

PATENT TERM EXTENSION AND NEW PATENTS - MAY 5, 2004 [SEE IMPORTANT INFORMATION ABOUT UPDATES](#)
 DOCKET NUMBER *95S-0117
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES		
021320 001	ABARELIX;PLENAXIS	5968895	DEC 11, 2016	DP				
		6180608	DEC 11, 2016	DP U549				
		6423686	JUN 07, 2015	DS				
		6455499	JUN 07, 2015		U549			
		5843901	DEC 01, 2015	DS DP				
		6699833	DEC 11, 2016	DP				
021539 001	ACETYLCYSTEINE;ACETADOTE				ODE	JAN 23, 2011		
020949 001	ALBUTEROL SULFATE;ACCUNEB	6702997	DEC 28, 2021	U558				
020949 002	ALBUTEROL SULFATE;ACCUNEB	6702997	DEC 28, 2021	U558				
020886 001	ALITRETINOIN;PANRETIN	5932622	AUG 03, 2016	U562				
021540 001	AMLODIPINE BESYLATE;CADUET	5273995	DEC 28, 2010	DS DP U162	NC	JAN 30, 2007		
		5273995*PED	JUN 28, 2011					
		6455574	AUG 11, 2018		U552			
		5969156	JUL 08, 2016	DS				
		5969156*PED	JAN 08, 2017					
		5686104	NOV 11, 2014	DP U213				
		5686104*PED	MAY 11, 2015					
		6126971	JAN 19, 2013	DP				
		6126971*PED	JUL 19, 2013					
		4681893	SEP 24, 2009	DS DP U161				
		4681893*PED	MAR 24, 2010					
		4879303	MAR 25, 2007	DS DP				
		4879303*PED	SEP 25, 2007					
		4572909	JUL 31, 2006	DS DP U3				
		4572909*PED	JAN 31, 2007					
		021540 002	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
				4681893*PED	MAR 24, 2010			
				4879303	MAR 25, 2007	DS DP		
				4879303*PED	SEP 25, 2007			
				4572909	JUL 31, 2006	DS DP U3		
4572909*PED	JAN 31, 2007							
5273995	DEC 28, 2010			DS DP U162				
5273995*PED	JUN 28, 2011							
6455574	AUG 11, 2018				U552			
5969156	JUL 08, 2016			DS				
5969156*PED	JAN 08, 2017							
5686104	NOV 11, 2014			DP U213				
5686104*PED	MAY 11, 2015							
6126971	JAN 19, 2013			DP				
6126971*PED	JUL 19, 2013							
021540 003	AMLODIPINE BESYLATE;CADUET			4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
				4681893*PED	MAR 24, 2010			
				4879303	MAR 25, 2007	DS DP		
				4879303*PED	SEP 25, 2007			
				4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007					
		5273995	DEC 28, 2010	DS DP U162				
		5273995*PED	JUN 28, 2011					
		6455574	AUG 11, 2018		U552			
		5969156	JUL 08, 2016	DS				
		5969156*PED	JAN 08, 2017					
		5686104	NOV 11, 2014	DP U213				
		5686104*PED	MAY 11, 2015					
		6126971	JAN 19, 2013	DP				
		6126971*PED	JUL 19, 2013					

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021540 004	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
		5273995	DEC 28, 2010	DS DP U162		
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			
		5686104	NOV 11, 2014	DP U213		
		5686104*PED	MAY 11, 2015			
		6126971	JAN 19, 2013	DP		
		6126971*PED	JUL 19, 2013			
021540 005	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
		5273995	DEC 28, 2010	DS DP U162		
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			
		5686104	NOV 11, 2014	DP U213		
		5686104*PED	MAY 11, 2015			
		6126971	JAN 19, 2013	DP		
		6126971*PED	JUL 19, 2013			
021540 006	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
		5273995	DEC 28, 2010	DS DP U162		
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			
		5686104	NOV 11, 2014	DP U213		
		5686104*PED	MAY 11, 2015			
		6126971	JAN 19, 2013	DP		
		6126971*PED	JUL 19, 2013			
021540 007	AMLODIPINE BESYLATE;CADUET	4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
		5273995	DEC 28, 2010	DS DP U162		
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			

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		5686104	NOV 11, 2014	DP U213		
		5686104*PED	MAY 11, 2015			
		6126971	JAN 19, 2013	DP		
021540 008	AMLODIPINE BESYLATE; CADUET	6126971*PED	JUL 19, 2013			
		4681893	SEP 24, 2009	DS DP U161	NC	JAN 30, 2007
		4681893*PED	MAR 24, 2010			
		4879303	MAR 25, 2007	DS DP		
		4879303*PED	SEP 25, 2007			
		4572909	JUL 31, 2006	DS DP U3		
		4572909*PED	JAN 31, 2007			
		5273995	DEC 28, 2010	DS DP U162		
		5273995*PED	JUN 28, 2011			
		6455574	AUG 11, 2018	U552		
		5969156	JUL 08, 2016	DS		
		5969156*PED	JAN 08, 2017			
		5686104	NOV 11, 2014	DP U213		
		5686104*PED	MAY 11, 2015			
		6126971	JAN 19, 2013	DP		
020114 001	AZELASTINE HYDROCHLORIDE; ASTELIN	6126971*PED	JUL 19, 2013			
		5164194	NOV 01, 2010	U207		
		5164194*PED	MAY 01, 2011			
019851 001	BENAZEPRIL HYDROCHLORIDE; LOTENSIN				M-30 PED	MAR 02, 2007 SEP 02, 2007
019851 002	BENAZEPRIL HYDROCHLORIDE; LOTENSIN				M-30 PED	MAR 02, 2007 SEP 02, 2007
019851 003	BENAZEPRIL HYDROCHLORIDE; LOTENSIN				M-30 PED	MAR 02, 2007 SEP 02, 2007
019851 004	BENAZEPRIL HYDROCHLORIDE; LOTENSIN				M-30 PED	MAR 02, 2007 SEP 02, 2007
021602 001	BORTEZOMIB; VELCADE	6713446	JAN 25, 2022	DP		
020746 001	BUDESONIDE; RHINOCORT	6686346	APR 29, 2017	DP U557		
020746 002	BUDESONIDE; RHINOCORT	6686346	APR 29, 2017	DP U557		
020452 001	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	DP U175		
020452 002	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	DP U175		
020452 003	CARBOPLATIN; PARAPLATIN	4657927	APR 14, 2004	DP U175		
021621 001	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2007	DS DP U565		
		4525358*PED	DEC 25, 2007			
		6455533	JUL 02, 2018	DP		
021621 002	CETIRIZINE HYDROCHLORIDE; ZYRTEC	4525358	JUN 25, 2007	DS DP U565		
		4525358*PED	DEC 25, 2007			
		6455533	JUL 02, 2018	DP		
021587 001	CHLORPHENIRAMINE MALEATE; CHILDREN'S ADVIL ALL				NP	FEB 24, 2007
>ADD> 021149 002	CHORIOGONADOTROPIN ALFA; OVIDREL	6706681	MAR 16, 2021	DP		
021688 001	CINACALCET HYDROCHLORIDE; SENSIPAR	6031003	DEC 14, 2016	U559	ODE	MAR 08, 2011
		6211244	OCT 23, 2015	DS DP U560	NCE	MAR 08, 2009
		6313146	DEC 14, 2016	DS DP		
		6011068	DEC 14, 2016	DS DP		
021688 002	CINACALCET HYDROCHLORIDE; SENSIPAR	6031003	DEC 14, 2016		ODE	MAR 08, 2011
		6211244	OCT 23, 2015	DS DP U560	NCE	MAR 08, 2009
		6313146	DEC 14, 2016	DS DP		
		6011068	DEC 14, 2016	DS DP		
021688 003	CINACALCET HYDROCHLORIDE; SENSIPAR	6031003	DEC 14, 2016	U559	ODE	MAR 08, 2011
		6211244	OCT 23, 2015	DS DP U560	NCE	MAR 08, 2009
		6313146	DEC 14, 2016	DS DP		
		6011068	DEC 14, 2016	DS DP		

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019537 001	CIPROFLOXACIN HYDROCHLORIDE;CIPRO				I-421 PED	MAR 25, 2007 SEP 25, 2007
019537 002	CIPROFLOXACIN HYDROCHLORIDE;CIPRO				I-421 PED	MAR 25, 2007 SEP 25, 2007
019537 003	CIPROFLOXACIN HYDROCHLORIDE;CIPRO				I-421 PED	MAR 25, 2007 SEP 25, 2007
019537 004	CIPROFLOXACIN HYDROCHLORIDE;CIPRO				I-421 PED	MAR 25, 2007 SEP 25, 2007
019847 001	CIPROFLOXACIN;CIPRO				I-421 PED	MAR 25, 2007 SEP 25, 2007
020780 001	CIPROFLOXACIN;CIPRO				I-421 PED	MAR 25, 2007 SEP 25, 2007
020780 002	CIPROFLOXACIN;CIPRO				I-421 PED	MAR 25, 2007 SEP 25, 2007
019857 001	CIPROFLOXACIN;CIPRO IN DEXTROSE 5%				I-421 PED	MAR 25, 2007 SEP 25, 2007
019858 001	CIPROFLOXACIN;CIPRO IN SODIUM CHLO	4670444 4705789 4957922 4808583 4670444*PED 4705789*PED 4808583*PED 4957922*PED	DEC 09, 2003 NOV 10, 2004 SEP 18, 2007 FEB 28, 2006 JUN 09, 2004 MAY 10, 2005 AUG 28, 2006 MAR 18, 2008			
021473 002	CIPROFLOXACIN;CIPRO XR	4670444 4670444*PED	DEC 09, 2003 JUN 09, 2004	DS DP U555		
021644 001	CLOBETASOL PROPIONATE;CLOBEX				NDF	FEB 05, 2007
021392 001	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
021392 002	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
021392 003	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
021392 004	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
021392 005	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
021392 006	DILTIAZEM HYDROCHLORIDE;CARDIZEM LA				I-133	APR 09, 2007
021168 001	DIVALPROEX SODIUM;DEPAKOTE ER	6528090	DEC 18, 2018	DP		
021168 002	DIVALPROEX SODIUM;DEPAKOTE ER	6528090	DEC 18, 2018	DP		
020931 001	DOFETILIDE;TIKOSYN	6528091	DEC 18, 2018			
020931 002	DOFETILIDE;TIKOSYN	4959366	SEP 25, 2007			
020931 003	DOFETILIDE;TIKOSYN	4959366	SEP 25, 2007			
020869 001	DORZOLAMIDE HYDROCHLORIDE;COSOPT	4959366	SEP 25, 2007			
018651 001	DRONABINOL;MARINOL	6316443	APR 17, 2011	DP U561		
018651 002	DRONABINOL;MARINOL	6703418	FEB 26, 2011	U563		
018651 003	DRONABINOL;MARINOL	6703418	FEB 26, 2011	U563		
021500 001	EMTRICITABINE;EMTRIVA	6703418	FEB 26, 2011	U563		
021371 001	ESTRADIOL HEMIHYDRATE;ESTRASORB	6703396	MAR 09, 2021	DS DP		
021166 001	ESTRADIOL;ESTROGEL				NDF	OCT 09, 2006
020992 002	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				NDF	FEB 09, 2007
020992 003	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				D-85	FEB 05, 2007
020992 004	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				D-85	FEB 05, 2007
020992 006	ESTROGENS, CONJUGATED SYNTHETIC A;CENESTIN				D-85	FEB 05, 2007
021490 001	ETHINYL ESTRADIOL;OVCON-35	6667050	JUN 12, 2021	DP U1	NS	FEB 05, 2007

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019922 001	FENOLDOPAM MESYLATE;CORLOPAM				I-422	APR 01, 2007
019949 001	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
		4404216*PED	JUL 29, 2004			
019949 002	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
		4404216*PED	JUL 29, 2004			
019949 003	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
		4404216*PED	JUL 29, 2004			
019949 004	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
		4404216*PED	JUL 29, 2004			
020090 001	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
		4404216*PED	JUL 29, 2004			
020090 002	FLUCONAZOLE;DIFLUCAN	4404216	JAN 29, 2004			
		4404216*PED	JUL 29, 2004			
019950 003	FLUCONAZOLE;DIFLUCAN IN DEXTROSE	4404216	JAN 29, 2004			
		4404216*PED	JUL 29, 2004			
019950 005	FLUCONAZOLE;DIFLUCAN IN DEXTROSE	4404216	JAN 29, 2004			
		4404216*PED	JUL 29, 2004			
019950 001	FLUCONAZOLE;DIFLUCAN IN SODIUM C	4404216	JAN 29, 2004			
		4404216*PED	JUL 29, 2004			
019950 002	FLUCONAZOLE;DIFLUCAN IN SODIUM C	4404216	JAN 29, 2004			
		4404216*PED	JUL 29, 2004			
019950 004	FLUCONAZOLE;DIFLUCAN IN SODIUM C	4404216	JAN 29, 2004			
		4404216*PED	JUL 29, 2004			
020985 001	FLUOROURACIL;CARAC	6670335	JUN 02, 2021	DP U68		
021235 001	FLUOXETINE HYDROCHLORIDE;PROZAC WEEKLY	5910319	MAY 29, 2017	U396		
		5985322	MAY 29, 2017	U397		
>ADD>	021211 001	FOLLITROPIN ALFA/BETA;FOLLISTIM AQ	5929028	JAN 14, 2018	DP U567	
>ADD>			5767251	JUN 16, 2015	DS	
>ADD>			4589402	JUL 26, 2004	U568	
>ADD>			4589402	JUL 26, 2004	U569	
>ADD>			4589402	JUL 26, 2004	U570	
>ADD>	021211 002	FOLLITROPIN ALFA/BETA;FOLLISTIM AQ	5929028	JAN 14, 2018	DP U567	
>ADD>			4589402	JUL 26, 2004	U568	
>ADD>			5767251	JUN 16, 2015	DS	
>ADD>			4589402	JUL 26, 2004	U569	
>ADD>			4589402	JUL 26, 2004	U570	
021493 001	GATIFLOXACIN;ZYMAR	6333045	AUG 20, 2019	DP		
021604 001	IBUPROFEN;CHILDREN'S ELIXSURE				NP	JAN 07, 2007
076478 001	IBUPROFEN;IBUPROFEN AND PSEUDO				PC	JUL 29, 2004
020723 001	IMIQUIMOD;ALDARA				I-420	MAR 02, 2007
020685 001	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
020685 003	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
020685 005	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
020685 006	INDINAVIR SULFATE;CRIXIVAN	6689761	FEB 10, 2021	U554		
021629 001	INSULIN GLULISINE;APIDRA				NCE	APR 16, 2009
020571 001	IRINOTECAN HYDROCHLORIDE;CAMPTOSAR	4604463	AUG 20, 2007			
		6403569	APR 28, 2020	U449		
		4604463*PED	FEB 20, 2008			
		6403569*PED	OCT 28, 2020			
020182 001	LEVOCARNITINE;CARNITOR	6696493	JAN 18, 2021	U433		
021571 001	LEVOFLOXACIN;IQUIX				NP	MAR 01, 2007
021451 001	LIDOCAINE;ORAQIX	6031007	APR 01, 2017	DP U553		

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021226 001	LOPINAVIR; KALETRA	6703403	JUN 26, 2016	U257			
021251 001	LOPINAVIR; KALETRA	6703403	JUN 26, 2016	U257			
075505 001	LORATADINE; LORATADINE				PC	AUG 20, 2004	
021249 001	LOVASTATIN; ADVICOR	6676967	SEP 20, 2013	U548			
021249 002	LOVASTATIN; ADVICOR	6676967	SEP 20, 2013	U548			
021249 003	LOVASTATIN; ADVICOR	6676967	SEP 20, 2013	U548			
013217 001	METAXALONE; SKELAXIN	6683102	DEC 03, 2021	U189			
013217 002	METAXALONE; SKELAXIN	6683102	DEC 03, 2021	U189			
076545 001	METFORMIN HYDROCHLORIDE; METFORMIN HCL				PC	MAY 29, 2004	
021308 001	MICONAZOLE NITRATE; MONISTAT 1 COMBINATI				RTO	JUN 29, 2004	
076307 001	MIRTAZAPINE; MIRTAZAPINE				PC	JUN 14, 2004	
076307 002	MIRTAZAPINE; MIRTAZAPINE				PC	JUN 14, 2004	
021598 001	MOXIFLOXACIN HYDROCHLORIDE; VIGAMOX				NCE	DEC 10, 2004	
					PED	JUN 10, 2005	
020381 002	NIACIN; NIASPAN	6676967	SEP 20, 2013	U548			
020381 003	NIACIN; NIASPAN	6676967	SEP 20, 2013	U548			
020381 004	NIACIN; NIASPAN	6676967	SEP 20, 2013	U548			
020592 001	OLANZAPINE; ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007	
		5229382	APR 23, 2001	U547			
020592 002	OLANZAPINE; ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007	
		5229382	APR 23, 2011	U547			
020592 003	OLANZAPINE; ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007	
		5229382	APR 23, 2011	U547			
020592 004	OLANZAPINE; ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007	
		5229382	APR 23, 2011	U547			
020592 005	OLANZAPINE; ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007	
		5229382	APR 23, 2011	U547			
020592 006	OLANZAPINE; ZYPREXA	5229382	APR 23, 2011	DS DP U149	I-417	JAN 14, 2007	
		5229382	APR 23, 2011	DS DP U547			
>ADD>	021253 001	OLANZAPINE; ZYPREXA	5229382	APR 23, 2011	DS DP U571	NDF	MAR 29, 2007
						NP	MAR 29, 2007
021086 001	OLANZAPINE; ZYPREXA ZYDIS				I-417	JAN 14, 2007	
					I-400	JUL 10, 2006	
021086 002	OLANZAPINE; ZYPREXA ZYDIS				I-417	JAN 14, 2007	
					I-400	JUL 10, 2006	
021086 003	OLANZAPINE; ZYPREXA ZYDIS				I-417	JAN 14, 2007	
					I-400	JUL 10, 2006	
021086 004	OLANZAPINE; ZYPREXA ZYDIS				I-417	JAN 14, 2007	
					I-400	JUL 10, 2006	
>ADD>	021087 001	OSELTAMIVIR PHOSPHATE; TAMIFLU	5866601*PED	AUG 02, 2016	NCE	OCT 27, 2004	
		5763483	DEC 27, 2016		PED	APR 27, 2005	
		5866601	FEB 02, 2016				
		5952375*PED	AUG 02, 2016				
		5952375	FEB 02, 2016				
		5763483*PED	JUN 27, 2017				
021246 001	OSELTAMIVIR PHOSPHATE; TAMIFLU	5866601	FEB 02, 2016		NCE	OCT 27, 2004	
		5952375	FEB 02, 2016		PED	APR 27, 2005	
		5763483	DEC 27, 2016	U376			
		5763483*PED	JUN 27, 2017				
		5866601*PED	AUG 02, 2016				
		5952375*PED	AUG 02, 2016				
020819 001	PARICALCITOL; ZEMPLAR				M-31	MAR 31, 2007	
					PED	OCT 01, 2007	

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020819 002	PARICALCITOL; ZEMPLAR	5246925 5246925*PED 5587497 5587497*PED 6136799 6136799*PED 6361758 6361758*PED	APR 17, 2012 OCT 17, 2012 DEC 24, 2013 JUN 24, 2014 APR 08, 2018 OCT 08, 2019 APR 08, 2018 OCT 08, 2018	U314 DP	M-31 PED	MAR 31, 2007 OCT 01, 2007	
021462 001	PEMETREXED DISODIUM; ALIMTA	5217974 5344932	MAR 29, 2011 SEP 06, 2011	U551 DS DP	NCE ODE	FEB 04, 2009 FEB 04, 2011	
020639 001	QUETIAPINE FUMARATE; SEROQUEL	4879288	SEP 26, 2011	DS DP U550	I-419	JAN 12, 2007	
020639 002	QUETIAPINE FUMARATE; SEROQUEL	4879288	SEP 26, 2011	DS DP U550	I-418 I-419	JAN 12, 2007 JAN 12, 2007	
020639 003	QUETIAPINE FUMARATE; SEROQUEL	4879288	SEP 26, 2011	DS DP U550	I-418 I-419	JAN 12, 2007 JAN 12, 2007	
020639 004	QUETIAPINE FUMARATE; SEROQUEL	4879288	SEP 26, 2011	DS DP U550	I-419 I-418	JAN 12, 2007 JAN 12, 2007	
020639 005	QUETIAPINE FUMARATE; SEROQUEL	4879288	SEP 26, 2011	DS DP U550	I-419 I-418	JAN 12, 2007 JAN 12, 2007	
020741 001	REPAGLINIDE; PRANDIN	6677358	JUN 12, 2018	DS DP U546			
020741 002	REPAGLINIDE; PRANDIN	6677358	JUN 12, 2018	DS DP U546			
020741 003	REPAGLINIDE; PRANDIN	6677358	JUN 12, 2018	DS DP U546			
020903 002	RIBAVIRIN; REBETOL	6177074 6177074*PED 6461605 6461605*PED 6472373 6472373*PED 6524570 6524570*PED	NOV 01, 2016 MAY 01, 2017 NOV 01, 2016 MAY 01, 2017 SEP 21, 2017 MAR 21, 2018 NOV 01, 2016 MAY 01, 2017	U454 U454 U478 U478 U479 U479 U499 U499			
076203 001	RIBAVIRIN; RIBASPHERE				PC	OCT 03, 2004	
076192 001	RIBAVIRIN; RIBAVIRIN				PC	OCT 03, 2004	
020659 001	RITONAVIR; NORVIR	6703403	JUN 26, 2016	U564			
020945 001	RITONAVIR; NORVIR	6703403	JUN 26, 2016	U564			
>ADD> >ADD>	021042 001	ROFECOXIB; VIOXX	5474995 6239173 5691374 5691374*PED 6239173*PED 6063811*PED 5474995*PED	JUN 24, 2013 JUN 24, 2013 MAY 18, 2015 NOV 18, 2015 DEC 24, 2013 NOV 06, 2017 DEC 24, 2013	DS DP U266 DS DP U266	NCE I-353 M-27 PED PED PED	MAY 20, 2004 APR 11, 2005 AUG 06, 2006 NOV 20, 2004 OCT 11, 2005 FEB 06, 2007
>ADD> >ADD>	021042 002	ROFECOXIB; VIOXX	6063811 5474995 6239173 5691374 5691374*PED 6239173*PED 6063811*PED 5474995*PED	MAY 06, 2017 JUN 24, 2013 JUN 24, 2013 MAY 18, 2015 NOV 18, 2015 DEC 24, 2013 NOV 06, 2017 DEC 24, 2013	U266 DS DP U266 DS DP U266	NCE I-353 M-27 PED PED	MAY 20, 2004 APR 11, 2005 AUG 06, 2006 NOV 20, 2004 OCT 11, 2005 FEB 06, 2007
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APPL/PROD NUMBER	INGREDIENT NAME; TRADE NAME	PATENT NUMBER	PATENT/PED EXCL EXPIRES	PATENT CODE(S)	EXCLUS CODE	EXCLUS EXPIRES
		5691374*PED	NOV 18, 2015		PED	FEB 06, 2007
		6063811*PED	NOV 06, 2017			
		6239173*PED	DEC 24, 2013			
021052 001	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U266	NCE	MAY 20, 2004
		5691374	MAY 18, 2015		I-353	APR 11, 2005
		6063811	MAY 06, 2017	U266	M-27	AUG 06, 2006
		6239173	JUN 24, 2013		PED	NOV 20, 2004
		5474995*PED	DEC 24, 2013		PED	FEB 06, 2007
		5691374*PED	NOV 18, 2015		PED	OCT 11, 2005
		6063811*PED	NOV 06, 2017			
		6239173*PED	DEC 24, 2013			
021052 002	ROFECOXIB;VIOXX	5474995	JUN 24, 2013	U266	NCE	MAY 20, 2004
		5691374	MAY 18, 2015		I-353	APR 11, 2005
		6063811	MAY 06, 2017	U266	M-27	AUG 06, 2006
		6239173	JUN 24, 2013		PED	NOV 20, 2004
		5474995*PED	DEC 24, 2013		PED	FEB 06, 2007
		5691374*PED	NOV 18, 2015		PED	OCT 11, 2005
		6063811*PED	NOV 06, 2017			
		6239173*PED	DEC 24, 2013			
021256 001	SECRETIN SYNTHETIC HUMAN;HUMAN SECRETIN				ODE	APR 04, 2009
					NCE	APR 09, 2009
020926 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 11, 2013			
021179 001	SEVELAMER HYDROCHLORIDE;RENAGEL	6509013	AUG 11, 2013			
021110 003	SIROLIMUS;RAPAMUNE				NCE	SEP 15, 2004
					I-386	APR 11, 2006
>ADD>	020168 001	SOMATROPIN RECOMBINANT;NUTROPIN	5096885	MAR 17, 2009	DP	
>ADD>	020168 002	SOMATROPIN RECOMBINANT;NUTROPIN	5096885	MAR 17, 2009	DP	
	020080 001	SUMATRIPTAN SUCCINATE;IMITREX	4816470	DEC 28, 2006	U72	
			5037845	AUG 06, 2008	U72	
			4816470*PED	JUN 28, 2007		
			5037845*PED	FEB 06, 2009		
020132 001	SUMATRIPTAN SUCCINATE;IMITREX	4816470	DEC 28, 2006	U72		
			5037845	AUG 06, 2008	U72	
			6368627	MAR 02, 2012	U444	
			5863559	JAN 26, 2016	U72	
			6020001	MAR 02, 2012	U444	
			6020001*PED	SEP 02, 2012		
			6368627*PED	SEP 02, 2012		
			4816470*PED	JUN 28, 2007		
			5037845*PED	FEB 06, 2009		
			5863559*PED	JUL 26, 2016		
020132 002	SUMATRIPTAN SUCCINATE;IMITREX	4816470	DEC 28, 2006	U72		
			5037845	AUG 06, 2008	U72	
			6368627	MAR 02, 2012	U444	
			5863559	JAN 26, 2016	U72	
			6020001	MAR 02, 2012	U444	
			6020001*PED	SEP 02, 2012		
			6368627*PED	SEP 02, 2012		
			4816470*PED	JUN 28, 2007		
			5037845*PED	FEB 06, 2009		
			5863559*PED	JUL 26, 2016		
020132 003	SUMATRIPTAN SUCCINATE;IMITREX	5037845	AUG 06, 2008	U72		
			4816470	DEC 28, 2006	U72	
			6368627	MAR 02, 2012	U444	
			5863559	JAN 26, 2016	U72	
			6020001	MAR 02, 2012	U444	

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020626 001	SUMATRIPTAN; IMITREX	6020001*PED	SEP 02, 2012					
		6368627*PED	SEP 02, 2012					
		4816470*PED	JUN 28, 2007					
		5037845*PED	FEB 06, 2009					
		5863559*PED	JUL 26, 2016					
		4816470	DEC 28, 2006	U72				
		5037845	AUG 06, 2008					
		5307953	DEC 02, 2012					
		5554639	SEP 10, 2013	U232				
		5705520	DEC 10, 2011	U232				
		5554639*PED	MAR 10, 2014					
		5705520*PED	JUN 10, 2012					
		4816470*PED	JUN 28, 2007					
020626 002	SUMATRIPTAN; IMITREX	5037845*PED	FEB 06, 2009					
		5307953*PED	JUN 02, 2013					
		4816470	DEC 28, 2006	U72				
		5037845	AUG 06, 2008					
		5307953	DEC 02, 2012					
		5554639	SEP 10, 2013	U232				
		5705520	DEC 10, 2011	U232				
		5554639*PED	MAR 10, 2014					
		5705520*PED	JUN 10, 2012					
		4816470*PED	JUN 28, 2007					
		5037845*PED	FEB 06, 2009					
		5307953*PED	JUN 02, 2013					
		4816470	DEC 28, 2006	U72				
020626 003	SUMATRIPTAN; IMITREX	5037845	AUG 06, 2008					
		5307953	DEC 02, 2012					
		5554639	SEP 10, 2013	U232				
		5705520	DEC 10, 2011	U232				
		5554639*PED	MAR 10, 2014					
		5705520*PED	JUN 10, 2012					
		4816470*PED	JUN 28, 2007					
		5037845*PED	FEB 06, 2009					
		5307953*PED	JUN 02, 2013					
		4816470	DEC 28, 2006	U72				
		5037845	AUG 06, 2008					
		5307953	DEC 02, 2012					
		5554639	SEP 10, 2013	U232				
5705520	DEC 10, 2011	U232						
021368 001	TADALAFIL; CIALIS	5859006	JAN 12, 2016	DS DP				
		6140329	JUL 11, 2016	DP U155				
		021368 002	TADALAFIL; CIALIS	5859006	JAN 12, 2016	DS DP		
				6140329	JUL 11, 2016	DP U155		
				021368 003	TADALAFIL; CIALIS	5859006	JAN 12, 2016	DS DP
6140329	JUL 11, 2016	DP U155						
021388 001	TALC; TALC							
021124 002	TERBINAFFINE HYDROCHLORIDE; LAMISIL AT	5681849	OCT 28, 2014		ODE	DEC 24, 2004		
020846 001	TERBINAFFINE; LAMISIL	4755534	DEC 30, 2006	U73				
		4680291	JUL 14, 2004	U73				
		6121314	MAY 18, 2012	U504				
		5681849	OCT 28, 2014	DP				
		6121314	MAY 18, 2012	DP U504				
		6121314	MAY 18, 2012	DP U540				
		6121314	MAY 18, 2012	DP U502				
020898 001	THYROTROPIN ALFA; THYROGEN	6365127	NOV 24, 2015	DS DP U556				
021395 001	TIOTROPIUM BROMIDE MONOHYDRATE; SPIRIVA	5610163	MAR 11, 2014	DS DP U566	NCE	JAN 30, 2009		

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020771 002	TOLTERODINE TARTRATE;DETROL	5559269	NOV 05, 2013	U318		
		5559269*PED	MAY 05, 2014			
021257 001	TRAVOPROST;TRAVATAN	6011062	DEC 22, 2014	DP		
		5849792	DEC 22, 2014	DP U383		
		5889052	DEC 02, 2014	DP U383		
		5510383	AUG 03, 2013	DP U383		
021630 001	VORICONAZOLE;VFEND	5116844	AUG 11, 2009	DP U540	NCE	MAY 24, 2007
		5364938	NOV 15, 2011	DS	I-409	NOV 14, 2006
		5567817	OCT 22, 2013	DS DP U540		
		5773443	JAN 25, 2011	DS DP U540		

Footnotes:

- Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(c)(3)(5).
- Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor:
 - DS = Drug Substance claim
 - DP = Drug Product claim
 - U and number = Method of Use claim (may be multiple). Specific Method of use claims are listed at <http://www.fda.gov/cder/orange/patex.htm>
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- *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.