODELS 262-16 AND 262-16R	INTERMEDICS, INC. ANGLETON, TX 77515	DEVICE DESIGN MODIFICATIONS TO INTERTACH I MODELS 262-16 & 262-16R
P860007/S14 05/17/94	INTERTACH PACING SYSTEM INTERTACH II PULSE GENERATORS MODELS 262-16 & 262-16R	INTERMEDICS, INC. ANGLETON, TX 77515	DEVICE DESIGN MODIFICATIONS TO INTERTACH I MODELS 262-16 & 262-16R
P860019/S81 05/06/94	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER LONG CRUISE 30 & LONG CRUISE 40 PTCA CATHETERS	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	DEVICE DESIGN CHANGES NEW TRADE NAMES SCIMED LONG CRUISE 30 & LONG CRUISE 40 PTCA CATHETERS

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
P870002/S12	APPLIED BUFFERED STERILE SALINE SOLUTION (AEROSOL)	APPLIED LABORATORIES, INC. COLUMBUS, IN 47202-0448	APPROVAL FOR SHELF LIFE PROTOCOL & SHELF LIFE EXTENSION	05/19/94
P870018/S8	LITHOSTAR LITHOTRIPTER FOR RENAL STONES	SIEMENS MEDICAL SYSTEMS, INC. ISELIN, NJ 08830	CHANGE IN POSTAPPROVAL PROTOCOL	05/05/94
P870018/S9	LITHOSTAR LITHOTRIPTER FOR RENAL STONES	SIEMENS MEDICAL SYSTEMS, INC. ISELIN, NJ 08830	CHANGE IN POSTAPPROVAL PROTOCOL; COMPONENT CHANGE	05/04/94
P870049/S18	MICROSCAN RAPIDE PANELS	BAXTER DIAGNOSTICS, INC. WEST SACRAMENTO, CA 95691	CHANGE IN MANUFACTURING PROCESS	05/09/94
P880010/S16	POSTERIOR CHAMBER INTRAOCULAR LENSES	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	CHANGES IN DEVICE DESIGN	05/05/94
P880027/S30	SCHNEIDER MICROSOFTRAC PTCA CATHETER SCHNEIDER MYSTIC 20 MC, 30 MC, AND 40 MC PTCA CATHETERS	SCHNEIDER (USA) INC. MINNEAPOLIS, MN 55442	DEVICE DESIGN CHANGES TO BE MARKETED AS MYSTIC 20MC, MYSTIC 30MC, AND MYSTIC 40 MC PTCA CATHETERS	05/17/94
P890043/S20	SIMPSON CORONARY ATHEROCATH	DEVICES FOR VASCULAR INTERVENTIONS, INC.	DEVICE DESIGN CHANGES TO THE ATHEROCATH	05/23/94

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
		REDWOOD CITY, CA 94063	SCA-EX, GTO, AND SCA-III DEVICES	
P890064/S2	VIRAPAP HUMAN PAPILLOMAVIRUS DNA DETECTION KIT HPV PROFILE HUMAN PAPILLOMAVIRUS (HPV) DNA GROUPING SYSTEM	DIGENE DIAGNOSTICS, INC. SILVER SPRING, MD 20904	DEVICE DESIGN CHANGES	05/19/94
P900061/S4	MEDTRONIC MODEL 7217B PCD TACHYARRHYTHMIA CONTROL DEVICE & EPICARDIAL & SUBCUTANEOUS PATCH LEAD MODELS 6721 S/M/L, 6921 S/M/L, 6939, & 6999	MEDTRONIC, INC. MINNEAPOLIS, MN 554323-3576	DEVICE DESIGN MODIFICATION TO THE EPICARDIAL AND SUBCUTANEOUS PATCH LEADS	05/25/94
P900061/S5	MEDTRONIC MODEL 7217B PCD TACHYARRHYTHMIA CONTROL DEVICE	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	DEVICE DESIGN CHANGE AND EXTENDED SHELFLIFE	05/25/94
P910020/S3	RELAY/DASH/ PACING SYSTEM RELAY/DASH/STRIDE/ DART PACING SYSTEMS	INTERMEDICS, INC. ANGLETON, TX 77515	DEVICE DESIGN AND LABELING CHANGES TO VARIOUS MODELS	05/06/94
P910023/S2	CADENCE TIERED THERAPY DEFIBRILLATOR	VENTRITEX, INC SUNNYVALE, CA 94086-6527	APPROVAL OF THE CADENCE TIERED THERAPY DEFIBRILLATOR	05/09/94

APPLICATION NO. / APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTALS	
	SYSTEM CADENCE MODEL V-100D PULSE GENERATOR & MODELS DP-3219 & DP-3238 EPICARDIAL DEFIBRILLATION LEADS		SYSTEM AND CADENCE MODEL V-100D PULSE GENERATOR
P920015/S2 05/25/94	MEDTRONIC MODEL 7217B PCD TACHYARRHYTHMIA CONTROL DEVICE & EPICARDIAL & SUBCUTANEOUS PATCH LEAD MODELS 6721 S/M/L, 6921 S/M/L, 6939, & 6999	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	DEVICE DESIGN MODIFICATION TO THE EPICARDIAL AND SUBCUTANEOUS PATCH LEADS
P810046/S131 06/14/94	SIMPSON-ROBERT CORONARY BALLOON DILATION CATHETER RX PRIMAFLOW CORONARY DILATION CATHETER	ADVANCE CARDIOVASCULAR SYSTEMS, INC. SANTA CLARA, CA 95052-8167	DEVICE DESIGN CHANGE; NEW MODEL RX PRIMAFLOW CORONARY DILATION CATHETER
P810046/S144 06/13/94	ACS EDGE CORONARY DILATION CATHETER	ADVANCED CARDIOVASCULAR TEMECULA, CA 92591-4628	DEVICE DESIGN CHANGES ADDS BALLOON SIZES AND LENGTHS TO ACS EDGE BALLOON DILATION CATHETER
P810046/S150 06/14/94	ACS CORONARY DILATATION CATHETERS	ADVANCED CARDIOVASCULAR TEMECULA, CA 92591-4628	ADDITION OF A QUALITY CONTROL TEST
P830037/S38	WESLEY-JESSEN	WESLEY-JESSEN	REVISED LABELING FOR

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	DUROSOFT 3 HYDROPHILIC CONTACT LENSES	CHICAGO, IL 60610-3496	MONOVISION FITTING TECHNIQUES	06/13/94
P840039/S42	ULTRAVIOLET-ABSORBING AND NON ULTRAVIOLET-ABSORBING POLYMETHYL-METHACRYLATE (PMMA) INTRAOCULAR LENSES (IOLS)	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	CHANGES IN STERILIZATION PROCEDURES AND AN ALTERNATE MANUFACTURING SITE AT CLEARWATER, FL	06/27/94
P840039/S43	ULTRAVIOLET-ABSORBING AND NON ULTRAVIOLET-ABSORBING POLYMETHYL-METHACRYLATE (PMAA) INTRAOCULAR LENSES (IOLS)	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	CHANGES IN STERILIZATION PROCEDURES AND AN ALTERNATE MANUFACTURING SITE AT CLEARWATER, FL	06/27/94
P840040/S40	POBA AND SAVVY PTCA CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172-2414	DEVICE DESIGN CHANGES NEW MODELS POBA AND SAVVY PTCA CATHETERS	06/24/94
P850079/S25	HYDRASOFT (METHAFILCON A & B) HYDROPHILIC CONTACT LENSES INCLUDING HYDRASOFT, HYDRASOFT XW, HYDRASOFT TORIC AND HYDRASOFT	COASTVISION HUNTINGTON, CA 92648	REVISED LABELING WARNING STATEMENT AND DIRECTIONS FOR USE	06/24/94

APPLICATION NO. / APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
	TORIC XW		
P860002/S14 06/27/94	ULTRAVIOLET-ABSORBING AND NON ULTRAVIOLET-ABSORBING POLYMETHYL-METHACRYLATE (PMAA) INTRAOCULAR LENSES (IOLS)	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	CHANGES IN STERILIZATION PROCEDURES AND AN ALTERNATE MANUFACTURING SITE AT CLEARWATER, FL
P860004/S24 06/30/94	SYNCHROMED 8810	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN 55440-9087	DEVICE DESIGN CHANGE REVISED SOFTWARE
P860047/S7 06/30/94	OCCUCOAT	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	ALTERNATE STERILIZATION PACKAGING AND DISTRIBUTION SITE AT CLEARWATER, FL
P870073/S14 06/27/94	ULTRAVIOLET-ABSORBING AND NON ULTRAVIOLET-ABSORBING POLYMETHYL-METHACRYLATE (PMAA) INTRAOCULAR LENSES (IOLS)	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	CHANGES IN STERILIZATION PROCEDURES AND AN ALTERNATE MANUFACTURING SITE AT CLEARWATER, FL
P880090/S9 06/21/94	MODELS 121UV AND S121UV ULTRAVIOLET-ABSORBING ANTERIOR CHAMBER	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	NEW DISTRIBUTER MDR MEDICAL CORPORATION NEW MODEL NAMES Z61UV AND Z60UV

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

INTRAOCULAR LENSES

P880090/S13 06/27/94	ULTRAVIOLET-ABSORBING AND NON ULTRAVIOLET-ABSORBING POLYMETHYL-METHACRYLATE (PMAA) INTRAOCULAR LENSES (IOLS)	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	CHANGES IN STERILIZATION PROCEDURES AND AN ALTERNATE MANUFACTURING SITE AT CLEARWATER, FL
P880101/S6 06/13/94	WESLEY-JESSEN AQUAFLEX HYDROPHILIC CONTACT LENSES	WESLEY-JESSEN CHICAGO, IL 60610-3496	REVISED LABELING FOR MONOVISION FITTING TECHNIQUES
P890034/S3 06/17/94	MODEL APT 1010 ULTRAHIGH FREQUENCY VENTILATOR	INFRASONICS, INC. ROCKY HILL, CT 06067-3440	DEVICE DESIGN CHANGE ALTERNATE POWER SUPPLY
P890047/S3 06/22/94	PROVISC VISCOELASTIC PREPARATION	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	REVISED LABELING DIRECTIONS FOR USE
P900023/S7 06/21/94	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	DEVICE DESIGNS CHANGE NEW VENDOR FOR CANNULAE
P900032/S18 06/14/94	DYMER 200+ EXCIMER LASER SYSTEM	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA 92718	DEVICE DESIGN CHANGE TO MODEL PC4010 LASER CATHETER

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P900032/S19	DYMER 200+ EXCIMER LASER SYSTEM	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA 92718	DEVICE DESIGN CHANGE TO MODEL PC4021 LASER CATHETER	06/14/94
P900061/S1	TACHYARRHYTHMIA PCD CONTROL DEVICE 7201 CARDIOVERTER/ DEFIBRILLATOR(CD) PCD B&D, 9789&9791 MEMORYMODS, & 6721 S/M/L EPICARDIAL DEFIBRILLATION	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	DEVICE DESIGN CHANGES MODELS 7201CD 9789, 9791, AND 6721	06/01/94
P910020/S5	RELAY-DASH PACING SYSTEM	INTERMEDICS, INC. ANGLETON, TX 77515	DEVICE DESIGN CHANGE ALTERNATE VENDOR FOR PULSE GENERATORS	06/09/94
P910023/S4	CADENCE TIERED THERAPY DEFIBRILLATOR SYSTEM CADENCE MODEL V-110 PULSE GENERATORS	VENTRITEX, INC. SUNNYVALE, CA 94086-6527	DEVICE DESIGN CHANGE AND NEW MODEL CADENCE MODEL V-110 SERIES PULSE GENERATOR AND PROGRAMMER SOFTWARE V3.2.	06/16/94
P920015/S1	MEDTRONIC TRANSVENE LEAD SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	DEVICE LABELING CHANGES TO TRANSVENE DF-1 LEAD MODELS 6933, 6936, 6939 - PRECAUTION STATEMENT	06/24/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

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

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR JUNE 1994.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR JUNE 1994.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR JUNE 1994.

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
Julie Stuart (301) 594-2186

Center for Biologics Evaluation and Research
Joyce Bagley (301) 594-2906

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

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July 1994

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

18-956 OMNIPAQUE 70 STERLING WINTHROP IOHEXOL
01-JUN-94 (SOLUTION) NEW YORK, NY 15.1%
(SUPPL-036) 10016 (NEW STRENGTH)

20-201 DOBUTAMINE HCL IN ABBOTT DOBUTAMINE HYDROCHLORIDE
07-JUL-94 DEXTROSE 5% ABBOTT PARK, IL EQ 400MG BASE/100ML
(SUPPL-003) IN PLASTIC CONTAINER 60064 (NEW STRENGTH)
(INJECTABLE)

20-222 COLESTID UPJOHN COLESTIPOL HYDROCHLORIDE
19-JUL-94 (TABLET) KALAMAZOO, MI 1GM
(3 P) 49001 (ANTIHYPERLIPIDEMIC)

19-537 CIPRO MILES CIPROFLOXACIN HYDROCHLORIDE
21-JUL-94 (TABLET) WEST HAVEN, CT EQ 250MG BASE
(SUPPL-013) 06516 EQ 500MG BASE

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

			EQ 750MG BASE
			(NEW INDICATION --
			UNCOMPLICATED GONORRHEA)
19-537	CIPRO	MILES	CIPROFLOXACIN HYDROCHLORIDE
21-JUL-94	(TABLET)	WEST HAVEN, CT	EQ 250MG BASE
(SUPPL-015)		06516	EQ 500MG BASE
			EQ 750MG BASE
			(NEW INDICATION --
			TYPHOID FEVER)

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

APPROVABLE ORIGINAL NDAs

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

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

20-347 25-JUL-94	TERAZOSIN HCL (CAPSULE) 60064 5MG 10MG (ALPHA-1 ADENORECEPTOR BLOCKER)	ABBOTT ABBOTT PK, IL 2MG	TERAZOSIN HYDROCHLORIDE 1MG
20-241 26-JUL-94	LAMICTAL (TABLET) 27709 200MG 250MG (ANTICONVULSANT) [ADJUNCTIVE THERAPY IN THE TREATMENT OF PARTIAL SEIZURES IN ADULTS WITH EPILEPSY]	BURROUGHS WELLC RES TRIANGLE PK, NC 150MG	LAMOTRIGINE 100MG
50-679 26-JUL-94	MAXIPIME (INJECTABLE) 06492 EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL	BRISTOL MYERS SQUIBB WALLINGFORD, CT	CEFEPIME HYDROCHLORIDE EQ 500MG BASE/VIAL

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

APPROVABLE ORIGINAL NDAs

(CEPHALOSPORIN)
[L- ARGININE FORMULATION]

50-678	DYNABAC	LILLY	DIRITHROMYCIN
28-JUL-94	(TABLET, DELAYED RELEASE)	INDIANAPOLIS, IN 46285	250MG (ANTIBIOTIC, MACROLIDE)

20-364	LOTREL 5/2.5	CIBA	AMLODIPINE BESYLATE
29-JUL-94	(CAPSULE)	SUMMIT, NJ 07901	EQ 2.5MG BASE BENAZEPRIL HYDROCHLORIDE 5MG (ANTIHYPERTENSIVE)

20-364	LOTREL 10/2.5	CIBA	AMLODIPINE BESYLATE
29-JUL-94	(CAPSULE)	SUMMIT, NJ 07901	EQ 2.5MG BASE BENAZEPRIL HYDROCHLORIDE 10MG (ANTIHYPERTENSIVE)

20-364	LOTREL 10/5	CIBA	AMLODIPINE BESYLATE
29-JUL-94	(CAPSULE)	SUMMIT, NJ 07901	EQ 5MG BASE BENAZEPRIL HYDROCHLORIDE 10MG (ANTIHYPERTENSIVE)

20-364	LOTREL 20/5	CIBA	AMLODIPINE BESYLATE
29-JUL-94	(CAPSULE)	SUMMIT, NJ 07901	EQ 5MG BASE BENAZEPRIL HYDROCHLORIDE 20MG (ANTIHYPERTENSIVE)

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

APPROVABLE ORIGINAL NDAs

20-392	CYSTAGON	MYLAN	CYSTEAMINE BITARTRATE
29-JUL-94	(CAPSULE)	MORGANTOWN, WV	EQ 50MG BASE
	26505		EQ 150MG BASE
		(CYSTINE DEPLETING AGENT)	

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

ORIGINAL ABBREVIATED NDAs

64-063	DEXASPORIN	BAUSCH AND LOMB	DEXAMETHASONE
25-JUL-94	(OINTMENT)	TAMPA, FL	0.1%
	33637		NEOMYCIN SULFATE
			EQ 3.5MG BASE/GM
			POLYMYXIN B SULFATE
			10,000 UNITS/GM
			(STEROID/ANTIBIOTIC)
40-064	TROPICAMIDE	BAUSCH AND LOMB	TROPICAMIDE
27-JUL-94	(SOLUTION/DROPS)	TAMPA, FL	1%
	33637		(MYDRIATIC)
40-067	TROPICAMIDE	BAUSCH AND LOMB	TROPICAMIDE
27-JUL-94	(SOLUTION/DROPS)	TAMPA, FL	0.5%
	33637		(MYDRIATIC)
40-065	PREDNISOLONE	BAUSCH AND LOMB	PREDNISOLONE
29-JUL-94	SODIUM PHOSPHATE	TAMPA, FL	SODIUM PHOSPHATE
	(SOLUTION/DROPS)	33637	EQ 0.11% PHOSPHATE
			(CORTICOSTEROID)
40-070	PREDNISOLONE	BAUSCH AND LOMB	PREDNISOLONE
29-JUL-94	SODIUM PHOSPHATE	TAMPA, FL	SODIUM PHOSPHATE
	(SOLUTION/DROPS)	33637	EQ 0.9% PHOSPHATE
			(CORTICOSTEROID)
40-091	SULFADIAZINE	EON LABS	SULFADIAZINE
29-JUL-94	(TABLET)	LAURELTON, NY	500MG
	11413		(SULFONAMIDE)
64-067	ERYTHROMYCIN	BAUSCH AND LOMB	ERYTHROMYCIN
29-JUL-94	(OINTMENT)	TAMPA, FL	0.5%
	33637		(ANTIBIOTIC, MACROLIDE)

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

ORIGINAL ABBREVIATED NDAs

74-294	ALPRAZOLAM	ZENITH LABS	ALPRAZOLAM
29-JUL-94	(TABLET)	NORTHVALE, NJ	0.25MG
	07647		0.5MG
			1MG
			2MG
		(ANXIOLYTIC)	
74-380	METOPROLOL TARTRATE	PUREPAC PHARM	METOPROLOL TARTRATE
29-JUL-94	(TABLET)	ELIZABETH, NJ	50MG
	07207		100MG
		(BETA ADRENERGIC BLOCKER)	
74-396	ENFLURANE	INHALON	ENFLURANE
29-JUL-94	(LIQUID)	BETHLEHEM, PA	99.9%
	18017	(ANESTHETIC, GENERAL)	

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

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

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

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS FOR JULY 1994.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-956	OMNIPAQUE 70	STERLING WINTHROP	IOHEXOL
01-JUN-94	(SOLUTION)	NEW YORK, NY	15.1%
	10016	(LABELING REVISION -- INDICATIONS AND USAGE; HOW SUPPLIED)	

18-956	OMNIPAQUE 140	STERLING WINTHROP	IOHEXOL
01-JUN-94	(SOLUTION)	NEW YORK, NY	30.2%
	10016	(LABELING REVISION -- INDICATIONS AND USAGE; HOW SUPPLIED)	

18-956	OMNIPAQUE 180	STERLING WINTHROP	IOHEXOL
01-JUN-94	(SOLUTION)	NEW YORK, NY	38.8%
	10016	(LABELING REVISION -- INDICATIONS AND USAGE; HOW SUPPLIED)	

18-956	OMNIPAQUE 210	STERLING WINTHROP	IOHEXOL
01-JUN-94	(SOLUTION)	NEW YORK, NY	45.3%
	10016	(LABELING REVISION -- INDICATIONS AND USAGE; HOW SUPPLIED)	

18-956	OMNIPAQUE 240	STERLING WINTHROP	IOHEXOL
01-JUN-94	(SOLUTION)	NEW YORK, NY	51.8%
	10016	(LABELING REVISION -- INDICATIONS AND USAGE; HOW SUPPLIED)	

18-956	OMNIPAQUE 300	STERLING WINTHROP	IOHEXOL
01-JUN-94	(SOLUTION)	NEW YORK, NY	64.7%
	10016	(LABELING REVISION -- 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

			HOW SUPPLIED)
18-956	OMNIPAQUE 350	STERLING WINTHROP	IOHEXOL
01-JUN-94	(INJECTABLE)	NEW YORK, NY	75.5%
	10016		(LABELING REVISION -- INDICATIONS AND USAGE; HOW SUPPLIED)
19-643	MEVACOR	MERCK	LOVASTATIN
05-JUL-94	(TABLET)	WEST POINT, PA	10MG
	19486		20MG
			40MG
			(LABELING REVISION -- ADVERSE REACTIONS)
18-354	ORTHO-NOVUM 10/11-21	JOHNSON RW	ETHINYL ESTRADIOL
06-JUL-94	(TABLET)	RARITAN, NJ	0.035MG
	08869		NORETHINDRONE
			0.5MG AND 1MG
			(LABELING REVISION -- PATIENT PACKAGE INSERT)
18-354	ORTHO-NOVUM 10/11-28	JOHNSON RW	ETHINYL ESTRADIOL
06-JUL-94	(TABLET)	RARITAN, NJ	0.035MG
	08869		NORETHINDRONE
			0.5MG AND 1MG
			(LABELING REVISION -- PRECAUTIONS; 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

18-936	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
06-JUL-94	(CAPSULE)	INDIANAPOLIS, IN 46285	EQ 10MG BASE EQ 20MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
20-101	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
06-JUL-94	(SOLUTION)	INDIANAPOLIS, IN 46285	EQ 20MG BASE/5ML (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
50-674	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
06-JUL-94	(TABLET)	KALAMAZOO, MI 49001	EQ 100MG BASE EQ 200MG BASE (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
50-675	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
06-JUL-94	(GRANULE, FOR RECONSTITUTION)	KALAMAZOO, MI 49001	EQ 50MG BASE/5ML EQ 100MG BASE/5ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
11-635	DIUPRES	MERCK	CHLOROTHIAZIDE
07-JUL-94	(TABLET)	WEST POINT, PA	250MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		19486	RESERPINE
			0.125MG
			(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
11-635	DIUPRES	MERCK	CHLOROTHIAZIDE
07-JUL-94	(TABLET)	WEST POINT, PA	500MG
		19486	RESERPINE
			0.125MG
			(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
20-201	DOBUTAMINE HCL	ABBOTT	DOBUTAMINE HYDROCHLORIDE
07-JUL-94	IN DEXTROSE 5%	ABBOTT PARK, IL	EQ 50MG BASE/100ML

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	60064	EQ 100MG BASE/100ML
	(INJECTABLE)		EQ 200MG BASE/100ML
			EQ 400MG BASE/100ML
			(LABELING REVISION --
			DESCRIPTION;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
16-402	ALUPENT	BOEHRINGER INGELHEIM	METAPROTERENOL SULFATE
08-JUL-94	(AEROSOL, METERED)	RIDGEFIELD, CT	0.65MG/INH
	06877	(LABELING REVISION --	
		HOW SUPPLIED)	
20-088	NORPLANT SYSTEM	WYETH AYERST	LEVONORGESTREL
11-JUL-94	(IMPLANT)	PHILADELPHIA, PA	36MG/IMPLANT
	19101	(LABELING REVISION --	
		INDICATIONS AND USAGE;	
		CONTRAINDICATIONS;	
		WARNINGS; PRECAUTIONS;	
		ADVERSE REACTIONS;	
		INSTRUCTIONS FOR REMOVAL;	
		PATIENT PACKAGE INSERT)	
12-339	BRONKOMETER	STERLING WINTHROP	ISOETHARINE MESYLATE
12-JUL-94	(AEROSOL, METERED)	NEW YORK, NY	0.34MG/INH
	10016	(LABELING REVISION --	
		HOW SUPPLIED)	
20-073	ROMAZICON	ROCHE	FLUMAZENIL
12-JUL-94	(INJECTABLE)	NUTLEY, NJ	0.1MG/ML
	07110	(LABELING REVISION --	
		CLINICAL PHARMACOLOGY;	
		WARNINGS)	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-183	CARAFATE	MARION MERRELL DOW	SUCRALFATE
13-JUL-94	(SUSPENSION)	KANSAS CITY, MO	1GM/10ML
	64134	(LABELING REVISION -- DRUG INTERACTIONS; ADVERSE REACTIONS; OVERDOSAGE)	
50-684	ZOSYN	LEDERLE	PIPERACILLIN SODIUM
13-JUL-94	(INJECTABLE)	PEARL RIVER, NY	EQ 2GM BASE/VIAL
	10969		TAZOBACTAM SODIUM EQ 250MG BASE/VIAL
		(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE)	
50-684	ZOSYN	LEDERLE	PIPERACILLIN SODIUM
13-JUL-94	(INJECTABLE)	PEARL RIVER, NY	EQ 3GM BASE/VIAL
	10969		TAZOBACTAM SODIUM EQ 375MG BASE/VIAL
		(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE)	
50-684	ZOSYN	LEDERLE	PIPERACILLIN SODIUM
13-JUL-94	(INJECTABLE)	PEARL RIVER, NY	EQ 4GM BASE/VIAL
	10969		TAZOBACTAM SODIUM EQ 500MG BASE/VIAL
		(LABELING REVISION --	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE)
50-684	ZOSYN	LEDERLE	PIPERACILLIN SODIUM
13-JUL-94	(INJECTABLE)	PEARL RIVER, NY	EQ 36GM BASE/VIAL
	10969		TAZOBACTAM SODIUM
			EQ 4.5GM BASE/VIAL
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE)
18-321	OSTEOSCAN HDP	MALLINCKRODT	TECHNETIUM TC-99M
14-JUL-94	(INJECTABLE)	SAINT LOUIS, MO	OXIDRONATE KIT
	63134		N/A
			(LABELING REVISION --
			NEW TRADE NAME --
			TECHNESCAN HDP)
18-333	CARAFATE	BLUE RIDGE	SUCRALFATE
14-JUL-94	(TABLET)	KANSAS CITY, MO	1GM
	64137		(LABELING REVISION --
			DRUG INTERACTIONS;
			INDICATIONS AND USAGE;
			ADVERSE REACTIONS;
			OVERDOSAGE;
			DOSAGE AND ADMINISTRATION)
17-968	DEPO-TESTADIOL	UPJOHN	ESTRADIOL CYPIONATE
15-JUL-94	(INJECTABLE)	KALAMAZOO, MI	2MG/ML
	49001		TESTOSTERONE CYPIONATE
			50MG/ML
			(LABELING REVISION --
			DRUG ABUSE AND DEPENDENCE)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-537	CIPRO	MILES	CIPROFLOXACIN HYDROCHLORIDE
21-JUL-94	(TABLET)	WEST HAVEN, CT	EQ 250MG BASE
	06516		EQ 500MG BASE
			EQ 750MG BASE
			(LABELING REVISION --
			INDICATIONS AND USAGE)
19-735	FLOXIN	JOHNSON RW	OFLOXACIN
21-JUL-94	(TABLET)	RARITAN, NJ	200MG
	08869		300MG
			400MG
			(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
20-011	LUPRON DEPOT	TAP	LEUPROLIDE ACETATE
21-JUL-94	(INJECTABLE)	DEERFIELD, IL	3.75MG/VIAL
	60015		(LABELING REVISION --
			ADVERSE REACTIONS)
18-768	VEPESID	BRISTOL MYERS SQUIBB	ETOPOSIDE
23-JUL-94	(INJECTABLE)	PRINCETON, NJ	20MG/ML
	08543		(LABELING REVISION --
			DESCRIPTION;
			CONTRAINDICATIONS;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-557	VEPESID	BRISTOL MYERS SQUIBB	ETOPOSIDE
23-JUL-94	(CAPSULE)	PRINCETON, NJ	50MG
	08543	(LABELING REVISION --	
		DESCRIPTION;	
		CONTRAINDICATIONS;	
		PRECAUTIONS;	
		ADVERSE REACTIONS;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	
19-558	PRINIVIL	MERCK	LISINOPRIL
24-JUL-94	(TABLET)	WEST POINT, PA	2.5MG
	19486		5MG
			10MG
			20MG
			40MG
		(LABELING REVISION --	
		ADVERSE REACTIONS)	
19-778	PRINZIDE 10-12.5	MERCK	HYDROCHLOROTHIAZIDE
24-JUL-94	(TABLET)	WEST POINT, PA	12.5MG
	19486		LISINOPRIL
			10MG
		(LABELING REVISION --	
		ADVERSE REACTIONS)	
19-778	PRINZIDE 20-12.5	MERCK	HYDROCHLOROTHIAZIDE
24-JUL-94	(TABLET)	WEST POINT, PA	12.5MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		19486	LISINOPRIL 20MG (LABELING REVISION -- ADVERSE REACTIONS)
19-778	PRINZIDE 20-25	MERCK	HYDROCHLOROTHIAZIDE
24-JUL-94	(TABLET)	WEST POINT, PA	25MG
		19486	LISINOPRIL 20MG (LABELING REVISION -- ADVERSE REACTIONS)
18-537	TRIDIL	DUPONT MERCK	NITROGLYCERIN
25-JUL-94	(INJECTABLE)	GARDEN CITY, NY	0.5MG/ML
		11530	5MG/ML (LABELING REVISION -- CONTRAINDICATIONS)
18-631	TRENTAL	HOECHST ROUSSEL	PENTOXIFYLLINE
25-JUL-94	(TABLET, EXTENDED RELEASE)	SOMERVILLE, NJ 08876	400MG (LABELING REVISION -- PRECAUTIONS)
18-709	CAPOZIDE 25/15	SQUIBB	CAPTOPRIL
25-JUL-94	(TABLET)	NEW BRUNSWICK, NJ	25MG
		08903	HYDROCHLOROTHIAZIDE 15MG (LABELING REVISION -- PRECAUTIONS)
18-709	CAPOZIDE 25/25	SQUIBB	CAPTOPRIL
25-JUL-94	(TABLET)	NEW BRUNSWICK, NJ	25MG
		08903	HYDROCHLOROTHIAZIDE 25MG (LABELING REVISION --

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
		LABELING SUPPLEMENTS TO ORIGINAL NDAs	
			PRECAUTIONS)
18-709 25-JUL-94	CAPOZIDE 50/15 (TABLET)	SQUIBB NEW BRUNSWICK, NJ 08903	CAPTOPRIL 50MG HYDROCHLOROTHIAZIDE 15MG (LABELING REVISION -- PRECAUTIONS)
18-709 25-JUL-94	CAPOZIDE 50/25 (TABLET)	SQUIBB NEW BRUNSWICK, NJ 08903	CAPTOPRIL 50MG HYDROCHLOROTHIAZIDE 25MG (LABELING REVISION -- PRECAUTIONS)
18-901 25-JUL-94	AMINESS 5.2% ESSENTIAL AMINO ACIDS W/HISTIDINE (INJECTABLE)	KABI CLAYTON, NC 27520	AMINO ACIDS 5.2% (LABELING REVISION -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
18-998 25-JUL-94	VASOTEC (TABLET)	MERCK WEST POINT, PA 19486	ENALAPRIL MALEATE 2.5MG 5MG 10MG 20MG (LABELING REVISION -- ADVERSE REACTIONS)
19-221 25-JUL-94	VASERETIC (TABLET)	MERCK WEST POINT, PA	ENALAPRIL MALEATE 10MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		19486	HYDROCHLOROTHIAZIDE 25MG (LABELING REVISION -- ADVERSE REACTIONS)
19-309	VASOTEC	MERCK	ENALAPRILAT
25-JUL-94	(INJECTABLE)	WEST POINT, PA	1.25MG/ML
		19486	(LABELING REVISION -- ADVERSE REACTIONS)
17-473	ORAP	LEMMON	PIMOZIDE
27-JUL-94	(TABLET)	SELLERSVILLE, PA	2MG
		18960	(LABELING REVISION -- DESCRIPTION; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
09-386	MYLERAN	BURROUGHS WELLC	BUSULFAN
29-JUL-94	(TABLET)	RES TRIANGLE PK, NC	2MG
		27709	(LABELING REVISION -- WARNINGS; ADVERSE REACTIONS)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

THERE ARE NO BIOLOGICAL PRODUCT LICENSES ISSUED FOR JULY 1994.

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK940023 07-05-94	NONE	BAXTER HLTHCARE ROUND LAKE, IL 60073	ACCESSORY WEIGHT SCALE FOR MEDICAL PURPOSES (C)
BK940022 07-14-94	ARROW QWIK-1	ARROW INTL READING, PA 19621	ARROW QWIK-1 BLOOD AND FLUID ADMINISTRATION SET (C)
BK920038 07-27-94	NONE	BAXTER HLTHCARE ROUND LAKE, IL 60073	CLOSED SYSTEM APHERESIS KIT WITH INTEGRAL LEUKOCYTE REMOVAL FILTER (C)
BK930017 07-27-94	NONE	COBE BCT LAKEWOOD, CO 80215	COBE SPECTRA APHERESIS SYSTEM (TRIPLE PLATELET PRODUCTS) (C)
BK930018 07-27-94	NONE	NPBI EMMER-COMPASCUUM NEDERLAND 7881 HM	BLOOD COLLECTION MIXER MW 5001 (C)
BK930020 07-27-94	NONE	NPBI EMMER-COMPASCUUM NEDERLAND 7881 HM	BIOTRANE SEPARATOR (C)
BK930034 07-27-94	VIROTROL III	BLACKHAWK BIOSYS SAN RAMON, CA 94583	VIROTROL III (C)
BK940013 07-27-94	NONE	BAXTER HLTHCARE ROUND LAKE, IL 60073	EXTENDED STORAGE PL 732 CONTAINERS WITH SEPACELL FILTER FOR LEUKOREDUCED PLATELETS (C)

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK940034 NONE MICRO TYPING SYS MTS CONTROL CARD
07-27-94 POMPANO BEACH, FL (C)
33069

(C) Substantially Equivalent

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

BIOLOGICAL NDA APPROVAL

94-0404 28-JUL-94	BLOOD PACK UNIT CPDA-1 60073	BAXTER HLTHCARE ROUND LAKE, IL	ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION, USP (CPDA-1) BLOOD-PACK (PL 2209 PLASTIC) (D)

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

(D) Approved

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 1994.

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

P810002/S32	ST. JUDE MEDICAL PROSTHETIC HEART VALVE	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	HEMODYNAMIC PLUS SERIES OF VALVES IN AORTIC AND MITRAL SIZES 23, 25, AND 27MM, THE CORRESPONDING VALVE SIZERS, HOLDERS, AND LABELING CHANGES	07/29/94
P810023/S2	COBE CENTRY THERAPEUTIC PLASMA EXCHANGE (TPE) SYSTEM	COBE BCT, INC. LAKEWOOD, CO 80215-4407	CHANGES TO THE STERILIZATION PROCESS	07/05/94
P810046/S148	SIMPSON-ROBERT CORONARY BALLOON DILATION CATHETER ACS RX FLOWTRACK LONG CORONARY DILATION CATHETER WITH A 30MM BALLOON	ADVANCED CARDIOVASCULAR SYS, INC SANTA CLARA, CA 95052-8167	ACS RX FLOWTRAK LONG CORONARY DILATION CATHETER WITH A 30MM BALLOON	07/11/94
P830045/S43	AFP MODEL 283 PULSE GENERATOR WITH MODEL 370 PROGRAMMER MODEL 385G FUNCTION PACK	SIEMENS PACESETTER, INC. SYLMAR, CA 91391-9221	NEW MODEL 385G FUNCTION PACK FOR USE WITH THE MODEL 380 HAND HELD PROGRAMMER	07/12/94
P830045/S44	AFP MODEL 283	SIEMENS PACESETTER, INC.	NEW MODEL PDX MODEL	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	PULSE GENERATOR WITH MODEL 370 PROGRAMMER PDX MODEL 3039 FUNCTION PACK	SYLMAR, CA 91392-9221	3039 FUNCTION PACK FOR USE WITH THE APS II MODEL 3003 PROGRAMMER	07/12/94
P840008/S49	DORNIER MFL5000 LITHOTRIPTER	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	ADDITIONAL TRAILER MANUFACTURER, MILLER MEDICAL, INC.	07/27/94
P840039/S46	ULTRAVIOLET-ABSORBING AND NON ULTRAVIOLET-ABSORBING POLYMETHYL-METHACRYLATE (PMMA) IOLS	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	ALTERNATE STERILIZATION METHOD	07/29/94
P840040/S44	MANSFIELD CORONARY BALLOON DILATION CATHETER SYSTEM SYNERGY II CONVERTIBLE RAPID EXCHANGE PTCA CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02272	ADDITION OF TWO QUALITY CONTROL INSPECTION PROCEDURES	07/26/94
P840068/S17	VISTA T VISTA T FAMILY PRODUCTS	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	ALTERNATE STERILIZATION SITE AT DEL CARIBE FACILITY IN DORADO, PUERTO RICO	07/26/94
P850021/S25	HYBRID PERCUTANEOUS	BAXTER HEALTHCARE CORPORATION	NEW MODEL DISTANCE .14 PTCA CATHETER	07/26/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

			TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER
P850021/S26 07/26/94	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	DISTANCE .14 PTCA CATHETER
P850088/S30 07/22/94	LENS PLUS OXYSEPT DISINFECTION SYSTEM ULTRACARE SYSTEM (ULTRACARE DISINFECTING SOLUTION/NEUTRALIZER)	ALLERGAN, INC. IRVINE, CA 92713-9534	TO MODIFY THE ADDS CYANOCOBALAMIN (VITAMIN B12) AS A COLOR INDICATOR, TO THE FORMULATION OF ULTRACARE NEUTRALIZING TABLET
P860002/S15 07/29/94	ULTRAVIOLET-ABSORBING AND NON-ULTRAVIOLET-ABSORBING POLYMETHYL-METHACRYLATE (PMMA) INTRAOCULAR LENSES (IOLS)	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	ALTERNATE STERILIZATION METHOD
P860061/S8 07/06/94	HYDROZYME WEEKLY ENZYMATIC CLEANER	ALLERGAN OPTICAL, INC. IRVINE, CA 92713-9534	USED AS AN ALTERNATE DILUENT FOR HYDROZYME WEEKLY ENZYMATIC CLEANER

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P870036/S28	MEDTRONIC SPIRIT 30 AND SPIRIT 40 PTCA CATHETERS	MEDTRONIC INTERVENTIONAL VASCULAR SAN DIEGO, CA 92121-2256	NEW TRADE NAME MEDTRONIC SPRINT 30 AND SPRINT 40; DESIGN CHANGE 30 AND 40 MM BALLOONS	07/26/94
P870045/S33	ULTRAVIOLET-ABSORBING (UV) AND NON-UV POSTERIOR CHAMBER PMMA INTRAOCULAR LENSES: "PRECISION SERIES" CHANGE IN LABELED POWER	CHIRON VISION CORP. IRVINE, CA 92718-1903	NEW METHOD FOR DETERMINING IOL POWER; REVISED LABELING 0.25 DIOPTER INCREMENTS	07/28/94
P870073/S15	ULTRAVIOLET-ABSORBING AND NON ULTRAVIOLET-ABSORBING POLYMETHYL-METHACRYLATE (PMMA) INTRAOCULAR LENSES (IOLS)	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	ALTERNATE STERILIZATION METHOD	07/29/94
P880006/S18	SENSOLOG MODEL 703 PULSE GENERATOR AND P700 PROGRAMMER PDX MODEL 3039	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	NEW MODEL PDX MODEL 3039 FUNCTION PACK FOR USE WITH THE APS II MODEL 3003 PROGRAMMER	07/12/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

			FUNCTION PACK	
P880031/S8	AMO VITRAX VISCOELASTIC SOLUTION	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	LABELING ADDITION FOR ENHANCING THE SAFE USE OF THE DEVICE	07/11/94
P880086/S23	SYNCHRONY MODEL 2020T PULSE GENERATOR AND APS II MODEL 3000 PROGRAMMER MODEL 385G FUNCTION PACK	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	NEW MODEL 385G FUNCTION PACK FOR USE WITH THE MODEL 380 HAND HELD PROGRAMMER	07/12/94
P880086/S24	SYNCHRONY MODEL 2020T PULSE GENERATOR AND APS II MODEL 3000 PROGRAMMER PDX MODEL 3039 FUNCTION PACK	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	NEW MODEL PDX MODEL 3039 FUNCTION PACK FOR USE WITH THE APS II MODEL 3003 PROGRAMMER	07/12/94
P880090/S15	ULTRAVIOLET-ABSORBING AND NON ULTRAVIOLET-ABSORBING POLYMETHYL-METHACRYLATE (PMMA) INTRAOCULAR	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	ALTERNATE STERILIZATION METHOD	07/29/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

LENSES (IOLS)

P880091/S3	ELASTIC LENS MODEL AA-4203F AND CHIROFLEX MODEL 32-C11XX SINGLE-PIECE SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	STAAR SURGICAL COMPANY FOR SOFTLENSCO, INC. MONROVIA, CA 91016	NEW MODEL ELASTIC LENS MDL AA-4203F SINGLE-PIECE SILICONE POSTERIOR CHAMBER IOL & CHIROFLEX MDL 32-C11XX SINGLE-PIECE SILICONE POSTERIOR CHAMBER IOL	07/29/94
P890001/S9	LEOCOR PERCUTANEOUS ANGIOPLASTY CATHETER, MODEL 5S LEOCOR PICO RUNNER PTCA CATHETER	LEOCOR, INC. HOUSTON, TX 77058	NEW MODEL LEOCOR PICO RUNNER PTCA CATHETER	07/28/94
P890045/S6	VASCUTEK GELSEAL VASCULAR GRAFT	CARBOMEDICS AUSTIN, TX 78752-1793	EXPANSION OF THE CONTROLLED ENVIRONMENT AT THE INCHINNAN, SCOTLAND, MANUFACTURING FACILITY	07/22/94
P890049/S3	LL-55 (METHAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS (SPHERICAL EXTENDED WEAR)	LOMBART LENSES LTD. NORFOLK, VA 23507	ALTERNATE MANUFACTURING SITE AT LOMBART LENSES, LTD. NORFOLK VIRGINIA	07/06/94
P900060/S5	CARBOMEDICS PROSTHETIC HEART VALVE	CARBOMEDICS, INC. AUSTIN, TX 78752-1793	ADD WARNING STATEMENT ABOUT SIZERS TO LABELING	07/08/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P900061/S6	MODEL 7217D PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	DEVICE MODIFICATION	07/20/94
P910023/S1	CADENCE TIERED THERAPY DEFIBRILLATOR SYSTEM CADENCE MODEL PR-1500 PROGRAMMER SOFTWARE VERSION 3.1	VENTRITEX, INC. SUNNYVALE, CA 94068-6527	NEW MODEL PR-1500 PROGRAMMER WITH SOFTWARE VERSION 3.1 AND THE MODEL WA-1000 WAND ADAPTER	07/29/94
P910058/S2	CHIROFLEX SINGLE PIECE SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	CHIRON VISION CORPORATION IRVINE, CA 92718-1903	ADDITION OF A TUMBLE POLISH PROCESS TO MANUFACTURING PROCESS	07/29/94
P910058/S3	CHIROFLEX MODEL 32-C11XX SINGLE-PIECE SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	CHIRON VISION CORPORATION IRVINE, CA 92718-1903	NEW MODEL CHIROFLEX MODEL 32-C11XX SINGLE PIECE SILICONE POSTERIOR CHAMBER IOL	07/29/94
P920015/S3	MEDTRONIC TRANSVENE LEAD SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFY DF-1 CONNECTOR PINS OF MODELS 6936 AND 6939	07/20/94

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

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR JULY 1994.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR JULY 1994.

SUPPLEMENTAL VETERINARY NADAs

121-473 05-31-94	PANACUR (GRANULES)	CARNIVOROUS AND OMNIVOROUS ZOO ANIMALS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	FENBENDAZOLE 222MG/GM
131-675 07-11-94	SAFE GUARD (PREMIX)	HOOFED ZOO AND WILDLIFE ANIMALS	HOECHST ROUSSELL AGRI VET SOMERVILLE, NJ 08876	FENBENDAZOLE 40GM/KG

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

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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Center for Devices and Radiological Health
Julie Stuart (301) 594-2186

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

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-199 HIVID ROCHE ZALCITABINE
05-AUG-94 (TABLET) NUTLEY, NJ 0.375MG
(SUPPL-003) 07110 0.75MG
(NEW INDICATION -- MONOTHERAPY TREATMENT OF HIV INFECTION IN ADULTS WITH ADVANCED HIV DISEASE WHO ARE EITHER INTOLERANT TO ZIDOVUDINE OR WHO HAVE DISEASE PROGRESSION WHILE RECEIVING ZIDOVUDINE)

19-655 RETROVIR BURROUGHS WELLC ZIDOVUDINE
08-AUG-94 (CAPSULE) RES TRIANGLE PK, NC 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

(SUPPL-023)		27709	(NEW INDICATION -- PREVENTION OF MATERNAL-FETAL HIV TRANSMISSION)
19-910	RETROVIR	BURROUGHS WELLC	ZIDOVUDINE
08-AUG-94	(SYRUP)	RES TRIANGLE PK, NC	50MG/5ML
(SUPPL-011)		27709	(NEW INDICATION -- PREVENTION OF MATERNAL-FETAL HIV TRANSMISSION)
19-951	RETROVIR	BURROUGHS WELLC	ZIDOVUDINE
08-AUG-94	(INJECTABLE)	RES TRIANGLE PK, NC	10MG/ML
(SUPPL-003)		27709	(NEW INDICATION -- PREVENTION OF MATERNAL-FETAL HIV TRANSMISSION)
20-343	PRIMACOR	STERLING WINTHROP	MILRINONE LACTATE
09-AUG-94	IN DEXTROSE 5%	COLLEGEVILLE, PA	EQ 10MG BASE/100ML*
(3 S)	IN PLASTIC CONTAINER	19426	EQ 15MG BASE/100ML*
	(INJECTABLE)		EQ 20MG BASE/100ML (INOTROPIC/VASODILATOR)
50-698	BIAXIN	ABBOTT	CLARITHROMYCIN
12-AUG-94	(GRANULE,	ABBOTT PARK, IL	125MG/5ML
(SUPPL-002)	FOR RECONSTITUTION)	60064	250MG/5ML (NEW INDICATION -- ACUTE OTITIS MEDIA IN CHILDREN)
50-698	BIAXIN	ABBOTT	CLARITHROMYCIN
12-AUG-94	(GRANULE,	ABBOTT PARK, IL	125MG/5ML
(SUPPL-003)	FOR RECONSTITUTION)	60064	250MG/5ML (NEW INDICATION -- PHARYNGITIS AND TONSILLITIS

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 CHILDREN)

50-698	BIAXIN	ABBOTT	CLARITHROMYCIN
12-AUG-94	(GRANULE,	ABBOTT PARK, IL	125MG/5ML
(SUPPL-004)	FOR RECONSTITUTION)	60064	250MG/5ML
			(NEW INDICATION -- UNCOMPLICATED SKIN AND SKIN STRUCTURE INFECTIONS IN CHILDREN)
20-392	CYSTAGON	MYLAN	CYSTEAMINE BITARTRATE
15-AUG-94	(CAPSULE)	MORGANTOWN, WV	EQ 50MG BASE
(1 P, V**)		26505	EQ 150MG BASE
			(CYSTINE DEPLETING AGENT) [MANAGEMENT OF NEPHROPATHIC CYSTINOSIS IN CHILDREN AND ADULTS]

* - Not Marketed At This Time
V** - Designated Orphan Drug

20-306	FLUDEOXYGLUCOSE F 18	DOWNSTATE CLINCL	FLUDEOXYGLUCOSE, F-18
19-AUG-94	(INJECTABLE)	PEORIA, IL	6.8-35.7mCi/ML
(1 P)		61636	(RADIOACTIVE DIAGNOSTIC) [POSITRON EMISSION TOMOGRAPHY FOR THE IDENTIFICATION OF REGIONS OF ABNORMAL GLUCOSE METABOLISM ASSOCIATED WITH FOCI OF EPILEPTIC SEIZURES]
19-603	MANNITOL 5%	ABBOTT	MANNITOL

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

25-AUG-94	IN PLASTIC CONTAINER	ABBOTT PARK, IL	5GM/100ML
(SUPPL-010)	(INJECTABLE)	60064	(NEW INDICATION -- ALL INDICATIONS TO INCLUDE CHILDREN)

19-603	MANNITOL 10%	ABBOTT	MANNITOL
25-AUG-94	IN PLASTIC CONTAINER	ABBOTT PARK, IL	10GM/100ML
(SUPPL-010)	(INJECTABLE)	60064	(NEW INDICATION -- ALL INDICATIONS TO INCLUDE CHILDREN)

19-603	MANNITOL 15%	ABBOTT	MANNITOL
25-AUG-94	IN PLASTIC CONTAINER	ABBOTT PARK, IL	15GM/100ML
(SUPPL-010)	(INJECTABLE)	60064	(NEW INDICATION -- ALL INDICATIONS TO INCLUDE CHILDREN)

19-603	MANNITOL 20%	ABBOTT	MANNITOL
25-AUG-94	IN PLASTIC CONTAINER	ABBOTT PARK, IL	20GM/100ML
(SUPPL-010)	(INJECTABLE)	60064	(NEW INDICATION -- ALL INDICATIONS TO INCLUDE CHILDREN)

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.

20-121	FLONASE	GLAXO	FLUTICASONE PROPIONATE
19-AUG-94	(SPRAY, METERED)	RES TRIANGLE PK, NC	0.05MG/INH
	27709	(GLUCOCORTICOID)	
		[SEASONAL AND PERENNIAL	
		ALLERGIC RHINITIS]	
20-256	NEUROLITE	DUPONT MERCK	TECHNETIUM Tc99m
19-AUG-94	(INJECTABLE)	N BILLERICA, MA	BICISATE KIT
	01862	N/A	
		(RADIOACTIVE DIAGNOSTIC)	
20-243	LUVOX	SOLVAY	FLUVOXAMINE MALEATE
30-AUG-94	(TABLET)	MARIETTA, GA	25MG
	30062		50MG
			100MG
			150MG
			(SEROTONIN REUPTAKE
			INHIBITOR)
			[OBSESSIVE COMPULSIVE
			DISORDER]

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

ORIGINAL ABBREVIATED NDAs

40-054	METHOTREXATE SODIUM	ROXANE	METHOTREXATE SODIUM
01-AUG-94	(TABLET)	COLUMBUS, OH	EQ 2.5MG BASE
	43216	(ANTINEOPLASTIC)	
74-128	CLOBETASOL PROPIONATE	NMC	CLOBETASOL PROPIONATE
03-AUG-94	(OINTMENT)	GLENDALE, NY	0.05%
	11385	(CORTICOSTEROID)	
74-139	CLOBETASOL PROPIONATE	NMC	CLOBETASOL PROPIONATE
03-AUG-94	(CREAM)	GLENDALE, NY	0.05%
	11385	(CORTICOSTEROID)	
74-254	DESONIDE	TARO	DESONIDE
03-AUG-94	(OINTMENT)	BRAMALEA, ONTARIO	0.05%
	CANADA	(CORTICOSTEROID)	
73-664	ACETYLCYSTEINE	ABBOTT	ACETYLCYSTEINE
30-AUG-94	(SOLUTION)	ABBOTT PARK, IL	10%
	60064	(MUCOLYTIC)	
74-037	ACETYLCYSTEINE	ABBOTT	ACETYLCYSTEINE
30-AUG-94	(SOLUTION)	ABBOTT PARK, IL	20%
	60064	(MUCOLYTIC)	
74-473	TOLMETIN SODIUM	MYLAN	TOLMETIN SODIUM
30-AUG-94	(TABLET)	MORGANTOWN, WV	EQ 600MG BASE
	26505	(NONSTEROIDAL ANTI-INFLAMMATORY)	
74-005*	CIMETIDINE HCL	ENDO LABS	CIMETIDINE HYDROCHLORIDE
31-AUG-94	(INJECTABLE)	GARDEN CITY, NY	EQ 300MG BASE/2ML
	11530	(HISTAMINE H2-RECEPTOR ANTAGONIST)	

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

ORIGINAL ABBREVIATED NDAs

* - First Time Product Available Generically

74-245*	CYTARABINE	CETUS BEN VENUE	CYTARABINE
31-AUG-94	(INJECTABLE)	EMERYVILLE, CA	1GM/VIAL
		94608	2GM/VIAL
			(ANTINEOPLASTIC)
74-360	GEMFIBROZIL	PUREPAC PHARM	GEMFIBROZIL
31-AUG-94	(TABLET)	ELIZABETH, NJ	600MG
		07207	(ANTIHYPERLIPIDEMIC)
74-367	NAPROXEN SODIUM	MYLAN	NAPROXEN SODIUM
31-AUG-94	(TABLET)	MORGANTOWN, WV	EQ 250MG BASE
		26504	EQ 500MG BASE
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
74-368	NADOLOL	COPLEY PHARM	NADOLOL
31-AUG-94	(TABLET)	CANTON, MA	80MG
		02021	120MG*
			160MG*
			(BETA ADRENERGIC BLOCKER)

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

ORIGINAL ABBREVIATED NDAs

* - First Time Product Available Generically

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

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

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

74-261 TIMOLOL ALCON TIMOLOL MALEATE
29-AUG-94 (SOLUTION/DROPS) FT WORTH, TX EQ 0.25% BASE
76134 (BETA ADRENERGIC BLOCKER)

74-262 TIMOLOL ALCON TIMOLOL MALEATE
29-AUG-94 (SOLUTION/DROPS) FT WORTH, TX EQ 0.5% BASE
76134 (BETA ADRENERGIC BLOCKER)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-384	NOROXIN	MERCK	NORFLOXACIN
01-JUL-94	(TABLET)	WEST POINT, PA	400MG
	19486	(LABELING REVISION -- ADVERSE REACTIONS)	

11-245	GASTROGRAFIN	SQUIBB	DIATRIZOATE MEGLUMINE
05-AUG-94	(SOLUTION)	PRINCETON, NJ	66%
	08543		DIATRIZOATE SODIUM
			10%
			(LABELING REVISION -- ADVERSE REACTIONS)

19-777	ZESTRIL	ZENECA PHARMS	LISINOPRIL
05-AUG-94	(TABLET)	WILMINGTON, DE	2.5MG*
	19897		5MG
			10MG
			20MG
			40MG
			(LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)

19-888	ZESTORETIC 10-12.5	ZENECA PHARMS	HYDROCHLOROTHIAZIDE
05-AUG-94	(TABLET)	WILMINGTON, DE	12.5MG
	19897		LISINOPRIL
			10MG
			(LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)

19-888	ZESTORETIC 20-12.5	ZENECA PHARMS	HYDROCHLOROTHIAZIDE
05-AUG-94	(TABLET)	WILMINGTON, DE	12.5MG
	19897		LISINOPRIL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20MG
(LABELING REVISION --
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS;
DOSAGE AND ADMINISTRATION)

* - Not Marketed At This Time

19-888 ZESTORETIC 20-25 ZENECA PHARMS HYDROCHLOROTHIAZIDE
05-AUG-94 (TABLET) WILMINGTON, DE 25MG
19897 LISINOPRIL
20MG
(LABELING REVISION --
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS;
DOSAGE AND ADMINISTRATION)

20-154 VIDEX BRISTOL MYERS SQUIBB DIDANOSINE
05-AUG-94 (TABLET, CHEWABLE) WALLINGFORD, CT 25MG
06492 50MG
100MG
150MG
(LABELING REVISION --
INDICATIONS AND USAGE)

20-155 VIDEX BRISTOL MYERS SQUIBB DIDANOSINE
05-AUG-94 (POWDER WALLINGFORD, CT 100MG/PACKET
FOR RECONSTITUTION) 06492 167MG/PACKET
250MG/PACKET
375MG/PACKET
(LABELING REVISION --
INDICATIONS AND USAGE)

20-156 VIDEX BRISTOL MYERS SQUIBB DIDANOSINE
05-AUG-94 (POWDER WALLINGFORD, CT 10MG/ML
FOR RECONSTITUTION) 06492 (LABELING REVISION --

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)

20-199	HIVID	ROCHE	ZALCITABINE
05-AUG-94	(TABLET)	NUTLEY, NJ	0.375MG
		07110	0.75MG
		(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)	
17-279	GLOFIL-125	ISO TEX DIAGS	IOTHALAMATE SODIUM, I-125
08-AUG-94	(INJECTABLE)	FRIENDSWOOD, TX	250-300 UCI/ML
		77546	(LABELING REVISION -- DESCRIPTION; CONTRAINDICATIONS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-655	RETROVIR	BURROUGHS WELLC	ZIDOVUDINE
08-AUG-94	(CAPSULE)	RES TRIANGLE PK, NC	100MG
		27709	(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-910	RETROVIR	BURROUGHS WELLC	ZIDOVUDINE
08-AUG-94	(SYRUP)	RES TRIANGLE PK, NC	50MG/5ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		27709	(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-951	RETROVIR	BURROUGHS WELLC	ZIDOVUDINE
08-AUG-94	(INJECTABLE)	RES TRIANGLE PK, NC	10MG/ML
		27709	(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
17-532	DIABETA	HOECHST ROUSSEL	GLYBURIDE
11-AUG-94	(TABLET)	SOMERVILLE, NJ	1.25MG
		08876	2.5MG
			5MG
			(LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
50-698	BIAXIN	ABBOTT LABS	CLARITHROMYCIN
12-AUG-94	(GRANULE, FOR RECONSTITUTION)	ABBOTT PARK, IL 60064	125MG/5ML
			250MG/5ML
			(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

CLINICAL STUDIES)

19-487	IMODIUM A-D	MCNEIL	LOPERAMIDE HYDROCHLORIDE
15-AUG-94	(SOLUTION)	FORT WASHINGTON, PA	1MG/5ML
	19034	(LABELING REVISION -- PATIENT INSTRUCTIONS) (OTC)	
19-860	IMODIUM A-D	MCNEIL	LOPERAMIDE HYDROCHLORIDE
15-AUG-94	(TABLET)	FORT WASHINGTON, PA	2MG
	19034	(LABELING REVISION -- PATIENT INSTRUCTIONS) (OTC)	
50-585	ROCEPHIN	ROCHE	CEFTRIAXONE SODIUM
18-AUG-94	(INJECTABLE)	NUTLEY, NJ	EQ 250MG BASE/VIAL
	07110	EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	
50-624	ROCEPHIN W/ DEXTROSE IN PLASTIC CONTAINER	ROCHE	CEFTRIAXONE SODIUM
18-AUG-94	(INJECTABLE)	NUTLEY, NJ	EQ 20MG BASE/ML
	07110	EQ 40MG BASE/ML (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	
18-445	DOLOBID	MSD	DIFLUNISAL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

22-AUG-94	(TABLET)	WEST POINT, PA	250MG
	19486		500MG
		(LABELING REVISION -- PRECAUTIONS)	
10-996	DARVON COMPOUND-65	LILLY	ASPIRIN
23-AUG-94	(CAPSULE)	INDIANAPOLIS, IN	389MG
	46285		CAFFEINE 32.4MG
			PROPOXYPHENE HYDROCHLORIDE 65MG
		(LABELING REVISION -- PRECAUTIONS)	
10-997	DARVON	LILLY	PROPOXYPHENE HYDROCHLORIDE
23-AUG-94	(CAPSULE)	INDIANAPOLIS, IN	65MG
	46285	(LABELING REVISION -- PRECAUTIONS)	
16-861	DARVON-N	LILLY	PROPOXYPHENE NAPSYLATE
23-AUG-94	(SUSPENSION)	INDIANAPOLIS, IN	50MG/5ML
	46285	(LABELING REVISION -- PRECAUTIONS)	
16-862	DARVON-N	LILLY	PROPOXYPHENE NAPSYLATE
23-AUG-94	(TABLET)	INDIANAPOLIS, IN	100MG
	46285	(LABELING REVISION -- PRECAUTIONS)	
16-863	DARVON-N W/ ASA	LILLY	ASPIRIN
23-AUG-94	(TABLET)	INDIANAPOLIS, IN	325MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		46285	PROPOXYPHENE NAPSYLATE 100MG (LABELING REVISION -- PRECAUTIONS)
17-122	DARVOCET-N 50	LILLY	ACETAMINOPHEN
23-AUG-94	(TABLET)	INDIANAPOLIS, IN	325MG
		46285	PROPOXYPHENE NAPSYLATE 50MG (LABELING REVISION -- PRECAUTIONS)
17-122	DARVOCET-N 100	LILLY	ACETAMINOPHEN
23-AUG-94	(TABLET)	INDIANAPOLIS, IN	650MG
		46285	PROPOXYPHENE NAPSYLATE 100MG (LABELING REVISION -- PRECAUTIONS)
18-261	PITOCIN	PARKE DAVIS	OXYTOCIN
23-AUG-94	(INJECTABLE)	MORRIS PLAINS, NJ	10 USP UNITS/ML
		07950	(LABELING REVISION -- HOW SUPPLIED)
20-272	RISPERDAL	JANSSEN	RISPERIDONE
24-AUG-94	(TABLET)	TITUSVILLE, NJ	1MG
		08560	2MG 3MG 4MG 5MG* (LABELING REVISION -- DOSAGE AND ADMINISTRATION)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

* - Not Marketed At This Time

50-609 ERYTHROCIN ABBOTT LABS ERYTHROMYCIN LACTOBIONATE
24-AUG-94 (INJECTABLE) ABBOTT PARK, IL EQ 500MG BASE/VIAL
60064 (LABELING REVISION --
CONTRAINDICATIONS;
PRECAUTIONS)

14-691 ALKERAN BURROUGHS WELLC MELPHALAN
25-AUG-94 (TABLET) RES TRIANGLE PK, NC 2MG
27709 (LABELING REVISION --
CLINICAL PHARMACOLOGY;
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS;
OVERDOSAGE)

16-269 MANNITOL 25% ABBOTT MANNITOL
25-AUG-94 (INJECTABLE) ABBOTT PARK, IL 12.5GM/50ML
60064 (LABELING REVISION --
DESCRIPTION;
INDICATIONS AND USAGE;
PRECAUTIONS;
DOSAGE AND ADMINISTRATION;
INSTRUCTIONS FOR USE;
HOW SUPPLIED)

19-603 MANNITOL 5% ABBOTT MANNITOL
25-AUG-94 IN PLASTIC CONTAINER ABBOTT PARK, IL 5GM/100ML
(INJECTABLE) 60064 (LABELING REVISION --
DESCRIPTION;
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

DOSAGE AND ADMINISTRATION;
HOW SUPPLIED)

19-603 MANNITOL 10% ABBOTT MANNITOL
25-AUG-94 IN PLASTIC CONTAINER ABBOTT PARK, IL 10GM/100ML
(INJECTABLE) 60064 (LABELING REVISION --
DESCRIPTION;
INDICATIONS AND USAGE;
PRECAUTIONS;
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED)

19-603 MANNITOL 15% ABBOTT MANNITOL
25-AUG-94 IN PLASTIC CONTAINER ABBOTT PARK, IL 15GM/100ML
(INJECTABLE) 60064 (LABELING REVISION --
DESCRIPTION;
INDICATIONS AND USAGE;
PRECAUTIONS;
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED)

19-603 MANNITOL 20% ABBOTT MANNITOL
25-AUG-94 IN PLASTIC CONTAINER ABBOTT PARK, IL 20GM/100ML
(INJECTABLE) 60064 (LABELING REVISION --
DESCRIPTION;
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

			DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
16-324	IMURAN	BURROUGHS WELLC	AZATHIOPRINE
30-AUG-94	(TABLET)	RES TRIANGLE PK, NC	50MG
	27709		(LABELING REVISION -- LABELING FORMAT REVISION PROGRAM)
17-391	IMURAN	BURROUGHS WELLC	AZATHIOPRINE
30-AUG-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 100MG BASE/VIAL
	27709		(LABELING REVISION -- LABELING FORMAT REVISION PROGRAM)
19-758	CLOZARIL	SANDOZ	CLOZAPINE
30-AUG-94	(TABLET)	EAST HANOVER, NJ	25MG
	07936		100MG
			(LABELING REVISION -- CLINICAL PHARMACOLOGY)
16-267	DESFERAL	CIBA	DEFEROXAMINE MESYLATE
31-AUG-94	(INJECTABLE)	SUMMIT, NJ	500MG/VIAL
	07901		(LABELING REVISION -- DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1122 25-AUG-94	NONE (INJECTABLE)	SARASOTA COMM BLOOD BANK SARASOTA, FL 34236	SOURCE LEUKOCYTES (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 ISSUED FOR AUGUST 1994.

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

P900043 08/02/94	PALMAZ-SCHATZ BALLOON-EXPANDABLE STENT	JOHNSON & JOHNSON INTERVENTIONAL SYS COM WARREN, NJ 07059	FOR USE IN A GROUP OF SELECTED PATIENTS ELIGIBLE FOR BALLOON ANGIOPLASTY WITH SYMPTOMATIC ISCHEMIC HEART DISEASE DUE TO DISCRETE, DE NOVO, NATIVE CORONARY ARTERY LESIONS
P900059 08/05/94	ALBUNEX ULTRASOUND CONTRAST MICROSPHERES	MOLECULAR BIOSYSTEMS, INC. SAN DIEGO, CA 92121-2789	FOR USE AS AN AID FOR ULTRASOUND CONTRAST ENHANCEMENT OF VENTRICULAR CHAMBERS AND IMPROVEMENT OF ENDOCARDIAL BORDER DEFINITION IN PATIENTS WITH SUBOPTIMAL ECHOES UNDERGOING VENTRICULAR FUNCTION AND REGIONAL WALL MOTION STUDIES
P930017 08/23/94	CIBA CORNING ACS CEA ASSAY	CIBA CORNING DIAGNOSTICS, CORP. MEDFIELD, MA 02052-1688	FOR THE QUANTITATIVE MEASUREMENT OF CEA IN SERUM TO AID IN THE MANAGEMENT OF CANCER PATIENTS IN WHOM CHANGING CONCENTRATIONS OF CEA ARE OBSERVED

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

N17600/S10 08/12/94	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT (MCH) FLOUR	MEDCHEM PRODUCTS, INC. WOBURN, MA 01801	ALTERNATE MANUFACTURING FACILITY AT 160 NEW BOSTON STREET, WOBURN, MA
N17755/S43 08/12/94	ZIMMER DOUGH TYPE AND L.V.C. LOW VISCOSITY BONE CEMENT	ZIMMER WARSAW, IN 46581-0708	ADDED PRECAUTIONS MODIFIES INSTRUCTIONS FOR USE
N50510/S59 08/30/94	VITEK GENERAL SUSCEPTIBILITY CARD	BIOMERIEUX VITEK, INC. HAZELWOOD, MO 63042-2395	45-WELL CARD FORMAT FOR SUSCEPTIBILITY TESTING ON THE VITEK INSTRUMENT
P810046/S149 08/04/94	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYS INC. TEMECULA, CA 92591-4628	DEVICE MODIFICATION AND CHANGES IN THE INSTRUCTIONS FOR USE FOR ACS RX ELIPSE
P810055/S53 08/23/94	MODEL UB89, UV95, UI67, AND RD-11 POSTERIOR INTRAOCULAR LENSES	PHARMACIA INC. OPHTHALMICS MONROVIA, CA 91017-7136	ALTERNATIVE MANUFACTURING PROCESS FOR UREX I CLEAR CM LENSES
P820003/S68 08/15/94	MODEL 9751C SYSTEM ENHANCEMENT MODULE (SEM) PRINTED	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFICATION TO MODEL 9751B SEM PRINTER TO BE MARKETED AS MODEL 9751C SEM PRINTER

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P820018/S64 08/30/94	REFLEX MODEL 8223E IMPLANTABLE CARDIAC PULSE GENERATOR	KLEINFELD, KAPLAN, AND BECKER WASHINGTON, D.C. 20036	MODIFICATION TO LABELING FOR REFLEX MODEL 8223E
P820049/S56 08/04/94	MODEL PC-42ANB, POSTERIOR CHAMBER INTRAOCULAR LENS (IOL)	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	CHANGE MODEL PC-42ANB AS A TIER A MODIFICATION OF PREVIOUSLY APPROVED ALLERGAN MEDICAL OPTICS IOLS
P820049/S58 08/09/94	MODELS PC-52ANB, PC-53ANB, PC-53ATB, PC-54ANB, PC-54ATB, PC-55NB, PC-55TTB, POSTERIOR CHAMBER INTRAOCULAR LENSES (IOLS)	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	TIER A MODIFICATIONS OF PREVIOUSLY APPROVED ALLERGAN MEDICAL OPTICS IOLS
P820069/S13 08/15/94	BOSTON CLEANER FOR RIGID GAS PERMEABLE CONTACT LENSES	POLYMER TECHNOLOGY WILMINGTON, MA 01887	CHANGE IN BOTTLE LABELING
P820083/S17 08/19/94	GORE-TEX SUTURE	W.L. GORE & ASSOCIATES, INC. FLAGSTAFF, AZ 86003-2300	ALTERNATE STERILIZATION FACILITY - COSMED MEDICAL STERILIZATION, INC. PLAINFIELD, NEW JERSEY

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P820083/S18	GORE-TEX EXPANDED PTFE SUTURE	W.L. GORE & ASSOCIATES, INC. FLAGSTAFF, AZ 86003-2300	ADDITION OF TRADE NAME "COSMETI-SUTURE" AND ADDITION TO WORDING ON LABELING "PLASTIC"	08/11/94
P830055/S32	ROTATING PLATFORM CONFIGURATION OF THE NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	ADDITION OF NOMINAL 22.5MM AND 25.0MM THICK DEEP DISH AND DEEP DISH BRIDGING BEARING INSERTS TO DEVICE	08/10/94
P830055/S33	NEW JERSEY LCS TOTAL KNEE SYSTEM WITH POROCOAT	DEPUY, INC. WARSAW, IN 46581-0988	DEVICE MODIFICATION - ADDITION OF A ONE PIECE ALL POLYETHYLENE PATELLAR COMPONENT	08/10/94
P830055/S36	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	MANUFACTURING CHANGE	08/23/94
P830060/S34	VENTAK MODEL 1550 AND 1555 AICD MODEL 6941 UNIDIRECTIONAL TORQUE WRENCH	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	DESIGN MODIFICATIONS TO THE UNIDIRECTIONAL TORQUE WRENCH	08/08/94
P840039/S40	ONE-PIECE POSTERIOR CHAMBER INTRAOCULAR LENSES	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	NEW MODEL ONE-PIECE LENSES WITH OVERALL DIAMETERS DOWN TO 11.5MM IN ANY APPROVED DESIGN	08/25/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

EXCEPT HAPTIC DESIGNS

P840039/S41	ULTRAVIOLET-ABSORBING AND NON ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER AND ANTERIOR CHAMBER INTRAOCULAR LENSES	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	ALTERNATE STERILIZATION CHAMBER	08/09/94
P840064/S11	VISCOAT AND PROVISC	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	COMBINED PACKAGING OF VISCOAT AND PROVISC UNDER THE TRADE NAME DUOVISC VISCOELASTIC SYSTEM	08/17/94
P850021/28	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER GRAFT DISTANCE PTCA CATHETER	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	NEW DEVICE MODEL GRAFT DISTANCE PTCA CATHETER	08/19/94
P850048/S9	TANDEM-R PST IMMUNORADIOMETRIC ASSAY, TANDEM-E PSA IMMUNOENZYMETRIC ASSAY, TANDEM-ERA PSA IMMUNOENZYMETRIC	HYBRITECH, INC. SAN DIEGO, CA 92196-9006	FOR QUART MEASUREMENT OF SERUM PSA IN CONJUNCTION WITH DIGITAL RECTAL EXAM AS AN AID IN THE DETECTION OF PROSTATE CANCER	08/25/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

ASSAY

P850049/S4 08/09/94	COOK BIRD'S NEST VENA CAVA FILTER GIANTURCO-ROEHM BIRD'S NEST VENA CAVA FILTER WITH MODIFIED PUSH-BUTTON HANDLE RELEASE	COOK, INC. BLOOMINGTON, IN 47402	DEVICE MODIFICATION TO PUSH BUTTON HANDLE RELEASE MECHANISM
P860002/S12 08/25/94	ONE-PIECE POSTERIOR CHAMBER INTRAOCULAR LENSES	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	DEVICE MODIFICATION- ONE-PIECE LENSES WITH OVERALL DIAMETERS DOWN TO 11.5 IN ANY APPROVED DESIGN EXCEPT HAPTIC DESIGNS
P860002/S13 08/09/94	ULTRAVIOLET-ABSORBING AND NON ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER AND ANTERIOR CHAMBER INTRAOCULAR LENSES	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	ALTERNATE STERILIZATION CHAMBER
P860004/S27 08/30/94	SYNCHROMED INFUSION SYSTEM MODEL 8551 REFILL KIT	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN 55440-9087	LABELING CHANGES TO INSTRUCTIONS FOR USE
P860004/S28 08/04/94	SYNCHROMED 8820 PROGRAMMER,	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN	NEW MODEL - SYNCHROMED 8820

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	SOFTWARE VERSION 4.0, REVISION C	55440-9087	PROGRAMMER	
P860004/S32	MEDTRONIC SYNCHROMED INFUSION SYSTEM	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN 55440-9087	LABELING CHANGES TO TECHNICAL MANUAL FOR SYNCHROMED PUMP AND MEDTRONIC MODEL 8703	08/30/94
P860005/S4	INTERPORE PRO OSTEON IMPLANT 500 CORALLINE HYDROXYAPATITE BONE VOID FILLER (FORMERLY INTERPORE 500)	INTERPORE INTERNATIONAL IRVINE, CA 92718-2402	EXPIRATION DATING FOR GRANULE FORM UP TO 12 MONTHS	08/08/94
P860019/S86	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	CHANGE IN STERILIZATION PROCESS	08/25/94
P860019/S89	SCIMED PTCA SCIMED NC COBRA 14 PTCA CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	DESIGN MODIFICATION TO SWIFT TIP	08/29/94
P860059/S70	ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	NEW RELABELING PROCESS	08/15/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P860059/S73	MODEL UPB330GS ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	NEW MODEL - UPB330GS UV ABSORBING IOL	08/05/94
P860059/S74	MODEL UPB330FS ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	IOPTEX RESEARCH, INC. IRWINDALE, CA 91706-2094	NEW MODEL UPB330FS UV ABSORBING IOL	08/05/94
P870036/S29	MEDTRONIC PANTHER 40 PTCA CATHETERS	MEDTRONIC INTERVENTIONAL VASCULA SAN DIEGO, CA 92121-2256	DEVICE MODIFICATION 40MM LONG BALLOONS FOR MEDTRONIC PANTHER PTCA CATHETER	08/30/94
P870036/S30	MEDTRONIC EVERGREEN PTCA CATHETERS	MEDTRONIC INTERVENTIONAL VASCULA SAN DIEGO, CA 92121-2256	NEW DEVICE MODEL EVERGREEN PTCA CATHETER	08/30/94
P870045/S35	POSTERIOR CHAMBER INTRAOCULAR LENS MODEL CM21U	CHIRON VISION CORPORATION IRVINE, CA 92718-1903	NEW MODEL CM21U	08/11/94
P870073/S13	ULTRAVIOLET-ABSORBING AND NON ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER AND ANTERIOR CHAMBER INTRAOCULAR LENSES	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	ALTERNATE STERILIZATION CHAMBER	08/09/94
P880003/S26	CORDIS PTCA	CORDIS CORPORATION	NEW MODEL	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

08/18/94	DILATATION CATHETER TRAKSTAR 14 PTCA DILATATION CATHETERS	MIAMI, FL 33102-5700	CORDIS TRAK STAR 14 PTCA CATHETER	
P880003/S27	CORDIS PTCA	CORDIS CORPORATION	NEW MODEL	
08/12/94	DILATATION CATHETER TRAKSTAR 18 PTCA DILATATION CATHETERS	MIAMI, FL 33102-5700	CORDIS TRAKSTAR 18 PTCA CATHETER	
P880086/S25	AFP MODEL 283	SIEMENS PACESETTER, INC.	NEW MODEL	
08/30/94	PULSE GENERATOR WITH MODEL 370 PROGRAMMER SOLUS MODEL 2002B PULSE GENERATOR	SYLMAR, CA 91392-9221	SOLUS MODEL 2002B PULSE GENERATOR	
P880091/S4	ELASTIC MODEL	SOFTLENSCO, INC.	REVISED LABELING	
08/30/94	AA-4203 SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS CHIROFLEX MODEL 32-C10XX SILICONE POSTERIOR CHAMBER INTRAOCULAR LENS	MONROVIA, CA 99101	ADDS 3-YEAR POSTOPERATIVE CLINICAL DATA RESULTS FOR STAAR ELASTIC MODEL AA-4203	
P890001/S10	PTCA CATHETER,	LEOCOR, INC.	CHANGE IN PACKAGING	
08/04/94	MODELS 1S, 5S, 7.5S LEOCOR PTCA CATHETER, MODEL 7.5 PT (COATED) AND PICO-ST (COATED)	HOUSTON, TX 77058	MATERIALS AND A CHANGE IN STERILIZATION VENDOR TO IRT CORPORATION, SAN DIEGO, CA 92121	
P890023/S2	HYDRON	MARTIN S. KNOPF	ALTERNATE	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

08/15/94	(OCUFILCON D) H55 HYDROPHILIC CONTACT LENS FOR DAILY AND EXTENDED WEAR	ASSOCIATES, INC. COLTS NECK, NJ 07722	MANUFACTURING METHOD, ALTERNATE MANUFACTURING SITE, CHANGE IN LABELING, NEW COLOR ADDITIVE	
P890047/S2 08/17/94	VISCOAT AND PROVISC	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	PACKAGE VISCOAT AND PROVISC TOGETHER UNDER THE TRADE NAME DUOVISC VISCOELASTIC SYSTEM	
P890054/S1 08/15/94	BOSTON ADVANCE CLEANER (BOSTON CLEANER II) FOR RIGID GAS PERMEABLE CONTACT LENSES	POLYMER TECHNOLOGY WILMINGTON, MA 01887	CHANGE IN BOTTLE LABELING	
P890061/S8 08/08/94	VENTAK P MODEL 1600 AICD MODEL 6941 UNIDIRECTIONAL TORQUE WRENCH	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	DESIGN MODIFICATION TO THE UNIDIRECTIONAL TORQUE WRENCH	
P910016/S4 08/23/94	UNICOMPARTMENTAL DEVICE CONFIGURATION OF THE NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	MANUFACTURING CHANGE TO THE METABOLIC POROUS COATED GENERAL COMPONENTS	
P910058/S5 08/11/94	CHIROFLEX MODEL 32-C10XX SILICONE	CHIRON VISION CORPORATION IRVINE, CA 92718	LABELING CHANGES	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	POSTERIOR CHAMBER INTRAOCULAR LENSES		
P910073/S1 08/05/94	0070 SERIES ENDOTAK C LEAD MODELS 0070, 0072, AND 0074	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	NEW MODELS 0700 SERIES ENDOTAK C LEADS MODELS 0070, 0072, AND 0074

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

ORIGINAL VETERINARY ANDAs

140-998	V-MAX	FEEDLOT	SMITHKLINE BEECHAM	VIRGINIAMYCIN
24-JUN-94	(PREMIX)	CATTLE	AM HLTH W CHESTER, PA 19380	227GM/LB
141-047	TORBUGESIC-SA	CATS	FT DODGE LABS	BUTORPHANOL TARTRATE
05-JUL-94	(LIQUID)		FT DODGE, IA 50501	2MG/ML

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

ORIGINAL ABBREVIATED VETERINARY NADAs

200-042	KETAJECT	CATS,	PHOENIX PHARMA	KETAMINE HYDROCHLORIDE
30-JUN-94	(SOLUTION)	SUBHUMAN PRIMATES	ST JOSEPH, MO 64506	100MG/ML
200-066	AGRIMYCIN-343	CHICKENS,	AGRI LABS LTD	OXYTETRACYCLINE
15-JUL-94	(POWDER)	SWINE, TURKEYS	ST JOSEPH, MO 64503	HYDROCHLORIDE 102.4GM/PACKET
200-073	KETAMINE	CATS	AM VET PRDTS	KETAMINE HYDROCHLORIDE
21-JUL-94	HYDROCHLORIDE (SOLUTION)		FT COLLINS, CO 80524	100MG/ML
200-106	R-PEN	TURKEYS	ID RUSSELL LABS	PENICILLIN G POTASSIUM
21-JUL-94	(POWDER)		LONGMONT, CO 80501	0.384 BILLION UNITS/ PACKET
200-141	ISOFLURANE	DOGS,	INHALON PHARMA	ISOFLURANE
26-JUL-94	(LIQUID)	HORSES	LEHIGH VALLEY, PA 18002	99.9%

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

SUPPLEMENTAL VETERINARY NADAs

065-071 15-JUN-94	AUREOMYCIN (POWDER)	CATTLE, CHICKENS, SWINE, TURKEYS	AM CYANAMID WAYNE, NJ 07470	CHLORTETRACYCLINE HYDROCHLORIDE 25GM/LB
065-440 15-JUN-94	AUREOMYCIN CONCENTRATE (POWDER)	CATTLE, CHICKENS, SWINE, TURKEYS	AM CYANAMID WAYNE, NJ 07470	CHLORTETRACYCLINE HYDROCHLORIDE 64GM/LB
034-254 & 039-402 29-JUN-94	MGA-/100/200 & MGA-500 LIQUID PREMIX (PREMIXES)	CATTLE	UPJOHN KALAMAZOO, MI 49001	MELENGESTROL ACETATE 100MG/LB 200MG/LB 500MG/LB
124-309 & 125-476 29-JUN-94	MGA-/100/200 PREMIXES/RUMENSIN; MGA-500 LIQUID PREMIX/RUMENSIN	CATTLE	UPJOHN KALAMAZOO, MI 49001	MELENGESTROL ACETATE 0.0000276-0.00022% MONENSIN SODIUM

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
	(PREMIXES)			50-1200GM/TON
139-876, 140-288, 138-904, 138-992 29-JUN-94	MGA-/100/200 PREMIXES/BOVATEC; MGA-500 LIQUID PREMIX/BOVATEC; MGA-100/200 PREMIXES/ BOVATEC/TYLAN; MGA-500 LIQUID PREMIX/BOVATEC/TYLAN (PREMIXES)	CATTLE	UPJOHN KALAMAZOO, MI 49001	MELENGESTROL ACETATE 0.0000276-0.00022% LASALOCID 100-1440GM/TON TYLOSIN 90-360GM/TON

SUPPLEMENTAL VETERINARY NADAs

138-792, 138-870, 138-995, 139-192 29-JUN-94	MGA-/100/200 PREMIXES/ RUMENSIN/TYLAN; MGA-500 LIQUID PREMIX/RUMENSIN/ TYLAN; MGA-100/200/TYLAN MGA-500/TYLAN (PREMIXES)	CATTLE	UPJOHN KALAMAZOO, MI 49001	MELENGESTROL ACETATE 0.0000276-0.00022% TYLOSIN PHOSPHATE 90-360GM/TON MONENSIN 50-1200GM/TON
139-472 07-JUL-94	DENAGARD TYPE A MEDICATED ARTICLE	SWINE	FERMENTA AN HLTH KANSAS CITY, MO	TIAMULIN HYDROGEN FUMARATE

NADA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	SPECIES	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
	(PREMIX)		64153	5GM/LB (1.1%) 10GM/LB (2.2%) 113.4GM/LB (25%)
140-338 13-JUL-94	NAXCEL (POWDER)	HORSES	UPJOHN KALAMAZOO, MI 49001	CEFTIOFUR SODIUM 50MG/ML
065-483 20-JUL-94	PFIZER-STREP (LIQUID)	CATTLE, DOGS, HORSES, SWINE	PFIZER NEW YORK, NY 10017	DIHYDROSTREPTOMYCIN SULFATE 500MG/ML

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

FDA DRUG AND DEVICE PRODUCT APPROVALS

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

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-328 HUMEGON ORGANON MENOTROPINS --
01-SEP-94 (INJECTABLE) WEST ORANGE, NJ FOLLICLE
(5 S) 07052 STIMULATING HORMONE
75IU/VIAL
LUTEINIZING HORMONE
75IU/VIAL
(GONADOTROPINS)

20-328 HUMEGON ORGANON MENOTROPINS --
01-SEP-94 (INJECTABLE) WEST ORANGE, NJ FOLLICLE
(5 S) 07052 STIMULATING HORMONE
150IU/VIAL
LUTEINIZING HORMONE
150IU/VIAL
(GONADOTROPINS)

20-036 AREDIA CIBA GEIGY PAMIDRONATE DISODIUM

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

21-SEP-94	(INJECTABLE)	SUMMIT, NJ	30MG/VIAL
(SUPPL-007)		07901	60MG/VIAL
			90MG/VIAL
			(NEW INDICATION --
			TREATMENT OF PAGET'S
			DISEASE OF BONE)
19-834	PLENDIL	MERCK	FELODIPINE
22-SEP-94	(TABLET,	WAYNE, PA	2.5MG
(SUPPL-002)	EXTENDED RELEASE)	19087	(NEW STRENGTH)
19-834	PLENDIL	MERCK	FELODIPINE
22-SEP-94	(TABLET,	WAYNE, PA	2.5MG
(SUPPL-002)	EXTENDED RELEASE)	19087	5MG
			10MG
			(NEW DOSAGE REGIMEN --
			DECREASE IN THE MAXIMUM
			RECOMMENDED DOSE FROM
			20MG TO 10MG)
20-103	ZOFRAN	GLAXO	ONDANSETRON HYDROCHLORIDE
26-SEP-94	(TABLET)	RES TRIANGLE PK, NC	EQ 4MG BASE
(SUPPL-004)		27709	EQ 8MG BASE
			(NEW INDICATION --
			PREVENTION OF NAUSEA
			AND VOMITING ASSOCIATED
			WITH RADIOTHERAPY)
50-693	ZITHROMAX	PFIZER	AZITHROMYCIN DIHYDRATE
28-SEP-94	(POWDER	GROTON, CT	EQ 1GM BASE/PACKET
(3 S)	FOR RECONSTITUTION)	06340	(ANTIBIOTIC, MACROLIDE)

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

APPROVABLE ORIGINAL NDAs

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

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

20-286 MONOPRIL HCT 10/12.5 BRISTOL MYERS SQUIBB FOSINOPRIL
29-SEP-94 (TABLET) PRINCETON, NJ 10MG
08543 HYDROCHLOROTHIAZIDE
12.5MG
(ANTIHYPERTENSIVE)

20-286 MONOPRIL HCT 20/12.5 BRISTOL MYERS SQUIBB FOSINOPRIL
29-SEP-94 (TABLET) PRINCETON, NJ 20MG
08543 HYDROCHLOROTHIAZIDE
12.5MG
(ANTIHYPERTENSIVE)

20-305 KYTRIL SMITHKLINE BEECHAM GRANISETRON
30-SEP-94 (TABLET) PHILADELPHIA, PA EQ 1MG BASE
19101 (ANTIEMETIC)
[PREVENTION OF NAUSEA
AND VOMITING ASSOCIATED
WITH CANCER THERAPY]

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

ORIGINAL ABBREVIATED NDAs

64-097	DOXORUBICIN HCL	CETUS BEN VENUE	DOXORUBICIN HYDROCHLORIDE
13-SEP-94	(INJECTABLE)	EMERYVILLE, CA	200MG/100ML
		94608	(ANTIBIOTIC, ANTITUMOR)
40-041	FLUOCINOLONE	TARO PHARMS	FLUOCINOLONE ACETONIDE
15-SEP-94	ACETONIDE	BRAMALEA, ONTARIO	0.025%
	(OINTMENT)	CANADA	(CORTICOSTEROID)
74-271	BETAMETHASONE	TARO PHARMS	BETAMETHASONE DIPROPIONATE
15-SEP-94	DIPROPIONATE	BRAMALEA, ONTARIO	EQ 0.05% BASE
	(OINTMENT)	CANADA	(CORTICOSTEROID)
40-037	TRIAMCINOLONE	TARO PHARMS	TRIAMCINOLONE ACETONIDE
30-SEP-94	ACETONIDE	BRAMALEA, ONTARIO	0.1%
	(OINTMENT)	CANADA	(CORTICOSTEROID)
40-040	TRIAMCINOLONE	TARO PHARMS	TRIAMCINOLONE ACETONIDE
30-SEP-94	ACETONIDE	BRAMALEA, ONTARIO	0.025%
	(OINTMENT)	CANADA	(CORTICOSTEROID)
40-081*	HYDROXYCHLOROQUINE	COPLEY PHARM	HYDROXYCHLOROQUINE SULFATE
30-SEP-94	SULFATE	CANTON, MA	200MG
	(TABLET)	02021	(ANTIMALARIAL/ANTIRHEUMATIC)
63-000	POLYMYXIN B SULFATE	PHARMA TEK	POLYMYXIN B SULFATE
30-SEP-94	(INJECTABLE)	HUNTINGTON, NY	EQ 500,000 UNITS BASE/VIAL
		11743	(ANTIBIOTIC, PEPTIDE)
64-076	AMOXICILLIN	BIOCHEMIE	AMOXICILLIN
30-SEP-94	(CAPSULE)	TYROL, AUSTRIA	250MG
			500MG
			(ANTIBIOTIC, PENICILLIN)
74-143	METOPROLOL TARTRATE	NOVOPHARM	METOPROLOL TARTRATE

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

ORIGINAL ABBREVIATED NDAs

30-SEP-94 (TABLET) SCARBOROUGH, ONTARIO 50MG
CANADA 100MG
(BETA ADRENERGIC BLOCKER)

* - First Time Product Available Generically
74-272 BETAMETHASONE TARO PHARMS BETAMETHASONE DIPROPIONATE
30-SEP-94 DIPROPIONATE BRAMALEA, ONTARIO EQ 0.05% BASE
(LOTION) CANADA (CORTICOSTEROID)

74-302 ALBUTEROL SULFATE MOVA PHARM ALBUTEROL SULFATE
30-SEP-94 (SYRUP) CAGUAS, PR EQ 2MG/5ML BASE
00725 (BETA-2 AGONIST)

74-416 ISOFLURANE INHALON ISOFLURANE
30-SEP-94 (LIQUID) BETHLEHEM, PA 99.9%
18017 (GENERAL ANESTHETIC)

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

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

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

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVAL FOR SEPTEMBER 1994.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

10-996 02-SEP-94	DARVON COMPOUND-65 (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	ASPIRIN 389MG CAFFEINE 32.4MG PROPOXYPHENE 65MG (LABELING REVISION -- ADVERSE REACTIONS)
10-997 02-SEP-94	DARVON (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	PROPOXYPHENE HYDROCHLORIDE 65MG (LABELING REVISION -- ADVERSE REACTIONS)
16-862 02-SEP-94	DARVON-N (TABLET)	LILLY INDIANAPOLIS, IN 46285	PROPOXYPHENE NAPSYLATE 100MG (LABELING REVISION -- ADVERSE REACTIONS)
17-122 02-SEP-94	DARVOCET-N 50 (TABLET)	LILLY INDIANAPOLIS, IN 46285	ACETAMINOPHEN 325MG PROPOXYPHENE NAPSYLATE 50MG (LABELING REVISION -- ADVERSE REACTIONS)
17-122 02-SEP-94	DARVOCET-N 100 (TABLET)	LILLY INDIANAPOLIS, IN 46285	ACETAMINOPHEN 650MG PROPOXYPHENE NAPSYLATE 100MG (LABELING REVISION -- ADVERSE REACTIONS)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-547	CLAFORAN	HOECHST ROUSSEL	CEFOTAXIME SODIUM
02-SEP-94	(INJECTABLE)	SOMERVILLE, NJ	EQ 500MG BASE/VIAL
		08876	EQ 1GM BASE/VIAL
			EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(LABELING REVISION --
			INDICATIONS AND USAGE;
			DOSAGE AND ADMINISTRATION)
50-596	CLAFORAN	HOECHST ROUSSEL	CEFOTAXIME SODIUM
02-SEP-94	IN PLASTIC CONTAINER	SOMERVILLE, NJ	EQ 20MG BASE/ML
	(INJECTABLE)	08876	EQ 40MG BASE/ML
			(LABELING REVISION --
			INDICATIONS AND USAGE;
			DOSAGE AND ADMINISTRATION)
19-627	DIPRIVAN	ZENECA	PROPOFOL
07-SEP-94	(INJECTABLE)	MACCLESFIELD,	10MG/ML
		UNITED KINGDOM	(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
50-578	FORTAZ	GLAXO	CEFTAZIDIME
07-SEP-94	(INJECTABLE)	RES TRIANGLE PK, NC	500MG/VIAL
		27709	1GM/VIAL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			2GM/VIAL 6GM/VIAL (LABELING REVISION -- PRECAUTIONS)
50-634	FORTAZ	GLAXO	CEFTAZIDIME SODIUM
07-SEP-94	IN PLASTIC CONTAINER (INJECTABLE)	RES TRIANGLE PK, NC 27709	EQ 20MG BASE/ML EQ 40MG BASE/ML (LABELING REVISION -- PRECAUTIONS)
50-646	CEPTAZ	GLAXO	CEFTAZIDIME
07-SEP-94	(INJECTABLE)	RES TRIANGLE PK, NC 27709	(ARGININE FORMULATION) 1GM/VIAL 2GM/VIAL 10GM/VIAL (LABELING REVISION -- PRECAUTIONS)
10-040	DIATRIZOATE MEGLUMINE	BRACCO	DIATRIZOATE MEGLUMINE
09-SEP-94	(INJECTABLE)	PRINCETON, NJ 08543	76% (LABELING REVISION -- BOXED WARNING)
10-040	RENOVIST	BRACCO	DIATRIZOATE MEGLUMINE
09-SEP-94	(INJECTABLE)	PRINCETON, NJ 08543	34.3% DIATRIZOATE SODIUM 35% (LABELING REVISION -- BOXED WARNING)
10-040	RENOVIST II	BRACCO	DIATRIZOATE MEGLUMINE
09-SEP-94	(INJECTABLE)	PRINCETON, NJ 08543	28.5% DIATRIZOATE SODIUM

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			29.1% (LABELING REVISION -- BOXED WARNING)
10-040 09-SEP-94	RENO-DIP (INJECTABLE)	BRACCO PRINCETON, NJ 08543	DIATRIZOATE MEGLUMINE 30% (LABELING REVISION -- BOXED WARNING)
10-040 09-SEP-94	RENO-60 (INJECTABLE)	BRACCO PRINCETON, NJ 08543	DIATRIZOATE MEGLUMINE 60% (LABELING REVISION -- BOXED WARNING)
10-040 09-SEP-94	RENOGRAFIN-60 (INJECTABLE)	BRACCO PRINCETON, NJ 08543	DIATRIZOATE MEGLUMINE 52% DIATRIZOATE SODIUM 8% (LABELING REVISION -- BOXED WARNING)
10-040 09-SEP-94	RENOGRAFIN-76 (INJECTABLE)	BRACCO PRINCETON, NJ 08543	DIATRIZOATE MEGLUMINE 66% DIATRIZOATE SODIUM 10% (LABELING REVISION -- BOXED WARNING)
10-040 09-SEP-94	CYSTOGRAFIN (SOLUTION)	BRACCO PRINCETON, NJ 08543	DIATRIZOATE MEGLUMINE 30% (LABELING REVISION --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

BOXED WARNING)

10-040	RENO-30	BRACCO	DIATRIZOATE MEGLUMINE
09-SEP-94	(SOLUTION)	PRINCETON, NJ	30%
		08543	(LABELING REVISION --
			BOXED WARNING)

17-078	DEXEDRINE	SMITHKLINE BEECHAM	DEXTROAMPHETAMINE SULFATE
12-SEP-94	(CAPSULE,	CONSHOHOCKEN, PA	5MG
	EXTENDED RELEASE)	19428	10MG
			15MG
			(LABELING REVISION --
			BOXED WARNING;
			CLINICAL PHARMACOLOGY;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)

13-174	DYRENIUM	SMITHKLINE BEECHAM	TRIAMTERENE
13-SEP-94	(CAPSULE)	KING OF PRUSSIA, PA	50MG
		19406	100MG
			(LABELING REVISION --
			ADVERSE REACTIONS;
			HOW SUPPLIED)

16-059	INDOCIN	MERCK	INDOMETHACIN
13-SEP-94	(CAPSULE)	WEST POINT, PA	25MG
		19486	50MG
			(LABELING REVISION --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			CLINICAL PHARMACOLOGY)
17-814	INDOCIN	MERCK	INDOMETHACIN
13-SEP-94	(SUPPOSITORY)	WEST POINT, PA	50MG
	19486		(LABELING REVISION --
			CLINICAL PHARMACOLOGY)
18-185	INDOCIN SR	MERCK	INDOMETHACIN
13-SEP-94	(CAPSULE,	WEST POINT, PA	75MG
	EXTENDED RELEASE)	19486	(LABELING REVISION --
			CLINICAL PHARMACOLOGY)
18-332	INDOCIN	MERCK	INDOMETHACIN
13-SEP-94	(SUSPENSION)	WEST POINT, PA	25MG/5ML
	19486		(LABELING REVISION --
			CLINICAL PHARMACOLOGY)
18-878	INDOCIN I.V.	MERCK	INDOMETHACIN SODIUM
13-SEP-94	(INJECTABLE)	WEST POINT, PA	EQ 1MG BASE/VIAL
	19486		(LABELING REVISION --
			CLINICAL PHARMACOLOGY)
19-057	HYTRIN	ABBOTT	TERAZOSIN HYDROCHLORIDE
14-SEP-94	(TABLET)	ABBOTT PARK, IL	EQ 1MG BASE
	60064		EQ 2MG BASE
			EQ 5MG BASE
			EQ 10MG BASE
			(LABELING REVISION --
			PRECAUTIONS)
50-547	CLAFORAN	HOECHST ROUSSEL	CEFOTAXIME SODIUM
14-SEP-94	(INJECTABLE)	SOMERVILLE, NJ	EQ 500MG BASE/VIAL
	08876		EQ 1GM BASE/VIAL
			EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENTS(S) STRENGTH(S) LABELING CHANGE(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
			(LABELING REVISION -- WARNINGS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
50-596 14-SEP-94	CLAFORAN IN PLASTIC CONTAINER (INJECTABLE)	HOECHST ROUSSEL SOMERVILLE, NJ 08876	CEFOTAXIME SODIUM EQ 20MG BASE/ML EQ 40MG BASE/ML (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-888* 15-SEP-94	ZESTORETIC 10-12.5 (TABLET)	ZENECA WILMINGTON, DE 19897	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 10MG (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

* - Not Marketed At This Time

19-888	ZESTORETIC 20-12.5	ZENECA	HYDROCHLOROTHIAZIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

15-SEP-94	(TABLET)	WILMINGTON, DE	12.5MG
	19897	LISINOPRIL	
			20MG
			(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
19-888	ZESTORETIC 20-25	ZENECA	HYDROCHLOROTHIAZIDE
15-SEP-94	(TABLET)	WILMINGTON, DE	25MG
	19897	LISINOPRIL	
			20MG
			(LABELING REVISION --
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
18-878	INDOCIN I.V.	MERCK	INDOMETHACIN SODIUM
21-SEP-94	(INJECTABLE)	WEST POINT, PA	EQ 1MG BASE/VIAL
	19486	(LABELING REVISION --	
		ADVERSE REACTIONS)	
20-036	AREDIA	CIBA GEIGY	PAMIDRONATE DISODIUM
21-SEP-94	(INJECTABLE)	SUMMIT, NJ	30MG/VIAL
	07901	60MG/VIAL	
		90MG/VIAL	
		(LABELING REVISION --	
		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

			PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-834 22-SEP-94	PLENDIL (TABLET, EXTENDED RELEASE)	MERCK WEST POINT, PA 19486	FELODIPINE 2.5MG 5MG 10MG (LABELING REVISION -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-297 23-SEP-94	NOVANTRONE (INJECTABLE)	IMMUNEX SEATTLE, WA 98101	MITOXANTRONE HYDROCHLORIDE EQ 2MG BASE/ML (LABELING REVISION -- WARNINGS)
19-806 23-SEP-94	SEMPREX-D (CAPSULE)	BURROUGHS WELLC RES TRIANGLE PK, NC 27709	ACRIVASTINE 8MG PSEUDOEPHEDRINE HYDROCHLORIDE 60MG (LABELING REVISION -- CLINICAL PHARMACOLOGY)
16-059 26-SEP-94	INDOCIN (CAPSULE)	MERCK WEST POINT, PA 19486	INDOMETHACIN 25MG 50MG (LABELING REVISION -- ADVERSE REACTIONS)
17-814 26-SEP-94	INDOCIN (SUPPOSITORY)	MERCK WEST POINT, PA	INDOMETHACIN 50MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		19486	(LABELING REVISION -- ADVERSE REACTIONS)
18-185	INDOCIN SR	MERCK	INDOMETHACIN
26-SEP-94	(CAPSULE, EXTENDED RELEASE)	WEST POINT, PA 19486	75MG (LABELING REVISION -- ADVERSE REACTIONS)
18-332	INDOCIN	MERCK	INDOMETHACIN
26-SEP-94	(SUSPENSION)	WEST POINT, PA 19486	25MG/5ML (LABELING REVISION -- ADVERSE REACTIONS)
18-859	VIRAZOLE	ICN	RIBAVIRIN
26-SEP-94	(POWDER FOR RECONSTITUTION)	COSTA MESA, CA 92626	6GM/VIAL (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
20-038	FLUDARA	BERLEX	FLUDARABINE PHOSPHATE
26-SEP-94	(INJECTABLE)	ALAMEDA, CA 94501	50MG/VIAL (LABELING REVISION -- BOXED WARNING; WARNINGS; ADVERSE REACTIONS)
20-103	ZOFRAN	GLAXO	ONDANSETRON HYDROCHLORIDE
26-SEP-94	(TABLET)	RES TRIANGLE PK, NC 27709	EQ 4MG BASE EQ 8MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; 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

19-898	PRAVACHOL	BRISTOL MYERS SQUIBB	PRAVASTATIN SODIUM
28-SEP-94	(TABLET)	PRINCETON, NJ	10MG
		08543	20MG
			40MG
			(LABELING REVISION -- CLINICAL PHARMACOLOGY; WARNINGS)
16-131	CLOMID	MERRELL DOW	CLOMIPHENE CITRATE
30-SEP-94	(TABLET)	CINCINNATI, OH	50MG
		45215	(LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

1127 28-SEP-94	NONE (INJECTABLE)	HUNTER BLOOD CTR CLEARWATER, FL 34616	PLATELETS (B)
1177 28-SEP-94	NONE (IN-VITRO)	MICRO TYPING SYS POMPANO BEACH, FL 33069	ANTI-HUMAN GLOBULIN (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

BK940018	AUTOPROCESSOR	PALL BIOMED PRODS	AUTOPROCESSOR
07-SEP-94		GLEN COVE, NY (C) 11542	
BK940016	COBE SPECTRA	COBE BCT	BLOOD BANK COMPUTER SOFTWARE
20-SEP-94	VERSION 4	LAKEWOOD, CO (C) 80215	
BK940019	HEMOPHARM PB-500	INSTA COOL	POCKET SEALER
26-SEP-94		RANCHO CORDOVA, CA (C) 95742	
BK940010	CAPTIA	MERCIA DIAG	TREPONEMAL TEST FOR SYPHILIS
27-SEP-94	SYPHILIS-G	SHALFORD, GUILDFORD (C) GU4 8EW UNITED KINGDOM	
BK940011	SANGUIN	SANGUIN INTL	BLOOD BANK COMPUTER SOFTWARE
27-SEP-94	MEDUSA 2000	SOUTHINGTON, CT (C) 06489	
BK940017	PRA-STAT	SANGSTAT MED	ELISA/PANEL REACTIVE ANTI-HLA
27-SEP-94	ELISA/PANEL	MENLO PARK, CA (C) 94025	CLASS I IgG Ab
BK920005	NONE	FUTUREMED	BLOOD AND PLASMA WARMING DEVICE
29-SEP-94		DEER PARK, NY (C) 11729	
BK940032	BAIR HUGGER	AUGUSTINE MED	PATIENT WARMING SYSTEM
29-SEP-94		EDEN PRAIRIE, MN (C) 55344	

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	PROPER NAME (DESCRIPTION)
BIOLOGICAL NDA APPROVAL			
19-841 27-SEP-94	NONE (INJECTABLE)	MALLINCKRODT MED ST LOUIS, MO 63134 (D)	INDIUM IN-111 CHLORIDE STERILE SOLUTION

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

(D) Approved

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

P900007	COOK CHORIONIC VILLUS SAMPLING (CVS) SET	COOK OB/GYN SPENCER, IN 47460	INDICATED FOR USE OBTAINING CHORIONIC TISSUE SAMPLES TRANSCERVICALLY FOR THE PURPOSE OF PRENATAL DIAGNOSIS OF GENETIC ABNORMALITIES DURING WEEKS 10-12.	09/30/94
P910031	ENDOSONICS ORACLE MICRO PTCA CATHETER MODELS 55120, 55125, 55130, AND 55135	ENDOSONICS CORPORATION RANCHO CORDOVA, CA 95670	1) FOR USE AS A PTCA CATHETER 2) IMAGE VESSEL LUMEN AND WALL STRUCTURES 3) MAKE DIMENSIONAL MEASUREMENTS FROM IMAGE	09/30/94
P910061	MODELS LI30U, LI32U, AND LI41U SOFLEX ULTRAVIOLET-ABSORBING SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES	IOLAB CORPORATION CLAREMONT, CA 91711	PRIMARY IMPLANTATION VISUAL CORRECTION OF APHAKIA IN PERSONS 60 YRS OF AGE OR OLDER WHERE A CATARACTOUS LENS WAS REMOVED BY EXTRACAPSULAR CATARACT EXTRACTION	09/02/94
P920014	HEARTMATE IP LVAS	THERMO CARDIOSYSTEM, INC. WOBURN, MA 01888-2697	CARDIAC TRANSPLANT LIST PTS, TEMPORARY MECHANICAL CIRCULATORY SUPPORT NONREVERSIBLE LEFT VENTRICULAR FAILURE	09/30/94

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

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

BRIDGE TO CARDIAC TRANSPLANTATION

P920030	CIBA CORNING ACS PSA +D	CIBA CORNING DIAGNOSTICS CORP. MEDFIELD, MA 02052-1688	QUANTITATIVE, SERIAL DETERMINATION OF PROSTATE-SPECIFIC ANTIGEN (PSA) SERUM & AID PTS WITH PROSTATE CANCER USING CIBA CORNING AUTOMATED CHEMILUMINESCENCE SYS	09/02/94
P940009	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER AND CORFLO HEMOPERFUSION PUMP	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MI 55311-1566	PTCA IN PTS WITH SIGNIFICANT CORONARY ARTERY DISEASE ACCEPTABLE CANDIDATES FOR CORONARY ARTERY BYPASS GRAFT SURGERY & MEET CERTAIN SELECTION CRITERIA	09/28/94
P940013	PRECISION UV (VASURFILCON A) HYDROPHILIC CONTACT LENS FOR EXTENDED WEAR	PILKINGTON BARNES HIND, USA SUNNYVALE, CA 94086-5200	FOR NON-APHAKIC DAILY OR EXTENDED WEAR FROM 1 TO 7 DAYS BETWEEN REMOVALS FOR CLEANING, RINSING, AND DISINFECTING, AS RECOMMENDED BY THE EYE CARE PRACTITIONER	09/30/94

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

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N17908/S45	ALCON SALINE SOLUTION FOR SENSITIVE EYES	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	ALTERNATE MANUFACTURING SITE PHOENIX, AZ	09/09/94
P780012/S7	IMX HAVAB	ABBOTT LABORATORIES ABBOTT PARK, IL 60064-3500	ALTERNATE MANUFACTURING SITE FOR COMPONENTS OF THE DEVICE IN PUERTO RICO	09/12/94
P790019/S5	IMX HAVAB-M	ABBOTT LABORATORIES ABBOTT PARK, IL 60064-3500	ALTERNATE MANUFACTURING SITE FOR COMPONENTS OF THE DEVICE IN PUERTO RICO	09/12/94
P800002/S10	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT (MCH)	MEDCHEM PRODUCTS, INC. WOBURN, MA 01801	1) ALTERNATE FINISHED DEVICE FACILITY (WOBURN, MA) 2) LABELING MODIFICATIONS RE:CHANGE IN FACILITY	09/09/94
P810055/S51	CM LABELING CLAIMS	PHARMACIA INC. OPHTHALMICS MONROVIA, CA 91017-7136	USE OF CEEON AS A BRAND NAME FOR ALL PHARMACIA IOLS & USE OF CM AS A FEATURE FOR CERTAIN ONE-PIECE LENSES	09/20/94
P820040/S30	DUNDEE LENS CARE SYSTEM	CIBA VISION CORPORATION DULUTH, GA 30136-1518	LABELING MODIFICATIONS - UNDER THE NEW MODIFICATIONS	09/30/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

			THE DEVICE WILL BE MARKETED UNDER THE NEW TRADE NAME DUNDEE LENS CARE SYSTEM	
P820076/S16	GEMNOS TC 04 PULSE GENERATOR AND SOFTWARE MODULE SWM 600, VERSION C25U01	BIOTRONIK, INC. LAKE OSWEGO, OR 97035	NEW MODELS MODEL GEMNOS TC 04 PULSE GENERATOR AND SOFTWARE MODULE SWM 600 VERSION C25U01	09/19/94
P830045/S46	AFP MODEL 203 PULSE GENERATOR WITH MODEL 370 PROGRAMMER	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	ALTERNATE 100% ETHYLENE OXIDE (ETO) STERILIZATION PROCESS	09/27/94
P840008/S47	DORNIER LITHOTRIPTER COMPACT (DLC)	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	NEW MODEL - AS MODIFIED THE DEVICE WILL BE MARKETED UNDER NEW TRADE NAME DORNIER LITHOTRIPTER COMPACT (DLC)	09/12/94
P840024/S52	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	LABELING MODIFICATIONS - CHANGES INCLUDE UPDATED PRECAUTIONS AND ADD ADVERSE REACTION INFORMATION	09/27/94
P840040/S45	MEDI-TECH CORONARY BALLOON	BOSTON SCIENTIFIC CORPORATION	1) ADDITION OF INSPECTION PROCEDURE	09/30/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	DILATATION CATHETER SYSTEM ALLY PTCA BALLOON CATHETER	WATERTOWN, MA 02172-2414	2) NEW TRADE NAME - ALLY PTCA BALLOON CATHETER	
P840040/S46	MANSFIELD CORONARY BALLOON DILATATION CATHETER SYSTEM MIGHTY PTCA CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02272	ADDITION OF 30 AND 40MM BALLOON LENGTHS TO MIGHTY PTCA BALLOON CATHETER	09/27/94
P850022/S7	ORTHOPAK BONE GROWTH STIMULATOR	BIOLECTRON, INC. HACKENSACK, NJ 07601	REVISED LABELING - REFLECTS 4 YEAR FOLLOW-UP SUCCESS RATE	09/20/94
P850051/S44	MEDTRONIC SINGLE CHAMBER PACEMAKERS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	ALTERNATIVE PACKAGING MATERIAL	09/06/94
P850088/S31	ULTRACARE AND OXYSEPT 2 NEUTRALIZING TABLETS	ALLERGAN IRVINE, CA 92713-9534	ALTERNATE IRRADIATION STERILIZATION SITE - WESTPORT IRELAND	09/09/94
P860004/S31	MEDTRONIC SYNCHROMED PUMPS WITH ALTERNATE ADDITIONAL COMPONENT OF A RESERVOIR VALVE	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN 55440-9087	DEVICE MODIFICATION - ALTERNATE ADDITIONAL COMPONENT OF A RESERVOIR VALVE	09/01/94
P860019/S85	SCIMED	SCIMED LIFE SYSTEMS, INC.	ALTERNATE	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER	MAPLE GROVE, MN 55311-1566	STERILIZATION RELEASE METHOD	09/13/94
P860019/S87	SCIMED PTCA CATHETERS EXPRESS+PTCA CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	NEW DEVICE MODEL - EXPRESS & PTCA CATHETER	09/22/94
P860019/S90	SCIMED PTCA CATHETER NC SHADOW, NC COBRA 14, NC RALLY, AND NC CRUISE CATHETERS	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	ADDITION OF BIOSLIDE COATING TO CATHETER MODELS WITH POLYETHYLENE TEREPHTHALATE BALLOONS AND WITHOUT DISTAL METAL SHAFT	09/12/94
P860019/S91	SCIMED PTCA CATHETERS XTRA COATING	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	USE OF A CARRIER SOLVENT FOR XTRA COATING AND COATING MANUFACTURING PROCESS CHANGE	09/27/94
P880003/S23	CORDIS PTCA DILATATION CATHETER CORDIS EUROPASS PTCA DILATATION CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	NEW MODEL - CORDIS EUROPASS PTCA DILATATOR CATHETER	09/30/94
P880003/S28	CORDIS PTCA DILATATION CATHETER	CORDIS CORPORATION MIAMI, FL	NEW MODEL WORLDPASS PTCA DILATATION	09/29/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	WORLDPASS PTCA DILATATION CATHETER	33102-5700	CATHETER WITH 20MM, 30MM, AND 40MM LONG BALLOONS	
P880003/S29	CORDIS PTCA DILATATION CATHETER 4.0 MM TRAKSTAR 14 PTCA DILATATION CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	NEW MODEL TRAKSTAR 14 DILATATION CATHETER WITH 20MM, 30MM, AND 40MM LONG BALLOONS	09/29/94
P880003/S30	CORDIS PTCA DILATATION CATHETER PREDATOR PTCA DILATATION CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	NEW MODEL PREDATOR PTCA DILATATION CATHETER WITH 150CM USABLE LENGTH	09/29/94
P880006/S20	SENSOLOG MODEL 703 PULSE GENERATOR AND P700 PROGRAMMER	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	ALTERNATE 100% ETHYLENE OXIDE (ETO) STERILIZATION PROCESS	09/09/94
P880079/S12	SOFTWEAR PLUS	CIBA VISION CORPORATION DULUTH, GA 30136-1518	ADDITION OF A SURFACTANT - AS MODIFIED DEVICE WILL BE MARKETED UNDER THE TRADE NAME SOFTWEAR PLUS	09/09/94
P880081/S11	SILICONE ULTRAVIOLET-ABSORBING MODELS SI-18B AND SI-18NB POSTERIOR CHAMBER LENSES (SLM-1UV)	ALLERGAN MEDICAL OPTICS, INC. IRVINE, CA 92718	REVISED LABELING - 3 YEAR FOLLOW-UP DATA; ADDRESSES DISCOLORATION OF SILICONE IOLS ("CENTRAL HAZE")	09/19/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P880081/S12	SILICONE ULTRAVIOLET-ABSORBING MODELS SI-18B AND SI-18NB POSTERIOR CHAMBER INTRAOCULAR LENSES (SLM-2UV)	ALLERGAN MEDICAL OPTICS, INC. IRVINE, CA 92718	ALTERNATE MANUFACTURING SITE IN ANASCO, PUERTO RICO	09/27/94
P880086/S27	SYNCHRONY MODEL 2020T PULSE GENERATOR AND APS II MODEL 3000 PROGRAMMER	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	ALTERNATE 100% ETHYLENE OXIDE (ETO) STERILIZATION PROCESS	09/27/94
P890003/S30	MEDTRONIC DUAL CHAMBER PACEMAKERS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	ALTERNATIVE PACKAGING MATERIAL	09/06/94
P890027/S22	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	LABELING MODIFICATIONS - UPDATED PRECAUTIONS AND ADDITION OF ADVERSE REACTION INFORMATION	09/27/94
P900023/S10	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	CHANGE IN THE BATTERY COMPONENT	09/23/94
P900023/S11	ABIOMED BVS 5000	ABIOMED, INC.	CHANGE IN CAPACITORS	

APPLICATION NO. / APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
09/30/94	BI-VENTRICULAR SUPPORT SYSTEM	DANVERS, MA 01923	
P900039/S5 09/30/94	COLLAGRAFT BONE GRAFT MATRIX	COLLAGEN CORPORATION PALO ALTO, CA 94303	ADDITION OF PRECAUTIONARY STATEMENT AND ADVERSE EFFECTS TABLE IN THE PACKAGE INSERT
P910007/S1 09/13/94	ABBOTT IMX PSA IMX PROSTATE SPECIFIC ANTIGEN (PSA)	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	APPROVAL FOR MANUFACTURE OF COMPONENTS AT PUERTO RICO SITE IN ADDITION TO LAKE COUNTY SITE
P910073/S2 09/13/94	COATED STYLET MODELS 6805, 6806, AND 6808	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	NEW MODELS - COATED STYLET MODELS 6805, 6806, AND 6808

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 SEPTEMBER 1994.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR SEPTEMBER 1994.

SUPPLEMENTAL VETERINARY NADAs

009-576 19-AUG-94	SYNOVEX-S (IMPLANT)	CATTLE	SYNTEX AGRIBUSINESS PALO ALTO, CA 94304	ESTRADIOL 20MG PROGESTERONE 200MG
128-686 01-SEP-94	BIO-COX (PREMIX)	QUAILS	AGRI BIO GAINESVILLE, GA 30503	SALINOMYCIN SODIUM TYPE A: 30GM/LB TYPE C: 0.02-0.03GM/LB

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

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-304 TRASYLOL MILES APROTININ BOVINE
12-OCT-94 (INJECTABLE) W HAVEN, CT 10,000KIU/ML
(SUPPL-002) 06516 (NEW DOSAGE REGIMEN --
ADDITIONAL DOSING REGIMEN
EQUAL TO HALF OF THE
ORIGINAL DOSING REGIMEN)

20-327 ISOVUE-200 BRACCO IOPAMIDOL
12-OCT-94 (INJECTABLE) PRINCETON, NJ 41%
(5 S) 08543 (DIAGNOSTIC RADIOPAQUE)

20-327 ISOVUE-250 BRACCO IOPAMIDOL
12-OCT-94 (INJECTABLE) PRINCETON, NJ 51%
(5 S) 08543 (DIAGNOSTIC RADIOPAQUE)

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

20-327	ISOVUE-300	BRACCO	IOPAMIDOL
12-OCT-94	(INJECTABLE)	PRINCETON, NJ	61%
(5 S)		08543	(DIAGNOSTIC RADIOPAQUE)

20-327	ISOVUE-370	BRACCO	IOPAMIDOL
12-OCT-94	(INJECTABLE)	PRINCETON, NJ	76%
(5 S)		08543	(DIAGNOSTIC RADIOPAQUE)

20-067	EC-NAPROSYN	SYNTEX	NAPROXEN
14-OCT-94	(TABLET,	PALO ALTO, CA	375MG
(3 S)	DELAYED RELEASE)	94304	500MG
			(NONSTEROIDAL ANTI-INFLAMMATORY) [TREATMENT OF RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, ANKYLOSING SPONDYLITIS, JUVENILE ARTHRITIS]

20-121	FLONASE	GLAXO	FLUTICASONE PROPIONATE
19-OCT-94	(SPRAY, METERED)	RES TRIANGLE PK, NC	0.05MG/INH
(3 S)		27709	(CORTICOSTEROID) [TREATMENT OF SEASONAL AND PERENNIAL ALLERGIC RHINITIS]

19-384	NOROXIN	MERCK	NORFLOXACIN
24-OCT-94	(TABLET)	W POINT, PA	400MG
(SUPPL-020)		19486	(NEW INDICATION -- PROSTATITIS)

20-323	VIVELLE	NOVEN	ESTRADIOL
28-OCT-94	(FILM,	MIAMI, FL	0.0375MG/24HR
(3 S)	EXTENDED RELEASE)	33186	0.05MG/24HR
			0.075MG/24HR
			0.1MG/24HR
			(ESTROGEN)

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

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.

20-405	LANOXIN	BURROUGHS WELLC	DIGOXIN
26-OCT-94	(TABLET)	RES TRIANGLE PK, NC	0.0625MG
		27709	0.125MG
			0.187MG
			0.25MG
			0.375MG
			0.5MG
			(CARDIAC GLYCOSIDE)

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

ORIGINAL ABBREVIATED NDAs

73-030	FLUOCINONIDE	FOUGERA	FLUOCINONIDE
17-OCT-94	(CREAM)	MELVILLE, NY	0.05%
	11747	(CORTICOSTEROID)	
74-156	GEMFIBROZIL	WATSON LABS	GEMFIBROZIL
24-OCT-94	(TABLET)	CORONA, CA	600MG
	91720	(ANTIHYPERLIPIDEMIC)	
40-038	TRIAMCINOLONE	TARO PHARMS	TRIAMCINOLONE ACETONIDE
26-OCT-94	ACETONIDE	BRAMALEA, ONTARIO	0.025%
	(CREAM)	CANADA	(CORTICOSTEROID)
74-083	NITROGLYCERIN	ABBOTT	NITROGLYCERIN
26-OCT-94	IN DEXTROSE 5%	ABBOTT PARK, IL	0.1MG/ML
	(INJECTABLE)	60064	(ANTIANGINAL)
40-010	HYDROXYZINE HCL	HI TECH PHARMA	HYDROXYZINE HYDROCHLORIDE
28-OCT-94	(SYRUP)	AMITYVILLE, NY	10MG/5ML
	11701	(ANXIOLYTIC/ANTIPRURITIC)	
74-170	AMANTADINE HCL	HI TECH PHARMA	AMANTADINE HYDROCHLORIDE
28-OCT-94	(SYRUP)	AMITYVILLE, NY	50MG/5ML
	11701	(ANTIVIRAL/ANTIPARKINSONIAN)	
40-035	FLUOCINOLONE	TARO PHARMS	FLUOCINOLONE ACETONIDE
31-OCT-94	ACETONIDE	BRAMALEA, ONTARIO	0.01%
	(CREAM)	CANADA	(CORTICOSTEROID)
40-042	FLUOCINOLONE	TARO PHARMS	FLUOCINOLONE ACETONIDE
31-OCT-94	ACETONIDE	BRAMALEA, ONTARIO	0.025%
	(CREAM)	CANADA	(CORTICOSTEROID)
40-097	HYDROCORTISONE	BAUSCH AND LOMB	ACETIC ACID, GLACIAL
31-OCT-94	AND ACETIC ACID	TAMPA, FL	2%

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

ORIGINAL ABBREVIATED NDAs

	(SOLUTION/DROPS)	33637	(ANTIBACTERIAL)
			HYDROCORTISONE
			1%
			(CORTICOSTEROID)
63-119	TOBRAMYCIN SULFATE	ASTRA	TOBRAMYCIN SULFATE
31-OCT-94	(INJECTABLE)	WESTBOROUGH, MA	EQ 10MG BASE/ML
		01581	(ANTIBIOTIC/AMINOGLYCOSIDE)
63-120	TOBRAMYCIN SULFATE	ASTRA	TOBRAMYCIN SULFATE
31-OCT-94	(INJECTABLE-VIAL)	WESTBOROUGH, MA	EQ 40MG BASE/ML
		01581	(ANTIBIOTIC/AMINOGLYCOSIDE)
63-121	TOBRAMYCIN SULFATE	ASTRA	TOBRAMYCIN SULFATE
31-OCT-94	(INJECTABLE-SYRINGE)	WESTBOROUGH, MA	EQ 40MG BASE/ML
		01581	(ANTIBIOTIC/AMINOGLYCOSIDE)
63-122	TOBRAMYCIN SULFATE	ASTRA	TOBRAMYCIN SULFATE
31-OCT-94	(INJECTABLE-	WESTBOROUGH, MA	EQ 40MG BASE/ML
	MULTI-DOSE VIAL)	01581	(ANTIBIOTIC/AMINOGLYCOSIDE)
63-266	AMIKACIN	ABBOTT	AMIKACIN SULFATE
31-OCT-94	(INJECTABLE)	ABBOTT PARK, IL	EQ 250MG BASE/ML
		60064	(ANTIBIOTIC/AMINOGLYCOSIDE)
63-283	AMIKACIN	ABBOTT	AMIKACIN SULFATE
31-OCT-94	(INJECTABLE)	ABBOTT PARK, IL	EQ 62.5MG BASE/ML
		60064	(ANTIBIOTIC/AMINOGLYCOSIDE)
74-277	DOBUTAMINE HCL	BEDFORD	DOBUTAMINE HYDROCHLORIDE
31-OCT-94	(INJECTABLE)	BEDFORD, OH	EQ 12.5MG BASE/ML
		44146	(VASODILATOR, INOTROPIC,
			ADRENERGIC)

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

ORIGINAL ABBREVIATED NDAs

74-332*	BUMETANIDE	SANOFI WINTHROP	BUMETANIDE
31-OCT-94	(INJECTABLE)	NEW YORK, NY	0.25MG/ML
	10016	(LOOP DIURETIC)	
74-337	FUROSEMIDE	SANOFI WINTHROP	FUROSEMIDE
31-OCT-94	(INJECTABLE)	NEW YORK, NY	10MG/ML
	10016	(LOOP DIURETIC)	

* - First Time Product Available GenericallY

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

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVAL FOR OCTOBER 1994.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-655	RETROVIR	BURROUGHS WELLC	ZIDOVUDINE
07-OCT-94	(CAPSULE)	RES TRIANGLE PK, NC	100MG
	27709	(LABELING REVISION -- CLINICAL PHARMACOLOGY; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)	
19-910	RETROVIR	BURROUGHS WELLC	ZIDOVUDINE
07-OCT-94	(SYRUP)	RES TRIANGLE PK, NC	50MG/5ML
	27709	(LABELING REVISION -- CLINICAL PHARMACOLOGY; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)	
19-951	RETROVIR	BURROUGHS WELLC	ZIDOVUDINE
07-OCT-94	(INJECTABLE)	RES TRIANGLE PK, NC	10MG/ML
	27709	(LABELING REVISION -- CLINICAL PHARMACOLOGY; PRECAUTIONS)	
20-014	MAXAIR	3M	PIRBUTEROL ACETATE
07-OCT-94	(AEROSOL, METERED)	ST PAUL, MN	EQ 0.2MG BASE/INH
	55144	(LABELING REVISION -- PATIENTS INSTRUCTIONS FOR USE)	
20-199	HIVID	ROCHE	ZALCITABINE
07-OCT-94	(TABLET)	NUTLEY, NJ	0.375MG
	07110		0.75MG
		(LABELING REVISION -- CLINICAL PHARMACOLOGY; PRECAUTIONS;	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

DOSAGE AND ADMINISTRATION)

18-602	CARDIZEM	MARION MERRELL DOW	DILTIAZEM HYDROCHLORIDE
12-OCT-94	(TABLET)	KANSAS CITY, MO	30MG
		64137	60MG
			90MG
			120MG
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			PRECAUTIONS)
19-614	VERELAN	ELAN	VERAPAMIL HYDROCHLORIDE
12-OCT-94	(CAPSULE,	GAINESVILLE, GA	120MG
	EXTENDED RELEASE)	30504	180MG
			240MG
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			PRECAUTIONS;
			DOSAGE AND ADMINISTRATION)
19-885	ACCUPRIL	PARKE DAVIS	QUINAPRIL HYDROCHLORIDE
12-OCT-94	(TABLET)	ANN ARBOR, MI	EQ 5MG BASE
		48105	EQ 10MG BASE
			EQ 20MG BASE
			EQ 40MG BASE
			(LABELING REVISION --
			CLINICAL PHARMACOLOGY;
			WARNINGS; 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

20-304	TRASYLOL	MILES	APROTININ BOVINE
12-OCT-94	(INJECTABLE)	W HAVEN, CT	10,000KIU/ML
	06516	(LABELING REVISION -- CLINICAL PHARMACOLOGY; DOSAGE AND ADMINISTRATION)	

50-578	FORTAZ	GLAXO	CEFTAZIDIME
20-OCT-94	(INJECTABLE)	RES TRIANGLE PK, NC	500MG/VIAL
	27709	1GM/VIAL 2GM/VIAL 6GM/VIAL (LABELING REVISION -- ADVERSE REACTIONS)	

50-634	FORTAZ	GLAXO	CEFTAZIDIME SODIUM
20-OCT-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 20MG BASE/ML
	27709	EQ 40MG BASE/ML (LABELING REVISION -- ADVERSE REACTIONS)	

50-646	CEPTAZ	GLAXO	CEFTAZIDIME
20-OCT-94	(INJECTABLE)	RES TRIANGLE PK, NC	1GM/VIAL
	27709	2GM/VIAL 10GM/VIAL (LABELING REVISION -- ADVERSE REACTIONS)	

17-646	PERGONAL	SERONO	MENOTROPINS --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

21-OCT-94	(INJECTABLE)	BRAINTREE, MA	FOLLICLE STIMULATING
	02184		HORMONE
			75IU/AMP
			LUTEINIZING HORMONE
			75IU/AMP
			(LABELING REVISION --
			HOW SUPPLIED)
17-646	PERGONAL	SERONO	MENOTROPINS --
21-OCT-94	(INJECTABLE)	BRAINTREE, MA	FOLLICLE STIMULATING
	02184		HORMONE
			150IU/AMP
			LUTEINIZING HORMONE
			150IU/AMP
			(LABELING REVISION --
			HOW SUPPLIED)
19-901	ALTACE	HOECHST ROUSSEL	RAMIPRIL
21-OCT-94	(CAPSULE)	SOMERVILLE, NJ	1.25MG
	08876		2.5MG
			5MG
			10MG
			(LABELING REVISION --
			ADVERSE REACTIONS;
			WARNINGS)
19-384	NOROXIN	MERCK	NORFLOXACIN
24-OCT-94	(TABLET)	W POINT, PA	400MG
	19486		(LABELING REVISION --
			INDICATIONS AND USAGE;
			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

18-554	EULEXIN	SCHERING	FLUTAMIDE
26-OCT-94	(CAPSULE)	KENILWORTH, NJ	125MG
		07033	(LABELING REVISION -- ADVERSE REACTIONS)
19-886	SYNAREL	SYNTEX	NAFARELIN ACETATE
26-OCT-94	(SPRAY, METERED)	PALO ALTO, CA	EQ 0.2MG BASE/INH
		94303	(LABELING REVISION -- PATIENT PACKAGE INSERT)
20-109	SYNAREL	SYNTEX	NAFARELIN ACETATE
26-OCT-94	(SPRAY, METERED)	PALO ALTO, CA	EQ 0.2MG BASE/INH
		94303	(LABELING REVISION -- PATIENT PACKAGE INSERT)
19-962	TOPROL-XL	ASTRA USA	METOPROLOL SUCCINATE
27-OCT-94	(TABLET, EXTENDED RELEASE)	WESTBOROUGH, MA	EQ 50MG TARTRATE
		01581	EQ 100MG TARTRATE
			EQ 200MG TARTRATE
			(LABELING REVISION -- DESCRIPTION)
50-517	MEFOXIN	MSD	CEFOXITIN SODIUM
27-OCT-94	(INJECTABLE)	WEST POINT, PA	EQ 1GM BASE/VIAL
		19486	EQ 2GM BASE/VIAL
			EQ 10GM BASE/VIAL
			(LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
50-558	ZINACEF	GLAXO	CEFUROXIME SODIUM
27-OCT-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 750MG BASE/VIAL
		27709	EQ 1.5GM 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 7.5GM BASE/VIAL
			(LABELING REVISION --
			ADVERSE REACTIONS)
50-581	MEFOXIN	MSD	CEFOXITIN SODIUM
27-OCT-94	IN PLASTIC CONTAINER	WEST POINT, PA	EQ 20MG BASE/ML
	(INJECTABLE)	19486	EQ 40MG BASE/ML
			(LABELING REVISION --
			INDICATIONS AND USAGE;
			DOSAGE AND ADMINISTRATION)
50-643	ZINACEF	GLAXO	CEFUROXIME SODIUM
27-OCT-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 15MG BASE/ML
		27709	EQ 30MG BASE/ML
			(LABELING REVISION --
			ADVERSE REACTIONS)
50-551	CEFOBID	PFIZER	CEFOPERAZONE SODIUM
28-OCT-94	(INJECTABLE)	NEW YORK, NY	EQ 1GM BASE/VIAL
		10017	EQ 2GM BASE/VIAL
			(LABELING REVISION --
			INDICATIONS AND USAGE;
			DOSAGE AND ADMINISTRATION)
50-613	CEFOBID	PFIZER	CEFOPERAZONE SODIUM
28-OCT-94	IN PLASTIC CONTAINER	NEW YORK, NY	EQ 20MG BASE/ML
	(INJECTABLE)	10017	EQ 40MG BASE/ML
			(LABELING REVISION --
			INDICATIONS AND USAGE;

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)
17-646 31-OCT-94	PERGONAL (INJECTABLE) 02184	SERONO BRAINTREE, MA	MENOTROPINS -- FOLLICLE STIMULATING HORMONE 75IU/AMP LUTEINIZING HORMONE 75IU/AMP (LABELING REVISION -- DESCRIPTION)
17-646 31-OCT-94	PERGONAL (INJECTABLE) 02184	SERONO BRAINTREE, MA	MENOTROPINS -- FOLLICLE STIMULATING HORMONE 150IU/AMP LUTEINIZING HORMONE 150IU/AMP (LABELING REVISION -- DESCRIPTION)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

0308 05-OCT-94	NONE (INJECTABLE)	GREER LABS LENOIR, NC 28645	PLAGUE VACCINE (B)
0747 28-OCT-94	NONE (INJECTABLE)	BLOOD ASSURANCE CHATTANOOGA, TN 37403	SOURCE LEUKOCYTES (B)
0942 28-OCT-94	NONE (INJECTABLE)	EAST TEXAS BLOOD CTR NACOGDOCHES, TX 75961	PLASMA (B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

(B) Product License Issued

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK940038	NONE	THOMSON AND NIELSEN LTD	BLOOD IRRADIATOR
18-OCT-94		OTTAWA, ONTARIO CANADA	DOSIMETRY SYSTEM (C)
BK940015	THE HLA B27	BECTON DICKINSON	LEUKOCYTE TYPING
24-OCT-94	SYSTEM	SAN JOSE, CA 95131	
BK930027	ACCURON 1	BOSTON BIOMEDICA	BLOOD SCREENING/
25-OCT-94	MARKER RUN CONTROLS	WEST BRIDGEWATER, MA 02379	DIAGNOSTIC SERUM CONTROL

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

P900009	SONIC ACCELERATED FRACTURE HEALING SYSTEM (SAFHS)	EXOGEN, INC. WEST CALDWELL, NJ 07006-6489	FOR ACCELERATION OF HEALING OF FRESH, CLOSED, DISTAL RADIUS (COLLES') FRACTURES & FRESH, CLOSED OR GRADE I OPEN TIBIAL FRACTURES WHEN THESE FRACTURES ARE MANAGED BY CLOSED REDUCTION & CAST IMMOBILIZATION	10/05/94
P920027	BARD ALBUMIN COATED DEBAKEY VASCULOUR-II VASCULAR PROSTHESIS	C.R. BARD, INC. BILLERICA, MA 01821	DEVICE INDICATED FOR REPLACEMENT OR BYPASS PROCEDURES IN THE TREATMENT OF ANEURYSMAL AND OCCLUSIVE DISEASES OF THE ABDOMINAL ARTERIES	10/21/94
P920047	EPT-1000 CARDIAC ABLATION SYSTEM	EP TECHNOLOGIES, INC. SUNNYVALE, CA 94086	INTERRUPTION OF AV CONDUCTION PATHWAYS FOR TACHYCARDIA, AV NODAL RE-ENTRANT TACHYCARDIA AND FOR CREATION OF AV BLOCK IN SPECIFIC PTS	10/28/94

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/S82	NATURALTINT 03 AND 04 SERIES OPTIMA FW, AND CRITERION ULTRA FW NATURALTINT (POLYMACON) EXTENDED WEAR SOFT (HYDROPHILIC) CONTACT LENSES	BAUSCH & LOMB ROCHESTER, NY 14692-0450	ALTERNATE MANUFACTURING SITE LOCATED AT BAUSCH & LOMB, INC., CONTACT LENS DIVISION, 2040 WHITFIELD AVE., SARASOTA, FL 34243	10/31/94
P800041/S14	ENDOCARDIAL CARBON TIP LEADS - MODELS 411S (FLANGED) AND 412S (TINED)	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	ALTERNATE STERILIZATION PROCESS	10/17/94
P800058/S15	BIOPOLYMERIC (FORMERLY N.C.G.T.) VASCULAR GRAFT	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	MODIFIED REPORTING REQUIREMENTS FOR THE POST APPROVAL STUDIES FOR ALL VERSIONS OF THIS GRAFT	10/25/94
P840039/S44	MODELS P512UV AND P552UV ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	NEW MODELS	10/25/94
P840040/S43	MEDI-TECH CORONARY BALLOON	BOSTON SCIENTIFIC CORPORATION	SYNERGY II LONG BALLOON DILATATION	10/06/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	DILATATION CATHETER AND SYNERGY II LONG BALLOON DILATATION CATHETER	WATERTOWN, MA 02172	CATHETER WITH 30 AND 40MM BALLOONS	
P840068/S21	VIGOR DDD PACEMAKER SYSTEM WITH MODEL 950 AND 955 PULSE GENERATORS	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	NEW MODELS	10/21/94
P850051/S43	MEDTRONIC SINGLE CHAMBER PACEMAKERS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	USE OF AN ALTERNATIVE BEAD BLASTED SHIELD FINISH ON THE IMPLANTABLE PULSE GENERATORS	10/06/94
P860004/S30	MEDTRONIC MODEL 8703W INTRASPINAL CATHETER FOR THE SYNCHROMED IMPLANTABLE PROGRAMMABLE PUMP	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN 55440-9087	ALTERNATE INTRASPINAL CATHETER	10/17/94
P860019/S83	SCIMED & SCIMED TRIO 14 TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETERS	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	NEW PTCA CATHETER MODEL, SCIMED TRIO 14 PERCUTANEOUS	10/14/94
P860019/S93	SCIMED PERCUTANEOUS	SCIMED LIFE SYSTEMS MAPLE GROVE, MN	ALTERNATIVE MANIFOLD TO BE USED WITH ALL	10/17/94

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETERS SCIMED COBRA PTCA CATHETERS	55311-1566	COBRA PTCA CATHETER MODELS THAT ARE COMPATIBLE WITH A 0.014" GUIDEWIRE	
P860047/S8	OCCUCOAT	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	ALTERNATE STERILIZATION PROCEDURE FOR THE OCCUCOAT	10/13/94
P880003/S31	CORDIS PTCA DILATATION CATHETER AND BASIC 18 PTCA DILATATION CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	BASIC 18 PTCA CATHETER WITH 20MM, 30MM, AND 40MM LONG BALLOONS	10/25/94
P880070/S5	MODEL UV65 ULTRAVIOLET LIGHT-ABSORBING ANTERIOR CHAMBER INTRAOCULAR LENS	PHARMACIA OPHTHALMICS, INC. MONROVIA, CA 91017-7136	REVISED LABELING FOR MODEL UV65 ULTRAVIOLET-ABSORBING ANTERIOR CHAMBER IOL TO INCLUDE 3YR CLINICAL DATA AND USE THE CEEON BRAND NAME	10/17/94
P880086/S22	PARAGON III AND PHOENIX III CARDIAC PULSE GENERATOR MODELS	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	NEW MODELS ADDED FOR PARAGON III (MODEL NO. 2304L, 2304T, & 2304 M/S) AND PHOENIX III (MODEL NOS. 2204L, 2204T, & 2204 M/S)	10/17/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P880086/S26	PARAGON III PULSE GENERATOR MODELS 2314L, 2341T, AND 2315M/S AND FUNCTION PACK MODEL 3054	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	NEW MODELS	10/31/94
P890003/S29	MEDTRONIC DUAL CHAMBER PACEMAKERS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	USE OF AN ALTERNATIVE BEAD BLASTED SHIELD FINISH, ON THE IMPLANTABLE PULSE GENERATORS	10/06/94
P910001/S6	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM VITESSE-C AND VITESSE-C II CATHETERS	SPECTRANETICS CORPORATION COLORADO SPRINGS, CO 80907-5159	NEW CATHETER MODELS FOR USE WITH THE SPECTRANETICS CVS-300 EXCIMER LASER SYSTEM	10/31/94
P910007/S3	ABBOTT IMX PSA	ABBOTT LABORATORIES ABBOTT PARK, IL 60064-3500	CHANGE IN LABELING TO STRENGTHEN THE WARNING REGARDING THE PRESENCE OF HUMAN ANTI-MOUSE ANTIBODY IN PATIENT SPECIMENS	10/17/94
P910023/S3	CADENCE TIERED THERAPY DEFIBRILLATOR SYSTEM WITH 0070 ENDOTAK LEAD SYSTEM	VENTRITEX, INC. SUNNYVALE, CA 94086-6527	APPROVAL FOR CADENCE MODELS V-100, V-100C AND V-110C WITH THE ENDOTAK LEAD SYSTEM	10/28/94
P910023/S6	CADENCE TIERED THERAPY	VENTRITEX, INC. SUNNYVALE, CA	APPROVAL FOR CADENCE MODELS V-100, V-100C,	10/28/94

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
		MEDICAL DEVICE - PMA SUPPLEMENTALS	
	DEFIBRILLATION SYSTEM WITH 0060 ENDOTAK LEAD SYSTEM	94086-6527	AND V-110C WITH THE 0060 ENDOTAK LEAD SYSTEM
P910064/S3 10/18/94	REALITY FEMALE CONDOM	WISCONSIN PHARMACAL COMPANY CHICAGO, IL 60611	PROFESSIONAL MONOGRAPH

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 OCTOBER 1994.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR OCTOBER 1994.

SUPPLEMENTAL VETERINARY NADAs

128-409 12-SEP-94	IVOMEC (INJECTABLE)	CATTLE	MERCK RAHWAY, NJ 07065	IVERMECTIN 10MG/ML
130-951 12-OCT-94	STENOROL (PREMIX)	CHICKENS, TURKEYS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	HALOFUGINONE HYDROBROMIDE 6GM/KG

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

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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

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

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

18-703 ZANTAC 150 GLAXO RANITIDINE HYDROCHLORIDE
03-NOV-94 (TABLET) RES TRIANGLE PK, NC EQ 150MG BASE
(SUPPL-047) 27709 (NEW INDICATION --
MAINTENANCE OF HEALING
OF EROSIVE ESOPHAGITIS)

18-703 ZANTAC 300 GLAXO RANITIDINE HYDROCHLORIDE
03-NOV-94 (TABLET) RES TRIANGLE PK, NC EQ 300MG BASE
(SUPPL-047) 27709 (NEW INDICATION --
MAINTENANCE OF HEALING
OF EROSIVE ESOPHAGITIS)

19-670 CLARITIN-D SCHERING LORATADINE
14-NOV-94 (TABLET, KENILWORTH, NJ 5MG
(4 S) EXTENDED RELEASE) 07033 (ANTIHISTAMINE)

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

			PSEUDOEPHEDRINE SULFATE
			120MG
			(DECONGESTANT)
20-135	MOTRIN	MCNEIL	IBUPROFEN
16-NOV-94	(TABLET, CHEWABLE)	FORT WASHINGTON, PA	50MG
(3 S)		19034	100MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
20-418	MOTRIN	MCNEIL	IBUPROFEN
16-NOV-94	(TABLET)	FORT WASHINGTON, PA	100MG
(3 S)		19034	(NONSTEROIDAL
			ANTI-INFLAMMATORY)
19-746	EFIDAC 24	ALZA	CHLORPHENIRAMINE MALEATE
18-NOV-94	CHLORPHENIRAMINE	PALO ALTO, CA	16MG
(3 S)	(TABLET,	94303	(ANTIHISTAMINE)
	EXTENDED RELEASE)		(OTC)
20-131	PROHANCE	BRACCO	GADOTERIDOL
21-NOV-94	(INJECTABLE)	PRINCETON, NJ	279.3MG/ML
(SUPPL-001)		08543	(NEW INDICATION --
			USE IN CHILDREN TO
			VISUALIZE LESIONS WITH
			ABNORMAL VASCULARITY IN THE
			BRAIN [INTRACRANIAL
			LESIONS], SPINE AND
			ASSOCIATED TISSUE)
20-131	PROHANCE	BRACCO	GADOTERIDOL
21-NOV-94	(INJECTABLE)	PRINCETON, NJ	279.3MG/ML
(SUPPL-002)		08543	(NEW INDICATION --
			USE IN MRI IN ADULTS
			TO VISUALIZE LESIONS
			IN THE HEAD AND NECK)

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

19-949	DIFLUCAN	PFIZER	FLUCONAZOLE
23-NOV-94	(TABLET)	GROTON, CT	50MG
(SUPPL-012)		06340	100MG
			200MG
			(EXPANDED PATIENT POPULATION -- USE IN PEDIATRIC PATIENTS WITH CRYPTOCOCCAL MENINGITIS AND CANDIDAL INFECTIONS)
19-950	DIFLUCAN	PFIZER	FLUCONAZOLE
23-NOV-94	(INJECTABLE)	NEW YORK, NY	2MG/ML
(SUPPL-016)		10017	(EXPANDED PATIENT POPULATION -- USE IN PEDIATRIC PATIENTS WITH CRYPTOCOCCAL MENINGITIS AND CANDIDAL INFECTIONS)
20-256	NEUROLITE	DUPONT MERCK	TECHNETIUM TC-99M
23-NOV-94	(INJECTABLE)	N BILLERICA, MA	BICISATE KIT
(1 S)		01862	N/A
			(RADIOACTIVE DIAGNOSTIC) [ADJUNCT TO CONVENTIONAL CT OR MRI IMAGING IN THE LOCALIZATION OF STROKE IN PATIENTS IN WHOM STROKE HAS ALREADY BEEN DIAGNOSED]
20-286	MONOPRIL-HCT	BRISTOL MYERS SQUIBB	FOSINOPRIL SODIUM
30-NOV-94	(TABLET)	PRINCETON, NJ	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

(4 S)	08543		HYDROCHLOROTHIAZIDE
			12.5MG
			(ANTIHYPERTENSIVE)
20-286	MONOPRIL-HCT	BRISTOL MYERS SQUIBB	FOSINOPRIL SODIUM
30-NOV-94	(TABLET)	PRINCETON, NJ	20MG
(4 S)	08543		HYDROCHLOROTHIAZIDE
			12.5MG
			(ANTIHYPERTENSIVE)

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.

20-403 02-NOV-94	ZOFRAN IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	GLAXO RES TRIANGLE PK, NC 27709	ONDANSETRON HYDROCHLORIDE EQ 0.08MG BASE/ML EQ 0.64MG BASE/ML (ANTIEMETIC)
20-152 07-NOV-94	SERZONE (TABLET)	BRISTOL MYERS SQUIBB WALLINGFORD, CT 06492	NEFAZODONE HYDROCHLORIDE 50MG 100MG 150MG 200MG 250MG 300MG (ANTIDEPRESSANT)
20-388 23-NOV-94	NAVELBINE (INJECTABLE)	BURROUGHS WELLC RES TRIANGLE PK, NC 27709	VINORELBINE TARTRATE EQ 10MG BASE/ML (ANTINEOPLASTIC) [NON-SMALL CELL LUNG CANCER]

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

ORIGINAL ABBREVIATED NDAs

74-370	GLIPIZIDE	CIRCA	GLIPIZIDE
22-NOV-94	(TABLET)	COPIAGUE, NY	5MG
	11726		10MG
		(BLOOD GLUCOSE REGULATOR)	
74-378	GLIPIZIDE	ENDO LABS	GLIPIZIDE
28-NOV-94	(TABLET)	GARDEN CITY, NY	5MG
	11530		10MG
		(BLOOD GLUCOSE REGULATOR)	
40-088	METHADONE HCL	UDL	METHADONE HYDROCHLORIDE
30-NOV-94	(CONCENTRATE)	LARGO, FL	10MG/ML
	34641	(NARCOTIC ANALGESIC)	
63-263	AMIKACIN	ABBOTT	AMIKACIN SULFATE
30-NOV-94	(INJECTABLE)	ABBOTT PARK, IL	EQ 50MG BASE/ML
	60064	(ANTIBIOTIC, AMINOGLYCOSIDE)	
63-264	AMIKACIN	ABBOTT	AMIKACIN SULFATE
30-NOV-94	(INJECTABLE-VIAL)	ABBOTT PARK, IL	EQ 250MG BASE/ML
	60064	(ANTIBIOTIC, AMINOGLYCOSIDE)	
63-265	AMIKACIN	ABBOTT	AMIKACIN SULFATE
30-NOV-94	(INJECTABLE-SYRINGE)	ABBOTT PARK, IL	EQ 250MG BASE/ML
	60064	(ANTIBIOTIC, AMINOGLYCOSIDE)	
74-436	CYCLOBENZAPRINE HCL	ROYCE LABS	CYCLOBENZAPRINE
30-NOV-94	(TABLET)	MIAMI, FL	HYDROCHLORIDE
	33014		10MG
		(SKELETAL MUSCLE RELAXANT)	

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

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

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

74-104 04-NOV-94	RANITIDINE HCL (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	RANITIDINE HYDROCHLORIDE EQ 150MG BASE EQ 300MG BASE (HISTAMINE H-2 RECEPTOR ANTAGONIST)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-285	MYCIFRADIN	UPJOHN	NEOMYCIN SULFATE
28-OCT-94	(SOLUTION)	KALAMAZOO, MI	125MG/5ML
	49001	(LABELING REVISION -- PRECAUTIONS)	
20-189	FELBATOL	WALLACE	FELBAMATE
01-NOV-94	(SUSPENSION)	CRANBURY, NJ	600MG/5ML
	08512	(LABELING REVISION -- BOXED WARNING; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)	
20-189	FELBATOL	WALLACE	FELBAMATE
01-NOV-94	(TABLET)	CRANBURY, NJ	400MG
	08512	600MG (LABELING REVISION -- BOXED WARNING; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)	
18-024	NUBAIN	DUPONT MERCK	NALBUPHINE HYDROCHLORIDE
02-NOV-94	(INJECTABLE)	GARDEN CITY, NY	10MG/ML
	11530	20MG/ML (LABELING REVISION -- WARNINGS)	
18-703	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(TABLET)	RES TRIANGLE PK, NC	EQ 150MG BASE
	27709	(LABELING REVISION -- ADVERSE REACTIONS)	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-703	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(TABLET)	RES TRIANGLE PK, NC	EQ 300MG BASE
	27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
19-090	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 25MG BASE/ML
	27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
19-593	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	IN PLASTIC CONTAINER	RES TRIANGLE PK, NC	EQ 1MG BASE/ML
	(INJECTABLE) 27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
19-675	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(SYRUP)	RES TRIANGLE PK, NC	EQ 15MG BASE/ML
	27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
20-095	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(CAPSULE)	RES TRIANGLE PK, NC	EQ 150MG BASE
	27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
20-095	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(CAPSULE)	RES TRIANGLE PK, NC	EQ 300MG BASE
	27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
20-251	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(GRANULE,	RES TRIANGLE PK, NC	EQ 150MG BASE/PACKET
	EFFERVESCENT) 27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
20-251	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(TABLET,	RES TRIANGLE PK, NC	EQ 150MG BASE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

	EFFERVESCENT)	27709	(LABELING REVISION -- ADVERSE REACTIONS)
18-817	CALAN	SEARLE	VERAPAMIL HYDROCHLORIDE
04-NOV-94	(TABLET)	SKOKIE, IL	40MG
		60077	80MG
			120MG
			(LABELING REVISION -- PRECAUTIONS)
20-264	MEGACE	BRISTOL MYERS SQUIBB	MEGESTROL ACETATE
04-NOV-94	(SUSPENSION)	PRINCETON, NJ	40MG/ML
		08543	(LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
19-813	DURAGESIC	ALZA	FENTANYL
07-NOV-94	(FILM, EXTENDED RELEASE)	PALO ALTO, CA 94303	0.6MG/24HR
			1.2MG/24HR
			1.8MG/24HR
			2.4MG/24HR
			(LABELING REVISION -- CLINICAL PHARMACOLOGY; CLINICAL TRIALS; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
50-573	SANDIMMUNE	SANDOZ	CYCLOSPORINE
10-NOV-94	(INJECTABLE)	EAST HANOVER, NJ	50MG/ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		07936	(LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
50-574	SANDIMMUNE	SANDOZ	CYCLOSPORINE
10-NOV-94	(SOLUTION)	EAST HANOVER, NJ	100MG/ML
		07936	(LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
50-625	SANDIMMUNE	SANDOZ	CYCLOSPORINE
10-NOV-94	(CAPSULE)	EAST HANOVER, NJ	25MG
		07936	50MG
			100MG
			(LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
20-095	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
14-NOV-94	(CAPSULE)	RES TRIANGLE PK, NC	EQ 150MG BASE
		27709	(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
20-095	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
14-NOV-94	(CAPSULE)	RES TRIANGLE PK, NC	EQ 300MG BASE
		27709	(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
20-235	NEURONTIN	PARKE DAVIS	GABAPENTIN
14-NOV-94	(CAPSULE)	ANN ARBOR, MI	100MG
		48105	300MG
			400MG
			(LABELING REVISION -- WARNINGS)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20-251	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
14-NOV-94	(GRANULE, EFFERVESCENT)	RES TRIANGLE PK, NC 27709	EQ 150MG BASE/PACKET (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
20-251	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
14-NOV-94	(TABLET, EFFERVESCENT)	RES TRIANGLE PK, NC 27709	EQ 150MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
19-884	MESNEX	ASTA	MESNA
16-NOV-94	(INJECTABLE)	FRANKFURT, GERMANY	100MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
20-131	PROHANCE	BRACCO	GADOTERIDOL
21-NOV-94	(INJECTABLE)	PRINCETON, NJ 08543	279.3MG/ML (LABELING REVISION -- CLINICAL TRIALS; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)
50-547	CLAFORAN	HOECHST ROUSSEL	CEFOTAXIME SODIUM
22-NOV-94	(INJECTABLE)	SOMERVILLE, NJ 08876	EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL (LABELING REVISION --

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)
50-596 22-NOV-94	CLAFORAN IN PLASTIC CONTAINER (INJECTABLE)	HOECHST ROUSSEL SOMERVILLE, NJ 08876	CEFOTAXIME SODIUM EQ 20MG BASE/ML EQ 40MG BASE/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
18-248 23-NOV-94	OXYTOCIN (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	OXYTOCIN 10 USP UNITS/ML (LABELING REVISION -- PRECAUTIONS)
19-949 23-NOV-94	DIFLUCAN (TABLET)	PFIZER GROTON, CT 06340	FLUCONAZOLE 50MG 100MG 200MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; CLINICAL STUDIES; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-950 23-NOV-94	DIFLUCAN (INJECTABLE)	PFIZER NEW YORK, NY 10017	FLUCONAZOLE 2MG/ML (LABELING REVISION -- CLINICAL PHARMACOLOGY; CLINICAL STUDIES; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
08-453 28-NOV-94	ANECTINE (INJECTABLE)	BURROUGHS WELLC RES TRIANGLE PK, NC 27709	SUCCINYLCHOLINE CHLORIDE 20MG/ML 500MG/VIAL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			1GM/VIAL (LABELING REVISION -- BOXED WARNING; DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
08-845 28-NOV-94	QUELICIN (INJECTABLE)	ABBOTT LABS ABBOTT PARK, IL 60064	SUCCINYLCHOLINE CHLORIDE 20MG/ML 50MG/ML 100MG/ML (LABELING REVISION -- BOXED WARNING; DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
08-847 28-NOV-94	SUCOSTRIN (INJECTABLE)	SQUIBB NEW BRUNSWICK, NJ 08903	SUCCINYLCHOLINE CHLORIDE 20MG/ML (LABELING REVISION -- BOX WARNING; 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	
			CONTRAINDICATIONS; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
20-151 28-NOV-94	EFFEXOR (TABLET)	WYETH AYERST PHILADELPHIA, PA 19101	VENLAFAXINE HYDROCHLORIDE EQ 25MG BASE EQ 37.5MG BASE EQ 50MG BASE EQ 75MG BASE EQ 100MG BASE (LABELING REVISION -- CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
16-672 29-NOV-94	OVRAL (TABLET)	WYETH AYERST PHILADELPHIA, PA 19101	ETHINYL ESTRADIOL 0.05MG NORGESTREL 0.5MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
16-806 29-NOV-94	OVRAL-28 (TABLET)	WYETH AYERST PHILADELPHIA, PA 19101	ETHINYL ESTRADIOL 0.05MG NORGESTREL 0.5MG (LABELING REVISION -- STD STATEMENT; 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

17-031	OVRETTE	WYETH AYERST	NORGESTREL
29-NOV-94	(TABLET)	PHILADELPHIA, PA	0.075MG
		19101	(LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
17-612	LO/OVRAL	WYETH AYERST	ETHINYL ESTRADIOL
29-NOV-94	(TABLET)	PHILADELPHIA, PA	0.03MG
		19101	NORGESTREL 0.3MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
17-802	LO/OVRAL-28	WYETH AYERST	ETHINYL ESTRADIOL
29-NOV-94	(TABLET)	PHILADELPHIA, PA	0.03MG
		19101	NORGESTREL 0.3MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
18-206	LO/OVRAL-28 AND	WYETH AYERST	ETHINYL ESTRADIOL
29-NOV-94	FERROUS FUMARATE	PHILADELPHIA, PA	0.03MG
(TABLET)		19101	FERROUS FUMARATE 75MG NORGESTREL 0.3MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
18-668	NORDETTE-21	WYETH AYERST	ETHINYL ESTRADIOL
29-NOV-94	(TABLET)	PHILADELPHIA, PA	0.03MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		19101	LEVONORGESTREL 0.15MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
18-782	NORDETTE-28	WYETH AYERST	ETHINYL ESTRADIOL
29-NOV-94	(TABLET)	PHILADELPHIA, PA	0.03MG
		19101	LEVONORGESTREL 0.15MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
20-189	FELBATOL	WALLACE LABS	FELBAMATE
29-NOV-94	(TABLET)	CRANBURY, NJ	400MG
		08512	600MG (LABELING REVISION -- BOXED WARNING; DESCRIPTION; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; PATIENT INFORMED CONSENT)
20-189	FELBATOL	WALLACE LABS	FELBAMATE
29-NOV-94	(SUSPENSION)	CRANBURY, NJ	600MG/5ML
		08512	(LABELING REVISION -- BOXED WARNING; DESCRIPTION; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

ADVERSE REACTIONS;
PATIENT INFORMED CONSENT)

50-467	ADRIAMYCIN RDF	PHARMACIA	DOXORUBICIN HYDROCHLORIDE
29-NOV-94	(INJECTABLE)	COLUMBUS, OH	10MG/VIAL
	43216		20MG/VIAL
			50MG/VIAL
			150MG/VIAL
			(LABELING REVISION --
			BOXED WARNING;
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
50-629	ADRIAMYCIN PFS	PHARMACIA	DOXORUBICIN HYDROCHLORIDE
29-NOV-94	(INJECTABLE)	COLUMBUS, OH	2MG/ML
	43216		200MG/100ML
			(LABELING REVISION --
			BOXED WARNING;
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;

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; DOSAGE AND ADMINISTRATION)
18-482 30-NOV-94	PROCARDIA (CAPSULE)	PFIZER NEW YORK, NY 10017	NIFEDIPINE 10MG 20MG (LABELING REVISION -- PRECAUTIONS)
19-684 30-NOV-94	PROCARDIA XL (TABLET, EXTENDED RELEASE)	PFIZER NEW YORK, NY 10017	NIFEDIPINE 30MG 60MG 90MG (LABELING REVISION -- PRECAUTIONS)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

0384 28-NOV-94	TYPHIM VI (INJECTABLE) (B)	PASTEUR MERIEUX SERUMS ET VACCINS, S.A. LYON, FRANCE	TYPHOID VI POLYSACCHARIDE VACCINE

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 NOVEMBER 1994.

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

P910071 11/04/94	ADATOMED SILICONE OIL OP5000	CHIRON VISION CORPORATION IRVINE, CA 92718-1903	A PROLONGED RETINAL TAMPONADE IN SELECTED CASES OF COMPLICATED RETINAL DETACHMENTS WHERE OTHER INTERVENTIONS ARE NOT APPROPRIATE FOR PATIENT MANAGEMENT

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

P820049/S57 10/04/94	MODELS PC-43NB, PC-44NB, AND PC45NB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	APPROVAL FOR MODELS PC-43NB, PC-44NB, AND PC-45NB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES
P870036/S21 10/04/94	MICROSCAN RAPID PANELS	BAXTER HEALTHCARE CORP MICROSCAN DIV. WEST SACRAMENTO, CA 95691	LABELING CHANGES THAT ADD A LIMITATION STATEMENT
P880082/S17 10/04/94	EYE TECH MDLS	EYE TECHNOLOGY, INC. ST. PAUL, MN 55117	ALTERNATE TRADE NAME ACCUTECH, AND CORRESPONDING MODEL NUMBERS
N17752/S35 11/09/94	HYDROCURVE 3 TORIC AND SOFTMATE II (BUFILCON A) SOFT CONTACT LENSES	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ADD THE MONOVISION FITTING TECHNIQUE TO THE LABELING OF A SINGLE VISION CONTACT LENS TO MANAGE PRESBYOPIA
N50510/S66 11/03/94	VITEK SYSTEMS "GENERAL SUSCEPTIBILITY CARD"	VITEK SYSTEMS, INC. HAZELWOOD, MO 63042-2395	LABELING CHANGE TO INCLUDE AN ADDITIONAL LIMITATIONS STATEMENT REGARDING THE DETECTION OF BETA-LACTAMASE PRODUCING ENTEROCOCCI

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P800022/S45 11/14/94	ZYDERM COLLAGEN IMPLANT AND ZYPLAST IMPLANT ADJUSTABLE DEPTH GUIDE NEEDLE	COLLAGEN CORPORATION PALO ALTO, CA 94303	LABELING CHANGE FOR THE ADJUSTABLE DEPTH GUIDE NEEDLE
P810046/S152 11/14/94	SIMPSON-ROBERT CORONARY BALLOON DILATION CATHETER ACS RX FLOWTRACK LONG CORONARY DILATION CATHETER WITH A 40MM BALLOON	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE ACS RX FLOWTRACK LONG CORONARY DILATION CATHETER WITH A 40MM BALLOON
P830055/S34 11/30/94	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	CHANGE IN THE PACKAGING PROCESS FOR THE POLYETHYLENE COMPONENTS
P830060/S35 11/23/94	VENTAK AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	REPLACEMENT OF FREON WITH HEPTANE IN THE MANUFACTURING PROCESS
P840040/S41 11/07/94	HEART TRAK CORONARY BALLOON DILATATION SYSTEM MIGHTY CORONARY BALLOON DILATATION CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172-2414	APPROVAL FOR THE MIGHTY CORONARY BALLOON DILATATION CATHETER
P850036/S1 11/07/94	BAUSCH & LOMB SENSITIVE EYES LENS LUBRICANT	BAUSCH & LOMB ROCHESTER, NY 14692-0450	CHANGE THE STABILITY SPECIFICATION OF SORBIC ACID FOR THE

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

REFERENCED DEVICE

P850064/S10	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL INC. SALT LAKE CITY, UT 84115	SOFTWARE CHANGES ASSOCIATED WITH PREVENTING OVERFLOW OF WATER FROM THE HUMIDIFIER TO THE BREATHING CIRCUIT	11/18/94
P850069/S11	KENNEDY LAD LIGAMENT AUGMENTATION DEVICE	3M CENTER ST. PAUL, MN 55133-3275	CHANGE OF MANUFACTURING SITE USED FOR THE BRAIDING, EXTRUSION AND REWINDING PROCEDURES TO GOR-MIL MANUFACTURING COMPANY, MILICA, MN	11/28/94
P860019/S84	SCIMED NC COBRA 18 PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	NEW MODEL OF PTCA CATHETER MARKETED UNDER THE TRADE NAME SCIMED NC COBRA 18 PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER	11/15/94
P860023/S8	BAUSCH & LOMB RENU MULTI-PURPOSE SOLUTION TRAVELER	BAUSCH & LOMB ROCHESTER, NY 14692-0450	ALTERNATE PACKAGING PROCESS AND PACKAGING DESIGN. THERE ARE NO	11/07/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

			CHANGES IN PRODUCT FORMULA OR INDICATIONS FOR USE
P870036/S25 11/09/94	MEDTRONIC THRUFLEX II, 18K, AND 14K PTCA CATHETERS	MEDTRONIC INTERVENTIONAL VASCUL SAN DIEGO, CA 92121-2256	ALTERNATE METHOD OF INSPECTING CATHETER LOTS PRIOR TO RELEASE
P880090/S14 11/29/94	MODELS 121UV AND S121UV ULTRAVIOLET ABSORBING ANTERIOR CHAMBER INTRAOCULAR LENSES (IOLS)	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	APPROVAL FOR MODELS M121UV AND M122UV; PRIVATE LABEL DISTRIBUTING; LABELING REVISIONS
P890003/S27 11/29/94	MODEL 9790 PROGRAMMER WITH THE MODELS 9870E, 9871E, AND 9872E SOFTWARE DISKETTES	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MODEL 9790 PROGRAMMER AND THE MODELS 9870E, 9871E, AND 9872E SOFTWARE DISKETTES
P890012/S3 11/09/94	GENTLE TOUCH (NETRAFILCON A) SOFT CONTACT LENSES	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ADD THE MONOVISION FITTING TECHNIQUE TO THE LABELING OF A SINGLE VISION CONTACT LENS TO MANAGE PRESBYOPIA
P890070/S2	PURE-DENT B851	GRAIN PROCESSING	CHANGE PH RANGE TO

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
		CORPORATION MUSCATINE, IA 52761-0349	4.0-6.0, TO BE MARKETED UNDER THE NEW TRADE NAME PURE-DENT B851	11/30/94
P900023/S9	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	SOFTWARE CHANGE FOR THE ABIOMED BVS 5000 BLOOD PUMP TO QUICKEN THE LOW PRESSURE AND LOW FLOW ALARM RESPONSE TIME	11/17/94
P900030/S2	CONTIGEN BARD COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303	ALTERNATIVE MANUFACTURING PROCESS (CROSS-FLOW FILTRATION) THAT WAS PREVIOUSLY APPROVED FOR ZYDERM AND ZYPLAST COLLAGEN IMPLANTS	11/23/94
P910001/S7	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORPORATION COLORADO SPRINGS, CO 80907-5159	APPROVAL FOR INCLUSION OF ADDITIONAL SALINE INFUSION INSTRUCTIONS INTO THE INSTRUCTION FOR USE OF THE SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM	11/15/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P910071/S1	ADATO SIL 5000	CHIRON VISION CORPORATION IRVINE, CA 92718-1903	TRADE NAME CHANGE FOR ADATOMED SILICONE OIL OP5000 TO ADATO SIL 5000. INDICATED FOR PROLONGED RETINAL TAMPONADE IN SELECTED CASES OF COMPLICATED RETINAL DETACHMENTS	11/30/94
P910073/S4	ENDOTAK LEAD SYSTEM	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	REPLACEMENT OF FREON WITH HEPTANE IN THE MANUFACTURING PROCESS	11/23/94
P910077/S1	VENTAK PRX AICD SYSTEM	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	REPLACEMENT OF FREON WITH HEPTANE IN THE MANUFACTURING PROCESS	11/23/94
P940013/S2	PRECISION UV (VASURFILCON A) SOFT CONTACT LENSES	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ADD THE MONOVISION FITTING TECHNIQUE TO THE LABELING OF A SINGLE VISION CONTACT LENS TO MANAGE PRESBYOPIA	11/09/94

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

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR NOVEMBER 1994.

ORIGINAL ABBREVIATED VETERINARY NADAs

200-103	PENICILLIN G	TURKEYS	SANOFI AN HLTH	PENICILLIN G POTASSIUM
18-OCT-94	POTASSIUM		OVERLAND PK, KS	0.5 BILLION IU/
	(POWDER)		66210	11.4OZ(324 GM)

SUPPLEMENTAL VETERINARY NADAs

140-338	NAXCEL	HORSES	UPJOHN	CEFTIOFUR SODIUM
13-JUL-94	(POWDER)		KALAMAZOO, MI	1GM/VIAL
			49001	4GM/VIAL

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

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

18-703 ZANTAC 150 GLAXO RANITIDINE HYDROCHLORIDE
03-NOV-94 (TABLET) RES TRIANGLE PK, NC EQ 150MG BASE
(SUPPL-047) 27709 (NEW INDICATION --
MAINTENANCE OF HEALING
OF EROSIVE ESOPHAGITIS)

18-703 ZANTAC 300 GLAXO RANITIDINE HYDROCHLORIDE
03-NOV-94 (TABLET) RES TRIANGLE PK, NC EQ 300MG BASE
(SUPPL-047) 27709 (NEW INDICATION --
MAINTENANCE OF HEALING
OF EROSIVE ESOPHAGITIS)

19-670 CLARITIN-D SCHERING LORATADINE
14-NOV-94 (TABLET, KENILWORTH, NJ 5MG
(4 S) EXTENDED RELEASE) 07033 (ANTIHISTAMINE)

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

			PSEUDOEPHEDRINE SULFATE
			120MG
			(DECONGESTANT)
20-135	MOTRIN	MCNEIL	IBUPROFEN
16-NOV-94	(TABLET, CHEWABLE)	FORT WASHINGTON, PA	50MG
(3 S)		19034	100MG
			(NONSTEROIDAL
			ANTI-INFLAMMATORY)
20-418	MOTRIN	MCNEIL	IBUPROFEN
16-NOV-94	(TABLET)	FORT WASHINGTON, PA	100MG
(3 S)		19034	(NONSTEROIDAL
			ANTI-INFLAMMATORY)
19-746	EFIDAC 24	ALZA	CHLORPHENIRAMINE MALEATE
18-NOV-94	CHLORPHENIRAMINE	PALO ALTO, CA	16MG
(3 S)	(TABLET,	94303	(ANTIHISTAMINE)
	EXTENDED RELEASE)		(OTC)
20-131	PROHANCE	BRACCO	GADOTERIDOL
21-NOV-94	(INJECTABLE)	PRINCETON, NJ	279.3MG/ML
(SUPPL-001)		08543	(NEW INDICATION --
			USE IN CHILDREN TO
			VISUALIZE LESIONS WITH
			ABNORMAL VASCULARITY IN THE
			BRAIN [INTRACRANIAL
			LESIONS], SPINE AND
			ASSOCIATED TISSUE)
20-131	PROHANCE	BRACCO	GADOTERIDOL
21-NOV-94	(INJECTABLE)	PRINCETON, NJ	279.3MG/ML
(SUPPL-002)		08543	(NEW INDICATION --
			USE IN MRI IN ADULTS
			TO VISUALIZE LESIONS
			IN THE HEAD AND NECK)

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

19-949	DIFLUCAN	PFIZER	FLUCONAZOLE
23-NOV-94	(TABLET)	GROTON, CT	50MG
(SUPPL-012)		06340	100MG
			200MG
			(EXPANDED PATIENT POPULATION -- USE IN PEDIATRIC PATIENTS WITH CRYPTOCOCCAL MENINGITIS AND CANDIDAL INFECTIONS)
19-950	DIFLUCAN	PFIZER	FLUCONAZOLE
23-NOV-94	(INJECTABLE)	NEW YORK, NY	2MG/ML
(SUPPL-016)		10017	(EXPANDED PATIENT POPULATION -- USE IN PEDIATRIC PATIENTS WITH CRYPTOCOCCAL MENINGITIS AND CANDIDAL INFECTIONS)
20-256	NEUROLITE	DUPONT MERCK	TECHNETIUM TC-99M
23-NOV-94	(INJECTABLE)	N BILLERICA, MA	BICISATE KIT
(1 S)		01862	N/A
			(RADIOACTIVE DIAGNOSTIC) [ADJUNCT TO CONVENTIONAL CT OR MRI IMAGING IN THE LOCALIZATION OF STROKE IN PATIENTS IN WHOM STROKE HAS ALREADY BEEN DIAGNOSED]
20-286	MONOPRIL-HCT	BRISTOL MYERS SQUIBB	FOSINOPRIL SODIUM
30-NOV-94	(TABLET)	PRINCETON, NJ	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

(4 S)	08543		HYDROCHLOROTHIAZIDE
			12.5MG
			(ANTIHYPERTENSIVE)
20-286	MONOPRIL-HCT	BRISTOL MYERS SQUIBB	FOSINOPRIL SODIUM
30-NOV-94	(TABLET)	PRINCETON, NJ	20MG
(4 S)	08543		HYDROCHLOROTHIAZIDE
			12.5MG
			(ANTIHYPERTENSIVE)

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.

20-403 ZOFRAN GLAXO ONDANSETRON HYDROCHLORIDE
02-NOV-94 IN DEXTROSE 5% RES TRIANGLE PK, NC EQ 0.08MG BASE/ML
IN PLASTIC CONTAINER 27709 EQ 0.64MG BASE/ML
(INJECTABLE) (ANTIEMETIC)

20-152 SERZONE BRISTOL MYERS SQUIBB NEFAZODONE HYDROCHLORIDE
07-NOV-94 (TABLET) WALLINGFORD, CT 50MG
06492 100MG
150MG
200MG
250MG
300MG
(ANTIDEPRESSANT)

20-388 NAVELBINE BURROUGHS WELLC VINORELBINE TARTRATE
23-NOV-94 (INJECTABLE) RES TRIANGLE PK, NC EQ 10MG BASE/ML
27709 (ANTINEOPLASTIC)
[NON-SMALL CELL LUNG CANCER]

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

ORIGINAL ABBREVIATED NDAs

74-370	GLIPIZIDE	CIRCA	GLIPIZIDE
22-NOV-94	(TABLET)	COPIAGUE, NY	5MG
	11726		10MG
		(BLOOD GLUCOSE REGULATOR)	
74-378	GLIPIZIDE	ENDO LABS	GLIPIZIDE
28-NOV-94	(TABLET)	GARDEN CITY, NY	5MG
	11530		10MG
		(BLOOD GLUCOSE REGULATOR)	
40-088	METHADONE HCL	UDL	METHADONE HYDROCHLORIDE
30-NOV-94	(CONCENTRATE)	LARGO, FL	10MG/ML
	34641	(NARCOTIC ANALGESIC)	
63-263	AMIKACIN	ABBOTT	AMIKACIN SULFATE
30-NOV-94	(INJECTABLE)	ABBOTT PARK, IL	EQ 50MG BASE/ML
	60064	(ANTIBIOTIC, AMINOGLYCOSIDE)	
63-264	AMIKACIN	ABBOTT	AMIKACIN SULFATE
30-NOV-94	(INJECTABLE-VIAL)	ABBOTT PARK, IL	EQ 250MG BASE/ML
	60064	(ANTIBIOTIC, AMINOGLYCOSIDE)	
63-265	AMIKACIN	ABBOTT	AMIKACIN SULFATE
30-NOV-94	(INJECTABLE-SYRINGE)	ABBOTT PARK, IL	EQ 250MG BASE/ML
	60064	(ANTIBIOTIC, AMINOGLYCOSIDE)	
74-436	CYCLOBENZAPRINE HCL	ROYCE LABS	CYCLOBENZAPRINE
30-NOV-94	(TABLET)	MIAMI, FL	HYDROCHLORIDE
	33014		10MG
		(SKELETAL MUSCLE RELAXANT)	

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

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

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

74-104	RANITIDINE HCL	NOVOPHARM	RANITIDINE HYDROCHLORIDE
04-NOV-94	(TABLET)	SCARBOROUGH, ONTARIO CANADA	EQ 150MG BASE EQ 300MG BASE (HISTAMINE H-2 RECEPTOR ANTAGONIST)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-285	MYCIFRADIN	UPJOHN	NEOMYCIN SULFATE
28-OCT-94	(SOLUTION)	KALAMAZOO, MI	125MG/5ML
	49001	(LABELING REVISION -- PRECAUTIONS)	
20-189	FELBATOL	WALLACE	FELBAMATE
01-NOV-94	(SUSPENSION)	CRANBURY, NJ	600MG/5ML
	08512	(LABELING REVISION -- BOXED WARNING; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)	
20-189	FELBATOL	WALLACE	FELBAMATE
01-NOV-94	(TABLET)	CRANBURY, NJ	400MG
	08512	600MG (LABELING REVISION -- BOXED WARNING; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)	
18-024	NUBAIN	DUPONT MERCK	NALBUPHINE HYDROCHLORIDE
02-NOV-94	(INJECTABLE)	GARDEN CITY, NY	10MG/ML
	11530	20MG/ML (LABELING REVISION -- WARNINGS)	
18-703	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(TABLET)	RES TRIANGLE PK, NC	EQ 150MG BASE
	27709	(LABELING REVISION -- ADVERSE REACTIONS)	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-703	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(TABLET)	RES TRIANGLE PK, NC	EQ 300MG BASE
	27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
19-090	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 25MG BASE/ML
	27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
19-593	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	IN PLASTIC CONTAINER	RES TRIANGLE PK, NC	EQ 1MG BASE/ML
	(INJECTABLE) 27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
19-675	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(SYRUP)	RES TRIANGLE PK, NC	EQ 15MG BASE/ML
	27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
20-095	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(CAPSULE)	RES TRIANGLE PK, NC	EQ 150MG BASE
	27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
20-095	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(CAPSULE)	RES TRIANGLE PK, NC	EQ 300MG BASE
	27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
20-251	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(GRANULE,	RES TRIANGLE PK, NC	EQ 150MG BASE/PACKET
	EFFERVESCENT) 27709	(LABELING REVISION --	
		ADVERSE REACTIONS)	
20-251	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
03-NOV-94	(TABLET,	RES TRIANGLE PK, NC	EQ 150MG BASE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

	EFFERVESCENT)	27709	(LABELING REVISION -- ADVERSE REACTIONS)
18-817	CALAN	SEARLE	VERAPAMIL HYDROCHLORIDE
04-NOV-94	(TABLET)	SKOKIE, IL	40MG
		60077	80MG
			120MG
			(LABELING REVISION -- PRECAUTIONS)
20-264	MEGACE	BRISTOL MYERS SQUIBB	MEGESTROL ACETATE
04-NOV-94	(SUSPENSION)	PRINCETON, NJ	40MG/ML
		08543	(LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
19-813	DURAGESIC	ALZA	FENTANYL
07-NOV-94	(FILM, EXTENDED RELEASE)	PALO ALTO, CA	0.6MG/24HR
		94303	1.2MG/24HR
			1.8MG/24HR
			2.4MG/24HR
			(LABELING REVISION -- CLINICAL PHARMACOLOGY; CLINICAL TRIALS; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
50-573	SANDIMMUNE	SANDOZ	CYCLOSPORINE
10-NOV-94	(INJECTABLE)	EAST HANOVER, NJ	50MG/ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		07936	(LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
50-574	SANDIMMUNE	SANDOZ	CYCLOSPORINE
10-NOV-94	(SOLUTION)	EAST HANOVER, NJ	100MG/ML
		07936	(LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
50-625	SANDIMMUNE	SANDOZ	CYCLOSPORINE
10-NOV-94	(CAPSULE)	EAST HANOVER, NJ	25MG
		07936	50MG
			100MG
			(LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
20-095	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
14-NOV-94	(CAPSULE)	RES TRIANGLE PK, NC	EQ 150MG BASE
		27709	(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
20-095	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
14-NOV-94	(CAPSULE)	RES TRIANGLE PK, NC	EQ 300MG BASE
		27709	(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
20-235	NEURONTIN	PARKE DAVIS	GABAPENTIN
14-NOV-94	(CAPSULE)	ANN ARBOR, MI	100MG
		48105	300MG
			400MG
			(LABELING REVISION -- WARNINGS)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20-251	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
14-NOV-94	(GRANULE, EFFERVESCENT)	RES TRIANGLE PK, NC 27709	EQ 150MG BASE/PACKET
		(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	

20-251	ZANTAC 150	GLAXO	RANITIDINE HYDROCHLORIDE
14-NOV-94	(TABLET, EFFERVESCENT)	RES TRIANGLE PK, NC 27709	EQ 150MG BASE
		(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	

19-884	MESNEX	ASTA	MESNA
16-NOV-94	(INJECTABLE)	FRANKFURT, GERMANY	100MG/ML
		(LABELING REVISION -- WARNINGS; PRECAUTIONS)	

20-131	PROHANCE	BRACCO	GADOTERIDOL
21-NOV-94	(INJECTABLE)	PRINCETON, NJ 08543	279.3MG/ML
		(LABELING REVISION -- CLINICAL TRIALS; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)	

50-547	CLAFORAN	HOECHST ROUSSEL	CEFOTAXIME SODIUM
22-NOV-94	(INJECTABLE)	SOMERVILLE, NJ 08876	EQ 500MG BASE/VIAL
		EQ 1GM BASE/VIAL	
		EQ 2GM BASE/VIAL	
		(LABELING REVISION --	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
50-596	CLAFORAN	HOECHST ROUSSEL	CEFOTAXIME SODIUM
22-NOV-94	IN PLASTIC CONTAINER	SOMERVILLE, NJ	EQ 20MG BASE/ML
	(INJECTABLE)	08876	EQ 40MG BASE/ML
			(LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
18-248	OXYTOCIN	FUJISAWA	OXYTOCIN
23-NOV-94	(INJECTABLE)	MELROSE PARK, IL	10 USP UNITS/ML
	60160		(LABELING REVISION -- PRECAUTIONS)
19-949	DIFLUCAN	PFIZER	FLUCONAZOLE
23-NOV-94	(TABLET)	GROTON, CT	50MG
	06340		100MG
			200MG
			(LABELING REVISION -- CLINICAL PHARMACOLOGY; CLINICAL STUDIES; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-950	DIFLUCAN	PFIZER	FLUCONAZOLE
23-NOV-94	(INJECTABLE)	NEW YORK, NY	2MG/ML
	10017		(LABELING REVISION -- CLINICAL PHARMACOLOGY; CLINICAL STUDIES; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
08-453	ANECTINE	BURROUGHS WELLC	SUCCINYLCHOLINE CHLORIDE
28-NOV-94	(INJECTABLE)	RES TRIANGLE PK, NC	20MG/ML
	27709		500MG/VIAL

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			1GM/VIAL (LABELING REVISION -- BOXED WARNING; DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
08-845 28-NOV-94	QUELICIN (INJECTABLE)	ABBOTT LABS ABBOTT PARK, IL 60064	SUCCINYLCHOLINE CHLORIDE 20MG/ML 50MG/ML 100MG/ML (LABELING REVISION -- BOXED WARNING; DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
08-847 28-NOV-94	SUCOSTRIN (INJECTABLE)	SQUIBB NEW BRUNSWICK, NJ 08903	SUCCINYLCHOLINE CHLORIDE 20MG/ML (LABELING REVISION -- BOX WARNING; 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	
			CONTRAINDICATIONS; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
20-151 28-NOV-94	EFFEXOR (TABLET)	WYETH AYERST PHILADELPHIA, PA 19101	VENLAFAXINE HYDROCHLORIDE EQ 25MG BASE EQ 37.5MG BASE EQ 50MG BASE EQ 75MG BASE EQ 100MG BASE (LABELING REVISION -- CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
16-672 29-NOV-94	OVRAL (TABLET)	WYETH AYERST PHILADELPHIA, PA 19101	ETHINYL ESTRADIOL 0.05MG NORGESTREL 0.5MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
16-806 29-NOV-94	OVRAL-28 (TABLET)	WYETH AYERST PHILADELPHIA, PA 19101	ETHINYL ESTRADIOL 0.05MG NORGESTREL 0.5MG (LABELING REVISION -- STD STATEMENT; 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

17-031	OVRETTE	WYETH AYERST	NORGESTREL
29-NOV-94	(TABLET)	PHILADELPHIA, PA	0.075MG
		19101	(LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
17-612	LO/OVRAL	WYETH AYERST	ETHINYL ESTRADIOL
29-NOV-94	(TABLET)	PHILADELPHIA, PA	0.03MG
		19101	NORGESTREL 0.3MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
17-802	LO/OVRAL-28	WYETH AYERST	ETHINYL ESTRADIOL
29-NOV-94	(TABLET)	PHILADELPHIA, PA	0.03MG
		19101	NORGESTREL 0.3MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
18-206	LO/OVRAL-28 AND	WYETH AYERST	ETHINYL ESTRADIOL
29-NOV-94	FERROUS FUMARATE	PHILADELPHIA, PA	0.03MG
	(TABLET)	19101	FERROUS FUMARATE 75MG NORGESTREL 0.3MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
18-668	NORDETTE-21	WYETH AYERST	ETHINYL ESTRADIOL
29-NOV-94	(TABLET)	PHILADELPHIA, PA	0.03MG

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

		19101	LEVONORGESTREL 0.15MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
18-782	NORDETTE-28	WYETH AYERST	ETHINYL ESTRADIOL
29-NOV-94	(TABLET)	PHILADELPHIA, PA	0.03MG
		19101	LEVONORGESTREL 0.15MG (LABELING REVISION -- STD STATEMENT; PATIENT PACKAGE INSERT)
20-189	FELBATOL	WALLACE LABS	FELBAMATE
29-NOV-94	(TABLET)	CRANBURY, NJ	400MG
		08512	600MG (LABELING REVISION -- BOXED WARNING; DESCRIPTION; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; PATIENT INFORMED CONSENT)
20-189	FELBATOL	WALLACE LABS	FELBAMATE
29-NOV-94	(SUSPENSION)	CRANBURY, NJ	600MG/5ML
		08512	(LABELING REVISION -- BOXED WARNING; DESCRIPTION; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

ADVERSE REACTIONS;
PATIENT INFORMED CONSENT)

50-467	ADRIAMYCIN RDF	PHARMACIA	DOXORUBICIN HYDROCHLORIDE
29-NOV-94	(INJECTABLE)	COLUMBUS, OH	10MG/VIAL
		43216	20MG/VIAL
			50MG/VIAL
			150MG/VIAL
			(LABELING REVISION --
			BOXED WARNING;
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			DOSAGE AND ADMINISTRATION)
50-629	ADRIAMYCIN PFS	PHARMACIA	DOXORUBICIN HYDROCHLORIDE
29-NOV-94	(INJECTABLE)	COLUMBUS, OH	2MG/ML
		43216	200MG/100ML
			(LABELING REVISION --
			BOXED WARNING;
			DESCRIPTION;
			CLINICAL PHARMACOLOGY;
			INDICATIONS AND USAGE;

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; DOSAGE AND ADMINISTRATION)
18-482 30-NOV-94	PROCARDIA (CAPSULE)	PFIZER NEW YORK, NY 10017	NIFEDIPINE 10MG 20MG (LABELING REVISION -- PRECAUTIONS)
19-684 30-NOV-94	PROCARDIA XL (TABLET, EXTENDED RELEASE)	PFIZER NEW YORK, NY 10017	NIFEDIPINE 30MG 60MG 90MG (LABELING REVISION -- PRECAUTIONS)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

0384 28-NOV-94	TYPHIM VI (INJECTABLE) (B)	PASTEUR MERIEUX SERUMS ET VACCINS, S.A. LYON, FRANCE	TYPHOID VI POLYSACCHARIDE VACCINE

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 NOVEMBER 1994.

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

P910071 11/04/94	ADATOMED SILICONE OIL OP5000	CHIRON VISION CORPORATION IRVINE, CA 92718-1903	A PROLONGED RETINAL TAMPONADE IN SELECTED CASES OF COMPLICATED RETINAL DETACHMENTS WHERE OTHER INTERVENTIONS ARE NOT APPROPRIATE FOR PATIENT MANAGEMENT

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

P820049/S57	MODELS PC-43NB, PC-44NB, AND PC45NB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	APPROVAL FOR MODELS PC-43NB, PC-44NB, AND PC-45NB ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	10/04/94
P870036/S21	MICROSCAN RAPID PANELS	BAXTER HEALTHCARE CORP MICROSCAN DIV. WEST SACRAMENTO, CA 95691	LABELING CHANGES THAT ADD A LIMITATION STATEMENT	10/04/94
P880082/S17	EYE TECH MDLS	EYE TECHNOLOGY, INC. ST. PAUL, MN 55117	ALTERNATE TRADE NAME ACCUTECH, AND CORRESPONDING MODEL NUMBERS	10/04/94
N17752/S35	HYDROCURVE 3 TORIC AND SOFTMATE II (BUFILCON A) SOFT CONTACT LENSES	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ADD THE MONOVISION FITTING TECHNIQUE TO THE LABELING OF A SINGLE VISION CONTACT LENS TO MANAGE PRESBYOPIA	11/09/94
N50510/S66	VITEK SYSTEMS "GENERAL SUSCEPTIBILITY CARD"	VITEK SYSTEMS, INC. HAZELWOOD, MO 63042-2395	LABELING CHANGE TO INCLUDE AN ADDITIONAL LIMITATIONS STATEMENT REGARDING THE DETECTION OF BETA-LACTAMASE PRODUCING ENTEROCOCCI	11/03/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P800022/S45 11/14/94	ZYDERM COLLAGEN IMPLANT AND ZYPLAST IMPLANT ADJUSTABLE DEPTH GUIDE NEEDLE	COLLAGEN CORPORATION PALO ALTO, CA 94303	LABELING CHANGE FOR THE ADJUSTABLE DEPTH GUIDE NEEDLE
P810046/S152 11/14/94	SIMPSON-ROBERT CORONARY BALLOON DILATION CATHETER ACS RX FLOWTRACK LONG CORONARY DILATION CATHETER WITH A 40MM BALLOON	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE ACS RX FLOWTRACK LONG CORONARY DILATION CATHETER WITH A 40MM BALLOON
P830055/S34 11/30/94	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	CHANGE IN THE PACKAGING PROCESS FOR THE POLYETHYLENE COMPONENTS
P830060/S35 11/23/94	VENTAK AUTOMATIC IMPLANTABLE CARDIOVERTER DEFIBRILLATOR	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	REPLACEMENT OF FREON WITH HEPTANE IN THE MANUFACTURING PROCESS
P840040/S41 11/07/94	HEART TRAK CORONARY BALLOON DILATATION SYSTEM MIGHTY CORONARY BALLOON DILATATION CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172-2414	APPROVAL FOR THE MIGHTY CORONARY BALLOON DILATATION CATHETER
P850036/S1 11/07/94	BAUSCH & LOMB SENSITIVE EYES LENS LUBRICANT	BAUSCH & LOMB ROCHESTER, NY 14692-0450	CHANGE THE STABILITY SPECIFICATION OF SORBIC ACID FOR THE

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

REFERENCED DEVICE

P850064/S10	MODEL 203 LIFE PULSE HIGH FREQUENCY VENTILATOR	BUNNELL INC. SALT LAKE CITY, UT 84115	SOFTWARE CHANGES ASSOCIATED WITH PREVENTING OVERFLOW OF WATER FROM THE HUMIDIFIER TO THE BREATHING CIRCUIT	11/18/94
P850069/S11	KENNEDY LAD LIGAMENT AUGMENTATION DEVICE	3M CENTER ST. PAUL, MN 55133-3275	CHANGE OF MANUFACTURING SITE USED FOR THE BRAIDING, EXTRUSION AND REWINDING PROCEDURES TO GOR-MIL MANUFACTURING COMPANY, MILICA, MN	11/28/94
P860019/S84	SCIMED NC COBRA 18 PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	NEW MODEL OF PTCA CATHETER MARKETED UNDER THE TRADE NAME SCIMED NC COBRA 18 PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER	11/15/94
P860023/S8	BAUSCH & LOMB RENU MULTI-PURPOSE SOLUTION TRAVELER	BAUSCH & LOMB ROCHESTER, NY 14692-0450	ALTERNATE PACKAGING PROCESS AND PACKAGING DESIGN. THERE ARE NO	11/07/94

APPLICATION NO. / APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
			CHANGES IN PRODUCT FORMULA OR INDICATIONS FOR USE
P870036/S25 11/09/94	MEDTRONIC THRUFLEX II, 18K, AND 14K PTCA CATHETERS	MEDTRONIC INTERVENTIONAL VASCUL SAN DIEGO, CA 92121-2256	ALTERNATE METHOD OF INSPECTING CATHETER LOTS PRIOR TO RELEASE
P880090/S14 11/29/94	MODELS 121UV AND S121UV ULTRAVIOLET ABSORBING ANTERIOR CHAMBER INTRAOCULAR LENSES (IOLS)	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	APPROVAL FOR MODELS M121UV AND M122UV; PRIVATE LABEL DISTRIBUTING; LABELING REVISIONS
P890003/S27 11/29/94	MODEL 9790 PROGRAMMER WITH THE MODELS 9870E, 9871E, AND 9872E SOFTWARE DISKETTES	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MODEL 9790 PROGRAMMER AND THE MODELS 9870E, 9871E, AND 9872E SOFTWARE DISKETTES
P890012/S3 11/09/94	GENTLE TOUCH (NETRAFILCON A) SOFT CONTACT LENSES	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ADD THE MONOVISION FITTING TECHNIQUE TO THE LABELING OF A SINGLE VISION CONTACT LENS TO MANAGE PRESBYOPIA
P890070/S2	PURE-DENT B851	GRAIN PROCESSING	CHANGE PH RANGE TO

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
		CORPORATION MUSCATINE, IA 52761-0349	4.0-6.0, TO BE MARKETED UNDER THE NEW TRADE NAME PURE-DENT B851	11/30/94
P900023/S9	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	SOFTWARE CHANGE FOR THE ABIOMED BVS 5000 BLOOD PUMP TO QUICKEN THE LOW PRESSURE AND LOW FLOW ALARM RESPONSE TIME	11/17/94
P900030/S2	CONTIGEN BARD COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303	ALTERNATIVE MANUFACTURING PROCESS (CROSS-FLOW FILTRATION) THAT WAS PREVIOUSLY APPROVED FOR ZYDERM AND ZYPLAST COLLAGEN IMPLANTS	11/23/94
P910001/S7	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORPORATION COLORADO SPRINGS, CO 80907-5159	APPROVAL FOR INCLUSION OF ADDITIONAL SALINE INFUSION INSTRUCTIONS INTO THE INSTRUCTION FOR USE OF THE SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM	11/15/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P910071/S1	ADATO SIL 5000	CHIRON VISION CORPORATION IRVINE, CA 92718-1903	TRADE NAME CHANGE FOR ADATOMED SILICONE OIL OP5000 TO ADATO SIL 5000. INDICATED FOR PROLONGED RETINAL TAMPONADE IN SELECTED CASES OF COMPLICATED RETINAL DETACHMENTS	11/30/94
P910073/S4	ENDOTAK LEAD SYSTEM	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	REPLACEMENT OF FREON WITH HEPTANE IN THE MANUFACTURING PROCESS	11/23/94
P910077/S1	VENTAK PRX AICD SYSTEM	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	REPLACEMENT OF FREON WITH HEPTANE IN THE MANUFACTURING PROCESS	11/23/94
P940013/S2	PRECISION UV (VASURFILCON A) SOFT CONTACT LENSES	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ADD THE MONOVISION FITTING TECHNIQUE TO THE LABELING OF A SINGLE VISION CONTACT LENS TO MANAGE PRESBYOPIA	11/09/94

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

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR NOVEMBER 1994.

ORIGINAL ABBREVIATED VETERINARY NADAs

200-103	PENICILLIN G	TURKEYS	SANOFI AN HLTH	PENICILLIN G POTASSIUM
18-OCT-94	POTASSIUM		OVERLAND PK, KS	0.5 BILLION IU/
	(POWDER)		66210	11.4OZ(324 GM)

SUPPLEMENTAL VETERINARY NADAs

140-338	NAXCEL	HORSES	UPJOHN	CEFTIOFUR SODIUM
13-JUL-94	(POWDER)		KALAMAZOO, MI	1GM/VIAL
			49001	4GM/VIAL

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
Julie Stuart (301) 594-2186

Center for Biologics Evaluation and Research
Joyce Bagley (301) 594-2906

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

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-243 | LUVOX | SOLVAY | FLUVOXAMINE MALEATE
05-DEC-94 | (TABLET) | MARIETTA, GA | 25MG*
(1 S) | | 30062 | 50MG
100MG
150MG*
(SEROTONIN REUPTAKE INHIBITOR)
[OBSESSIVE-COMPULSIVE DISORDER]

19-698 | TORADOL | SYNTEX | KETOROLAC TROMETHAMINE
07-DEC-94 | (INJECTABLE) | PALO ALTO, CA | 15MG/ML
(SUPPL-011) | | 94303 | 30MG/ML
(NEW ROUTE -- INTRAVENOUS ADMINISTRATION)

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

19-946	NUROMAX	BURROUGHS WELLC	DOXACURIUM CHLORIDE
08-DEC-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 1MG BASE/ML
(SUPPL-002)		27709	(EXPANDED PATIENT POPULATION -- USE IN ICU PATIENTS)

20-408	TRUSOPT	MERCK	DORZOLAMIDE HYDROCHLORIDE
09-DEC-94	(SOLUTION/DROPS)	WEST POINT, PA	EQ 2% BASE
(1 P)		19486	(CARBONIC ANHYDRASE INHIBITOR) [TREATMENT OF ELEVATED INTRAOCULAR PRESSURE IN PATIENTS WITH OCULAR HYPERTENSION OR OPEN-ANGLE GLAUCOMA]

* - Not Marketed At This Time

20-347	HYTRIN	ABBOTT	TERAZOSIN HYDROCHLORIDE
14-DEC-94	(CAPSULE)	ABBOTT PARK, IL	EQ 1MG BASE
(3 S)		60064	EQ 2MG BASE EQ 5MG BASE EQ 10MG BASE (ALPHA-1 ADENORECEPTOR BLOCKER)

20-058	THIOPLEX	LEDERLE	THIOTEPA
22-DEC-94	(INJECTABLE)	PEARL RIVER, NY	15MG/VIAL
(3 S)		10965	(ALKYLATING AGENT)

20-152	SERZONE	BRISTOL MYERS SQUIBB	NEFAZODONE HYDROCHLORIDE
22-DEC-94	(TABLET)	WALLINGFORD, CT	50MG*
(1 S)		06492	100MG 150MG 200MG 250MG

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

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

			300MG*
			(ANTIDEPRESSANT)
20-287	FRAGMIN	PHARMACIA	DALTEPARIN SODIUM
22-DEC-94	(INJECTABLE)	COLUMBUS, OH	2500IU/0.2ML
(1 S)		43216	(LOW MOLECULAR
			WEIGHT HEPARIN)
			[PROPHYLAXIS AGAINST
			DEEP VEIN THROMBOSIS]
20-375	CLIMARA	3M	ESTRADIOL
22-DEC-94	(FILM,	ST PAUL, MN	0.05MG/24HR
(5 S)	EXTENDED RELEASE)	55144	0.1MG/24HR
			(ESTROGEN)
20-460	CYTOVENE	SYNTEX	GANCICLOVIR
22-DEC-94	(CAPSULE)	PALO ALTO, CA	250MG
(3 P)		94304	(ANTIVIRAL)
			[MAINTENANCE TREATMENT
			OF CMV RETINITIS]

* - Not Marketed At This Time

20-388	NAVELBINE	BURROUGHS WELLC	VINORELBINE TARTRATE
23-DEC-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 10MG BASE/ML
(1 P)		27709	(ANTINEOPLASTIC)
			[NON-SMALL CELL LUNG CANCER]
20-241	LAMICTAL	BURROUGHS WELLC	LAMOTRIGINE
27-DEC-94	(TABLET)	RES TRIANGLE PK, NC	25MG
(1 P)		27709	50MG*
			100MG
			150MG
			200MG
			250MG*
			(ANTICONVULSANT)

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

[ADJUNCTIVE THERAPY IN
THE TREATMENT OF PARTIAL
SEIZURES IN ADULTS WITH
EPILEPSY]

20-240	RENORMAX	SANDOZ	SPIRAPRIL HYDROCHLORIDE
29-DEC-94	(TABLET)	EAST HANOVER, NJ	3MG
(1 S)		07936	6MG
			12MG
			24MG
			(ANGIOTENSIN CONVERTING
			ENZYME INHIBITOR)
			[HYPERTENSION]
20-357	GLUCOPHAGE	LIPHA	METFORMIN HYDROCHLORIDE
29-DEC-94	(TABLET)	NEW YORK, NY	500MG
(1 P)		10019	850MG
			(BLOOD GLUCOSE REGULATOR)
18-932	REVIA	DUPONT MERCK	NALTREXONE HYDROCHLORIDE
30-DEC-94	(TABLET)	GARDEN CITY, NY	50MG
(SUPPL-010)		11530	(NEW INDICATION --
			TREATMENT OF ALCOHOL
			DEPENDENCE)

* - Not Marketed At This Time

20-303	PREMPHASE	WYETH AYERST	CONJUGATED ESTROGENS
30-DEC-94	(PREMARIN/CYCRIN 14/14)	PHILADELPHIA, PA	0.625MG
(4 S)	(TABLET 28-DAY)	19101	(ESTROGEN)
			MEDROXYPROGESTERONE ACETATE
			5MG
			(PROGESTIN)
20-303	PREMPRO	WYETH AYERST	CONJUGATED ESTROGENS

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

30-DEC-94	(PREMARIN/CYCRIN 14/14)	PHILADELPHIA, PA	0.625MG
(4 S)	(TABLET 28-DAY)	19101	(ESTROGEN)
			MEDROXYPROGESTERONE ACETATE
			2.5MG
			(PROGESTIN)
20-474	VEXOL	ALCON	RIMEXOLONE
30-DEC-94	(SUSPENSION/DROPS)	FORT WORTH, TX	1%
(1 P)		76115	(CORTICOSTEROID)
			[TREATMENT OF POSTOPERATIVE
			INFLAMMATION FOLLOWING
			OCULAR SURGERY AND IN THE
			TREATMENT OF ANTERIOR
			UVEITIS]

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.

50-673	CECLOR CD	LILLY	CEFACLOR
28-DEC-94	(TABLET)	INDIANAPOLIS, IN	EQ 375MG BASE
	46285		EQ 500MG BASE
		(ANTIBIOTIC, CEPHEM)	

50-685	CEDAX	SCHERING	CEFTIBUTEN
29-DEC-94	(CAPSULE)	KENILWORTH, NJ	400MG
	07033	(ANTIBIOTIC, CEPHEM)	

50-686	CEDAX	SCHERING	CEFTIBUTEN
29-DEC-94	(POWDER,	KENILWORTH, NJ	90MG/5ML
	FOR ORAL SUSPENSION)	07033	180MG/5ML
		(ANTIBIOTIC, CEPHEM)	

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

ORIGINAL ABBREVIATED NDAs

74-495	NAPROXEN SODIUM	INVAMED	NAPROXEN SODIUM
05-DEC-94	(TABLET)	DAYTON, NJ	EQ 250MG BASE
		08810	EQ 500MG BASE
			(NONSTEROIDAL ANTI-INFLAMMATORY)
74-119	PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN	LEMMON	ACETAMINOPHEN
19-DEC-94		SELLERSVILLE, PA	650MG
	(TABLET)	18960	PROPOXYPHENE NAPSYLATE 100MG
			(ANALGESIC)
74-353	CIMETIDINE HCL	LUITPOLD	CIMETIDINE HYDROCHLORIDE
20-DEC-94	(INJECTABLE)	SHIRLEY, NY	EQ 300MG BASE/2ML
		11967	(HISTAMINE H2-RECEPTOR ANTAGONIST)
74-251	CIMETIDINE HCL	ENDO LABS	CIMETIDINE HYDROCHLORIDE
22-DEC-94	(SOLUTION)	GARDEN CITY, NY	EQ 300MG BASE/5ML
		11530	(HISTAMINE H2-RECEPTOR ANTAGONIST)
74-361	CIMETIDINE	ROXANE	CIMETIDINE
23-DEC-94	(TABLET)	COLUMBUS, OH	300MG
		43216	400MG
			(HISTAMINE H2-RECEPTOR ANTAGONIST)
74-371	CIMETIDINE	ROXANE	CIMETIDINE
23-DEC-94	(TABLET)	COLUMBUS, OH	800MG
		43216	(HISTAMINE H2-RECEPTOR ANTAGONIST)
74-269*	CIMETIDINE HCL IN	ABBOTT	CIMETIDINE HYDROCHLORIDE

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

ORIGINAL ABBREVIATED NDAs

27-DEC-94	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT PARK, IL 60064	EQ 6MG BASE/ML (HISTAMINE H2-RECEPTOR ANTAGONIST)

* - First Time Product Available Generically

40-066	SULFACETAMIDE SODIUM	BAUSCH AND LOMB	SULFACETAMIDE SODIUM
28-DEC-94	(SOLUTION/DROPS)	TAMPA, FL 33637	10% (ANTIBACTERIAL)

89-997	ACETAMINOPHEN AND	ROYCE LABS	ACETAMINOPHEN
28-DEC-94	CODEINE PHOSPHATE	MIAMI, FL	300MG
	(TABLET)	33014	CODEINE PHOSPHATE 15MG (ANALGESIC)

89-998	ACETAMINOPHEN AND	ROYCE LABS	ACETAMINOPHEN
28-DEC-94	CODEINE PHOSPHATE	MIAMI, FL	300MG
	(TABLET)	33014	CODEINE PHOSPHATE 30MG (ANALGESIC)

89-999	ACETAMINOPHEN AND	ROYCE LABS	ACETAMINOPHEN
28-DEC-94	CODEINE PHOSPHATE	MIAMI, FL	300MG
	(TABLET)	33014	CODEINE PHOSPHATE 60MG (ANALGESIC)

74-468*	CIMETIDINE HCL IN	ABBOTT	CIMETIDINE HYDROCHLORIDE
29-DEC-94	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT PARK, IL 60064	EQ 90MG BASE/100ML EQ 120MG BASE/100ML EQ 180MG BASE/100ML EQ 240MG BASE/100ML EQ 360MG BASE/100ML

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

ORIGINAL ABBREVIATED NDAs

			EQ 480MG BASE/100ML
			(HISTAMINE H2-RECEPTOR
			ANTAGONIST)
63-186	CEPHALEXIN	APOTHECON	CEPHALEXIN
30-DEC-94	(CAPSULE)	PRINCETON, NJ	EQ 250MG BASE
		08543	EQ 500MG BASE
			(ANTIBIOTIC, CEPHEM)

* - First Time Product Available Generically

72-933	FLUOCINONIDE	FOUGERA	FLUOCINONIDE
30-DEC-94	(GEL)	MELVILLE, NY	0.05%
		11747	(CORTICOSTEROID)

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

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

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

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVAL FOR DECEMBER 1994.

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

11-793	ESIDRIX	CIBA	HYDROCHLOROTHIAZIDE
01-DEC-94	(TABLET)	SUMMIT, NJ	25MG
		07901	50MG
			100MG
			(LABELING REVISION -- PRECAUTIONS)
12-489	EXNA	ROBINS	BENZTHIAZIDE
01-DEC-94	(TABLET)	RICHMOND, VA	50MG
		23220	(LABELING REVISION -- PRECAUTIONS; HOW SUPPLIED)
16-042	DYAZIDE	SMITHKLINE	HYDROCHLOROTHIAZIDE
01-DEC-94	(CAPSULE)	KING OF PRUSSIA, PA	25MG
		19406	TRIAMTERENE
			37.5MG
			(LABELING REVISION -- CLINICAL PHARMACOLOGY)
19-501	ROGAINE	UPJOHN	MINOXIDIL
01-DEC-94	(SOLUTION)	KALAMAZOO, MI	2%
		49001	(LABELING REVISION -- CLINICAL PHARMACOLOGY; CLINICAL TRIAL EXPERIENCE - MALES; CLINICAL TRIAL EXPERIENCE - FEMALES; PRECAUTIONS; ADVERSE REACTIONS; IMPORTANT INFORMATION)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20-246	DEPO-PROVERA	UPJOHN	MEDROXYPROGESTERONE ACETATE
01-DEC-94	(INJECTABLE)	KALAMAZOO, MI	150MG/ML
	49001	(LABELING REVISION --	
		STD WARNING;	
		INDICATIONS AND USAGE;	
		WARNINGS;	
		ADVERSE REACTIONS;	
		DOSAGE AND ADMINISTRATION;	
		PATIENT PACKAGE INSERT)	
06-460	PROTAMINE SULFATE	LILLY	PROTAMINE SULFATE
06-DEC-94	(INJECTABLE)	INDIANAPOLIS, IN	10MG/ML
	46285	(LABELING REVISION --	
		DESCRIPTION;	
		PRECAUTIONS;	
		HOW SUPPLIED)	
19-645	TORADOL	SYNTEX LABS	KETOROLAC TROMETHAMINE
07-DEC-94	(TABLET)	PALO ALTO, CA	10MG
	94303	(LABELING REVISION --	
		BOXED WARNING;	
		INDICATIONS AND USAGE;	
		CONTRAINDICATIONS;	
		DOSAGE AND ADMINISTRATION)	
19-698	TORADOL	SYNTEX LABS	KETOROLAC TROMETHAMINE
07-DEC-94	(INJECTABLE)	PALO ALTO, CA	15MG/ML
	94303		30MG/ML

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			(LABELING REVISION -- BOXED WARNING; INDICATIONS AND USAGE; CONTRAINDICATIONS; DOSAGE AND ADMINISTRATION)
20-214	ZEMURON	ORGANON	ROCURONIUM BROMIDE
07-DEC-94	(INJECTABLE)	WEST ORANGE, NJ	10MG/ML
	07052		(LABELING REVISION -- PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
20-214	ZEMURON (P/F)	ORGANON	ROCURONIUM BROMIDE
07-DEC-94	(INJECTABLE)	WEST ORANGE, NJ	10MG/ML
	07052		(LABELING REVISION -- PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
18-922	LODINE	WYETH AYERST	ETODOLAC
08-DEC-94	(CAPSULE)	PHILADELPHIA, PA	200MG
	19101		300MG (LABELING REVISION -- DESCRIPTION; ADVERSE REACTIONS; HOW SUPPLIED)
18-922	LODINE	WYETH AYERST	ETODOLAC
08-DEC-94	(TABLET)	PHILADELPHIA, PA	400MG
	19101		(LABELING REVISION -- DESCRIPTION; ADVERSE REACTIONS; HOW SUPPLIED)

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-946	NUROMAX	BURROUGHS WELLC	DOXACURIUM CHLORIDE
08-DEC-94	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 1MG BASE/ML
	27709	(LABELING REVISION --	
		PRECAUTIONS;	
		INDICATIONS AND USAGE;	
		DOSAGE AND ADMINISTRATION)	
16-640	QUESTRAN	BRISTOL MYERS	CHOLESTYRAMINE
12-DEC-94	(POWDER)	EVANSVILLE, IN	EQ 4GM RESIN/PACKET
	47721	EQ 4GM RESIN/SCOOPFUL	
		(LABELING REVISION --	
		PRECAUTIONS;	
		ADVERSE REACTIONS;	
		DOSAGE AND ADMINISTRATION)	
19-669	QUESTRAN LIGHT	BRISTOL MYERS	CHOLESTYRAMINE
12-DEC-94	(POWDER)	EVANSVILLE, IN	EQ 4GM RESIN/PACKET
	47721	EQ 4GM RESIN/SCOOPFUL	
		(LABELING REVISION --	
		PRECAUTIONS;	
		ADVERSE REACTIONS;	
		DOSAGE AND ADMINISTRATION)	
06-008	MESANTOIN	SANDOZ	MEPHENYTOIN
14-DEC-94	(TABLET)	E HANOVER, NJ	100MG
	07936	(LABELING REVISION --	
		DESCRIPTION;	
		HOW SUPPLIED)	
20-057	CEREDASE	GENZYME	ALGLUCERASE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

14-DEC-94	(INJECTABLE)	BOSTON, MA	10 UNITS/ML
	02111		80 UNITS/ML
		(LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)	
11-635	DIUPRES-250	MSD	CHLOROTHIAZIDE
16-DEC-94	(TABLET)	WEST POINT, PA	25OMG
	19486		RESERPINE 0.125MG
		(LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)	
11-635	DIUPRES-500	MSD	CHLOROTHIAZIDE
16-DEC-94	(TABLET)	WEST POINT, PA	50OMG
	19486		RESERPINE 0.125MG
		(LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)	
11-958	HYDROPRES 25	MSD	HYDROCHLOROTHIAZIDE
16-DEC-94	(TABLET)	WEST POINT, PA	25MG
	19486		RESERPINE 0.125MG
		(LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)	
11-958	HYDROPRES 50	MSD	HYDROCHLOROTHIAZIDE

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

16-DEC-94	(TABLET)	WEST POINT, PA	50MG
	19486	RESERPINE	
		0.125MG	
		(LABELING REVISION --	
		CONTRAINDICATIONS;	
		PRECAUTIONS)	
13-400	ALDOMET	MSD	METHYLDOPA
16-DEC-94	(TABLET)	WEST POINT, PA	125MG
	19486	250MG	
		500MG	
		(LABELING REVISION --	
		CONTRAINDICATIONS;	
		PRECAUTIONS)	
13-401	ALDOMET	MSD	METHYLDOPATE HYDROCHLORIDE
16-DEC-94	(INJECTABLE)	WEST POINT, PA	50MG/ML
	19486	(LABELING REVISION --	
		CONTRAINDICATIONS;	
		PRECAUTIONS)	
13-402	ALDORIL 15	MERCK	HYDROCHLOROTHIAZIDE
16-DEC-94	(TABLET)	WEST POINT, PA	15MG
	19486	METHYLDOPA	
		250MG	
		(LABELING REVISION --	
		CONTRAINDICATIONS;	
		PRECAUTIONS)	
13-402	ALDORIL 25	MERCK	HYDROCHLOROTHIAZIDE
16-DEC-94	(TABLET)	WEST POINT, PA	25MG
	19486	METHYLDOPA	

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			250MG
			(LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)
13-402	ALDORIL D30	MERCK	HYDROCHLOROTHIAZIDE
16-DEC-94	(TABLET)	WEST POINT, PA	30MG
	19486		METHYLDOPA
			500MG
			(LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)
13-402	ALDORIL D50	MERCK	HYDROCHLOROTHIAZIDE
16-DEC-94	(TABLET)	WEST POINT, PA	50MG
	19486		METHYLDOPA
			500MG
			(LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)
16-016	ALDOCLOR-150	MSD	CHLOROTHIAZIDE
16-DEC-94	(TABLET)	WEST POINT, PA	150MG
	19486		METHYLDOPA
			250MG
			(LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)
16-016	ALDOCLOR-250	MSD	CHLOROTHIAZIDE
16-DEC-94	(TABLET)	WEST POINT, PA	250MG
	19486		METHYLDOPA
			250MG
			(LABELING REVISION --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

			CONTRAINDICATIONS;
			PRECAUTIONS)
18-389	ALDOMET	MSD	METHYLDOPA
16-DEC-94	(SUSPENSION)	WEST POINT, PA	250MG/5ML
	19486	(LABELING REVISION --	
		CONTRAINDICATIONS;	
		PRECAUTIONS)	
11-300	PARAFLEX	RW JOHNSON	CHLORZOXAZONE
19-DEC-94	(TABLET)	SPRING HOUSE, PA	250MG
	19477	(LABELING REVISION --	
		WARNINGS;	
		ADVERSE REACTIONS)	
11-529	PARAFON FORTE DSC	RW JOHNSON	CHLORZOXAZONE
19-DEC-94	(TABLET)	SPRING HOUSE, PA	500MG
	19477	(LABELING REVISION --	
		WARNINGS;	
		ADVERSE REACTIONS)	
11-751	PROLIXIN	APOTHECON	FLUPHENAZINE HYDROCHLORIDE
20-DEC-94	(TABLET)	PRINCETON, NJ	1MG
	08543		2.5MG
			5MG
			10MG
			(LABELING REVISION --
			HOW SUPPLIED)
19-643	MEVACOR	MERCK	LOVASTATIN
21-DEC-94	(TABLET)	WEST POINT, PA	10MG
	19486		20MG
			40MG
			(LABELING REVISION --
			WARNINGS;

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

PRECAUTIONS;
ADVERSE REACTIONS;
HOW SUPPLIED)

19-766	ZOCOR	MERCK	SIMVASTATIN
21-DEC-94	(TABLET)	WEST POINT, PA	5MG
	19486		10MG
			20MG
			40MG
			(LABELING REVISION --
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS)
20-236	SEREVENT	GLAXO	SALMETEROL XINAFOATE
23-DEC-94	(AEROSOL, METERED)	RES TRIANGLE PK, NC	EQ 0.021MG BASE/INH
	27709		(LABELING REVISION --
			WARNINGS; PRECAUTIONS;
			ADVERSE REACTIONS;
			PATIENT INSTRUCTIONS)
10-909	MIRADON	SCHERING	ANISINDIONE
30-DEC-94	(TABLET)	KENILWORTH, NJ	50MG
	07033		(LABELING REVISION --
			WARNINGS; PRECAUTIONS;
			DOSAGE AND ADMINISTRATION;
			HOW SUPPLIED)
18-932	REVIA	DUPONT MERCK	NALTREXONE HYDROCHLORIDE
30-DEC-94	(TABLET)	GARDEN CITY, NY	50MG
	11530		(LABELING REVISION --

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

LABELING SUPPLEMENTS TO ORIGINAL NDAs

NEW TRADE NAME)

18-932 30-DEC-94	REVIA (TABLET) 11530	DUPONT MERCK GARDEN CITY, NY	NALTREXONE HYDROCHLORIDE 50MG (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
20-180 30-DEC-94	PROSCAR (TABLET) 19486	MSD WEST POINT, PA	FINASTERIDE 5MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

0017 06-DEC-94	NONE (INJECTABLE) 10965	LEDERLE PEARL RIVER, NY	HAEMOPHILUS B CONJUGATE VACCINE (DIPHTHERIA CRM197 PROTEIN CONJUGATE)
1178 22-DEC-94	REOPRO (INJECTABLE)	CENTOCOR B V NETHERLANDS, NL	ABOIXIMAB (ADJUNCT TO PTCA TO PREVENT ACUTE CARDIAC ISCHEMIC COMPLICATIONS IN PATIENTS AT HIGH RISK FOR ABRUPT CLOSURE OF THE TREATED CORONARY VESSEL) (A&B)

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

BIOLOGICAL PRODUCT LICENSES ISSUED

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

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK940036 22-DEC-94	NONE	BAXTER HLTHCARE ROUND LAKE, IL 60073	PLASTIC PLATELET STORAGE CONTAINERS (C)
BP910001 23-DEC-94	ORASURE	EPITOPE BEAVERTON, OR 97005	HIV-1 ORAL SPECIMEN COLLECTION DEVICE (D)
BK940055 27-DEC-94	NONE	FUTUREMED AMERICA DEER PK, NY 11729	EMPTY FLUID WARMING BAG (C)
BK940056 27-DEC-94	NONE	LEVEL 1 TECH ROCKLAND, MA 02370	LEVEL 1 FLUID WARMER (C)
BK940062 27-DEC-94	CRYOCYTE	BAXTER HLTHCARE ROUND LAKE, IL 60073	FREEZING CONTAINERS (C)

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

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent
(D) Approved

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

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

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

P930014 12/22/94	ACRYSOF MODELS MA60BM & MA30BA ULTRAVIOLET-ABSORBING ACRYLIC FOLDABLE UV-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES (IOLS)	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	INDICATED FOR REPLACEMENT OF HUMAN LENS FOR VISUAL CORRECTION OF APHAKIA IN PATIENTS 60 YEARS AND OLDER

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

N17004/S4	SURGICAL SIMPLEX P RADIOPAQUE BONE CEMENT	HOWMEDICA, INC. RUTHERFORD, NJ 07070-2584	APPROVAL FOR MANUFACTURING OF POWDER COMPONENT OF THE CEMENT AT RAHEEN INDUSTRIAL ESTATE, LIMERICK, IRELAND	12/30/94
N17908/S46	ALCON SALINE SOLUTION	ALCON LABORATORIES, INC. FORTH WORTH, TX 76134-2099	APPROVAL TO MODIFY THE "WARNINGS" SECTION AND THE "DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	12/13/94
N17945/S27	ADAPETTES LUBRICATING AND REWETTING SOLUTION	ALCON LABORATORIES, INC. FORTH WORTH, TX 76134-2099	APPROVAL TO MODIFY THE "WARNINGS" SECTION AND THE "DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	12/13/94
N17974/S47	PREFLEX DAILY CLEANING SOLUTION	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MODIFY THE "WARNINGS" SECTION AND THE "DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	12/13/94
N18143/S32	FLEX-CARE RINSING, DISINFECTING, AND	ALCON LABORATORIES, INC. FORTH WORTH, TX 76134-2099	APPROVAL TO MODIFY THE "WARNINGS" SECTION AND THE	12/13/94

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE	APPROVAL DATE
MEDICAL DEVICE - PMA SUPPLEMENTALS				
	STORAGE SOLUTION		"DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	
N18331/S24	PDS II (POLYDIOXANONE) SUTURE, DYED AND UNDYED	ETHICON, INC. SOMERVILLE, NJ 08876-0151	APPROVAL FOR USE OF A SINGLE PEELABLE PRIMARY FOIL PACKAGE FOR USE IN PDS II SUTURES	12/21/94
N50510/S65	VITEK SYSTEMS GENERAL SUSCEPTIBILITY CARD	BIOMERIEUX VITEK, INC. HAZELWOOD, MO 63042-2395	APPROVAL FOR SUSCEPTIBILITY TESTING OF ENTEROCOCCI WITH AMPICILLIN	12/14/94
P790011/S20	UNISOL 4 SALINE SOLUTION AND UNISOL-PLUS SALINE SOLUTION	ALCON LABORATORIES, INC. FORTH WORTH, TX 76134-2099	APPROVAL TO MODIFY THE "WARNINGS" SECTION AND THE "DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	12/13/94
P800026/S10	PLIAGEL CLEANING SOLUTION	ALCON LABORATORIES, INC. FORTH WORTH, TX 76134-2099	APPROVAL TO MODIFY THE "WARNINGS" SECTION AND THE "DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	12/13/94
P800034/S15	CLERZ LUBRICATING AND REWETTING	ALCON LABORATORIES, INC. FORT WORTH, TX	APPROVAL TO MODIFY THE "WARNINGS"	12/13/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

	DROPS AND CLERZ 2 LUBRICATING AND REWETTING DROPS	76134-2099	SECTIONS AND THE "DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	
P810055/S63	MODEL 809A ULTRAVIOLET LIGHT-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS	PHARMACIA INC. OPHTHALMICS MONROVIA, CA 91017-7136	APPROVAL FOR MODEL 809A ULTRAVIOLET LIGHT-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS & TO USE THE CEEON TRADE NAME	12/02/94
P820001/S17	OPTI-ZYME ENZYMATIC CLEANER, OPTI-FREE ENZYMATIC CLEANER, AND SUPRA-ZYME ENZYMATIC CLEANER	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MODIFY "WARNINGS" SECTION AND THE "DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	12/13/94
P820036/S12	OPTI-CLEAN DAILY CLEANER	ALCON LABORATORIES, INC. FORTH WORTH, TX 76134-2099	APPROVAL TO MODIFY THE "WARNINGS" SECTION AND THE "DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	12/13/94
P830023/S7	MIRASEPT SYSTEM	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MODIFY THE "WARNINGS" SECTION AND THE "DIRECTIONS FOR USE" SECTION OF THE PACKAGE INSERT	12/13/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P830034/S25	OPTI-CLEAN II & OPTI-FREE DAILY CLEANER, OPTI-FREE REWETTING DROPS, RINSING, DISINFECTING, & STORAGE SOLUTION, OPTI-TEARS SOOTHING DROPS, OPTI-SOFT DISINFECTING SOLUTION & OPTI-ONE MULTI-PURPOSE SOLUTION	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MODIFY THE "WARNINGS" SECTION AND THE "DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	12/13/94
P830045/S48	MODEL 3026 ECG CABLE ASSEMBLY AND MODEL 3027 THREE-LEAD PATIENT ECG CABLE ASSEMBLY	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	APPROVAL FOR MODEL 3026 ECG CABLE ASSEMBLY AND MODEL 3027 THREE-LEAD PATIENT ECG CABLE ASSEMBLY	12/13/94
P830055/S21	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	APPROVAL FOR ADDITIONAL MANUFACTURING FACILITY AT ST.ANTHONY'S ROAD, LEEDS, ENGLAND	12/19/94
P830061/S24	STER TIP PACING LEAD MODELS 4003 & 4503 MEDTRONIC CAPSURE SP TRANSVENOUS PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	NEW DISTRIBUTOR VITATRON, INC., OF APPROVED PACING LEADS - MARKETED UNDER THE TRADE NAME EXCELLENCE+	12/12/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P830071/S5	OPTI-SOAK CONDITIONING SOLUTION	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MODIFY "WARNINGS" SECTION AND THE "DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	12/13/94
P840068/S20	DELTA PACING SYSTEM VISTA 6 MODEL 448 AND 449 PULSE GENERATORS	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	APPROVAL TO COMMERCIALLY DISTRIBUTE THE VISTA 6 PULSE GENERATOR MODELS 448 AND 449, AND MODEL 2057 SOFTWARE MODULE	12/08/94
P850009/S7	CENTOCOR CA 125 II	CENTOCOR, INC. MALVERN, PA 19355-1307	DEVICE MODIFICATIONS MARKETED UNDER THE TRADE NAME CENTOCOR CA 125 II	12/21/94
P850021/S27	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER LONG DISTANCE PTCA CATHETER	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	APPROVAL FOR LONG DISTANCE PTCA CATHETER	12/13/94
P850023/S14	HEMOTENE (NOVACOL ABSORBABLE COLLAGEN HEMOSTAT) HEMOPAD (FIBRILLAR COLLAGEN)	BIOPLEX CORPORATION MONTVALE, NJ 07645	APPROVAL FOR NEW MANUFACTURING FACILITY FOR NOVACOL AT 11 SELZERBEEKLAAN, VAALS, THE NETHERLANDS	12/22/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P850035/S17	EBI SPF SPINAL FUSION STIMULATOR	ELECTRO-BIOLOGY, INC. PARSIPPANY, NJ 07054-1079	APPROVAL FOR PRECAUTIONARY AND WARNING STATEMENTS RE:MRI, AS WELL AS A STATEMENT RE:EXPLANATION OF THE DEVICE FOLLOWING TREATMENT COMPLETION	12/21/94
P850089/S29	STER TIP PACING LEAD MODELS 5025 AND 5525 CAPSURE SP MODELS 5024M AND 5524M AND CPI DEXATIP MODEL 4262 PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR ADDITION OF A NEW STYLET TO THE STERILE PACKAGE OF THE MODELS 5024M AND 4262 LEADS AND DESIGN CHANGES TO THE MODEL 5524M LEAD	12/08/94
P850089/S31	STER TIP PACING LEAD MODELS 5025 AND 5525 MEDTRONIC CAPSURE SP TRANSVENOUS PACING LEADS, MODELS 5023M, 5024M, AND 5524M	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR NEW DISTRIBUTOR VITATRON, INC., OF APPROVED PACING LEADS. DEVICE WILL BE MARKETED UNDER TRADE NAME EXCELLENCE S+	12/13/94
P860019/S88	SCIMED PTCA CATHETERS 10MM NC COBRA PTCA CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-1566	APPROVAL FOR THE 10MM NC COBRA PTCA CATHETER	12/13/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

P860040/S11	BIO CURVE SOFT (METHAFILCON A) AND BIO CURVE SOFT TORIC (METHAFILCON A) CONTACT LENSES	CAL BIONICS NOVATO, CA 94947	APPROVAL FOR RELOCATION OF THE ALTERNATE MANUFACTURING SITE	12/12/94
P870015/S18	MEDSTONE STS EXTRACORPOREAL SHOCK WAVE LITHOTRIPTER	MEDSTONE INTERNATIONAL, INC. ALISO VIEJO, CA 92656-4114	APPROVAL FOR MODIFICATION OF THE ELECTRODE INSULATION	12/22/94
P870049/S22	MICROSCAN RAPID GRAM POSITIVE PANELS	BAXTER DIAGNOSTICS, INC. WEST SACRAMENTO, CA 95691	APPROVAL FOR REMOVAL OF THE LIMITATION FOR DETECTION OF AMPICILLIN RESISTANCE WITH ENTEROCOCCI	12/08/94
P890032/S19	CORDIS ORION STEERABLE PTCA BALLOON CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	QUALITY CONTROL IN MANUFACTURING PROCESS: ROUTINE MANUFACTURING TORQUE TEST ON FINAL CATHETER ASSEMBLY AND STATISTICAL PROCESS CONTROL MONITORING FOR ROUTINE MANUFACTURING COREWIRE PULL TESTING	12/13/94
P890039/S12	A-TRACK AND OEM PACING LEADS	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	APPROVAL FOR MODIFICATIONS TO THE A-TRACK MODELS, CARDIAC CONTROL SYSTEMS (CCS) LEADS, OEM MODELS, AND	12/02/94

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

INTERMEDICS (ITM) LEADS

P890043/S25	SIMPSON CORONARY ATHEROCATH SCA-EX, SCA-EX 7 FRENCH GRAFT AND ATHEROCATH-GTO	DEVICES FOR VASCULAR INTERVENTION, INC. REDWOOD CITY, CA 94063	APPROVAL FOR THE IMPROVED DURABLE CUTTING SYSTEM FOR THE SCA-EX, SCA-EX 7 FRENCH GRAFT AND ATHEROCATH-GTO MODELS OF THE SIMPSON CORONARY ATHEROCATH	12/02/94
P890047/S4	PROVISC VISCOELASTIC PREPARATION	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL FOR USE OF BIOLOGICAL INDICATORS AS AN ALTERNATE TEST FOR STERILITY OF THE EXTERIOR OF THE SYRINGE	12/13/94
P890059/S1	PD 1343 DISINFECTING TABLET	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MODIFY THE "WARNINGS" AND THE "DIRECTIONS FOR USE" SECTION IN THE PACKAGE INSERT	12/13/94
P890067/S4	STERIDYNE STERILE PRESERVED SALINE SOLUTION	STERIDYNE LABORATORIES, INC. EAST BRUNSWICK, NJ 08816	APPROVAL OF A PROTOCOL FOR SHELF-LIFE EXTENSION FROM 24 TO 36 MONTHS	12/12/94
P930005/S2	KC STERILE	REPRESENTATIVE FOR KC	SHELF-LIFE EXTENSION	

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

MEDICAL DEVICE - PMA SUPPLEMENTALS

12/12/94	PRESERVED SALINE SOLUTION	PHARMACEUTICALS, INC. EAST BRUNSWICK, NJ 08816	FROM 24 TO 36 MONTHS

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

ORIGINAL VETERINARY NADAs

140-937 11-08-94	COBAN AND BMD (POWDER)	TURKEYS	ELANCO AN HLTH INDIANAPOLIS, IN 46285	BACITRACIN METHYLENE DISALICYLATE 10GM/LB 25GM/LB 30GM/LB 40GM/LB 50GM/LB 60GM/LB MONENSIN SODIUM 45-60GM/LB
140-934 11-10-94	VALBAZEN (SUSPENSION)	SHEEP	SMITHKLINE BEECHAM AN HLTH PRODS WEST CHESTER, PA 19380	ALBENDAZOLE 4.55%

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR DECEMBER 1994.

SUPPLEMENTAL VETERINARY NADAs

200-075 10-14-94	SACOX (POWDER)	CHICKENS	HOECHST ROUSSEL AGRI VET SOMERVILLE, NJ 08876	SALINOMYCIN SODIUM 60GM/LB