Approved prescription drug products with therapeutic equivalence evaluations.

[Washington, D.C.?]: U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, Bureau of Drugs: 1980-

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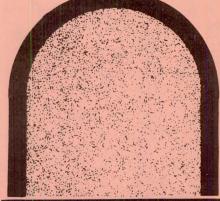
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CUMULATIVI SUPPLEMENT 4

AUG'84 - DEC'84



APPROVED PRESCRIPTION DRUG PRODUCTS

WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS



5™ EDITION

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FOOD AND DRUG ADMINISTRATION APPROVED PRESCRIPTION DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS CUMULATIVE SUPPLEMENT

PREFACE

This cumulative supplement is one of a series of monthly updates to the Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 5th Edition (the List), to cover interim revisions to the annual publication of the List in its entirety. The List is comprised of several parts and some by their nature, are identified by the term "list." The cumulative supplements routinely provide updates to two of these lists: The Drug Product List and the DESI Addendum.

The List cannot be used effectively without the current cumulative supplement. Users may wish to place an asterisk (*) in the List to the left of the ingredient(s) in the Drug Product List and the product name in the Addendum to indicate that changes to that entry appear in the cumulative supplement. It is also suggested that earlier cumulative supplements be discarded to avoid possible confusion. In this way, only the List and current cumulative supplement need be referenced.

A. DRUG PRODUCT LIST

The Drug Product List cumulative supplements include the changes made since August 1, 1984. Each subsequent cumulative supplement replaces previous month's cumulative supplement. the

Information in this cumulative supplement follows the format of the Drug Product List. The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Context information on drug products is provided in each cumulative supplement for completeness to assist in locating the proper place in Drug Product List for the revision. (Strength(s) which already exist the publication will not be repeated for context.) A page number in parentheses referring to the Drug Product List is located to the right the ingredient(s). A page number in Tocated to the right of in

Additions to the Drug Product List are indicated by new information in the cumulative supplement. Additions new to the current cumulative supplement are indicated by the symbol >_ADD_> to the left of the line on which new information exists. The >_ADD_> symbol is dropped in subsequent cumulative supplements for that item.





of the Deletions from the Drug Product List are indicated by overstruck print in the cumulative supplement. Deletions new to the current cumulative supplement are indicated by the symbol > DLT > (DELETE) to the left of the > DLT > Symbol is dropped subsequent cumulative supplements for that item. The line containing the overstruck print.

of A newly approved product is identified by the lozenge (*) to the right its strength. This identifier remains throughout all cumulative supplements for this edition.

B. ADDENDUM: DESI Pending List

Information in this cumulative supplement follows the format of the Addendum. Additions and deletions are indicated in the same manner as in the cumulative supplement to the Drug Product List. A change in Current Status of a DESI product is also indicated by an addition and a deletion.

I. SPECIAL NOTES

A. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

ategories of counts derived from product information in the Drug Product ist and from this cumulative supplement are presented. The report ncludes counts of new molecular entities approved by the agency during the current month. List

PRODUCTS REQUIRING REVISED LABELING FOR FULL APPROVAL B.

Drug products in this category (1) initially received approval only on the basis of safety before effectiveness studies were required, or (2) were conditionally approved under the temporary exemption that allowed these products to be marketed while effectiveness studies were being conducted. Listed below are those drugs which are now required to revise their labeling and provide additional information necessary for full approval on the basis of requirements listed in the Federal Register. As approval is granted by the Agency for a specific product, based on additional information submitted by the applicant, the product will be included in the Drug Product List.

Products	Federal Register Referenc	Regist	er Re	feren
dicyclomine hydrochloride isosorbide dinitrate	JUN 22, 1984 (49 FR 25681 AUG 3, 1984 (49 FR 31151 JUL 15, 1983 (48 FR 32395	1984 (49 FR 49 FR 48 FR	25681 31151 32395

8

(continued)

(continued)

MAY 4, 1984 (49 FR 19147) MAY 4, 1984 (49 FR 19147) SEP 7, 1984 (49 FR 35428) SEP 17, 1984 (49 FR 35428) SEP 17, 1984 (49 FR 36446) JUL 29, 1983 (48 FR 34516) AUG 22, 1983 (48 FR 38097) MAR 22, 1984 (49 FR 10708)	sulfamethoxazole sulfanilamide and aminacrine AUG 22, tranylcypromine sulfate MAR 22,	parenteral multivitamin products SEP 17, phenazopyridine hydrochloride and JUL 29,	SIS	nitrodlycerin (cansule controlled release:oral) SFP 7.	bacitracin zinc, and hydrocortisone	neomycin sulfate, polymyxin B sulfate, MAY 4,	dermatologic use]	[topical anti-infectives for	methylprednisolone acetate.	hydrocortisone, or	flurandrenolide,	fluocinolone acetonide,	dexamethasone sodium phosphate,	neomycin sulfate with either: MAR 26,
(49 FR 19147) (49 FR 19147) (49 FR 35428) (49 FR 35428) (49 FR 36446) (48 FR 34516) (48 FR 38097) (49 FR 10708)	1983 1984	1984	1984	1984		1984								1984
FR 19147) FR 35428) FR 35428) FR 36446) FR 36446) FR 38097) FR 10708)	(48 (49	(49	(49	(49		(49								(49
19147) 19147) 35428) 35428) 36446) 34516) 38097) 10708)	77	FR	FR:	FR		FR								FR
	38097) 10708)	36446)	35428)	35428)		19147)								11888)

0. APPLICANT (NAME) CHANGES

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approved product lines ar product involved will app supplement. The current Because it is not practical to identify in the cumulative supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name, the cumulation of these transfers and name changes will be identified in this Special Notes section only. Where only partial t lines are transf d will appear as a e current list of transferred an applicant name change in the cu applicant holder changes follows. between applicants, each applicants, each applicants the cumulative

APPLICANT (NAME) CHANGES

ANAOHEST	ANADITET	OHIO MEDICAL ANDSTHETICS
New Abbreviated Name	New Applicant (Name)	Former Applicant (Name)

D. ADDENDUM: DRUG PRICE COMPETITION AND PATENT TERM RESTORATION

Agency by 1984." The addendum of the of this supplement provides "Drug Price Competition and and information required of the d Patent Term Restoration Ac Act of



III. REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

DESCRIPTION OF REPORT

The following report provides summary counts derived from product information in the Drug Product List and the current cumulative supplement. The counts appear in two sections. Section A. refers to the products in the List and Section B. to products in the current cumulative supplement. A new column of data will appear in Section A. each three-month period following July '84. Section A. therefore will provide baseline and quarterly data while Section B. provides monthly activity.

USE OF REPORT

From the data presented under Section B., users should be able to observe such things as (1) newly approved, DESI effective and remarketed drug products which are added to the List; (2) products that are being removed from the List as the result of withdrawal of approval, changes from prescription to over-the-counter status and discontinued marketing of products; and, (3) trends in approval of products as either multisource or single source during each month within the quarter. The report does not reflect category changes from multisource to single source and vice versa. However, the net gain that results from all additions, deletions and category single source products.

Drug Product Definition

For this report, a drug product is the representation in the Drug Product List of an active moiety (includes molecular entity and its salts, esters and derivatives) either as a single entity or as a combination product, provided in a specific dosage form and strength for a given route of administration marketed by a product a particular generic or trade name.

New Molecular Entity

The active moiety has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or part of a combination.

Drug Product Count

This report provides counts in several categories from the list composed of domestically marketed drug products approved for both safety and effectiveness under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. Counts of products still pending in the DESI review are not provided. Excluded also are those approved drug products marketed by distributors; those marketed solely abroad; and products now regarded as medical devices, biologics or foods.

REPORT OF COUNTS FOR THE DRUG PRODUCT LIST

A. COUNTS CUMULATIVE BY QUARTERS

CATEGORIES COUNTED	JULY '84 (BASELINE)	OCT '84
DRUG PRODUCTS LISTED	7415	7609
SINGLE SOURCE	2005 (27.0%)	2045 (26.9%)
MULTISOURCE (1)	5410 (72.9%)	5564 (73.1%)
THERAPEUTICALLY EQUIVALENT	4393 (59.2%)	4497 (59.1%)
NOT THERAPEUTICALLY EQUIVALENT	999 (13.4%)	1032 (13.5%)
EXCEPTIONS (2)	18 (0.3%)	26 (0.3%)
NEW MOLECULAR ENTITIES APPROVED	<u>-</u>	4
NUMBER OF APPLICANTS	295	300

B. ACTIVITY FOR SUPPLEMENT NUMBER 4

	NOV '84	DEC '84	CUMULATIVE
DRUG PRODUCTS ADDED:	65	68	133
NEWLY APPROVED	65	68	133
DESI EFFECTIVE	0	0	0
REMARKETED	0	0	0
DRUG PRODUCTS REMOVED:	1	0	1
WITHDRAWN APPROVAL	0	0	0
RX TO OTC SWITCH	0	0	0
DISCONTINUED MARKETING		0	1
NET GAIN IN DRUG PRODUCTS	64	68	132
SINGLE SOURCE PRODUCTS APPROVED	16	26	42
MULTISOURCE DRUG PRODUCTS APPROVED	49	42	91
NEW MOLECULAR ENTITIES APPROVED:	2	7	9
AS THE ENTITY	0	2	2
AS A SALT, ESTER OR DERIVATIVE			
OF THE ENTITY	2	5	7

- (I) THERAPEUTIC EQUIVALENCE EVALUATIONS PROVIDED ONLY FOR MULTISOURCE PRODUCTS (i.e., AVAILABLE FROM MORE THAN ONE APPLICANT)
- (2) AMINO ACID-CONTAINING PRODUCTS OF VARYING COMPOSITION (SEE PAGE I-5 OF THE LIST)







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APPROVED PRESCRIPTION DRUG PRODUCTS DRUG PRODUCT LIST

CUMULATIVE SUPPLEMENT NUMBER 4 / AUGUST '84 - DECEMBER '84

>_ADD_>	ACEBUTOLOL HYDROCHLORIDE (PAGE 3-1)			ACET	IC ACID, GLACIAL (PAGE	3-3)	
> ADD > > ADD > > ADD > > ADD >	CAPSULE; ORAL SECTRAL IVES LABS/AMHO	EQ 200MG BASEM EQ 400MG BASEM	N 18917 N 18917	4		LUTION/DROPS; OTIC ACETIC ACID THAMES PHARMACAL	<u>2%</u> n	N 88638
	ACETAMINOPHEN; BUTALBITAL TABLET; ORAL BUTALBITAL AND ACETAMI DANBURY PHARMACAL ACETAMINOPHEN; BUTALBITAL; CAPSULE; ORAL ESGIC GILBERT LABORATORIES TABLET; ORAL ESGIC GILBERT LABORATORIES FICRICET AB SANDOZ PHARMS/SANDOZ	NOPHEN 325MG;50MGH CAFFEINE (PAGE 3-1) 325MG;50MG;40MGH	N 87550 N 88825 N 87629 N 82616		TAB AB AB AB AB AB AB	PURINOL (PAGE 3-5) BLET; ORAL ALLOFURINOL BOLAR PHARMACEUTICAL CHELSEA LABORATORIES DANBURY PHARMACAL NOCILLIN (PAGE 3-6) JECTABLE; INJECTION COACTIN HOFFMANN-LA ROCHE	300NG#	N 18241 N 18241 N 18785 N 18785 N 18832 N 18877
> ADD > > ADD >	ACETAMINOPHEN; HYDROCODONE TABLET; ORAL HYDROCODONE BITARTRATE	BITARTRATE (PAGE 3-2)	N 83577	<u> Aug</u>	IN	ACIN SULFATE (PAGE 3-6 JECTABLE; INJECTION AMIKIN BRISTOL LABS/B-M		N 62562 N 62562
> <u>ADD</u> > > <u>ADD</u> >	ACETAMINOPHEN; OXYCODONE H CAPSULE; ORAL TYLOX MCNEIL PHARM TYLOX-325 MCNEIL PHARM TABLET; ORAL /cdiidet/ OXYCET HALSEY DRUG	YDROCHLORIDE (PAGE 3-2) 500MG;5MGM 325MG;5MGM	N 88790 N 88246 N 87463		IN	TRAVENOL LABS TRAVASOL 5.5% W/O ELEC TRAVENOL LABS	4% n	N 18678 N 18684 N 18931 N 18931
							1976	

AMINO ACIDS; DEXTROSE (PAGE 3-7)

INJECTABLE; INJECTION

AMINOSYN 3.5% W/ DEXTROSE 5% IN PLASTIC CONTAINER

ABBOTT LABORATORIES 3.5%;55M/100ML

N 19120



29161 N	OINTHENT; TOPICAL OINTHENT; TOPICAL	27202 N	POWDER FOR RECONSTITUTION; ORAL AUGHENTIN '125' BEECHAM LABS/BEECHAM 125MG√5ML; EQ 31.25MG ACID√5ML¤
	BETAMETHASONE DIPROPIONATE (PAGE 3-22)		1740 110121212101031 402 424 104
	(00 2 3574) 2277724040404 377057712377224		AMOXICILLIN; POTASSIUM CLAVULANATE (PAGE 3-13)
	14114414141		
/x <i>y</i> q y x.\/	\amaga:.o:amoa\ \&\tao\\:\h\\\\	72888 N	BP 100MGM
	,\A-\N\z=/ ,	23888 N	PP 75MG# 100MG#
	\江外村位、"沙丁县江南外七人	55888 N	20MCH 20MCH
	(IS-E 3049)\ aliqaj\$\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	42888 N	BP 25MS#
	(10.1 3341)/4444444444444444444444444444444444	£2888 N	ВР SUPERPHARM 10Мбы
		88888 N	BP LEGEN LEGEN
49505 N	DEBNIK\BOBEK-PWCHEW PX: 2Xm	78888 N	BP 100MGH
	BENZYMACIN	98888 N	BP 75MGM
	GEL; TOPICAL	28888 N	8P 50MGH
		48888 N	8P S5NG#
	BENZOLF PEROXIDE; ERYTHROMYCIN (PAGE 3-21)	₹8888 N	BP SIDMAK LABORATORIES 10MGH
	(to E dold) life/Madimydd 13df/Aega Mariiad	20788 N	BP L50MGH
		10788 N	BP 100MSm
ZE728 N	CHELSEA LABORATORIES 289MG; 32.4MG; 6EMG#	00788 N	PP 75MGm
	PROPOXYPHENE HOL W/ ASPIRIM AND CAFFEINE	66988 N	BP 50MCm
77058 N	AD > AA ZENITH LABORATORIES 389MG; 35. 4MG; 65MGH		BP S5KG#
The state of the s	PROFOXYPHENE COMPOUND 65	46988 N	BP PAR PHARMACEUTICAL 10MGH
	CAPSULE; ORAL	\$4988 N	ВЬ ТООИСЯ
		₩2988 N	#SM27
3-16)	ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE (PAGE	27388 N	BP 50MGH
		27388 N	BP AMERICAN THERAPEUTIC 25MGm
			AMITEIPTYLINE HOL
I 82ctI	AB ZENITH LABORATORIES SSEME; GOMG#		JARO ; TABLET;
	BUTALBITAL COMPOUND		
	TABLET; ORAL		AMITRIPIYLINE HYDROCHLORIDE (PAGE 3-10)
	ASPIRIN; BUTALBITAL; CAFFEINE (PAGE 3-16)		
	ASDIDIN: BITAIBITAL: CAFEFINE (DACE 3-16)	49188 N	D > AP ABBOTT LABORATORIES SOCKEALCOML; GEONG/100MLM
		27188 M	AMINOPHYLLINE O.2X IN SODIUM CHLORIDE O.4EX
T0658 N	TOWER	49188 N	A ABBOTT LABORATORIES LOCHE, GEGUE/ CECHE GEGUER
T0628 N	LANNETT SMGM	E9100 H	ANTHORNY CHICANA CHICARDE 0.65X
10020 11	ANTHE SULFATE	42681 N	20045/1004C# 20046/1004C# COURT COUR
	TABLET; CRAL	42981 N	0 >
	1700 .131471	N 18924	D > VB
	AMPHETAMINE SULFATE (PAGE 3-13)	N 18924	D > AP ABBOTT LABORATORIES LOCHS/100HL; GEONG/100HLH
	THE POTENTIAL PROPERTY.		D > AMINOPHYLLING IN SODIUM CHLORIDE 0.45X IN PLASTIC CO
			INJECTABLE; INJECTION
99909 N	BEECHAM LABS/BEECHAM 500MG; EQ 125MG ACIDM		
4	AUGMENTIN '500'		WINOPHYLLINE; SODIUM CHLORIDE (PAGE 3-9)
99905 N	BEECHAM LABS/BEECHAM 250MG; EQ 125MG ACIDM		
100	AUGMENTIN '250'		
	TABLET; ORAL	61161 N	ABBOTT LABORATORIES 4.25%;256M/100ML
	1400 -131041		
	TABLET: COAL		AMINOSYN 4.25% W/ DEXTROSE 25% IN PLASTIC CONTAINER
52505 N #7W5/	BEECHAM LABS/BEECHAM SSOMG/SML;EQ 62.5MG ACID.	81161 N	ABBOTT LABORATORIES 3.5%;256M/100ML AMINOSYN 4.25% W/ DEXTROSE 25% IN PLASTIC CONTAINER
בעבסב N אואבע			

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 4 / AUGUST '84 - DECEMBER '84

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AMOXICILLIN; POTASSIUM CLAVULANATE (PAGE 3-13)

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AMINO ACIDS; DEXTROSE (PAGE 3-7)

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T9988 N	SPONER	LENSYON	<u>8A</u> < <u>00A</u> <			
05888 N	HEHOOT	SENITH LABORATORIES	<u>8A</u> < <u>00A</u> <	18505 N	EG COME BYSEVAL; SOME/ALK	
96988 N	SPONGE		<u>84</u>	T8505 N	EG SOME BYSE/MT:20HG/MF#	W2&D/MERCK
55988 N	TOCKER	SUPERPHARM	84		IN PLASTIC CONTAINER	MEFOXIN IN DEXTROSE 5X
83788 M	TOURER	LEMMON	<u>8A</u>			INJECTABLE; INJECTION
6T683 N	SZONER		8A			
81688 N	TOCHER	DURANED PHARMS	84		(byee 2-22)	CELOXILIN 20DIOM: DEXIBOSE
92888 N	SZONER		84			
N 88852	TOOKER	DANBURY PHARMACAL	84			
92788 W	SZONER		<u>88</u>	N 62579	206M/VIAL#	
22788 N	TOCHER	CORD LABORATORIES	<u>84</u>	N 62579	106M/VIAL#	
60728 H	SPORGE		<u>aa</u>	672S3 N	SGM/VIAL#	
80788 M	TOCHER	COLMED LABORATORIES	88	67253 N	TCW\VIALK	
59898 N	TOORER	CHELSEA LABORATORIES	84	67529 N	200MG/VIALM	M-8\28AJ JOTZIAB
N 88372	SPONGE		84			PRECEF
N 8881S	TOOMER	CHLGRFRGPAMIDE BARR LABORATORIES	<u>8A</u>			INJECTABLE; INJECTION
		TABLET; ORAL				CEEOBANIDE (PAGE 3-33)
		LORPROPAMIDE (PAGE 3-42)	СН			NOT 107017 (770117
					let-	INJECTABLE; INJECTION
ACTOR II	W100 010000	TURNING I NOTCOTH			/7:	thiahthad: ;
72781 N	3006M/B0Tm	CALCIBIND PHARMACAL				CVEBVCHOF (LVCE 3-31)
		POWDER; ORAL				(12 2 2014) 1011014410
		1100 1000				
	(PAGE 3-34)	TELLESE SODIUM PHOSPHATE	S	60781 N	20MG; 25MGM	EE SONIBB VAD SONS CYLOSIDE 20\SP
COCOC N	EG IOCM BASE/VIALM		< <u>00A</u> <	60781 N	20MC: TEMER	ER SQUIBB AND SONS
N 20285 N 20285	EQ 26M BASE/VIALM		< <u>ddy</u> <	6078I N	SEME! SEMER	CAPOZIDE 50/15 ER SQUIBB AND SONS
S8505 N	EG 10GM BASE/VIALM		< <u>dd4</u> <	00281 N	SEME . SEMEM	CAPOZIDE 25/25
N 20285	EQ 500MG BASE/VIALM		< <u>00A</u> <	6078I N	SPME! TRHEM	ER SQUIBB AND SOMS
58505 N	EQ SEOMG BASE/VIALE	HOFFMANN-LA ROCHE	< <u>00A</u> <	00281 N	SEME . J EMCM	CAPOZIDE 25/15
N EDEGE	EO SEOME BASE ALIALM	ROCEPHIN	< <u>aav</u> <			TABLET; ORAL
		INJECTABLE; INJECTION	< <u>QQA</u> <			1490 :131441
		11011031111 1314112031112			(TC-C 3984) 30T	CAPTOPRIL; HYDROCHLOROTHIAZ
	(22)	FTRIAXONE SODIUM (PAGE 3-	> VDD > CE		(12 2 30/4/ 342	TILLOUGH HOUSEAN TILLUGE
				\\$\$\${\$.N\	Ed '9645 'CALCIUA/EHL'	\\\\$\\\$'.\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\
N 20289	EG 40MG BASE/ML; 50MG/ML#					SALCIUM GLUCEPTATE
N 20289	EG SOMG BASE/ML; SOMG/MLM	SK&F LABORATORIES				INJECTABLE; INJECTION
	IN PLASTIC CONTAINER	CELIZOX IN DEXIBOSE 5X				
		INJECTABLE; INJECTION			(05-	CALCIUM GLUCEPTATE (PAGE 3-
		Control of the Contro			•	
	SE (PAGE 3-33)	FTIZOXIME SODIUM; DEXTROS	CE		Manager Manager Manager	
				18883 N	tt8MG/100ML#	
ALLENS TO THE					5.08MG/100ML;538MG/100ML;	
N POSSE	EG COME BASE/ML; SHG/NLM	No.		Ving 1 1 - 1 - 1 - 1	SE. TMS/100ML; 4. SEGM/100ML;	Т региер
N 20281	EG SOMG BASE/ML; 9MG/MLM	WS&D/MERCK		GONTAINER	SK LOW MAGNESTUM IN PLASTIC	
RER	SIDE 0.9% IN PLASTIC CONTAIN					SOLUTION; INTRAPERITONEAL
		INJECTABLE; INJECTION				TIVIAVA HATAGE /ACTUATION
	(SS-S ROW!) ROTUGE!	IN HOTGOS SHOTGOS HTLTVO	70			CHLORIDE; SODIUM LACTATE (
	(FF-F 3-34)	FOXITIN SODIUM; SODIUM CH	10		WAGNESIUM CHLORIDE; SODIUM	CALCTIM CHIORTDE: DEYTDOSE:

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		DROS PRODUCT EIST / CONCENTS	VL SOFFEEI	IN NOUDE	K 4 /	AUGUST 04 - DECEMBER	04 3	
CH	YMOPAPAIN (PAGE 3-43)				COR	TICOTROPIN (PAGE 3-47)		
	INJECTABLE; INJECTION CHYMODIACTIN				1	NJECTABLE; INJECTION CORTICOTROPIN		
	SMITH LABORATORIES	4,000 UNITS/VIALM	N 18663		AP	CARTER-GLOGAU LABS	40 UNITS/VIAL	N 88772
CI	SPLATIN (PAGE 3-44)				CRO	MOLYN SODIUM (PAGE 3-48)	
	INJECTABLE; INJECTION /piátinoi/				S	OLUTION/DROPS; OPHTHALM OPTICROM	ic	
	/apistol.iabs/bh/	/16M6/ML/ /50M6/V1AL/	/N 18657/			FISONS	4% x	N 18155
	PLATINOL-AQ	THE PERSON AS A SECOND AS A SE	114 FFFFFF					
	BRISTOL LABS/B-M	0.5MG/ML	N 18057		DES	ERPIDINE; METHYCLOTHIAZ	IDE (PAGE 3-52)	
CI	ONIDINE (PAGE 3-45)				T	ABLET; ORAL ENDURONYL		
CL	CHIDINE (PAGE 3-43)				BP	ABBOTT LABORATORIES	0 SEMC.EMC	N 12775
	FILM, CONTROLLED RELEASE	· DEDCLITANEOUS			DP	ENDURONYL FORTE	0.25116,5116	N 12/15
	CATAPRES-TTS-1	, PERCOTANEOUS			BP	ABBOTT LABORATORIES	O EMC:EMC	N 12775
	BOEHRINGER INGELHEIM	2 EMGH	N 18891		ьг	METHYCLOTHIAZIDE AND D		14 12//3
	CATAPRES-TTS-2	2.51104	14 10071		BP	BOLAR PHARMACEUTICAL		N 88486
	BOEHRINGER INGELHEIN	EMCH	N 18891		BP	BOLAR FHARMACEOTICAL	0.5MG;5MGH	N 88452
	CATAPRES-TTS-3	I Sligh	N 10071		DF		0.5116,51164	14 00432
		1 7 FMCW	N 70007					
	BOEHRINGER INGELHEIM	7.5NGA	N 18891		DEC	OUTDE (DAGE 7 ET)		
					DES	ONIDE (PAGE 3-53)		
-	DETLE BUSCOULTE: BUENZIE	PURTUE HYPROCHI OPTRE			-	DELM. TODTOLL		
_	DEINE PHOSPHATE; PHENYLE				L	REAM; TOPICAL		
<u>P</u>	ROMETHAZINE HYDROCHLORIC	E (PAGE 3-46)		> ADD >		DESOMEN		
				>_ADD_>	AB	OWEN LABS/DERM PRODS	0.05%n	N 19048
	SYRUP; ORAL		1			TRIDESILON		
	PHENERGAN VC W/ CODEIN			> <u>ADD</u> >	AB	MILES PHARMS/MILES	0.05%	N 17010
AA	WYETH LABS/AMHO PROMETH VC W/ CODEINE	10MG/5ML;5MG/5ML;6.25MG/5ML	N 08306					
AA	NATL PHARM MFG/BARRE	10MG/5ML;5MG/5ML;6.25MG/5ML	N 88764		DEX	AMETHASONE; NEOMYCIN SU	LFATE; POLYMIXIN B SULFATE	(PAGE 3-55)
					S	USPENSION/DROPS; OPHTHA	LMIC	
CO	DEINE PHOSPHATE; PROMETH	AZINE HYDROCHLORIDE (PAGE 3-4	6)			DEXACIDIN		
					AT	COOPERVISION PHARMS	0.1%; EQ 3.5MG BASE/ML;	
	SYRUP; ORAL				AT		10,000 UNITS/MLE	N 62544
	PHENERGAN W/ CODETHE							
AA	WYETH LABS/ANHO	10MG/5ML;6.25MG/5ML	N 08306					
	PROMETH W/ CODEINE				DEX	TROMETHORPHAN HYDROBROM	IDE; PROMETHAZINE	
AA	NATL PHARM MFG/BARRE	10MG/5ML;6.25MG/5MLH	N 83763			DROCHLORIDE (PAGE 3-57)		
>	PROMETHAZINE W/ CODEIN	E						
> AA	BAY LABORATORIES	10MG/5HL;6.25MG/5MLH	N 88875		S	YRUP; ORAL		
						PHENERGAN W/ DEXTRONET	HORPHAN	
					AA	WYETH LABS/AMHO	15NG/EML;6.25MG/5ML	N 11265
co	DETNE PHOSPHATE: PSEUDOF	PHEDRINE HYDROCHLORIDE; TRIPR	OI TOTHE			PROMETH W/ DEXTROMETHO		
	YDROCHLORIDE (PAGE 3-46)		OCIOZNE		AA		15MG/5ML;6.25MG/5MLH	N 88762
-	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					THE PROPERTY OF THE PROPERTY O		
	SYRUP; ORAL							
	ACTIFED W/ CODEINE							
AA	BURROUGHS WELLCOME	10MG/5ML;30MG/5ML;1.25MG/5ML	N 12575					
AA		Today ant, Soday ant, 1.25mg/ both	H 153/5					
	PSEUDODINE C	TOUR PEUT TROUR PEUT TE COMPOSED	W N 00044					
<u>AA</u>	BAY LABORATORIES	10MG/5ML;30MG/5ML;1.25MG/5ML	#_H 65555			- (0)		



REHATOCHT: COONSTOCHTE 44 < 00A < H TOSTT H TOSTI REMYTOOME ! SOOMEYTOOME AA < GOA < TIZET N ECHATOCHE : TRONG LTOCHER 4A < 00A < 4A < 00A < H TOSTI REHATOONE; BORGATOONER ZEN/TOONF: CONE/TOONFR AA < GGA < ABBOTA LABORATORIES THEOPHYLLINE IN DEXTROSE SX IN PLASTIC CONTAINER < QQA < <u>4A</u> ROWLIGGHE; 400HCH AR MCGAWARM HOSP THEOPHYLLINE O.GN AND DEXTROSE 5N IN PLASTIC CONTAINER RENTTOONT: SCONELTCONER AM MCGAW/AM HOSP <u>aa</u> THEOFHYLLINE O.2X AND DEXTROSE 5X IN PLASTIC CONTAINER PENTIONE; TRONELTOONER <u>aa</u> AM MCGAW/AM HOSP THEOFHYLLINE O.16X AND DEXTROSE SX IN PLASTIC CONTAINER BENYTOONT : BONEYTOONTH <u>aa</u> AM MCGAW/AM HOSP THEOPHYLLINE O.08N AND DEXTROSE 5N IN PLASTIC CONTAINER <u>AA</u> REMITOOMT: COMELTOOMTH AN MCGAWAM HOSP THEOPHYLLINE 0.04X AND DEXTROSE 5X IN FLASTIC CONTAINER <u>aa</u> THOOT/SHOOM: THOOT/HOS **AA** RENYTOCHT: SOOMEYTOOM ECHITOCHT: TROKETTOCHT <u>aa</u> <u>aa</u> ECHITOCHT! BCHCYTOCHT ZEN/TOONF: CCHE/TOOMF <u>aa</u> TRAVENOL LABS THEOPHAFITHE AND DEXIBOSE EN IN PLASTIC CONTAINER INJECTABLE; INJECTION DEXIROSE; THEOPHYLLINE (PAGE 3-62) SEME/IOOML; 320MG/IOOML# < QQA < PEM/IOOML; SIME/IOOML; ISOME/IOOML; < <u>QQA</u> < AM MCGAW/AM HOSP ISOLYTE P W/ DEXTROSE 5% IN PLASTIC CONTAINER < 007 < INJECTABLE; INJECTION < QQA < PHOSPHATE, DIBASIC; SODIUM ACETATE (PAGE 3-58) < QQA < DEXIBORE; WYCHESINW CHIORIDE; POTASSIUM CHLORIDE; POTASSIUM < QQY < < 004 < PCM/I00ML;1,000 UNITS/100ML* N 19130 AM MCGAW/AM HOSP CONTAINER < QQA < HEPARIN SODIUM 5000 UNITS AND DEXTROSE 5% IN PLASTIC < <u>QQA</u> < AJEOUTISTEN OOS: JHJOT/HOS 4A < GOA < AM MCGAW/AM HOSP CCHTATHER < QQA < HEPARIN SCOTUM SOOD UNITS AND DEXTROSE SN IN PLASTIC < QQA < REMITTOOME SOO ONILEVICONER 4A < GGA < AM MCGAW/AM HOSP CCHTAINER < 007 < HEPRETH SOUTH TOOD UNITS AND DEXTROSE SN IN PLASTIC < 004 < INJECTABLE; INJECTION DEXIBOSE! HEPARIN SODIUM (PAGE 3-58) ABBOTT LABORATORIES 38.56M/100MLM DEXTROSE 36.5% IN PLASTIC CONTAINER INJECTABLE; INJECTION

DEXTROSE (PAGE 3-57)

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N 18340

N 88499 N 88506

N 87156

/N 80434/

N 87157

/N°80433/

/N. 80432/

N 88766

N 88767

N 18569

N 18415

N 18419

N 16273

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N 19129 SOME; 75MGK MYLAN PHARMS MAXZIDE TABLET; ORAL HYDROCHLOROTHIAZIDE; TRIAMTERENE (PAGE 3-98) MXE **5506T N CHAIL MUINTIX** LURGEX TIMOLIDE 10-25 EMULSION; TOPICAL TABLET; ORAL HEXYCH TO BOHENE (LYCE 3-64) HYDROCHLOROTHIAZIDE; TIMOLOL MALEATE (PAGE 3-98) LINYSTINU DES LKINS-SINN/AHROBINS/26,666 UNITESAL/ SENG: SENGE BA 88025 N ASCOT HOSP PHARMS SEIECHST VOLGHE + HABBOCHFOROTHIESTOE HEPARIN SODIUM TABLET; ORAL dA HTW/SIIMA OOT dA N 88530 TO MATTENAL dA HADROCH COROTHIZIDE; SPIRONOLACTONE (PAGE 3-98) 45488 N SOLOPAK LABORATORIES 10 UNITTE/NLM TS9LT N HTW/SIINA GOT 4A LYPHOMED HEDVEIN FOCK EFACH PA N 18303 POWE: TOOMER **CEIGX/CIBA-GEIGX** < 004 < TS9LT N TO CHITS/HLM LYPHOMED < QQA < LOPRESSOR HCT 100/50 HED-EFREN TO INJECTABLE; INJECTABLE GEIGY/CIBA-GEIGY < QQA < N 18303 SPWC: TOOMCH < 004 < LOPRESSOR HCT 100/25 N 18303 SPWC: POWCH GEIGY/CIBA-GEIGY < QQV < HEPARIN SODIUM (PAGE 3-91) LOPRESSOR HCT 50/25 < QQA < TABLET; ORAL < QQV < HALCG-E > ADD > HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE (PAGE 3-98) \HALGINERH\ CREAM; TOPICAL 8A < GOA < HYFCINONIDE (LYCE 2-00) N 888829 TOOMER N 822328 REMEN <u>ea</u> < <u>00a</u> < SENER BA < GGA < N 88887 **MAAH939US** **£**\$9**£**\$.*N*\ HADROCKFORDTHIVETOR TABLET; ORAL TABLET; ORAL HADROCHLOROTHIAZIDE ((PAGE 3-96) GLUTETHIMIDE (PAGE 3-88) AA 68788 H ROMOS SPILER AA EG 2WG BYZENER IA 85788 N N 62452 ALLERGAN PHARMS TONOT AA **78788 N** CENOBLIC SUPERPHARM AA < GGA < H SERTT RECHEM SOLUTION/DROPS; OPHTHALMIC N SCRIO SELLER ASCOT HOSP PHARMS AA < GGA < AA 65533 H ROMER N 62534 EG THE BYZELENA ЫНРВИКОЕВИ\ВАК-СГОИ IA AA EG THE BYZELENA 09588 H ANIDE PHARMACEUTICAL SEMBN N 62533 E LONGERA/BYK-GLDN IA HALBYLAZINE HOL GENTAMICIN SULFATE

DRUG PRODUCT LIST / CUMULATIVE SUPPLEMENT NUMBER 4 / AUGUST '84 - DECEMBER '84

TABLET; ORAL

HADBALAZINE HYDROCHLORIDE (PAGE 3-95)



OINTMENT; TOPICAL

GENTAMICIN SULFATE (PAGE 3-86)

	HYDROCORTISONE (PAGE 3-99	9)			INDOMETHACIN (PAGE 3-108)		
	CREAM; TOPICAL HYBROCORTISONE T THAMES PHARMACAL	2 E/W	N 88799		CAPSULE; ORAL INDOMETHACIN AB PAR PHARMACEUTICAL	2EMPY	N 18829
4	THAMES PHARMACAL	2.5% u	N 00/77			<u>25MG</u> ¤ 50HG¤	N 18829
	POWDER; FOR RX COMPOUNT	DING			AB PARKE-DAVIS/W-L	25M9#	N 18306
	H-CCRT	The second second			AB	501GM	N 18806
/ <u>A</u>	A/ /PARAMEX. LABORATORI	\$/ <u>1662</u> /	/n.′ <i>87834</i> /				
A	A TORCH LABORATORIES		N 87834		SUPPOSITORY; RECTAL		
					INDOCIN		
	HYDROCORTISONE ACETATE (PAGE 3-102)			MS&D RES LABS/MERCK	50MGX	N 17814
	The Aller of the State of the S						
	/AEROSOL; TOPICAL/			> <u>ADD</u> >	IODOHIPPURATE SODIUM, I-1	<u>23</u> (PAGE 3-109)	
	/EPIFOAM/	1413.11	131277441				
	LAEED & CYANATCK, LAYAN	15/17/	/n 86457/	> <u>ADD</u> >	INJECTABLE; INJECTION		
				> <u>ADD</u> > > ADD >	NEPHROFLOW MEDI-PHYSICS	1MCI/ML¤	N 18289
	HYDROCORTISONE ACETATE: I	PRAMOXINE HYDROCHLORIDE (PAGE	3-103)	ADD	HEBI-PHISICS	INCIPILLA	N 10207
	AEROSOL; TOPICAL				ISOETHARINE MESYLATE (PAG	E 3-110)	
	EPIFOAM						
	REED&CARNRICK PHAR	15 1%;1%	N 86457		AEROSOL; INHALATION		
					BRONKOMETER	11111131	13.11111
	HYDROELIMETHATTE (DAGE	7 104)			/ʁ̞deˈonˈiʎøś/sterling BN BREON LABS/STERLING		/n/12339/ N 12339
	HYDROFLUMETHIAZIDE (PAGE	3-104)			BN BREON LABS/STERLING ISOETHARINE MESYLATE	0.34/16/ INH	N 12339
	TABLET; ORAL				BN NATL PHARM MFG/BARR	E 0.34MG/INHM	N 87858
	HYDROFLUMETHIAZIDE						
A	B CHELSEA LABORATORII	ES 50MGH	N 88528				
					KANAMYCIN SULFATE (PAGE 3	-112)	
	HYDROXYZINE HYDROCHLORIDI	[(PAGE 3-105)			INJECTABLE; INJECTION KANTREX		
	TABLET; ORAL				AP BRISTOL LABS/B-M	EQ 75MG BASE/2MLM	N 62564
	HYDROXYZINE HCL				AP	EQ 500NG BASE/2MLH	H 62564
A	B PUREPAC/KALIPHARMA	10MGH	N 88120		AP	EQ 1GM DASE/3MLH	N 62564
	<u>B</u>	25MGH	N 88121				
_	<u>B</u>	50MG#	N 88122				
ADD > A		10MSH 25MSH	N 88794 N 88795		LABETALOL HYDROCHLORIDE (PAGE 3-113)	
ADD > A		50MGH	N 88796		INJECTABLE; INJECTION		
KDU K		501134	11 65776		NORMODYNE		
					SCHERING	5MG/ML#	N 18687
	IMIPRAMINE HYDROCHLORIDE	(PAGE 3-107)					
					TABLET; ORAL		
	TABLET; ORAL SK-FRAMINE				MORMODYNE AB SCHERING	200MG#	N 18686
DLT >/A		/ <u>1686</u> /	/K. 18081/		AB SCHERING	200HG#	N 18686
DLT >/A	B/	/25NG/	/K 18683/		AB	400115x	N 18686
DLT > 7		/ <u>FORG</u> /	/KEROSI //		TRANDATE		
ADD > A		10MG	N 83827		AB GLAXO	200MG¤	N 18716
A C DDA		25MG	N 83827		AB	300HG#	N 18716
ADD >	bP .	50MG	N 83827		<u>AB</u>	400MG#	N 18716



59581 N	TWG/ML#						
5958I N	0.5MG/MLM	ETKIN2-21NN/AHROBIN2					
		DURAMORPH PF		48888 H	MZE	DEPROCO	<u>aa</u>
		INJECTABLE; INJECTION				ZCYHDOMEZI DEVIN	
		11011031111 131011031111	•	65988 H	nZC	SOORY MAAHY ARTEA	4A
	166	SHINE SULFATE (PAGE 3-13	IOU	14700 H	~~~	POLOCATHE	
	(32	F-F 3340) 3143 IIIS JINING	ION	A / / CO !!	SNu	AUTACO IOG	-
				07788 M			<u>9A</u>
				69788 N	n ZT	CARTER-GLOSAU LABS	44
88881 N	200MG#	ORTHO PHARMACEUTICAL			<u></u>	MEPIVACATIE HOL	
		E TATZINOM		H ISS20	<u> </u>	BREON LABS/STERLING	<u>aa</u>
		JANIĐAV ;YROTIZOPPU				CARROCAINE	
						INJECTABLE; INJECTION	E
	-134)	CONTROLE NITRATE (PAGE 3-	IW				
					(PAGE 3-123)	DIVACAINE HYDROCHLORIDE	WEL
25007 H	SZOWER	ГЕННОИ	8A < 00A <				
		METRYL		84280 N	Ed 20WG BASE/ML		
60004 N	ROGIGA		EA < GOA <	N 08248	EG TEMS BYSEVME	MYETH LABS/AMHO	
80007 H	SECHER	SUPERPHARM	8A < 00A <		\74\54\0£\	Olditi Gavi Inzakii	
25007 N	SOOMER	Mavinausuris	<u>aa < <u>aaa <</u></u>		/ .\r\ \r\ \r\ \r\ \r\ \r\ \r\ \r\ \r\ \r	18019 18893 WEST	
	SOMER	CTTYCLENOGES NEUGTC	8A < 00A <	/n.qq\$qq\	/\f\/\$\\\$\/	\drid\\e\a\\	
72007 M	SEUMER	SIDMAK LABORATORIES	AA < UUA <			MYAMINE SULFATE	
		METRONIDAZOLE			<i>.</i>	INJECTABLE; INJECTION	L
		JARO (TELET)			3222 2 2		
	A STATE OF THE STA				E 3-153)	HENTERMINE SULFATE (PAG	MEF
S4007 M	ROOMENTOOMER	ГЕИМОИ	<u>qa</u> < <u>qqa</u> <				
		VI JYSTEM	< <u>ada <</u>	6.00000000			_
ITOOT H	200MG/TOOMF#	ГХЬНОИЕВ	9A < 00A <	05988 N	TOOMER	BARR LABORATORIES	AA
		METRONIDAZOLE				NELEKIDINE HOF	
		INJECTABLE; INJECTION				TABLET; ORAL	L
		KONIDAZOLE (PAGE 3-133)	WE	N 86222	TORELAL	INTL MEDICATION SYS	<u>aa</u>
				N 88¢25	TORELNER	ABBOTT LABORATORIES	4A
						WELEKIDINE HOF	
42788 N	PAGE		<u>88</u>			INJECTABLE; INJECTION	1
02788 M	S. SHER	CHELSEA LABORATORIES	BA				
		HETHYCLOTHIAZIDE			PAGE 3-122)	DEBIDINE HADBOCHTOBIDE (WEL
		TABLET; ORAL					
	(67	HACFOLHIVSIDE (PAGE 3-12	au	T6188 N	NZĪ	BAY LABORATORIES	IA
		AL L SOVEY SELECTIONS		20200 11	~~	TINDANE	
						SHAMPOS; TOPICAL	•
OCC00 N	אדעדו נזכעם פוופכז אז	IL GACGNA TOLOTHO				IANTOO: TOPICAL	•
N 86358	EQ 250MG BASE/VIALM	M-8\28AJ JOTZIAB			TXH		IA
		MEXATE		0 88 T 80	HZT.	EBORATORIES YAS	TA
		NUECTABLE; INJECTION				LINDANE	_
						LOTION; TOPICAL	1
	(851-8)	HOTREXATE SODIUM (PAGE	ME				
						<u>IDANE</u> (PAGE 3-116)	ILI
	NY BE WAS DESIGNATED						
/62399, N/	/511992/		/ <u>∀</u> ÿ/ / ∀ ÿ/				_
/4.86229/	\266Mc\	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	/44/	N 88288	O. OSMG/ML; 2Na	DEPROCO	<u>AA</u>
		MEPROBAMATE				SCYNDONEST L	
		TABLET; ORAL	<u> </u>			MUECTABLE; INJECTION	[:-
	The state of the s						1
		PROBAMATE (PAGE 3-123)	WEI		HADBOCHFOBIDE (PAGE 3-114)	VONORDEFRIN; MEPIVACAINE	TEA
							0.00
	01 79	AUGUST 184 - DECEMBER	IT NUMBER 4	NE SOBBLEMEN	DRUG PRODUCT LIST \ CUMULATIV		

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OXYPHENBUTAZONE (PAGE 3-143)

	INJECTABLE; INJECTION			Т	ABLET; ORAL		
	AP BRISTOL LABS/B-M NALLPEN	EQ 10GM BASE/VIAL	N 62527	AB	BOLAR PHARMACEUTICAL TANDEARIL	100M5¤	N 88399
	AP BEECHAM LABS/BEECHAM	EQ 10GM BASE/VIAL	N 61999	AB	GEIGY/CIBA-GEIGY	100MG	N 12542
	NAETREXONE HYDROCHLORIDE (PAGE 3-136)		PEN	TAMIDINE ISETHIONATE (P	AGE 3-148)	
	TABLET; ORAL TREXAN			I	NJECTABLE; INJECTION PENTAM 300		
	DUPONT PHARMS/DUPONT	50MG¤	N 18932		LYPHOMED	300MG/VIALM	N 19264
	NEOMYCIN SULFATE; POLYMYXI	N B SULFATE (PAGE 3-137)		PHE	NTERMINE HYDROCHLORIDE	(PAGE 3-151)	
	SOLUTION/DROPS; OPHTHALM STATROL	ic		С	APSULE; ORAL PHENTERMINE HOL		
	ALCON LABORATORIES	EQ 3.5MG BASE/ML; 16,250 UNITS/ML¤	N 62339	> <u>ADD</u> > <u>AA</u>	PHARM BASICS	<u>30MG</u> n	N 88797
> ADD >	NOMIFENSINE MALEATE (PAGE	3-140)		PEN	TOXIFYLLINE (PAGE 3-149)	
>_ADD_>	CAPSULE; ORAL			Т	ABLET, CONTROLLED RELEA	SE; ORAL	
> ADD > > ADD >	MERITAL HOECHST-ROUSSEL	25MG¤	N 18224		HOECHST-ROUSSEL	400MG¤	N 18631
> <u>ADD</u> >		50MG¤	N 18224		NYLEPHRINE HYDROCHLORID AGE 3-153)	E; PROMETHAZINE HYDROCHLORIDE	
	NYSTATIN (PAGE 3-141)				YRUP; ORAL		
	SUSPENSION; ORAL MYSTATIM			AA	PHEHERGAN VC WYETH LABS/AMHO	5MG/5ML;6.25MG/5ML	N 08604
	AA BAY LABORATORIES	100,000 UNITS/ML¤	N 62512	AA	NATL PHARM MFG/BARRE	5MG/5ML;6.25MG/5ML¤	N 88761
	TABLET; ORAL NYSTATIN AA QUANTUM PHARMICS	500,000 UNITS¤	N 62525	PHE	NYTOIN SODIUM (PAGE 3-1	53)	
					NJECTABLE; INJECTION		
	OXTRIPHYLLINE (PAGE 3-143) ELIXIR; ORAL			> ADD > AP > ADD > AP	SOLOPAK LABORATORIES	50MG/ML¤	H 88519 H 88520
	CHOLEDYL AA PARKE-DAVIS/W-L	100MG/5ML¤	N 09268	> ADD > AP		50MG/MLH	N 88521
	OXTRIPHYLLINE BAY LABORATORIES	100MG/5ML	N 88243	PHE	NYTOIN SODIUM, EXTENDED	(PAGE 3-153)	
				С	APSULE; ORAL		
				> ADD > AB > ADD >	PARKE-DAVIS/W-L EXTENDED PHENYTOIN SCD	IOMB	N 84349
				> ADD > AB	BOLAR PHARMACEUTICAL		N 89711



NAFCILLIN SODIUM (PAGE 3-135)

			01518 N 95053 N 89498 N 89498 N	\\$Moè 2002 2003 2003 2003 2003 2003	<u>фв</u> фв \\$ç\ _ РАРКЕ-DAVIS√W-L	< 004 < 004 < 004 < 004 <
			SES28 N	120HE#		< <u>004</u> <
	• .		H 8322¢ N 88222	POCHER Spaner	AB BOLAR PHARMACEUTICAL	< <u>QQA</u> <
0606T N	EFFXO EG SZWE BYZE/WLX		22200 W		PROCAINAMIDE HCL	< <u>ddA</u> <
•	INJECTABLE; INJECTION			TASO:35	TABLET, CONTROLLED RELEAS	
	WILLIDINE HYDROCHLORIDE (PAGE 3-171)	ង		(PAGE 3-163)	PROCALIVAMIDE HYDROCHLORIDE	
		_	78888 N	SOMEK	. 29	
\ ₹ ₹\${\$` <i>N</i> \	ROWELL LABORATORIES / 20046/	萝/	99888 N	IOHER	Xa	
	CIN-GAIN		29888 N	2NG#	вх сорежения	
	TABLET; ORAL				TABLET; ORAL PREDNISONE	
•	UINIDINE SULFATE (PAGE 3-170)	5	€0788 N	MJIIC /OUG	ROXANE LABORATORIES	
			20200 11	~ 1717 571	PREDNISONE	
85278 N	TRICCOLDINE HOL AND PSEUDOEPHEDRINE HOL	AA < QQA <			SOLUTION; ORAL	
	TABLET; ORAL				<u> PREDNISONE</u> (PAGE 3-161)	
N 882¢J		AA	16788 H		VI COOPERVISION PHARMS	
	LEILEGOLDINE HOL AND PSEUDOEPHEDRINE HOL Syrup; oral				HIGIOCSAV	
	(PAGE 3-169)		SE088 H	<u> </u>	<u>PREDSULFAIR</u> PHARMAFAIR	
ORIDE	SENDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHL				ОІИТИЕИТ; ОРНТНАСИІС	
				CETAMIDE SODIUM (PAGE 3-160)	PREDNISOLONE ACETATE; SULF	
ET920 N	PROTAMINE SULFATE SE om S/VIALM					
	INJECTABLE; INJECTION		2868I N	34.08GM/PACKETM		
	ACCT A TOWN THE TOWN THE TOWN	-		10.086M/PACKET;8.766M/PACKET;		
	ROTAMINE SULFATE (PAGE 3-168)	đ	£8681 N	200W\bYCKEI; <ahreaday.byckei; SI'20W\bYCKEI;<ahreaday.byckei;< td=""><td></td><td></td></ahreaday.byckei;<></ahreaday.byckei; 		
	<u></u>			6.366M/PACKET;5.536M/PACKET;		
ST988 N		AA	60/07 11	227.16N/PACKET;2.826M/PACKET		
	EBGEDXAEHE NE HOF CABROLE: OKAL		£8681 N	II.36GM/PACKET# 3.36GM/PACKET;2.92GM/PACKET;		
				ISOGM/PACKET; L. 49GM/PACKET;	EDLAW PREPARATIONS	
	MODOXXEHENE HADBOCHTOBIDE (PAGE 3-167)	ਰ		4: DKAL	COLYTE POWDER FOR RECONSTITUTION	
26588 N	BAY LABORATORIES <u>EG SWG BASE/SML</u> M	44		IDE; SODIUM SULFATE (PAGE 3-155		
20200 N	PROCHLCRPERAZINE EDISYLATE	••	``		POLYETHYLENE GLYCOL 3350; I	
	SYRUP; 0RAL	_				
86288 N	BRY LABORATORIES <u>EG 10MG BASE/ML</u> K	AA	96781 N	χ ν	PILOPINE HS ALCON LABORATORIES	
	CONCENTRATE; ORAL				GEL; OPHTHALMIC	
	ROCHLORPERAZINE EDISYLATE (PAGE 3-164)	ਰ		(PAGE 3-154)	PILOCARPINE HYDROCHLORIDE	
	Y YNCH21,84 - DECEMBEK,84 TS	е узапои ти	3M3J4406 :	DRUG PRODUCT LIST / CUMULATIVE	•	
•	2. Aei machanan - Aei Taimia / .	, dament Til	ana IUUIIƏ i	anaay meale / aca i acidodu Siluu		

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N 88786

N 88717

N 18969 N 18970

N 18946 N 18946 N 70006

N 70007 N 70000 N 70002

N 18762

RITODRINE HYDROCHLORIDE (PAGE 3-173)		SODIUM POLYSTYRENE SULFONATE (PAGE 3-179)
INJECTABLE; INJECTION /#ifdd#ine 'Hot'/		POWDER; ORAL, RECTAL SCOTUM FOLYSTYRENE SULFONATE
/AP/ / JOHFHAR, TABS/ /1646/41/ YUTOPAR	/n.1\$2\$\$/	AA BAY LABORATORIES 453.6GM/BOTH
AP/ ASTRA PHARM PRODS 10MG/ML 15MG/ML#	N 18580 N 18580	SUSPENSION; ORAL, RECTAL SCRIUM FOLYSTYRENE SULFONATE AA BAY LABORATORIES 155M/60MLM
TABLET; ORAL /kitchkine'hci/		
/AB/ プロリテード TABS/ / Johs/ YUTOPAR	/N.18280/	SOYBEAN DIL (PAGE 3-180)
AB/ ASTRA PHARM PRODUCTS 10MG	N 18555	INJECTABLE; INJECTION LIPOSYM III 10%
SAFFLOWER OIL; SOYBEAN OIL (PAGE 3-174)		AP ABBOTT LABORATORIES 10% ABBOTT LABORATORIES 20% ABB
INJECTABLE; INJECTION LIPOSYN II 10%		_
ABBOTT LABORATORIES 5%;5%m LIPOSYN II 20%	N 18997	SUCCINYLCHOLINE CHLORIDE (PAGE 3-181)
ABBOTT LABORATORIES 10%;10%	N 18991	INJECTABLE; INJECTION SUCCINFLENCINE CHLORIDE /AP/ /TRAVENOL'LABS/ /56685/VtAL/
SCOPOLAMINE (PAGE 3-174)		/AB/ /TRAVENOL, LABS/ /SOCIETYTAL/
FILM, CONTROLLED RELEASE; PERCUTANEOUS		
/1RANSDERN-V/ /ALZA/ /1.5Ns/	/N.17874/	SULFAMETHOXAZOLE; TRIMETHOPRIM (PAGE 3-183)
TRANSDERM-SCOP CIBA/CIBA-GEIGY 1.5MG	N 17874	TABLET; ORAL SULFAMETHOXAZOLE & TRIMETHOPRIM AB HEATHER DRUG 400M3;80M5m
SODIUM CHLORIDE (PAGE 3-176)		SULFAMETHOXAZOLE AND TRINSTROFRIM AB BARR LABORATORIES 400MS;80MS
INJECTABLE; INJECTION		BARR LABORATORIES 400MS;80MS SULFAMETHOXAZOLE AND TRINETHOFRIM DOUBLE STRENGTH
/AP/ SODIUM CHLCRIDE IN PLASTIC CONTAINER /AM MCSAW/AM HOSP/ /SOUS/ACOUL/ SODIUM CHLCRIDE 0.9% IN PLASTIC CONTAINER	/N:17464/	AB BARR LABORATORIES 800WS;160WSH TRINETH/SULFA D/S AB CHELSEA LABORATORIES 800WG;160WSH
AP AM MCGAW/AM HOSP 900MG/100ML	N 17464	TRIMETH/SULFA S/S AB CHELSEA LABORATORIES 400MS;80MSx
SODIUM LACTATE (PAGE 3-178)		
INJECTABLE; INJECTION		TERBUTALINE SULFATE (PAGE 3-187)
SODIUM LACTATE IN PLASTIC CONTAINER ABBOTT LABORATORIES 5MEQ/MLM	N 18947	AEROSOL; INHALATION BRETHAIRE GEIGY/CIBA-GEIGY 0.2MG/INHX
SODIUM POLYSTYRENE SULFONATE (PAGE 3-179)		
POWDER; ORAL, RECTAL KAYEXALATE		
AA BREON LABS/STERLING 453.66M/BOT	N 11287	



18788 N

08788 N

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LEDERLE LABS/AM CYAN 0.12x

OINTMENT; TOPICAL

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/ASCERBLE ACTOS BLOTTINS CYANDECHALANTINS FOLLE ACTOS/
/NTACTUANTOES PANTHEROLS PYRTOCKINE HYDROCHICERDES REBOFLAVINS/
/THICKINE HYDROCHICREDES VITANIA AS VITANIA BS VITANIA E/ (PAGE AD2) (SEE SPECIAL

/injectable; injection/
/nultivitanin applitive/
/abbott Laboratories//iddne/shi;d.dshe/shi;d.ddshe/shi;
/d.aboratories//iddne/shi;sone/shi;ishd/shi;/
/d.aboratories//iddne/shi;sone/shi;ishd/shi;/
/4.aboratories//
/4.aboratories// (SEE SPECIAL NOTE B.) /N'18223/ /ASCORBIC ACID; BIOTIN; DEXPANTHENCL; NIACTHAMIDE; PYRIDOXINE/
/HYDROCHLORIDE; RIEGELAVIN; THIAMINE HYDROCHLORIDE/(PAGE AD2) (SEE SPECIAL NOTE B.) /injectable; injection/ /berocca c/ /\$0M6/HL;0:1M6/HL;10M6/HL;40M6/HL;/ /10M6/HL;5M6/HL;5M6/HL/ /N:06 /HOFFMAN-LA ROCHE/ /N. 06071/ /BEROCCA C BOO! /HOFFMAN-LA ROCHE/ /125h6/ML;10h6/ML;10h6/ML;40h6/ML/ /10h6/ML;5h6/ML;5h6/ML/ /N. 06071/ /ASCORBIC 'ACID; 'BEXPANTHENOL; 'NIACINAMIDE; 'PYRIDOXINE/ /HYDROCHICATOE; RIBOFLAVIN; THIGHTHE HYDROCHLORIDE; VITAMIN'A;/ /VITAMIN B; VITAMIN E/(PAGE AD3) (SEE SPECIAL NOTE B.) /injectable; injection/ /m.v.i./ /usv.pharhaceutical/ /50M6/ML;2:5M6/ML;10M6/ML;1:5M6/ML; /iM6/ML;5M6/ML;1;000 iU/ML;100 iU/ML;/ /0.5M6/ML/ /N. 05509/ /100M6/ML;5M6/ML;20M6/ML;3M6/ML; /2M6/ML;10M6/ML;2,000 iU/ML;/ /200 iU/ML;1M6/ML/ /N'08509/

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\TABLET.; CONTROLLED 'KELEASE; OKAL' (ALL PRODUCTS - SEE SPECIAL NOTE B.)

\¢AÞ\$UĽĖ, ĊĎNŤŔĎĽĽĖĎ ŘĔĽĔÁŠĖ; ĎŔŘĽ\ (ALL PRODUCTS – SEE SPECIAL NOTE B.)

NITROGLYCERIN (PAGE AD7)

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/+/9:5+:,/99:./

COMULATIVE SUPPLEMENT NUMBER 4 / AUGUST 084 - DECEMBER. 84
DESI PENDING LIST - 'EXEMPT' (COURT ORDER) CATEGORY

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CURRENT STATUS - INEFFECTIVE

/BENTYL W/ PHENOBARBITAL/ / MERRELL BOW/DOW CHEN/ / DICYCLONINE HYDROCHLORIDES PHENOBARBITAL/

BEROCCA C HOFFMANN-LA ROCHE

ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE

HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE

BEROCCA C 500 HOFFMANN-LA ROCHE

ASCORBIC ACID; BIOTIN; DEXPANTHENOL; NIACINAMIDE; PYRIDOXINE

HYDROCHLORIDE; RIBOFLAVIN; THIAMINE HYDROCHLORIDE

DIMETAPP AH ROBINS
BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE;
PHENYLPROPANOLAMINE HYDROCHLORIDE

ELIXIR DIMETAPP AH ROBINS
BROMPHENIRAMINE MALEATE; PHENYLEPHRINE HYDROCHLORIDE;
PHENYLPROPANOLAMINE HYDROCHLORIDE

/terra-cortric/ /pfizer Labs/pfizer/ /hyprocortisone: oxytetracycline hcl/

TUSS-ORNADE SK&F LABORATORIES
CARAMIPHEN EDISYLATE; CHLORPHENIRAMINE MALEATE;
ISOPROPAMIDE IODIDE; PHENYLPROPANOLAMINE HYDROCHLORIDE

CURRENT STATUS - EFFECTIVENESS TO BE DETERMINED

M.V.I. PEDIATRIC USV PHARMACEUTICAL
ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL;
ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE;
PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN FHOSPHATE SODIUM;
THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E





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505 of the Federal Food, Drug and Cosmetic Act, authorizing the Agency to accept abbreviated new drug applications for most previously approved drug products. This new legislation also provides for extending the term of a patent which claims a product, use, or method of manufacture that was subject to a regulatory review period in accordance with the Act. On September 24, 1984, the President signed into Taw the Drug Price Competition and Patent Term Restoration Act of 1984. The Act amends section

The statute requires that FDA make publicly available a list of products containing the following information: approved drug

- an alphabetical list of all drugs by official and proprietary name approved for safety and effectiveness, with monthly updates;
- 2) the application number and approval date for approved after 1981; and 1981; and each drug product
- $\frac{\omega}{\omega}$ whether in vitro and/or for ANDA approval. in vivo bioequivalence studies are required

Evaluations, 5th currement. The Approved Prescription Drug Products with Therapeutic Equivalence Evaluations, 5th Edition, (APDP) and its monthly supplements will be used to

In addition, the APDP will identify drugs which qualify under the new statute for periods of exclusivity (during which ANDAs and paper NDAs for those drugs may not be submitted or made effective as identified below) and will provide information on the current patent status of the listed drugs. Exclusivity prevents the filing and/or approval of ANDAs or paper NDAs. It does not prevent the filing or approval of a second NDA. Applications qualifying for periods of exclusivity are:

(1) A new drug application approved between January 1, 1982, and September 24, 1984, for a drug product involving an active ingredient (including any ester or salt of the active ingredient) which had never been approved in any other application. Approval of an ANDA or paper NDA for the same drug may not be made effective for a period of years from the date of the approval of the original application. ten

- application. Generally, no subsequent ANDA or paper NDA for the same drug may be submitted for a period of five application, except that such an application may be submitted after four years if it contains a certification that a patent claiming the drug is invalid or will not be infringed by the product for which approval is sought. A new drug application approved after September 24, 1984, the active ingredient) which has never been approved in any other new drug active ingredient for a drug product involving an (including any ester or salt of (2)
- A new drug application approved after September 24, 1984, for a drug product involving an active ingredient (or any ester or salt of that active ingredient) that has been approved in an earlier new drug application and which includes reports of new clinical investigations (other than bioavailability studies). Such investigations must have been essential to approval of the application. If these 5 requirements are met, the approval of a subsequent ANDA nay not be made effective for the same drug before texpiration of three years from the date of approval of original application.
- essential to the approval of the supplement and conducted or sponsored by the firm submitting the supplement. The approval of a subsequent application for a change approved in the supplement may not be made effective for three years from the date of approval of the original supplement. A supplement to a new drug application approved after September 24, 1984, which contains reports of new clinical investigations (other than bioavailability studies) (4)
- A new drug application (or supplement to a new drug application) approved during the period from January 1, 1982, to September 24, 1984, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application. The approval of a subsequent application for the drug or the change made in a supplement may not be made effective for two years from September 24, (2)

The following explains how the APDP implements this.

Antibiotics, Insulin and Biologicals

Title I of the Act has been interpreted by the Agency not to include antibiotic and insulin products. Because of this, (1) antibiotic and insulin products are not considered eligible for exclusivity protection, (2) holders of approved applications for insulin and antibiotic products need not submit the patent information as required of NDA application holders, and (3) Antibiotic Form 6 sponsors are not required to provide the patent certification statement which must be included in ANDAs.

However, Title II, the patent term restoration portion of the Act, specifically addresses antibiotic, non-antibiotic, and human biological products (as those terms are used in the Federal Food, Drug and Cosmetic Public Health Service Acts) in its provisions. and

Bioavailability/Bioequivalence Requirements

The therapeutic equivalence evaluation codes in Appendix D of the APDP will enable firms to determine whether in vitro and/or in vivo bioavailability/bioequivalence study data must be included with their ANDA submissions.

forms. Currently, drugs approved prior to 1962 fall into three major biopharmaceutic classes: (1) those which pose an actual or potential bioequivalence problem, and for which demonstration of bioequivalence through in vivo testing and acceptable dissolution performance is necessary; (2) those which pose an actual or potential bioequivalence problem but for which an in vivo study may be waived if acceptable dissolution performance is demonstrated (the list of such drugs is provided under TABLE I); and (3) those which pose no actual or potential bioequivalence problem and for which the only biopharmaceutic requirement is demonstration of acceptable dissolution for solid oral dosage

All firms submitting an abbreviated new drug application for a single source drug product or a drug product which was first approved after 1962 will be required to demonstrate in vivo bioequivalence or else submit information sufficient to permit the Agency to waive demonstration of in vivo bioequivalence. Manufacturers of drug products formulated in dosage forms which do not present bioequivalence problems, such as an intravenous solutio may request that the in vivo bioequivalence requirement be waived.



Before the passage of the Drug Price Competition and Patent Term Restoration Act, the Agency approved various drugs with bioavailability/bioequivalence problems and deferred the in vivo testing requirement for a number of reasons. The new law requires information to show that the proposed ANDA drug product is bioequivalent to the listed drug. Therefore, new applications for drugs such as amitriptyline hydrochloride which formerly may have been approved without an in vivo study now require an in vivo study as a condition for approval under the new Act.

Topicals

In the absence of contrary data, FDA regarded all pharmaceutically equivalent topical products of pre-1962 (DESI) drugs to be therapeutically equivalent. However, the Agency required that applicants for topical drug products initially approved after 1962, including "paper NDAs," either demonstrate the safety and efficacy of their products through clinical trials or through a bioequivalence study in order to be evaluated as therapeutically equivalent.

The new Act requires applicants to demonstrate the bioequivalence of their topical drug product to the listed drug as one of the requirements for ANDA approval. This is the same policy that is presently being used in the "paper NDA" approval process. The Agency is now reviewing the therapeutic equivalence evaluation policy that has been made on the pre-1962 topical products to determine whether a change in this policy is warranted. In the meantime, an in vivo demonstration of bioequivalence will be required for approval of all topical products unless a waiver or in vitro alternatives can be justified by the applicant.

OTC Drug Products Eligible for Abbreviated New Drug Applications

Previous editions of the APDP excluded OTC drug products because the main purpose of that publication was to provide information to states regarding FDAs recommendation as to which generic prescription drug products were acceptable candidates for drug product selection. With the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, the Agency now has the responsibility to publish an up-to-date list of all marketed drug products, OTC as well as prescription, that have been approved for safety and efficacy and for which new drug applications are required. There are some drugs for which there are both approved and unapproved OTC drug products in the market place. This situation occurs as a result of the Agency's current OTC compliance policy which allows the marketing of various unapproved OTC drug products pending the effective date of the applicable final OTC monograph. The OTC products included in APDP cumulative supplement TABLE II are limited to those for which approved applications are currently required as a condition of marketing. Appropriate patent numbers and expiration dates are also included.

All products accepted and approved under Section 505 of the Act as NDAs by the Office of Biological Research and Review (OBRR) will now be published in the APDP (see TABLE III). The application holder should have submitted relevant patent and exclusivity information as for other NDA drug products. These products will be listed drugs and ANDA applications may be submitted for marketing of drugs from this group. Appropriate patent numbers and expiration dates are also included.

Patent and Exclusivity Information

submitted patent information in excess of that covered by the statute, FDA has reviewed all of the patent information to assure that only appropriate patent are listed. The patents that FDA regards as covered by the statutory provisions for submission of patent information are those on the active ingredient or ingredients, or use patents for a particular indication or method of using the product. The agency will not publish patents relating to chemical intermediates, methods of manufacturing, excipients or formulations. Table IV contains patent numbers and expiration dates and, for drug products approved after 1982, the date of approval and application number as required by the Act. It was originally planned that Table IV of Cumulative Supplement 2 to would contain patent and exclusivity information. Because some firms the APDP patents FDA has

Firms submitting ANDAs after September 24, 1984, that certified that no patent information had been filed should now amend their applications with the appropriate patent certification statement.

Table IV now also identifies drugs which qualify under the new statute for periods of 5 or 10 years exclusivity. To qualify for 10 years exclusivity, a new drug application must have been approved between January 1, 1982, and September 24, 1984, for a drug product involving a new chemical entity (NCE), including any ester or salt of the chemical entity, which had never been approved in any other application. To qualify for 5 years exclusivity, the NCE must have been approved after September 24, 1984.

FDA invites comments from all interested parties on whether it has exclude any patent or exclusivity information that should have been included or included patent or exclusivity information that should have been excluded. Any revisions to the list will be published in subsequent supplements. exc luded

FDA plans to publish the remaining exclusivity information, drugs which qualify for 2 or 3 years exlusivity, in the 5th supplement to the the APDP.



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TABLE I. LIST OF DRUG PRODUCTS WHICH MUST DEMONSTRATE IN VIVO BIOAVAILABILITY ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION

ACETAMINOPHEN; ASPIRIN; BUTALBITAL; CAPSULE OR TABLET; ORAL 160-165MG; 160-165MG; 50MG

ACETAMINOPHEN; ASPIRIN; BUTALBITAL CAPSULE OR TABLET; ORAL 325MG; 325MG; 50MG

ACETAMINOPHEN; ASPIRIN; BUTALBITAL; CAFFEINE CAPSULE OR TABLET; ORAL 160-165MG; 160-165MG; 50MG; 40MG

ACETAMINOPHEN; ASPIRIN; BUTALBITAL; CAFFEINE CAPSULE OR TABLET; ORAL 325MG; 325MG; 50MG; 40MG

ACETAMINOPHEN; BUTALBITAL CAPSULE OR TABLET; ORAL 325; 50MG 650; 50MG

ACETAMINOPHEN; BUTALBITAL; CAFFEINE CAPSULE OR TABLET; ORAL 325MG; 50MG; 40MG 650MG; 50MG; 40MG

AMINOPHYLLINE TABLET; ORAL 100MG 200MG

650; 50MG

ASPIRIN; BUTALBITAL; CAPSULE OR TABLET; ORAL 325; 50MG ASPIRIN; BUTALBITAL, CAFFEINE CAPSULE OR TABLET; ORAL 325MG; 50MG; 40MG; 650MG; 50MG; 40MG;

ASPIRIN; CAFFEINE; CARISOPRODOL TABLET; ORAL 160MG; 32MG; 200MG

ASPIRIN; CAFFEINE; CARISOPRODOL; CODEINE PHOSPHATE TABLET; ORAL 160MG; 32MG; 200MG; 16MG

ASPIRIN; CARISOPRODOL TABLET; ORAL 325MG; 200MG

ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE 325MG; 200MG; IOMG

ASPIRIN; MEPROBAMATE TABLET; ORAL 325MG; 200MG

ASPIRIN; METHOCARBAMOL TABLET; ORAL 325MG; 200MG

CHLOROTHIAZIDE TABLET; ORAL 250MG

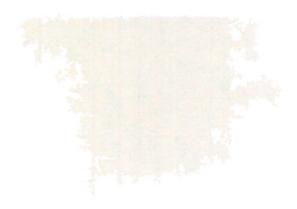
ESTROGENS, CONJUGATED; MEPROBAMATE TABLET; ORAL 0.4MG; 200MG 0.4MG; 400MG

HYDROXYZINE HYDROCHLORIDE TABLET; ORAL

25MG 50MG 100MG

IOMG





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TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
ACETAM I NOPHEN	NEOPAP	WEBCON PHARMS/ALCON	16-401		
1 20MG	(SUPPOSITORY; RECTAL)		11-07-68		
ACETAM I NOPHEN	TYLENOL	MCNEIL LABORATORIES	17-756		
650MG	(SUPPOSITORY; RECTAL)		05-26-76		
ACETAM I NOPHEN	TYLENOL	MCNEIL LABORATORIES	17-756		
120MG	(SUPPOSITORY; RECTAL)		05-26-76		
ACETAM I NOPHEN	ACEPHEN	G AND W LABORATORIES	18-060		
120MG	(SUPPOSITORY; RECTAL)		02-09-78		
ACETAM I NOPHEN	ACEPHEN	G AND W LABORATORIES	18-060		
650MG	(SUPPOSITORY; RECTAL)		02-09-78		
ACETAM I NOPHEN	ACETAM I NOPHEN	UPSHER-SMITH LABS	18-337		
650MG	(SUPPOSITORY; RECTAL)		04-22-80		
ACETAM I NOPHEN	ACETAM I NOPHEN	UPSHER-SMITH LABS	18-337		
120MG	(SUPPOSITORY; RECTAL)		09-12-83		
ALUMINUM HYDROXIDE; MAGNESIUM	GAVISCON	MARION LABORATORIES	18-685		
TRISILICATE 80MG; 20MG	(TABLET, CHEWABLE; ORAL)		12-09-83		
ALUMINUM HYDROXIDE; MAGNESIUM	GAVISCON-2	MARION LABORATORIES	18-685		
TRISILICATE 160MG; 40MG	(TABLET, CHEWABLE; ORAL)		12-09-83		
BROMPHENIRAMINE MALEATE	DIMETANE	AH ROBINS	10-799		
8MG	(TABLET, CONTROLLED RELEASE; ORAL)		06-10-83		



EXCLUSIVITY
EXP. DATE

TABLE II. OTC DRUG PRODUCTS WHICH CURRENTLY REQUIRE APPROVED APPLICATIONS AS A CONDITION OF MARKETING

	(1100 -3513 130		
I SMC	(TABLET, CONTROLLED		87-81-01
CHLORPHENIRAMINE MALEATE	CHLOR-TR I METON	SCHER ING	8 £ 9– 7 0
,	RELEASE; ORAL)		
SMC.	(TABLET, CONTROLLED		87-81-01
CHLORPHEN IRAM INE MALEATE	CHLOR-TR IMETON	SCHERING	829-40
	RELEASE; ORAL)		
ISMS	(CAPSULE, CONTROLLED		84-11-90
CHLORPHENIRAMINE MALEATE	TELDRIN	WENTEX 8 JAMES/SKF	692-11
	RELEASE; ORAL)		
SMB	(CAPSULE, CONTROLLED		84-11-90
CHLORPHEN IRAM INE MALEATE	TELDRIN	MENTEX 8 JAMES/SKF	69⊊-∠1
% b	(SPONGE; TOPICAL)		18-72-80
CHLORHEXIDINE GLUCONATE	HIBICLENS	ICI AMERICAS	18-423
80	(SOLUTION; TOPICAL)		94-41-60
CHLORHEXIDINE GLUCONATE	HIBICLENS	ICI VMEBICAS	894-41
% t	(AEROSOL; TOPICAL)		12-24-84
CHLORHEXIDINE GLUCONATE	EXIDINE	28AJ MUISTTX	121-61
***	(SOLUTION; TOPICAL)		12-24-84
CHLORHEXIDINE GLUCONATE	EXIDINE	28AJ MUISTTX	971-61
%⊆° 0	(SOLUTION; TOPICAL)		08-52-80
CHLORHEX ID I NE GLUCONATE	TATZIBIH	ICI VMEBICVZ	18-300
%⊆° 0	(TINCTURE; TOPICAL)		87-81-21
CHLORHEXIDINE GLUCONATE	HIBITANE	ICI AMERICAS	670-81
	RELEASE; ORAL)		
I SWC	(TABLET, CONTROLLED		£8−01−90
BROMPHENIRAMINE MALEATE	DIMETANE	AH ROBINS	664-01
21RENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE EXP. DA
ACTIVE INGREDIENT(S)	TRADE NAME	APPLI CANT NAME	NDA # ADN

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RELEASE; ORAL)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 8MG; 75MG	CONTAC (CAPSULE, CONTROLLED RELEASE; ORAL)	MENLEY & JAMES/SKF	18-099 02-04-80		
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 12MG; 75MG	TRIAMINIC-12 (TABLET, CONTROLLED RELEASE; ORAL)	DORSEY LABS/SANDOZ	18-115 07-23-81		aci
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 4MG; 25MG	DEMAZIN (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-556 05-14-84		
CHLORPHENIRAMINE MALEATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 8MG; 75MG	PHENYLPROPANOLAMINE HCL W/ CHLORPHENIRAMINE MALEATE (CAPSULE, CONTROLLED RELEASE; ORAL)	CENTRAL PHARMS	18-809 05-07-84		
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 8MG; 120MG	CHLOR-TRIMETON (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-397 03-31 - 81		
CHLORPHENIRAMINE POLISTIREX; PHENYLPROPANOLAMINE POLISTIREX EQ 4MG MALEATE/5ML; EQ 37.5MG HCL/5ML	CORSYM (SYRUP; ORAL)	PENNWALT PHARM	18-050 01-04-84	4	
DEXBROMPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE 6MG; 120MG	DRIXORAL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	13-483 09-13-82		



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LL-80-Z0 (INJECTABLE; INJECTION) WIXED BEEL AND PORK 926-L1 TITTL BES TYBS DIA NPH ILETIN (BEEF-PORK) INSULIN SUSPENSION, ISOPHANE, JM/STINU 001 10-28-82 (INJECTABLE; INJECTION) BIOSYNTHETIC HUMAN 187-81 ברו רוררג HOWOLIN N INSULIN SUSPENSION, ISOPHANE, JM/STINU 001 **LL-80-20** (INJECTABLE; INJECTION) BEEF 17-929 SQUIBB-NOVO SEMILENTE INSULIN INSULIN SUSPENSION, ISOPHANE, JM/STINU 04 77-80-20 (INJECTABLE; INJECTION) BEEF 11-656 SÓN I BB-NO AO SEMILENTE INSULIN INSULIN SUSPENSION, ISOPHANE, 18-81-90 (TABLET; ORAL) **500MG** 02-58-82 388888 19-012 UPJOHN MANUFACTURING NIARIN IBUPROFEN 05-28-85 18-81-90 (TABLET; ORAL) **200MG** 3385886 WHITEHALL LABS/AMHO ADVIL 686-81 IBUPROFEN 84-90-01 (TABLET; ORAL) SEMG PF I ZER 990-81 MOSINA DOXYLAMINE SUCCINATE 18-70-80 (SYRUP; ORAL) 12,5MG/5ML 715-90 PARKE-DAVIS/W-L **BENALIN** DI SHENHADBAM I NE HYDROCHLORI DE RELEASE; ORAL) (SUSPENSION, CONTROLLED 10-08-82 EQ 30MG HBR/5ML 859-81 PENNWALT PHARM DETRAW DEXTROMETHORPHAN RESIN COMPLEX RELEASE; ORAL) **EMG: 120MG** 28-21-60 (TABLET, CONTROLLED PSEUDOEPHEDRINE SULFATE DEXBROMPHENIRAMINE MALEATE; 13-483 DISOPHROL SCHER I NG EXP. DATE EXP. DATE APPROVAL DATE (DOSAGE FORM; ROUTE) STRENGTH(S) # YON ACTIVE INGREDIENT(S) EXCLUSIVITY PATENT # APPLICANT NAME **TRADE NAME**

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
INSULIN SUSPENSION, ISOPHANE, MIXED BEEF AND PORK IOO UNITS/ML	NPH ILETIN (BEEF-PORK) (INJECTABLE; INJECTION)	LILLY RES LABS DIV	17 - 936 02 - 08 - 77		
INSULIN SUSPENSION, ISOPHANE, PURIFIED BEEF 100 UNITS/ML	NPH ILETIN II (INJECTABLE; INJECTION)	ELI LILLY	18-479 06-12-80		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK 100 UNITS/ML	INSULIN INSULATARD NPH NORDISK (INJECTABLE; INJECTION)	NORDISK	18-194 01-16-80		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK 100 UNITS/ML	NPH ILETIN II (PORK) (INJECTABLE; INJECTION)	ELI LILLY	18-345 12-05-79		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK 100 UNITS/ML	PROTAPHANE (INJECTABLE; INJECTION)	SQU I BB-NO VO	18-623 07-30-81		
INSULIN SUSPENSION, ISOPHANE, PURIFIED PORK; INSULIN, PURIFIED PORK 100 UNITS/ML	INSULIN NORDISK MIXTARD (PORK) (INJECTABLE; INJECTION)	NORDISK	18-195 01-16-80		
INSULIN SUSPENSION, PROTAMINE ZINC, MIXED BEEF AND PORK 100 UNITS/ML	PROTAMINE, ZINC & ILETIN (BEEF-PORK) (INJECTABLE; INJECTION)	ELI LILLY	17-932 02-08-77		
INSULIN SUSPENSION, PROTAMINE ZINC, MIXED BEEF AND PORK; INSULIN, MIXED BEEF AND PORK 100 UNITS/ML	PROTAMINE, ZINC & ILETIN (BEEF-PORK) (INJECTABLE; INJECTION)	ELI LILLY	17-932 02-08-77		



SOUIBB-NOVO

SÓN I BB-NO AO

(INJECTABLE; INJECTION)

(INJECTABLE; INJECTION)

ULTRATARD

MAMUH GRATONOM

08-71-50

28-02-80

LLL-81

18-385

JM/STINU 001

JM/STINU 001

BIOSYNTHETIC HUMAN

EXTENDED, PURIFIED BEEF

INSULIN ZINC SUSPENSION,

INSULIN ZINC SUSPENSION,

LL-80-Z0 (INJECTABLE; INJECTION) TW/SLIND OOL 866-71 SÓNIBB-NOAO LENTE INSULIN INSULIN ZINC SUSPENSION, BEEF **LL-80-20** (INJECTABLE; INJECTION) TW/SIIND OF SÓN IBB-NOVO 866-L1 **LENTE INSULIN** INSULIN ZINC SUSPENSION, BEEF JM/STINU 001 (INJECTABLE; INJECTION) PURIFIED PORK 15-05-79 ILETIN II(PORK) ZINC' PURIFIED PORK; INSULIN, 975-81 ברו רוררג PROTAMINE ZINC AND INSULIN SUSPENSION, PROTAMINE TW/SLIND OOI (INJECTABLE; INJECTION) PURIFIED BEEF 08-71-90 ZINC' DURIFIED BEEF; INSULIN, ILETIN II ברו רוררג 947-81 PROTAMINE ZINC AND INSULIN SUSPENSION, PROTAMINE JM/STINU 001 LL-80-Z0 (INJECTABLE; INJECTION) ZINC' DURIFIED BEEF 876-71 ER SOUIBB AND SONS PROTAMINE ZINC INSULIN INSULIN SUSPENSION, PROTAMINE TW/SIINN OF **LL-80-20** (INJECTABLE; INJECTION) ZINC' ENBIFIED BEEF 17-928 ER SQUIBB AND SONS PROTAMINE ZINC INSULIN INSULIN SUSPENSION, PROTAMINE EXP. DATE EXP. DATE APPROVAL DATE (DOSAGE FORM; ROUTE) STRENGTH(S) **EXCLUSIVITY** PATENT # # YON APPLICANT NAME TRADE NAME ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
INSULIN ZINC SUSPENSION, EXTENDED, PURIFIED BEEF 100 UNITS/ML	ULTRALENTE INSULIN (INJECTABLE; INJECTION)	SQU I BB-NO VO	17-997 02-08-77		
INSULIN ZINC SUSPENSION, PROMPT, BEEF 100 UNITS/ML	SEMILENTE INSULIN (INJECTABLE; INJECTION)	SQU IBB-NOVO	17-996 02-08-77		
INSULIN ZINC SUSPENSION, PROMPT, PURIFIED PORK 100 UNITS/ML	SEMITARD (INJECTABLE; INJECTION)	SQU IBB-NOVO	18-382 03-17-80		
INSULIN ZINC SUSPENSION, PURIFIED BEEF 100 UNITS/ML	LENTE ILETIN II (INJECTABLE; INJECTION)	ELI LILLY	18-477 06-12-80		
INSULIN ZINC SUSPENSION, PURIFIED BEEF AND PORK 100 UNITS/ML	LENTARD (INJECTABLE; INJECTION)	SQU IBB-NOVO	18-384 03-17-80		
INSULIN ZINC SUSPENSION, PURIFIED PORK 100 UNITS/ML	LENTE ILETIN II (PORK) (INJECTABLE; INJECTION)	ELI LILLY	18-347 12-05-79		
INSULIN ZINC SUSPENSION, PURIFIED PORK 100 UNITS/ML	MONOTARD (INJECTABLE; INJECTION)	SQU IBB-NOVO	18-383 03-17-80		
INSULIN, BIOSYNTHETIC HUMAN IOO UNITS/ML	ACTRAPID HUMAN (INJECTABLE; INJECTION)	SQU IBB-NOVO	18-778 08-30-83		



(TABLET; ORAL)

130MG

10-14-82

		CO 71 01		(1400 -17 1041)	0/1021
		199- 81	ANBEX	TA201	POTASSIUM IODIDE
		78-61-20		(SOLUTION; ORAL)	JM/MD I
		18-551	ROXANE LABORATORIES	POTASSIUM IODIDE	POTASSIUM IODIDE
		64-60-11		(TABLET; ORAL)	130MG
		70 2- 81	MALLACE LABS/C-W	THYRO-BLOCK	POTASSIUM IODIDE
		28-10-40		(SPONGE; VAGINAL)	I GW
		Σ89−8Ι	VLI CORPORATION	YAGOT	6-TONAXONON
		08-71-20		(INJECTABLE; INJECTION)	JM\STINU OOI
		182-81	SÓN IBB-NOAO	OI 9ARTOA	INSULIN, PURIFIED PORK
		15-05-79		(INJECTABLE; INJECTION)	JM/STINU 001
		18-344	ברו רוררג	REGULAR ILETIN II (PORK)	INSULIN, PURIFIED PORK
				(INJECTABLE; INJECTION)	
		08-91-10		(PORK)	JM/STINU 001
		£61 - 81	NOKDISK INSULIN LABS	INSULIN NORDISK ÓDICK	INSULIN, PURIFIED PORK
		08-21-90		(INJECTABLE; INJECTION)	JM/STINU 001
		874-81	ברו רוררג	REGULAR ILETIN II	INSULIN, PURIFIED BEEF
		<i>LL</i> -80-20		(INJECTABLE; INJECTION)	JM/STINU 001
		976-71	SQUIBB-NOVO	INSULIN	INSULIN, PORK
		<i>LL</i> -80-20		(INJECTABLE; INJECTION)	JM/STINU O4
		926-11	SÓN I BB-NO AO	INSULIN	INSULIN, PORK
		10-28-82		(INJECTABLE; INJECTION)	JM/STINU 001
		087-81	ברו רוררג	HUMULIN R	INSULIN, BIOSYNTHETIC HUMAN
EXP. DATE	EXP. DATE	APPROVAL DATE		(DOSAGE FORM; ROUTE)	STRENGTH(S)
EXCLUSIVITY	PATENT #	# YON	APPL I CANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)



ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
PSEUDOEPHEDRINE HYDROCHLORIDE	SUDAFED S.A. (CAPSULE, CONTROLLED RELEASE; ORAL)	BURROUGHS WELLCOME	17-941 01-15-79		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	ACTIFED (SYRUP; ORAL)	BURROUGHS WELLCOME	11-935 11-26-82		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	ACTIFED (TABLET; ORAL)	BURROUGHS WELLCOME	11-936 11-26-82		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	ALLERBAN PLUS (SYRUP; ORAL)	BAY LABORATORIES	88-116 03-04-83		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRI-SUDO (TABLET; ORAL)	MD PHARMACEUTICAL	85-024 01-10-84		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 60MG; 2.5MG	TRIPODRINE (TABLET; ORAL)	DANBURY PHARMACAL	88-112 01-20-83		
PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE 30MG/5ML; 1.25MG/5ML	TRIOFED (SYRUP; ORAL)	NATL PHARM MFG/BARRE	88-115 03-04-83		
PSEUDOEPHEDRINE SULFATE	AFRINOL (TABLET, CONTROLLED RELEASE; ORAL)	SCHERING	18-191 10-30-80		
TIOCONAZOLE	TROSYD (CREAM; TOPICAL)	PFIZER CEN RES/PFIZR	18-682 02-18-83	4062966 12 - 13 - 94	NCE 02-18-93



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ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXP. DATE
ANTICOAGULANT CITRATE DEXTROSE SOLUTION USP	NONE (INJECTABLE; INJECTION)	_CUTTER BIOL/MILES	10-102 12-14-61		٤
302011011 031	(MOZOT/DZZ, MOZOTION)		12 14 01		1
ANTICOAGULANT CITRATE DEXTROSE	NONE	DELMED	11-912		
SOLUTION USP	(INJECTABLE; INJECTION)		9-2-59		
ANTICOAGULANT CITRATE DEXTROSE	NONE	TRAVENOL LABS	10-855		
SOLUTION USP	(INJECTABLE; INJECTION)		06-11-59		
ANTICOAGULANT CITRATE DEXTROSE	NONE	TRAVENOL LABS	16-918		
SOLUTION USP	(INJECTABLE; INJECTION)		3-17-78		
ANTICOAGULANT CITRATE	NONE	CUTTER BIOL/MILES	80-77		
PHOSPHATE DEXTROSE ADENINE-I SOLUTION	(INJECTABLE; INJECTION)		11-6-80		
ANTICOAGULANT CITRATE PHOSPHATE	NONE	DELMED	78-519		
DEXTROSE ADENINE SOLUTION	(INJECTABLE; INJECTION)	DELMED	4-23-80		
	NAME .	TERUNA MERIAL	00.500		
ANTICOAGULANT CITRATE PHOSPHATE DEXTROSE ADENINE SOLUTION	NONE (INJECTABLE; INJECTION)	TERUMO AMERICA	82-528 11-3-82		
DEXTROSE ADENTILE SOCIETION	(INSECTABLE, INSECTION)		11-3-62		
ANTICOAGULANT CITRATE PHOSPHATE	NONE	TRAVENOL LABS	77-420		
DEXTROSE ADENINE SOLUTION	(INJECTABLE; INJECTION)		5-12-78		
ANTICOAGULANT CITRATE	NONE	CUTTER BIOL/MILES	16-527		
PHOSPHATE DEXTROSE SOLUTION USP	(INJECTABLE; INJECTION)		6-22-70		
ANTICOAGULANT CITRATE	NONE	CUTTER BIOL/MILES	80-222		
PHOSPHATE DEXTROSE SOLUTION USP	(INJECTABLE; INJECTION)		8-23-82		~
031					



0.42GM/100ML, DIBASIC SODIUM CHLORIDE USP 0.285GM/100ML, ADENINE 0.017GM/100ML, GM/100ML, ADENINE 0.017GM/100ML, GM/100ML O.396GM/100ML, GM/100ML O.396GM/100ML, GM/100ML O.396GM/100ML

DOUBLE DEXTROSE SOLUTION WITH:

ANTIONAGULANT CITRATE PHOSPHATE

AS-2: CITRIC ACID USP

ADENINE 0.27GM/100ML

EXP. DATE

EXCLUSIVITY

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9-22-83

85-915

MANNITOL USP 0.75GM/100ML, SODIUM CHLORIDE USP 0.9GM/100ML, (INJECTABLE; INJECTION) AS-1: DEXTROSE USP 2,2GM/100ML, 28-91-9 PRESERVATION SOLUTION DEXTROSE SOLUTION USP WITH: 1011-18 ANTICOAGULANT CITRATE PHOSPHATE TRAVENOL LABS ADSOLR RED CELL 58-82-9 (INJECTABLE; INJECTION) DEXTROSE SOLUTION USP 81-1012 TRAVENOL LABS NONE ANTIONAGULANT CITRATE PHOSPHATE 15-6-77 (INJECTABLE; INJECTION) DEXTROSE SOLUTION USP 107-41 TRAVENOL LABS NONE ANTICOAGULANT CITRATE PHOSPHATE 18-01-9 (INJECTABLE; INJECTION) DEXTROSE SOLUTION USP 1121-84 TERUMO AMERICA NONE ANTICOAGULANT CITRATE PHOSPHATE 51-51-5 (INJECTABLE; INJECTION) DEXIBOSE SOLUTION USP 406-91 DECMED NONE ANTICOAGULANT CITRATE PHOSPHATE (DOSAGE FORM; ROUTE) APPROVAL DATE EXP. DATE STRENGTH(S) PATENT # # AQN APPLICANT NAME TRADE NAME ACTIVE INGREDIENT(S)

CUTTER BIOL/MILES

(INJECTABLE; INJECTION)

Y2-2 NUTRICEL ADITIVE

SYSTEM

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ANTICOAGULANT CITRATE PHOSPHATE DOUBLE DEXTROSE SOLUTION WITH: AS-3: CITRIC ACID USP 0.042 GM/100ML, MONOBASIC SODIUM PHOSPHATE USP 0.276GM/100ML, SODIUM CHLORIDE USP 0.410 GM/100ML, ADENINE 0.30	AS-3 NUTRICEL ADDITIVE SYSTEM (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	82-915 10-19 - 84		
GM/100ML, DEXTROSE USP 1.10 GM/100ML, SODIUM CITRATE USP 0.588GM/100ML					
ANTICOAGULANT HEPARIN SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	77-822 5-17-78		
ANTICOAGULANT HEPARIN SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	81-1217 5-16-83		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	ALPHA THERAPEUTIC	81-416 10-12-83		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	CUTTER BIOL/MILES	76-305 6-30-78		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	DELMED	16-702 12-28-70		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TERUMO AMERICA	78-1214 2-8-80		
ANTICOAGULANT SODIUM CITRATE SOLUTION USP	NONE (INJECTABLE; INJECTION)	TRAVENOL LABS	77-923 1-20-78		



WEERICAN MCGAW

(INJECTABLE; INJECTION)

NONE

04-9-7

L9L-91

0.9GM/100ML

DEXTROSE 5%

10GW/100WF IN

DEXTRAN 40, 10%

SODIUM CHLORIDE 0.9%

04-9-4 (INJECTABLE; INJECTION) 10GW/100WL 1N 191-91 AMERICAN MCGAW NONE DEXTRAN 40, 10% 0.9GM/100ML SODIUM CHLORIDE 0.9% 2-4-83 (INJECTABLE; INJECTION) NI 7W001/W99 18-253 ABBOTT LABORATORIES NONE DEXTRAN 75, 6% 0.9GM/100ML SODIUM CHLORIDE 0.9% 25-15-5 (INJECTABLE; INJECTION) NI 7W001/W09 DEXTRAN 75, 6% 618-8 ABBOTA LABORATOR I ES NONE 2GW/100WL DEXTROSE 5% (INJECTABLE; INJECTION) NI 7W001/WD9 25-15-5 ABBOTT LABORATORIES DEXTRAN 75, 6% 618-8 NONE 0.9GM/100ML SODIUM CHLORIDE 0.9% 19-52-L (INJECTABLE; INJECTION) 10GW/100WF 1N 515-91 ABBOTT LABORATORIES NONE DEXTRAN 40, 10% 2CW/100ML DEXTROSE 5% 1-25-67 (INJECTABLE; INJECTION) I DEW/ I DOWN IN DEXTRAN 40, 10% SLE-91 ABBOTT LABORATORIES NONE EXP. DATE EXP. DATE APPROVAL DATE (DOSAGE FORM; ROUTE) STRENGTH(S) EXCLUSIVITY PATENT # # YON APPLICANT NAME TRADE NAME ACTIVE INGREDIENT(S)

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ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
DEXTRAN 70, 6%	NONE	AMERICAN MCGAW	9-024		
6GM/100ML IN	(INJECTABLE; INJECTION)		8-18-69		
SODIUM CHLORIDE 0.9%					
0.9GM/100ML					
DEXTRAN 40, 10%	NONE	CUTTER BIOL/MILES	16-653		
IOGM/IOOML IN	(INJECTABLE; INJECTION)		9-23-69		
DEXTROSE 5%					
5GM/100ML					
DEXTRAN 40, 10%	NONE	CUTTER BIOL/MILES	16-653		
IOGM/IOOML IN	(INJECTABLE; INJECTION)		9-23-69		
SODIUM CHLORIDE 0.9%					
0.9GM/100ML					
DEXTRAN 70, 6%	NONE	CUTTER BIOL/MILES	8-716		
6GM/IOOML IN	(INJECTABLE; INJECTION)		8-11-69		
SODIUM CHLORIDE 0.9%					
0.9GM/100ML					
DEXTRAN 40, 10%	NONE	PHARMACHEM	16-836		
IOGM/IOOML IN	(INJECTABLE; INJECTION)		11-14-70		
DEXTROSE 5%					
5GM/100ML					
DEXTRAN 40, 10%	NONE	PHARMACHEM	16-836		
IOGM/IOOML IN	(INJECTABLE; INJECTION)		11-14-70		
SODIUM CHLORIDE 0.9%					
0.9GM/100ML					
DEXTRAN 75, 6%	NONE	PHARMACHEM	8-564		
6GM/100ML IN	(INJECTABLE; INJECTION)		9-19-52		
SODIUM CHLORIDE 0.9%					
0.9GM/100ML					





2GW/100WF



ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTRAN 40, 10% 10GM/10OML IN SODIUM CHLORIDE 0.9% 0.9GM/10OML	GENTRAN ^R 40 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-628 11-4-68		
DEXTRAN 75, 6% 6GM/IOOML IN SODIUM CHLORIDE 0.9% 0.9GM/IOOML	GENTRAN ^R 75 (INJECTABLE; INJECTION)	TRAVENOL LABS	16-607 1-26-70		
DEXTRAN 75, 6% INVERTED SUGAR 10% 6GM/100ML;10GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	6% GENTRAN ^R 75 AND 10% TRAVERT ^R (INJECTABLE; INJECTION)	TRAVENOL LABS	8-788 2-9-53		
HETASTARCH, 6% 6GM/100ML IN SODIUM CHLORIDE 0.9% 0.9GM/100ML	HESPANR (INJECTABLE; INJECTION)	AM CRITICAL CARE	16-889 7-17-72	3523938 8-11 - 87	
PROPIOLACTONE 99% 99GM/100ML	BETAPRONE (SOLUTION; CHEMICAL STERILIZING AGENT)	ONEAL JONES&FELDMAN	11 - 657 9-11-59		
UROKINASE 5000 IU/VIAL	ABBOKINASE OPEN-CATHETER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	76-1021 12-15-83		
UROKINASE 250,000 IU/VIAL	ABBOKINASE (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	76-1021 7-31-78		
UROKINASE 250,000 IU/VIAL	BREOKINASE (INJECTABLE; INJECTION)	STERLING DRUG	17-873 8-28-79		





ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
ACEBUTOLOL HYDROCHLORIDE	SECTRAL	IVES LABS/AMHO	18-917	3726919	NCE
EQ 200MG BASE	(CAPSULE; ORAL)		12-28-84	04-10-90	12-28-89
				3857952	
				12-31-91	
ACEBUTOLOL HYDROCHLORIDE	SECTRAL	IVES LABS/AMHO	18-917	3726919	NCE
EQ 300MG BASE	(CAPSULE; ORAL)		12-28-84	04-10-90	12-28-89
				3857952	
				12-31-91	
ACEBUTOLOL HYDROCHLORIDE	SECTRAL	IVES LABS/AMHO	18-917	3726919	NCE
EQ 400MG BASE	(CAPSULE; ORAL)	TVES ENDS/NAIN	12-28-84	04-10-90	12-28-89
	(5/11/5522)		12 20 01	3857952	12 20 05
				12-31-91	
ACETAMINOPHEN; PENTAZOCINE HYDROCHLORIDE	TALACEN	STERLING DRUG	18-458	4105659	
625MG; EQ 25MG BASE	(TABLET; ORAL)	-	09-23-82	08-08-95	
ACETAZOLAMIDE	DIAMOX	LEDERLE LABS/AM CYAN	12-945	3544005	
500MG	(CAPSULE, CONTROLLED RELEASE; ORAL)		01-25-62	06-08-88	
ACETIC ACID, GLACIAL	ACETIC ACID 0.25%	TRAVENOL LABS	18-523		
250MG/100ML	IN PLASTIC CONTAINER		02-19-82		
	(SOLUTION; URETHRAL)				
ACETOHYDROXAMIC ACID	LITHOSTAT	URO-RESEARCH	18-749		NCE
250MG	(TABLET; ORAL)		05-31-83		05 -31-93
ACYCLOVIR	ZOVIRAX	BURROUGHS WELLCOME	18-604	4199574	NCE
5%	(OINTMENT; TOPICAL)		03-29-82	04-22-97	03-29-92



BOLAR PHARMACEUTICAL

BOLAR PHARMACEUTICAL

SCHER ING

11-16-84

11-16-84

12-14-85

12-14-85

707-81

18-241

18-241

15-14-65

15-14-65

26-62-50

EXP. DATE

EXCLUSIVITY

NCE

NCE

NCE

96-40-11

4124707

96-40-11

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4124707 18-702 SCHER I NG **WADERM** ALCLOMETASONE DIPROPIONATE 12-05-89 3705233 02-22-89 05-07-82 (TABLET; ORAL) EÓ 4WG BYZE 2644353 SCHER ING 558-L1 PROVENTIL ALBUTEROL SULFATE 15-05-89 3705233 02-22-89 28-10-90 (TABLET; ORAL) EÓ SWG BYZE 3644353 17-853 SCHEBING PROVENTIL ALBUTEROL SULFATE 12-05-89 3705233 02-22-89 18-10-90 (AEROSOL; INHALATION) 0.09MG/1NH 2644353 274-81 **GLAXO VENTOL IN** ALBUTEROL 12-05-89 3705233 02-22-89 18-10-90 (AEROSOL; INHALATION) HN1/9W60'0 2644353 699-11 SCHER I NG PROVENTIL **ALBUTEROL** 04-22-97 10-22-82 (INJECTABLE; INJECTION) EÓ 200MG BYSE/VIAL 7L96617 ZOVIRAX **VCACTONIE SODIUM** 18-603 BURROUGHS WELLCOME EXP. DATE APPROVAL DATE (DOSAGE FORM; ROUTE) STRENGTH(S) PATENT # TRADE NAME ACTIVE INGREDIENT(S) # YON APPLICANT NAME TABLE IV. NDA'S APPROVED FROM I-I-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

(TABLET; ORAL)

(TABLET; ORAL)

(CREAM; TOPICAL)

(OINTMENT; TOPICAL)

ALLOPUR I NOL

ALLOPUR I NOL

WADERM

300MG

100We

\$50.0

\$50.0

ALLOPUR I NOL

ALLOPUR I NOL

ALCLOMETASONE DIPROPIONATE

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ALLOPURINOL 100MG	ALLOPURINOL (TABLET; ORAL)	CHELSEA LABORATORIES	18-785 09-28-84		
ALLOPURINOL 300MG	ALLOPURINOL (TABLET; ORAL)	CHELSEA LABORATORIES	18-785 09-28-84		
ALLOPURINOL I OOMG	ALLOPURINOL (TABLET; ORAL)	DANBURY PHARMACAL	18-832 09-28-84		
ALLOPURI NOL 300MG	ALLOPURINOL (TABLET; ORAL)	DANBURY PHARMACAL	18-877 09-28-84		
ALLOPUR I NOL I OOMG	ZYLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	16-084 08-19-66	3624205 11-30-88	
ALLOPURI NOL 300MG	ZYLOPRIM (TABLET; ORAL)	BURROUGHS WELLCOME	16-084 01-14-74	3624205 11-30-88	
ALLOPURINOL 100MG	LOPURIN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-297 06-10-80	3624205 11-30-88	
ALLOPURINOL 300MG	LOPURIN (TABLET; ORAL)	BOOTS PHARMACEUTICAL	18-297 06-10-80	3624205 11-30-88	
ALPRAZOLAM 0.25MG	XANAX (TABLET; ORAL)	UPJOHN	18-276 10-16-81	3987052 10-19-93 3980789 09-14-93	
ALPRAZOLAM 0.5MG	XANAX (TABLET; ORAL)	UPJOHN	18-276 10-16-81	3987052 10-19-93 3980789 09-14-93	



TRAVENOL LABS

(INJECTABLE; INJECTION)

(INJECTABLE; INJECTION)

BRANCHAMIN 4\$

80

88

AMINO ACIDS

3950529 949-81 AM MCGAW/AM HOSP HEPATAMINE 8% AMINO ACIDS (INJECTABLE; INJECTION) 8t.11 28-60-80 MOVAMINE 11.4% **LS6-L1** CUTTER LABS/MILES AMINO ACIDS 28-60-80 (INJECTABLE; INJECTION) \$5.8 L96-L1 CUTTER LABS/MILES MOVAMINE 8.5% AMINO ACIDS 10-12-82 (INJECTABLE; INJECTION) 85.9 RENAMIN W/O ELECTROLYTES 267-11 TRAVENOL LABS AMINO ACIDS (INJECTABLE; INJECTION) 58-11-90 \$6.9 FREAMINE HBC 6.9% 16-822 AM MCGAW/AM HOSP WINO ACIDS PMG: 50MG 15-52-60 18-50-01 (TABLET; ORAL) HYDROCHLOROTHI AZ I DE 18-201 MODURETIC 5/50 WILLORIDE HYDROCHLORIDE; 3781430 MS&D/MERCK 18-51-11 (OINTMENT; TOPICAL) 81.0 96-71-90 CYCLOCORT 4158055 864-81 LEDERLE LABS/AM CYAN **WICHONIDE** 96-71-90 17-81-01 (CREAM; TOPICAL) \$1.0 41 28022 911-81 LEDERLE LABS/AM CYAN CYCLOCORT **WCINONIDE** £6-11-60 687086₹ **Σ6-61-01** 18-91-01 (TABLET; ORAL) IWC 3987052 972-81 NHOL 9U XANAX MAJOZARAJA EXP. DATE EXP. DATE APPROVAL DATE (DOSAGE FORM; ROUTE) STRENGTH(S) EXCLUSIVITY PATENT # # AUN APPLICANT NAME TRADE NAME ACTIVE INGREDIENT(S)

TABLE IV. NDA'S APPROVED FROM I-I-82 TO I2-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION



10-02-50

4438144

26-21-40

48-82-60

08-03-82

879-81

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
AMINO ACIDS	BRANCHAMIN 4%	TRAVENOL LABS	18-684	4438144	
4%	IN PLASTIC CONTAINER		09-28-84	03-20-01	
	(INJECTABLE; INJECTION)				
AMINO ACIDS	NEOPHAM 6.5%	CUTTER-VITRUM	18-792		
6.5%	(INJECTABLE; INJECTION)	COTTER-VITRON	01-17-84		
0.0%	(INJECTABLE; INJECTION)		01-17-84		
AMINO ACIDS	AMINOSYN 3.5%	ABBOTT LABORATORIES	18-804		
3.5%	IN PLASTIC CONTAINER		05-15-84		
	(INJECTABLE; INJECTION)				
AMINO ACIDS	AMINOSYN 3.5%	ABBOTT LABORATORIES	18-875		
3.5%	IN PLASTIC CONTAINER	- English Control of the	08-08-84		
	(INJECTABLE; INJECTION)		00 00 01		
AMINO ACIDS	AMINESS 5.2% ESSENTIAL	CUTTER-VITRUM	18-901		
5.2%	AMINO ACIDS W/ HISTADINE	COTTER-VITROM	04-06-84		
J. 26	(INJECTABLE; INJECTION)		04-00-84		
	CHISCOTABLE, INSECTION				
AMINO ACIDS	TRAVASOL 5.5%	TRAVENOL LABS	18-931		
5.5%	W/O ELECTROLYTES		08-23-84		
	IN PLASTIC CONTAINER				
	(INJECTABLE; INJECTION)				
AMINO ACIDS	TRAVASOL 8.5%	TRAVENOL LABS	18-931		
8.5%	W/O ELECTROLYTES IN PLASTIC CONTAINER		08-23-84		
	(INJECTABLE; INJECTION)				
AMINO ACIDS	TRAVASOL 10%	TRAVENOL LABS	18-931		
10%	W/O ELECTROLYTES	MATERIOL DIDS	08-23-84		
	IN PLASTIC CONTAINER		00 25 04		
	(INJECTABLE; INJECTION)				
	, , , , , , , , , , , , , , , , , , , ,				





Original from UNIVERSITY OF MICHIGAN

TABLE IV. NDA'S APPROVED FROM I-I-82 TO I2-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

2°28; ZIMG/100ML; 40MG/100ML;					
SODINM CHTORIDE	(INJECTABLE; INJECTION)				
PHOSPHORIC ACID; POTASSIUM ACETATE;	IN PLASTIC CONTAINER		t8-G1-G0		
AMINO ACIDS; MAGNESIUM ACETATE;	M %2° NYSONIMA	ABBOTT LABORATORIES	†08−8I		
	(INJECTABLE; INJECTION)				
	IN PLASTIC CONTAINER				
4°52°%	W/ DEXTROSE 25%		18-11-01		
AMINO ACIDS; DEXTROSE	\$2.4 NYSONIMA	ABBOTT LABORATORIES	611-61		
	(INTECTABLE; INTECTION)				
	IN PLASTIC CONTAINER				
3.5%; 25%	M/ DEXTROSE 25%		18-11-01		
AMINO ACIDS; DEXTROSE	\$6.5 NYZONIMA	ABBOTT LABORATORIES	811-61		
	(INJECTABLE; INJECTION)				
	IN PLASTIC CONTAINER				
%c :%c.c	M/ DEXTROSE 5%		†8-11-01		
WINO ACIDS; DEXTROSE	\$6.5 NYZONIMA	ABBOTT LABORATORIES	071-61		
1 MG/ 1 00M					
149M6/100ML; 204M6/100ML;					
24M6/100ML; 41M6/100ML;					
2%; 26M6/100ML; 36M/100ML;					
SODIUM ACETATE; SODIUM CHLORIDE					
PHOSPHORIC ACID; POTASSIUM CHLORIDE;					
GLYCERIN; MAGNESIUM ACETATE;	(INJECTABLE; INJECTION)		Z8-80-G0		
WINO ACIDS; CALCIUM ACETATE;	PER I PHRAM I NE	AM MCGAW/AM HOSP	Z8 G- 81		
THE VEHICLE CONTROL OF THE CONTROL O	SAT WYONG T GOD	ason NV/MVSON NV	69-61		
% 9	(INJECTABLE; INJECTION)		₽8- 02- L 0		
WINO VCIDS	XOPHAMINE 6%	AM MCGAW/AM HOSP	810-61		
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# YON	PATENT #	EXCLUSIVITY

128MG/100ML; 234MG/100ML

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE 3.5%; 21MG/100ML; 40MG/100ML; 128MG/100ML; 234MG/100ML	AMINOSYN 3.5% M IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-875 08-08-84		
AMINOACETIC ACID 1.5GM/100ML	AMINOACETIC ACID 1.5% IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-522 02-19-82		
AMINOCAPROIC ACID 250MG/ML	AMINOCAPROIC ACID (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-590 10-29-82		
AMINOGLUTETHIMIDE 250MG	CYTADREN (TABLET; ORAL)	CIBA/CIBA-GEIGY	18-202 10-29-80	3595960 07-27-88 3944671 03-16-93	
AMINOPHYLLINE 300MG/5ML	SOMOPHYLLIN (ENEMA; RECTAL)	FISONS	18-232 04-02-82		
AMINOPHYLLINE; SODIUM CHLORIDE 100MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	8-924 2- 2-84		*
AMINOPHYLLINE; SODIUM CHLORIDE 200MG/100ML; 450MG/100ML	AMINOPHYLLINE W/ SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-924 12-12-84		





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02-23-99

				00-26-60	
15° 2We ? 2We				1689124	
CHLORDIAZEPOXIDE	(TABLET; ORAL)		12-23-77	98-12-90	
AMITRIPTYLINE HYDROCHLORIDE;	LIMBITROL	HOFFMANN-LA ROCHE	676-91	2384663	
I OMG/ML	(INTECTABLE; INTECTION)		19-11-40	58-17-50	
AMITRIPTYLINE HYDROCHLORIDE	ELAVIL	MS&D/MERCK	12-704	2384663	
1 50MG	(TABLET; ORAL)		94-41-60	98-17-90	
MITRIPTYLINE HYDROCHLORIDE	ELAVIL	MS&D/MERCK	12-703	2384663	
100WG	(TABLET; ORAL)		10-28-76	98-17-90	
MITRIPTYLINE HYDROCHLORIDE	ELAVIL	MS&D/MERCK	12-703	2384663	
∆ ≥WC	(TABLET; ORAL)		97-82-01	98-17-90	
MITRIPTYLINE HYDROCHLORIDE	ELAVIL	MS&D/MERCK	12-703	2384663	
9W09	(TABLET; ORAL)		19-20-40	98-17-90	
MITRIPTYLINE HYDROCHLORIDE	ELAVIL	MS&D/MERCK	12-703	2384663	
SPMG	(TABLET; ORAL)		⊅ ∠-≤0-∠0	98-12-90	
AMITRIPTYLINE HYDROCHLORIDE	ELAVIL	W2&D/MERCK	12-703	2384663	
IOMG	(TABLET; ORAL)		19-10-40	98-17-90	
MITRIPTYLINE HYDROCHLORIDE	ELAVIL	MS&D/MERCK	12-703	2384663	
	(INTECTABLE; INTECTION)				
	IN PLASTIC CONTAINER				
200MG/100ML; 450MG/100ML	SODINM CHLORIDE 0.45%		12-12-84		
WINOPHYLLINE; SODIUM CHLORIDE	AMINOPHYLLINE W/	ABBOTT LABORATORIES	₱Z6 - 81		
	(INJECTABLE; INJECTION)				
	IN PLASTIC CONTAINER				
400We/100WL; 450M6/100ML	SODINM CHLORIDE 0.45\$		12-12-84		
WINOPHYLLINE; SODIUM CHLORIDE	AMINOPHYLLINE W/	ABBOTT LABORATORIES	18-924		
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# AQN	PATENT #	EXCLUSIVITY

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
AMITRIPTYLINE HYDROCHLORIDE;	LIMBITROL	HOFFMANN-LA ROCHE	16-949	3384663	
CHLORD I AZEPOX IDE	(TABLET; ORAL)		12-23-77	05-21-85	
25MG; 10MG				4316897	
				02-23-99	
AMITRIPTYLINE HYDROCHLORIDE;	ETRAFON A	SCHERING	14-713	3384663	
PERPHENAZ I NE	(TABLET; ORAL)		12-30-65	05-21-85	
IOMG; 4MG					
AMITRIPTYLINE HYDROCHLORIDE;	ETRAFON 2-25	SCHERING	14-713	3384663	
PERPHENAZINE	(TABLET; ORAL)		12-30-65	05-21-85	
25MG; 2MG					
AMITRIPTYLINE HYDROCHLORIDE;	ETRAFON-FORTE	SCHERING	14-713	3384663	
PERPHENAZINE	(TABLET; ORAL)		12-30-65	05-21-85	
25MG; 4MG					
AMITRIPTYLINE HYDROCHLORIDE;	ETRAFON 2-10	SCHER ING	14-713	3384663	
PERPHENAZINE	(TABLET; ORAL)		12-30-65	05-21-85	
IOMG; 2MG					
AMITRIPTYLINE HYDROCHLORIDE;	TRIAVIL 4-10	MS&D/MERCK	14-715	3384663	
PERPHENAZINE	(TABLET; ORAL)		12-30-65	05-21-85	
IOMG; 4MG					
AMITRIPTYLINE HYDROCHLORIDE;	TRIAVIL 2-25	MS&D/MERCK	14-715	3384663	
PERPHENAZINE	(TABLET; ORAL)		08-23-65	05-21-85	
25MG; 2MG					
AMITRIPTYLINE HYDROCHLORIDE;	TRIAVIL 2-10	MS&D/MERCK	14-715	3384663	
PERPHENAZINE	(TABLET; ORAL)		04-04-67	05-21-85	
10MG; 2MG					



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EXCLUSIVITY	PATENT #	NDA #	APPLICANT NAME	TRADE NAME (DOSAGE FORM; ROUTE)	ACTIVE INGREDIENT(S)
	2384663	51 7- 41	W2&D/MERCK	₹2-4 JIVAIAT	AMITRIPTYLINE HYDROCHLORIDE;
	9-12-90	69-52-80		(TABLET; ORAL)	S≥MG; 4MG PERPHENAZINE
	2384663	517 -4 1	M2&D/MERCK	OR-4-50	AMITRIPTYLINE HYDROCHLORIDE;
	02-51-82	87-51-50	NOVELL (CINC)	(TABLET; ORAL)	PERPHENAZINE
					SOME; 4MG
	2246226	120-81	TEDEBLE LABS/AM CYAN	VZENDIN	AMOXAP I NE
	12-08-87	09-22-80		(TABLET; ORAL)	S≥WC
	9692992				
	68-91-90				
	68-10-80 LSC189C				
	60-10-00				
	3246226	18-021	LEDERLE LABS/AM CYAN	YZEND IN	AMOXAPINE
	12-08-87	09-22-80		(TABLET; ORAL)	9W0⊆
	9692992				
	68-91-90		Carlotte Control		
	68-10-80				
	3546226	18-021	LEDERLE LABS/AM CYAN	Y SEND IN	AMOXAPINE
	12-08-87	09-22-80		(TABLET; ORAL)	I OOMG
	9692992				
	68-91-90				
	7681357				
	68-10-80				
	3546226	18-021	LEDERLE LABS/AM CYAN	YZEND I N	AMOXAPINE
	12-08-87	09-22-80		(TABLET; ORAL)	150MG
	9692992				
	68-91-90				
	7681357				
	68-10-80				

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
AMRINONE LACTATE EQ 5MG BASE/ML	INOCOR (INJECTABLE; INJECTION)	WINTHROP LABS/STERL	18-700 07-31-84	4072746 02-07-95	NCE 07-31-94
ASPIRIN; CAFFEINE; DIHYDROCODEINE BITARTRATE 356.4MG; 30MG; 16MG	SYNALGOS-DC (CAPSULE; ORAL)	IVES LABS/AMHO	11-483 09-06-83		
ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE 385MG; 30MG; 25MG	NORGESIC (TABLET; ORAL)	RIKER LABS/3M	13-416 10-27-82		
ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE 770MG; 60MG; 50MG	NORGESIC FORTE (TABLET; ORAL)	RIKER LABS/3M	13-416 10-27-82		
ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE 389MG; 32.4MG; 32MG	DARVON COMPOUND (CAPSULE; ORAL)	ELI LILLY INDSTRS/PR	10-996 03-08-83		
ASPIRIN; CAFFEINE; PROPOXYPHENE HYDROCHLORIDE 389MG; 32.4MG; 65MG	DARVON COMPOUND-65 (CAPSULE; ORAL)	ELI LILLY INDSTRS/PR	10-996 03-08-83		
ASPIRIN; CARISOPRODOL 325MG; 200MG	SOMA COMPOUND (TABLET; ORAL)	WALLACE PHARMS/C-W	12-365 07-11-83		
ASPIRIN; CARISOPRODOL; CODEINE PHOSPHATE 325MG; 200MG; 16MG	SOMA COMPOUND W/ CODEINE (TABLET; ORAL)	WALLACE PHARMS/C-W	12-366 07-11-83		
ASPIRIN; MEPROBAMATE 325MG; 200MG	EQUAGESIC (TABLET; ORAL)	WYETH LABS/AMHO	11-702 12-29-83		





16-71-60 17665 29-71-60 16-71-60

1095995

48-80-90

097-81

STUART PHARMS/ICI AM

16-11-60 1793585 26-02-10 3934032 68-91-90 (TABLET; ORAL) 100MG; 25MG 48-80-90 1095995 094-81 STUART PHARMS/ICI AM TENORETIC 100 ATENOLOL; CHLORTHAL IDONE 16-11-60 1799285 01-50-63 3934032 (TABLET; ORAL) 68-91-90 18-61-80 100MG 2092992 18-240 STUART PHARMS/ICI AM TENORMIN **ATENOLOL** 16-11-60 1799285 01-50-63 3934032 68-91-90 18-61-80 (TABLET; ORAL) SOMG 2092992 18-240 STUART PHARMS/ICI AM TENORMIN **ATENOLOL** 96-80-80 11-15-15 (TABLET; ORAL) 225MG; EQ 12,5MG BASE 6999017 168-91 WINTHROP LABS/STERL TALWIN COMPOUND ASPIRIN; PENTAZOCINE HYDROCHLORIDE EXP. DATE APPROVAL DATE (DOSAGE FORM; ROUTE) EXP. DATE STRENGTH(S) **EXCLUSIVITY** # TN3TA9 # YON APPLICANT NAME ACTIVE INGREDIENT(S) **TRADE NAME**

TABLE IV. NDA'S APPROVED FROM I-I-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

Original from UNIVERSITY OF MICHIGAN

(TABLET; ORAL)

TENORETIC 50

DOMG: SOMG

ATENOLOL; CHLORTHAL I DONE

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ATRACURIUM BESYLATE	TRACRIUM	BURROUGHS WELLCOME	18-831	4179507	NCE
I OMG/ML	(INJECTABLE; INJECTION)		11-23-83	12-18-96	11-23-93
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE	MOTOFEN HALF-STRENGTH	MCNEIL LABORATORIES	17-744	3646207	
0.025MG; 0.5MG	(TABLET; ORAL)		07-14-78	02-28-89	
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE	MOTOFEN	MCNEIL LABORATORIES	17-744	3646207	
0.025MG; IMG	(TABLET; ORAL)		07-14-78	02-28-89	
AZATADINE MALEATE	OPTIMINE	SCHER I NG	17-601	3366635	
IMG	(TABLET; ORAL)		03-29-77	01-30-85	
				3419565	
				12-31-85	
				3717647	
				02-20-90	
AZATADINE MALEATE;	TRINALIN	SCHERING	18-506	3366635	
PSEUDOEPHEDRINE SULFATE	(TABLET, CONTROLLED		03-23-82	01-30-85	
IMG; I20MG	RELEASE; ORAL)			3419565	
				12-31-85	
				3717647	
				02-20-90	
BACLOFEN	LIORESAL	GEIGY/CIBA-GEIGY	17-851	3471548	
IOMG	(TABLET; ORAL)		11-22-77	10-07-86	
BACLOFEN	LIORESAL DS	GEIGY/CIBA-GEIGY	17-851	3471548	
20MG	(TABLET; ORAL)		01-20-82	10-07-86	
BENDROFLUMETH I AZ IDE	NATURETIN-2.5	ER SQUIBB AND SONS	12-164	3392168	
2.5MG	(TABLET; ORAL)		12-07-59	07-09-85	
BENDROFLUMETHIAZIDE	NATURET IN-5	ER SQUIBB AND SONS	12-164	3392168	
5MG	(TABLET; ORAL)		12-07-59	07-09-85	



BETAMETHASONE DIPROPIONATE EQ 0.05\$ BASE	DIPROLENE; TOPICAL)	SCHER I NG	147-81 Σ8-72-70		
SMG/ML; EQ 3MG BASE/ML					
BETAMETHASONE SODIUM PHOSPHATE	(INJECTABLE; INJECTION)		59-50-50	12-23-86	
BETAMETHASONE ACETATE;	CELESTONE SOLUSPAN	SCHERING	14-602	3485854	
%z.o	(CKEAM; TOPICAL)		t9-01-t0	12-23-86	
BETAMETHASONE	CELESTONE	SCHEKING	797-41	3485854	
O* ewe/swr	(SYRUP; ORAL)		t9-81-t0	12-23-86	
BETAMETHASONE	CELESTONE	SCHERING	14-215	2485854	
0* ewe	(TABLET; ORAL)		19-11-70	12-23-86	
BETAMETHASONE	CELESTONE	SCHERING	12-657	7485854	
				06-01-40	
				3745212	
200MG,77.5ML	(SOLUTION; ORAL)		12-29-83	16-20-40	15-58-63
BENTIROMIDE	CHAMEX	ADRIA LABORATORIES	992-81	2801262	NCE
				26-12-10	
				1925262	
≥We; 80Me	(TABLET; ORAL)		28-52-50	26-17-60	
BENDROFLUMETHIAZIDE; NADOLOL	301 ZACO	EK SÓNIBB VND SONS	149-81	1202862	
				26-12-10	
				2935262	
PMG; 40MG	(TABLET; ORAL)		02-52-82	26-17-60	
BENDROFLUMETHIAZIDE; NADOLOL	∞RZ I DE	EK SÓNIBB VND SONS	L+9-81	1202862	
I OWC	(TABLET; ORAL)		LL-6Z-£0	98-60-40	
BENDROFLUMETH1 AZ I DE	OI-NITANTAN	EK SÓNIBB AND SONS	12-164	8912655	
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPRO VAL DATE	EXP. DATE	EXP. DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# AUN	PATENT #	EXCLUSIVITY

TABLE IV. NDA'S APPROVED FROM I-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

Original from UNIVERSITY OF MICHIGAN

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (CREAM; TOPICAL)	PHARMADERM/BYK-GLDN	19-136 06-26-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (CREAM; TOPICAL)	E FOUGERA/BYK-GLDN	19-137 06-26 - 84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	ALPHATREX (CREAM; TOPICAL)	SAVAGE LABS/BYK-GLDN	19-138 06-26-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (OINTMENT; TOPICAL)	PHARMADERM/BYK-GLDN	19-140 09-04-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	BETAMETHASONE DIPROPIONATE (OINTMENT; TOPICAL)	E FOUGERA/BYK-GLDN	19-141 09-04-84		
BETAMETHASONE DIPROPIONATE EQ 0.05% BASE	ALPHATREX (OINTMENT; TOPICAL)	SAVAGE LABS/BYK-GLDN	19-143 09-04-84		
BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE EQ 0.05% BASE; 1%	LOTRISONE (CREAM; TOPICAL)	SCHERING	18-827 07-10-84	3660577 05 - 02 - 89	
				3705172 12-05-89 4298604	
				11-03-98 3839573 10-01-91	
BETAMETHASONE VALERATE EQ 0.1% BASE	BETA-VAL (CREAM; TOPICAL)	LEMMON	18-642 03-24-83		
BETAMETHASONE VALERATE EQ 0.1% BASE	BETADERM (CREAM; TOPICAL)	TJ ROACO	18-839 06-30-83		



12-28-89

NCE

96-90-70

1858517

05-10-87

2109675

05-10-87

2105675

12-28-84

011-81

18-67-50

18-67-90

58-15-80

078-81

5L9-L1

5L9-L1

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EXCLUSIVITY EXP. DATE

Original from UNIVERSITY OF MICHIGAN

58-15-80 (LOTION; TOPICAL) EQ 0.1% BASE 198-81 SAVAGE LABS/BYK-GLDN **XARTATAB** BETAMETHASONE VALERATE EQ 0.1% BASE **28-12-80** (LOTION; TOPICAL) 998-81 E LONGERA/BYK-GLDN BETAMETHASONE VALERATE BETAMETHASONE VALERATE EQ 0.1% BASE (OINTMENT; TOPICAL) 28-12-80 BETAMETHASONE VALERATE 998-81 E LONCEBY/BYK-GLDN BETAMETHASONE VALERATE (OINTMENT; TOPICAL) EQ 0.1% BASE 28-12-80 18-864 PHARMADERM/BYK-GLDN BETAMETHASONE VALERATE BETAMETHASONE VALERATE 58-15-80 (OINTMENT; TOPICAL) EQ 0.1% BASE 298-81 SAVAGE LABS/BYK-GLDN **X38TAT38** BETAMETHASONE VALERATE 28-12-80 (CREAM; TOPICAL) EQ 0.1% BASE 18-862 SAVAGE LABS/BYK-GLDN **BETATREX** BETAMETHASONE VALERATE (CREAM; TOPICAL) 28-12-80 EQ 0.1% BASE BETAMETHASONE VALERATE BETAMETHASONE VALERATE 198-81 E LONGERA/BYK-GLDN 28-12-80 (CREAM; TOPICAL) EÓ 0.1% BASE BETAMETHASONE VALERATE 098-81 PHARMADERM/BYK-GLDN BETAMETHASONE VALERATE (DOSAGE FORM; ROUTE) EXP. DATE APPROVAL DATE STRENGTH(S) PATENT # ACTIVE INGREDIENT(S) # YON APPLICANT NAME TRADE NAME TABLE IV. NDA'S APPROVED FROM I-I-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

WINTHROP-BREON/STERL

PHARMADERM/BYK-GLDN

SNI BOR HA

AH ROBINS

(AEROSOL; INHALATION)

TORNALATE

NAHTANT

NAHTANT

(TABLET; ORAL)

(TABLET; ORAL)

(LOTION; TOPICAL)

BETAMETHASONE VALERATE

%8°0

SZWG

I OWC

BITOLTEROL MESYLATE

BETHANIDINE SULFATE

BETHANIDINE SULFATE

BETAMETHASONE VALERATE

EQ 0.1% BASE

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXP. DATE
BRETYLIUM TOSYLATE 50MG/ML	BRETYLOL (INJECTABLE; INJECTION)	AM CRITICAL CARE/AHS	17-954 07-18-78	RE29618 04-29-86	
BROMOCRIPTINE MESYLATE EQ 2.5MG BASE	PARLODEL (TABLET; ORAL)	SANDOZ PHARMS/SANDOZ	17-962 06-28-78	3752888 08-14-90 3752814 08-14-90	u
BROMOCRIPTINE MESYLATE EQ 5MG BASE	PARLODEL (CAPSULE; ORAL)	SANDOZ PHARMS/SANDOZ	17-962 03-01-82	3752888 08-14-90 3752814 08-14-90	
BROMODIPHENHYDRAMINE HYDROCHLORIDE; CODEINE PHOSPHATE 12.5MG/5ML; IOMG/5ML	AMBENYL (SYRUP; ORAL)	MARION LABORATORIES	09-319 01-10-84		
BROMPHENIRAMINE MALEATE; CODEINE PHOSPHATE; PHENYLPROPANOLAMINE HYDROCHLORIDE 2MG/5ML; IOMG/5ML; I2.5MG/5ML	DIMETANE-DC (SYRUP; ORAL)	AH ROBINS	11 - 694 03-29-84		
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; IOMG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AH ROBINS	11-694 03-29-84		
BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE 2MG/5ML; IOMG/5ML; 30MG/5ML	DIMETANE-DX (SYRUP; ORAL)	AH ROBINS	19 - 279 08-24-84		



0.75%; 0.0091MG/ML

IN SWIDOU O JEEL O						
EPINEPHRINE BITARTRATE	(INJECTA	E; INJECTION)		28-20-60		
BUP I VACA I NE HYDROCHLOR I DE;	SENSORCA	3	SOORY MAAHY ARTZA	18-304		
JM/5M1600.0 ; %5.0						
EPINEPHRINE BITARTRE	(INJECTA	E: INTECTION)		28-20-60		
BUPTVACAINE HYDROCHLORIDE;	SENSORCA		20099 MAAH9 AST2A	18-304		
\$52.8 : \$51.0	(INJECTA	E; INTECTION)		78-70- €0		
BUPIVACAINE HYDROCHLORIDE; DEXTROSE	MARCAINE	□∀NIc	BREON LABS/STERLING	769-81		
					16-52-40	
					\$806534	
0°S2WG/WL	(INJECTA	E: INTECTION)		02-28-83	68-11-10	02-28-93
BUMETANIDE	BUMEX		HOFFMANN-LA ROCHE	18-226	2634583	NCE
					16-52-40	
					\$29085	
0° 2WG	(TABLET;	(JAS		02-28-83	68-11-10	26-82-20
BUMETANIDE	BUMEX		HOFFMANN-LA ROCHE	18-225	2634583	NCE
					16-22-40	
					7806534	
IWC	(TABLET;	SAL)		02-28-83	68-11-10	02-28-93
BUMETANIDE	BUMEX		HOFFMANN-LA ROCHE	18-225	3634583	NCE
TWG/2ML; Z5MG/5ML						
PHENYLPROPANOLAMINE HYDROCHLORIDE	(ברוצוש:	(TV)		18-62-20		
BROMPHENIRAMINE MALEATE;	פרוצוע ס	44 A T∃	AH ROBINS	780-₹1		
I SWC: 15WC	BELEASE	(7∀80				
PHENYLPROPANOLAMINE HYDROCHLORIDE	(TABLET,	DNTROLLED		04-05-84		
BROMPHENIRAMINE MALEATE;	DIMETAPP		AH ROBINS	12-436		
2TRENGTH(S)	(DOSVCE	SM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
ACTIVE INGREDIENT(S)	AN ENAME NA		APPLICANT NAME	# YON	PATENT #	EXCLUSIVITY

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
BUTORPHANOL TARTRATE	STADOL	BRISTOL LABS/B-M	17-857	3819635	
IMG/ML	(INJECTABLE; INJECTION)		08-22-78	06-25-91	
BUTORPHANOL TARTRATE	STADOL	BRISTOL LABS/B-M	17-857	3819635	
2MG/ML	(INJECTABLE; INJECTION)		08-22-78	06-25-91	
CALCEFEDIOL, ANHYDROUS	CALDEROL	UPJOHN	18-312	3833622	
0.02MG	(CAPSULE; ORAL)		08-05-80	09-03-91	
				3565924	
				03-23-86	
CALCEFEDIOL, ANHYDROUS	CALDEROL	UPJOHN	18-312	3833622	
0.05MG	(CAPSULE; ORAL)		08-05-80	09-03-91	
				3565924	
				03-23-86	
CALCITRIOL	ROCALTROL	HOFFMANN-LA ROCHE	18-044	3697559	
0.25 UGM	(CAPSULE; ORAL)		08-17-78	10-10-89	
				4391802	
				07-05-00	
				4341774	
				07-27-99	
				4225596	
				09-30-97	
CALCITRIOL	ROCALTROL	HOFFMANN-LA ROCHE	18-044	3697559	
0.5 UGM	(CAPSULE; ORAL)		08-17-78	10-10-89	
				4391802	
				07-05-00	
				4341774	
				07-27-99	
				4225596	
				09-30-97	





*				IN PLASTIC CONTAINER	SODIUM CHLORIDE
		28-92-80		W∕ DEXTROSE 50\$	MAGNESIUM CHLORIDE; SODIUM ACETATE;
		708-81	AM MCGAW/AM HOSP	DIALYTE CONCENTRATE	CALCIUM CHLORIDE; DEXTROSE;
					9°46W/100ML; 116M/100ML
,				(SOLUTION; INTRAPERITONEAL)	210MG/100ML; 30GM/100ML; 200MG/100ML;
				IN PLASTIC CONTAINER	SODIUM CHLORIDE
		28-92-80		W/ DEXTROSE 30%	MAGNESIUM CHLORIDE; SODIUM ACETATE;
		708-81	WW MCGAW/AM HOSP	DIALYTE CONCENTRATE	CALCIUM CHLORIDE; DEXTROSE;
					6°56W/100ME; 9°66W/100ME
				(SOLUTION; INTRAPERITONEAL)	210MG/100ML; 50GM/100ML; 200MG/100ML;
				IN PLASTIC CONTAINER	SODIAM CHLORIDE
		28-92-80		M/ DEXIBOSE 20%	MAGNESIUM CHLORIDE; SODIUM ACETATE;
		708-81	WW MCGAW/AM HOSP	DIALYTE CONCENTRATE	CALCIUM CHLORIDE; DEXTROSE;
					6°56M/100ML; 9°66M/100ML
				(SOLUTION; INTRAPERITONEAL)	210M6/100ML; 306M/100ML; 200M6/100ML;
				IN PLASTIC CONTAINER	SODIUM ACETATE; SODIUM CHLORIDE
		08-56-83		W/ DEXTROSE 30%	WYENEZINW CHTOKIDE?
		708-81	WW WCCAW/AM HOSP	DIALYTE CONCENTRATE	CALCIUM CHLORIDE; DEXTROSE;
					74MG/100ML
					14M6/100ML; 640M6/100ML; 500M6/100ML;
					24M6/100ML; 5GM/100ML; 30M6/100ML;
					SODIUM CHLORIDE; SODIUM CITRATE
				(INJECTABLE; INJECTION)	SODIUM ACETATE;
		£8-71-10		IN PLASTIC CONTAINER	WAGNESIUM CHLORIDE; POTASSIUM CHLORIDE;
		18-269	AM MCGAW/AM HOSP	ISOLYTE E W/ DEXTROSE 5\$	CALCIUM CHLORIDE; DEXTROSE;
EXP. DATE	EXP. DATE	APPROVAL DATE		(DOSAGE FORM; ROUTE)	STRENGTH(S)
EXCLUSIVITY	PATENT #	# AQN	APPLICANT NAME	TAADE NAME	ACTIVE INGREDIENT(S)



(SOLUTION; INTRAPERITONEAL)

9.4GM/100ML; 11GM/100ML

210M6/100ML; 506M/100ML; 200MG/100ML;

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXP. DATE
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML;	DELFLEX W/ DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
15.2MG/100ML; 567MG/100ML; 392MG/100ML					
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 2.5GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLEX W/ DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 4.25GM/100ML; 15.2MG/100ML; 567MG/100ML; 392MG/100ML	DELFLEX W/ DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 1.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE 25.7MG/100ML; 2.5GM/100ML; 5.08MG/100ML; 538MG/100ML; 448MG/100ML	DELFLEX W/ DEXTROSE 2.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION; INTRAPERITONEAL)	DELMED	18-883 11-30-84		



TRAYENOL LABS

(INJECTABLE; INJECTION)

DEXTROSE 5% AND RINGER'S

IN PLASTIC CONTAINER

20WC/100WL; 860MC/100ML

23MG/100ML; 5GM/100ML;

CALCIUM CHLORIDE; DEXTROSE;

POTASSIUM CHLORIDE; SODIUM CHLORIDE

260MG/100ML; 390MG/100ML				
SEME/100ML; 2.56M/100ML; 15M6/100ML;	(SOLUTION; INTRAPERITONEAL)			
SODIUM LACTATE	IN PLASTIC CONTAINER			
WYENEZINW CHROKIDE: SODINW CHROKIDE:	W/ DEXTROSE 2.5\$		11-02-83	
PECLIUM CHLORIDE; DEXTROSE;	DIALYTE	AM MCGAW/AM HOSP	094-81	
228MG/100ML; 448MG/100ML				
25.7MG/100ML; 4.25GM/100ML; 5.08MG/100ML;	(SOLUTION; INTRAPERITONEAL)			
SODIUM LACTATE	IN PLASTIC CONTAINER			
WAGNESIUM CHLORIDE; SODIUM CHLORIDE;	W/ DEXTROSE 4.25%		28-70-70	
ALCIUM CHLORIDE; DEXTROSE;	INPERSOL-LM	ABBOTT LABORATORIES	67 Σ-8 Ι	
2.08MG/100ML; 538MG/100ML; 448MG/100ML				
25.7MG/100ML; 2.5GM/100ML;	(SOLUTION; INTRAPERITONEAL)			
SODIUM LACTATE	IN PLASTIC CONTAINER .			
WYENEZINW CHROKIDE: RODINW CHROKIDE:	M/ DEXIBOSE 2.5%		28-70-70	
ALCIUM CHLORIDE; DEXTROSE;	INPERSOL-LM	ABBOTT LABORATORIES	67 2- 81	
2.08MG/100ML; 538MG/100ML; 448MG/100ML				
25.7MG/100ML; 1.5GM/100ML;	(SOLUTION; INTRAPERITONEAL)			
SODIUM LACTATE	IN PLASTIC CONTAINER			
WYENEZINW CHTOKIDE: ZODINW CHTOKIDE:	W/ DEXTROSE 1.5%		28-70-70	
ALCIUM CHLORIDE; DEXTROSE;	INPERSOL-LM	ABBOTT LABORATORIES	672 - 81	
12°5We/100WF; 267We/100ML; 392We/100ML				
2'08WE/100WF; 538WE/100WL; 448WE/100WL	(SOLUTION; INTRAPERITONEAL)			
25.7MG/100ML; 4.25GM/100ML;	IN PLASTIC CONTAINER			
SODIUM LACTATE	FOM WYCHESINM			
WYENEZIOW CHROKIDE: RODIOW CHROKIDE:	W/ DEXTROSE 4.25%		11-30-84	
ALCIUM CHLORIDE; DEXTROSE;	DELFLEX	DEFWED	Σ88-81	
TRENGTH(S)	(DOSYGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE EXP. DA
CLINE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# VON	PATENT # EXCLUS



58-70-20

559-81

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 16.5MG/ML; 25.4MG/ML; 74.6MG/ML; 12IMG/ML; 16.IMG/ML	TPN ELECTROLYTES IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-895 07-20-84		
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM CITRATE 35MG/100ML; 30MG/100ML; 74MG/100ML; 640MG/100ML; 500MG/100ML; 74MG/100ML	ISOLYTE E IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-899 10-31-83		
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 17.6MG/100ML; 325.3MG/100ML; 119.3MG/100ML; 643MG/100ML	PLEGISOL IN PLASTIC CONTAINER (SOLUTION; PERFUSION, CARDIAC)	ABBOTT LABORATORIES	18-608 02-26-82		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE 20MG/100ML; 30MG/100ML; 380MG/100ML; 600MG/100ML	ACETATED RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-725 11-29-82		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 30MG/100ML; 860MG/100ML	RINGER'S IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-495 02-19-82		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 30MG/100ML; 860MG/100ML	RINGERS INJECTION IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-648 02-07 - 83		
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 33MG/100ML; 30MG/100ML; 860MG/100ML	RINGER'S IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-721 11-09-82		





EXP. DATE

21-80

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				20 01 00
				421 1347
SEMC; I SMC	(TABLET; ORAL)		10-12-84	96-80-80
CAPTOPRIL; HYDROCHLOROTHIAZIDE	CAPOZIDE 25/15	EK SÓNIBB VND SONS	607-81	9110014
100We	(TABLET; ORAL)		18-90-10	⊆6-80-80
CAPTOPRIL	CAPOTEN	EK SÓNIBB YND SONS	18-242	9110011
ZSWG	(TABLET; ORAL)		18-90-70	⊆6-80-80
CAPTOPRIL	CAPOTEN	EK SÓNIBB VND SONS	18-343	9116014
≥OWG	(TABLET; ORAL)		18-90-10	96-80-80
CAPTOPRIL	CAPOTEN	EK SÓNIBB VND SONS	18-343	91109114
0.35MG/ML; 140.1MG/ML; 461.8MG/ML	(INJECTABLE; INJECTION)		₽ ∠-0⊊- ₽ 0	98-70-11
CALCIUM; MEGLUMINE; METRIZOIC ACID	1SOPAQUE 280	WINTHROP LABS/STERL	905-11	2089742
0.78MG/ML; 0.15MG/ML; 75.9MG/ML; 16.6MG/ML				
MEGLUMINE METRIZOATE; METRIZOATE SODIUM	(INJECTABLE; INJECTION)		57-71-11	98-10-11
CALCIUM METRIZOATE; MAGNESIUM METRIZOATE;	1 SOPAQUE 440	WINTHROP LABS/STERL	Lt8-91	3476802
900We/100WF; 310Me/100ML				
SOME/100ML; SOME/100ML;	(SOLUTION; IRRIGATION)			
SODIUM CHLORIDE; SODIUM LACTATE	IN PLASTIC CONTAINER		48-20-40	
CALCIUM CHLORIDE; POTASSIUM CHLORIDE;	LACTATED RINGER'S	TRAVENOL LABS	126-81	
900We/100WF; 310We/100ML				
SOME/100ML; SOME/100ML;	(SOLUTION; IRRIGATION)			
SODIUM CHLORIDE; SODIUM LACTATE	IN PLASTIC CONTAINER		12-27-82	
CALCIUM CHLORIDE; POTASSIUM CHLORIDE;	LACTATED RINGER'S	AM MCGAW/AM HOSP	189-81	
900MG/100ML; 310MG/100ML				
SOME/100ML; SOME/100ML;	(SOLUTION; IRRIGATION)			
SODIUM CHLORIDE; SODIUM LACTATE	IN PLASTIC CONTAINER		05-19-82	
CALCIUM CHLORIDE; POTASSIUM CHLORIDE;	LACTATED RINGER'S	TRAVENOL LABS	464-81	
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# YON	PATENT #
			# F	

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CAPTOPRIL; HYDROCHLOROTHIAZIDE 50MG; 15MG	CAPOZIDE 50/15 (TABLET; ORAL)	ER SQUIBB AND SONS	18-709 10-12-84	4105776 08-08-95 4217347 08-12-97	3
CAPTOPRIL; HYDROCHLOROTHIAZIDE 50MG; 25MG	CAPOZIDE 50/25 (TABLET; ORAL)	ER SQUIBB AND SONS	18-709 10-12-84	4105776 08-08-95 4217347 08-12-97	
CARBAMAZEPINE 200MG	TEGRETOL (TABLET; ORAL)	GEIGY/CIBA-GEIGY	16-608 03-11-68	4409212 10-11-00	
CARBAMAZEP I NE I O OMG	TEGRETOL (TABLET, CHEWABLE; ORAL)	GEIGY/CIBA-GEIGY	18-281 12-14-81	4409212 10-11-00	
CARB IDOPA 25MG	LODOSYN (TABLET; ORAL)	MS &D/MERCK	17-830 04-25-77	3830827 08-20-91 3781415 12-25-90	
CARBIDOPA; LEVODOPA IOMG; IOOMG	SINEMET (TABLET; ORAL)	MS&D/MERCK	17-555 05-02-75	3769424 10-30-90 3781415 12-25-90 3830827 08-20-91 RE29892 10-30-90	
CARBIDOPA; LEVODOPA 25MG; 25OMG	SINEMET (TABLET; ORAL)	MS&D/MERCK	17-555 05-02-75	3769424 10-30-90 3781415 12-25-90 3830827 08-20-91 RE29892 10-30-90	



KELEASE; ORAL)

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05-53-99 09-12-83 (CAPSULE, CONTROLLED 30MG 76831E4 218-L1 HOFFMANN-LA ROCHE **LIBRELEASE** CHLORD I AZEPOX IDE 05-53-99 99-15-01 (TABLET; ORAL) 1 OWC 76831E4 120-51 ROCHE PRODUCTS **LIBRITABS** CHLORDIAZEPOXIDE 05-23-99 99-15-01 (TABLET; ORAL) **SMG** 76891E4 170-51 ROCHE PRODUCTS LIBRITABS CHLORDI AZEPOX I DE 05-53-99 99-15-01 (TABLET; ORAL) SZWG 76831E4 140-51 ROCHE PRODUCTS **LIBRITABS** CHLORD I AZEPOX IDE (TABLET; ORAL) £6-82-70 07-28-83 SZOMG NCE 515-81 ROWELL LABORATORIES CHENIX CHENODIOL 98-11-01 15-24-81 (INTECTABLE; INTECTION) O'OSWE/WL 967-81 ADRIA LABORATORIES 3472832 **NASTMYT** CERULETIDE DIETHYLAMINE 12-28-92 12-28-82 (POWDER; ORAL) 2.5GM/PACKET BON 18-757 MISSION PHARMACAL CALCIBIND CELLULOSE SODIUM PHOSPHATE 06-11-10 64-60-10 (INJECTABLE; INJECTION) EÓ O'SEWE BYSE/WI 3728382 686-11 MHOL9U MRI\NIT2099 CARBOPROST TROMETHAM I NE 10-30-90 RE29892 16-07-80 7880282 12-25-90 3781415 10-30-90 08-21-20 (TABLET; ORAL) S≥WG: 100WG \$769424 **GGG-LI** MS&D/MERCK SINEMET CARBIDOPA, LEVODOPA EXP. DATE EXP. DATE APPROVAL DATE (DOSYGE FORM; ROUTE) STRENGTH(S) EXCLUSIVITY # TN3TA9 TRADE NAME ACTIVE INGREDIENT(S) # YON APPLICANT NAME

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
CHLORDIAZEPOXIDE HYDROCHLORIDE	LIBRIUM	ROCHE PRODUCTS	12-249	4316897	
5MG	(CAPSULE; ORAL)		02-24-60	02-23-99	
CHLORD I AZEPOX I DE HYDROCHLORI DE	LIBRIUM	ROCHE PRODUCTS	12-249	4316897	
I OMG	(CAPSULE; ORAL)		02-24-60	02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE	LIBRIUM	ROCHE PRODUCTS	12-249	4316897	
25MG	(CAPSULE; ORAL)		02-24-60	02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE	LIBRIUM	HOFFMANN-LA ROCHE	12-301	4316897	
I OOMG/AMP	(INJECTABLE; INJECTION)		07-21-61	02-23-99	
CHLORDIAZEPOXIDE HYDROCHLORIDE;	LIBRAX	HOFFMANN-LA ROCHE	12-750	4316897	
CLIDINIUM BROMIDE 5MG; 2.5MG	(CAPSULE; ORAL)		05-02-61	02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED	MENRIUM 5-2	HOFFMANN-LA ROCHE	14-740	4316897	
5MG; 0.2MG	(TABLET; ORAL)		10-27-69	02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED	MENRIUM 5-4	HOFFMANN-LA ROCHE	14-740	4316897	
5MG; 0.4MG	(TABLET; ORAL)		10-27-69	02-23-99	
CHLORDIAZEPOXIDE; ESTROGENS, CONJUGATED	MENRIUM 10-4	HOFFMANN-LA ROCHE	14-740	4316897	
IOMG; 0.4MG	(TABLET; ORAL)		10-27-69	02-23-99	
CHLOROXINE	CAPITROL	WESTWOOD PHARMS	17-594	3886277	
2%	(SHAMPOO; TOPICAL)		10-19-76	05-27-92	
CHLORTHAL IDONE; CLONIDINE HYDROCHLORIDE	COMBIPRES	BOEHRINGER INGELHEIM	I 7-503	3454701	
15MG; 0.1MG	(TABLET; ORAL)		08-22-74	07-08-86	





1724271

26-21-40 LL-91-80 (TABLET; ORAL) **300MG EEE026E** 0Z6-L1 SKIL LAB TAGAMET CIMETIDINE \$6-L1-90 1724204 26-21-40 LL-91-80 (TABLET; ORAL) SOOMG 2550362 17-920 SKIL LAB TAGAMET CIMETIDINE 02-12-65 12-30-82 (CREAM; TOPICAL) \$1 12-30-92 NCE 3883545 847-81 HOECHST-ROUSSEL LOPROX CICCOPIROX OLAMINE 10-92-20 48-12-80 (INJECTABLE; INJECTION) JAIV\ZTINU 000,4 CHYMOPAPA I N 4439423 299-81 SMITH LABORATORIES CHYMODIACTIN 11-10-65 (INTECTABLE; INTECTION) JAIV\ZTINU 000,01 10-97-20 11-10-82 NCE £99-81 CHYMODIACTIN CHYMOPAPAIN 4439423 SAITH LABORATORIES 48-81-10 (INTECTABLE; INTECTION) 12,500 UNITS/VIAL 18-625 TRAVENOL LABS DISCASE CHYMOPAPA I N 9-81-90 21-20-80 (POWDER; ORAL) EQ 46M RESIN/PACKET 1822822 **UESTRAN** 049-91 MEAD JOHNSON/B-M CHOL ESTYRAM I NE (POWDER; ORAL) EÓ 46M RESIN/PACKET 9-81-90 15-09-99 3383281 610-91 MEAD JOHNSON/B-M NASTRAN CHOLEST YRAM I NE 98-80-70 18-01-10 (TABLET; ORAL) I PMG; 0.3MG CHLORTHAL IDONE; CLONIDINE HYDROCHLORIDE 1074242 209-L1 BOEHBINGER INGETHEIM COMB I PRES 47-22-80 (TABLET; ORAL) 15MG; 0.2MG 98-80-70 1074242 209-L1 BOEHKINGEK INGETHEIW CHLORTHALIDONE; CLONIDINE HYDROCHLORIDE COMB I PRES EXP. DATE EXP. DATE APPROVAL DATE (DOSAGE FORM; ROUTE) STRENGTH(S) EXCLUSIVITY * TN3TA9 # YON APPLICANT NAME TRADE NAME ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
CIMETIDINE	TAGAMET	SK&F LAB	17-920	3950333	
400MG	(TABLET; ORAL)		12-14-83	04-13-93	
				4024271	
				05-17-94	
CIMETIDINE HYDROCHLORIDE	TAGAMET	SK&F LAB	17-924	3950333	
EQ 300MG BASE/5ML	(SOLUTION; ORAL)		08-16-77	04-13-93	
				4024271	
				05-17-94	
CIMETIDINE HYDROCHLORIDE	TAGAMET	SK&F LAB	17-939	3950333	
EQ 150MG BASE/ML	(INJECTABLE; INJECTION)		08-16-77	04-13-93	
				4024271	
				05-17-94	
CINOXACIN	CINOBAC	ELI LILLY	18-067	3669965	
250MG	(CAPSULE; ORAL)		06-13-80	06-13-89	
CINOXACIN	CINOBAC	ELI LILLY	18-067	3669965	
500MG	(CAPSULE; ORAL)		06-13-80	06-13-89	
CISPLATIN	PLATINOL-AQ	BRISTOL LABS/B-M	18-507	4177263	
0.5MG/ML			07-18-84	12-04-96	
CITRIC ACID; MAGNESIUM OXIDE;	IRRIGATING SOLUTION G	TRAVENOL LABS	18-519		
SODIUM CARBONATE	IN PLASTIC CONTAINER		06-22-82		
3.24GM/100ML; 380MG/100ML; 430MG/100ML	(SOLUTION; IRRIGATION)				
CITRIC ACID; MAGNESIUM OXIDE;	UROLOGIC G	ABBOTT LABORATORIES	18-904		
SODIUM CARBONATE	IN PLASTIC CONTAINER		05-27-83		
3.24GM/100ML; 380MG/100ML; 430MG/100ML	(SOLUTION; IRRIGATION)				
CLEMASTINE FUMARATE;	TAVIST D	DORSEY LABS/SANDOZ	18-298	3933999	
PHENYLPROPANOLAMINE HYDROCHLORIDE	(TABLET, CONTROLLED		12-15-82	01-20-93	
EQ IMG BASE; 75MG	RELEASE; ORAL)				







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EXCLUSIVITY

EXP. DATE

Original from UNIVERSITY OF MICHIGAN

RE28315	6∠-0Z-60	ABBOTT LABORATORIES	TRANXENE	CLORAZEPATE DIPOTASSIUM
	64-02-60			
98-80-10			(TABLET; ORAL)	o.3MG
1074242	704-71	BOEHKINGEK INGETHEIW	CATAPRES	CLONIDINE HYDROCHLORIDE
98-80-40	⊅ ∠- Σ 0-60		(TABLET; ORAL)	O.2MG
1074542	104-11	BOEHBINGER INGELHEIM	CATAPRES	CLONIDINE HYDROCHLORIDE
98-80-40	7 Δ-20-60		(TABLET; ORAL)	0°IWC
1074542	704-71	BOEHBINGER INGELHEIM	CATAPRES	CLONIDINE HYDROCHLORIDE
			PERCUTANEOUS)	
98-80-70	19-01-01		(FILM, CONTROLLED RELEASE;	9we°L
1074542	168-81	BOEHRINGER INGELHEIM	CATAPRES-TTS-3	CCONIDINE
			PERCUTANEOUS)	
98-80-40	48-01-01		(FILM, CONTROLLED RELEASE;	≥W6
1074242	168-81	BOEHKINGEK INGELHEIM	CATAPRES-TTS-2	CFONIDINE
			PERCUTANEOUS)	
98-80-40	10-10-84		(FILM, CONTROLLED RELEASE;	Z° 5WG
1074242	168-81	BOEHKINGEK INGECHEIM	CATAPRES-TTS-1	CLONIDINE
02-23-99	SL-70-90		(TABLET; ORAL)	SMC
7689124	555-71	HOFFMANN-LA ROCHE	CLONOP I N	CLONAZEPAM
02-23-99	ST-40-80		(TABLET; ORAL)	ІМС
7683124	555-71	HOFFMANN-LA ROCHE	CLONOPIN	CLONAZEPAM
05-23-99	SL-70-90		(TABLET; ORAL)	O°≥WC
7689124	229-L1	HOFFMANN-LA ROCHE	CLONOPIN	CLONAZEPAM
	03-22-82		(TABLET; ORAL)	20MG
	192-81	PLANTEX\ I KAPHARM	CLOMIPHENE CITRATE	CLOMIPHENE CITRATE
EXP. DATE	APPROVAL DATE		(DOSAGE FORM; ROUTE)	STRENGTH(S)
PATENT #	# YON	APPLICANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)

(DOSAGE FORM; ROUTE)		ADDDOVAL DATE		
		APPROVAL DATE	EXP. DATE	EXP. DATE
TRANXENE	ABBOTT LABORATORIES	17-105	RE28315	
(CAPSULE; ORAL)		06-23-72	06-23-87	
TRANXENE	ABBOTT LABORATORIES	17-105	RE28315	
(CAPSULE; ORAL)		06-23-72	06-23-87	
TRANXENE SD	ABBOTT LABORATORIES	17-105	RE28315	
(TABLET; ORAL)		03-31-75	06-23-87	
TRANXENE SD	ABBOTT LABORATORIES	17-105	RE28315	
(TABLET; ORAL)		08-04-76	06-23-87	
TRANXENE	ABBOTT LABORATORIES	17-105	RE28315	
(TABLET; ORAL)		03-10-80	06-23-87	
TRANXENE	ABBOTT LABORATORIES	17-105	RE28315	
(TABLET; ORAL)		03-10-80	06-23-87	
TRANXENE	ABBOTT LABORATORIES	17-105	RE28315	
(TABLET; ORAL)		03-10-80	06-23-87	
LOTRIMIN	SCHERING	17-613	3660577	
(SOLUTION; TOPICAL)		02-03-75	05-02-89	
			3839573	
			10-01-91	
LOTRIMIN	SCHERING	17-619	3660577	
(CREAM; TOPICAL)		03-18-75	05-02-89	
	TRANXENE (CAPSULE; ORAL) TRANXENE SD (TABLET; ORAL) TRANXENE SD (TABLET; ORAL) TRANXENE (TABLET; ORAL) TRANXENE (TABLET; ORAL) TRANXENE (TABLET; ORAL) LOTRIMIN (SOLUTION; TOPICAL)	TRANXENE (CAPSULE; ORAL) TRANXENE SD (TABLET; ORAL) TRANXENE SD (TABLET; ORAL) TRANXENE SD (TABLET; ORAL) TRANXENE (TABLET; ORAL) SCHERING	TRANXENE (CAPSULE; ORAL) TRANXENE SD (TABLET; ORAL) TRANXENE SD (TABLET; ORAL) TRANXENE SD (TABLET; ORAL) TRANXENE SD (TABLET; ORAL) TRANXENE (TABLET; ORAL)	TRANXENE (CAPSULE; ORAL) ABBOTT LABORATORIES (CAPSULE; ORAL) TRANXENE SD (ABBOTT LABORATORIES 17-105 RE28315 (TABLET; ORAL) TRANXENE SD (ABBOTT LABORATORIES 17-105 RE28315 (TABLET; ORAL) TRANXENE SD (ABBOTT LABORATORIES 17-105 RE28315 (TABLET; ORAL) TRANXENE (ABBOTT LABORATORIES 17-105 RE28315 (TABLET; ORAL) TRANXENE (ABBOTT LABORATORIES 17-105 RE28315 (TABLET; ORAL) TRANXENE (TABLET; ORAL) TRANXENE (TABLET; ORAL) ABBOTT LABORATORIES 17-105 RE28315 (TABLET; ORAL) TRANXENE (TABLET; ORAL) TRANXENE (TABLET; ORAL) ABBOTT LABORATORIES 17-105 RE28315 (TABLET; ORAL) TRANXENE (TABLET; ORAL) TRANXENE (TABLET; ORAL) TRANXENE (TABLET; ORAL) ABBOTT LABORATORIES 17-105 RE28315 (TABLET; ORAL) TRANXENE (TABLET; ORAL) TRANXENE (TABLET; ORAL) ABBOTT LABORATORIES 17-105 RE28315 (TABLET; ORAL) TRANXENE (TABL



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68-20-€0 **LLS099**E 15-05-89 3705172

18-052 SCHER I NG GYNE-LOTRIMIN APPROVAL DATE (DOSAGE FORM; ROUTE) TRADE NAME # YON APPLICANT NAME TABLE IV. NDA'S APPROVED FROM I-I-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

Original from UNIVERSITY OF MICHIGAN

16-10-01 67-72-20 (TABLET; VAGINAL) LOOMG **ET**86E8E 18-182 WILES PHARMS/MILES WLCELEX-G CLOTR I MAZOLE 02-05-88 LL9099£ 15-02-89 2712072 16-10-01 81 64-91-10 (SOLUTION; TOPICAL) **2**496282 181-81 WIFES PHARMS/MILES **CLOTR I MAZOLE** MACELEX 02-05-89 **LL9099**£ 12-05-89 3705172 (TABLET; VAGINAL) 16-10-01 97-42-20 100MG **2739282** L11-L1 SCHEK I NO GYNE-LOTRIMIN CLOTRIMAZOLE 02-05-89 **LL9099**£ 15-02-89 2712072 31 16-10-01 87-80-11 (CREAM; VAGINAL) **273928**2 CLOTR I MAZOLE EXP. DATE EXP. DATE STRENGTH(S) EXCLUSIVITY ACTIVE INGREDIENT(S) PATENT #

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CLOTR I MAZOLE	MYCELEX (CREAM; TOPICAL)	MILES PHARMS/MILES	18-183 01-15-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTR I MAZOLE	MYCELEX-G (CREAM; VAGINAL)	MILES PHARMS/MILES	18-230 02-16-79	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTR IMAZOLE IOMG	MYCELEX (TROCHE/LOZENGE; ORAL)	MILES PHARMS/MILES	18-713 06-17-83	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CLOTRIMAZOLE I%	LOTRIMIN (LOTION; TOPICAL)	SCHER ING	18-813 02-17-84	3839573 10-01-91 3705172 12-05-89 3660577 05-02-89	
CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE IOMG/5ML; 5MG/5ML; 6.25MG/5ML	PHENERGAN VC W/ CODE INE (SYRUP; ORAL)	WYETH LABS/AMHO	08-306 04-02-84		





Original from UNIVERSITY OF MICHIGAN

				76-67-40	
				RE28399	
				12-01-87	
				3803308	
				16-80-10	
				1982872	
				76-60-80	
	(ANTRAUTER INE.)			1140404	
ISOME	(INTRAUTERINE DEVICE;		64-91-80	05-16-88	
СОРРЕЯ	T-MUTAT	SEARLE PHARMS	18-205	3563235	
				76-67-40	
				RE28399	
				12-01-87	
				8022082	
				16-80-10	
				1982872	
				76-60-80	
	(AN I MARAUTER I NE)			L1+0+0+	
9W68	(INTRAUTERINE DEVICE;		02-25-74	05-16-88	
ООРРЕЯ	Cn-1	SEARLE PHARMS	804-71	3263235	
200€M/B01	(GRANULE; ORAL)		LL-40-40	68-61-60	
COLESTIPOL HYDROCHLORIDE	ΦΓΕ21ΙD	NHOLAU	595-11	\$682692	
2GM/PACKET	(GEVANULE; ORAL)		LL-40-40	68-61-60	
COLESTIPOL HYDROCHLORIDE	ODLEST ID	NHOLAU	595-11	3682692	
10MG/5ML; 30MG/5ML; 1.25MG/5ML					
TRIPROLIDINE HYDROCHLORIDE					
PSEUDOEPHEDRINE HYDROCHLORIDE;	(SYRUP; ORAL)		p8-p0-p0		
CODE INE PHOSPHATE;	ACTIFED W/ CODEINE	BURROUGHS WELLCOME	12-575		
111111111111111111111111111111111111111	1411300 / H 011115V	THE SHOULD IN SHOULD IN	323 01		
IOMG/5ML; 6.25MG/5ML					
PROMETHAZINE HYDROCHLORIDE	(JANO : 9NAK2)		04-02-84		
CODE INE PHOSPHATE;	PHENERGAN W/ CODE INE	MXETH LABS/AMHO	902-80		
artidoord antadoo	and add the first and a second	Citity COV I HEAVI	702 00		
STRENGTH(S)	(DOSVGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
VCTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# YON	* TN3TA9	EXCLUSIVITY
(0/2/12/0300/11/201	2000	arrive arrive loav	" '	,	

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
CROMOLYN SODIUM 20MG	INTAL (CAPSULE; INHALATION)	FISONS	16-990 06-20-73	3686412 08-22-89 3777033 08-22-89 3419578 12-31-85	
CROMOLYN SODIUM	NASALCROM (SOLUTION; NASAL)	FISONS	18-306 03-18-83	3686412 08-22-89 3777033 08-22-89 3419578 12-31-85 3975536 08-17-93 4053628 10-11-94	
CROMOLYN SODIUM 4%	OPTICROM (SOLUTION; OPHTHALMIC)	FISONS	18-155 10-03-84	3686412 08-22-89 3777033 08-22-89 3419578 12-31-85 3975536 08-17-93 4053628 10-11-94	





EXCLUSIVITY

EXP. DATE

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SOMG	(CAPSULE; ORAL)		SL-01-01	15-10-82
DANTROLENE SODIUM	MUISTNAG	NORWICH EATON/P&G	544-71	2415821
Loome	(CAPSULE; ORAL)		7 ∠-⊊1-10	15-10-82
DANTROLENE SODIUM	MUIЯTNAG	NORWICH EATON/P&G	544-71	2415821
∑≥WG	(CAPSULE; ORAL)		7 ∠-⊊1-10	15-10-82
DANTROLENE SODIUM	MUISTNAG	NORWICH EATON/P&G	544-71	2415821
ZGM/VIALAL	(INTECTABLE; INTECTION)		28-02-80	
CACTOBHO2PHAM IDE	CYTOXAN	WEVD 10HM20M\B-W	12-142	
JAIV/WĐI	(INJECTABLE; INJECTION)		Z8-02-80	
CACTOBHO2PHAM IDE	СУТОХАИ	MEAD JOHNSON/B-M	12-142	
				26-90-90 2885246
IOMG	(TABLET; ORAL)		LL-9Z-80	98-80-40
CACLOBENZAPRINE HYDROCHLORIDE	FLEXERIL	MS&D/MERCK	128-71	2494545
				76-90-90
				3882246
€WG	(TABLET; ORAL)		LL-9Z-80	98-80-70
CACTOBENZYBEINE HADBOCHTOBIDE	FLEXERIL	MS&D/MERCK	178-71	2494542
				Σ6-11-80
				9255762
				12-21-85
				8776142
				08-22-89
				EEOTTTE
I OMG/ML	(SOLUTION; INHALATION)		02-28-82	08-22-89
CROMOLYN SODIUM	⊿ АТИІ	FISONS	969-81	3686412
гленетн(s)	(DOSYGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# AQN	PATENT #

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
DANTROLENE SODIUM	DANTRIUM	NORWICH EATON/P&G	18-264	3415821	
20MG/VIAL	(INJECTABLE; INJECTION)		09-18-79	12-10-85	
DEFEROXAMINE MESYLATE	DESFERAL MESYLATE	CIBA/CIBA-GEIGY	16-267	3471476	
500MG/VIAL	(INJECTABLE; INJECTION)		04-01-68	10-07-86	
DESIPRAMINE HYDROCHLORIDE	PERTOFRANE	USV LABORATORIES	13-621	3454698	
25MG	(CAPSULE; ORAL)		12-18-64	07-08-86	
				3454554	
				07-08-86	
DESIPRAMINE HYDROCHLORIDE	PERTOFRANE	USV LABORATORIES	13-621	3454698	
50MG	(CAPSULE; ORAL)		04-10-68	07-08-86	
				3454554	
				07-08-86	
DESIPRAMINE HYDROCHLORIDE	NORPRAMIN	MERRELL DOW/DOW CHEM	14-399	3454698	
25MG	(TABLET; ORAL)		11-20-64	07-08-86	
				3454554	
				07-08-86	
DESIPRAMINE HYDROCHLORIDE	NORPRAMIN	MERRELL DOW/DOW CHEM	14-399	3454698	
50MG	(TABLET; ORAL)		01-09-67	07-08-86	
				3454554	
				07-08-86	
DESIPRAMINE HYDROCHLORIDE	NORPRAMIN	MERRELL DOW/DOW CHEM	14-399	3454698	
75MG	(TABLET; ORAL)		03-01-77	07-08-86	
				3454554	
				07-08-86	
DESIPRAMINE HYDROCHLORIDE	NORPRAMIN	MERRELL DOW/DOW CHEM	14-399	3454698	
100MG	(TABLET; ORAL)		03-01-77	07-08-86	
				3454554	
				07-08-86	



EXP. DATE EXCLUSIVITY

Original from UNIVERSITY OF MICHIGAN

03-26-85				
RE28369				
03-26-85	85-05-01		(TABLET; ORAL)	9M≥7.0
1975725	799- 11	MS&D/MERCK	DECYDBON	DEXAMETHASONE
03-26-85				
RE28369				
03-26-85	89-05-01		(TABLET; ORAL)	O. 5MG
1925752	1 99-11	MS&D/MERCK	DECADRON	DEXAMETHASONE
	£8-0£-60		(OINTMENT; TOPICAL)	% SZ*0
	₹9∠- 81	HOE CHST-ROUSSEL	TA00190T	DEZOXIMETASONE
	78-67-20		(GEL; TOPICAL)	% 90°0
	98⊊-81	HOECHST-ROUSSEL	T900190T	DEZOXIMETASONE
	12-14-84		(CREAM; TOPICAL)	% 50°0
	840-61	OMEN LABS/DERM PRODS	DEZOMEN	DE ZON I DE
02-24-87	48-02-20		(INJECTABLE; INJECTION)	0°004WC/WF
1647642	826-81	MAAHA AUOMAA	qvadd	DESMOPRESSIN ACETATE
02-24-87	02-21-78		(SOLUTION; NASAL)	%10°0
1647648	17-922	МЯАНЧ ЯИОМЯА	AVA 00	DESMOPRESSIN ACETATE
98-80-40				
3454554				
98-80-10	02-11-82		(TABLET; ORAL)	1 OWC
8694545	665-41	MERRELL DOW/DOW CHEM	N1 MA ЯЧЯОИ	DESIBERMINE HYDROCHLORIDE
98-80-10				
3454554				
98-80-70	LL-10-ξ0		(TABLET; ORAL)	I ≥OMC
8694545	665-41	MERRELL DOW/DOW CHEM	N1 MASPIGON	DESTEWNINE HYDROCHLORIDE
EXP. DATE	APPROVAL DATE		(DOSYGE FORM; ROUTE)	STRENGTH(S)
# TN3TA9	# YON	APPL I CANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXAMETHASONE I.5MG	DECADRON (TABLET; ORAL)	MS &D/MERCK	-6 64 0-30-58	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 0.25MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11 - 664 07 - 26-79	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 4MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 07-26-79	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 6MG	DECADRON (TABLET; ORAL)	MS&D/MERCK	11-664 07-30-82	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 0.5MG/5ML	DECADRON (ELIXIR; ORAL)	MS&D/MERCK	12-376 09-02-60	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE 0.5MG/5ML	HEXADROL (ELIXIR; ORAL)	ORGANON/AKZONA	12-674 04-23-64	RE28369 03-26-85	
DEXAMETHASONE 0.5MG	HEXADROL (TABLET; ORAL)	ORGANON/AKZONA	2-675 07-0 -78	RE28369 03-26-85	
DEXAMETHASONE 0.75MG	HEXADROL (TABLET; ORAL)	ORGANON/AKZONA	12-675 07-01-78	RE28369 03-26-85	







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				03-26-85
				RE28369
EQ 0.1\$ PHOSPHATE	(CREAM; TOPICAL)		69-97-80	03-26-85
DEXAMETHASONE SODIUM PHOSPHATE	DECADRON	MS&D/MERCK	£86−11	1925725
				68-92-20
				RE28369
EQ 0.05\$ PHOSPHATE	(OINTMENT; OPHTHALMIC)		09-05-59	03-26-85
DEXAMETHASONE SODIUM PHOSPHATE	DECADRON	MS&D/MERCK	<i>LL</i> 6-11	1925725
				S8-9Z-Σ0
				RE28369
EÓ 8WC BYZE\WIT	(INJECTABLE; INJECTION)		£L-90-60	03-26-85
DEXAMETHASONE ACETATE	DECADRON-LA	MS&D/MERCK	919-91	1925725
				68-92-50
				KE28369
\$1°0	(GEL; TOPICAL)		99-20-90	03-26-85
DEXAMETHASONE	DECADERM	MS&D/MERCK	825-21	1925752
% †0°0	(CREAM; TOPICAL)		L9-60-10	03-26-85
DEXAMETHASOUE	HEXADROL	ORGANON/AKZONA	13-304	KE28369
		•		68-92-50
				RE28369
I OMG/25GM	(AEROSOL; TOPICAL)		19-67-20	03-26-85
DEXAMETHASONE	DECASPRAY	MS &D/MERCK	12-731	1925725
4MC	(TABLET; ORAL)		7 4-10-40	58-92-20
DEXAMETHASONE	HEXYDBOL	ORGANON/AKZONA	12-675	RE28369
I • ≥we	(TABLET; ORAL)		69-77-60	68-92-20
DEXAMETHASONE	HEXADROL	ORGANON/AKZONA	12-675	RE28369
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# AdN	PATENT #

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXAMETHASONE SODIUM PHOSPHATE EQ 0.1% PHOSPHATE	DECADRON (SOLUTION; OPHTHALMIC, OTIC)	MS&D/MERCK	11 - 984 09-23-59	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 4MG PHOSPHATE/ML	DECADRON (INJECTABLE; INJECTION)	MS&D/MERCK	12-071 05-12-61	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 24MG PHOSPHATE/ML	DECADRON (INJECTABLE; INJECTION)	MS&D/MERCK	12-071 03-01-77	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 0.IMG PHOSPHATE/INH	DECADRON (AEROSOL; INHALATION)	MS&D/MERCK	13-413 09-17-62	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 0.1MG PHOSPHATE/INH	DECADRON (AEROSOL; NASAL)	MS&D/MERCK	14-242 12-17-65	3375261 03-26-85 RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 4MG PHOSPHATE/ML	HEXADROL (INJECTABLE; INJECTION)	ORGANON/AKZONA	14-694 03-14-75	RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ IOMG PHOSPHATE/ML	HEXADROL (INJECTABLE; INJECTION)	ORGANON/AKZONA	14-694 03-14-75	RE28369 03-26-85	
DEXAMETHASONE SODIUM PHOSPHATE EQ 20MG PHOSPHATE/ML	HEXADROL (INJECTION)	ORGANON/AKZONA	14-694 04-27-81	RE28369 03-26-85	





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			INJECTION)	(INJECTABLE;	
	03-23-82			MAINIATHOO	206M/100ML
	299-81	ABBOTT LABORATORIES	SIN PLASTIC	DEXTROSE 50	DEXTROSE
			: INTECTION)	(INJECTABLE;	
	03-23-82			SONTA I NER	100W 100W
	18-562	ABBOTT LABORATORIES	S IN PLASTIC	DEXTROSE 409	DEXTROSE
			INTECTION	(INJECTABLE;	
	28-22-80			MATA INER	706M/100ML
	199-81	ABBOTT LABORATORIES	SITEAJA NI S	ROT 3809TX30	DEXTROSE
04-24-90	09-22-85		INJECTION)	(INJECTABLE;	TM001/W909
892627₹	966-11	AM MCGAW/AM HOSP	1	DEXTROSE 60	DEXTROSE
			: INJECTION)	(INJECTABLE;	•
04-24-90	87-72-40			SONTA I NER	1/W909
8956272	966-11	AM MCGAW/AM HOSP	SITEAJY NI 3	DEXTROSE 609	DEXIBOSE
			INTECTION		
	03-26-82			SONTA I NER	700ML
	17-521	TRAVENOL LABS	SITEAJA NI S	ROT 3808TX30	DEXTROSE
			INTECTION)		
	03-26-82			RENTA I NER	7W001/W909
	125-71	TRAVENOL LABS	SITEASTIC	DEXTROSE 609	DEXTROSE
					I ZWG/ZWF: 9°SZWG/ZWF
	48-20-40		(-	(SYRUP; ORAL	PROMETHAZ I NE HYDROCHLOR I DE
	11-265	MYETH LABS/AMHO	NAH9ROHTANORTXAN	PHENERGAN W/	DEXTROMETHORPHAN HYDROBROMIDE;
03-26-85	Marie Control				
RE28369					EQ 4MG PHOSPHATE/ML; IOMG/ML
03-26-85	29-11-70		(NOIECTION)	(INJECTABLE;	LIDOCAINE HYDROCHLORIDE
3375261	₽ Σ 2 −Σ1	MS&D/MERCK	XXLOCAINE	DECYDBON M\	DEXAMETHASONE SODIUM PHOSPHATE;
EXP. DATE	APPROVAL DATE		N; ROUTE)	(DOSVEE FORM	STRENGTH(S)
* TN3TA9	# AON	APPLICANT NAME		AMAN ADAMT	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE 20GM/100ML	DEXTROSE 20% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-564 03-23-82		
DEXTROSE 38.5GM/100ML	DEXTROSE 38.5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-923 09-19-84		
DEXTROSE 50MG/ML	DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-222 07-13-84		
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 80MG/100ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 02-04-82		
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 160MG/100ML	DOPAMINE HCL (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-132 02-04-82		
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 80MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 160MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		
DEXTROSE; DOPAMINE HYDROCHLORIDE 5GM/100ML; 320MG/100ML	DOPAMINE HCL IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-826 09-30-83		
DEXTROSE; HEPARIN SODIUM 5GM/100ML; 200 UNITS/100ML	HEPARIN SODIUM I,000 UNITS AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-130 12-31-83		





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	(INJECTABLE; INJECTION)				
	IN PLASTIC CONTAINER				
2GM/100ML; 400MG/100ML	AND DEXTROSE 5%		▶8-0 ₹-₹0		
DEXIBOSE; LIDOCAINE HYDROCHLORIDE	LIDOCAINE HCL 0.4\$	AM MCGAW/AM HOSP	L96-81		
	(INJECTABLE; INJECTION)				
	IN PLASTIC CONTAINER				
20W/100ML; 200MG/100ML	AND DEXTROSE 5%		₽8-02-20		
DEXTROSE; LIDOCAINE HYDROCHLORIDE	LIDOCAINE HCL 0.2\$	AM MCGAW/AM HOSP	<i>L</i> 96-81		
	(INJECTABLE; INJECTION)				
	IN PLASTIC CONTAINER				
26M/100ML; 800MG/100ML	AND DEXTROSE 5%		02-22-82		
DEXIMORE; LIDOCAINE HYDROCHLORIDE	LIDOCAINE HCL 0.8%	TRAVENOL LABS	194-81		
	(INJECTABLE; INJECTION)				and the last
	IN PLASTIC CONTAINER				
≥GM/100ML; 800MG/100ML	IN DEXTROSE 5%		11-05-82		
DEXIBOSE; LIDOCAINE HYDROCHLORIDE	LIDOCAINE HCL 0.8%	ABBOTT LABORATORIES	882-81		
	(INJECTABLE; INJECTION)				
	PLASTIC CONTAINER				
5GM/100ML; 4,000 UNITS/100ML	AND DEXTROSE 5% IN		58-15-01		
DEXTROSE; HEPARIN SODIUM	HEPARIN SODIUM 20,000 UNITS	TRAVENOL LABS	118-81		
	(INJECTABLE; INJECTION)				
	PLASTIC CONTAINER				
SGM/100ML; 1,000 UNITS/100ML	AND DEXTROSE 5\$ IN		12-31-83		
DEXTROSE; HEPARIN SODIUM	STINU OOO, 7 MUIDOS NIAAAH	AM MCGAW/AM HOSP	051-61		
	(INTECTABLE; INTECTION)			•	
	PLASTIC CONTAINER				
5GM/100ML; 200 UNITS/100ML	AND DEXTROSE 5% IN		12-21-82		
DEXTROSE; HEPARIN SODIUM	HEPARIN SODIUM 2,000 UNITS	AN MCGAW/AM HOSP	051-61		
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# Adv	PATENT #	EXCLUSIVITY

STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE; LIDOCAINE HYDROCHLORIDE 5GM/100ML; 800MG/100ML	LIDOCAINE HCL 0.8% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-967 03-30-84		
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE DIBASIC; SODIUM ACETATE 5GM/IOOML; 3IMG/IOOML; I3OMG/IOOML; 26MG/IOOML; 320MG/IOOML	ISOLYTE P W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-025 12-27-84		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 75MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.075% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 150MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.15% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 220MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.22% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		
DEXTROSE; POTASSIUM CHLORIDE 5GM/100ML; 300MG/100ML	DEXTROSE 5% AND POTASSIUM CHLORIDE 0.3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	18-744 11-09-82		



TRAYENOL LABS

TRAVENOL LABS

TRAVENOL LABS

02-10-83

58-01-20

58-01-20

999-81

995-81

999-81

26M/100ML; 300M6/100ML; 450M6/100ML	20MEQ IN PLASTIC CONTAINER		
CHLOR IDE	0.45\$ AND POTASSIUM CHLORIDE		05-10-83
DEXTROSE; POTASSIUM CHLORIDE; SODIUM	DEXTROSE 5\$, SODIUM CHLORIDE	TRAYENOL LABS	999-81
	(INJECTABLE; INJECTION)		
SCH/100HL; 224MG/100ML; 450MG/100ML	ISMEQ IN PLASTIC CONTAINER		
CHTOK IDE	0.45\$ AND POTASSIUM CHLORIDE		05-10-83
DEXTROSE; POTASSIUM CHLORIDE; SODIUM	DEXIBOSE 28° SODINW CHTORIDE	TRAYENOL LABS	99⊆-81
	(INTECTABLE; INTECTION)		
26M/100ML; 150M6/100ML; 450M6/100ML	IOMEQ IN PLASTIC CONTAINER		
CHTOK IDE	0.45\$ AND POTASSIUM CHLORIDE		05-10-83
DEXTROSE; POTASSIUM CHLORIDE; SODIUM	DEXTROSE 5\$, SODIUM CHLORIDE	TRAVENOL LABS	999-81
ISOME/100MF; SSOME/100ME			
2GM/100ML; 205MG/100ML; 100MG/100ML;			
SODIUM LACTATE	(INJECTABLE; INJECTION)		
PHOSPHATE, MONOBASIC; SODIUM CHLORIDE;	NO 75 IN PLASTIC CONTAINER		28-62-90
DEXTROSE; POTASSIUM CHLORIDE; POTASSIUM	DEXTROSE 5\$ AND ELECTROLYTE	TRAVENOL LABS	048-81
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE
VCLINE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# VON

(INJECTABLE; INJECTION) 40MEQ IN PLASTIC CONTAINER

(INJECTABLE; INJECTION) 30MEQ IN PLASTIC CONTAINER

(INJECTABLE; INJECTION) SOMEQ IN PLASTIC CONTAINER

(INJECTABLE; INJECTION)

0.45% AND POTASSIUM CHLORIDE

0.45\$ AND POTASSIUM CHLORIDE

0.45\$ AND POTASSIUM CHLORIDE

DEXTROSE 5\$, SODIUM CHLORIDE

DEXIBOSE 5%, SODIUM CHLORIDE

DEXIBOSE 28° SODIUM CHLORIDE

26M/100ML; 300M6/100ML; 450M6/100ML

DEXIBOSE; POTASSIUM CHLORIDE; SODIUM

26M/100ML; 224MG/100ML; 450MG/100ML

DEXIROSE; POTASSIUM CHLORIDE; SODIUM

26M/100ML; 150M6/100ML; 450M6/100ML

DEXTROSE; POTASSIUM CHLORIDE; SODIUM

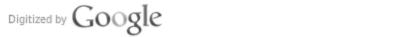
CHLOR IDE

CHLORIDE

CHLORIDE

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXP. DATE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16-83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 200MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.2% AND POTASSIUM CHLORIDE 30MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-567 02-16 - 83		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 75MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 5MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 150MG/100ML; 330MG/100ML	DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE IOMEQ IN PLASTIC CONTAINER	TRAVENOL LABS	18-629 03-23-82		
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE 5GM/100ML; 224MG/100ML; 330MG/100ML	(INJECTABLE; INJECTION) DEXTROSE 5%, SODIUM CHLORIDE 0.33% AND POTASSIUM CHLORIDE 15MEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-629 03-23-82		







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TRADE NAME

ACTIVE INGREDIENT(S)

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

APPLICANT NAME

		IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	
12-14-84		DEXTROSE 5%	26M/100ML; 40M6/100ML
117-61	ABBOTT LABORATORIES	THEOPHYLLINE IN	DEXTROSE; THEOPHYLLINE
110 01	3374627466477 1164647	THE SHIP PARTIES AND ADDRESS OF THE SHIP PARTIES AND ADDRESS O	THE PARTY OF THE P
		(INJECTABLE; INJECTION)	
		40MEQ IN PLASTIC CONTAINER	26M/100ML; 300M6/100ML; 330M6/100ML
03-23-82		0.33% AND POTASSIUM CHLORIDE	CHLOR IDE
679-81	TRAVENOL LABS	DEXTROSE 5%, SODIUM CHLORIDE	DEXTROSE; POTASSIUM CHLORIDE; SODIUM
		(INJECTABLE; INJECTION)	
		30MEQ IN PLASTIC CONTAINER	26M/100ML; 224MG/100ML; 330MG/100ML
03-23-82		0.33% AND POTASSIUM CHLORIDE	CHLORIDE
679-81	TRAVENOL LABS	DEXTROSE 5\$, SODIUM CHLORIDE	DEXTROSE; POTASSIUM CHLORIDE; SODIUM
		(INJECTABLE; INJECTION)	
		SOMEQ IN PLASTIC CONTAINER	26M/100ML; 300M6/100ML; 330MG/100ML
03-23-82		0.33% AND POTASSIUM CHLORIDE	CHLOR IDE
679-81	TRAVENOL LABS	DEXTROSE 58, SODIUM CHLORIDE	DEXTROSE; POTASSIUM CHLORIDE; SODIUM
		(INTECTABLE; INTECTION)	
		IOMEQ IN PLASTIC CONTAINER	26M/100ML; 75M6/100ML; 330M6/100ML
03-23-82		0.33% AND POTASSIUM CHLORIDE	CHLOR IDE
679-81	TRAVENOL LABS	DEXTROSE 58, SODIUM CHLORIDE	DEXTROSE; POTASSIUM CHLORIDE; SODIUM
		(INTECTABLE; INTECTION)	
		SOMEQ IN PLASTIC CONTAINER	26M/100ML; 150M6/100ML; 330MG/100ML
03-23-82		0.33\$ AND POTASSIUM CHLORIDE	CHLOR IDE
679-81	TRAVENOL LABS	DEXTROSE 5\$, SODIUM CHLORIDE	DEXIBOSE; POTASSIUM CHLORIDE; SODIUM
APPROVAL DATE		(DOSAGE FORM; ROUTE)	21KENG1H(2)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE; THEOPHYLLINE 5GM/100ML; 40MG/100ML	THEOPHYLLINE 0.04% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-083 11-07-84		
DEXTROSE; THEOPHYLLINE 5GM/IOOML; 80MG/IOOML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 80MG/100ML	THEOPHYLLINE 0.08% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-083 11-07-84	¥	
DEXTROSE; THEOPHYLLINE 5GM/100ML; 160MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 160MG/100ML	THEOPHYLLINE 0.16% AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	AM MCGAW/AM HOSP	19-083 11-07-84		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 200MG/100ML	THEOPHYLLINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-211 12-14-84		



		INJECTION)	(INJECTABLE;	
78-97	C-L0	ЯЗИТАТИС	IN PLASTIC C	2GW/100WF; 160MG/100ML
679	NOL LABS 18-6	AND DEXTROSE 5% TRAVE	THEOPHYLL INE	DEXTROSE; THEOPHYLLINE
		INDECTION)	(INJECTABLE;	
78-97	7-/0		O PLASTIC C	26M/100ML; 80M6/100ML
	9-81 SBAL LONE			DEXTROSE; THEOPHYLLINE
		INJECTION)	(INJECTABLE;	
78-97	C-LO	A3N1ATNO:	IN PLASTIC C	26M/100ML; 400MG/100ML
679	NOL LABS	AND DEXTROSE 5\$ TRAVE	THEOPHYLL INE	DEXTROSE; THEOPHYLLINE
		INJECTION)	(INJECTABLE;	
		ЗЭИТАТИС	IN PLASTIC C	
78-70)-11	% 9 3	AND DEXTROSE	2GW/100ML; 400MG/100ML
212	C-61 ASOH MA/WAD	O. 4\$ AM MC	THEOPHYLL INE	DEXTROSE; THEOPHYLLINE
		INJECTION)	(INJECTABLE;	
		RALINER	OD DITEALS IN PLASTIC CO	
18-1	-21		\$₹ ∃SORTXBO	26M/100ML; 400MG/100ML
117	T LABORATORIES 19-3	TO88A NI	THEOPHYLLINE	DEXTROSE; THEOPHYLLINE
		INJECTION)	(INJECTABLE;	
		ЗЭИТАТИЕЯ	IN PLASTIC C	
78-70) - [[% 9 3	AND DEXTROSE	26M/100ML; 200MG/100ML
212	C-61 HOSP 19-2	0.2% AM MC	THEOPHYLLINE	DEXTROSE; THEOPHYLLINE
SOVAL DATE		ROUTE)	(DOSYGE LOKW)	STRENGTH(S)
#	CANT NAME NDA		TRADE NAME	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DEXTROSE; THEOPHYLLINE 5GM/100ML; 200MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		
DEXTROSE; THEOPHYLLINE 5GM/100ML; 400MG/100ML	THEOPHYLLINE AND DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-649 07-26-82		
DTAZEPAM 2MG	VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263 11-15-63	4316897 02-23-99 3371085 02-27-85	
DIAZEPAM 5MG	VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263 11-15-63	4316897 02-23-99 3371085 02-27-85	
D I AZEPAM I OMG	VALIUM (TABLET; ORAL)	HOFFMANN-LA ROCHE	13-263 11-15-63	4316897 02-23-99 3371085 02-27-85	
D I AZEPAM 5MG/ML	VALIUM (INJECTABLE; INJECTION)	HOFFMANN-LA ROCHE	16-087 08-24-66	4316897 02-23-99 3371085 02-27-85	
DIAZEPAM I5MG	VALRELEASE (CAPSULE, CONTROLLED RELEASE; ORAL)	HOFFMANN-LA ROCHE	18-179 03-12-81	4316897 02-23-99 3371085 02-27-85	





0.05MG	(CAPSULE; ORAL)		28-92-70		
DIGOXIN	LANOX I CAPS	BURROUGHS WELLCOME	811-81		
0° ZWG	(CAPSULE; ORAL)		28-92-10		
DIEOXIN	LANOX I CAPS	BURROUGHS WELLCOME	811-81		
				68-70-70	
				0784782	
L) 200W€	(TABLET; ORAL)		78-61-40	68-10-80	76-61-40
DIFLUNISAL DO	DOFOB ID	MS&D/MERCK	544−81	3714226	NCE
				68-40-70	
				3674870	
Z2OWG (1	(TABLET; ORAL)		28-61-10	68-10-80	04-19-95
DIFLUNISAL DO	DOFOBID	WS&D/MERCK	944-81	3714226	NCE
\$60°0	(OINTMENT; TOPICAL)		87-10-20	£6-71-60	
DIFLORASONE DIACETATE	FLORONE	NHOLAU	766-LI	8770862	
\$60.0	(CREAM; TOPICAL)		LL-71-60	26-71-60	
DIFLORASONE DIACETATE FL	FLORONE	NHOLAU	147-71	8770862	
5) I OMG/SML	(SYRUP; ORAL)		18-51-01		
DICACTOMINE HADBOCHTOBIDE BE	BENTYL	WEBBELL DOW/DOW CHEM	196-40		
1 OM6/ML	(INJECTABLE; INJECTION)		1 8−91−01		
DICACTOMINE HADBOCHTOBIDE BE	BENTYL	WERRELL DOW/DOW CHEM	07 Z- 80		
SOMG	(CAPSULE; ORAL)		19-51-01		
DICACTOMINE HADBOCHTOBIDE BE	BENTYL	WERRELL DOW/DOW CHEM	604-70		
) OWC	(CAPSULE; ORAL)		10-12-84		
DICACTOMINE HADBOCHTOBIDE BE	BENTYL	WERRELL DOW/DOW CHEM	604-70		
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPL I CANT NAME	# VON	PATENT #	EXCLUSIVITY
DICYCLOMINE HYDROCHLORIDE BE	(CAPSULE; ORAL) (CAPSULE; ORAL)	MER	SKELL DOW/DOW CHEM	SKELL DOW/DOW CHEM 07-409	APPROVAL DATE EXP. DATE NO-15-84 10-15-84

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
DIGOXIN O.IMG	LANOXICAPS (CAPSULE; ORAL)	BURROUGHS WELLCOME	18-118 07-26-82		
DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE 0.5MG/0.5ML; 2500 UNITS/0.5ML; 5.33MG/0.5ML	EMBOLEX (INJECTABLE; INJECTION)	SANDOZ PHARMS/SANDOZ	18-885 11-30-84		
DIHYDROERGOTAMINE MESYLATE; HEPARIN SODIUM; LIDOCAINE HYDROCHLORIDE 0.5MG/0.7ML; 5000 UNITS/0.7ML; 7.46MG/0.7ML	EMBOLEX (INJECTABLE; INJECTION)	SANDOZ PHARMS/SANDOZ	18-885 11-30-84		
DILTIAZEM HYDROCHLORIDE 30MG	CARDIZEM (TABLET; ORAL)	MARION LABORATORIES	18-602 11-05-82	3562257 02-09-88	NCE 11-05-92
DILTIAZEM HYDROCHLORIDE 60MG	CARDIZEM (TABLET; ORAL)	MARION LABORATORIES	18-602 11-05-82	3562257 02-09 - 88	NCE 11-05-92
DINOPROST TROMETHAMINE EQ 5MG BASE/ML	PROSTIN F2 ALPHA (INJECTABLE; INJECTION)	UP JOHN	17-434 11-26-73	3706789 12-19-89 3778506 12-11-90	
DINOPROSTONE 20MG	PROSTIN E2 (SUPPOSITORY; VAGINAL)	UPJOHN	17-810 08-23-77	3899587 08-12-92 3598858 08-10-88	
DIPIVEFRIN HYDROCHLORIDE 0.1%	PROPINE (SOLUTION; OPHTHALMIC)	ALLERGAN PHARMS	18-239 05-02-80	3839584 10-01-91 3809714 05-07-91	



PFIZER LABS/PFIZER

SOORY MAAHY ARTZA

BRISTOL LABS/B-M

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EXP. DATE

EXCLUSIVITY

98-70-10

3420851

69-27-60

28-82-90

28-11-20

03-22-82

675-81

999-81

864-91

865-81 ELK I NS-S I NN/AHROB I NS DOPAMINE HYDROCHLORIDE DOPAMINE 28-60-70 (INJECTABLE; INJECTION) 80WG/WL 18-132 ABBOTT LABORATOR IES DOPAMINE HCL DOPAMINE HYDROCHLORIDE 26-61-01 84-81-40 (INTECTABLE; INJECTION) EQ 250MG BASE/VIAL 3987200 17-820 ברו רוררג DOBUTREX DOBUTAMINE HYDROCHLORIDE (JARO 58-01-50 (TABLET, ENTERIC COATED; EÓ 200WG BYZE 18-723 ABBOTT LABORATORIES **DEPAKOTE** DI VALPROEX SODIUM (JARO (TABLET, ENTERIC COATED; 58-01-50 EÓ SZOWE BYZE 18-723 ABBOTT LABORATORIES DEPAKOTE DIVALPROEX SODIUM **KELEASE; ORAL)** 28-02-70 (CAPSULE, CONTROLLED EÓ 120WC BYZE 959-81 SEARLE/SEARLE PHARMS NORPACE OR DISOPYRAMIDE PHOSPHATE **KELEASE; ORAL)** 28-02-70 (CAPSULE, CONTROLLED EÓ 100WC BYZE 559-81 SEARLE/SEARLE PHARMS MORPACE OR DISOPYRAMIDE PHOSPHATE EXP. DATE APPROVAL DATE (DOSAGE FORM; ROUTE) STRENGTH(S) PATENT # # VON APPLICANT NAME TRADE NAME ACTIVE INGREDIENT(S) TABLE IV. NDA'S APPROVED FROM I-I-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

(CAPSULE; ORAL)

(INJECTABLE; INJECTION)

(INJECTABLE; INJECTION)

(INJECTABLE; INJECTION)

SINEOUAN

DOPAMINE

DOPAMINE HCL

EÓ SZWE BYZE

4 OWC/WL

TOWE\WI

80MC/ML

DOXEPIN HYDROCHLORIDE

DOPAMINE HYDROCHLORIDE

DOPAMINE HYDROCHLORIDE

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
DOXEPIN HYDROCHLORIDE	SINEQUAN	PFIZER LABS/PFIZER	16-798	3420851	
EQ 50MG BASE	(CAPSULE; ORAL)		09-23-69	01-07-86	
DOXEPIN HYDROCHLORIDE	SINEQUAN	PFIZER LABS/PFIZER	16-798	3420851	
EQ IOMG BASE	(CAPSULE; ORAL)		03-31-75	01-07-86	
DOXEPIN HYDROCHLORIDE	SINEQUAN	PFIZER LABS/PFIZER	16-798	3420851	
EQ TOOMG BASE	(CAPSULE; ORAL)		03-31-75	01-07-86	
DOXEPIN HYDROCHLORIDE	SINEQUAN	PFIZER LABS/PFIZER	16-798	3420851	
EQ 75MG BASE	(CAPSULE; ORAL)		06-04-76	01-07-86	
DOXEPIN HYDROCHLORIDE	SINEQUAN	PFIZER LABS/PFIZER	16-798	3420851	
EQ 150MG BASE	(CAPSULE; ORAL)		03-15-78	01-07-86	
DOXEPIN HYDROCHLORIDE	ADAPIN	PENNWALT PHARM	16-987	3420851	
EQ IOMG BASE	(CAPSULE; ORAL)		01-31-72	01-07-86	
DOXEPIN HYDROCHLORIDE	ADAPIN	PENNWALT PHARM	16-987	3420851	
EQ 25MG BASE	(CAPSULE; ORAL)		01-31-72	01-07-86	
DOXEPIN HYDROCHLORIDE	ADAPIN	PENNWALT PHARM	16-987	3420851	
EQ 50MG BASE	(CAPSULE; ORAL)		01-31-72	01-07-86	
DOXEPIN HYDROCHLORIDE	ADAPIN	PENNWALT PHARM	16-987	3420851	
EQ 100MG BASE	(CAPSULE; ORAL)		12-12-77	01-07-86	
DOXEPIN HYDROCHLORIDE	ADAPIN	PENNWALT PHARM	16-987	3420851	
EQ 75MG BASE	(CAPSULE; ORAL)		04-15-80	01-07-86	
DOXEPIN HYDROCHLORIDE	SINEQUAN	PFIZER LABS/PFIZER	17-516	3420851	
EQ IOMG BASE/ML	(CONCENTRATE; ORAL)		03-11-74	01-07-86	
ECONAZOLE NITRATE	SPECTAZOLE	ORTHO PHARMACEUTICAL	18-751	3717655	NCE
1%	(CREAM; TOPICAL)		12-23-82	02-20-90	12-23-92
				3839574 10-01-91	





EXP. DATE

EXCLUSIVITY

16-97-11 26265 16-97-11 1160585 69-20-60

8€8999€

16-17-50

05-10-82

10-56-84

ξ8-81-10

907-81

287-40

899-81

3812147 (INJECTABLE; INJECTION) 0.005MG/ML; 1.5% 76-17-10 94-05-80 3862321 191-11 **20099 MAAH9 ARTZA TSBNARUQ** EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE 16-17-50 7412185 76-17-10 94-05-80 (INJECTABLE; INJECTION) 0.005MG/ML; 18 3862321 19L-L1 **20099 MAAH9 AST2A** EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE DURANEST 16-17-90 7412182 (INJECTABLE; INJECTION) \$5.0 ; JM/5M200.0 76-17-10 94-05-80 3862321 191-11 DURANEST EPINEPHRINE; ETIDOCAINE HYDROCHLORIDE **20089 MAAH9 ASTZA 78-80-60** 3527813 \$6.66 98-22-60 27-82-80 (LIQUID; INHALATION) 1106912 **L80-71 ANAQUEST/BOC ETHRANE** ENFLURANE EXP. DATE APPROVAL DATE STRENGTH(S) (DOSAGE FORM; ROUTE) ACTIVE INGREDIENT(S) PATENT # # AQN APPLICANT NAME TRADE NAME TABLE IV. NDA'S APPROVED FROM I-I-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

(TABLET; ORAL-21)

NORDETTE-21

PREMAR IN

(TABLET; ORAL)

(CAPSULE; ORAL)

HADEBOINE FC

0.03MG; 0.15MG

ESTROGENS, CONJUGATED

ERGOLOID MESYLATES

9M6.0

IWC

ETHINYL ESTRADIOL; LEVONORGESTREL

99-11

MYETH LABS/AMHO

AYERST LABS/AMHO

SOUNAS\SMAHY SOUNAS

STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ETHINYL ESTRADIOL; LEVONORGESTREL	NORDETTE-28	WYETH LABS/AMHO	18-782	3666858	
0.03MG; 0.15MG	(TABLET; ORAL-28)		07-21-82	05-30-89	
				3850911	
				11-26-91	
				3959322	
				11-26-91	
ETHINYL ESTRADIOL; LEVONORGESTREL	TRIPHASIL-28	WYETH LABS/AMHO	19-190	3666858	
0.03MG; 0.05MG	(TABLET; ORAL-28)		11-01-84	05-30-89	
0.04MG; 0.075MG				3850911	
0.03MG; 0.125MG				11-26-91	
				3959322	
				11-26-91	
				3957982	
				05-18-93	
ETHINYL ESTRADIOL; LEVONORGESTREL	TRIPHASIL-21	WYETH LABS/AMHO	19-192	3666858	
0.03MG; 0.05MG	(TABLET; ORAL-21)		11-01-84	05-30-89	
0.04MG; 0.075MG				3850911	
0.03MG; 0.125MG				11-26-91	
				3959322	
				11-26-91	
				3957982	
				05-18-93	
ETHINYL ESTRADIOL; NORETHINDRONE	ORTHO-NO VUM 10/11-21	ORTHO PHARMACEUTICAL	18-354		
0.035MG; 0.5MG AND IMG	(TABLET; ORAL-21)		01-11-82		
ETHINYL ESTRADIOL; NORETHINDRONE	ORTHO-NOVUM 10/11-28	ORTHO PHARMACEUTICAL	18-354		
0.035MG; 0.5MG AND IMG	(TABLET; ORAL-28)		01-11-82		
ETHINYL ESTRADIOL; NORETHINDRONE	TRI-NORINYL 21-DAY	SYNTEX (FP)	18-977	4390531	
0.035MG; 0.5MG AND IMG	(TABLET; ORAL-21)		04-13-84	06-28-00	





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					16-96-11	
					2959322	
		**			16-97-11	
					1160582	
	0.05MG; 0.5MG	(TABLET; ORAL-28)		89-97-11	68-05-50	
	ETHINYL ESTRADIOL; NORGESTREL	0VRAL-28	MYETH LABS/AMHO	908-91	8€8999€	
					16-97-11	
					2959322	
					16-97-11	
					1160585	
·	0.05MG; 0.5MG	(TABLET; ORAL-21)		89-91-70	68-05-50	
	ETHINYL ESTRADIOL; NORGESTREL	OVRAL	MAETH LABS/AMHO	7.19–91	8≤8999€	
	0.035MG; 0.5MG AND IMG	(TABLET; ORAL-28)		48-40-40		
	ETHINYL ESTRADIOL; NORETHINDRONE	ORTHO-NOVUM 7/14-28	ORTHO PHARMACEUTICAL	7 00-61		
	O.035MG; O.5MG AND IMG	(TABLET; ORAL-21)		48-40-40		
	ETHINYL ESTRADIOL; NORETHINDRONE	IS-41/7 MUVON-OHTAO	ORTHO PHARMACEUTICAL	700−6 I		
	O. OSANA DIA PARE AND LAME AND	(TABLET; ORAL-28)		48-40-40		
	ETHINYL ESTRADIOL; NORETHINDRONE	BS-F/F/ MUVON-OHTAO	ORTHO PHARMACEUTICAL	986-81		
	0.035MG; 0.5MG, 0.75MG AND IMG	(TABLET; ORAL-21)		48-40-40		
ħ.	ETHINYL ESTRADIOL; NORETHINDRONE	IS-T\T\ MUYON-OHTAO	ORTHO PHARMACEUTICAL	986−81		
	0.035MG; 0.5MG AND IMG	(TABLET; ORAL-28)		₽8−21−₽ 0	00-82-90	
	ETHINYL ESTRADIOL; NORETHINDRONE	YAQ-8S JYNIAON-IAT	SYNTEX (FP)	<i>LL</i> 6-81	1230624	
•	STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
1	ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# YON	PATENT #	EXCLUSIVITY

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ETHINYL ESTRADIOL; NORGESTREL 0.03MG; 0.3MG	LO/OVRAL (TABLET; ORAL-21)	WYETH LABS/AMHO	17-612 03-17-75	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETHINYL ESTRADIOL; NORGESTREL 0.03MG; 0.3MG	LO/OVRAL-28 (TABLET; ORAL-28)	WYETH LABS/AMHO	17-802 03-16-76	3666858 05-30-89 3850911 11-26-91 3959322 11-26-91	
ETIDOCAINE HYDROCHLORIDE 0.5%	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
ETIDOCAINE HYDROCHLORIDE	DURANEST (INJECTABLE; INJECTION)	ASTRA PHARM PRODS	17-751 08-30-76	3862321 01-21-92 3812147 05-21-91	
ETIDRONATE DISODIUM 200MG	DIDRONEL (TABLET; ORAL)	NORWICH EATON/P&G	17-831 09-01-77	4254114 03-03-98 4216211 09-05-97 4137309 01-30-96 3683080 08-08-89	,



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	05-13-85	17-25-11		(CYDENTE: OBYT)	∑50MG
	8268922	100-11	HOFFMANN-LA ROCHE	ANCOBON	FLUCYTOSINE
		48-11-70		(INJECTABLE; INJECTION)	EÓ 0°02WG BYZE\WT
		101-61	ELK INS-SINN/AHROBINS	FENTANYL	FENTANYL CITRATE
	88-71-80	94-91-50		(TABLET; ORAL)	EÓ POOME BYZE
	7540095	014-41	DISTA PRODS/LILLY	NALFON	FENOPROFEN CALCIUM
	88-71 - 80	08-51-01		(CAPSULE; ORAL)	EÓ SOOMG BYZE
	7540095	709-LI	DISTA PRODS/LILLY	NALFON 200	FENOPROFEN CALCIUM
	88-71-80	94-91-20		(CYBRITE: OBYT)	EÓ 200WG BYZE
	78400de	209-71	DISTA PRODS/LILLY	NALFON	FENOPROFEN CALCIUM
				RELEASE; ORAL)	
		28-72-70		(TABLET, CONTROLLED	9W09
		819-91	AH ROBINS	PONDIMIN	FENFLURAMINE HYDROCHLORIDE
26-01-11	78-81-80	28-01-11		(INJECTABLE; INJECTION)	SOMG/MIL
NCE	3524844	897-81	BRISTOL LABS/B-M	NEbE2 ID	E10POS I DE
76-70-60		Z8-70 - 60		(INJECTABLE; INJECTION)	SWG/WL
NCE		722-81	ABBOTA LABORATOR I ES	AMIDATE	ETOM IDATE
· 4	68-80-80				
	3683080				
	96-05-10				
	6027214				
	<i>L</i> 6− ⊆ 0−60				
	4216211				
	86-20-20	78-90-40		(TABLET; ORAL)	400WE
	4254114	158-71	NORWICH EATON/P&G	DIDBONEF	MUIGOSIG STANDROITE
EXP. DATE	EXP. DATE	APPROVAL DATE	<u> </u>	(DOSAGE FORM; ROUTE)	STRENGTH(S)
EXCLUSIVITY	* TN3TA9	# AdN	APPL I CANT NAME	AMAN BOAST	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
FLUCYTOS INE 500MG	ANCOBON (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	17-001 11-26-71	3368938 02-13-85	
FLUNISOLIDE 0.025MG/INH	BRONALIDE (AEROSOL; INHALATION)	SYNTEX LABS/SYNTEX	18-340 08-17-84		
FLUOCINONIDE 0.05%	LIDEX (SOLUTION; TOPICAL)	SYNTEX LABS/SYNTEX	18-849 04-06-84		
FLUOCINONIDE 0.05%	VASODERM (CREAM; TOPICAL)	K-LINE PHARMS	19-117 06-26-84		
FLUPHENAZINE DECANOATE 25MG/ML	PROLIXIN DECANOATE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	16-727 06-20-72	3394131 07-23-85	
FLUPHENAZINE ENANTHATE 25MG/ML	PROLIXIN ENANTHATE (INJECTABLE; INJECTION)	ER SQUIBB AND SONS	16-110 03-15-67	3394131 07-23-85	
FLURANDRENOLIDE 0.004MG/SQ CM	CORDRAN (TAPE; TOPICAL)	DISTA PRODS/LILLY	16-455 07-29-69	3632740 01-04-89	
FLURAZEPAM HYDROCHLORIDE	DALMANE (CAPSULE; ORAL)	ROCHE PRODUCTS	16-721 04-07-70	4316897 02 - 23 - 99	
FLURAZEPAM HYDROCHLORIDE 30MG	DALMANE (CAPSULE; ORAL)	ROCHE PRODUCTS	16-721 04-07-70	4316897 02-23-99	
FUROSEM I DE 20MG	FUROSEMIDE (TABLET; ORAL)	CHELSEA LABORATORIES	18-369 05-14-82		
FUROSEM IDE 40MG	FUROSEMIDE (TABLET; ORAL)	CHELSEA LABORATORIES	18-369 05-14-82		





28-02-10

EXP. DATE

PATENT #

EXP. DATE

EXCLUSIVITY

TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

177, 6710 1	(11012031111 3 1012031111)		00 02 20
L NBOSEM IDE	ENBOSEMIDE	LYPHOMED	L0G-81
I OMG/ML	(INJECTABLE; INJECTION)		02-26-82
FUROSEMIDE	ENBOSEM IDE	PARKE-DAVIS/W-L	18-420
80MC	(JARO :TABLET)		18-21-11
FUROSEM IDE	FUROSEMIDE	PARKE-DAVIS/W-L	617-81
4 OMG	(TABLET; ORAL)		28-12-10
FUROSEMIDE	ENBOSEM IDE	PARKE-DAVIS/W-L	614-81
SOMG	(TABLET; ORAL)		28-12-10
FUROSEMIDE	ENBOSEM I DE	PARKE-DAVIS/W-L	614-81
80MG	(TABLET; ORAL)		11-56-84
ENROSEM I DE	FUROSEMIDE	LEDERLE LABS/AM CYAN	214-81
5W0†	(TABLET; ORAL)		28-72-70
FUROSEMIDE	FUROSEMIDE	LEDERLE LABS/AM CYAN	614-81
SOMG	(TABLET; ORAL)		28-72-70
ENBOSEM IDE	FUROSEMIDE	LEDERLE LABS/AM CYAN	614-81
. 5MO+	(TABLET; ORAL)		28-02-11
FUROSEM I DE	FUROSEMIDE	ZENITH LABORATORIES	514-81
SOME	(TABLET; ORAL)		28-02-11
FUROSEMIDE	FUROSEMIDE	ZENITH LABORATORIES	214-81
SOMG	(TABLET; ORAL)		78-92-90
FUROSEMIDE	ENBOSEM IDE	MAAHARA	072-81
9W0†	(TABLET; ORAL)		02-10-82
FUROSEMIDE	ENBOSEMIDE	MAAHARA	075-81
STRENGTH(S)	(DOSAGE FORM; ROUTE)		STAU JAVORA
ACTIVE INGREDIENT(S)	TRADE NAME	APPL I CANT NAME	# AUN

(INTECTABLE; INJECTION)

I OMG/ML

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVIT
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
FUROSEMIDE	FUROSEMIDE	CORD LABORATORIES	18-569		
80MG	(TABLET; ORAL)		08-14-84		
UROSEMIDE	FUROSEMIDE	NATCON	18-579		
I OMG/ML	(INJECTABLE; INJECTION)		11-30-83		
UROSEMIDE	FUROSEMIDE	ABBOTT LABORATORIES	18-667		
I OMG/ML	(INJECTABLE; INJECTION)		05-28-82		
FUROSEM IDE	FUROSEMIDE	WYETH LABS/AMHO	18-670		
I OMG/ML	(INJECTABLE; INJECTION)		07-20-82		
FUROSEM IDE	FUROSEMIDE	DRUMMER/PHOEN IX	18-750		
40MG	(TABLET; ORAL)		07-30-84		
UROSEMIDE	FUROSEMIDE	INTL MEDICATION SYS	18-753		
20MG	(TABLET; ORAL)		02-28-84		
FUROSEMIDE	FUROSEMIDE	INTL MEDICATION SYS	18-753		
40MG	(TABLET; ORAL)		02-28-84		
FUROSEMIDE	FUROSEMIDE	BARR LABORATORIES	18-790		
40MG	(TABLET; ORAL)		11-29-83		
FUROSEMIDE	FUROSEMIDE	ROXANE LABORATORIES	18-823		
20MG	(TABLET; ORAL)		11-10-83		
FUROSEMIDE	FUROSEMIDE	ROXANE LABORATORIES	18-823		
40MG	(TABLET; ORAL)		11-10-83		
UROSEMIDE	FUROSEMIDE	KALAPHARM	18-868		
20MG	(TABLET; ORAL)		06-28-83		
FUROSEMIDE	FUROSEMIDE	KALAPHARM	18-868		
4 OMG	(TABLET; ORAL)		06-28-83		





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2903861 21-0003861 22-01-04 22-01-05 22-01		04-51-65				
*** **** **** ***** ***** ****** ******						
*** **** **** ***** ***** ****** ******		76-17-40				
7-346 (1-62) (1-64) (1-						
SAME **ABINIDE* MICHONIVE*** MICHONIVE** MICHONIVE* MICHONIV		04-51-95				
Labor Labo		2424632				
Companies Comp	76-10-⊆0	04-51-65	78-10- €0		(TABLET; ORAL)	S°⊇WG
220.06 220.	NOE	2426067	86 7- 71	NHOLAU	MICRONASE	GE ABNB IDE
12-21-64		76-17-40				
CAPILITIE CAPI		19670₹				
Companies		04-51-65				
Table Tabl		7 967032				
*** PARKED HISTORY (**** INTECTION) 05-01-84 04-21-92 05-01-94 **** PARKED HISTORY (***** INTECTION) 05-01-84 04-21-92 05-01-94 **** PARKED HISTORY (************************************		04-21-65				
''BIRIDE MI GROWERE NE JOHN 17-48 3450057 NCE ''IBIZIDE GFNOZIGE KOEKI (C/PFIZER) 05-08-84 04-21-32 05-08-94 ''IPIZIDE GLOOZIROL ROERI (C/PFIZER) 05-08-84 04-21-92 05-08-94 ''IPIZIDE GLOOZIROL ROERI (C/PFIZER) 05-08-84 04-21-92 05-08-94 ''IPIZIDE GLOOZIROL ROERI (C/PFIZER) 12-21-81 07-04-89 SWORE (CAPSULE) ROREN (CAPSULE) 12-21-81 07-04-89 SWORE (CAPSULE) ROREN (CAPSULE) 12-21-81 07-04-89 SWORE (CAPSULE) ROREN (CAPSULE) 08-12-84 07-04-89 SWORE (CAPSULE) (CAPSULE) (CAPSULE) 08-12-84 SWORE (CAPSULE) (CAPSULE) (CAPSULE		2424632				
OWENT (INTECTABLE) OF SPANIS (TABLET; ORALL) OF OB-84 OF OF OF ORE OF OT OR OF ORE OF OT OR OF OT OTHER OF OTHER OTHER OF OTHER OTHER OF OTHER OTHER OF OTHER	76-10-SO	04-21-65	78-10-90		(TABLET; ORAL)	1°Z≥WG
TIMESTRE GENOTROL ROERIG/PETZER 17-783 3669966 NCE N	NCE	Z426067	864-71	NHOLAU	MICRONASE	GLYBURIDE
## BROZIL	76-80- ⊊0	Z6-1Z- 1 0	78-80- ⊆0		(TABLET; ORAL)	I OMG
OPTION O	NCE	996699€	₹87-7 1	ROER I G/PF I ZER	GLUCOTROL	GLIPIZIDE
200MG (CVB-2NTE 2 0BVFT) 15-51-81 01-04-89 200MG (CVB-2NTE 2 0BVFT) 19-455 2914839 200MG (CVB-2NTE 2 0BVFT) 15-51-81 01-04-89 200MG (CVB-2NTE 2 0BVFT) 15-51-81 01-04-89 200MG (INTECTION) 08-12-81 01-04-89 200MG (INTECTION) 08-12-84 02-04-89 200MG (INTECTION) 08-12-84 02-04-89 200MG (INTECTION) 08-12-84 02-05-84 200MG (INTECTION) 02-55-84 02-55-84 200MG (INTECTION) 02-55-84 02-05-84 200MG (INTECTION) 02-55-84 02-55-84 200MG (INTECTION) 02-55-84 02-55-84 200MG 02-55-84 02-55-84 02-55-84 200MG 02-55-84 02-55-84 02-55-84	7 6−80−⊊0	04-21-65	78-80-⊆0		(TABLET; ORAL)	SMG
DANE IBROZIC LOPID PARKE-DAVIS/W-L 18-422 3674836 OMG/ML (INJECTABLE; INJECTION) 05-22-84 07-04-89 OMG/ML (INJECTABLE; INJECTION) 08-15-84 07-04-89 OMG/ML (INJECTABLE; INJECTION) 08-15-84 07-04-89 OMG/ML (INJECTABLE; INJECTION) 08-15-84 07-04-89 PROSEMIDE INVENEX LABS/LIFE 18-902 3674836	NCE	996699£	₹87-7 I	ROER I G/PF I ZER	GLUCOTROL	GLIPIZIDE
DROSEMIDE (CAPSULE; ORAL) ONG-LIFE 18-902 ONG-/ML (INJECTABLE; INJECTION) PARKE-DAVIS/W-L 18-422 3674836 ONG-/ML (INJECTABLE; INJECTION) 05-22-84 ONG-/ML (INJECTABLE; INJECTION) 05-13-84 ONG-ML OS-13-84 ON		68-40-70	12-21-81		(CAPSULE; ORAL)	200₩€
DMC/NT COLID DARKE-DAVIS/W-L 18-422 3674836 DMC/NT (INTECTABLE; INTECTION) 08-13-84 DMC/NT (INTECTABLE; INTECTION) 05-22-84 DROSEMIDE INVENEX LABS/LIFE 18-902 REPOSEMIDE INVENEX LABS/LIFE 18-902		9884798	18-422	PARKE-DAVIS/W-L	רספום	GEME IBROZ I C
OWG/ML		68-40-70	12-21-81		(CVb2NTE: OBVT)	SOOME
DBOSEWIDE LINGSEWIDE INAEMEX FYBS\FILE 19-03e OW6\MT 02-55-84 BBOSEWIDE INAEMEX FYBS\FILE 18-305		9284792	18-422	PARKE-DAVIS/W-L	UPID	GEME IBROZ I L
OW@/WIT (INTECTABLE; INTECTION) OS-22-84 IROSEMIDE INVENEX LABS/LIFE 18-902			78−21−80		(INTECTABLE; INTECTION)	IM/9MO I
BOSEWIDE INVENEX LAROSEMIDE INVENEX LABORLE 18-902			920-61	INVENEX LABS/LIFE	FUROSEMIDE	FUROSEMIDE
			02-22-84		(INJECTABLE; INJECTION)	IM/9M0 I
RENGTH(S) APPENDALE FORM; ROUTE) APPROVAL DATE EXP. DATE EXP. DATE			206-81	INVENEX LABS/LIFE	FUROSEMIDE	E NBOSEW I DE
	EXP. DATE	EXP. DATE	APPROVAL DATE		(DOSAGE FORM; ROUTE)	2ТЯЕИСТН(S)
TRADE NAME NOREDIENT(S) TRADE NAME NDA # EXCLUSIVITY	EXCLUSIVITY	PATENT #	# YON	APPLICANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
GLYBURIDE 5MG	MICRONASE (TABLET; ORAL)	UP JOHN	17-498 05-01-84	3426067 04-21-92 3454635	NCE 05-01-94
				04-21-92 3507954 04-21-92 3507961	
				04-21-92	
GLYBURIDE 1.25MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84	3426067 04-21-92 3454635 04-21-92	NCE 05-01-94
				3507961 04-21-92 3507954	
				04-21-92 4060634 09-07-93	
GLYBURIDE 2.5MG	DIABETA (TABLET; ORAL)	HOECHST-ROUSSEL	17-532 05-01-84	3426067 04-21-92 3454635 04-21-92 3507961 04-21-92 3507954 04-21-92 4060634 09-07-93	NCE 05-01-94

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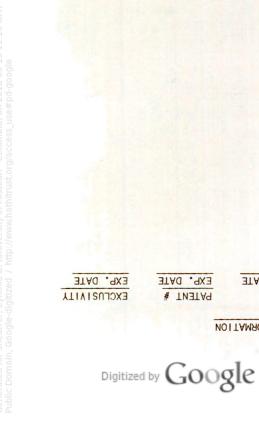
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15-56-65	12-12-81	28-6Z-Z1		(TABLET; ORAL)	SZWG
NCE	1267422	18-104	NHOLAU	HALOREL	GUANADREL SÜLFATE
15-58-65	18-51-51	12-29-82		(TABLET; ORAL)	IOWG
NCE	1967422	18-104	NHOLAU	НАГОВЕГ	GUANADREL SULFATE
Z6-L0 - 60	68-52-40	28-70-60		(TABLET; ORAL)	EÓ BWC BYZE
NCE	Σ668≤9Σ	78 2−81	WYETH LABS/AMHO	MATENSIN	GUANABENZ ACETATE
Z6-L0-60	04-25-89	28-70-60		(TABLET; ORAL)	EÓ 11MC BYZE
NOE	Σ668⊆9Σ	78 2– 81	MAETH LABS/AMHO	MALENZIN	GUANABENZ ACETATE
	9-52-80				
	4110438				
26-02- 6 0	₹6-0₹-₹0	28-0 2-6 0		(INJECTABLE; INJECTION)	EÓ 0.5MG BASE/VIAL
NCE	6957465	18-123	AYERST LABS/AMHO	FACTREL	GONYDOKET IN HYDROCHLORIDE
	6-29-95				
	4110438				
26-0 2- 60	26−02−20	Z8-0 ∑- 60		(INJECTABLE; INJECTION)	EÓ O'IME BYZE/AIVT
NCE	6957468	18-123	AYERST LABS/AMHO	FACTREL	CONTROLE IN HYDROCHLORIDE
	Σ6-L0-60				
	409090				
	04-21-65				
	\$56702£				
	04-21-65				
	196∠0⊊£				
	04-51-65				
	2424635				
76-10-⊆0	04-51-65	78-10-⊆0		(TABLET; ORAL)	≥We
NCE	Z426067	252-71	HOECHST-ROUSSEL	AT38A10	GLYBUR IDE
EXP. DATE	EXP. DATE	APPROVAL DATE		(DOSAGE FORM; ROUTE)	STREMGTH(S)
EXCLUSIVITY	PATENT #	¥ ∀QN	APPLICANT NAME	AMAN BOLAST	VCLIAE INGSEDIENT(S)

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PATENT # EXP. DATE

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TABLE IV. NDA'S APPROVED FROM I-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

	(INTEGRADIE)		
	IN PLASTIC CONTAINER		
100 UNITS/ML; 4.5MG/ML	IN SODINM CHLORIDE 0.45%		18-12-10
HEPARIN SODIUM; SODIUM CHLORIDE	HEPARIN SODIUM 5,000 UNITS	ABBOTT LABORATORIES	916-81
	(INTECTABLE; INTECTION)		
	IN PLASTIC CONTAINER		
5,000 UNITS/100ML; 900MG/100ML	IN SODINM CHFOBIDE 0.9%		48-12-10
HEPARIN SODIUM; SODIUM CHLORIDE	STINU OOF, SI MUIDOS NIRATEH	ABBOTT LABORATORIES	916-81
	(INTECTABLE; INTECTION)		
	IN PLASTIC CONTAINER		
10,000 UNITS/100ML; 900MG/100ML	IN SODINM CHLORIDE 0.9%		48-12-10
HEPARIN SODIUM; SODIUM CHLORIDE	HEPARIN SODIUM 10,000 UNITS	ABBOTT LABORATORIES	916-81
	(INJECTABLE; INJECTION)		bearing .
	IN PLASTIC CONTAINER		
1,000 UNITS/100ML; 900MG/100ML	IN SODINM CHLORIDE 0.9%		48-12-10
HEPARIN SODIUM; SODIUM CHLORIDE	STINU OOOS MUIDOS NIAATH	ABBOTT LABORATORIES	916-81
	(INTECTABLE; INJECTION)		
	IN PLASTIC CONTAINER		
500 UNITS/100ML; 900M6/100ML	AND SODIUM CHLORIDE 0.9%		04-28-82
HEPARIN SODIUM; SODIUM CHLORIDE	STINU SODIUM 5000 UNITS	TRAVENOL LABS	609-81
	(INTECTABLE; INJECTION)		
	IN PLASTIC CONTAINER		
200 UNITS/100ML; 900MG/100ML	AND SODIUM CHLORIDE 0.9%		04-28-82
HEPARIN SODIUM; SODIUM CHLORIDE	STINU OOOS MUIOS NIJAAJH	TRAVENOL LABS	609-81
	(INTECTABLE; INTECTION)		
	IN PLASTIC CONTAINER		
200 UNITS/100ML; 900MG/100ML	AND SODIUM CHLORIDE 0.9%		04-28-82
HEPARIN SODIUM; SODIUM CHLORIDE	HEPARIN SODIUM 1000 UNITS	TRAVENOL LABS	609-81
STRENGTH(S)	(DOSYGE FORM; ROUTE)		APPROVAL DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# YON

(INJECTABLE; INJECTION)

STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXP. DATE
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 10,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 12,500 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 10,000 UNITS/100ML; 450MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEPARIN SODIUM; SODIUM CHLORIDE 5,000 UNITS/100ML; 900MG/100ML	HEPARIN SODIUM 25,000 UNITS IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-916 01-31-84		
HEXACHLOROPHENE 3%	TURGEX (SOLUTION; TOPICAL)	XTTRIUM LABS	19-055 11-30-84		
HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE 25MG; 50MG	LOPRESSOR HCT 50/25 (TABLET; ORAL)	GEIGY/CIBA-GEIGY	18-303 12-31-84	3876802 04-08-92 3998790 12-21-93	
HYDROCHLOROTHIAZIDE; METOPROLOL TARTRATE 25MG; 100MG	LOPRESSOR HCT 100/25 (TABLET; ORAL)	GEIGY/CIBA-GEIGY	18-303 12-31-84	3876802 04-08-92 3998790 12-21-93	

IV-69



(TABLET; ORAL)

400MG





05-28-85

7L-61-60

3385886 £97-L1 UPJOHN MANUFACTURING NIATOM IBUPROFEN £6-90-L0 12-01-67 (CAPSULE; ORAL) **200WG** 3968249 967-91 ER SOUIBB AND SONS HYDREA HYDROXYUREA 76-11-10 48-11-10 (INJECTABLE; INJECTION) I OWE /WE NCE 7£0-61 KNOLL PHARMACEUTICAL DILAUDID-HP HADBOMORPHONE HYDROCHLORIDE **ξ8-80-80** (OINTMENT; TOPICAL) \$2.0 MESTWOOD PHARMS **MESTOORT** HYDROCORTISONE VALERATE 18-726 48-50-70 (OINTMENT; TOPICAL) 81.0 901-61 OMEN LABS/DERM PRODS TOCOID HYDROCORTISONE BUTYRATE 28-40-10 (CREAM; TOPICAL) 81.0 964-81 OMEN LABS/DERM PRODS TOCOID HYDROCORTISONE BUTYRATE 02-10-85 (AEROSOL; RECTAL) 801 195-11 REED&CARNRICK PHARMS HYDROCORTISONE ACETATE MAOJITACO (TABLET; ORAL) 10-55-84 POWC: 12MG 04-24-01 694777 19-159 MYLAN PHARMS MAXZIDE HYDROCHLOROTHIAZIDE; TRIAMTERENE 15-09-31 4238485 68-11-40 12-11-81 (TABLET; ORAL) SZWC: 10MG 2999999 190-81 W2&D/MERCK TIMOLIDE HYDROCHLOROTHIAZIDE; TIMOLOL MALEATE 15-51-63 0618662 20WC : 100WC (TABLET; ORAL) 04-08-92 12-31-84 METOPROLOL TARTRATE LOPRESSOR HCT 100/50 HYDROCHLOROTHIAZIDE; 3876802 505-81 GEIGY/CIBA-GEIGY EXP. DATE EXP. DATE (DOSVGE FORM; ROUTE) STRENGTH(S) APPROVAL DATE ACTIVE INGREDIENT(S) EXCLUSIVITY PATENT # # YON TRADE NAME APPL I CANT NAME

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
IBUPROFEN	MOTRIN	UPJOHN MANUFACTURING	17-463	3385886	
300MG	(TABLET; ORAL)		09-19-74	05-28-85	
IBUPROFEN	MOTRIN	UPJOHN MANUFACTURING	17-463	3385886	
600MG	(TABLET; ORAL)		03-09-79	05-28-85	
IBUPROFEN	RUFEN	BOOTS PHARMACEUTICAL	18-197	3385886	
400MG	(TABLET; ORAL)		05-19-81	05-28-85	
IBUPROFEN	RUFEN	BOOTS PHARMACEUTICAL	18-197	3385886	
60 OMG	(TABLET; ORAL)		03-05-84	05-28-85	
INDAPAMIDE	LOZOL	USV PHARMACEUTICAL	18-538	3565911	NCE
2.5MG	(TABLET; ORAL)		07-06-83	02-23-88	07-06-93
INDOMETHACIN	INDOCIN	MS&D RES LABS/MERCK	17-814		
50MG	(SUPPOSITORY; RECTAL)		08-13-84		
INDOMETHACIN	INDOCIN SR	MS&D/MERCK	18-185		
75MG	(CAPSULE, CONTROLLED RELEASE; ORAL)		02-23-82		
INDOMETHACIN	INDOMETHACIN	CHELSEA LABORATORIES	18-690		
25MG	(CAPSULE; ORAL)		07-31-84		
INDOMETHACIN	INDOMETHACIN	CHELSEA LABORATORIES	18-690		
50MG	(CAPSULE; ORAL)		07-31-84		
INDOMETHACIN	INDOMETHACIN	ZENITH LABORATORIES	18-730		
25MG	(CAPSULE; ORAL)		05-04-84		
INDOMETHACIN	INDOMETHACIN	ZENITH LABORATORIES	18-730		
50MG	(CAPSULE; ORAL)		05-04-84		



	68-40-40	18-41-80		(INTECTABLE; INTECTION)	% 6*6
	3654272	770-8I	EK SÓNIBB YND SONS	CHOLOVUE	IODOXAMATE MEGLUMINE
	68-40-40	18-11-80		(INJECTABLE; INJECTION)	\$£.04
	3654272	940-81	ER SQUIBB AND SONS	CHOLOVUE	IODOXAMATE MEGLUMINE
					IWCI /WF
12-28-89		12-28-84		(INJECTABLE; INJECTION)	1-122
NCE		18–289	WED1-bHX21C2	NEPHROFLOW	IODOH I PPURATE SOD I UM,
		11-23-84		(CAPSULE; ORAL)	≥0MG
		908-81	PARKE-DAVIS/W-L	INDOMETHACIN	INDOMETHACIN
		11-23-84		(CAPSULE; ORAL)	S≥WG
		908-81	PARKE-DAVIS/W-L	INDOMETHACIN	INDOMETHACIN
		04-20-84		(CAPSULE; ORAL)	20₩6
		858-81	MYLAN PHARMS	INDOMETHACIN	INDOMETHACIN
		04-20-84		(CAPSULE; ORAL)	SEMG
		858-81	MYLAN PHARMS	INDOMETHACIN	INDOMETHACIN
		\$8-81-GO		(CAPSULE; ORAL)	≥OM6
		158-81	LEDERLE LABS/AM CYAN	INDOMETHACIN	INDOMETHACIN
		78-81-≤0		(C∀B2NFE: OKYF)	S≥WG
		198-81	LEDERLE LABS/AM CYAN	INDOMETHACIN	INDOMETHACIN
		78-90-80		(CAPSULE; ORAL)	S≥WC
		628-81	PAR PHARMACEUTICAL	INDOMETHACIN	INDOMETHACIN
		18-90-80		(CVB2NFE: OKVF)	≥owe
		628-81	PAR PHARMACEUTICAL	INDOMETHACIN	INDOMETHACIN
EXP. DATE	EXP. DATE	APPROVAL DATE		(DOSVGE FORM; ROUTE)	21RENGTH(S)
EXCLUSIVITY	PATENT #	# YON	APPLICANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
ISOFLURANE 99.9%	FORANE (GAS; INHALATION)	ANAQUEST/BOC	17-624 12-18-79	3535425 01-24-93 3535388 01-24-93	
ISOTRET INOIN IOMG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 05-07-82	4200647 04-29-97 4322438 03-30-99 4464394 08-07-01	NCE 05-07-92
ISOTRET INO IN 20MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 03-28-83	4200647 04-29-97 4322438 03-30-99 4464394 08-07-01	NŒ 05-07-92
ISOTRETINOIN 40MG	ACCUTANE (CAPSULE; ORAL)	HOFFMANN-LA ROCHE	18-662 05-07-82	4200647 04-29-97 4322438 03-30-99 4464394 08-07-01	NCE 05-07-92
KETOCONAZOLE 200MG	NIZORAL (TABLET; ORAL)	JANSSEN PHARMA	18-533 06-12-81	4335125 06-15-99	
LABETALOL HYDROCHLORIDE 200MG	NORMODYNE (TABLET; ORAL)	SCHERING	18-686 08-01-84	4012444 03-15-94 4006755 01-03-95	





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	96- 20-10				
	4006755				1
76-10-80	1 6−⊆1−€0	48-10-80		(TABLET; ORAL)	400MG
NCE	4012444	917-81	er∀xo	TRAUNA ST	LABETALOL HYDROCHLORIDE
	⊊6− Σ 0−10				
	€€76004				
76-10-80	16-51-50	48-10-80		(TABLET; ORAL)	300MG
NCE	4012444	917-81	er⊌xo	TAUNA ST	LABETALOL HYDROCHLORIDE
	⊆6−Σ0−10				
	€€78004				
46-10-80	\$6- ⊆ 1 <i>-</i> ⊊ 0	48-10-80		(TABLET; ORAL)	SOOMG
NCE	4012444	917-81	er y x0	TRAUDATE	LABETALOL HYDROCHLOR IDE
	66-40-90				
	4328213				
	96-20-10				
	SSL9007				
\$6-10-80	76-51-50	48-10-80		(INJECTABLE; INJECTION)	SMG/ML
NCE	4012444	Z89-81	SCHEB ING	NOBWODYNE	LABETALOL HYDROCHLORIDE
	55 50 10				
	56-50-10				
14 10 00	557004	10.10.00		(441000
76- 10-80	46-91-80	78-10-80		(TABLET; ORAL)	400MG
NCE	4012444	989-81	SCHERING	NORMODYNE	LABETALOL HYDROCHLORIDE
	56-20-10				
	567600A				
76- 10-80	46-51-50	48-10-80		(TABLET; ORAL)	200MG
NCE	4012444	989-81	SCHEK I NG	NORMODANE	LABETALOL HYDROCHLORIDE
EXP. DATE	EXP. DATE	APPRO VAL DATE		(DOSVGE FORM; ROUTE)	STRENGTH(S)
EXCLUSIVITY	PATENT #	# VON	APPLICANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
LACTULOSE	CEPHULAC	MERRELL DOW/DOW CHEM	17-657	3461204	
10GM/15ML	(SYRUP; ORAL)		03-25-76	08-12-86	
				3867524	
				02-18-92	
				3860708	
				01-14-92	
				3860707	
				01-14-92	
				3562388	
				02-09-88	
				3558774	
				01-26-88	
LEUCOVORIN CALCIUM	WELLCOVORIN	BURROUGHS WELLCOME	18-342		
EQ 5MG BASE	(TABLET; ORAL)		07-08-83		
LEUCOVORIN CALCIUM	WELLCOVORIN	BURROUGHS WELLCOME	18-342		
EQ 25MG BASE	(TABLET; ORAL)		07-08-83		
LITHIUM CARBONATE	ESKALITH CR	SK&F LABORATORIES	18-152		
450MG	(TABLET, CONTROLLED		03-29-82		
	RELEASE; ORAL)				
LITHIUM CARBONATE	LITHIUM CARBONATE	ROXANE LABORATORIES	18-558		
300MG	(TABLET; ORAL)	NOMINE EXECUTIONIES	01-29-82		
30010	(MEEL) OWE		01 25 02		
LOPERAMIDE HYDROCHLORIDE	IMODIUM	JANSSEN PHARMA	17-694	3714159	
2MG	(CAPSULE; ORAL)		12-28-76	01-30-90	
LOPERAMIDE HYDROCHLORIDE	IMOD I UM	JANSSEN PHARMA	19-037	3714159	
IMG/5ML	(SOLUTION; ORAL)		07-31-84	01-30-90	
LOXAPINE HYDROCHLORIDE	LOXITANE	LEDERLE LABS/AM CYAN	18-039	3546226	
EQ 50MG BASE/ML	(INJECTABLE; INJECTION)		10-26-79	12-08-87	





MAFENIDE ACETATE EQ 85MG BASE/GM	SULFAMYLON (CREAM; TOPICAL)	WINTHROP LABS/STERL	69-75-10 19-763	2497599 88-62-10	
EÓ ≥OMG BYZE FOXYЫNE 2NCCINYLE	(CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	67-52-75 17-525	12-08-87	
		LEDEDI E I ABC VAM CVAN			
LOXAPINE SUCCINATE EQ 25MG BASE	CONTANE (CAPSULE; ORAL)	REDEBLE LABS/AM CYAN	05-25-75 17 - 525	3546226	
EÓ IOWE BYZE TOXYBINE 2NCCINYLE	(CAPSULE; ORAL)	LEDERLE LABS/AM CYAN	05-52-12 17-525	12-08-87	
EÓ 2WG BYZE	(CAPSULE; ORAL)		LL-5Z-01	18-80-21	
LOXAPINE SUCCINATE	LOXITANE	LEDERLE LABS/AM CYAN	17-525	3546226	
				6086+0 + 07-60	
EÓ S⊋WG BYZE∖WF FOXY⊾INE HADKOCHFOKIDE	(CONCENTRATE; ORAL)	FEDERIE FYBRYWW CLYN	9L-70-90 899-11	12-08-87	
		NAY2 MA/284 I 3 19303 I			
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXCLUSIVITY EXP. DATE

I SWG/100ML

270MG/100ML; 530MG/100ML; 500MG/100ML;



ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE 30MG/100ML; 37MG/100ML; 222MG/100ML; 526MG/100ML; 502MG/100ML	PHYSIOSOL IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	ABBOTT LABORATORIES	17-637 07-08-82		
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE 30MG/100ML; 37MG/100ML; 222MG/100ML; 526MG/100ML; 502MG/100ML	PHYSIOSOL IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	ABBOTT LABORATORIES	18-406 07-08-82		
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE 30MG/100ML; 37MG/100ML; 370MG/100ML; 530MG/100ML; 500MG/100ML	PHYSIOLYTE IN PLASTIC CONTAINER (SOLUTION; IRRIGATION)	AM MCGAW/AM HOSP	19-024 06-08-84		
MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE 20MG/100ML; 40MG/100ML; 6.25MG/100ML; 800MG/100ML; 8.75MG/100ML	TIS-U-SOL (SOLUTION; IRRIGATION)	TRAVENOL LABS	18-508 02-19-82		
MALATHION	PRIODERM	PURDUE FREDERICK	18-613		NCE
0.5%	(LOTION; TOPICAL)	TONDOE THEBENION	08-02-82		08-02-92
MAPROTILINE HYDROCHLORIDE 25MG	(TABLET; ORAL)	CIBA/CIBA-GEIGY	17-543 12-01-80	3399201 08-27-85	
MAPROTILINE HYDROCHLORIDE 50MG	LUDIOMIL (TABLET; ORAL)	CIBA/CIBA-GEIGY	17-543 12-01-80	3399201 08-27-85	
MAPROTILINE HYDROCHLORIDE 75MG	LUDIOMIL (TABLET; ORAL)	CIBA/CIBA-GE IGY	17-543 09-30-82	3399201 08-27-85	
		17			



BOEHKINGEK INGECHEIW

(SYRUP; ORAL)

(AEROSOL; INHALATION)

ALUPENT

I OMG/SML

0° 65MG/1NH

METAPROTERENOL SULFATE

HIII/SNEE	(NOTE INNIT - 1030014)		ZL IZ LU	30 11 10	
METAPROTERENOL SULFATE	ALUPENT	BOEHKINGEK INGETHEIM	16-402	3422196	
I OWC	(TABLET; ORAL)		<i>LL</i> -80-80	98-11-10	
METAPROTERENOL SULFATE	ALUPENT	BOEHKINGEK INGELHEIM	748-G1	3422196	
SOME	(TABLET; ORAL)		71-51-60	98-11-10	
METAPROTERENOL SULFATE	ALUPENT	BOEHKINGEK INGETHEIM	≯ ∠8-⊊1	3422196	
140.1M6/ML; 461.8M6/ML	(INJECTABLE; INJECTION)		74-05-40	98-10-11	
MEGLUMINE; METRIZOIC ACID	ISOPAQUE-280	WINTHROP LABS/STERL	909-11	2089742	
#00WE/WF	(INJECTABLE; INJECTION)		94-91-10	98-60-10	
MEDROXYPROGESTERONE ACETATE	DEPO-PROVERA	NHOLAU	12-541	4927722	
I OOMG/ML	(INJECTABLE; INJECTION)		94-91-10	98-60-40	
MEDROXYPROGESTERONE ACETATE	DEPO-PROVERA	NHOLAU	15-241	4957755	
I OOWE	(TABLET, CHEWABLE; ORAL)		14-82-90	68-81-40	
WEBENDAZOLE	NEBWOX	JANSSEN PHARMA	184-71	2657267	
IWE	(TABLET; ORAL)		02-02-82	10-05-90	
MAZ I NDOL	RONAZAM	MYETH LABS/AMHO	086-71	8712972	
SWe	(TABLET; ORAL)		08-82-80	06-20-01	
WYZ I NDOF	RONAZAM	WYETH LABS/AMHO	086-71	8712972	
SWC	(TABLET; ORAL)		ΣL-71-90	10-05-90	
WAZ I NDOL	SANOREX	SOUNAS\SMAAH9 SOUNAS	17-247	8712972	
IWG	(TABLET; ORAL)		£1-41-90	10-02-90	
MAZ I NDOL	SANOREX	SOUNAS\SMAHH SOUNAS	17-247	8712972	
STRENGTH(S)	(DOSYGE FORM; ROUTE)	t .	APPROVAL DATE	EXP. DATE	EXP. DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# YON	PATENT #	EXCLUSIVITY

TABLE IV. NDA'S APPROVED FROM I-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION



98-11-10

98-11-10

3422196

97-23-75

5L-15-LO

119-11

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
METAPROTERENOL SULFATE	ALUPENT	BOEHRINGER INGELHEIM	17-659	3422196	
5%	(SOLUTION; INHALATION)		09-18-80	01-14-86	
METAPROTERENOL SULFATE	ALUPENT	BOEHRINGER INGELHEIM	18-761	3422196	
0.6%	(SOLUTION; INHALATION)		06-30-83	01-14-86	
METHYLDOPA	METHYLDOPA	CORD LABORATORIES	18-934		
250MG	(TABLET; ORAL)		06-29-84		
METHYLDOPA	METHYLDOPA	CORD LABORATORIES	18-934		
500MG	(TABLET; ORAL)		06-29-84		
METHYLPHENIDATE HYDROCHLORIDE	RITALIN-SR	CIBA/CIBA-GEIGY	18-029		
20MG	(TABLET, CONTROLLED RELEASE; ORAL)		03-30-82		
METOCLOPRAM IDE	REGLAN	AH ROBINS	18-821		
EQ 5MG BASE/5ML	(SYRUP; ORAL)		3-25-83		
METOPROLOL TARTRATE	LOPRESSOR	GEIGY/CIBA-GEIGY	17-963	3998790	
50MG	(TABLET; ORAL)		08-07-78	12-21-93	
	Lapproces	05107/0184-05107	17.067	7000700	
METOPROLOL TARTRATE 100MG	LOPRESSOR (TABLET; ORAL)	GEIGY/CIBA-GEIGY	17-963 08-07-78	3998790 12 - 21 - 93	
METOPROLOL TARTRATE	LOPRESSOR	GEIGY/CIBA-GEIGY	18-704	3998790	
IMG/ML	(INJECTABLE; INJECTION)		03-30-84	12-21-93	





9000€	(TABLET; ORAL)		12-20-82		
METRON ID AZOLE	METRON IDAZOLE	DANBURY PHARMACAL	t9L-81		
Z≥0WG	(TABLET; ORAL)		78-71-60		
METRON ID AZOLE	METRON IDAZOLE	DANBURY PHARMACAL	\$91-81		
9000€	(TABLET; ORAL)		10-22-82		
AETRON I DAZOLE	METRON I DAZOLE	CORD LABORATORIES	047-81		
250MG	(TABLET; ORAL)		10-22-82		
AETRON I DAZOLE	METRON IDAZOLE	CORD LABORATORIES	047-81		
7M001/9M00≤	(INJECTABLE; INJECTION)		28-12-80		
METRONIDAZOLE	WETRO I.V.	AM MCGAW/AM HOSP	<i>₽</i> ∠9 - 81		
200WC	(TABLET; ORAL)		68-20-90		
METRONIDAZOLE	METRYL 500	DRUMMER/PHOEN IX	18-620		
S≥0MC	(TABLET; ORAL)		28-40-20		
METRONIDAZOLE	METRYL	DRUMMER/PHOEN I X	029-81		
9W009	(TABLET; ORAL)		02-13-84		
METRON I DAZOLE	METRON IDAZOLE	CHELSEA LABORATORIES	669-81		
S≥0MC	(TABLET; ORAL)		28-71-60		
METRON ID AZOLE	METRON I DAZOLE	CHELSEA LABORATORIES	669-81		
SOOMG	(TABLET; ORAL)		28-90-90		
METRONIDAZOLE	METRON IDAZOLE	ZENITH LABORATORIES	∠1 ⊆ -81		
JAIV\MORT.8	(INTECTABLE; INTECTION)		87-22-80	68-12-01	
METRIZAMIDE	3UQA91 MA	WINTHROP LABS/STERL	786-71	1771072	
JAIV\MOET.E	(INJECTABLE; INJECTION)		87-22-80	68-12-01	
METRIZAMIDE	AN I PAQUE	WINTHROP LABS/STERL	786-71	1771072	
STRENGTH(S)	(DOSVGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP, DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# YON	PATENT #	EXCLUSIVITY

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
METRONIDAZOLE	METRONIDAZOLE	BARR LABORATORIES	18-818		
25 QMG	(TABLET; ORAL)		02-16-83		
METRONIDAZOLE	METRONIDAZOLE	BARR LABORATORIES	18-818		
500MG	(TABLET; ORAL)		02-16-83		
METRONIDAZOLE	METRONIDAZOLE	PAR PHARMACEUTICAL	18-845		
250MG	(TABLET; ORAL)		08-18-83		
METRON ID AZOLE	PROTOSTAT	ORTHO PHARMACEUTICAL	18-871		
250MG	(TABLET; ORAL)		03-02-83		
METRONIDAZOLE	PROTOSTAT	ORTHO PHARMACEUTICAL	18-871		
500MG	(TABLET; ORAL)		03-02-83		
METRONIDAZOLE	METRON IDAZOLE	ABBOTT LABORATORIES	18-889		
500MG/100ML	(INJECTABLE; INJECTION)		11-18-83		
METRONIDAZOLE	METRONIDAZOLE IN PLASTIC	ABBOTT LABORATORIES	18-890		
500MG/100ML	CONTAINER		11-18-83		
	(INJECTABLE; INJECTION)				
METRON ID AZOLE	METRO I.V. IN PLASTIC	AM MCGAW/AM HOSP	18-900		
500MG/100ML	CONTAINER (INJECTABLE; INJECTION)		09-29-83		
			100000		
METRONIDAZOLE 500MG/100ML	METRONIDAZOLE (INJECTABLE; INJECTION)	ELKINS-SINN/AHROBINS	18-907 03-30-84		
JOSHO TOOPE	CHOLOTIDEE, MOLOTION		03 30 04		
METRONIDAZOLE	METRONIDAZOLE	PAR PHARMACEUTICAL	18-930		
500MG	(TABLET; ORAL)		08-18-83		
METRONIDAZOLE	METRONIDAZOLE	LNK INTERNATIONAL	19-029		
25 OMG	(TABLET; ORAL)		04-10-84		







EXCLUSIVITY

EXP. DATE

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98-11-80	6 7-81- 01		(TABLET; ORAL)	S° ≥WG
1941945	18-154	NHOLAU	CONITEN	MINOXIDIF
16-10-01				
4 736282				
05-50-60	78-51-80		(SUPPOSITORY; VAGINAL)	SOOMG
GG9L 1 L C	888-81	ORTHO PHARMACEUTICAL	E TATELNOM	MICONAZOLE NITRATE
16-10-01				
₽ ₹26282				
05-20-60	28-51-50		(SUPPOSITORY; VAGINAL)	LOOMG
33117E	18-520	ORTHO PHARMACEUTICAL	T TATSINOM	MICONAZOLE NITRATE
16-10-01				
4726282				
05-50-60	ST-81-21		(LOTION; TOPICAL)	\$7
5 5 97 1 <i>1</i> 5	65T-T1	ORTHO PHARMACEUTICAL	MON ISTAT-DERM	MICOUAZOLE NITRATE
16-10-01				
47 26282				
05-50-60	10-30-14		(CREAM; TOPICAL)	\$ Z
32175	\$6\$-LI	ORTHO PHARMACEUTICAL	MON I STAT-DERM	MICONAZOLE NITRATE
16-10 - 01				
₽ ₹26282				
05-50-60	₽ ∠-0€-10		(CREAM; VAGINAL)	\$2
6697 178	054-71	ORTHO PHARMACEUTICAL	T TATZI NOM	MICONAZOLE NITRATE
16-10-01				
\$ 726282				
05-50-60	87-40-01	·	(INJECTABLE; INJECTION)	I OME/WI
3597178	040-81	JANSSEN PHARMA	TATZINOM	MICONVSOLE
98-60-10	6L-E0-01		(CAPSULE; ORAL)	∑20Me
678S9SE	178-71	MS&D/MERCK	DEWZEK	METYROS I NE
EXP. DATE	APPROVAL DATE		(DOSVGE FORM; ROUTE)	21КЕИСТН(S)
* TN3TA9	∦ AŒN	APPLICANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
MINOXIDIL	LONITEN	UP JOHN	18-154	3461461	
I OMG	(TABLET; ORAL)		10-18-79	08-12-86	
MOLINDONE HYDROCHLORIDE	MOBAN	DUPONT PHARMS/DUPONT	17-111	3491093	
5MG	(TABLET; ORAL)		07-03-74	01-20-87	
MOLINDONE HYDROCHLORIDE	MOBAN	DUPONT PHARMS/DUPONT	17-111	3491093	
IOMG	(TABLET; ORAL)		07-03-74	01-20-87	
MOLINDONE HYDROCHLORIDE	MOBAN	DUPONT PHARMS/DUPONT	17-111	3491093	
25MG	(TABLET; ORAL)		07-03-74	01-20-87	
MOLINDONE HYDROCHLORIDE	MOBAN	DUPONT PHARMS/DUPONT	17-111	3491093	
50MG	(TABLET; ORAL)		01-05-81	01-20-87	
MOLINDONE HYDROCHLORIDE	MOBAN	DUPONT PHARMS/DUPONT	17-111	3491093	
I OOMG	(TABLET; ORAL)		01-05-81	01-20-87	
MOLINDONE HYDROCHLORIDE	MOBAN	DUPONT PHARMS/DUPONT	17-938	3491093	
20MG/ML	(CONCENTRATE; ORAL)		12-28-79	01-20-87	
MORPHINE SULFATE	DURAMORPH PF	ELKINS-SINN/AHROBINS	18-565		
0.5MG/ML	(INJECTABLE; INJECTION)		09-18-84		
MORPHINE SULFATE	DURAMORPH PF	ELKINS-SINN/AHROBINS	18-565		
IMG/ML	(INJECTABLE; INJECTION)		09-18-84		
NADOLOL	CORGARD	ER SQUIBB AND SONS	18-063	3982021	
40MG	(TABLET; ORAL)		12-10-79	09-21-93 3935267	
				01-27-93	
NADOLOL	₩	ER SQUIBB AND SONS	18-063	3982021	
80MG	(TABLET; ORAL)	EN OQUIES AND SONS	12-10-79	09-21-93	
				3935267	
				01-27-93	



(TABLET; ORAL)

SZOWG

88-62-90

12-27-67

9200692 14-214 WINTHROP LABS/STERL NEGGRAM NALIDIXIC ACID 98-91-40 64-91-90 (INJECTABLE; INJECTION) I OMG/ML 18-024 7615625 **DUPONT PHARMS/DUPONT** NIABUN NALBUPHINE HYDROCHLORIDE 26-72-10 2935267 26-12-60 17-10-79 (TABLET; ORAL) 160MG 3982021 18-064 ER SQUIBB AND SONS CORGARD NADOLOL 26-72-10 1925265 (TABLET; ORAL) 26-17-60 15-10-79 1 2 OMG EK SÓNIBB VND SONS 1202862 18-064 NADOLOL CORGARD 26-12-10 1925265 26-17-60 (TABLET; ORAL) 12-10-79 **80MG** 3982021 18-064 ER SOUIBB AND SONS CORGARD NADOLOL 01-27-93 3935267 12-10-13 (TABLET; ORAL) 26-17-60 40MG 1202865 18-064 ER SQUIBB AND SONS CORGARD NADOLOL 26-12-10 1925265 09-21-93 15-10-13 (TABLET; ORAL) 160MG 1202865 290-81 EK SÓNIBB VND SONS **CORGARD** NADOLOL 01-57-93 2932562 26-17-60 17-10-79 (TABLET; ORAL) I SOMG 3982021 £90-81 EK SÓNIBB VND SONS CORGARD NADOLOL APPROVAL DATE EXP. DATE EXP. DATE (DOSAGE FORM; ROUTE) STRENGTH(S) # TN3TA9 **EXCLUSIVITY** # YON APPLICANT NAME TRADE NAME ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
NALIDIXIC ACID 500MG	NEGGRAM (TABLET; ORAL)	W.INTHROP LABS/STERL	14-214 03-06-64	3590036 06-29-88	
NALIDIXIC ACID	NEGGRAM (TABLET; ORAL)	WINTHROP LABS/STERL	14-214 03-06-64	3590036 06-29-88	
NALIDIXIC ACID 250MG/5ML	NEGGRAM (SUSPENSION; ORAL)	WINTHROP LABS/STERL	17-430 04-17-73	3590036 06-29-88	
NALOXONE HYDROCHLORIDE; PENTAZOCINE HYDROCHLORIDE 0.5MG; EQ 50MG BASE	TALWIN NX (TABLET; ORAL)	WINTHROP LABS/STERL	18-733 12-16-82	4105659 08-08-95	
NALTREXONE HYDROCHLORIDE 50MG	TREXAN (TABLET; ORAL)	DUPONT PHARMS/DUPONT	18-932 11-20-84		NCE 11-20-89
NAPROXEN I 25MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17 - 581 03 - 11 <i>-</i> 76	3998966 12-21-93 4009197 09-09-92 4001301 09-09-92 3904682 09-09-92	
NAPROXEN 250MG	NAPROSYN (TABLET; ORAL)	SYNTEX PR	17-581 03-11-76	3998966 12-21-93 4009197 09-09-92 4001301 09-09-92 3904682 09-09-92	







Original from UNIVERSITY OF MICHIGAN

	2644627 3644627	18-11-31 18-485	PFIZER LABS/PFIZER	PROCARDIA (CAPSULE; ORAL)	10WG
⊅6-Σ1-1 0		78-∑1-10		(GNW CHEMING! OBYT)	EÓ SWG BYZE
NCE		219-81	WEBBETT DOM/DOM CHEW	ATT3800 IN	NICOTINE RESIN COMPLEX
76-14-60		78- 11 -90		(TABLET, CHEWABLE; ORAL)	SOOMG
NCE		699-81	MILES PHARMS/MILES	NICTOCIDE	NICFOSTMIDE
	76-60-60				
	∠61600 ₽				
	76-60-60				
	1001201				
	12-21-62	08-40-60		(TABLET; ORAL)	SJ2WG
	996866£	191-81	SYNTEX PR	XOFFANA	NAPROXEN SODIUM
	Z6 - 60-60				
	289≯06⊊				
	Z6-60-60				
	1021001				
	Z6-60-60				
	£61600 ≯				
	12-21-93	04-12-85		(TABLET; ORAL)	≥00MG
	996866€	185-71	SYNTEX PR	NYSOSTI	NAPROXEN
	Z6-60-60				
	2891065				
	76-60-60				
	10€ 100₽				
	76-60-60				
	£6 1600₽				
	15-51-62	08-81-70		(TABLET; ORAL)	SYSME
	996866€	185-71	SYNTEX PR	NY 205FIAN	ИАРВОХЕИ
EXP. DATE	EXP. DATE	VPPROVAL DATE		(DOSVGE FORM; ROUTE)	STRENGTH(S)
EXCENSIVITY	PATENT #	# VON	APPLICANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
NITROGLYCERIN	TRIDIL	AM CRITICAL CARE/AHS	18-537		
O.5MG/ML	(INJECTABLE; INJECTION)		06-16-83		
NITROGLYCERIN	NITROSTAT	PARKE-DAVIS/W-L	18-588		
5MG/ML	(INJECTABLE; INJECTION)		12-23-83		
NITROGLYCERIN	NITRO-BID	MARION LABORATORIES	18-621		
5MG/ML	(INJECTABLE; INJECTION)		01-05-82		
NITROGLYCERIN	NITRONAL	G POHL-BOSKAMP	18-672		
IMG/ML	(INJECTABLE; INJECTION)		08-30-83		
NITROGLYCERIN	NITRONAL	G POHL-BOSKAMP	18-672		
5MG/ML	(INJECTABLE; INJECTION)		08-30-83		
NITROGLYCERIN	NITROL	KREMERS-URBAN	18-774		
O.8MG/ML	(INJECTABLE; INJECTION)		01-19-83		
NOMIFENSINE MALEATE	MERITAL	HOECHST-ROUSSEL	18-224		NCE
25MG	(CAPSULE; ORAL)		12-31-84		12-31-89
NOMIFENSINE MALEATE	MERITAL	HOECHST-ROUSSEL	18-224		NCE
50MG	(CAPSULE; ORAL)		12-31-84		12-31-89
NORETHINDRONE ACETATE	AYGESTIN	AYERST LABS/AMHO	18-405		
5MG	(TABLET; ORAL)		04-21-82		
NORGESTREL	OVRETTE	WYETH LABS/AMHO	17-031	3666858	
0.075MG	(TABLET; ORAL)		10-23-73	05-30-89 3850911	
				11-26-91	
				3959322	
				11-26-91	
NORTRIPTYLINE HYDROCHLORIDE	AVENTYL HCL	ELI LILLY	14-684	3922305	
EQ IOMG BASE	(CAPSULE; ORAL)		11-06-64	11-25-92	
				•	

I V-87



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80WC OXSEROTOR HADBOCHROBIDE	TRASICOR (CAPSULE; ORAL	יר)	CIBA/CIBA-GEIGY	15-58-83 18-199	12 - 09-86	15-58-93 NCE
9MOt	(CAPSULE; ORAL	()		12-28-83	12-09-86	12-28-93
OXPRENOLOL HYDROCHLORIDE	RAS I COR		CIBA/CIBA-GEIGY	991-81	3483221	NOE
SOMG	(CAPSULE; ORAL	(ד)		12-28-83	15-09-86	26-82-21
OXPRENOLOL HYDROCHLORIDE	ACO I ZAAT		CIBA/CIBA-GEIGY	991-81	3483221	NCE
					75-60-21	
					1625262	
			•		16-87-90	
					3821228	
S2OWC	(CAPSULE; ORAL	ר)		08-22-70	26-20-60	
OXAMNIQUINE	NANSIL		PFIZER LABS/PFIZER	690-81	2903283	
EÓ 20MC BYZE	(CAPSULE; ORAL	יר)		61-41-90	76-57-11	
NORTRIPTYLINE HYDROCHLORIDE	PAMELOR		SOUNAS\SMAHY SOUNAS	210-81	3922305	
EÓ 12WG BYZE	(CAPSULE; ORAL	(ד)		64-71-90	76-52-11	
NORTRIPTYLINE HYDROCHLORIDE	PAMELOR		SANDOZ PHARMS/SANDOZ	510-81	3922305	
EÓ SZWG BYZE	(CAPSULE; ORAL	(٦)		LL-10-80	11-52-65	
NORTRIPTYLINE HYDROCHLORIDE	PAMELOR		SOUNAS\SMAHY SOUNAS	210-81	3922305	
EÓ I OWE BYZE	(CAPSULE; ORAL	٦)		LL-10-80	76-52-11	
NORTR I PTYL INE HYDROCHLORIDE	PAMELOR		SOUNAS\SMAAH9 SOUNAS	∑10-81	3922305	
EÓ I OME BYZE/2ML	(SOLUTION; ORA	(JV		LL-10-80	76-52-11	
NORTRIPTYLINE HYDROCHLORIDE	PAMELOR		SOUNAS\SMAHH SOUNAS	210-81	3922305	
E6 IOWE BYSE\2WL	(SOLUTION; ORA	(JA		7 9-90-11	76-57-11	
NORTRIPTYLINE HYDROCHLORIDE	AVENTYL HCL		ברו ר וררג	989-41	3922305	
EÓ SZWE BYZE	(CAPSULE; ORAL	ר)		1 9-90-11	11-52-65	
NORTRIPTYLINE HYDROCHLORIDE	AVENTYL HCL		פרו רוררג	t89-t1	3922305	
STRENGTH(S)	(DOSYCE LOKW!	ROUTE		APPROVAL DATE	EXP. DATE	EXP. DATE
ACTIVE INGREDIENT(S)	TRADE NAME		APPLICANT NAME	# YON	PATENT #	EXCLUSIVITY

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
OXPRENOLOL HYDROCHLORIDE	TRAS I COR	CIBA/CIBA-GEIGY	18-166	3483221	NCE
160MG	(CAPSULE; ORAL)		12-28-83	12-09-86	12-28-93
PANCURON I UM BROM I DE	PAVULON	ORGANON/AKZONA	17-015	3553212	
2MG/ML	(INJECTABLE; INJECTION)		10-24-72	01-05-88	
PANCURONIUM BROMIDE	PAVULON	ORGANON/AKZONA	17-015	3553212	
IMG/ML	(INJECTABLE; INJECTION)		09-14-73	01-05-88	
PARAMETHASONE ACETATE	HALDRONE	ELI LILLY	12-772	3499016	
IMG	(TABLET; ORAL)		04-17-61	03-03-87	
PARAMETHASONE ACETATE	HALDRONE	ELI LILLY	12-772	3499016	
2MG	(TABLET; ORAL)		04-17-61	03-03-87	
PENTAGASTRIN	PEPTAVLON	AYERST LABS/AMHO	17-048	3896103	
0.25MG/ML	(INJECTABLE; INJECTION)		07-26-74	07-22-92	
ENTAMIDINE ISETHIONATE	PENTAM 300	LYPHOMED	19-129		
300MG/VIAL	(INJECTABLE; INJECTION)		10-16-84		
PENTAZOCINE LACTATE	TALWIN	WINTHROP LABS/STERL	16-194	4105659	
EQ 30MG BASE/ML	(INJECTABLE; INJECTION)		07-24-67	08-08-95	
PENTETATE INDIUM DISODIUM, IN-III	MPI INDIUM DTPA IN III	MEDI-PHYSICS	17-707		NCE
IMC1/ML	(INJECTABLE; INJECTION)		02-18-82		02-18-92
PENTOXIFYLLINE	TRENTAL	HOECHST-ROUSSEL	18-631	3737433	NCE
400MG	(TABLET, CONTROLLED RELEASE; ORAL)		08-30-84	06-05-90	08-30-94
	RELEASE; URAL)				



26-20-60

98-10-01

28-20-60

TABLE IV. NDA'S APPROVED FROM I-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION TRADE NAME APPLICANT NAME NDA # 15-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

ONST	100 1011		00 -00		
PINDOLOL	AISKEN	AS\SMAAH9 SOUDAS	18-285	3471515	NCE
1 OWO	(TABLET; ORA		28-20-60	98-40-01	26-20-60
PINDOLOL	A I SKEN	AS\SMAAH9 SOUDAS	18-285	3151745	NCE
≥MG	(TABLET; ORA		28-20-60	98-40-01	76-€0-60
PINDOLOL	AIRKEN	AS\SMAHA SOUDAS	18-285	3471515	NCE
SWE	(TABLET; ORA		48-12-70		76-12-40
PIMOZIDE	4A90	WCNEIL PHARM	274-71		NCE
\$ t	(GEL; OPHTHA	(78-10-01		
PILOCARPINE HYDROCHLORIDE	PILOPINE HS	ALCON LABORATOR IE	967-81		
	RELEASE; OP	гиіс)			
IIWG	(INSERT, CON	ΓED	27-92-72	26-80-90	
PILOCARPINE	OCUSERT PILO	VZ7V	846-71	39162	
	RELEASE; OP	TMIC)			
≥WC	(INSERT, CON	TED	74-67-10	26-80-90	
PILOCARPINE	OCUSERT PILO	∀Z⊤V	154-71	829162	
ZWG/SWF: 6.25WG/5ML					
HYDROCHLOR IDE	(SYRUP; ORAL		04-02-84		
PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE	PHENERGAN VC	MAETH LABS/AMHO	≯ 09 − 80		
STRENGTH(S)	(DOSAGE FORM	()	APPROVAL DATE	EXP. DATE	EXP. DATE
ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# VON	PATENT #	EXCLUSIVITY

(TABLET; ORAL)

I 2WC

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
			1211101112		
PIROXICAM	FELDENE	PFIZER LABS/PFIZER	18-147	3591584	NCE
I OMG	(CAPSULE; ORAL)		04-06-82	07-06-88	04-06-92
				3674876	
				07-04-89	
				3862319	
				01-21-92	
				4100347	
				07-11-95	
				3927002	
				12-16-92	
				RE29668	
				12-10-91	
PIROXICAM	FELDENE	PFIZER LABS/PFIZER	18-147	3591584	NCE
20MG	(CAPSULE; ORAL)		04-06-82	07-06-88	04-06-92
				3674876	
				07-04-89	
				3862319	
				01-21-92	
				4100347	
				07-11-95	
				3927002	
				12-16-92	
				RE29668	
				12-10-91	
DOLVETUN ENE OLVON 7750	OOL WITH W				
POLYETHYLENE GLYCOL 3350;	GOLYTELY	BRAINTREE LABS	19-011		
POTASSIUM CHLORIDE;	(POWDER FOR		07-13-84		
SODIUM BICARBONATE;	RECONSTITUTION; ORAL)				
SODIUM CHLORIDE;					
SODIUM SULFATE					
236GM/BOT;					

14-91



2.97GM/BOT; 6.74GM/BOT; 5.86GM/BOT; 22.74GM/BOT

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TABLE IV. NDA'S APPROVED FROM 1-1-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

10-56-84 (POWDER FOR POLYETHYLENE GLYCOL 3350; 286-81 COLYTE EDLAW PREPARATIONS EXP. DATE EXP. DATE APPROVAL DATE (DOSAGE FORM; ROUTE) STRENGTH(S) EXCLUSIVITY PATENT # TRADE NAME ACTIVE INGREDIENT(S) # YON APPLICANT NAME

RECONSTITUTION; ORAL)

RECONSTITUTION; ORAL)

(POWDER FOR

COLYTE

2.92GM/PACKET; 1.49GM/PACKET;

POTASSIUM CHLORIDE; (POWDER FOR POLYETHYLENE GLYCOL 3350;

RECONSTITUTION; ORAL) SODIUM BICARBONATE;

SODIUM SULFATE SODIUM CHLORIDE;

2.82GM/PACKET; 227.1GM/PACKET;

SODIUM BICARBONATE;

POTASSIUM CHLORIDE;

POLYETHYLENE GLYCOL 3350;

6.36GM/PACKET;

21.5GM/PACKET

34.08GM/PACKET 8.76GM/PACKET; 10.08GM/PACKET; 4.47GM/PACKET; 360GM/PACKET; SODIUM SULFATE SODIUM CHLORIDE;

5.53GM/PACKET;

COLYTE

11.36GM/PACKET

3.36GM/PACKET;

I 20GM/PACKET;

SODIUM SULFATE

SODIUM CHLORIDE;

SODIUM BICARBONATE;

POTASSIUM CHLORIDE;

UNIVERSITY OF MICHIGAN

10-26-84

10-26-84

286-81

£86-81

EDLAW PREPARATIONS

EDLAW PREPARATIONS

STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXP. DATE
POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE 0.5MG; IMG	MINIZIDE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-986 06-13-80	3511836 05-12-87 3663706 05-16-89 4130647 12-19-95	
POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE 0.5MG; 2MG	MINIZIDE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-986 06-13-80	3511836 05-12-87 3663706 05-16-89 4130647 12-19-95	
POLYTHIAZIDE; PRAZOSIN HYDROCHLORIDE 0.5MG; 5MG	MINIZIDE (CAPSULE; ORAL)	PFIZER LABS/PFIZER	17-986 06-13-80	3511836 05-12-87 3663706 05-16-89 4130647 12-19-95	
POTASSIUM ACETATE 2MEQ/ML	POTASSIUM ACETATE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-896 07-20-84		
POTASSIUM CHLORIDE IOMEQ	KLOTRIX (TABLET, CONTROLLED RELEASE; ORAL)	MEAD JOHNSON/B-M	17-850 05-22-80	4140756 02-20-96	
POTASSIUM CHLORIDE; SODIUM CHLORIDE 150MG/100ML; 900MG/100ML	SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE IOMEQ IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	18-630 02-17-83		





AM MCGAW/AM HOSP

11-09-82

18-722

IN PLASTIC CONTAINER (INJECTION)

POTASSIUM CHLORIDE 0.3%

SODIUM CHLORIDE 0.9% AND

200WG/100WL; 900MG/100ML

POTASSIUM CHLORIDE; SODIUM CHLORIDE

(INJECTABLE; INJECTION) IN PLASTIC CONTAINER 78-60-11 POTASSIUM CHLORIDE 0.22\$ 220MG/100ML; 900MG/100ML 18-722 AM MCGAW/AM HOSP SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE; SODIUM CHLORIDE (INJECTABLE; INJECTION) IN PLASTIC CONTAINER 11-09-82 POTASSIUM CHLORIDE 0,15% 150MG/100ML; 900MG/100ML 18-722 AM MCGAW/AM HOSP SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE; SODIUM CHLORIDE (INJECTABLE; INJECTION) IN PLASTIC CONTAINER POTASSIUM CHLORIDE 0.075% JSMG/100ML; 900MG/100ML 78-60-11 SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE; SODIUM CHLORIDE 18-722 AM MCGAW/AM HOSP (INTECTABLE; INTECTION) IN PLASTIC CONTAINER 05-17-83 POTASSIUM CHLORIDE 40MEQ 200MG/100ML; 900MG/100ML POTASSIUM CHLORIDE; SODIUM CHLORIDE 059-81 TRAVENOL LABS SODIUM CHLORIDE 0.9% AND (INJECTABLE; INJECTION) IN PLASTIC CONTAINER 28-11-20 POTASSIUM CHLORIDE 20MEQ 150MG/100ML; 900MG/100ML POTASSIUM CHLORIDE; SODIUM CHLORIDE 059-81 TRAVENOL LABS SODIUM CHLORIDE 0.9% AND (INJECTABLE; INJECTION) IN PLASTIC CONTAINER 02-17-83 POTASSIUM CHLORIDE 20MEQ 200MG/100ML; 900MG/100ML SODIUM CHLORIDE 0.9% AND POTASSIUM CHLORIDE; SODIUM CHLORIDE 059-81 TRAVENOL LABS EXP. DATE EXP. DATE APPROVAL DATE (DOSAGE FORM; ROUTE) STRENGTH(S) EXCLUSIVITY PATENT # ACTIVE INGREDIENT(S) # YON TRADE NAME APPLICANT NAME

(DOSAGE FORM; ROUTE)				
		APPROVAL DATE	EXP. DATE	EXP. DATE
PRALIDOXIME CHLORIDE	AYERST LABS/AMHO	18-799		
(INJECTABLE; INJECTION)		12-13-82		
PROTOPAM	SURVIVAL TECHNOLOGY	18-986		
(INJECTABLE; INJECTION)		04-26-83		
CENTRAX	PARKE-DAVIS/W-L	18-144		
(CAPSULE; ORAL)		05-10-82		
BILTRICIDE	MILES PHARMS/MILES	18-714	4001411	NCE
(TABLET; ORAL)		12-29-82	01-04-94	12-29-92
MINIPRESS	PFIZER LABS/PFIZER	17-442	3511836	
(CAPSULE; ORAL)		06-23-76	05-12-87	
			3663706 05-16-89	
			4092315	
		4130647	05-30-95	
		4130047	12-19-95	
MINIPRESS	PFIZER LABS/PFIZER	17-442	3511836	
(CAPSULE; ORAL)		06-23-76	05-12-87	
			3663706	
			12-19-95	
	(INJECTABLE; INJECTION) PROTOPAM (INJECTABLE; INJECTION) CENTRAX (CAPSULE; ORAL) BILTRICIDE (TABLET; ORAL) MINIPRESS (CAPSULE; ORAL)	(INJECTABLE; INJECTION) PROTOPAM (INJECTABLE; INJECTION) CENTRAX (CAPSULE; ORAL) BILTRICIDE (TABLET; ORAL) MINIPRESS (CAPSULE; ORAL) MINIPRESS (CAPSULE; ORAL) MINIPRESS PFIZER LABS/PFIZER	12-13-82 PROTOPAM SURVIVAL TECHNOLOGY 18-986 (1NJECTABLE; INJECTION) 04-26-83 O4-26-83 O4-26-83 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-10-82 O5-	PROTOPAM



AYERST LABS/AMHO

AYERST LABS/AMHO

AYERST LABS/AMHO

AYERST LABS/AMHO

HOFFMANN-LA ROCHE

EXP. DATE

EXCLUSIVITY

78-12-70

2250526

76-17-10 3862332 88-72-40

288372**2**

15-16-62 T490514 96-02-90 4092315 68-91-90 907**2**332

78-21-60

3511836

EXP. DATE

£8-61-10

£8-61-10

28-81-10

28-81-10

69-22-40

LL-10-Z0

97-22-90

APPROVAL DATE

17-442

525-71

987-91

256-81

817-91

817-91

252-81

* TN3TA9 # YON APPLICANT NAME TABLE IV. NDA'S APPROVED FROM I-I-82 TO 12-31-84 AND NDA'S WITH APPROPRIATE PATENT INFORMATION

Original from UNIVERSITY OF MICHIGAN **80MG**

160MG

9W06

9W09

EÓ 20WG BYZE

PROPRANOLOL HYDROCHLORIDE

PROPRAIOLOL HYDROCHLORIDE

PROPRANOLOL HYDROCHLORIDE

PROPRANOLOL HYDROCHLORIDE

PROCARBAZINE HYDROCHLORIDE

RELEASE; ORAL)

KELEASE; ORAL)

INDERAL LA

INDERAL LA

INDERAL

INDERAL

BNAJUTAM

(TABLET; ORAL)

(TABLET; ORAL)

(CAPSULE; ORAL)

(CAPSULE, CONTROLLED

(CAPSULE, CONTROLLED

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
PROPRANOLOL HYDROCHLORIDE	INDERAL LA	AYERST LABS/AMHO	18-553		
1 20MG	(CAPSULE, CONTROLLED		04-19-83		
	RELEASE; ORAL)				
PROTAMINE SULFATE	PROTAMINE SULFATE	UP JOHN	07-413		
250MG/VIAL	(INJECTABLE; INJECTION)	OI JOHN	08-02-84		
			00 01 01		
PROTIRELIN	THYPINONE	ABBOTT LABORATORIES	17-638	3746697	
O.5MG/ML	(INJECTABLE; INJECTION)		11-05-76	07-17-90	
PROTIRELIN	RELEFACT TRH	HOECHST-ROUSSEL	18-087	3746697	
0.5MG/ML	(INJECTABLE; INJECTION)	HOLOHSI KOOSSEE	07-18-78	07-17-90	
PROTRIPTYLINE HYDROCHLORIDE	VIVACTIL	MS&D/MERCK	16-012	3372196	
5MG	(TABLET; ORAL)		09-27-67	03-05-85	
PROTRIPTYLINE HYDROCHLORIDE	VIVACTIL	MS&D/MERCK	16-012	3372196	
IOMG	(TABLET; ORAL)		09-27-67	03-05-85	
DVDANTSI DAMOATE	ANTIMINITI	DOED 10 /DE 17ED	16.007	7644604	
PYRANTEL PAMOATE EQ 250MG BASE/5ML	ANTIMINTH (SUSPENSION; ORAL)	ROER IG/PF I ZER	16-883 12-30-71	3644624 02-22-89	
EQ 250110 Brock Still	toos Enoron, older		12 30 71	3549624	
				12-22-87	
DANIET IN INF. HYPROCH, OR INF.	ZANTAO	OLA VO	10 707	4100650	NOT
RANITIDINE HYDROCHLORIDE EQ 150MG BASE	ZANTAC (TABLET; ORAL)	GLAXO	18-703 06-09-83	4128658 12-05-95	NCE 06-09-93
EQ TOUNG BASE	(TABLET; ORAL)		00-09-03	12-05-95	06-09-93
RANITIDINE HYDROCHLORIDE	ZANTAC	GLAXO	19-090	4128658	NCE
EQ 25MG BASE/ML	(INJECTABLE; INJECTION)		10-19-84	12-05-95	06-09-93
RITODRINE HYDROCHLORIDE	YUTOPAR	ASTRA PHARM PRODS	18-555	3410944	
IOMG	(TABLET; ORAL)	No non marin mose	12-12-80	11-12-85	
RITODRINE HYDROCHLORIDE	YUTOPAR	ASTRA PHARM PRODS	18-580	3410944	
I OMG/ML	(INJECTABLE; INJECTION)		12-12-80	11-12-85	





(SOLUTION; IRRIGATION)

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	(MOLTANIANI - MOLTH 102)				
\$20WC/100WF	IN PLASTIC CONTAINER		05-19-85		
ODINW CHLORIDE	SODINM CHLORIDE 0.45%	TRAVENOL LABS	764-81		
	(INJECTABLE; INJECTION)				
SMEQ/ML	PLASTIC CONTAINER		28-40-30		
SUDDIUM ACETATE, ANHYDROUS	SODIUM ACETATE IN	ABBOTT LABORATORIES	€68-81		
O.OO5MG/VIAL	(INJECTABLE; INJECTION)		94-12-40	16-10-01	
INCALIDE	KINEAVC	EK SÓNIBB AND SONS	L69-L1	3839315	
81	(CREAM; TOPICAL)		78-52-20		
ILVER SULFADIAZINE	dss	TRAVENOL LABS	872-81		
\$1	(CREAM; TOPICAL)		21-92-11	06-77-60	
ILVER SULFADIAZINE	SILVADENE	. MARION LABORATORIES	185-71	0691945	
				86-11-10	
	RELEASE; PERCUTANEOUS)			4262003	
I * 2WC	(FILM, CONTROLLED		12-31-79	76-87-90	
COPOLAMINE	TRANSDERM-SCOP	CIBA/CIBA-GE16Y	≯ 78−71	4681204	
				26-12-90	
				1219885	
EQ 0.6MG BASE/ML	(INJECTABLE; INJECTION)		18-62-90	26-21-10	
TATADA NI SALASA	SARENIN	NORWICH EATON/P&G	600-81	2922624	
%S : %S	(INJECTABLE; INJECTION)		48-72-80		
AFFLOWER CIL; SOYBEAN OIL	LIPOSYN II 10%	ABBOTT LABORATORIES	<i>L</i> 66-81		
\$01 : \$01	(INJECTABLE; INJECTION)		48-72-80		
AFFLOWER OIL; SOYBEAN OIL	LIPOSYN II 20%	ABBOTT LABORATORIES	166-81		
I SMG/ML	(INJECTABLE; INJECTION)		48-72-60	11-12-85	
I TODRINE HYDROCHLORIDE	AAGOTUY	SOORY MAAHY ARTZA	18-580	4460145	
TRENGTH(S)	(DOSYGE FORM; ROUTE)	/	APPROVAL DATE	EXP. DATE	EXP. DATE
CLINE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	# AUN	PATENT #	EXCLUSIVITY

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXP. DATE
SODIUM CHLORIDE 9MG/ML	BACTERIOSTATIC SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER	ABBOTT LABORATORIES	18-800 10-29-82		
5th ed. Suppl. 6	(INJECTABLE; INJECTION)				
ALORIDE	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-803 10-29-82		
SODIUM CHLORIDE 2.5MEQ/ML	SODIUM CHLORIDE IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	18-897 07-20-84		
SODIUM CHLORIDE 3GM/100ML	SODIUM CHLORIDE 3% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-022 11-01-83		
SODIUM CHLORIDE 5GM/100ML	SODIUM CHLORIDE 5% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	TRAVENOL LABS	19-022 11-01-83		
SODIUM CHLORIDE 9MG/ML	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-217 07-13-84		
SODIUM CHLORIDE 9MG/ML	SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	ABBOTT LABORATORIES	19-218 07-13-84		
SODIUM IODIDE, I-123	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PHARM	18–671 05–27–82		
SODIUM IODIDE, 1-123 200 UCI	SODIUM IODIDE I 123 (CAPSULE; ORAL)	BENEDICT NUCLR PHARM	18-671 05-27-82		





EXP. DATE

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NDA #	APPLICANT NAME	TRADE NAME (DOSAGE FORM; ROUTE)	ACTIVE INGREDIENT(S) STRENGTH(S)
179-81	BENEDICT NUCLR PHARM	SODINW IODIDE I 152	20DI NW 10DI DE' 1-132
28-72-80		(CAPSULE; ORAL)	400 nc1
746-81	ABBOTT LABORATORIES	SODIUM LACTATE IN	SODIUM LACTATE
₽8− ⊆0 − 60		PLASTIC CONTAINER	SMEQ/ML
		(INJECTABLE; INJECTION)	
18-581	ETKIN2-2 INN/VHBOBIN2	SODIUM NITROPRUSSIDE	SODIUM NITROPRUSSIDE
Z8-8Z-70		(INTECTABLE; INTECTION)	741 ∀ 10
268-81	ABBOTT LABORATORIES	SODIUM PHOSPHATES	SODIUM PHOSPHATE, DIBASIC; SODIUM
£8-01-£0		IN PLASTIC CONTAINER (INJECTABLE; INJECTION)	PHOSPHATE, MONOBASIC
•			
92 <i>L-L</i> j	SERONO LABS	ASELLACRIN 2	NIGORTAMOS
£8-12-40		(INJECTABLE; INJECTION)	Z IU/VIAL
212-81	TRAVENOL LABS	SORBITOL 3% IN PLASTIC	SORBITOL
Z8-LZ - G0		CONTAINER (SOLUTION; IRRIGATION)	7M00 I / M9⊊
	`		
29.96.30	ALPHA THERAPEUTIC	SOVACAL 10\$	SOABEVN OIL
£8 - 67-90		(INJECTABLE; INJECTION)	±01
099-81	TRAYENOL LABS	TRAVAMULSION 10\$	SOYBEAN OIL
78-97-20		(INJECTABLE; INJECTION)	\$ 01
857-81	TRAVENOL LABS	TRAVAMULSION 20\$	SOMBEAN OIL
05-12-83		(INJECTABLE; INJECTION)	\$ 07
987-81	ALPHA THERAPEUTIC	SOYACAL 20%	SOYBEAN OIL
£8-6Z-90		(INTECTABLE; INTECTION)	\$ 0Z
696-81	ABBOTT LABORATORIES	LIPOSYN III 10%	SOVBEAN OIL
78-77-60		(INTECTABLE; INTECTION)	% 01

ACTIVE INGREDIENT(S)	TRADE NAME	APPLICANT NAME	NDA #	PATENT #	EXCLUSIVITY
STRENGTH(S)	(DOSAGE FORM; ROUTE)		APPROVAL DATE	EXP. DATE	EXP. DATE
SOYBEAN OIL	LIPOSYN III 20%	ABBOTT LABORATORIES	18-970		
20%	(INJECTABLE; INJECTION)		09-25-84		
STANOZOLOL	WINSTROL	WINTHROP LABS/STERL	12-885	3704295	
2MG	(TABLET; ORAL)		11-30-61	11-28-89	
STREPTOZOCIN	ZANOSAR	UP JOHN	17-961		NCE
IGM/VIAL	(INJECTABLE; INJECTION)		05-07-82		05-07-92
SUCRALFATE	CARAFATE	MARION LABORATORIES	18-333	3432489	
IGM	(TABLET; ORAL)		10-30-81	03-11-86	
SUFENTANIL CITRATE	SUFENTA	JANSSEN PHARMA	19-050	3998834	NCE
EQ 0.05MG BASE/ML	(INJECTABLE; INJECTION)		05-04-84	12-21-93	05-04-94
SULFAMETHOXAZOLE; TRIMETHOPRIM	BACTRIM	HOFFMANN-LA ROCHE	17-377	RE28636	
400MG; 80MG	(TABLET; ORAL)		07-30-73	06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM	BACTRIM DS	HOFFMANN-LA ROCHE	17-377	RE28636	
800MG; 160MG	(TABLET; ORAL)		03-01-78	06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM	BACTRIM	HOFFMANN-LA ROCHE	17-560	RE28636	
200MG/5ML; 40MG/5ML	(SUSPENSION; ORAL)		04-16-75	06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM	BACTRIM PEDIATRIC	HOFFMANN-LA ROCHE	17-560	RE28636	
200MG/5ML; 40MG/5ML	(SUSPENSION; ORAL)		12-10-79	06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM	BACTRIM	HOFFMANN-LA ROCHE	18-374	3551564	
80MG/ML; I6MG/ML	(INJECTABLE; INJECTION)		06-23-81	12-29-87 RE28636	
				06-02-87	
SULFAMETHOXAZOLE; TRIMETHOPRIM	SULFAMETHOXAZOLE AND	DRUMMER/PHOEN I X	18-598		
400MG; 80MG	TRIMETHORRIM		05-19-82		
	(TABLET; ORAL)				





PATENT # EXP. DATE

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		OK√L)	
28-90-40		(TABLET, ENTERIC COATED;	200WC
Σ Τ0 - Γ0	PHARMAC1A/PHARMAC1A	AZULF IDINE	SULFASALAZINE
		(TABLET; ORAL)	
48-01-80		MI APOHTAMI AT	800MG; 160MG
9 76- 81	HEATHER DRUG	SULFAMETHOXAZOLE &	SULFAMETHOXAZOLE; TRIMETHOPRIM
		(TABLET; ORAL)	
48-01-80		MIRACHTAMIRT	400Me: 80Me
976-81	HEATHER DRUG	SULF AMETHOXAZOLE &	SULFAMETHOXAZOLE; TRIMETHOPRIM
		(TABLET; ORAL)	
28-60-50		TRIMETHOPRIM DOUBLE STRENGTH	800MG; 160MG
≯ 58−81	DANBURY PHARMACAL	SULFAMETHOXAZOLE AND	SULFAMETHOXAZOLE; TRIMETHOPRIM
		(TABLET; ORAL)	
28-60-40		MIRAOHTAMIRT	400Me; 80Me
18-852	DANBURY PHARMACAL	SULFAMETHOXAZOLE AND	SULF AMETHOXAZOLE; TRIMETHOPRIM
£8-01-90		(SUSPENSION; ORAL)	SOOME\SMF #10ME\SMF
18-81	BIOCRAFT LABS	SMZ-TMP PEDIATRIC	SULFAMETHOXAZOLE; TRIMETHOPRIM
28-82-10		(SUSPENSION; ORAL)	200MG/5ML: 40MG/5ML
18-81	BIOCRAFT LABS	, dML-ZWS	SULFAMETHOXAZOLE; TRIMETHOPRIM
Σ8− ∠0−10		(SUSPENSION; ORAL)	ZOOMG/FML: 4OMG/5ML
⊊19 - 81	NATL PHARM MFG/BARRE	SULFATRIM	WIRACHTHORAZOLE; TRIMETHOPRIM
₹8−₹0−10		(SUSPENSION; ORAL)	\$\$\$\$\\\\$\\\$\\\$\\\$\\\$\\\$\\\$\\\$\\\$\\\$\\\$\
⊆19 - 81	NATL PHARM MFG/BARRE	SULFATRIM PEDIATRIC	SULFAMETHOXAZOLE; TRIMETHOPRIM
		(TABLET; ORAL)	
Z8-61 - 90		TRIMETHOPRIM DOUBLE STRENGTH	800MG; 160MG
86⊆-81	DBÒMMEB\BHOEN I X	SULFAMETHOXAZOLE AND	SULFAMETHOXAZOLE; TRIMETHOPRIM
APPROVAL DATE		(DOSVGE FORM; ROUTE)	STRENGTH(S)
# VON	APPL I CANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
STREMOTING?	TOOSAGE TONIN, ROOTE		MITHOTAL DATE	EN . DATE	EXI. DATE
SUL INDAC	CLINORIL	MS&D/MERCK	17-911	3654349	
150MG	(TABLET; ORAL)		09-27-78	04-04-89	
				3725548	
				04-03-90	
SULINDAC	CLINORIL	MS &D/MERCK	17-911	3725548	
200MG	(TABLET; ORAL)		09-27-78	04-03-90	
				3654349	
				04-04-89	
SUTILAINS	TRAVASE	TRAVENOL LABS	12-828	3409719	
82,000 UNITS/GM	(OINTMENT; TOPICAL)		06-12-69	11-05-85	
TECHNETIUM, TC-99M SODIUM PERTECHNETATE	MINITEC	ER SQUIBB AND SONS	17-339	4041317	
GENERATOR	(SOLUTION; INTRAVENOUS,		06-03-74	08-09-94	
0.22-2.22CI/GENERATOR	ORAL)				
TECHNETIUM, TC-99M, ALBUMIN AGGREGATED	CINTICHEM TECHNETIUM 99M MAA	CINTICHEM	17-773	3987157	
KIT	(INJECTABLE; INJECTION)		11-18-76	10-19-93	
N/A					
TECHNETIUM, TC-99M, ALBUMIN COLLOID	MICROLITE	MED DIAG/NE NUCLEAR	18-263	4226846	
KIT	(INJECTABLE; INJECTION)		03-25-83	10-07-97	
N/A			4		
TECHNETIUM, TC-99M, ALBUMIN KIT	CINTICHEM TECHNETIUM 99M HSA	CINTICHEM	17-775	3987157	
N/A	(INJECTABLE; INJECTION)		04-01-77	10-19-93	
TECHNETIUM, TC-99M, DISOFENIN KIT	HEPATOL ITE	MED DIAG/NE NUCLEAR	18-467		NCE
N/A	(INJECTABLE; INJECTION)		03-16-82		03-16-92
TECHNETIUM, TC-99M, GLUCEPTATE KIT	TECHNESCAN GLUCEPTATE	MS&D/MERCK	18-272	4027005	
N/A	(INJECTABLE; INJECTION)		01-27-82	05-31-94	



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	76-80-20				
	4011258				
	05-10-93	94-11-90		(TABLET; ORAL)	2,5MG
	8287262	648-7 I	GE1GY/C1BA-GE1GY	BRETHINE	TERBUTALINE SULFATE
	⊅6-80- Σ0				
	4011258				
	05-10-93	04-22-75		(TABLET; ORAL)	≥WC
	8287262	819-71	MERRELL DOW/DOW CHEM	BRICANYL	TERBUTALINE SULFATE
	⊅6-80- Σ0				
	4011258				
	05-10-93	04-22-75		(TABLET; ORAL)	2. SMG
	8287262	819-11	MEKKELL DOW/DOW CHEM	BR I CANYL	TERBUTALINE SULFATE
	76-80- Σ0				
	4011258				
	05-10-32	77-25-74		(INJECTABLE; INJECTION)	IM6/ML
	8587595	997-11	MEKKETT DOM/DOM CHEM	BRICANYL	TERBUTALINE SULFATE
	<u> </u>				
	4233285				
76-81-90	16-11-90	28-81-90		(INJECTABLE; INJECTION)	V/N
NCE	4208398	446-11	WED1-PHYS1CS	MPI DMSA KIDNEY REAGENT	TECHNETIUM, TC-99M, SUCCIMER KIT
		78-50-80		(INJECTABLE; INJECTION)	A/N
		18-335	AMERSHAM/RAD I OCHEM	W EE CAN	TECHNETIUM, TC-99M, MEDRONATE
	76-97-90	LL-91-71		(INJECTABLE; INJECTION)	Α/N
	4032625	276-71	WED DIVENE NUCLEAR	OSTEOLITE	TECHNETIUM, TC-99M, MEDRONATE
EXP. DATE	EXP. DATE	APPROVAL DATE		(DOSYGE FORM; ROUTE)	STRENGTH(S)
EXCLUSIVITY	PATENT #	# AdN	APPLICANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)
IOA.3	// TIMITAG	" VOIV	THAIL THAOLIGGA	TO A DATE	(0/21/21/02/00)(1 2//12/04

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
TERBUTALINE SULFATE	BRETHINE	GEIGY/CIBA-GEIGY	17-849	3937838	
5MG	(TABLET; ORAL)		05-17-76	02-10-93	
				4011258	
				03-08-94	
TERBUTALINE SULFATE	BRETHINE	GEIGY/CIBA-GEIGY	18-571	3937838	
IMG/ML	(INJECTABLE; INJECTION)		11-30-81	02-10-93	
				4011258	
				03-08-94	
TERBUTAL INE SULFATE	BRETHAIRE	GEIGY/CIBA-GEIGY	18-762	3937838	
0.2MG/INH	(AEROSOL; INHALATION)		08-17-84	02-10-93	
				4011258	
				03-08-94	
THALLOUS CHLORIDE, TL-201	THALLOUS CHLORIDE TL 201	MEDI-PHYSICS	18-110		
2MC I /ML	(INJECTABLE; INJECTION)		02-01-82		
THALLOUS CHLORIDE, TL-201	THALLOUS CHLORIDE TL 201	AMERSHAM/RAD LOCHEM	18-548		
IMCI/ML	(INJECTABLE; INJECTION)		12-30-82		
TIMOLOL MALEATE	BLOCADREN	MS&D/MERCK	18-017	3655663	
5MG	(TABLET; ORAL)		11-25-81	04-11-89	
TIMOLOL MALEATE	BLOCADREN	MS&D/MERCK	18-017	3655663	
IOMG	(TABLET; ORAL)		11-25-81	04-11-89	
TIMOLOL MALEATE	BLOCADREN	MS&D/MERCK	18-017	3655663	
20MG	(TABLET; ORAL)		11-25-81	04-11-89	
TIMOLOL MALEATE	TIMOPTIC	MS&D/MERCK	18-086	4195085	
EQ 0.25% BASE	(SOLUTION; OPHTHALMIC)		08-17-78	03-25-97	
				3655663	
				04-11-89	





	98-05-40	12-24-81		(TABLET; ORAL)	LOOMG
	60018€€	18-207	WEAD JOHNSON/B-M	DESABEL	TRAZODONE HYDROCHLORIDE
	98-05-40	12-24-81		(TABLET; ORAL)	≥OMC
9	6001822	18-207	MEAD JOHNSON/B-M	DESABET	TRAZODONE HYDROCHLORIDE
	06-11-80	6L-0E-01		(CAPSULE; ORAL)	EÓ 100MC BYZE
	3752826	≯ 80−81	MCNEIL LABORATORIES	TOLECTIN DS	TOLMETIN SODIUM
	06-11-80	97-24-20		(TABLET; ORAL)	EÓ SOOME BYSE
	3752826	879-71	MCNEIL LABORATORIES	TOLECTIN	TOLMETIN SODIUM
		11-02-84		(TABLET; ORAL)	≥00MG
		468-81	ZENITH LABORATORIES	TOLAZAMIDE	TOLAZAMIDE
		11-02-84		(TABLET; ORAL)	S≥0WG
		18-81	ZENITH LABORATORIES	TOLAZAMIDE	TOLAZAMIDE
		11-02-84		(TABLET; ORAL)	LOOMG
		18-81	ZENITH LABORATORIES	TOLAZAMIDE	TOLAZAM IDE
	12-02-97				
	4237068				
76-60-11	16-61-80	78-60-11		(TABLET; ORAL)	900We
NCE	4218477	752-81	MS&D/MERCK	TONOCARD	TOCAINIDE HYDROCHLORIDE
	4237068 12-02-97				
76-60-11	46-61-80	78-60-11		(TABLET; ORAL)	400WG
NCE	7748124	18-257	MS &D/MERCK	TONOCARD	TOCAINIDE HYDROCHLORIDE
	68-11-10				
	2996692		(2)		
	76-25-50	87-71-80		(SOLUTION; OPHTHALMIC)	EØ 0°2% BYZE
	980961₽	980-81	MS &D/MERCK	JIT90MIT	TIMOLOL MALEATE
EXP. DATE	EXP. DATE	APPROVAL DATE		(DOSYCE FORM; ROUTE)	STRENGTH(S)
EXCLUSIVITY	# TN3TA9	# Adv	APPLICANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
TRETINOIN	RETIN-A	ORTHO PHARMACEUTICAL	16-921	3729568	
0.05%	(SOLUTION; TOPICAL)		10-20-71	04-24-90	
TRETINOIN	RETIN-A	ORTHO PHARMACEUTICAL	17-340	3729568	
0.1%	(CREAM; TOPICAL)		01-26-73	04-24-90	
TRETINOIN	RETIN-A	ORTHO PHARMACEUTICAL	17-522	3729568	
0.05%	(CREAM; TOPICAL)		07-19-74	04-24-90	
TRETINOIN	RETIN-A	ORTHO PHARMACEUTICAL	17-955	3729568	
0.01%	(GEL; TOPICAL)		10-05-78	04-24-90	
TRETINOIN	RETIN-A	ORTHO PHARMACEUTICAL	17-579	3729568	
0.025%	(GEL; TOPICAL)		04-18-75	04-24-90	
TRIAMCINOLONE ACETONIDE	AZMACORT	WILLIAM H RORER	18-117	3897779	
0.25MG/INH	(AEROSOL; INHALATION)		04-23-83	08-05-92 3927806	
				12-23-92	
TRIAZOLAM	HALCION	UPJOHN	17-892	3980790	NCE
0.25MG	(TABLET; ORAL)	OF JOHN	11-15-82	09-14-93	11-15-92
				3987052	
				10-19-93	
TRIAZOLAM	HALCION	UPJOHN	17-892	3980790	NCE
0.5MG	(TABLET; ORAL)		11-15-82	09-14-93 3987052	11-15-92
				10-19-93	
TRILOSTANE	MODRASTANE	WINTHROP LABS/STERL	18-719		NCE
30MG	(CAPSULE; ORAL)		12-21-84		12-21-89
TRILOSTANE	MODRASTANE	WINTHROP LABS/STERL	18-719		NCE
60MG	(CAPSULE; ORAL)		12-21-84		12-21-89



		48-05-50		(INJECTABLE; INJECTION)	S° 2We/WL
		526-81	SEARLE PHARMS	CALAN	VERAPAMIL HYDROCHLORIDE
		18-01-60		(TABLET; ORAL)	ISOMG
		718-81	SEARLE/SEARLE PHARMS	CALAN	VERAPAMIL HYDROCHLORIDE
		78-01-60		(TABLET; ORAL)	80We
		718-81	SEARLE/SEARLE PHARMS	CALAN	VERAPAMIL HYDROCHLORIDE
		28-80-20		(TABLET; ORAL)	ISOMG
		265-81	KNOLL PHARMACEUTICAL	NIT9021	VERAPAMIL HYDROCHLORIDE
		28-80-20		(TABLET; ORAL)	80MG
		€65-81	KNOLL PHARMACEUTICAL	NIT9021	VERAPAMIL HYDROCHLORIDE
	86-72-01				
	12-02-97				
	4237126				
04-20-94 NCE	2125352	48-02-40	ORGANON/AKZONA	(INTECTABLE; INTECTION)	IOMG/VIAL VECURONIUM BROMIDE
		764-91 764-91	I AES LABS/AMHO	(CAPSULE; ORAL)	TRIMIPRAMINE MALEATE EQ 100MG BASE
		Z8 - 0£-40		(TABLET; ORAL)	1 00We
		679-81	BIOCRAFT LABS	MI RETHOPRIM	MI METHOPRIM
		78-60-11		(TABLET; ORAL)	SOOMG
		756-71	HOFFMANN-LA ROCHE	TRIMPEX 200	MINETHOPRIM
		28-41-70		(TABLET; ORAL)	SOOME
		246-71	BNBBONGHS METFCOME	MI A901089	MINETHOPRIM
EXP. DATE	EXP. DATE	APPROVAL DATE		(DOSAGE FORM; ROUTE)	STRENGTH(S)
EXCLUSIVITY	PATENT #	# Adv	APPLICANT NAME	TRADE NAME	ACTIVE INGREDIENT(S)

ACTIVE INGREDIENT(S) STRENGTH(S)	TRADE NAME (DOSAGE FORM; ROUTE)	APPLICANT NAME	NDA # APPROVAL DATE	PATENT # EXP. DATE	EXCLUSIVITY EXP. DATE
VERAPAMIL HYDROCHLORIDE 2.5MG/ML	CALAN (INJECTABLE; INJECTION)	SEARLE PHARMS	19-038 03-30-84		
WATER FOR INJECTION, STERILE	STERILE WATER FOR INJECTION IN PLASTIC CONTAINER (LIQUID; N/A)	TRAVENOL LABS	18-595 01-17-83		
WATER FOR INJECTION, STERILE 100%	STERILE WATER IN PLASTIC CONTAINER (LIQUID; N/A)	TRAVENOL LABS	18-632 06-30-82		
WATER FOR INJECTION, STERILE	STERILE WATER IN PLASTIC CONTAINER (LIQUID; N/A)	ABBOTT LABORATORIES	18-801 10-27-82		
WATER FOR INJECTION, STERILE	BACTERIOSTATIC WATER IN PLASTIC CONTAINER (LIQUID; N/A)	ABBOTT LABORATORIES	18-802 10-27-82		
WATER FOR INJECTION, STERILE 100%	STERILE WATER FOR INJECTION IN PLASTIC CONTAINER (LIQUID; N/A)	AM MCGAW/AM HOSP	19-077 03-02-84		
XENON, XE-127 5MCI/VIAL	XENON XE 127 (GAS; INHALATION)	MALLINCKRODT	18-536 10-01-82	NCE 10-01-92	
XENON, XE-127 IOMCI/VIAL	XENON XE 127 (GAS; INHALATION)	MALLINCKRODT	18-536 10-01-82	NCE 0-0 -92	
XENON, XE-133 IOMCI/VIAL	XENON XE 133 (GAS; INHALATION)	MALLINCKRODT	18-327 03-09-82		
XENON, XE-133 20MCI/VIAL	XENON XE 133 (GAS; INHALATION)	MALLINCKRODT	18-327 03-09-82		

