

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Abacavir Sulfate	Tablets	300 mg	Ziagen 20977	1/28/2009
Abacavir	Oral Solution	20 mg/mL	Ziagen 20977	12/27/2012
Abacavir Sulfate, Dolutegravir and Lamivudine	Tablets	600 mg/50 mg/300 mg	Triumeq 205551	8/14/2017
Abacavir Sulfate and Lamivudine	Tablets	600 mg/300 mg	Epzicom 21652	9/27/2007
Abacavir Sulfate, Lamivudine and Zidovudine	Tablets	300 mg/150 mg/300 mg	Trizivir 21205	3/22/2011
Abiraterone Acetate	Tablets	250 mg	Zytiga 202379	4/28/2015
Abiraterone Acetate	Tablets	500 mg	Zytiga 202379	8/23/2017
Acarbose	Tablets	25 mg, 50 mg and 100 mg	Precose 20482	3/22/2005
Acetylcysteine	Injection	200 mg/mL, 30 mL vials	Acetadote 21539	4/4/2012
Acetaminophen*	Injection	1000 mg/100 mL (10 mg/mL)	Ofirmev 22450	4/7/2011
Acetaminophen	Extended-release Tablets	650 mg	Tylenol 19872	
Acetaminophen and Tramadol Hydrochloride	Tablets	325 mg/ 37.5 mg	Ultracet 21123	
Acetaminophen/ Aspirin/ Caffeine	Tablets	250 mg/ 250 mg/ 65 mg	Excedrin (migraine)) 20802	
Acyclovir Sodium	Injection	50 mg/mL, 10 mL and 20 mL vials	Zovirax 18603	
Adapalene	Topical Gel	0.30%	Differin 21753	9/15/2009
Adapalene and Benzoyl Peroxide	Gel	0.1%/2.5%	Epiduo 22320	12/30/2011
Adapalene and Benzoyl Peroxide	Gel	0.3%/2.5%	Epiduo Forte 207917	5/4/2016
Adefovir Dipivoxil	Tablets	10 mg	Hepsera 21449	6/8/2010
Afatinib Dimaleate	Tablets	20 mg, 30 mg and 40 mg	Gilotrif 201292	7/12/2017
Adenosine	Injection	3 mg/mL, 20 mL and 30 mL vials	Adenoscan 20059	4/16/2005
Albuterol Sulfate	Oral Syrup	2 mg(base)/ 5 mL	Ventolin 19621	

**Paragraph IV Patent Certifications
June 14, 2018**

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Albuterol Sulfate	Extended-release Tablets	4 mg and 8 mg	Volmax 19604	
Albuterol Sulfate	Inhalation Solution	0.021% and 0.042%	Accuneb 20949	10/19/2005
Albuterol Sulfate/ Ipratropium Bromide	Inhalation Solution	0.083%/ 0.017%	Duoneb 20950	
Albuterol Sulfate	Inhalation Aerosol	0.09 mg base per actuation	Pro-Air HFA 21457	5/18/2012
Albuterol Sulfate	Inhalation Aerosol	0.09 mg base per actuation	Proventil HFA 20503	5/20/2015
Alcaftadine*	Ophthalmic Solution	0.25%	Lastacaft 22134	7/30/2014
Alendronate Sodium*	Oral Solution	70 mg/75 mL	Fosamax 21575	9/7/2007
Alendronate Sodium	Tablets	5 mg, 10 mg, 35 mg, 40 mg and 70 mg	Fosamax 20560	
Alendronate Sodium and Cholecalciferol	Tablets	70 mg/2800 IU and 70 mg/5600 IU	Fosamax Plus D 21762	11/20/2007
Alfuzosin Hydrochloride	Extended-release Tablets	10 mg	Uroxatral 21287	6/12/2007
Aliskiren Hemifumarate	Tablets	150 mg and 300 mg	Tekturna 21985	1/27/2014
Aliskiren Hemifumarate and Hydrochlorothiazide	Tablets	150 mg/12.5 mg 150 mg/25 mg 300 mg/12.5 mg 300 mg/25 mg	Tekturna HCT 22107	3/7/2014
Almotriptan Malate	Tablets	6.25 mg and 12.5 mg	Axert 21001	12/8/2005
Alogliptin	Tablets	6.25 mg, 12.5 mg and 25 mg	Nesina 22271	1/25/2017
Alogliptin and Metformin Hydrochloride	Tablets	12.5 mg/500 mg and 12.5 mg/1000 mg	Kazano 203414	1/25/2017
Alosetron Hydrochloride	Tablets	0.5 mg and 1 mg	Lotronex 21107	12/2/2010
Alprazolam	Orally Disintegrating Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Niravam 21726	12/27/2005
Alprazolam	Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Xanax 18276	

**Paragraph IV Patent Certifications
June 14, 2018**

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Alvimopan	Capsules	12 mg	Entereg 21775	6/16/2017
Amantadine	Extended-release Capsules	137 mg	Gocovri 208944	1/16/2018
Ambrisentan	Tablets	5 mg and 10 mg	Letairis 22081	2/9/2015
Amifostine	For Injection	500 mg/vial	Ethyol 20221	4/16/2004
Amlodipine Besylate	Tablets	2.5 mg, 5 mg and 10 mg	Norvasc 19787	
Amlodipine Besylate and Atorvastatin Calcium	Tablets	2.5 mg/10 mg 2.5 mg/20 mg 10 mg/40 mg	Caduet 21540	9/17/2009
Amlodipine Besylate and Atorvastatin Calcium	Tablets	2.5 mg/40 mg	Caduet 21540	9/17/2009
Amlodipine Besylate and Atorvastatin Calcium*	Tablets	5 mg/10 mg 5 mg/20 mg 5 mg/40 mg 10 mg/10 mg 10 mg/20 mg 10 mg/80 mg	Caduet 21540	12/29/2006
Amlodipine Besylate and Atorvastatin Calcium	Tablets	5 mg/80 mg	Caduet 21540	4/7/2009
Amlodipine Besylate and Benazepril Hydrochloride	Capsules	2.5 mg/10 mg 5 mg/10 mg 5 mg/20 mg 10 mg/20 mg	Lotrel 20364	6/9/2004
Amlodipine Besylate and Benazepril Hydrochloride	Capsules	5 mg/40 mg and 10 mg/40 mg	Lotrel 20364	11/17/2006
Amlodipine Besylate and Olmesartan Medoxomil	Tablets	5 mg/20 mg and 10 mg/40 mg	Azor 22100	2/11/2008
Amlodipine Besylate and Olmesartan Medoxomil	Tablets	10 mg/20 mg and 5 mg/40 mg	Azor 22100	3/31/2008
Amlodipine Besylate and Valsartan	Tablets	5 mg/160 mg	Exforge 21990	10/22/2007
Amlodipine Besylate and Valsartan	Tablets	5 mg/320 mg	Exforge 21990	11/26/2007
Amlodipine Besylate and Valsartan	Tablets	10 mg/160 mg	Exforge 21990	10/1/2007
Amlodipine Besylate and Valsartan	Tablets	10 mg/320 mg	Exforge 21990	11/9/2007

**Paragraph IV Patent Certifications
June 14, 2018**

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Amlodipine, Hydrochlorothiazide and Valsartan	Tablets	5 mg/12.5 mg/160 mg, 5 mg/25 mg/160 mg, 10 mg/25 mg/160 mg and 10 mg/25 mg/320 mg	Exforge HCT 22314	9/14/2009
Amlodipine, Hydrochlorothiazide and Valsartan	Tablets	10 mg/12.5 mg/160 mg	Exforge HCT 22314	10/22/2009
Amoxicillin and Clavulanate Potassium	Extended-release Tablets	1000 mg/62.5 mg	Augmentin XR 50785	1/21/2009
Amphetamine	Extended-release Orally Disintegrating Tablets	3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, 18.8 mg	Adzenys XR-ODT 204326	5/10/2016
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate	Extended-release Capsules	37.5 mg and 50 mg	Mydayis 22063	8/3/2017
Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate	Extended-release Capsules	12.5 mg and 25 mg	Mydayis 22063	8/7/2017
Apixaban	Tablets	2.5 mg and 5 mg	Eliquis 202155	12/28/2016
Apremilast	Tablets	10 mg, 20 mg and 30 mg	Otezla 205437	3/22/2018
Aprepitant	Capsule	40 mg, 80 mg and 125 mg	Emend 21549	11/3/2008
Aprepitant	for Oral Suspension	125 mg/Kit	Emend 207865	11/23/2016
Arformoterol Tartrate *	Inhalation Solution	Eq. 0.015 mg base/2 mL	Brovana 21912	10/1/2009
Argatroban*	Injection	100 mg/mL, 2.5 mL vials	Argatroban 20883	9/24/2007
Argatroban in Sodium Chloride*	Injection	1 mg/mL, 50 mL vials	Argatroban 22434	12/16/2011
Aripiprazole	Oral Solution	1 mg/mL	Abilify 21713	12/20/2007
Aripiprazole	Tablets	2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg	Abilify 21436	11/15/2006

**Paragraph IV Patent Certifications
June 14, 2018**

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Aripiprazole	Orally Disintegrating Tablets	10 mg, 15 mg, 20 mg and 30 mg	Abilify 21729	11/15/2006
Armodafinil	Tablets	50 mg, 150 mg and 250 mg	Nuvigil 21875	7/24/2009
Armodafinil *	Tablets	100 mg	Nuvigil 21875	9/8/2009
Armodafinil *	Tablets	200 mg	Nuvigil 21875	9/3/2009
Arsenic Trioxide	Injection	1 mg/mL	Trisenox 21248	8/11/2015
Asenapine Maleate	Sublingual Tablets	5 mg and 10 mg	Saphris 22117	8/13/2013
Asenapine Maleate	Sublingual Tablets	2.5 mg	Saphris 22117	7/27/2017
Aspirin and Omeprazole *	Delayed-release Tablets	81 mg/40 mg and 325 mg/40 mg	Yosprala 205103	10/14/2016
Aspirin and Dipyridamole	Extended-release Capsules	25 mg and 200 mg	Aggrenox 20884	2/1/2007
Atazanavir Sulfate	Capsules	100 mg and 150 mg	Reyataz 21567	3/19/2010
Atazanavir Sulfate	Capsules	200 mg	Reyataz 21567	2/16/2010
Atazanavir Sulfate	Capsules	300 mg	Reyataz 21567	7/20/2009
Atazanavir Sulfate and Cobicistat	Tablets	300 mg/150 mg	Evotaz 206353	9/13/2017
Atenolol	Tablets	25 mg, 50 mg and 100 mg	Tenormin 18240	
Atenolol/ Chlorthalidone	Tablets	50 mg/25 mg and 100 mg/25 mg	Tenoretic 18760	
Atovaquone*	Oral Suspension	750 mg/5 mL	Mepron 20500	10/20/2009
Atovaquone and Proguanil Hydrochloride	Tablets	62.5 mg/25 mg	Malarone 21078	9/14/2010
Atovaquone and Proguanil Hydrochloride	Tablets	250 mg/100 mg	Malarone 21078	4/3/2009
Atomoxetine Hydrochloride	Capsules	10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg	Strattera 21411	5/29/2007
Atorvastatin Calcium	Tablets	10 mg, 20 mg, 40 mg and 80 mg	Lipitor 20702	

**Paragraph IV Patent Certifications
June 14, 2018**

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Avanafil	Tablets	50 mg, 100 mg and 200 mg	Stendra 202276	4/27/2016
Axitinib	Tablets	1 mg and 5 mg	Inlyta 202324	2/23/2018
Azelaic Acid	Gel	15%	Finacea 21470	7/27/2012
Azelaic Acid	Topical Foam	15%	Finacea 207071	9/14/2017
Azelastine Hydrochloride	Nasal Spray	0.125 mg base/spray	Astelin 20114	11/14/2005
Azelastine Hydrochloride	Nasal Spray	205.5 mcg/spray	Astepro 22203	12/15/2011
Azelastine Hydrochloride	Ophthalmic Solution	0.05%	Optivar 21127	12/13/2006
Azelastine Hydrochloride and Fluticasone Propionate	Nasal Spray	137 mcg/50 mcg per spray	Dymista 202236	6/13/2014
Azithromycin	for Injection	500 mg/vial	Zithromax 20733	6/17/2011
Azithromycin	Ophthalmic Solution	1%	Azasite 50810	3/3/2011
Balsalazide Disodium	Tablets	1.1 g	Giazo 22205	11/5/2013
Bendamustine Hydrochloride	Injection	25 mg/vial and 100 mg/vial	Treanda 22249	6/4/2013
Bendamustine Hydrochloride	Injection	90 mg/mL, 0.5 mL and 2 mL in single-dose vials	Treanda 22249	6/19/2014
Bendamustine Hydrochloride	Injection	100 mg/4 mL (25 mg/mL) multiple-dose vials	Bendeka 208194	5/4/2017
Benzyl Alcohol	Lotion	5%	Ulesfia 22129	4/11/2016
Bepotastine Besilate	Ophthalmic Solution	1.5%	Bepreve 22288	9/9/2013
Betamethasone Valerate	Foam	0.12%	Luxiq 20934	8/10/2007
Betamethasone Dipropionate	Topical Spray	0.05%	Sernivo 208079	2/15/2018
Betaxolol	Ophthalmic Solution	0.5%(base)	Betoptic 19270	
Bexarotene	Capsules	75 mg	Targretin 20155	6/6/2011
Bimatoprost	Ophthalmic Solution	0.01%	Lumigan 22184	4/5/2011

**Paragraph IV Patent Certifications
June 14, 2018**

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Bimatoprost	Ophthalmic Solution	0.03%	Lumigan 21275	12/22/2008
Bimatoprost	Topical Solution	0.03%	Latisse 22369	5/3/2010
Bismuth Subcitrate Potassium, Metronidazole, and Tetracycline Hydrochloride	Capsules	140 mg/125 mg/125 mg	Pylera 50786	8/12/2014
Bivalirudin	For Injection	250 mg/vial	Angiomax 20873	9/1/2009
Bosutinib	Tablets	100 mg and 500 mg	Bosulif 203341	9/6/2016
Brimonidine	Topical Gel	0.33%	Mirvaso 204708	12/15/2014
Bortezomib*	For Injection	3.5 mg/vial	Velcade 21602	11/20/2008
Brimonidine Tartrate	Ophthalmic Solution	0.1%	Alphagan P 21770	12/20/2006
Brimonidine Tartrate	Ophthalmic Solution	0.15%	Alphagan P 21262	11/03/2006
Brimonidine Tartrate	Ophthalmic Solution	0.2%	Alphagan 20613	
Brimonidine Tartrate and Timolol Maleate	Ophthalmic Solution	0.2%/0.5%	Combigan 21398	11/21/2008
Bromfenac Sodium	Ophthalmic Solution	0.07%	Prolensa 203168	7/26/2013
Bromfenac Sodium	Ophthalmic Solution	0.075%	Bromsite 206911	10/25/2017
Budesonide	Enteric Coated Capsules	3 mg	Entocort EC 21324	2/1/2008
Budesonide	Nasal Spray	0.032 mg (32 mcg)/spray	Rhinocort 20746	5/14/2007
Budesonide	Inhalation Suspension	0.25 mg/2 mL and 0.5 mg/2 mL	Pulmicort Respules 20929	9/15/2005
Budesonide	Inhalation Suspension	1 mg/2 mL	Pulmicort Respules 20929	5/28/2010
Budesonide	Extended-release Tablets	9 mg	Uceris 203634	3/11/2013
Buprenorphine and Naloxone	Buccal Film	2.1 mg/0.3 mg and 4.2 mg/0.7 mg	Bunavail 205637	11/23/2016
Buprenorphine and Naloxone	Buccal Film	6.3 mg/1 mg	Bunavail 205637	12/21/2015

**Paragraph IV Patent Certifications
June 14, 2018**

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Buprenorphine Hydrochloride	Buccal Film	75 mcg and 150 mcg	Belbuca 207932	10/24/2016
Buprenorphine Hydrochloride	Buccal Film	300 mcg, 450 mcg, 600 mcg and 750 mcg	Belbuca 207932	10/4/2016
Buprenorphine Hydrochloride	Buccal Film	900 mcg	Belbuca 207932	9/12/2016
Buprenorphine Hydrochloride and Naloxone Hydrochloride	Sublingual Film	2 mg/0.5 mg* and 8 mg/2 mg	Suboxone 22410	10/15/2012
Buprenorphine Hydrochloride and Naloxone Hydrochloride*	Sublingual Film	4 mg/1 mg	Suboxone 22410	5/14/2013
Buprenorphine Hydrochloride and Naloxone Hydrochloride*	Sulingual Film	12 mg/3 mg	Suboxone 22410	5/14/2013
Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate	Sublingual Tablets	1.4 mg/0.36 mg and 5.7 mg/1.4 mg	Zubsolv 204242	10/22/2013
Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate	Sublingual Tablets	8.6 mg/2.1 mg and 11.4 mg/2.9 mg	Zubsolv 204242	7/24/2015
Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate	Sublingual Tablets	2.9 mg/7.1 mg	Zubsolv 204242	12/21/2015
Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate	Sublingual Tablets	0.7 mg/0.18 mg	Zubsolv 204242	5/4/2017
Buprenorphine *	Transdermal System	5 mcg/hr 10 mcg/hr 20 mcg/hr	Butrans 21306	6/6/2013
Buprenorphine *	Transdermal System	15 mcg/hr	Butrans 21306	12/16/2013
Bupropion Hydrobromide	Extended-release Tablets	174 mg	Aplenzin 22108	9/28/2009
Bupropion Hydrobromide	Extended-release Tablets	348 mg	Aplenzin 22108	9/24/2009
Bupropion Hydrobromide	Extended-release Tablets	522 mg	Aplenzin 22108	12/24/2009
Bupropion Hydrochloride	Extended-release Tablets	100 mg, 150 mg and 200 mg	Wellbutrin SR 20358	
Bupropion Hydrochloride	Extended-release Tablets	150 mg	Zyban 20711	

**Paragraph IV Patent Certifications
June 14, 2018**

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Bupropion Hydrochloride	Extended-release Tablets	150 mg and 300 mg	Wellbutrin XL 21515	9/21/2004
Bupropion Hydrochloride	Extended-release Tablets	450 mg	Forfivo XL 22497	2/28/2013
Bupropion Hydrochloride	Tablets	75 mg and 100 mg	Wellbutrin 18644	
Buspirone Hydrochloride	Tablets	5 mg, 7.5 mg, 10 mg, 15 mg and 30 mg	Buspar 18731	
Busulfan	Injection	6 mg/mL	Busulfex 20954	12/26/2012
Butoconazole Nitrate	Vaginal Cream	2%	Gynazole-1 200923	12/23/2009
Butorphanol Tartrate	Nasal Spray	10 mg/mL	Stadol NS 19890	
Cabazitaxel	Injection	60 mg/1.5 mL	Jevtana 201023	6/17/2014
Calcipotriene	Topical Cream	0.005%	Dovonex 20554	12/2/2009
Calcipotriene	Topical Solution	0.005%	Dovonex 20611	5/19/2006
Calcipotriene and Betamethasone Dipropionate	Ointment	0.005%/0.064%	Taclonex 21852	3/31/2010
Calcitonin-Salmon	Nasal Spray	200 IU/spray	Miacalcin 20313	
Calcitonin-Salmon (Recombinant)	Nasal Spray	200 IU/spray	Fortical 21406	3/29/2006
Calcitriol	Injection	1 mcg/mL and 2 mcg/mL, 1 mL vials	Calcijex 18874	
Calcium Acetate	Capsules	EQ 169 mg calcium	PhosLo 21160	5/31/2005
Calcium Acetate	Oral Solution	667 mg/5 mL	Phoslyra 22581	12/5/2013
Calcium Carbonate/ Famotadine/ Magnesium Hydroxide	Chewable Tablets	800 mg/ 10 mg/ 165 mg (OTC)	Pepcid Complete 20958	11/1/2004
Canagliflozin	Tablets	100 mg and 300 mg	Invokana 204042	3/29/2017
Canagliflozin and Metformin Hydrochloride	Tablets	50 mg/500 mg 50 mg/1000 mg 150 mg/500 mg 150 mg/1000 mg	Invokamet 204353	3/29/2017

**Paragraph IV Patent Certifications
June 14, 2018**

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Candesartan Cilexetil	Tablets	4 mg, 8 mg, 16 mg and 32 mg	Atacand 20838	12/22/2006
Candesartan Cilexetil and Hydrochlorothiazide	Tablets	16 mg/12.5 mg and 32 mg/12.5 mg	Atacand HCT 21093	6/25/2008
Candesartan Cilexetil and Hydrochlorothiazide	Tablets	32 mg/25 mg	Atacand HCT 21093	3/6/2009
Capecitabine	Tablets	150 mg and 500 mg	Xeloda 20896	11/10/2008
Captopril	Tablets	12.5 mg, 25 mg, 50 mg, and 100 mg	Capoten 18343	
Carbamazepine	Extended-release Capsules	100 mg and 200 mg	Carbatrol 20712	2/2/2006
Carbamazepine*	Extended-release Capsules	200 mg and 300 mg	Equetro 21710	8/21/2007
Carbamazepine	Extended-release Capsules	100 mg	Equetro 21710	5/23/2014
Carbamazepine	Extended-release Capsules	300 mg	Carbatrol 20712	
Carbamazepine	Extended-release Tablets	100 mg	Tegretol-XR 20234	12/30/2005
Carbamazepine	Extended-release Tablets	200 mg and 400 mg	Tegretol-XR 20234	
Carbidopa, Levodopa and Entacapone	Tablets	12.5 mg, 50 mg and 200 mg	Stalevo 50 21485	8/5/2008
Carbidopa, Levodopa and Entacapone	Tablets	18.75 mg/75 mg/200 mg and 31.25 mg/125 mg/200 mg	Stalevo 75 and Stalevo 125 21485	5/19/2009
Carbidopa, Levodopa and Entacapone	Tablets	25/100/200 mg and 37.5/150/200 mg	Stalevo 100 and Stalevo 150 21485	6/29/2007
Carbidopa, Levodopa and Entacapone	Tablets	50 mg/200 mg/200 mg	Stalevo 200 21485	8/28/2008
Carbidopa/ Levodopa	Extended-release Tablets	25 mg/100 mg and 50 mg/200 mg	Sinemet CR 19856	
Carbidopa and Levodopa	Extended-release Capsules	61.25 mg/245 mg	Rytary 203312	6/10/2015
Carbidopa and Levodopa	Extended-release Capsules	23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg	Rytary 203312	6/24/2015

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Carboplatin	For Injection	50 mg/vial, 150 mg/vial and 450 mg/vial	Paraplatin 19880	
Carboplatin	Injection	50 mg/vial, 150 mg/vial and 450 mg/vial	Paraplatin 20452	
Carfilzomib	For Injection	60 mg/vial	Kyprolis 202714	7/20/2016
Carfilzomib	For Injection	30 mg/vial	Kyprolis 202714	10/5/2017
Carisoprodol/ Aspirin	Tablets	200 mg/ 325 mg	Soma Compound 12365	
Carisoprodol/ Aspirin/ Codeine	Tablets	200 mg/ 325 mg/ 16 mg	Soma Compound with Codeine 12366	
Carvedilol	Tablets	3.125 mg, 6.25 mg, 12.5 mg and 25 mg	Coreg 20297	
Carvedilol Phosphate	Extended-release Capsules	10 mg and 20 mg	Coreg CR 22012	3/18/2008
Carvedilol Phosphate	Extended-release Capsules	40 mg	Coreg CR 22012	12/21/2007
Carvedilol Phosphate	Extended-release Capsules	80 mg	Coreg CR 22012	11/19/2007
Caspofungin Acetate *	for Injection	50 mg/vial and 70 mg/vial	Cancidas 21227	6/26/2009
Cefixime	for Oral Suspension	500 mg/5 mL	Suprax 202091	7/22/2014
Ceftaroline Fosamil	for Injection	400 mg/vial and 600 mg/vial	Teflaro 200327	10/29/2014
Celecoxib*	Capsules	50 mg	Celebrex 20998	3/21/2008
Celecoxib	Capsules	100 mg, 200 mg and 400 mg	Celebrex 20998	
Cetirizine Hydrochloride	Syrup	5 mg/5 mL	Zyrtec 20346	3/19/2007
Cetirizine Hydrochloride	Chewable Tablets	5 mg and 10 mg	Zyrtec 21621	3/25/2005
Cetirizine Hydrochloride and Pseudoephedrine	Extended-release Tablets	5 mg/120 mg	Zyrtec-D 21150	6/2/2004
Cevimeline Hydrochloride	Capsules	30 mg	Evoxac 20989	2/27/2009

**Paragraph IV Patent Certifications
June 14, 2018**

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Chlorhexidine Gluconate	Scrub brush/sponge	4%	Hibiclens 18423	
Chlorpheniramine Polistirex and Hydrocodone Polistirex	Extended-release Capsules	8 mg/10 mg and 4 mg/5 mg	Tussionex 19111	9/10/2004
Ciclesonide	Nasal Spray	50 mcg	Omnaris 22004	2/13/2012
Ciclopirox	Gel	0.77%	Loprox 20519	5/10/2006
Cinacalcet Hydrochloride *	Tablets	30 mg, 60 mg and 90 mg	Sensipar 21688	3/10/2008
Ciprofloxacin	Oral Suspension	250 mg/5 mL and 500 mg/ 5 mL	Cipro 20780	10/16/2009
Ciprofloxacin Hydrochloride	Tablets	100 mg, 250 mg, 500 mg and 750 mg	Cipro 19537	
Ciprofloxacin and Dexamethasone	Otic Suspension	0.3%/0.1%	Ciprodex 21537	7/31/2012
Cisatracurium Besylate (multi- dose)	Injection	2 mg/mL, 10 mL vial	Nimbex 20551	8/12/2009
Cisatracurium Besylate (preserve free)	Injection	2 mg/mL, 5 mL vial and 10 mg/mL, 20 mL vial	Nimbex 20551	8/4/2009
Cisplatin	Injection	1 mg/mL, 10 mL, 50 mL, 100 mL and 200 mL vials	Platinol-AQ 18057	
Cisplatin	For Injection	10 mg/vial and 50 mg/vial	Platinol 18057	
Clarithromycin	Extended-release Tablets	500 mg	Biaxin XL 50775	PIV received prior to 2/5/2009
Clindamycin Phosphate	Foam	1%	Evoclin 50801	PIV received prior to 2/5/2009
Clindamycin Phosphate	Vaginal Cream	2%	Clindesse 50793	2/5/2015
Clindamycin Phosphate and Benzoyl Peroxide	Gel	1% / 5%	Duac 50741	12/11/2008
Clindamycin Phosphate and Tretinoin	Gel	1.2%/0.025%	Ziana 50802	12/17/2010
Clindamycin Phosphate and Benzoyl Peroxide	Gel	1.2%/2.5%	Acanya 50819	12/20/2012

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Clindamycin Phosphate and Benzoyl Peroxide	Gel	1.2%/3.75%	Onexton 50819	9/30/2015
Clobetasol Propionate	Emulsion Foam	0.05%	Olux-E 22013	2/25/2010
Clobetasol Propionate	Topical Foam	0.05%	Olux 21142	6/27/2005
Clobetasol Propionate	Lotion	0.05%	Clobex 21535	3/27/2006
Clobetasol Propionate	Spray	0.05%	Clobex 21835	9/29/2008
Clobetasol Propionate	Topical Shampoo	0.05%	Clobex 21644	1/9/2008
Clofarabine	Injection	1 mg/mL, 20 mL vial	Clolar 21673	2/23/2012
Clonidine Hydrochloride	Extended-release Tablets	0.1 mg and 0.2 mg	Jenloga 22331	3/4/2011
Clonidine Hydrochloride	Extended-release Tablets	0.1 mg and 0.2 mg	Kapvay 22331	3/4/2011
Clonidine Hydrochloride	Transdermal System	1.1 mg/day 1.2 mg/day 1.3 mg/day	Catapres-TTS 18891	
Clopidogrel Bisulfate	Tablets	75 mg	Plavix 20839	
Clopidogrel Bisulfate	Tablets	300 mg	Plavix 20839	3/4/2009
Clozapine	Orally Disintegrating Tablets	12.5 mg	Fazaclo 21590	6/5/2008
Clozapine	Orally Disintegrating Tablets	25 mg and 100 mg	Fazaclo 21590	4/28/2008
Clozapine	Orally Disintegrating Tablets	150 mg	Fazaclo 21590	4/8/2011
Clozapine	Orally Disintegrating Tablets	200 mg	Fazaclo 21590	4/18/2011
Cobicistat	Tablets	150 mg	Tybost 203094	11/14/2016
Colchicine	Capsules	0.6 mg	Mitigare 204820	6/10/2016
Colchicine	Tablets	0.6 mg	Colcrys 22352	12/23/2011
Colesevelam Hydrochloride *	Powder for Oral Suspension	1.875 g/Package and 3.75 g/Package	Welchol 22362	4/9/2010
Colesevelam Hydrochloride	Tablets	625 mg	Welchol 21176	7/1/2009

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Colestipol Hydrochloride	Tablets	1 g	Colestid 02222	8/23/2005
Conjugated Estrogen (Synthetic A)	Tablets	0.3 mg, 0.45 mg and 0.9 mg	Cenestin 20992	3/19/2009
Conjugated Estrogen (Synthetic A)	Tablets	1.25 mg	Cenestin 20992	11/3/2008
Conjugated Estrogen (Synthetic A)	Tablets	0.625 mg	Cenestin 20992	3/2/2009
Conjugated Estrogens	Tablets	0.3 mg and 0.625 mg	Premarin 04782	
Cyanocobalamin	Nasal Spray	500 mcg/spray	Nascobal 19722	4/28/2017
Cyclobenzaprine Hydrochloride	Tablets	10 mg	Flexeril 17821	
Cyclobenzaprine Hydrochloride	Extended-release Capsule	15 mg and 30 mg	Amrix 21777	8/11/2008
Cyclophosphamide	For Injection	100 mg/vial 200 mg/vial 500 mg/vial 1 g/vial 2 g/vial	Cytosan 12142	
Dabigatran Etexilate Mesylate	Capsules	eq. to 75 mg base and 150 mg base	Pradaxa 22512	10/20/2014
Dabigatran Etexilate Mesylate	Capsules	eq. to 110 mg base	Pradaxa 22512	12/15/2015
Dalfampridine	Extended-release Tablets	10 mg	Ampyra 22250	1/22/2014
Dapagliflozin	Tablets	5 mg and 10 mg	Farxiga 202293	1/8/2018
Dapagliflozin and Saxagliptan	Tablets	10 mg/5 mg	Qtern 209091	1/8/2018
Dapagliflozin and Metformin Hydrochloride	Extended-release Tablets	5 mg/500 mg 5 mg/1000 mg 10 mg/500 mg 10 mg/1000 mg	Xigduo XR 205649	1/8/2018
Dapsone	Gel	7.5%	Aczone 207154	2/13/2017
Daptomycin	For Injection	500 mg/vial	Cubicin 21572	11/19/2008
Darifenacin Hydrobromide	Extended-release Tablets	7.5 mg and 15 mg	Enablex 21513	12/22/2008

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Darunavir Ethanolate	Tablets	75 mg, 150 mg, 300 mg, 400 mg and 600 mg	Prezista 21976	6/23/2010
Darunavir Ethanolate	Tablets	800 mg	Prezista 21976	5/14/2013
Dasatinib	Tablets	80 mg and 140 mg	Sprycel 21986	6/17/2011
Dasatinib	Tablets	20 mg, 50 mg, 70 mg and 100 mg	Sprycel 21986	6/28/2010
Deferasirox	Tablets	125 mg, 250 mg, and 500 mg	Exjade 21882	10/28/2011
Deferasirox *	Tablets	90 mg and 360 mg	Jadenu 206910	10/19/2015
Deferasirox	Tablets	180 mg	Jadenu 206910	4/28/2016
Deferiprone	Tablets	500 mg	Ferriprox 21825	1/29/2016
Desflurane	Inhalation	99.9%	Suprane 20118	9/11/2008
Desloratadine	Tablets	5 mg	Clarinx 21165	6/21/2006
Desloratadine	Orally Disintegrating Tablets	2.5 mg and 5 mg	Clarinx 21165	6/21/2006
Desloratadine	Oral Solution	0.5 mg/mL	Clarinx Syrup 21300	5/8/2008
Desloratadine and Pseudoephedrine Sulfate	Extended-release Tablets	2.5 mg/120 mg	Clarinx-D 24 Hour 21313	6/1/2007
Desloratadine and Pseudoephedrine Sulfate	Extended-release Tablets	5 mg/240 mg	Clarinx-D 24 Hour 21313	6/21/2006
Desmopressin Acetate	Injection	4 mcg/mL, 1 mL and 10 mL vials	DDAVP 18938	
Desmopressin Acetate	Nasal Spray	0.01%	DDAVP 17922	
Desmopressin Acetate	Tablets	0.1 mg and 0.2 mg	DDAVP 19955	
Desogestrel; Ethinyl Estradiol Tablets	Tablets	0.15mg/ 0.02 mg and 0.01 mg	Mircette 20713	
Desonide	Gel	0.05%	Desonate 21844	12/1/2010
Desoximetasone	Topical Spray	0.25%	Topicort 204141	12/18/2013

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Desvenlafaxine Succinate	Extended-release Tablets	50 mg and 100 mg	Pristiq 21992	2/29/2012
Desvenlafaxine Succinate	Extended-release Tablets	25 mg	Pristiq 21992	5/8/2015
Dexlansoprazole	Delayed-release Capsules	30 mg	Dexilant 22287	11/30/2010
Dexlansoprazole	Delayed-release Capsules	60 mg	Dexilant 2287	8/25/2010
Dexmedetomidine	Injection	100 mcg/mL	Precedex 21038	4/8/2009
Dexmedetomidine	Injection	4 mcg/mL, 50 mL and 100 mL vials	Precedex 21038	12/26/2013
Dexmedetomidine	Injection	4 mcg/mL, 20 mL vials	Precedex 21038	9/30/2015
Dexmethylphenidate Hydrochloride	Tablets	2.5 mg	Focalin 21278	7/27/2004
Dexmethylphenidate Hydrochloride	Tablets	5 mg and 10 mg	Focalin 21278	5/27/2004
Dexmethylphenidate Hydrochloride	Extended-release Capsules	15 mg	Focalin XR 21802	5/14/2007
Dexmethylphenidate Hydrochloride	Extended-release Capsules	5 mg, 10 mg and 20 mg	Focalin XR 21802	3/30/2007
Dexmethylphenidate Hydrochloride	Extended-release Capsules	30 mg	Focalin XR 21802	12/15/2010
Dexmethylphenidate Hydrochloride	Extended-release Capsules	40 mg	Focalin XR 21802	12/20/2010
Dexmethylphenidate	Extended-release Capsules	35 mg	Focalin XR 21802	9/29/2011
Dexmethylphenidate	Extended-release Capsules	25 mg	Focalin XR 21802	9/30/2011
Dexrazoxane	For Injection	250 mg/vial	Zinecard 20212	
Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate	Extended-release Capsules	5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg	Adderall XR 21303	
Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate	Tablets	5 mg, 10 mg, 20 mg, 30 mg	Adderall 11522	11/18/2009

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate	Tablets	7.5 mg, 12.5 mg and 15 mg	Adderall 11522	
Dextromethorphan Polistirex	Extended-release Suspension	30 mg/5 mL	Delsym 18658	1/12/2009
Dextromethorphan Hydrobromide and Quinidine Sulfate *	Capsules	20 mg/10 mg	Nuedexta 21879	3/7/2011
Diazepam	Tablets	2 mg, 5 mg and 10 mg	Valium 13263	
Diazepam	Rectal Gel	2.5 mg/0.5 mL 5 mg/mL 10 mg/2 mL 15 mg/3 mL 20 mg/4 mL	Diastat 20648	3/23/2004
Diazepam	Rectal Gel	5 mg/mL, 4mL pre-filled syringe	Diastat Acudial 20648	12/8/2008
Diazepam	Rectal Gel	5 mg/mL, 2mL pre-filled syringe	Diastat Acudial 20648	12/23/2008
Diclofenac Potassium	Oral Solution (Sachet)	50 mg	Cambia 22165	1/24/2011
Diclofenac Potassium	Capsules	25 mg	Zipsor 22202	11/14/2012
Diclofenac Sodium	Injection	37.5 mg/mL, 1 mL single-dose vials	Dyloject 22396	12/15/2015
Diclofenac Sodium	Topical Gel	3%	Solaraze 21005	12/16/2009
Diclofenac Sodium	Topical Solution	1.5%	Pennsaid 20947	7/11/2012
Diclofenac Sodium	Topical Solution	2.0%	Pennsaid 204623	6/3/2014
Diclofenac	Capsules	18 mg and 35 mg	Zorvolex 204592	6/6/2014
Diclofenac Epolamine	Topical Patch	1.3%	Flector 21234	6/26/2015
Diclofenac Sodium and Misoprostol*	Delayed-release Tablets	50 mg/0.2 mg	Arthrotec 20607	6/29/2009
Diclofenac Sodium and Misoprostol*	Delayed-release Tablets	75 mg/0.2 mg	Arthrotec 20607	11/28/2008

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Didanosine	Delayed-release Capsules	200 mg, 250 mg and 400 mg	Videx EC 21183	6/1/2004
Difluprednate	Ophthalmic Emulsion	0.05%	Durezol 22212	5/1/2014
Diltiazem Hydrochloride	Extended-release Capsules	60 mg, 90 mg and 120 mg	Cardizem SR 19471	
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg and 240 mg	Dilacor XR 20092	
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg, 240 mg, 300 mg and 360 mg	Cardizem CD 20062	
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg, 240 mg, 300 mg, 360 mg and 420 mg	Tiazac 20401	
Diltiazem Hydrochloride	Extended-release Tablets	120 mg, 180 mg, 240 mg, 300 mg and 360 mg	Cardizem LA 21392	8/30/2005
Diltiazem Hydrochloride	Extended-release Tablets	420 mg	Cardizem LA 21392	4/25/2005
Dimethyl Fumarate	Delayed-release Capsules	120 mg and 240 mg	Tecfidera 204063	3/27/2017
Divalproex Sodium	Delayed-release Tablets	125 mg, 250 mg and 500 mg	Depakote 18723	
Divalproex Sodium*	Extended-release Tablets	250 mg	Depakote ER 21168	5/3/2004
Divalproex Sodium	Extended-release Tablets	500 mg	Depakote ER 21168	2/8/2005
Docetaxel	Injection	40 mg/mL, 0.5 mL and 2 mL vials	Taxotere 20449	6/30/2009
Dofetilide	Capsules	0.125 mg, 0.25 mg, and 0.5 mg	Tikosyn 20931	5/1/2014
Dolutegravir Sodium	Tablets	10 mg, 25 mg and 50 mg	Tivicay 204790	8/14/2017
Donepezil Hydrochloride	Tablets	5 mg and 10 mg	Aricept 20690	
Donepezil Hydrochloride	Orally Disintegrating Tablets	5 mg and 10 mg	Aricept ODT 21720	6/30/2010
Donepezil Hydrochloride	Tablets	23 mg	Aricept 22568	7/9/2013
Doripenem	Injection	250 mg/vial and 500 mg/vial	Doribax 22106	10/12/2011

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Dorzolamide Hydrochloride	Ophthalmic Solution	2%	Trusopt 20408	10/11/2005
Dorzolamide Hydrochloride and Timolol Maleate	Ophthalmic Solution	2%/0.5%	Cosopt 20869	10/11/2005
Doxazosin Mesylate	Tablets	1 mg, 2 mg, 4 mg and 8 mg	Cardura 19668	
Doxepin Hydrochloride	Tablets	3 mg and 6 mg	Silenor 22036	9/16/2010
Doxercalciferol	Capsules	1 mcg	Hectorol 20862	2/12/2010
Doxercalciferol	Capsules	0.5 mcg and 2.5 mcg	Hectorol 20862	3/25/2009
Doxercalciferol*	Injection	2 mcg/mL, 2 mL ampules	Hectorol 21027	10/15/2007
Doxercalciferol*	Injection	2 mcg/mL, 1 mL in 2 mL vial	Hectorol 21027	12/28/2011
Doxycycline	Delayed-release Capsules	40 mg	Oracea 50805	12/11/2008
Doxycycline Hyclate	Delayed-release Tablets	75 mg and 100 mg	Doryx 50795	PIV received prior to 2/5/2009
Doxycycline Hyclate	Delayed-release Tablets	150 mg	Doryx 50795	12/19/2008
Doxycycline Hyclate	Delayed-release Tablets	200 mg	Doryx 50795	5/19/2014
Doxycycline Hyclate	Delayed-release Tablets	80 mg	Doryx 50795	7/1/2015
Doxycycline Hyclate	Delayed-release Tablets	50 mg	Doryx 50795	11/5/2015
Doxycycline Hyclate	Delayed-release Tablets	60 mg and 120 mg	Doryx MPC 50795	9/28/2017
Doxylamine Succinate and Pyridoxine Hydrochloride	Delayed-release Tablets	10 mg/10 mg	Diclegis 21876	8/1/2013
Dronabinol	Oral Solution	5 mg/mL	Syndros	4/17/2017
Dronedarone Hydrochloride	Tablets	400 mg	Multaq 22425	7/1/2013
Drospirenone and Estradiol	Tablets	0.5 mg/1 mg	Angeliq 21355	12/26/2007
Drospirenone and Estradiol	Tablets	0.25 mg/0.5 mg	Angeliq 21355	1/8/2015

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Drospirenone and Ethinyl Estradiol	Tablets	3 mg/0.02 mg	Yaz 21676	9/29/2006
Drospirenone and Ethinyl Estradiol	Tablets	3 mg/0.03 mg	Yasmin 21098	1/7/2005
Drospirenone and Ethinyl Estradiol and Levomefolate Calcium and Levomefolate Calcium	Tablets	3 mg/0.03 mg/0.451 mg and 0.451 mg	Safyral 22574	9/28/2012
Drospirenone and Ethinyl Estradiol and Levomefolate Calcium and Levomefolate Calcium	Tablets	3 mg/0.02 mg/0.451 mg and 0.451 mg	Beyaz 22532	11/13/2012
Duloxetine Hydrochloride	Delayed-release Capsules	20 mg, 30 mg and 60 mg	Cymbalta 21427	8/4/2008
Duloxetine Hydrochloride	Delayed-release Capsules	40 mg	Cymbalta 21427	5/10/2012
Dutasteride	Capsules	0.5 mg	Avodart 21319	10/29/2007
Dutasteride and Tamsulosin Hydrochloride	Capsules	0.5 mg/0.4 mg	Jalyn 22460	10/26/2010
Efavirenz	Tablets	600 mg	Sustiva 21360	4/9/2009
Efavirenz	Capsules	50 mg, 100 mg and 200 mg	Sustiva 20972	11/3/2016
Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate	Tablets	600 mg/200 mg/300 mg	Atripla 21937	12/29/2008
Eletriptan Hydrobromide *	Tablets	20 mg and 40 mg	Relpax 21016	3/29/2010
Eltrombopag Olamine	Tablets	50 mg and 75 mg	Promacta 22291	1/7/2014
Eltrombopag Olamine	Tablets	12.5 mg and 25 mg	Promacta 22291	2/4/2014
Emtricitabine	Capsules	200 mg	Emtriva 21500	7/16/2012
Emtricitabine and Tenofovir Disoproxil Fumarate	Tablets	200 mg/300 mg	Truvada 21752	9/26/2008
Emtricitabine and Tenofovir Disoproxil Fumarate	Tablets	100 mg/150 mg 133 mg/200 mg 167 mg/250 mg	Truvada 21752	5/19/2017

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Emtricitabine, Rilpivirine, and Tenofovir Disoproxil Fumarate	Tablets	200 mg/25 mg/300 mg	Complera 202123	5/20/2015
Enalapril Maleate	Tablets	2.5 mg, 5 mg, 10 mg and 20 mg	Vasotec 18998	
Enalapril Maleate	Powder for Oral Solution	1 mg/mL	Epaned Kit 204308	6/21/2016
Enoxaparin Sodium	Injection	100 mg/mL, 0.3 mL, 0.4 mL, 0.6 mL, 0.8 mL and 1 mL prefilled syringes	Lovenox 20164	
Enoxaparin Sodium	Injection	150 mg/mL, 0.6 mL, 0.8 mL and 1 mL prefilled syringes	Lovenox 20164	
Enoxaparin Sodium	Injection	100 mg/mL, 3 mL vials	Lovenox 20164	12/7/2006
Entacapone	Tablets	200 mg	Comtan 20796	4/11/2007
Entecavir	Tablets	0.5 mg and 1 mg	Baraclude 21797	6/14/2010
Enzalutamide	Capsules	40 mg	Xtandi 203415	8/31/2016
Epinastine Hydrochloride	Ophthalmic Solution	0.05%	Elestat 21565	10/14/2008
Epinephrine	Injection (Auto-injector)	0.15 mg/0.3 mL and 0.3 mg/0.3 mL	Epipen and Epipen Jr. 19430	7/20/2009
Epinephrine	Injection	1 mg/mL ampules	Adrenalin 204200	3/9/2016
Eplerenone	Tablets	25 mg and 50 mg	Inspra 21437	9/27/2006
Epoprostenol Sodium	Injection	0.5m/vial and 1.5 mg/vial	Veletri 22260	3/31/2017
Eptifibatide	Injection	0.75 mg/mL, 100 mL vial	Integrilin 21437	6/5/2009
Eptifibatide	Injection	2 mg/mL, 10 mL vial	Integrilin 20718	9/30/2008
Eptifibatide	Injection	2 mg/mL, 100 mL vial	Integrilin 20718	12/18/2008
Eprosartan Mesylate	Tablets	400 mg and 600 mg	Teveten 20738	5/10/2010
Erlotinib Hydrochloride	Tablets	25 mg, 100 mg and 150 mg	Tarceva 21743	11/18/2008

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Ertapenem*	Injection	1 g/vial	Invanz 21337	12/21/2012
Escitalopram Oxalate	Capsules	5 mg	Lexapro 21323	8/17/2005
Escitalopram Oxalate	Capsules	10 mg and 20 mg	Lexapro 21323	3/30/2005
Escitalopram Oxalate	Tablets	5 mg, 10 mg and 20 mg	Lexapro 21323	
Eslicarbazepine Acetate	Tablets	200 mg, 400 mg, 600 mg and 800 mg	Aptiom 22416	11/8/2017
Esmolol Hydrochloride	Injection	10 mg/mL, 10 mL vial	Brevibloc 19386	
Esmolol Hydrochloride	Injection	10 mg/mL, 250 mL infusion bags and 20 mg/mL, 100 mL infusion bags	Brevibloc 19386	1/31/2014
Esomeprazole Magnesium	Delayed-release Capsules	20 mg and 40 mg	Nexium 21153	8/5/2005
Esomeprazole Magnesium	Delayed-release Capsules	20 mg	Nexium (OTC) 204655	4/24/2014
Esomeprazole Magnesium	Delayed-release for Oral Suspension	20 mg and 40 mg	Nexium 21597	8/1/2013
Esomeprazole	Delayed-release Tablets	20 mg	Nexium 24HR (OTC) 207920	9/9/2016
Esomeprazole Sodium	For Injection	20 mg/vial and 40 mg/vial	Nexium IV 21689	11/23/2009
Estradiol	Transdermal System	0.025 mg/day 0.0375 mg/day 0.05 mg/days 0.075 mg/day 0.1 mg/day	Vivelle Dot 20538	4/27/2010
Estradiol	Transdermal System	0.0375 mg/day and 0.06 mg/day	Climara 20375	
Estradiol	Transdermal System	0.05 mg/day and 0.1 mg/day	Climara 20375	9/12/2005
Estradiol	Vaginal Tablets	10 mcg	Vagifem 20908	1/2/2013
Estradiol	Transdermal System	0.0375 mg/day 0.05 mg/day 0.075 mg/day 0.1 mg/day	Minivelle 203752	8/18/2014

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Estradiol	Transdermal System	0.025 mg/day	Minivelle 203752	5/8/2015
Estradiol; Estradiol and Norgestimate	Tablets	1 mg; 1 mg and 0.09 mg	Prefest 21040	
Estradiol Valerate and Dienogest	Tablets	3 mg;2 mg/2 mg;2 mg/3 mg and 1 mg	Natazia 22252	10/22/2010
Eszopiclone	Tablets	1 mg, 2 mg and 3 mg	Lunesta 21476	12/15/2008
Ethinyl Estradiol and Etonogestrel	Vaginal Ring	0.015 mg/24 hour 0.12 mg/24 hour	Nuvaring 21187	6/17/2013
Etodolac	Extended-release Tablets	400 mg, 500 mg and 600 mg	Lodine XL 20584	
Everolimus	Tablets	0.25 mg, 0.5 mg, and 0.75 mg	Zortress 21560	9/30/2013
Everolimus	Tablets	10 mg	Afinitor 22334	6/18/2014
Everolimus	Tablets	2.5 mg, 5 mg, and 7.5 mg	Afinitor 22334	12/10/2014
Everolimus	Tablets for Oral Suspension	2 mg, 3 mg and 5 mg	Afinitor Disperz 203985	12/30/2016
Exenatide	Injection	250 mg/mL, 1.2 mL and 2.4 mL prefilled syringe	Byetta 21773	6/11/2014
Ezetimibe	Tablets	10 mg	Zetia 21445	10/25/2006
Ezetimibe and Simvastatin *	Tablets	10 mg/10 mg 10 mg/20 mg 10 mg/40 mg 10 mg/80 mg	Vytorin 21687	7/27/2009
Famciclovir	Tablets	125 mg, 250 mg and 500 mg	Famvir 20363	12/28/2004
Famotidine	Injection	10 mg/mL, 2 mL vials; unpreserved	Pepcid	
Famotidine	Injection	10 mg/mL, 4 mL and 20 mL vials; preserved	Pepcid	
Famotidine	Injection	10 mg/mL, 50 mL vial, pharmacy bulk package; unpreserved	Pepcid	
Famotidine	Tablets	10 mg (OTC)	Pepcid AC	

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Famotidine	Tablets	20 mg and 40 mg	Pepcid 19462	
Famotidine	Tablets (Chewable)	10 mg (OTC)	Pepcid AC (chewable) 20801	
Febuxostat	Tablets	40 mg and 80 mg	Uloric 21856	2/13/2013
Felodipine	Extended-release Tablets	2.5 mg, 5 mg and 10 mg	Plendil ER 19834	
Fenofibrate*	Tablets	40 mg and 120 mg	Fenoglide 22118	3/17/2010
Fenofibrate	Capsules	43 mg and 130 mg	Antara 21695	9/15/2008
Fenofibrate Choline	Delayed-release Capsules	45 mg	Trilipix 22224	9/2/2009
Fenofibrate Choline	Delayed-release Capsules	135 mg	Trilipix 22224	9/1/2009
Fenofibrate	Capsules	67 mg, 134 mg and 200 mg	Tricor 19304	
Fenofibrate	Tablets	48 mg	Tricor 21656	7/1/2008
Fenofibrate	Tablets	54 mg, 107 mg and 160 mg	Tricor 21203	
Fenofibrate	Tablets	145 mg	Tricor 21656	10/19/2007
Fentanyl	Transdermal Extended-release Film	0.6 mg/24 hr 1.2 mg/ 24 hr 1.8 mg/ 24 hr 2.4 mg/ 24 hr	Duragesic 19813	
Fentanyl Citrate	Buccal Tablets	0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.6 mg and 0.8 mg	Fentora 21947	11/13/2007
Fentanyl Citrate	Lozenges	0.2 mg	Actiq 20747	10/29/2004
Fentanyl Citrate	Lozenges	0.4 mg	Actiq 20747	10/6/2004
Fentanyl Citrate	Lozenges	0.6 mg	Actiq 20747	12/20/2004
Fentanyl Citrate	Lozenges	0.8 mg, 1.2 mg and 1.6 mg	Actiq 20747	11/22/2004
Fentanyl	Sublingual Spray	0.4 mg/spray	Subsys 202788	5/22/2017

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Fentanyl	Sublingual Spray	1.1 mg/spray, 1.2 mg/spray, 0.6 mg/spray, 0.8 mg/spray, 1.2 mg/spray, 1.6 mg/spray	Subsys 202788	12/7/2017
Fentanyl Citrate	Sublingual Tablets	0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.6 mg and 0.8 mg	Abstral 22510	6/19/2014
Ferumoxytol	Injection	30 mg/mL, 17 mL single-use vials	Feraheme 22180	12/4/2015
Fesoterodine Fumarate	Extended-release Tablets	4 mg and 8 mg	Toviaz 22030	10/31/2012
Fexofenadine Hydrochloride	Oral Suspension	30 mg/5 mL	Allegra	1/25/2010
Fexofenadine Hydrochloride	Capsules	60 mg	Allegra 20625	
Fexofenadine Hydrochloride	Tablets	30 mg, 60 mg and 180 mg	Allegra 20872	
Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride	Extended-release Tablets	60 mg/120 mg	Allegra-D 20786	
Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride	Extended-release Tablets	180 mg/240 mg	Allegra-D 24 Hour 21704	6/6/2007
Finasteride	Tablets	1 mg	Propecia 20788	
Finasteride	Tablets	5 mg	Proscar 20180	
Fingolimod	Capsules	0.5 mg	Gilenya 22527	9/22/2014
Fidaxomicin	Tablets	200 mg	Dificid 201699	5/27/2015
Flecainide Acetate	Tablets	50 mg, 100 mg and 150 mg	Tambocor 18830	
Fluconazole	For Oral Suspension	50 mg/5 mL and 200 mg/5 mL	Diflucan for Oral Suspension 20090	
Fluconazole	Tablets	50 mg, 100 mg, 150 mg and 200 mg	Diflucan 19949	
Flunisolide	Nasal Solution	0.025%	Nasalide 18148	

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Fluocinonide	Cream	0.1%	Vanos 21758	1/31/2008
Fluocinonide	Ointment	0.05%	Lidex 16909	
Fluorouracil	Cream	0.5%	Carac 20985	7/29/2011
Fluoxetine Hydrochloride	Tablets	10 mg and 20 mg	Prozac 20974	
Fluoxetine Hydrochloride	Capsules	10 mg, 20 mg and 40 mg	Prozac 18936	
Fluoxetine Hydrochloride	Delayed-release Capsules	90 mg	Prozac Weekly 21235	
Fluoxetine Hydrochloride	Oral Solution	20 mg (base)/5 mL	Prozac 20101	
Fluoxetine Hydrochloride	Capsules	10 mg and 20 mg	Sarafem 18936	
Flutamide	Capsules	125 mg	Eulexin 18554	
Fluticasone Furoate	Nasal Spray	27.5 mcg	Veramyst	7/15/2011
Fluticasone Propionate	Lotion	0.05%	Cutivate 21152	7/28/2008
Fluticasone Propionate	Inhalation Aerosol	0.11 mcg/inh	Flovent HFA 21433	12/23/2016
Fluvastatin	Capsules	20 mg and 40 mg	Lescol 20261	6/4/2008
Fluvastatin Sodium	Extended-release Tablets	80 mg	Lescol XL 21192	3/15/2007
Fluvoxamine Maleate	Extended-release Capsules	100 mg	Luvox CR 22033	4/20/2009
Fluvoxamine Maleate	Extended-release Capsules	150 mg	Luvox CR 22033	4/13/2009
Formoterol Fumarate*	Inhalation Solution	0.02 mg/2 mL	Perforomist 22007	1/21/2009
Fosamprenavir Calcium	Tablets	700 mg	Lexiva 21548	1/18/2012
Fosaprepitant Dimeglumine	Injection	115 mg/vial	Emend 22023	1/25/2012
Fosaprepitant Dimeglumine*	Injection	150 mg/vial	Emend 22023	1/25/2012
Fosinopril Sodium	Tablets	10 mg, 20 mg and 40 mg	Monopril 19915	

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Fosinopril Sodium and Hydrochlorothiazide	Tablets	10 mg/12.5 mg and 20 mg/12.5 mg	Monopril HCT 20286	
Frovatriptan Succinate	Tablets	2.5 mg	Frova 21006	3/9/2011
Fulvestrant*	Injection	50 mg/mL, 2.5 mL and 5 mL syringe	Faslodex 21344	10/1/2009
Gabapentin	Capsules	100 mg, 300 mg and 400 mg	Neurontin 20235	
Gabapentin	Tablets	100 mg, 300 mg and 400 mg	Neurontin 20235	
Gabapentin	Oral Solution	250 mg/5 mL	Neurontin 21129	
Gabapentin	Tablets	600 mg and 800 mg	Neurontin 20882	
Gabapentin	Tablets	300 mg and 600 mg	Gralise 22544	10/31/2011
Galantamine Hydrobromide	Extended-release Capsules	8 mg	Razadyne ER 21615	3/2/2006
Galantamine Hydrobromide	Extended-release Capsules	16 mg and 24 mg	Razadyne ER 21615	3/11/2006
Galantamine Hydrobromide	Tablets	4 mg, 8 mg and 12 mg	Razadyne 21169	2/28/2005
Ganciclovir Sodium	Capsules	250 mg and 500 mg	Cytovene 20460	
Ganirelix Acetate	Injection	250 mcg/0.5 mL, 1 mL PFS	Ganirelix Acetate 21057	3/30/2012
Gatifloxacin	Injection	10 mg/mL, 20 mL and 40 mL vials	Tequin	11/24/2004
Gatifloxacin	Ophthalmic Solution	0.3 %	Zymar 21493	7/19/2007
Gatifloxacin	Ophthalmic Solution	0.5 %	Zymaxid 22548	12/7/2010
Gatifloxacin	Tablets	200 mg and 400 mg	Tequin	
Gatifloxacin in Dextrose 5% in Plastic Container	Injection	2 mg/mL, 100 mL and 200 mL containers (plastic)	Tequin	12/13/2004
Gemcitabine	For Injection	200 mg/vial	Gemzar 20509	11/1/2005
Gemcitabine	For Injection	1g/vial	Gemzar 20509	11/14/2005

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Gemcitabine	For Injection	2 g/vial	Gemzar	8/24/2007
Gemifloxacin Mesylate	Tablets	320 mg	Factive 21158	3/4/2008
Glatiramer Acetate	Injection	20 mg/mL, 1 mL pre-filled syringe	Copaxone 20622	12/27/2007
Glatiramer Acetate	Injection	40 mg/mL, 1 mL pre-filled syringe	Copaxone 20622	2/26/2014
Glimepiride and Rosiglitazone Maleate	Tablets	1 mg/4 mg 2 mg/4 mg 4 mg/4 mg	Avandaryl 21700	12/22/2006
Glimepiride and Rosiglitazone Maleate	Tablets	8 mg/2 mg 8 mg/4 mg	Avandaryl 21700	5/30/2008
Glipizide	Extended-release Tablets	2.5 mg, 5 mg and 10 mg	Glucotrol XL 20329	
Glyburide	Tablets	1.5 mg, 3 mg, 4.5 mg and 6 mg	Glynase 20051	
Glyburide/ Metformin Hydrochloride	Tablets	1.25mg/250 mg 2.5 mg/500 mg 5 mg/500 mg	Glucovance 21178	
Glycerol Phenylbutyrate	Oral Liquid	1.1 g/mL	Ravicti 203284	11/19/2013
Glycopyrrolate *	Tablets	1 mg	Robinul 12827	8/14/2009
Glycopyrrolate	Tablets	1.5 mg	Robinul Forte	5/6/2009
Glycopyrrolate	Tablets	2 mg	Robinul Forte 12827	10/12/2010
Glycopyrrolate	Oral Solution	1 mg/5 mL	Cuvposa 22571	6/20/2012
Granisetron Hydrochloride	Injection	0.1 mg/mL, 1 mL single dose vial	Kytril 20239	3/8/2007
Granisetron Hydrochloride	Injection	1 mg/mL, 1 mL vials	Kytril 20239	6/1/2004
Granisetron Hydrochloride	Injection	1 mg/mL, 4 mL multi-dose vials	Kytril 20239	7/19/2004
Granisetron Hydrochloride	Transdermal System	3.1 mg/24 hrs	Sancuso 22198	10/9/2015
Guaifenesin *	Extended-release Tablets	600 mg and 1.2 gm	Mucinex 21282	6/9/2006
Guaifenesin and Dextromethorphan	Extended-release Tablets	600 mg/30 mg and 1200 mg/60 mg	Mucinex DM 21620	12/17/2008

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Guaifenesin and Pseudoephedrine Hydrochloride	Extended-release Tablets	600 mg/60 mg and 1200 mg/120 mg	Mucinex-D 21585	12/29/2008
Guanfacine Hydrochloride	Extended-release Tablets	1 mg, 2 mg, 3 mg and 4 mg	Intuniv 22037	12/29/2009
Halobetasol Propionate	Lotion	0.05%	Ultavate 208183	1/24/2018
Hydrocodone Bitartrate	Extended-release Capsules	10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg	Zohydro ER 202880	2/26/2014
Hydrocodone Bitartrate and Ibuprofen	Tablets	2.5 mg/200 mg	Vicoprofen	2/24/2006
Hydrocodone Bitartrate and Ibuprofen	Tablets	5 mg/200 mg	Vicoprofen	5/27/2005
Hydrocodone Bitartrate and Ibuprofen	Tablets	7.5 mg/200 mg	Vicoprofen 20716	
Hydrocodone Bitartrate and Ibuprofen	Tablets	10 mg/200 mg	Vicoprofen	
Hydrocodone Bitartrate	Extended-release Tablets	20 mg, 60 mg, and 120 mg	Hysingla ER 206627	4/15/2015
Hydrocodone Bitartrate	Extended-release Tablets	30 mg, 40 mg, 80 mg, and 100 mg	Hysingla ER 206627	5/8/2015
Hydrocortisone Butyrate	Cream	0.10%	Locoid Lipocream 20769	6/28/2010
Hydrocortisone Butyrate	Lotion	0.10%	Locoid 22076	8/31/2016
Hydromorphone Hydrochloride	Extended-release Tablets	8 mg and 12 mg	Exlago 21217	9/2/2010
Hydromorphone Hydrochloride	Extended-release Tablets	16 mg	Exlago 21217	8/2/2010
Hydromorphone Hydrochloride	Oral Solution	5 mg/5mL	Dilaudid 19891	2/25/2011
Hydromorphone Hydrochloride	Injection	10 mg/mL	Dilaudid-HP 19034	11/4/2011
Hydromorphone Hydrochloride	Injection	2 mg/mL	Dilaudid 19034	6/22/2011
Hydromorphone Hydrochloride	Tablets	2 mg, 4 mg, and 8 mg	Dilaudid 19892	8/5/2013
Ibandronate Sodium*	Injection	1 mg/mL, 3 mL Vial	Boniva 21858	8/31/2007

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Ibandronate Sodium	Tablets	2.5 mg and 150 mg	Boniva 21455	5/16/2007
Ibrutinib	Capsules	140 mg	Imbruvica 205552	11/13/2017
Ibuprofen	Oral Drops	40 mg/mL	Children's Motrin Drops 20603	
Ibuprofen	Oral Suspension	50 mg/1.25 mL	Concentrated Motrin Infant Drops	6/29/2007
Ibuprofen	Oral Suspension	100 mg/5 mL (Rx)	Motrin	
Ibuprofen	Oral Suspension	100 mg/5 mL (OTC)	Children's Motrin	
Ibuprofen	Chewable Tablets	50 mg and 100 mg	Children's Motrin, Junior Strength Motrin 20601	
Ibuprofen Lysine	Injection	10 mg/mL, 2 mL vials	Neoprofen 21903	10/1/2010
Ibuprofen and Diphenhydramine Hydrochloride	Capsules	200 mg/25 mg	Advil PM 21393	2/16/2016
Ibuprofen and Diphenhydramine Citrate	Tablets	200 mg/38 mg	Advil PM 21394	12/28/2017
Ibuprofen and Famotidine	Tablets	800 mg/26.6 mg	Duexis 22519	12/6/2011
Ibuprofen and Pseudoephedrine Hydrochloride	Oral Suspension	100 mg/ 15 mg per 5 mL	Children's Motrin Cold	
Ibuprofen and Pseudoephedrine Hydrochloride	Tablets	200 mg/30 mg	Advil Cold and Sinus	
Ibuprofen Potassium and Pseudoephedrine Hydrochloride	Capsules	200 mg/30 mg	Advil Cold and Sinus	12/27/2004
Icatibant	Injection	10 mg/mL	Firazyr 22150	8/25/2015
Icosapent Ethyl	Capsules	1 g	Vascepa 202057	7/26/2016
Icosapent Ethyl	Capsules	500 mg	Vascepa 202057	8/29/2017

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Ifosfamide	For Injection	1 g/vial and 3 g/vial	Ifex 19763	
Ifosfamide	Injection	50 mg/mL, 20 mL vials and 60 mL vials	Ifex	
Ifosfamide/ Mesna	For Injection/ Injection Kit	1 g/vial; 100 mg/mL, 10 mL vials and 3 g/vial; 100 mg/mL, 10 mL vials	Ifex/ Mesnex Kit 19763	
Ifosfamide/ Mesna	Injection/ Injection Kit	50 mg/mL, 20 mL and 60 mL vials; 100 mg/mL, 10 mL vial	Ifex/ Mesnex Kit	
lloperidone	Tablets	1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg	Fanapt 22192	5/6/2013
Imatinib Mesylate	Tablets	100 mg and 400 mg	Gleevec 21588	3/12/2007
Imatinib Mesylate*	Capsules	400 mg	Gleevec	1/24/2014
Imiquimod	Cream	5%	Aldara 20723	10/17/2006
Imiquimod	Cream	2.5%	Zyclara 22483	6/17/2014
Imiquimod	Cream	3.75%	Zyclara 22483	8/8/2012
Indomethacin	Extended-release Capsules	75 mg	Indocin SR 18185	
Ingenol Mebutate	Gel	0.05%	Picato 202833	1/27/2016
Ingenol Mebutate	Gel	0.015%	Picato 202833	1/27/2016
Irbesartan	Tablets	75 mg, 150 mg and 300 mg	Avapro 20757	5/25/2004
Irbesartan and Hydrochlorothiazide	Tablets	150 mg/12.5 mg and 300 mg/12.5 mg	Avalide 20758	11/10/2004
Irbesartan and Hydrochlorothiazide	Tablets	300 mg/25 mg	Avalide 20758	6/6/2006
Irinotecan Hydrochloride	Injection	20 mg/mL, 2 mL and 5 mL vials	Camptosar 20571	7/26/2004
Isotretinoin	Capsules	30 mg and 40 mg	Absorica 21951	12/31/2012

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Isotretinoin	Capsules	20 mg	Absorica 21951	1/7/2013
Isotretinoin	Capsules	10 mg	Absorica 21951	6/19/2013
Isotretinoin	Capsules	35 mg	Absorica 21951	11/25/2015
Isotretinoin	Capsules	25 mg	Absorica 21951	5/16/2016
Itraconazole	Capsules	100 mg	Sporanox 20083	
Itraconazole	Oral Solution	10 mg/mL	Sporanox 20657	5/3/2013
Ivermectin	Lotion	0.50%	Sklice 202736	9/1/2017
Ivermectin	Cream	1%	Soolantra 206255	12/30/2016
Ixabepilon	Injection	15 mg/vial and 45 mg/vial, single-use vials	Ixempra Kit 22065	4/16/2012
Ketoconazole	Foam	2%	Extina 21738	7/30/2009
Ketoprofen	Capsules	25 mg, 50 mg and 75 mg	Orudis 18754	
Ketorolac Tromethamine	Injection	15 mg/mL and 30 mg/mL	Toradol 19698	
Ketorolac Tromethamine	Ophthalmic Solution	0.45%	Acuvail 22427	8/24/2011
Ketorolac Tromethamine	Ophthalmic Solution	0.4%	Acular LS 21528	1/28/2005
Ketorolac Tromethamine	Tablets	10 mg	Toradol 19645	
Ketorolac Tromethamine*	Nasal Spray	15.75 mg/spray	Sprix 22382	3/12/2012
Ketotifen Fumarate	Ophthalmic Solution	0.025%	Zaditor 21066	12/23/2004
Lacosamide	Oral Solution	10 mg/mL	Vimpat 22255	10/29/2012
Lacosamide	Tablets	50 mg, 100 mg, 150 mg, and 200 mg	Vimpat 22253	10/29/2012
Lacosamide	Injection	10 mg/mL, 20 mL	Vimpat 22254	6/30/2016
Lactulose	Oral Syrup	10 g/15 mL	Cephulac 17657	

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Lactulose	Oral Syrup	10 g/15 mL	Chronulac 17884	
Lamivudine*	Tablets	100 mg	Epivir-HBV	10/31/2007
Lamivudine	Tablets	150 mg and 300 mg	Epivir	10/16/2007
Lamivudine and Zidovudine	Tablets	150 mg/300 mg	Combivir	6/26/2007
Lamivudine	Oral Solution	10 mg/mL	Epivir	11/22/2011
Lamotrigine	Tablets	25 mg, 100 mg, 150 mg and 200 mg	Lamictal 20241	
Lamotrigine	Chewable Tablets	2 mg, 5 mg and 25 mg	Lamictal CD 20764	
Lamotrigine	Orally Disintegrating Tablets	25 mg, 50 mg, 100 mg, and 200 mg	Lamictal ODT 22251	12/21/2009
Lamotrigine	Extended-release Tablets	25 mg, 50 mg, 100 mg, 200 mg, 250 mg, and 300 mg	Lamictal XR 22115	2/12/2014
Lansoprazole	Delayed-release Pellets/Capsules	15 mg and 30 mg	Prevacid 20406	12/05/2005
Lansoprazole	Delayed-release Orally Disintegrating Tablets	15 mg and 30 mg	Prevacid 21428	12/27/2006
Lanthanum Carbonate	Chewable Tablet	500 mg, 750 mg and 1000 mg	Fosrenol 21468	10/27/2008
Lanthanum Carbonate	Oral Powder	750 mg and 1000 mg	Fosrenol 204734	11/25/2015
Lapatinib Ditosylate	Tablets	250 mg	Tykerb 22059	3/14/2011
Latanoprost	Ophthalmic Solution	0.005%	Xalatan 20597	
Lenalidomide	Capsules	5 mg, 10 mg and 15 mg	Revlimid 21880	8/30/2010
Lenalidomide	Capsules	25 mg	Revlimid 21880	7/12/2010
Lenalidomide	Capsules	2.5 mg and 20 mg	Revlimid 21880	7/12/2016
Letrozole	Tablets	2.5 mg	Femara 20726	3/2/2006
Leuprolide Acetate	Injection (depot)	7.5 mg/vial	Lupron Depot 19732	

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Levalbuterol Hydrochloride	Inhalation Solution	0.0103%, 0.021% and 0.042%	Xopenex 20837	6/20/2005
Levalbuterol Hydrochloride	Inhalation Solution	0.25%	Xopenex 20837	5/23/2006
Levalbuterol Tartrate*	Inhalation Aerosol	0.045 mg/actuation	Xopenex HFA 21730	2/27/2012
Levetiracetam	Tablets	250 mg, 500 mg and 750 mg	Keppra 21035	
Levetiracetam	Tablets	1000 mg	Keppra 21035	1/24/2007
Levetiracetam	Extended-release Tablets	500 mg and 750 mg	Keppra XR 22285	1/7/2011
Levetiracetam*	Extended-release Tablets	1000 mg	Keppra XR 22285	1/7/2011
Levocetirizine Dihydrochloride	Oral Solution	0.5 mg/mL	Xyzal 22157	1/14/2009
Levocetirizine Dihydrochloride New	Oral Solution	0.5 mg/mL	Xyzal Allergy 24 HR (OTC) 209090	1/4/2018
Levocetirizine Dihydrochloride	Tablets	5 mg	Xyzal 22064	12/17/2007
Levofloxacin	Injection	5 mg/mL; 50 mL, 100 mL and 150 mL vials	Levaquin in Dextrose 5% in Plastic Container 20635	
Levofloxacin	Injection	25 mg/mL	Levaquin 20635	
Levofloxacin	Ophthalmic Solution	0.5%	Quixin 21199	
Levofloxacin	Oral Solution	25 mg/mL	Levaquin 21721	7/30/2009
Levofloxacin	Tablets	250 mg, 500 mg and 750 mg	Levaquin 20634	
Levoleucovorin Calcium	Injection	10 mg/mL, 17.5 mL vial and 25 mL vial	Fusilev 20140	10/26/2011
Levoleucovorin Calcium	Injection	50 mg/vial	Fusilev 20140	12/19/2013
Levomilnacipran	Extended-release Capsules	20 mg, 40 mg, 80 mg and 120 mg	Fetzima 204168	7/25/2017
Levonorgestrel and Ethinyl Estradiol	Tablets	0.09 mg/0.02 mg	Lybrel 21864	10/5/2007

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Levonorgestrel and Ethinyl Estradiol	Tablets	0.15 mg/0.03 mg	Seasonale 21544	3/29/2004
Levonorgestrel; Ethinyl Estradiol; Ethinyl Estradiol	Tablets	0.1 mg/0.02 mg and 0.01 mg	LoSeasonique 22262	11/16/2009
Levonorgestrel; Ethinyl Estradiol; Ethinyl Estradiol	Tablets	0.15 mg/0.03 mg/0.01 mg	Seasonique 21840	1/22/2008
Levonorgestrel; Ethinyl Estradiol; Ethinyl Estradiol	Tablets	0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg	Quartette 204061	7/10/2013
Levothyroxine Sodium	Tablets	0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.1 mg, 0.112 mg, 0.125 mg, 0.150 mg, 0.175 mg, 0.2 mg and 0.3 mg	Levoxyl 21301	
Levothyroxine Sodium	for Injection	100 mcg/vial and 500 mcg/vial	Levothyroxine Sodium 202231	4/14/2015
Levothyroxine Sodium	for Injection	200 mcg/vial	Levothyroxine Sodium 202231	5/1/2015
Levothyroxine Sodium	Capsules	75 mcg and 150 mcg	Tirosint 21924	12/29/2017
Lidocaine	Topical Patch	5%	Lidoderm 20612	11/13/2009
Linaclotide	Capsules	145 mcg and 290 mcg	Linzess 202811	8/30/2016
Linaclotide	Capsules	72 mcg	Linzess 202811	11/7/2017
Linagliptin	Tablets	5 mg	Tradjenta 201280	5/4/2015
Linagliptin and Metformin Hydrochloride	Tablets	2.5 mg/500 mg 2.5 mg/850 mg 2.5 mg/1000 mg	Jentadueto 201281	5/4/2015
Linagliptin and Metformin Hydrochloride	Extended-release Tablets	2.5 mg/1000 mg 5 mg/1000 mg	Jentadueto XR 208026	3/28/2018

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Linezolid	Injection	2 mg/mL, 100 mL bag	Zyvox 21131	12/29/2009
Linezolid	Injection	2 mg/mL, 300 mL bag	Zyvox 21131	9/1/2009
Linezolid	Oral Suspension	100 mg/5 mL	Zyvox 21132	8/3/2009
Linezolid	Tablets	600 mg	Zyvox 21130	12/21/2005
Liraglutide	Injection	18 mg/3 mL prefilled syringe	Victoza 22341	12/12/2016
Lisdexamfetamine Dimesylate	Capsules	20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg	Vyvanse 21977	2/23/2011
Loperamide Hydrochloride and Simethicone	Chewable Tablets	2 mg/125 mg	Imodium Multi-Symptom Relief 20606	
Loperamide Hydrochloride and Simethicone	Tablets	2 mg/125 mg	Imodium Multi-Symptom Relief 21140	12/29/2004
Lopinavir and Ritonavir	Tablets	100 mg/25 mg and 200 mg/50 mg	Kaletra 21906	12/23/2008
Lopinavir and Ritonavir	Oral Solution	80 mg/20 mg per mL	Kaletra 21251	6/19/2014
Loratadine	Syrup	1 mg/mL	Claritin 20641	
Loratadine	Tablets	10 mg	Claritin 19658	
Loratadine	Orally Disintegrating Tablets	10 mg	Claritin RediTabs 20704	
Loratadine/ Pseudoephedrine	Extended-release Tablets	5 mg/120 mg	Claritin D-12 hour 19670	
Loratadine/ Pseudoephedrine	Extended-release Tablets	10 mg/240 mg	Claritin D-24 hour 20470	
Lorcaserin Hydrochloride	Extended-release Tablets	20 mg	Belviq XR 208524	12/13/2016
Lorcaserin Hydrochloride	Tablets	10 mg	Belviq 22529	6/27/2016

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Losartan Potassium	Tablets	25 mg, 50 mg, and 100 mg	Cozaar 20386	
Losartan Potassium and Hydrochlorothiazide	Tablets	50 mg/12.5 mg and 100 mg/25 mg	Hyzaar 20387	5/24/2004
Losartan Potassium and Hydrochlorothiazide	Tablets	100 mg/12.5 mg	Hyzaar 20387	4/4/2006
Lovastatin and Niacin	Extended-release Tablets	20 mg/500 mg	Advicor	9/22/2008
Lovastatin and Niacin	Extended-release Tablets	20 mg/750 mg	Advicor	12/17/2008
Lovastatin and Niacin	Extended-release Tablets	20 mg/1000 mg	Advicor	5/22/2008
Lovastatin and Niacin	Extended-release Tablets	40 mg/1000 mg	Advicor	11/19/2009
Lubiprostone	Capsules	8 mcg and 24 mcg	Amitiza 21908	8/20/2012
Lurasidone Hydrochloride	Tablets	20 mg, 40 mg, 60 mg, 80 mg, and 120 mg	Latuda 200603	10/28/2014
Macitentan	Tablets	10 mg	Opsumit 204410	10/18/2017
Malathion	Topical Lotion	0.50%	Ovide	3/16/2011
Maraviroc	Tablets	150 mg and 300 mg	Selzentry	8/8/2011
Mefloquine Hydrochloride	Tablets	250 mg	Lariam	
Megestrol Acetate	Oral Suspension	40 mg/mL	Megace	
Megestrol Acetate	Oral Suspension	125 mg/mL	Megace ES	4/27/2011
Meloxicam *	Oral Suspension	7.5 mg/5 mL	Mobic	12/17/2009
Meloxicam	Capsules	5 mg and 10 mg	Vivlodex	1/9/2017
Melphalan Hydrochloride	Injection	50 mg/vial	Evomela	9/8/2017
Memantine Hydrochloride	Tablets	5 mg and 10 mg	Namenda	10/16/2007
Memantine Hydrochloride	Extended-release Capsules	7 mg, 14 mg, 21 mg, and 28 mg	Namenda XR	6/10/2013

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Memantine Hydrochloride Extended-release and Donepezil Hydrochloride	Capsules	14 mg/10 mg and 28 mg/10 mg	Namzaric	5/18/2015
Memantine Hydrochloride Extended-release and Donepezil Hydrochloride	Capsules	21 mg/10 mg	Namzaric	9/23/2016
Memantine Hydrochloride Extended-release and Donepezil Hydrochloride	Capsules	7 mg/10 mg	Namzaric	9/26/2016
Mesalamine*	Delayed-release Tablets	400 mg	Asacol	6/22/2007
Mesalamine	Delayed-release Tablets	800 mg	Asacol HD	7/13/2011
Mesalamine	Delayed-release Tablets	1.2 g	Lialda	12/16/2009
Mesalamine	Extended-release Capsules	0.375 g	Apriso	4/3/2012
Mesalamine	Suppository	1000 mg	Canasa	5/24/2013
Mesalamine	Delayed-release Capsules	400 mg	Delzicol	6/17/2014
Metaxalone	Tablets	400 mg	Skelaxin	
Metaxalone	Tablets	800 mg	Skelaxin	11/4/2004
Metformin Hydrochloride	Extended-release Tablets	500 mg	Glucophage XR	
Metformin Hydrochloride	Extended-release Tablets	750 mg	Glucophage XR	
Metformin Hydrochloride	Extended-release Tablets	500 mg and 1000 mg	Fortamet	10/14/2008
Metformin Hydrochloride	Extended-release Tablets	500 mg and 1000 mg	Glumetza	7/27/2009
Metformin Hydrochloride	Oral Solution	500 mg/5 mL	Riomet 21591	2/2/2018
Methylnaltrexone Bromide	Injection	12 mg/0.6 mL	Relistor	7/22/2015
Methylnaltrexone Bromide	Injection	8 mg/0.4 mL	Relistor	9/8/2015
Methylnaltrexone Bromide	Tablets	150 mg	Relistor	9/6/2016

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Methylphenidate Hydrochloride*	Extended-release Capsules	10 mg	Ritalin LA	5/21/2007
Methylphenidate Hydrochloride	Extended-release Capsules	10 mg, 20 mg and 30 mg	Metadate CD	5/13/2005
Methylphenidate Hydrochloride	Extended-release Capsules	20 mg, 30 mg and 40 mg	Ritalin LA	8/21/06
Methylphenidate Hydrochloride	Extended-release Capsules	40 mg	Metadate CD	3/15/2007
Methylphenidate Hydrochloride	Extended-release Chewable Tablets	20 mg, 30 mg and 40 mg	Quillchew ER	4/25/2016
Methylphenidate Hydrochloride	Extended-release Tablets	18 mg*, 27 mg, 36 mg and 54 mg	Concerta	7/19/2005
Methylphenidate Hydrochloride	Oral Solution	5 mg/5 mL 10 mg/5 mL	Methylin	4/13/2010
Methylphenidate	Transdermal System	10 mg/9 hrs 15 mg/9 hrs 20 mg/9 hrs 30 mg/9 hrs	Daytrana	4/13/2011
Methylphenidate Hydrochloride	Extended-release Oral Suspension	5 mg/mL	Quillivant XR	8/2/2013
Methylphenidate Hydrochloride	Extended-release Capsules	60 mg	Aptensio XR	12/23/2015
Methylphenidate Hydrochloride	Extended-release Capsules	10 mg	Aptensio XR	12/24/2015
Methylphenidate Hydrochloride	Extended-release Capsules	15 mg, 20 mg, 40 mg and 50 mg	Aptensio XR	12/28/2015
Methylphenidate Hydrochloride	Extended-release Capsules	30 mg	Aptensio XR	3/28/2016
Methylphenidate	Extended-release Orally Disintegrating Tablets	8.6 mg, 17.3 mg and 25.9 mg	Cotempla XR-ODT	9/1/2017
Metoclopramide Hydrochloride	Injection	5 mg/mL, 2 mL, 10 mL, 20 mL and 30 mL vials	Reglan	
Metoclopramide Hydrochloride	Orally Disintegrating Tablets	5 mg and 10 mg	Metozolv ODT	8/24/2010
Metoprolol Succinate	Extended-release Tablets	25 mg, 50 mg, 100 mg and 200 mg	Toprol XL	

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Metronidazole	Vaginal Gel	0.75%	MetroGel-Vaginal	9/2/2004
Metronidazole	Topical Gel	1%	Metrogel	10/21/2008
Micafungin Sodium	For Injection	50 mg/vial 100 mg/vial	Mycamine	6/16/2014
Miconazole Nitrate	Vaginal Cream and Suppository	2% and 1.2 g	Monistat 1 Combination Pack	12/5/2007
Mifepristone	Tablets	300 mg	Korlym 202107	12/15/2017
Milnacipran Hydrochloride	Tablets	12.5 mg, 25 mg, 50 mg, and 100 mg	Savella	1/14/2013
Minocycline Hydrochloride	Extended-release Tablet	45 mg, 90 mg and 135 mg	Solodyn	PIV received prior to 2/5/2009
Minocycline Hydrochloride	Extended-release Tablet	55 mg	Solodyn	12/2/2010
Minocycline Hydrochloride	Extended-release Tablet	65 mg and 115 mg	Solodyn	11/19/2009
Minocycline Hydrochloride	Extended-release Tablet	80 mg	Solodyn	10/27/2010
Minocycline Hydrochloride	Extended-release Tablet	105 mg	Solodyn	12/13/2010
Minoxidil	Topical Aerosol Foam	5%	Men's Rogaine	4/6/2009
Mirabegron	Extended-release Tablets	25 mg and 50 mg	Myrbetriq	6/28/2016
Mirtazapine	Tablets	7.5 mg, 15 mg, 30 mg, and 45 mg	Remeron	
Mirtazapine	Orally Disintegrating Tablets	15 mg, 30 mg and 45 mg	Remeron SolTab	
Modafinil	Tablets	100 mg and 200 mg	Provigil	
Moexipril Hydrochloride	Tablets	7.5 mg and 15 mg	Univasc	
Moexipril Hydrochloride and Hydrochlorothiazide	Tablets	7.5mg/12.5mg, 15 mg/25 mg and 15 mg/12.5 mg	Uniretic	1/15/2004
Mometasone Furoate	Nasal Spray	50 mcg/ Spray	Nasonex	8/7/2009
Mometasone Furoate	Topical Solution (Cream)	0.1%	Elocon	
Mometasone Furoate	Topical Solution (Lotion)	0.1%	Elocon	6/10/2004

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Montelukast	Tablets	10 mg	Singulair	2/20/2007
Montelukast Sodium	Chewable Tablets	4 mg and 5 mg	Singulair	12/26/2006
Montelukast Sodium	Oral Granules	4 mg	Singular Granules	10/17/2008
Morphine Sulfate	Extended-release Capsules	30 mg, 60 mg, 90 mg and 120 mg	Avinza	6/4/2007
Morphine Sulfate*	Extended-release Capsules	45 mg and 75 mg	Avinza	7/30/2009
Morphine Sulfate	Extended-release Tablets	15 mg, 30 mg and 60 mg	Arymo ER 208603	12/29/2017
Morphine Sulfate and Naltrexone Hydrochloride	Extended-release Capsules	100 mg/4 mg	Embeda	5/3/2010
Morphine Sulfate and Naltrexone Hydrochloride	Extended-release Capsules	60 mg/2.4 mg	Embeda	5/25/2010
Morphine Sulfate and Naltrexone Hydrochloride	Extended-release Capsules	30 mg/1.2 mg 50 mg/2 mg 80 mg/3.2 mg	Embeda	5/28/2010
Moxifloxacin Hydrochloride*	Ophthalmic Solution/Drops	0.5%	Vigamox	12/22/2005
Moxifloxacin Hydrochloride	Ophthalmic Solution	0.5%	Moxeza	2/29/2012
Moxifloxacin Hydrochloride	Tablets	400 mg	Avelox	
Moxifloxacin Hydrochloride	Injection	1.6 mg/mL	Avelox in Sodium Chloride 0.8% in plastic container	2/7/2014
Mycophenolic Acid	Delayed-release Tablets	180 mg	Myfortic	6/3/2009
Mycophenolic Acid	Delayed-release Tablets	360 mg	Myfortic	2/2/2009
Mycophenolic Mofetil	For Oral Suspension	200 mg/mL	Cellcept	3/25/2011
Nabumetone	Tablets	500 mg and 750 mg	Relafen	
Naftifine Hydrochloride	Gel	2%	Naftin Gel	2/27/2015
Naloxone Hydrochloride	Nasal Spray	2 mg/spray	Narcan 208411	12/28/2017
Naloxone Hydrochloride	Nasal Spray	4 mg/spray	Narcan 208411	7/15/2016

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Naltrexone Hydrochloride and Bupropion Hydrochloride	Extended-release Tablets	8 mg/90 mg	Contrave	3/12/2015
Naproxen Sodium	Extended-release Tablets	375 mg (base) and 500 mg (base)	Naprelan	
Naproxen Sodium	Capsules	200 mg	Naproxen Sodium 21920	11/15/2017
Naproxen and Esomeprazole Magnesium	Delayed-release Tablets	375 mg/20 mg and 500 mg/20 mg	Vimovo	11/5/2010
Naproxen Sodium and Sumatriptan Succinate *	Tablets	500 mg/85 mg	Treximet	7/23/2008
Nateglinide	Tablets	60 mg and 120 mg	Starlix	12/22/2004
Nebivolol Hydrochloride	Tablets	2.5 mg, 5 mg, 10 mg, and 20 mg	Bystolic	12/19/2011
Nebivolol Hydrochloride and Valsartan	Tablets	5 mg/80 mg	Byvalson	6/9/2017
Nefazodone Hydrochloride	Tablets	50 mg, 100 mg, 150 mg, 200 mg and 250 mg	Serzone	
Nepafenac	Ophthalmic Suspension	0.3%	Ilevro	12/21/2015
Nevirapine	Extended-release Tablets	400 mg	Viramune XR	6/21/2013
Niacin	Extended-release Tablets	500 mg, 750 mg and 1000 mg	Niaspan	
Niacin and Simvastatin	Extended-release Tablets	500 mg/20 mg	Simcor	2/12/2010
Niacin and Simvastatin	Extended-release Tablets	750 mg/20 mg	Simcor	2/17/2010
Niacin and Simvastatin	Extended-release Tablets	1000 mg/20 mg	Simcor	9/17/2009
Niacin and Simvastatin	Extended-release Tablets	1000 mg/40 mg	Simcor	2/4/2011
Niacin and Simvastatin	Extended-release Tablets	500 mg/40 mg	Simcor	2/9/2011
Nicardipine Hydrochloride	Injection	2.5 mg/mL, 10 mL Ampoules	Cardene	12/27/2006

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Nicardipine Hydrochloride	Injection	0.1 mg/mL, 200 mL 0.2mg/mL, 200 mL	Cardene in 0.86% Sodium Chloride in plastic container and Cardene 0.83% Sodium Chloride in plastic container	1/9/2013
Nicotine	Transdermal System	7 mg/day, 14 mg/day 21 mg/day	Habitrol	
Nicotine	Transdermal System	7 mg/24 hrs 14 mg/24 hrs 21 mg/24 hrs	Nicoderm CQ	5/30/2014
Nicotine Polacrilex	Troche/Lozenge	2 mg and 4 mg	Commit	
Nicotine Polacrilex	Troche/Lozenge (Mini)	2 mg and 4 mg	Nicorette	12/2/2015
Nicotine Polacrilex	Gum	2 mg	Nicorette	1/22/2013
Nicotine Polacrilex	Gum	4 mg	Nicorette	1/22/2013
Nifedipine	Capsules	10 mg and 20 mg	Procardia	
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Adalat CC	
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Procardia XL	
Nilotinib	Capsules	150 mg and 200 mg	Tasigna	11/8/2013
Nitric Oxide	for Inhalation	100 ppm and 800 ppm	INOmax	5/20/2014
Nisoldipine	Extended-release Tablets	8.5 mg and 17 mg	Sular	3/2/2009
Nisoldipine	Extended-release Tablets	20 mg and 30 mg	Sular	11/7/2007
Nisoldipine	Extended-release Tablets	25.5 mg and 34 mg	Sular	11/28/2008
Nisoldipine	Extended-release Tablets	40 mg	Sular	6/11/2007
Nitrofurantoin Monohydrate/ Macrocrystals	Capsules	75 mg/25 mg	Macrobid	
Nitroglycerin*	Sublingual Tablets	0.3 mg, 0.4 mg, and 0.6 mg	Nitrostat	10/19/2005

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Nitroglycerin	Transdermal System	0.1 mg/hr	Transderm-Nitro	
Nitroglycerin	Transdermal System	1.1 mg/hr 1.2 mg/hr 1.3 mg/hr 1.4 mg/hr 0.6 mg/hr 0.8 mg/hr	Nitro-dur	
Nitroglycerin	Sublingual Spray	400 mcg/spray, 4.9 g and 12 g bottles	Nitrolingual Pumpspray	4/17/2012
Nizatidine	Capsules	150 mg and 300 mg	Axid	
Nizatidine	Oral Solution	15 mg/mL	Axid	5/14/2008
Norelgestromin and Ethinyl Estradiol*	Transdermal System	0.15 mg/0.02 mg per 24 hours	Ortho Evra	3/22/2007
Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/0.005 mg	Femhrt	
Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/ 0.02 mg 1 mg/0.03 mg 1 mg /0.035 mg	Estrostep Fe	
Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/0.02 mg 1 mg/ 0.03 mg and 1 mg /0.035 mg	Estrostep 21	
Norethindrone Acetate/ Ethinyl Estradiol and Ferrous Fumarate	Tablets	1 mg/0.02 mg and 75 mg	Loestrin 24 Fe	4/17/2006
Norethindrone Acetate and Ethinyl Estradiol / Ethinyl Estradiol and Ferrous Fumarate	Tablets	1 mg/0.01 mg, 0.01 mg and 75 mg	Lo Loestrin Fe	4/29/2011
Norethindrone and Ethinyl Estradiol and Ferrous Fumarate	Chewable Tablets	0.4 mg/0.035 mg	Ovcon-35 Fe Femcon Fe NDA 21-490	4/27/2007
Norethindrone and Ethinyl Estradiol and Ferrous Fumarate	Chewable Tablets	0.8 mg/0.025 mg and 75 mg	Generess Fe	8/5/2011
Norethindrone Acetate and Ethinyl Estradiol and Ferrous Fumarate	Chewable Tablets	1 mg/0.02 mg and 75 mg	Minastrin 24 Fe	4/23/2014
Norethindrone/ Ethinyl Estradiol	Tablets	0.5 mg/ 0.035 mg, 0.75 mg/ 0.035 mg and 1 mg /0.035 mg	Ortho-Novum 7/7/7, 21 and 28 day	

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Norgestimate/ Ethinyl Estradiol	Tablets	0.18 mg /0.025 mg, 0.215 mg /0.025 mg and 0.25 mg /0.025 mg	Ortho Tri- Cyclen Lo, 28 day	
Norgestimate/ Ethinyl Estradiol	Tablets	0.18 mg /0.035 mg, 0.215 mg /0.035 mg and 0.25 mg /0.035 mg	Ortho Tri- Cyclen, 21 and 28 day	
Nortriptyline Hydrochloride	Capsules	10 mg, 25 mg, 50 mg and 75 mg	Pamelor	
Octreotide Acetate	Injection	0.05 mg /mL, 0.1 mg /mL and 0.5 mg/mL, 1 mL vials	Sandostatin (Preservative- free)	
Octreotide Acetate	Injection	0.2 mg/mL and 1 mg /mL, 5 mL vials	Sandostatin	
Octreotide Acetate	Injection	0.05 mg/mL (base), 0.1 mg/mL (base) and 0.5 mg/mL (base) packaged in 1 mL pre-filled syringes (preservative-free)	Octreotide Acetate Injection	1/17/2008
Ofloxacin	Otic Solution	0.3%	Floxin	
Olanzapine	Tablets	2.5 mg, 5 mg, 7.5 mg, 10 mg and 15 mg	Zyprexa	
Olanzapine	Tablets	20 mg	Zyprexa	
Olanzapine	Orally Disintegrating Tablets	5 mg, 10 mg, 15 mg and 20 mg	Zyprexa Zydis	
Olanzapine and Fluoxetine Hydrochloride	Capsules	6 mg/25 mg 12 mg/25 mg 6 mg/50 mg 12 mg/50 mg	Symbyax	1/10/2005
Olmesartan Medoxomil	Tablets	5 mg, 20 mg and 40 mg	Benicar	4/25/2006
Olmesartan Medoxomil and Hydrochlorothiazide	Tablets	20 mg/12.5 mg	Benicar HCT	5/11/2007
Olmesartan Medoxomil and Hydrochlorothiazide	Tablets	40 mg/12.5 mg and 40 mg/25 mg	Benicar HCT	2/15/2007

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Olopatadine Hydrochloride	Nasal Spray	0.665 mg/ Spray	Patanase	6/29/2009
Olopatadine Hydrochloride	Ophthalmic Solution	0.1%	Patanol	7/17/2006
Olopatadine Hydrochloride	Ophthalmic Solution	0.2%	Pataday	9/8/2008
Olopatadine Hydrochloride	Ophthalmic Solution	0.7%	Pazeo	9/10/2015
Omacetaxine Mepesuccinate	for Injection	3.5 mg/vial	Synribo	10/26/2016
Omega-3-Acid Ethyl Esters	Capsules	1 g	Lovaza	11/10/2008
Omeprazole	Delayed-release Capsules	10 mg, 20 mg and 40 mg	Prilosec	
Omeprazole and Sodium Bicarbonate	Capsules	20 mg/1100 mg and 40 mg/1100 mg	Zegerid	4/30/2007
Omeprazole and Sodium Bicarbonate	Capsules	20 mg/1100 mg	Zegerid OTC	4/20/2010
Omeprazole and Sodium Bicarbonate	Powder for Oral Suspension	20mg/1680mg per packet	Zegerid	11/13/2007
Omeprazole and Sodium Bicarbonate	Powder for Oral Suspension	40 mg/1680 mg per packet	Zegerid	8/24/2007
Omeprazole Magnesium	Delayed-release Capsules	20 mg	Prilosec OTC	3/19/2007
Omeprazole Magnesium	Delayed-release Tablets	20 mg	Prilosec OTC	3/30/2012
Omeprazole	Delayed-release Tablets	20 mg	Omeprazole	6/3/2015
Ondansetron Hydrochloride	Injection	2 mg/mL, 2 mL vials (Preservative-free)	Zofran	
Ondansetron Hydrochloride	Injection	2 mg/mL, 20 mL vials	Zofran	
Ondansetron Hydrochloride	Injection	0.64 mg/mL, 50 mL container (plastic)	Zofran in Plastic Container	
Ondansetron Hydrochloride	Oral Solution	4 mg/5 mL	Zofran	12/20/2004
Ondansetron Hydrochloride	Orally Disintegrating Tablets	4 mg and 8 mg	Zofran ODT	
Ondansetron Hydrochloride	Tablets	4 mg, 8 mg, 16 mg and 24 mg	Zofran	
Orlistat	Capsules	60 mg	Alli	9/8/2010

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Osetamivir Phosphate	Capsules	30 mg and 45 mg	Tamiflu	8/2/2011
Osetamivir Phosphate	Capsules	75 mg	Tamiflu	11/15/2010
Osetamivir Phosphate	for Oral Suspension	6 mg/mL	Tamiflu	6/18/2015
Oxaliplatin	For Injection	50 mg/vial and 100 mg/vial	Eloxatin	2/9/2007
Oxaliplatin	Injection	5 mg/mL, 10 mL and 20 mL vials	Eloxatin	2/9/2007
Oxaliplatin *	Injection	5 mg/mL, 40 mL vials	Eloxatin	7/16/2007
Oxandrolone	Tablets	2.5 mg and 10 mg	Oxandrin	6/19/2006
Oxazepam	Capsules	10 mg, 15 mg and 30 mg	Serax	
Oxcarbazepine	Tablets	150 mg, 300 mg and 600 mg	Trileptal	5/5/2006
Oxcarbazepine	Oral Suspension	300 mg/5 mL	Trileptal	12/26/2006
Oxcarbazepine*	Extended-release Tablets	600 mg	Oxtellar XR	3/20/2013
Oxcarbazepine*	Extended-release Tablets	150 mg and 300 mg	Oxtellar XR	4/12/2013
Oxybutynin	Transdermal System Extended-release	3.9 mg/24 hrs	Oxytrol	8/19/2008
Oxybutynin Chloride	Extended-release Tablets	5 mg, 10 mg and 15 mg	Ditropan XL	
Oxybutynin Chloride	Gel	10%	Gelnique	6/19/2014
Oxycodone	Extended-release Tablets	10 mg, 20 mg, 40 mg, 80 mg and 160 mg	Oxycontin (NDA 020553)	
Oxycodone Hydrochloride	Extended-release Tablets	15 mg	Oxycontin (NDA 020553)	2/15/2007
Oxycodone Hydrochloride	Extended-release Tablets	30 mg and 60 mg	Oxycontin (NDA 020553)	1/3/2007
Oxycodone Hydrochloride	Extended-release Tablets	10 mg	Oxycontin (NDA 022272)	10/25/2010
Oxycodone Hydrochloride	Extended-release Tablets	15 mg	Oxycontin (NDA 022272)	10/28/2010
Oxycodone Hydrochloride	Extended-release Tablets	20 mg	Oxycontin (NDA 022272)	10/29/2010

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Oxycodone Hydrochloride*	Extended-release Tablets	30 mg, 60 mg and 80 mg	Oxycontin (NDA 022272)	10/18/2010
Oxycodone Hydrochloride	Extended-release Tablets	40 mg	Oxycontin (NDA 022272)	10/4/2010
Oxycodone Hydrochloride	Tablets	5 mg and 7.5 mg	Oxecta	2/7/2012
Oxycodone	Extended-release Capsules	9 mg, 13.5 mg, 18 mg, 27 mg and 36 mg	Xtampza ER 208090	11/15/2017
Oxycodone Hydrochloride and Acetaminophen	Extended-release Tablets	7.5 mg/325 mg	Xartemis XR	4/3/2014
Oxymorphone Hydrochloride	Extended-release Tablets	5 mg, 10 mg, 20 mg and 40 mg	Opana ER	11/23/2007
Oxymorphone Hydrochloride	Extended-release Tablets	7.5 mg and 15 mg	Opana ER	5/29/2008
Oxymorphone Hydrochloride	Extended-release Tablets	30 mg	Opana ER	6/12/2008
Oxymorphone Hydrochloride*	Extended-release Tablets	7.5 mg, 10 mg, and 15 mg	Opana ER (NDA 201655)	3/23/2012
Oxymorphone Hydrochloride	Extended-release Tablets	5 mg	Opana ER (NDA 201655)	3/26/2012
Oxymorphone Hydrochloride	Extended-release Tablets	20 mg, 30 mg and 40 mg	Opana ER (NDA 201655)	4/3/2012
Paclitaxel	Injection	6 mg/mL, 5 mL, 16.7 mL, 25 mL, 33.3 mL and 50 mL vials	Taxol	
Paclitaxel Protein-Bound Particles	For Injection Suspension	100 mg/vial	Abraxane	12/11/2015
Paliperidone Palmitate	Extended-release Injectable Suspension	39 mg/0.25 mL, 78 mg/0.5 mL, 117 mg/0.75 mL, 156 mg/mL and 234 mg/1.5 mL	Invega Sustenna 22264	11/21/2017
Palonosetron Hydrochloride	Injection	0.05 mg/mL, 1.5 mL and 5 mL vials	Aloxi	5/27/2011
Pamidronate Disodium	For Injection	30 mg/vial 60 mg/vial 90 mg/vial	Aredia	

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Pamidronate Disodium	Injection	30 mg/vial 60 mg/vial 90 mg/vial	Aredia	
Pantoprazole Sodium	For Injection	40 mg/vial	Prontonix IV	4/7/2005
Pantoprazole Sodium	Delayed-release Tablets	20 mg and 40 mg	Protonix	2/2/2004
Paricalcitol*	Injection	0.002 mg per mL in 1 mL vial and 0.005 mg per mL in 1 mL and 2 mL vials	Zemplar	11/28/2008
Paricalcitol	Capsules	1 mcg and 2 mcg	Zemplar	10/14/2008
Paricalcitol	Capsules	4 mcg	Zemplar	8/25/2008
Paroxetine Hydrochloride	Capsules	10 mg and 20 mg	Paxil	
Paroxetine Hydrochloride	Oral Suspension	10 mg/5 mL	Paxil	2/10/2005
Paroxetine Hydrochloride	Tablets	10 mg, 20 mg, 30 mg and 40 mg	Paxil	
Paroxetine Hydrochloride	Extended-release Tablets	25 mg	Paxil CR	9/9/2005
Paroxetine Hydrochloride	Extended-release Tablets	37.5 mg	Paxil CR	5/19/2009
Paroxetine	Capsules	7.5 mg	Brisdelle	4/7/2014
Pemetrexed Disodium *	For Injection	100 mg/vial	Alimta	7/1/2008
Pemetrexed Disodium *	For Injection	500 mg/vial	Alimta	2/4/2008
Pemetrexed Disodium *	For Injection	1000 mg/vial	Alimta	6/27/2012
Pemetrexed Disodium	For Injection	750 mg/vial	Alimta	10/6/2016
Perampanel	Tablets	2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg	Fycompa	10/24/2016
Pergolide Mesylate	Tablets	0.05 mg, 0.25 mg and 1 mg	Permax	
Perindopril Arginine and Amlodipine	Tablets	3.5 mg/2.5 mg, 7 mg/5 mg and 14 mg/10 mg	Prestalia	11/4/2016
Perindopril Erbumine	Tablets	2 mg, 4 mg and 8 mg	Aceon	6/6/2006

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Phentermine Hydrochloride	Orally Disintegrating Tablets	15 mg and 30 mg	Suprenza	10/19/2012
Phentermine Hydrochloride	Orally Disintegrating Tablets	37.5 mg	Suprenza	3/22/2013
Phentermine Hydrochloride and Topiramate	Extended-release Capsules	3.75 mg/23 mg 7.5 mg/46 mg 11.25 mg/69 mg 15 mg/92 mg	Qsymia	7/18/2013
Phenylephrine and Ketorolac	Injection	1%/0.3%	Omidria	5/29/2015
Pioglitazone Hydrochloride	Tablets	15 mg, 30 mg and 45 mg	Actos	
Pioglitazone Hydrochloride and Glimepiride	Tablets	30 mg/2 mg and 30 mg/4 mg	Duetact	12/22/2009
Pioglitazone Hydrochloride and Metformin Hydrochloride	Extended-release Tablets	15 mg/1000 mg and 30 mg/1000 mg	Actoplus Met XR	9/23/2011
Pioglitazone Hydrochloride and Metformin Hydrochloride	Tablets	15 mg/500 mg and 15 mg/850 mg	Actoplus Met	3/6/2008
Piperacillin Sodium and Tazobactam Sodium	For Injection	2.25 g/vial 3.375 g/vial 4.5 g/vial	Zosyn	PIV received prior to 2/5/2009
Piperacillin Sodium and Tazobactam Sodium	For Injection	12 g/1.5 g per vial (pharmacy bulk)	Zosyn	12/6/2011
Pitavastatin Calcium	Tablets	1 mg, 2 mg, and 4 mg	Livalo	8/5/2013
Plerixafor	Injection	24 mg/1.2 mL vials (20 mg/mL)	Mozobil	12/17/2012
Polyethylene Glycol 3350	Powder for Oral Solution	17g/Scoopful	Miralax	
Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride and Bisacodyl	For Oral Solution and Delayed-release Tablet	210 g, 5.6 g, 0.74 g, 2.86 g and 5 mg (1 Tablet Regimen)	Halflytely and Bisacodyl	7/30/2010
Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate, Potassium Chloride and Bisacodyl	For Oral Solution and Delayed-release Tablets	210 g, 5.6 g, 0.74 g, 2.86 g and 5 mg (2 Tablet Regimen)	Halflytely and Bisacodyl	1/28/2008

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Polyethylene Glycol 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate and Ascorbic Acid	For Oral Solution	100 g, 7.5 g, 2.691 g, 1.015 g, 5.9 g and 4.7 g per pouch	Moviprep	11/27/2007
Pomalidomide	Capsules	1 mg, 2 mg, 3 mg and 4 mg	Pomalyst	2/8/2017
Posaconazole	Oral Suspension	40 mg/mL	Noxafil	2/28/2011
Posaconazole	Delayed-release Tablets	100 mg	Noxafil	6/16/2014
Posaconazole	Injection	18 mg/mL, 16.7 mL vials	Noxafil 205596	11/24/2015
Potassium Chloride	Extended-release Capsules	8 mEq and 10 mEq	Micro K	
Potassium Chloride	Extended-release Tablets	10 mEq and 20 mEq	K-Dur	
Pralatrexate	Injection	20 mg/mL and 40 mg/2 mL	Folotyn	9/24/2013
Pramipexole Dihydrochloride	Tablets	0.125 mg, 0.5 mg, 1 mg and 1.5 mg	Mirapex	6/24/2005
Pramipexole Dihydrochloride	Tablets	0.25 mg	Mirapex	5/27/2005
Pramipexole Dihydrochloride	Tablets	0.75 mg	Mirapex	7/31/2008
Pramipexole Dihydrochloride	Extended-release Tablets	0.375 mg, 0.75 mg, 1.5 mg, 3 mg and 4.5 mg	Mirapex ER	6/1/2010
Pramipexole Dihydrochloride	Extended-release Tablets	2.25 mg and 3.75 mg	Mirapex ER	7/26/2011
Prasugrel Hydrochloride	Tablets	5 mg and 10 mg	Effient	7/10/2013
Pravastatin Sodium	Tablets	10 mg, 20 mg, 40 mg and 80 mg	Pravachol	
Pravastatin Sodium	Tablets	30 mg	Pravachol	6/1/2005
Prazosin Hydrochloride	Capsules	1 mg, 2 mg and 5 mg	Minipress	

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Prednisolone Sodium Phosphate	Oral Solution	5 mg(base)/ 5 mL and 15 mg (base)/ 5 mL	Pediapred	
Prednisolone Sodium Phosphate	Orally Disintegrating Tablets	10 mg, 15 mg and 30 mg	Orapred	7/22/2010
Prednisone	Delayed-release Tablets	1 mg, 2 mg, and 5 mg	Rayos	11/26/2012
Pregabalin	Capsules	25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg	Lyrica 21446	12/30/2008
Pregablin	Oral Solution	20 mg/mL	Lyrica 22488	5/19/2010
Pregabalin	Extended-release Tablets	330 mg	Lyrica CR 209501	1/29/2018
Pregabalin	Extended-release Tablets	82.5 mg and 165 mg	Lyrica CR 209501	2/2/2018
Propafenone	Extended-release Capsules	325 mg	Rythmol SR	11/07/2006
Propafenone Hydrochloride	Extended-release Capsules	225 mg and 425 mg	Rythmol SR	10/11/2006
Propofol	Injection	10 mg/mL ; 20 mL, 50 mL and 100 mL vials and 20 mL syringe	Diprivan	
Propranolol Hydrochloride	Extended-release Capsules	60 mg, 80 mg, 120 mg and 160 mg	Inderal LA	
Quetiapine Fumarate	Extended-release Tablets	400 mg	Seroquel XR	6/18/2008
Quetiapine Fumarate	Extended-release Tablets	150 mg	Seroquel XR	11/17/2008
Quetiapine Fumarate	Extended-release Tablets	200 mg and 300 mg	Seroquel XR	6/12/2008
Quetiapine Fumarate	Extended-release Tablets	50 mg	Seroquel XR	10/17/2008
Quetiapine Fumarate	Tablets	25 mg	Seroquel	8/12/2005
Quetiapine Fumarate	Tablets	50 mg, 150 mg and 400 mg	Seroquel	2/12/2007

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Quetiapine Fumarate	Tablets	100 mg, 200 mg and 300 mg	Seroquel	2/21/2006
Quinapril Hydrochloride	Tablets	5 mg, 10 mg, 20 mg and 40 mg	Accupril	
Quinapril Hydrochloride/ Hydrochlorothiazide	Tablets	10 mg/12.5 mg 20 mg/12.5 mg 20mg/25 mg	Accuretic	
Rabeprazole Sodium	Delayed-release Tablets	20 mg	Aciphex	
Regadenoson	Injection	0.08 mg/mL, 5 mL vial	Lexiscan	4/10/2012
Raltegravir	Tablets	400 mg	Isentress	10/12/2011
Raloxifene Hydrochloride	Tablets	60 mg	Evista	
Ramelteon	Tablets	8 mg	Rozerem	7/22/2009
Ramipril	Capsules	1.25 mg, 2.5 mg, 5 mg and 10 mg	Altace	
Ranitidine	Capsules	150 mg and 300 mg	Zantac	
Ranitidine	Injection	25 mg/mL, 2 mL and 6 mL and 40 mL vials	Zantac	
Ranitidine	Oral Solution	15 mg/mL	Zantac	
Ranitidine	Tablets	75 mg, 150 mg and 300 mg	Zantac	
Ranitidine Hydrochloride	Tablets	150 mg	Zantac 150 (NDA 21698/Product 002)	10/30/2007
Ranolazine	Extended-release	500 mg and 1000 mg	Renexa	5/17/2010
Rasagiline Mesylate	Tablets	0.5 mg and 1 mg	Azilect	5/17/2010
Regorafenib	Tablets	40 mg	Stivarga	9/27/2016
Remifentanil Hydrochloride	for Injection	1 mg/vial, 2 mg/vial and 5 mg/vial	Ultiva	12/27/2013
Repaglinide	Tablets	0.5 mg*, 1 mg and 2 mg	Prandin	2/10/2005

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Repaglinide and Metformin Hydrochloride*	Tablets	1 mg/500 mg and 2 mg/500 mg	Prandimet	4/9/2009
Ribavirin	Capsules	200 mg	Rebetol	
Ribavirin	for Inhalation Solution	6 gm/vial	Virazole	5/22/2014
Rifaximin	Tablets	550 mg	Xifaxan	12/18/2015
Riociguat	Tablets	0.5 mg, 1 mg, 1.5 mg, 2 mg and 2.5 mg	Adempas 204819	10/10/2017
Risedronate Sodium	Tablets	5 mg, 30 mg and 35 mg	Actonel	4/23/2004
Risedronate Sodium*	Tablets	75 mg	Actonel	9/10/2007
Risedronate Sodium	Tablets	150 mg	Actonel	8/12/2008
Risedronate Sodium	Delayed-release Tablets	35 mg	Atelvia	6/9/2011
Risedronate Sodium with Calcium Carbonate *	Tablets	35 mg; 500 mg	Actonel with Calcium	12/18/2007
Risperidone	Oral Solution	1 mg/mL	Risperdal	
Risperidone	Tablets	0.25 mg, 1 mg, 2 mg, 3 mg and 4 mg	Risperdal	
Risperidone	Orally Disintegrating Tablets	0.25 mg	Risperdal	4/11/2005
Risperidone	Orally Disintegrating Tablets	0.5 mg, 1 mg and 2 mg	Risperdal	
Risperidone	Orally Disintegrating Tablets	3 mg and 4 mg	Risperdal	3/23/2005
Ritonavir	Tablets	100 mg	Norvir	12/21/2010
Ritonavir	Capsules	100 mg	Norvir	10/31/2012
Rivastigmine Tartrate	Capsules	1.5 mg, 3 mg, 4.5 mg and 6 mg	Exelon	4/21/2004
Rivastigmine Tartrate	Oral Solution	2 mg/mL	Exelon	11/5/2004
Rivastigmine	Transdermal System Extended-release	4.6 mg/24 hr and 9.5 mg/24 hr	Exelon	4/27/2011

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Rivastigmine	Transdermal System Extended-release	13.3 mg/24 hr	Exelon	1/22/2013
Rivaroxaban	Tablets	10 mg, 15 mg, and 20 mg	Xarelto	7/1/2015
Rizatriptan Benzoate	Tablets	5 mg and 10 mg	Maxalt	9/2/2004
Rizatriptan Benzoate	Orally Disintegrating Tablets	5 mg and 10 mg	Maxalt-MLT	2/17/2006
Rofecoxib	Tablets	12.5 mg, 25 mg and 50 mg	Vioxx	
Roflumilast	Tablets	500 mcg	Daliresp	3/2/2015
Romidepsin	Injection	10 mg/vial	Istodax	11/5/2013
Ropinirole Hydrochloride	Extended-release Tablets	2 mg	Requip XL	10/14/2008
Ropinirole Hydrochloride	Extended-release Tablets	4 mg	Requip XL	10/31/2008
Ropinirole Hydrochloride	Extended-release Tablets	6 mg	Requip XL	7/14/2009
Ropinirole Hydrochloride	Extended-release Tablets	8 mg	Requip XL	11/3/2008
Ropinirole Hydrochloride	Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Requip	12/22/2004
Ropinirole Hydrochloride	Tablets	3 mg, 4 mg and 5 mg	Requip	2/4/2005
Ropinirole Hydrochloride*	Extended-release Tablets	3 mg	Requip XL	1/8/2009
Ropinirole Hydrochloride	Extended-release Tablets	12 mg	Requip XL	2/5/2009
Ropivacaine Hydrochloride	Injection	2 mg/mL, 5 mg/mL and 10 mg/mL, 20 mL, 30 mL and 20 mL vials	Naropin	11/13/2006
Ropivacaine Hydrochloride	Injection	2 mg/mL, 100 mL	Naropin	1/30/2015
Ropivacaine Hydrochloride	Injection	2 mg/mL, 200 mL	Naropin	9/3/2015
Rosiglitazone Maleate	Tablets	2 mg, 4 mg and 8 mg	Avandia	

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Rosiglitazone Maleate and Metformin Hydrochloride	Tablets	1 mg/ 500 mg, 2 mg/ 500mg 4 mg/ 500 mg 2 mg/ 1000 mg 4 mg/ 1000 mg	Avandamet	10/22/2004
Rosuvastatin Calcium	Tablets	5 mg, 10 mg, 20 mg and 40 mg	Crestor	8/13/2007
Rotigotine	Extended-release Transdermal Film	1 mg/24 hr 2 mg/24 hr 3 mg/24 hr 4 mg/24 hr 6 mg/24 hr 8 mg/24 hr	Neupro	11/26/2013
Rufinamide	Tablets	100 mg, 200 mg and 400 mg	Banzel	11/14/2012
Rufinamide	Oral Suspension	40 mg/mL	Banzel	6/16/2014
Ruxolitinib	Tablets	5 mg, 10 mg, 15 mg, 20 mg, and 25 mg	Jakafi	12/17/2015
Sapropterin Dihydrochloride	Tablets	100 mg	Kuvan	6/5/2014
Sapropterin Dihydrochloride	Powder for Oral Solution	100 mg per packet	Kuvan	11/9/2015
Sapropterin Dihydrochloride	Powder for Oral Solution	500 mg per packet	Kuvan	2/23/2017
Saxagliptin Hydrochloride	Tablets	2.5 mg and 5 mg	Onglyza	7/31/2013
Saxagliptin Hydrochloride and Metformin Hydrochloride	Extended-release Tablets	5 mg/500 mg 2.5 mg/1000 mg 5 mg/1000 mg	Kombiglyze XR	7/31/2013
Sertraline Hydrochloride	Oral Concentrate	20 mg/mL	Zoloft	
Sertraline Hydrochloride	Tablets	25 mg, 50 mg and 100 mg	Zoloft	
Sertraline Hydrochloride	Tablets	150 mg and 200 mg	Zoloft	11/9/2005
Sevelamer Carbonate *	Powder for Oral Suspension	0.8 g/packet and 2.4 g/packet	Renvela	12/30/2009
Sevelamer Carbonate	Tablets	800 mg	Renvela	12/4/2008

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Sitagliptin Phosphate and Simvastatin	Tablets	50 mg/10 mg 50 mg/20 mg 50 mg/40 mg	Juvisync	11/6/2012
Sofosbuvir	Tablets	400 mg	Sovaldi 204671	12/6/2017
Sorafenib Tosylate	Tablets	200 mg	Nexavar 21923	2/28/2014
Sumatriptan Succinate	Injection	6 mg/0.5 mL, 0.5 mL vials	Imitrex	10/25/2004
Sumatriptan Succinate*	Injection	6 mg/0.5 mL, 0.5 mL (prefilled syringes)	Imitrex	5/9/2006
Sumatriptan Succinate	Tablets	25 mg, 50 mg and 100 mg	Imitrex	
Sunitinib Malate	Capsules	12.5 mg, 25 mg, 37.5 mg and 50 mg	Sutent	1/26/2010
Tacrolimus	Ointment	0.03%	Protopic	11/22/2010
Tacrolimus	Ointment	0.10%	Protopic	9/9/2010
Tacrolimus	Extended-release Capsules	0.5 mg, 1 mg, and 5 mg	Astagraf XL	9/24/2013
Tadalafil	Tablets	2.5 mg	Cialis	10/14/2008
Tadalafil	Tablets	5 mg, 10 mg and 20 mg	Cialis	11/21/2007
Tadalafil	Tablets	20 mg	Adcirca	10/15/2009
Tafluprost	Ophthalmic Solution	0.0015%	Zioptan	2/10/2016
Tamoxifen Citrate	Tablets	10 mg and 20 mg	Nolvadex	
Tamsulosin Hydrochloride	Capsules	0.4 mg	Flomax	12/20/2004
Tapentadol Hydrochloride	Tablets	50 mg, 75 mg, and 100 mg	Nucynta	11/20/2012
Tapentadol Hydrochloride	Extended-release Tablets	50 mg, 100 mg, 150 mg, 200 mg, and 250 mg	Nucynta ER	11/20/2012
Tapentadol	Oral Solution	20 mg/mL	Nucynta	12/20/2013
Tasimelteon	Capsules	20 mg	Hetlioz 205677	1/31/2018

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Teduglutide	Injection	5 mg/vial	Gattex Kit 203411	12/21/2016
Telmisartan	Tablets	20 mg, 40 mg and 80 mg	Micardis	12/26/2006
Telmisartan and Hydrochlorothiazide	Tablets	80 mg/12.5 mg and 40 mg/12.5 mg	Micardis HCT	12/31/2008
Temazepam	Capsules	7.5 mg	Restoril	11/01/2006
Temozolomide	Capsules	5 mg, 20 mg, 100 mg and 250 mg	Temodar	3/20/2007
Temozolomide	Capsules	140 mg and 180 mg	Temodar	3/24/2008
Temsirolimus*	Injection	25 mg/mL, 1.8 mL vial	Torisel	5/25/2011
Tenofovir Disoproxil Fumarate	Tablets	300 mg	Viread	1/26/2010
Tenofovir Disoproxil Fumarate	Tablets	150 mg, 200 mg, and 250 mg	Viread	5/17/2012
Terazosin Hydrochloride	Capsules	1 mg, 2 mg, 5 mg and 10 mg	Hytrin	
Terazosin Hydrochloride	Tablets	1 mg, 2 mg, 5 mg and 10 mg	Hytrin	
Terbinafine Hydrochloride	Tablets	250 mg	Lamisil	
Terfenadine	Tablets	60 mg	Seldane	
Teriparatide	Injection	250 mcg/mL, 2.4 mL prefilled Pen	Forteo	7/27/2015
Testosterone	Gel	1%	Androgel	
Testosterone *	Gel	1%	Testim	8/21/2008
Testosterone	Gel	1% (pump)	Androgel	12/19/2008
Testosterone	Gel	1.62% (pump)	Androgel	4/6/2012
Testosterone	Gel	1.62% (1.25 g and 2.5 g packets)	Androgel	6/19/2013
Testosterone	Gel	10 mg/actuation	Fortesta	8/14/2012
Testosterone	Topical Solution	30 mg/1.5 mL	Axiron	1/29/2013
Testosterone Undecanoate	Injection	250 mg/mL	Aveed	6/11/2014

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Thalidomide	Capsules	50 mg and 100 mg	Thalomid	12/18/2006
Thalidomide	Capsules	200 mg	Thalomid	9/25/2006
Thalidomide	Capsules	150 mg	Thalomid	2/3/2014
Tiagabine Hydrochloride	Tablets	2 mg and 4 mg	Gabitril	2/1/2005
Tiagabine Hydrochloride	Tablets	12 mg and 16 mg	Gabitril	1/24/2014
Ticagrelor	Tablets	90 mg	Brilinta	7/20/2015
Ticagrelor	Tablets	60 mg	Brilinta	9/30/2015
Ticlopidine Hydrochloride	Tablets	250 mg	Ticlid	
Tigecycline	For Injection	50 mg per vial	Tygacil	6/15/2009
Timolol Maleate	Ophthalmic Solution	0.25% and 0.5%	Timoptic	
Timolol Maleate	Ophthalmic Solution	0.5%	Istalol	10/19/2012
Tizanidine Hydrochloride	Capsules	2 mg, 4 mg and 6 mg	Zanaflex	8/10/2007
Tobramycin	Inhalation Solution	300 mg/5 mL	Tobi	6/29/2009
Tobramycin	Inhalation Solution	300 mg/4 mL	Bethkis	8/31/2017
Tofacitinib	Tablets	5 mg	Xeljanz	11/7/2016
Tofacitinib	Extended-release Tablets	11 mg	Xeljanz XR	11/7/2016
Tolterodine Tartrate	Extended-release Capsules	2 mg and 4 mg	Detrol LA	7/30/2007
Tolterodine Tartrate*	Tablets	1 mg and 2 mg	Detrol	
Tolvaptan	Tablets	30mg	Samsca 22275	9/23/2013
Tolvaptan	Tablets	15 mg	Samsca 22275	10/10/2013
Tolvaptan	Tablets	60 mg	Samsca 22275	3/26/2018
Topiramate	Capsules	15 mg and 25 mg	Topamax Sprinkle	9/7/2005

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Topiramate	Tablets	25 mg, 100 mg and 200 mg	Topamax	12/26/2001
Topiramate	Tablets	50 mg	Topamax	9/8/2005
Topiramate	Extended-release Capsules	25 mg, 50 mg, 100 mg, 150 mg, and 200 mg	Qudexy XR	12/24/2015
Topiramate	Extended-release Capsules	200 mg	Trokendi XR	4/3/2014
Topiramate	Extended-release Capsules	25 mg, 50 mg, and 100 mg	Trokendi XR	5/12/2014
Torseamide	Tablets	5 mg, 10 mg, 20 mg, and 100 mg	Demadex	
Tramadol Hydrochloride	Tablets	50 mg	Ultram	
Tramadol Hydrochloride	Extended-release Tablets	100 mg	Ultram ER	1/8/2007
Tramadol Hydrochloride	Extended-release Tablets	200 mg	Ultram ER	3/28/2007
Tramadol Hydrochloride	Extended-release Tablets	300 mg	Ultram ER	9/25/2007
Tramadol Hydrochloride	Extended-release Tablets	100 mg, 200 mg and 300 mg	Ryzolt	6/18/2009
Trandolapril	Tablets	1 mg, 2 mg and 4 mg	Mavik	10/4/2004
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	2 mg/180 mg and 2 mg/240 mg	Tarka	11/9/2007
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	1 mg/240 mg	Tarka	2/20/2008
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	4 mg/ 240 mg	Tarka	7/24/2007
Tranexamic Acid	Tablets	650 mg	Lysteda	5/24/2011
Travoprost	Ophthalmic Solution	0.003%	Izba	12/30/2015
Travoprost	Ophthalmic Solution	0.004%	Travatan	11/28/2008
Travoprost (Preserved)	Ophthalmic Solution	0.004%	Travatan Z	2/19/2009
Trazodone Hydrochloride	Tablets	150 mg	Desyrel	
Trazodone Hydrochloride	Extended-release Tablets	150 mg and 300 mg	Oleptro	10/18/2010

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Treprostinil Sodium	Injection	10 mg/mL, 20 mL vial	Remodulin	12/2/2011
Treprostinil Sodium	Injection	1 mg/mL, 2.5 mg/mL, and 5 mg/mL, 20 mL vial	Remodulin	12/7/2012
Treprostinil Sodium	Inhalation Solution	0.6 mg/mL, 2.9 mL ampules	Tyvaso	4/13/2015
Treprostinil	Extended-release Tablets	2.5 mg	Orenitram	12/24/2015
Treprostinil	Extended-release Tablets	0.25 mg and 1 mg	Orenitram	5/19/2016
Tretinoin	Cream	0.025%, 0.05% and 0.1%	Retin-A	
Tretinoin	Gel	0.025%	Retin-A	
Tretinoin	Gel	0.04%	Retin-A Micro	12/20/2010
Tretinoin	Gel	0.1%	Retin-A Micro	7/8/2010
Triamcinolone Acetonide	Nasal Spray	0.055 mg/Spray	Nasacort AQ	12/29/2005
Triamterene/ Hydrochlorothiazide	Tablets	37.5 mg/25 mg and 75 mg/50 mg	Maxzide	
Trospium Chloride	Extended-release Capsules	60 mg	Sanctura XR	3/2/2009
Ulipristal Acetate	Tablets	30 mg	Ella	8/13/2014
Unoprostone Isopropyl*	Ophthalmic Solution	0.15%	Rescula	5/12/2014
Valacyclovir Hydrochloride	Tablets	500 mg and 1000 mg	Valtrex	
Valganciclovir Hydrochloride	for Oral Solution	50 mg/mL	Valcyte	3/21/2011
Valganciclovir Hydrochloride	Tablets	450 mg	Valcyte	12/27/2005
Valsartan	Tablets	40 mg, 80 mg, 160 mg and 320 mg	Diovan	12/28/2004
Valsartan and Hydrochlorothiazide	Tablets	80 mg/12.5 mg 160 mg/12.5 mg 160 mg/25 mg	Diovan HCT	12/2/2005
Valsartan and Hydrochlorothiazide	Tablets	320 mg/12.5 mg and 320 mg/25 mg	Diovan HCT	2/7/2007
Vardenafil Hydrochloride	Tablets	2.5 mg	Levitra	9/4/2009
Vardenafil Hydrochloride	Tablets	5 mg and 10 mg	Levitra	7/10/2009

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Vardenafil Hydrochloride	Tablets	20 mg	Levitra	3/5/2009
Vardenafil Hydrochloride	Orally Disintegrating Tablets	10 mg	Staxyn	12/22/2011
Varenicline Tartrate	Tablets	0.5 mg and 1 mg	Chantix	5/10/2010
Vasopressin	Injection	20 units/mL, 1 mL	Vasostriect 204485	3/23/2018
Vecuronium Bromide	For Injection	10 mg/vial and 20 mg/vial	Norcuron	
Venlafaxine Hydrochloride	Extended-release Capsules	37.5 mg, 75 mg and 150 mg	Effexor XR	
Venlafaxine Hydrochloride	Tablets	25 mg, 37.5 mg, 50 mg, 75 mg and 100 mg	Effexor	11/03/2005
Venlafaxine Hydrochloride	Extended-release Tablets	37.5 mg, 75 mg and 150 mg	Effexor XR	5/3/2007
Venlafaxine Hydrochloride	Extended-release Tablets	37.5 mg, 75 mg and 150 mg	Venlafaxine Hydrochloride	2/12/2009
Venlafaxine Hydrochloride	Extended-release Tablets	225 mg	Venlafaxine Hydrochloride	1/10/2011
Verapamil Hydrochloride	Extended-release Capsules	100 mg and 200 mg	Verelan PM	7/20/2006
Verapamil Hydrochloride	Extended-release Capsules	120 mg, 180 mg and 240 mg	Verelan SR	
Verapamil Hydrochloride	Extended-release Tablets	180 mg	Isoptin SR	
Verapamil Hydrochloride	Extended-release Tablets	240 mg	Covera HS	
Verapamil Hydrochloride	Extended-release Capsules	300 mg	Verelan PM	5/19/2006
Vilazodone Hydrochloride	Tablets	10 mg, 20 mg, and 40 mg	VIIBRYD	1/21/2015
Vincristine Sulfate	Injection	1 mg/mL, 1 mL, 2 mL and 5 mL vials	Oncovin	
Voriconazole	For Injection	200 mg/vial	Vfend	9/12/2008
Voriconazole	Oral Suspension	40 mg/mL	Vfend	10/8/2010
Voriconazole	Tablets	50 mg and 200 mg	Vfend	4/14/2008
Vortioxetine	Tablets	5 mg, 10 mg, 15 mg and 20 mg	Trintellix 204447	10/2/2017

**Paragraph IV Patent Certifications
June 14, 2018**

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION
Zafirlukast	Tablets	10 mg and 20 mg	Accolate	2/29/2008
Zaleplon	Capsules	5 mg and 10 mg	Sonata	6/21/2005
Zidovudine	Capsules	100 mg	Retrovir	
Ziprasidone Hydrochloride	Capsules	20 mg, 40 mg, 60 mg and 80 mg	Geodon	2/7/2005
Zoledronic Acid*	Injection	0.05 mg/mL, 100 mL vial	Reclast	8/29/2008
Zoledronic Acid*	Injection	0.8 mg (base) /mL	Zometa	6/11/2008
Zoledronic Acid *	Injection	4 mg/100 mL, 100 mL vial	Zometa	1/31/2012
Zolmitriptan	Nasal Spray	2.5 mg/spray	Zomig	6/9/2016
Zolmitriptan	Nasal Spray	5 mg/spray	Zomig	11/14/2013
Zolpidem Tartrate	Extended-release Tablets	6.25 mg	Ambien CR	2/24/2006
Zolpidem Tartrate	Extended-release Tablets	12.5 mg	Ambien CR	1/19/2006
Zolpidem Tartrate	Sublingual Tablets	5 mg and 10 mg	Edluar	4/29/2010
Zolpidem Tartrate	Sublingual Tablets	1.75 mg and 3.5 mg	Intermezzo	4/10/2012
* ANDA withdrawn or exclusivity relinquished				