Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Abacavir Sulfate	Tablets	300 mg	Ziagen 20977	1/28/2009	1	Eligible	2/11/2020	6/18/2012	6/19/2012	5/14/2018
Abacavir	Oral Solution	20 mg/mL	Ziagen 20978	12/27/2012	1	Eligible	2/11/2020	9/26/2016	9/15/2017	5/14/2018
Abacavir Sulfate, Dolutegravir and Lamivudine	Tablets	600 mg/50 mg/ 300 mg	Triumeq 205551	8/14/2017	5					12/8/2029
Abacavir Sulfate, Dolutegravir and Lamivudine	Tablets for Oral Suspension	60 mg/5 mg/30 mg	Triumeq PD 215413	3/31/2023	1					12/8/2029
Abacavir Sulfate and Lamivudine	Tablets	600 mg/300 mg	Epzicom 21652	9/27/2007	1	Eligible	2/11/2020	9/29/2016	9/29/2016	5/14/2018
Abacavir Sulfate, Lamivudine and Zidovudine	Tablets	300 mg/150 mg/ 300 mg	Trizivir 21205	3/22/2011	1	Eligible	2/11/2020	12/5/2013	12/17/2013	5/14/2018
Abaloparatide	Subcutaneous Injection	3.12 mg/1.56 mL	Tymlos 208743	6/21/2022	1					1/10/2040
Abiraterone Acetate	Tablets	125 mg	Yonsa 210308	7/23/2018	1	Deferred	7/25/2022	6/24/2022		3/17/2034
Abiraterone Acetate	Tablets	250 mg	Zytiga 202379	4/28/2015	13	Eligible	6/18/2019	10/31/2018	11/21/2018	8/24/2027
Abiraterone Acetate	Tablets	500 mg	Zytiga 202379	8/23/2017	1	Extinguished	1/12/2021			8/24/2027
Acalabrutinib	Capsules	100 mg	Calquence 210259	11/1/2021	5					7/1/2036
Acalabrutinib Maleate	Tablets	100 mg	Calquence 216387	2/13/2024	1					7/1/2036
Acarbose	Tablets	25 mg, 50 mg and 100 mg	Precose 20482	3/22/2005	1	Extinguished	2/11/2020	5/7/2008		9/6/2009
Acetylcysteine	Injection	200 mg/mL, 30 mL vials	Acetadote 21539	4/4/2012	3	Eligible	2/11/2020	11/7/2012	11/30/2012	5/21/2026
Acetaminophen	Injection	650 mg/65 mL (10 mg/mL)	Ofirmev 22450	7/31/2024	1	Eligible	6/9/2025	5/21/2025	7/11/2025	9/11/2031
Acetaminophen	Injection	1000 mg/100 mL (10 mg/mL)	Ofirmev 22450	4/7/2011	1	Extinguished	2/11/2020			6/6/2021
Acetaminophen	Extended-release Tablets	650 mg	Tylenol 19872	Pre-MMA						
Acetaminophen and Tramadol Hydrochloride	Tablets	325 mg/ 37.5 mg	Ultracet 21123	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Acetaminophen/ Aspirin/ Caffeine	Tablets	250 mg/ 250 mg/ 65 mg	Excedrin (migraine) 20802	Pre-MMA						
Acyclovir Sodium	Injection	50 mg/mL, 10 mL and 20 mL vials	Zovirax 18603	Pre-MMA						
Adapalene	Topical Gel	0.30%	Differin 21753	9/15/2009	1	Eligible	2/11/2020	6/14/2012	4/28/2014	2/23/2025
Adapalene and Benzoyl Peroxide	Gel	0.1%/2.5%	Epiduo 22320	12/30/2011	1	Eligible	2/11/2020	9/30/2015	7/27/2017	7/18/2027
Adapalene and Benzoyl Peroxide	Gel	0.3%/2.5%	Epiduo Forte 207917	5/4/2016	1	Eligible	6/18/2019	10/17/2018	12/1/2021	3/12/2023
Adefovir Dipivoxil	Tablets	10 mg	Hepsera 21449	6/8/2010	1	Eligible	2/11/2020	8/29/2013	9/3/2013	7/23/2018
Afatinib Dimaleate	Tablets	20 mg, 30 mg and 40 mg	Gilotrif 201292	7/12/2017	7					12/19/2029
Adenosine	Injection	3 mg/mL, 20 mL and 30 mL vials	Adenoscan 20059	4/18/2005	1	Eligible	2/11/2020	8/29/2013	9/23/2013	3/24/2015
Albuterol Sulfate	Oral Syrup	2 mg(base)/ 5 mL	Ventolin 19621	Pre-MMA						
Albuterol Sulfate	Extended-release Tablets	4 mg and 8 mg	Volmax 19604	Pre-MMA						
Albuterol Sulfate	Inhalation Solution	0.021%	Accuneb 20949	10/19/2005	1	Eligible	2/11/2020	9/25/2007		12/28/2021
Albuterol Sulfate	Inhalation Solution	0.042%	Accuneb 20949	4/6/2004	1	Eligible	2/11/2020	6/28/2004		12/28/2021
Albuterol Sulfate and Ipratropium Bromide	Inhalation Solution	0.083%/ 0.017%	Duoneb 20950	Pre-MMA						
Albuterol Sulfate and Ipratropium Bromide	Inhalation Aerosol	100 mcg/20 mcg per actuation	Combivent Respimat 21747	3/30/2023	1					10/16/2030
Albuterol Sulfate	Inhalation Aerosol	0.09 mg base per actuation	Pro-Air HFA 21457	5/18/2012	1	Non-Forfeiture Deferred	8/24/2020 3/10/2020	2/24/2020	2/26/2020	9/12/2023
Albuterol Sulfate	Inhalation Aerosol	0.09 mg base per actuation	Proventil HFA 20503	5/20/2015	1	Extinguished	2/11/2020			12/28/2016
Alcaftadine	Ophthalmic Solution	0.25%	Lastacaft 22134	7/30/2014	1	Extinguished	8/27/2019			10/5/2029
Alectinib	Capsules	150 mg	Alecensa 208434	12/11/2019	1					3/4/2032
Alendronate Sodium	Oral Solution	70 mg/75 mL	Fosamax 21575	9/7/2007	1	Extinguished	2/11/2020			7/17/2018
Alendronate Sodium	Tablets	5 mg, 10 mg, 35 mg, 40 mg and 70 mg	Fosamax 20560	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Alendronate Sodium and Cholecalciferol	Tablets	70 mg/2800 IU and 70 mg/5600 IU	Fosamax Plus D 21762	11/20/2007	1	Extinguished	2/11/2020			7/17/2018
Alfuzosin Hydrochloride	Extended-release Tablets	10 mg	Uroxatral 21287	6/12/2007	9	Eligible	2/11/2020	7/18/2011	7/18/2011	8/22/2017
Aliskiren Hemifumarate	Tablets	150 mg and 300 mg	Tekturna 21985	1/27/2014	1	Deferred	8/13/2019	3/22/2019	3/25/2019	2/19/2026
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	1	Extinguished	2/11/2020			7/13/2028
Almotriptan Malate	Tablets	6.25 mg and 12.5 mg	Axert 21001	12/8/2005	1	Extinguished	2/112020	7/7/2015		5/7/2015
Alogliptin	Tablets	6.25 mg, 12.5 mg and 25 mg	Nesina 22271	1/25/2017	5					6/16/2029
Alogliptin and Metformin Hydrochloride	Tablets	12.5 mg/500 mg and 12.5 mg/1000 mg	Kazano 203414	1/25/2017	3					5/24/2029
Alosetron Hydrochloride	Tablets	0.5 mg and 1 mg	Lotronex 21107	12/2/2010	1	Deferred	2/11/2020	5/4/2015	5/21/2015	10/5/2018
Alprazolam	Orally Disintegrating Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Niravam 21726	12/27/2005	1	Extinguished Eligible	7/2/2019 7/2/2019	1/9/2009	1/14/2009	4/9/2018
Alprazolam	Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Xanax 18276	Pre-MMA						
Alvimopan	Capsules	12 mg	Entereg 21775	6/16/2017	1	Deferred	1/2/2020	12/19/2019	12/19/2019	7/31/2030
Amantadine	Extended-release Capsules	137 mg	Gocovri 208944	1/16/2018	1					12/2/2030
Amantadine	Extended-release Capsules	68.5 mg	Gocovri 208944	4/30/2020	1	Eligible	9/2/2024	8/26/2024		12/4/2034
Ambrisentan	Tablets	5 mg and 10 mg	Letairis 22081	2/9/2015	1	Extinguished	8/27/2019	3/28/2019		7/9/2018
Amifampridine Phosphate	Tablets	10 mg	Firdapse 208078	11/28/2022	3					2/25/2037
Amifostine	For Injection	500 mg/vial	Ethyol 20221	4/16/2004	1	Eligible	2/11/2020	3/14/2008	3/27/2008	7/31/2012
Amiodarone Hydrochloride	Injection	150 mg/100 mL	Nexterone 22325	6/24/2025	1					3/13/2029

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Amlodipine Benzoate	Oral Suspension	1 mg/mL	Katerzia 211340	12/29/2020	1	Eligible	6/26/2023	6/13/2023		4/11/2039
Amlodipine Besylate	Tablets	2.5 mg, 5 mg and 10 mg	Norvasc 19787	Pre-MMA						
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	1	Extinguished	2/11/2020	11/29/2013	2/1/2011	8/11/2018
Amlodipine Besylate and Atorvastatin Calcium	Tablets	2.5 mg/40 mg	Caduet 21540	9/17/2009	1	Extinguished	2/11/2020	11/29/2013	2/1/2011	8/11/2018
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	1	Extinguished	2/11/2020			8/11/2018
Amlodipine Besylate and Atorvastatin Calcium	Tablets	5 mg/80 mg	Caduet 21540	4/7/2009	1	Extinguished	2/11/2020			8/11/2018
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	1	Eligible	2/11/2020	3/18/2007		12/19/2017
Amlodipine Besylate and Benazepril Hydrochloride	Capsules	5 mg/40 mg and 10 mg/40 mg	Lotrel 20364	11/17/2006	1	Eligible	2/11/2020	7/29/2010	1/3/2011	12/19/2017
Amlodipine Besylate and Celecoxib	Tablets	2.5 mg/200 mg, 5 mg/200 mg, 10 mg/200 mg	Consensi 210045	6/29/2020	1					6/14/2038
Amlodipine Besylate and Olmesartan Medoxomil	Tablets	5 mg/20 mg and 10 mg/40 mg	Azor 22100	2/11/2008	1	Extinguished	2/11/2020			4/25/2016
Amlodipine Besylate and Olmesartan Medoxomil	Tablets	10 mg/20 mg and 5 mg/40 mg	Azor 22100	3/31/2008	1	Extinguished	2/11/2020			4/25/2016
Amlodipine Besylate and Valsartan	Tablets	5 mg/160 mg	Exforge 21990	10/22/2007	1	Eligible	2/11/2020	3/28/2013	9/30/2014	7/8/2019
Amlodipine Besylate and Valsartan	Tablets	5 mg/320 mg	Exforge 21990	11/26/2007	1	Eligible	2/11/2020	3/28/2013	9/30/2014	7/8/2019
Amlodipine Besylate and Valsartan	Tablets	10 mg/160 mg	Exforge 21990	10/1/2007	1	Eligible	2/11/2020	3/28/2013	9/30/2014	7/8/2019
Amlodipine Besylate and Valsartan	Tablets	10 mg/320 mg	Exforge 21990	11/9/2007	1	Eligible	2/11/2020	3/28/2013	9/30/2014	7/8/2019

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
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	1	Eligible	2/11/2020	9/25/2012	12/1/2014	7/18/2017
Amlodipine, Hydrochlorothiazide and Valsartan	Tablets	10 mg/12.5 mg/ 160 mg	Exforge HCT 22314	10/22/2009	1	Eligible	2/11/2020	9/25/2012	12/1/2014	7/18/2017
Amoxicillin and Clavulanate Potassium	Extended-release Tablets	1000 mg/62.5 mg	Augmentin XR 50785	1/21/2009	1	Eligible	2/11/2020	4/21/2010		4/4/2020
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	1	Deferred	6/26/2023	6/22/2023		1/28/2032
Amphetamine	Extended-release Tablets	5 mg, 10 mg, 15 mg and 20 mg	Dyanavel XR 210526	1/22/2025	1					9/24/2038
Amphetamine Aspartate;Amphetamine Sulfate;Dextroamphetamine Saccharate; Dextroamphetamine Sulfate	Extended-release Capsules	37.5 mg and 50 mg	Mydayis 22063	8/3/2017	1	Extinguished Deferred	9/4/2023 2/8/2022	1/31/2022		8/24/2029
Amphetamine Aspartate;Amphetamine Sulfate;Dextroamphetamine Saccharate; Dextroamphetamine Sulfate	Extended-release Capsules	12.5 mg and 25 mg	Mydayis 22063	8/7/2017	1	Extinguished Deferred	9/4/2023 2/8/2022	1/31/2022		8/24/2029
Angiotensin II Acetate	Injection	2.5 mg/mL	Giapreza 209360	12/21/2021	1	Eligible	6/9/2025	6/3/2025		12/18/2034
Apalutamide	Tablets	60 mg	Erleada 210951	2/14/2022	5	Eligible	3/17/2025	3/17/2025		4/30/2038
Apalutamide	Tablets	240 mg	Erleada 210951	3/20/2025	1					1/30/20240
Apixaban	Tablets	2.5 mg and 5 mg	Eliquis 202155	12/28/2016	25	Eligible	1/14/2020	12/23/2019		2/24/2031
Apremilast	Tablets	10 mg, 20 mg and 30 mg	Otezla 205437	3/22/2018	11	Eligible	2/22/2021	2/17/2021		5/29/2034
Aprepitant	Capsule	40 mg, 80 mg and 125 mg	Emend 21549	11/3/2008	1	Deferred	2/11/2020	9/24/2012	12/27/2016	4/17/2015
Aprepitant	for Oral Suspension	125 mg/Kit	Emend 207865	11/23/2016	1	Extinguished	2/11/2020			9/26/2027

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Aprepitant	Intravenous Emulsion	32 mg/4.4 mL	Aponvie 216457	11/7/2023	1					9/18/2035
Aprepitant	Intravenous Emulsion	130 mg/18 mL	Cinvanti 209296	4/29/2022	1					9/18/2035
Arformoterol Tartrate	Inhalation Solution	Eq. 0.015 mg base/ 2 mL	Brovana 21912	10/1/2009	1	Extinguished	7/2/2019			11/9/2021
Argatroban	Injection	100 mg/mL, 2.5 mL vials	Argatroban 20883	9/24/2007	1	Extinguished	2/11/2020			6/30/2014
Argatroban in Sodium Chloride	Injection	1 mg/mL, 50 mL vials	Argatroban 22434	12/16/2011	1	Extinguished	2/11/2020			9/26/2027
Aripiprazole	Oral Solution	1 mg/mL	Abilify 21713	12/20/2007	1	Extinguished	2/11/2020			4/24/2022
Aripiprazole	Tablets	2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg	Abilify 21436	11/15/2006	8	Extinguished	2/11/2020			10/20/2014
Aripiprazole	Orally Disintegrating Tablets	10 mg, 15 mg, 20 mg and 30 mg	Abilify 21729	11/15/2006	1	Extinguished	2/11/2020			10/20/2014
Aripiprazole	Extended-release Injectable Suspension	300 mg/vial and 400 mg/vial	Abilify Maintena Kit 202971	12/20/2021	1	Deferred	2/17/2025	12/3/2024		3/8/2034
Armodafinil	Tablets	50 mg, 150 mg and 250 mg	Nuvigil 21875	7/24/2009	1	Eligible	2/11/2020	6/1/2012	6/1/2016	12/18/2024
Armodafinil	Tablets	100 mg	Nuvigil 21875	9/8/2009	1	Extinguished	2/11/2020			12/18/2023
Armodafinil	Tablets	200 mg	Nuvigil 21875	9/3/2009	1	Extinguished	2/11/2020			12/18/2023
Arsenic Trioxide	Injection	1 mg/mL	Trisenox 21248	8/11/2015	1	Deferred	2/11/2020	8/31/2018		11/10/2018
Asenapine Maleate	Sublingual Tablets	5 mg and 10 mg	Saphris 22117	8/13/2013	4	Eligible	1/12/2021	12/10/2020	12/10/2020	4/6/2026
Asenapine Maleate	Sublingual Tablets	2.5 mg	Saphris 22117	7/27/2017	1	Deferred	1/12/2021	12/10/2020	12/10/2020	4/6/2026
Aspirin and Omeprazole	Delayed-release Tablets	81 mg/40 mg and 325 mg/40 mg	Yosprala 205103	10/17/2016	1	Extinguished	2/11/2020			2/28/2023
Aspirin and Dipyridamole	Extended-release Capsules	25 mg and 200 mg	Aggrenox 20884	2/1/2007	1	Deferred	2/11/2020	8/14/2009	7/1/2015	1/18/2017
Atazanavir Sulfate	Capsules	100 mg and 150 mg	Reyataz 21567	3/19/2010	1	Eligible	2/11/2020	4/22/2014	12/27/2017	12/21/2018
Atazanavir Sulfate	Capsules	200 mg	Reyataz 21567	2/16/2010	1	Eligible	2/11/2020	4/22/2014	12/27/2017	12/21/2018
Atazanavir Sulfate	Capsules	300 mg	Reyataz 21567	7/20/2009	1	Eligible	2/11/2020	4/22/2014	12/27/2017	12/21/2018

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Atazanavir Sulfate and Cobicistat	Tablets	300 mg/150 mg	Evotaz 206353	9/13/2017	1					9/3/2029
Atenolol	Tablets	25 mg, 50 mg and 100 mg	Tenormin 18240	Pre-MMA						
Atenolol/ Chlorthalidone	Tablets	50 mg/25 mg and 100 mg/25 mg	Tenoretic 18760	Pre-MMA						
Atovaquone	Oral Suspension	750 mg/5 mL	Mepron 20500	10/20/2009	1	Extinguished	2/11/2020			
Atovaquone and Proguanil Hydrochloride	Tablets	62.5 mg/25 mg	Malarone 21078	9/14/2010	1	Extinguished	2/11/2020	5/27/2014		11/25/2013
Atovaquone and Proguanil Hydrochloride	Tablets	250 mg/100 mg	Malarone 21078	4/3/2009	1	Eligible	2/11/2020	1/12/2011	9/15/2011	11/25/2013
Atomoxetine Hydrochloride	Capsules	10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg	Strattera 21411	5/29/2007	10	Extinguished	2/11/2020	5/30/2017		11/26/2016
Atorvastatin Calcium	Tablets	10 mg, 20 mg, 40 mg and 80 mg	Lipitor 20702	Pre-MMA						
Avanafil	Tablets	50 mg, 100 mg and 200 mg	Stendra 202276	4/27/2016	1	Deferred	7/8/2024	6/14/2024	10/29/2024	4/27/2025
Avibactam Sodium and Ceftazidime	For Injection	0.5 g/2 g per vial	Avycaz 206494	2/26/2024	2					6/15/2032
Axitinib	Tablets	1 mg and 5 mg	Inlyta 202324	2/23/2018	1					12/14/2030
Azacitidine	Tablets	200 mg and 300 mg	Onureg 214120	9/30/2021	1					6/3/2030
Azelaic Acid	Gel	15%	Finacea 21470	7/27/2012	1	Extinguished	2/11/2020	11/19/2018		11/18/2018
Azelaic Acid	Topical Foam	15%	Finacea 207071	9/14/2017	1	Eligible	9/6/2022	10/7/2020		2/28/2029
Azelastine Hydrochloride	Nasal Spray	0.125 mg base/spray	Astelin 20114	11/14/2005	1	Eligible	2/11/2020	4/30/2009	6/23/2010	5/1/2011
Azelastine Hydrochloride	Nasal Spray	205.5 mcg/spray	Astepro 22203	12/15/2011						
Azelastine Hydrochloride	Nasal Spray	205.5 mcg/spray	Astepro Allergy (OTC) 213872	7/12/2021	1	Extinguished	5/13/2024			6/4/2028

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Azelastine Hydrochloride	Nasal Spray	205.5 mcg/spray	Children's Astepro Allergy (OTC) 213872	7/12/2021	1	Non-Forfeiture Deferred	2/17/2025 6/10/2024	5/29/2024		6/4/2028
Azelastine Hydrochloride	Ophthalmic Solution	0.05%	Optivar 21127	12/13/2006	1	Eligible	2/11/2020	8/3/2009	12/1/2009	5/1/2011
Azelastine Hydrochloride and Fluticasone Propionate	Nasal Spray	137 mcg/50 mcg per spray	Dymista 202236	6/13/2014	1	Eligible	6/18/2019	4/28/2017	3/2/2020	8/24/2026
Azilsartan Kamedoxomil	Tablets	40 mg and 80 mg	Edarbi 200796	4/10/2020	1	Eligible	9/6/2022	7/20/2022		3/26/2028
Azilsartan Kamedoxomil and Chlorthalidone	Tablets	40 mg/12.5 mg and 40 mg/25 mg	Edarbyclor 202331	4/19/2022	1	Eligible	2/17/2025	1/21/2025		7/1/2031
Azithromycin	for Injection	500 mg/vial	Zithromax 20733	1/26/2009	2	Eligible	2/11/2020	3/24/2009	5/11/2009	7/31/2018
Azithromycin	Ophthalmic Solution	1%	Azasite 50810	3/3/2011	1	Extinguished	2/11/2020			3/31/2019
Baclofen	Oral Solution	5 mg/5 mL	Ozobax 208193	7/26/2021	1	Eligible	2/17/2025	12/6/2024	1/15/2025	8/30/2039
Baclofen	Oral Suspension	25 mg/5 mL	Fleqsuvy 215602	5/20/2022	1	Eligible	6/12/2023	6/8/2023	6/19/2023	9/29/2037
Baloxavir Marboxil	Tablets	40 mg and 80 mg	Xofluza 210854	10/24/2022	1					9/25/2038
Balsalazide Disodium	Capsules	750 mg	Colazal 20610	5/26/2022	1	Eligible	4/14/2025	6/8/2023	6/8/2023	8/24/2026
Balsalazide Disodium	Tablets	1.1 g	Giazo 22205	11/5/2013	1	Eligible	2/11/2020	9/8/2015		6/23/2031
Baricitinib	Tablets	1 mg and 2 mg	Olumiant 207924	5/31/2022	2	Eligible	3/17/2025	7/22/2024		6/8/2030
Baricitinib	Tablets	4 mg	Olumiant 207924	10/3/2023	1	Eligible	8/18/2025	8/8/2025		6/8/2030
Beclomethasone Dipropionate	Inhalation Aerosol	40 mcg/actuation and 80 mcg/actuation	Qvar 20911	1/10/2020	1					5/18/2031
Beclomethasone Dipropionate	Inhalation Aerosol	40 mcg/actuation	Qvar Redihaler 207921	10/30/2023	1					8/19/2041
Beclomethasone Dipropionate	Inhalation Aerosol	80 mcg/actuation	Qvar Redihaler 207921	7/31/2024	1					8/19/2041
Belinostat	Injection	500 mg/vial	Beleodaq 206256	7/3/2018	1					10/27/2027
Bempedoic Acid	Tablets	180 mg	Nexletol 211616	2/21/2024	9					6/19/2040

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Bempedoic Acid and Ezetimibe	Tablets	180 mg/10 mg	Nexlizet 211617	2/21/2024	3					6/19/2040
Bendamustine Hydrochloride	Injection	25 mg/vial and 100 mg/vial	Treanda 22249	6/4/2013	10	Eligible	1/10/2023	12/7/2022	12/7/2022	10/26/2030
Bendamustine Hydrochloride	Injection	90 mg/mL, 0.5 mL and 2 mL in single-dose vials	Treanda 22249	6/19/2014	1					9/23/2029
Bendamustine Hydrochloride	Injection	100 mg/4 mL (25 mg/mL) multiple-dose vials	Bendeka 208194	5/4/2017	1					3/15/2033
Bendamustine Hydrochloride	Injection	100 mg/4 mL (25 mg/mL) multiple-dose vials	Belrapzo 205580	7/17/2018	1	Extinguished	8/19/2024			1/28/2031
Benzyl Alcohol	Lotion	5%	Ulesfia 22129	4/11/2016	1	Extinguished	6/15/2020			5/19/2024
Bepotastine Besilate	Ophthalmic Solution	1.5%	Bepreve 22288	9/9/2013	3	Extinguished Deferred	2/11/2020 2/11/2020	3/5/219		9/19/2019
Berotralstat Hydrochloride	Capsules	110 mg and 150 mg	Orladeyo 214094	12/3/2024	1					11/1/2039
Betamethasone Valerate	Foam	0.12%	Luxiq 20934	8/10/2007	1	Deferred	2/11/2020	11/26/2012		5/24/2017
Betamethasone Dipropionate	Topical Spray	0.05%	Sernivo 208079	2/15/2018	1	Eligible	7/13/2020	6/17/2020		8/31/2030
Betaxolol	Ophthalmic Solution	0.5%(base)	Betoptic 19270	Pre-MMA						
Bexarotene	Capsules	75 mg	Targretin 20155	6/6/2011	1	Eligible	2/11/2020	8/12/2014	7/9/2015	10/5/2016
Bictegravir Sodium, Emtricitabine and Tenofovir Alafenamide Fumarate	Tablets	30 mg/120 mg/ 15 mg	Biktarvy 210251	9/28/2023	1					6/19/2035
Bictegravir Sodium, Emtricitabine and Tenofovir Alafenamide Fumarate	Tablets	50 mg/200 mg/ 25 mg	Biktarvy 210251	2/7/2022	3					11/8/2036
Bimatoprost	Ophthalmic Solution	0.01%	Lumigan 22184	4/5/2011	1	Extinguished	3/17/2025			6/13/2027
Bimatoprost	Ophthalmic Solution	0.03%	Lumigan 21275	12/22/2008	1	Extinguished	2/11/2020			
Bimatoprost	Topical Solution	0.03%	Latisse 22369	5/3/2010	1	Extinguished Deferred	6/18/2019 6/18/2019	12/1/2014		5/25/2024

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Binimetinib	Tablets	15 mg	Mektovi 210498	6/27/2022	3					10/18/2033
Binimetinib	Tablets	45 mg	Mektovi 210498	6/26/2025	1					10/18/2033
Bismuth Subcitrate Potassium, Metronidazole, and Tetracycline Hydrochloride	Capsules	140 mg/125 mg/ 125 mg	Pylera 50786	8/12/2014	1	Extinguished	2/11/2020			12/14/2018
Bivalirudin	For Injection	250 mg/vial	Angiomax 20873	9/1/2009	1	Extinguished	2/11/2020			7/27/2028
Bosentan	for Oral Suspension	32 mg	Tracleer 209279	2/8/2019	1	Eligible	2/17/2025	2/5/2025	8/18/2025	12/28/2027
Bosutinib	Tablets	100 mg and 500 mg	Bosulif 203341	9/6/2016	2	Deferred	6/9/2025	5/23/2025		11/23/2026
Bosutinib	Tablets	400 mg	Bosulif 203341	10/25/2018	1					11/23/2026
Bortezomib	For Injection	3.5 mg/vial	Velcade 21602	11/20/2008	1	Extinguished	1/27/2020			1/25/2022
Brexpiprazole	Tablets	0.25 mg	Rexulti 205422	7/10/2019	17	Eligible	9/6/2022	8/11/2022		10/12/2032
Brexpiprazole	Tablets	0.5 mg, 1 mg, 2 mg and 3 mg	Rexulti 205422	7/10/2019	18	Eligible	9/6/2022	8/11/2022		10/12/2032
Brexpiprazole	Tablets	4 mg	Rexulti 205422	7/10/2019	16	Eligible	9/6/2022	8/11/2022		4/12/2026
Brimonidine	Topical Gel	0.33%	Mirvaso 204708	12/15/2014	1	Extinguished	10/8/2019			6/13/2031
Brimonidine Tartrate	Ophthalmic Solution	0.1%	Alphagan P 21770	12/20/2006	1	Extinguished	12/13/2022			7/28/2021
Brimonidine Tartrate	Ophthalmic Solution	0.15%	Alphagan P 21262	11/03/2006	1	Extinguished	2/11/2020			1/28/2022
Brimonidine Tartrate	Ophthalmic Solution	0.15%	Qoliana 21764	10/24/2023	1					8/19/2025
Brimonidine Tartrate	Ophthalmic Solution	0.2%	Alphagan 20613	Pre-MMA						
Brimondinie Tartrate	Ophthalmic Solution	0.025%	Lumify (OTC) 208144	7/12/2021	1	Eligible	3/4/2024	2/16/2024		7/14/2030
Brimonidine Tartrate and Timolol Maleate	Ophthalmic Solution	0.2%/0.5%	Combigan 21398	11/21/2008	1	Extinguished	5/5/2022			4/19/2022
Brinzolamide and Brimonidine Tartrate	Ophthalmic Suspension	1%/0.2%	Simbrinza 204251	8/1/2022	1					10/30/2030

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Brivaracetam	Injection	50 mg/5 mL	Briviact 205837	5/12/2020	2					2/21/2026
Brivaracetam	Oral Solution	10 mg/mL	Briviact 205838	5/12/2020	1					2/21/2026
Brivaracetam	Tablets	10 mg, 25 mg, 50 mg, 75 mg and 100 mg	Briviact 205836	5/12/2020	7	Eligible	7/25/2022	6/9/2022		2/21/2026
Bromfenac Sodium	Ophthalmic Solution	0.07%	Prolensa 203168	7/26/2013	1	Non-Forfeiture	11/19/2019	11/22/2023	1/8/2024	9/11/2025
Bromfenac Sodium	Ophthalmic Solution	0.075%	Bromsite 206911	10/25/2017	1	Deferred	2/19/2024	2/2/2024	2/12/2024	8/7/2029
Budesonide	Enteric Coated Capsules	3 mg	Entocort EC 21324	2/1/2008	1	Extinguished	2/11/2020	4/2/2014		1/1/2015
Budesonide	Nasal Spray	0.032 mg (32 mcg)/spray	Rhinocort 20746	5/14/2007	1	Deferred	2/11/2020	5/12/2014	5/13/2014	10/29/2017
Budesonide	Inhalation Suspension	0.25 mg/2 mL and 0.5 mg/2 mL	Pulmicort Respules 20929	9/15/2005	1	Extinguished	4/7/2020	11/18/2008		2/27/2006
Budesonide	Inhalation Suspension	1 mg/2 mL	Pulmicort Respules 20929	5/28/2010	1	Eligible	2/11/2020	9/27/2013	7/27/2015	12/23/2018
Budesonide	Extended-release Tablets	9 mg	Uceris 203634	3/11/2013	1	Deferred	6/18/2019	7/3/2018	7/5/2018	6/9/2020
Budesonide	Delayed-release Capsules	4 mg	Tarpeyo 215935	12/26/2024	1					1/23/2043
Budesonide	Oral Suspension	2 mg/10 mL	Eohilia 213976	3/31/2025	1					1/10/2039
Budesonide and Formoterol Fumarate Dihydrate	Metered Inhalation	80 mcg/4.5 mcg per inhalation and 160 mcg/4.5 mcg per inhalation	Symbicort 21929	6/26/2018	1	Deferred	3/18/2022	3/15/2022	7/31/2023	10/16/2028
Bupivacaine Liposome	Injectable Suspension	133 mg/10 mL	Exparel 22496	12/28/2021	1	Deferred	7/8/2024	7/1/2024		1/22/20241
Bupivacaine Liposome	Injectable Suspension	266 mg/20 mL	Exparel 22496	8/20/2021	1	Deferred	7/8/2024	7/1/2024		1/22/2041
Buprenorphine and Naloxone	Buccal Film	2.1 mg/0.3 mg and 4.2 mg/0.7 mg	Bunavail 205637	11/23/2016	1					8/20/2032
Buprenorphine and Naloxone	Buccal Film	6.3 mg/1 mg	Bunavail 205637	12/21/2015	1					8/20/2032

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Buprenorphine Hydrochloride	Buccal Film	75 mcg and 150 mcg	Belbuca 207932	10/24/2016	1	Extinguished Non-Forfeiture	6/29/2021 2/9/2021			7/23/2027
Buprenorphine Hydrochloride	Buccal Film	300 mcg, 450 mcg, 600 mcg and 750 mcg	Belbuca 207932	10/4/2016	1	Extinguished Non-Forfeiture	6/29/2021 2/9/2021			7/23/2027
Buprenorphine Hydrochloride	Buccal Film	900 mcg	Belbuca 207932	9/12/2016	1	Extinguished Non-Forfeiture	6/29/2021 2/9/2021			7/23/2027
Buprenorphine Hydrochloride and Naloxone Hydrochloride	Sublingual Film	2 mg/0.5 mg* and 8 mg/2 mg	Suboxone 22410	10/15/2012	1	Extinguished	2/25/2020			2/13/2023
Buprenorphine Hydrochloride and Naloxone Hydrochloride	Sublingual Film	4 mg/1 mg	Suboxone 22410	5/14/2013	1	Extinguished	2/25/2020			2/13/2023
Buprenorphine Hydrochloride and Naloxone Hydrochloride	Sublingual Film	12 mg/3 mg	Suboxone 22410	5/14/2013	1	Extinguished	2/25/2020			2/13/2023
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	1	Extinguished	10/3/2024			5/22/2030
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	1	Extinguished	10/3/2024			9/18/2032
Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate	Sublingual Tablets	2.9 mg/7.1 mg	Zubsolv 204242	12/21/2015	1	Extinguished	10/3/2024			9/18/2032
Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate	Sublingual Tablets	0.7 mg/0.18 mg	Zubsolv 204242	5/4/2017	1	Extinguished	10/3/2024			9/18/2032
Buprenorphine	Transdermal System	5 mcg/hr 10 mcg/hr 20 mcg/hr	Butrans 21306	6/6/2013	1	Extinguished	6/18/2019	11/20/2018		9/29/2017
Buprenorphine	Transdermal System	15 mcg/hr	Butrans 21306	12/16/2013	1	Extinguished	6/18/2019	11/20/2018		9/29/2017
Bupropion Hydrobromide	Extended-release Tablets	174 mg	Aplenzin 22108	9/28/2009	1	Extinguished	2/25/2020			6/27/2026
Bupropion Hydrobromide	Extended-release Tablets	348 mg	Aplenzin 22108	9/24/2009	1	Extinguished	2/25/2020			6/27/2026
Bupropion Hydrobromide	Extended-release Tablets	522 mg	Aplenzin 22108	12/24/2009	1	Extinguished	2/25/2020			6/27/2026
Bupropion Hydrochloride	Extended-release Tablets	100 mg, 150 mg and 200 mg	Wellbutrin SR 20358	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Bupropion Hydrochloride	Extended-release Tablets	150 mg	Zyban 20711	Pre-MMA						
Bupropion Hydrochloride	Extended-release Tablets	150 mg and 300 mg	Wellbutrin XL 21515	9/21/2004	1	Eligible	2/25/2020	12/14/2006	5/30/2008 - 150 mg 12/4/2006 - 300 mg	10/30/2018
Bupropion Hydrochloride	Extended-release Tablets	450 mg	Forfivo XL 22497	2/28/2013	1	Extinguished	2/25/2020		10/1/2018	6/25/2027
Bupropion Hydrochloride	Tablets	75 mg and 100 mg	Wellbutrin 18644	Pre-MMA						
Buspirone Hydrochloride	Tablets	5 mg, 7.5 mg, 10 mg, 15 mg and 30 mg	Buspar 18731	Pre-MMA						
Busulfan	Injection	6 mg/mL	Busulfex 20954	12/26/2012	1	Extinguished	2/25/2020	9/21/2018		9/30/2013
Butoconazole Nitrate	Vaginal Cream	2%	Gynazole-1 19881	12/23/2009	1	Eligible	2/25/2020	5/18/2012	11/15/2012	11/17/2017
Butorphanol Tartrate	Nasal Spray	10 mg/mL	Stadol NS 19890	Pre-MMA						
Cabazitaxel	Injection	60 mg/1.5 mL	Jevtana Kit 201023	6/17/2014	8	Eligible Deferred	2/20/2023 7/25/2022	6/23/2022		12/10/2025
Cabozantinib	Tablets	20 mg, 40 mg and 60 mg	Cabometyx 208692	8/16/2019	1					7/9/2033
Calcipotriene	Topical Cream	0.005%	Dovonex 20554	12/2/2009	1	Eligible	2/25/2020	5/30/2012	7/27/2012	6/9/2015
Calcipotriene	Topical Solution	0.005%	Dovonex 20611	5/19/2006	1	Eligible	2/25/2020	5/6/2008	5/6/2008	6/9/2015
Calcipotriene and Betamethasone Dipropionate	Ointment	0.005%/0.064%	Taclonex 21852	3/31/2010	1	Eligible	2/25/2020	1/14/2013	3/31/2014	1/27/2020
Calcipotriene and Betamethasone Dipropionate	Topical Foam	0.005%/0.064%	Enstilar 207589	6/22/2020	1	Eligible	4/18/2023	3/21/2023		6/10/2031
Calcitonin-Salmon	Nasal Spray	200 IU/spray	Miacalcin 20313	Pre-MMA						
Calcitonin-Salmon (Recombinant)	Nasal Spray	200 IU/spray	Fortical 21406	3/29/2006	1	Extinguished	4/7/2020			2/2/2021
Calcitriol	Injection	1 mcg/mL and 2 mcg/mL, 1 mL vials	Calcijex 18874	Pre-MMA						
Calcium Acetate	Capsules	EQ 169 mg calcium	PhosLo 21160	5/31/2005	1	Eligible	2/25/2020	2/26/2008		4/3/2021

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Calcium Acetate	Oral Solution	667 mg/5 mL	Phoslyra 22581	12/5/2013	2	Extinguished	3/17/2025			2/23/2030
Calcium Carbonate/ Famotadine/ Magnesium Hydroxide	Chewable Tablets	800 mg/10 mg/ 165 mg (OTC)	Pepcid Complete 20958	11/1/2004	1	Deferred	3/10/2020	2/6/2008		3/30/2016
Calcium Oxybate, Magnesium Oxybate, Potassium Oxybate and Sodium Oxybate	Oral Solution	0.234 g/0.096 g/ 013 g/0.04 g per mL	Xywav 212690	4/12/2021	1					3/15/2033
Canagliflozin	Tablets	100 mg and 300 mg	Invokana 204042	3/29/2017	10					2/26/2029
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	6					2/26/2029
Canagliflozin and Metformin Hydrochloride	Extended-release Tablets	50 mg/500 mg 50 mg/1000 mg 150 mg/500 mg 150 mg/1000 mg	Invokamet-XR 205879	11/21/2018	1					2/26/2029
Candesartan Cilexetil	Tablets	4 mg, 8 mg, 16 mg and 32 mg	Atacand 20838	12/22/2006	1	Eligible	3/10/2020	5/3/2013	5/21/2013	1/9/2014
Candesartan Cilexetil and Hydrochlorothiazide	Tablets	16 mg/12.5 mg and 32 mg/12.5 mg	Atacand HCT 21093	6/25/2008	1	Extinguished	3/10/2020	12/4/2012		2/24/2015
Candesartan Cilexetil and Hydrochlorothiazide	Tablets	32 mg/25 mg	Atacand HCT 21093	3/6/2009	1	Eligible	3/10/2020	12/4/2012	12/4/2012	2/24/2015
Cangrelor	For Injection	50 mg/vial	Kengreal 204958	6/24/2019	2					7/10/2035
Cannabidiol	Oral Solution	100 mg/mL	Epidiolex 210365	9/28/2022	10					3/1/2041
Capecitabine	Tablets	150 mg and 500 mg	Xeloda 20896	11/10/2008	1	Extinguished	3/10/2020	8/8/2014		12/14/2013
Capmatinib	Tablets	150 mg and 200 mg	Tabrecta 213591	5/6/2024	1					7/22/2035
Captopril	Tablets	12.5 mg, 25 mg, 50 mg, and 100 mg	Capoten 18343	Pre-MMA						
Carbamazepine	Extended-release Capsules	100 mg and 200 mg	Carbatrol 20712	2/2/2006	1	Extinguished	3/10/2020			6/15/2016

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Carbamazepine	Extended-release Capsules	200 mg and 300 mg	Equetro 21710	8/21/2007	1	Extinguished	3/10/2020			5/19/2024
Carbamazepine	Extended-release Capsules	100 mg	Equetro 21710	5/23/2014	1	Extinguished	3/10/2020			5/19/2024
Carbamazepine	Extended-release Capsules	300 mg	Carbatrol 20712	Pre-MMA						
Carbamazepine	Extended-release Tablets	100 mg	Tegretol-XR 20234	12/30/2005	1	Deferred	3/10/2020	3/31/2009		2/8/2011
Carbamazepine	Extended-release Tablets	200 mg and 400 mg	Tegretol-XR 20234	Pre-MMA						
Carbidopa, Levodopa and Entacapone	Tablets	12.5 mg, 50 mg and 200 mg	Stalevo 50 21485	8/5/2008	1	Extinguished Deferred	3/10/2020 3/10/2020	11/20/2012		6/29/2020
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	1	Deferred	3/10/2020	11/20/2012		6/29/2020
Carbidopa, Levodopa and Entacapone	Tablets	25/100/200 mg and 37.5/150/200 mg	Stalevo 100 and Stalevo 150 21485	6/29/2007	1	Extinguished	4/7/2020	5/10/2012		6/29/2020
Carbidopa, Levodopa and Entacapone	Tablets	50 mg/200 mg/ 200 mg	Stalevo 200 21485	8/28/2008	1	Deferred	3/10/2020			
Carbidopa and Levodopa	Extended-release Tablets	25 mg/100 mg and 50 mg/200 mg	Sinemet CR 19856	Pre-MMA						
Carbidopa and Levodopa	Extended-release Capsules	61.25 mg/245 mg	Rytary 203312	6/10/2015	1	Non-Forfeiture	8/10/2020			12/26/2028
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	1	Non-Forfeiture	8/10/2020			12/26/2028
Carbidopa and Levodopa	Extended-release Capsules	35 mg/140 mg 52.5 mg/210 mg 70 mg/280 mg 87.5 mg/350 mg	Crextont 217186	9/23/2024	1					12/21/2041
Carboplatin	For Injection	50 mg/vial, 150 mg/vial and 450 mg/vial	Paraplatin 19880	Pre-MMA						
Carboplatin	Injection	50 mg/vial, 150 mg/vial and 450 mg/vial	Paraplatin 20452	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Carfilzomib	For Injection	10 mg/vial	Kyprolis 202714	11/28/2018	1	Deferred	7/13/2021	6/11/2021		2/27/2033
Carfilzomib	For Injection	60 mg/vial	Kyprolis 202714	7/20/2016	9	Eligible	7/13/2021	9/9/2019		12/7/2027
Carfilzomib	For Injection	30 mg/vial	Kyprolis 202714	10/5/2017	1	Eligible	7/25/2022	3/20/2020		2/27/2033
Cariprazine	Capsules	1.5 mg, 3 mg, 4.5 mg and 6 mg	Vraylar 204370	9/17/2019	3	Eligible	10/4/2022	9/9/2022		7/16/2029
Carisoprodol/ Aspirin	Tablets	200 mg/ 325 mg	Soma Compound 12365	Pre-MMA						
Carisoprodol/ Aspirin/ Codeine	Tablets	200 mg/325 mg/ 16 mg	Soma Compound with Codeine 12366	Pre-MMA						
Carvedilol	Tablets	3.125 mg, 6.25 mg, 12.5 mg and 25 mg	Coreg 20297	Pre-MMA						
Carvedilol Phosphate	Extended-release Capsules	10 mg and 20 mg	Coreg CR 22012	3/18/2008	1	Deferred	4/7/2020	10/25/2017	11/8/2017	12/27/2023
Carvedilol Phosphate	Extended-release Capsules	40 mg	Coreg CR 22012	12/21/2007	1	Deferred	4/7/2020	10/25/2017	11/8/2017	12/27/2023
Carvedilol Phosphate	Extended-release Capsules	80 mg	Coreg CR 22012	11/19/2007	1	Deferred	4/7/2020	10/25/2017	11/8/2017	12/27/2023
Caspofungin Acetate	for Injection	50 mg/vial and 70 mg/vial	Cancidas 21227	6/26/2009	1	Extinguished	3/10/2020			3/28/2017
Cefixime	for Oral Suspension	500 mg/5 mL	Suprax 202091	7/22/2016	1	Deferred	4/7/2020	2/6/2017		12/14/2028
Ceftaroline Fosamil	for Injection	400 mg/vial and 600 mg/vial	Teflaro 200327	10/29/2014	2	Deferred	10/19/2021	9/21/2021		2/10/2031
Celecoxib	Capsules	50 mg	Celebrex 20998	3/21/2008	1	Extinguished	3/10/2020	5/30/2014		4/14/2018
Celecoxib	Capsules	100 mg, 200 mg and 400 mg	Celebrex 20998	Pre-MMA						
Cenobamate	Tablets	12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg and 200 mg	Xcopri 212839	3/11/2024	2					6/16/2039
Cetirizine Hydrochloride	Syrup	5 mg/5 mL	Zyrtec 20346	3/19/2007	1	Extinguished	4/7/2020	5/11/2012		6/25/2007
Cetirizine Hydrochloride	Chewable Tablets	5 mg and 10 mg	Zyrtec 21621	3/25/2005						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Cetirizine Hydrochloride and Pseudoephedrine	Extended-release Tablets	5 mg/120 mg	Zyrtec-D 21150	6/2/2004	1	Extinguished	4/7/2020	2/25/2008		7/13/2019
Cevimeline Hydrochloride	Capsules	30 mg	Evoxac 20989	2/27/2009	1	Extinguished	4/7/2020			7/7/2013
Chlorhexidine Gluconate	Scrub brush/sponge	4%	Hibiclens 18423	Pre-MMA						
Chlorpheniramine Polistirex and Hydrocodone Polistirex	Extended-release Capsules	8 mg/10 mg and 4 mg/5 mg	Tussionex 19111	9/10/2004	1	Extinguished	4/7/2020	10/4/2007		8/9/2005
Ciclesonide	Nasal Spray	50 mcg	Omnaris 22004	2/13/2012	1	Extinguished	2/22/2021			10/21/2020
Ciclopirox	Gel	0.77%	Loprox 20519	5/10/2006	1	Extinguished	4/7/2020	1/7/2009	12/3/2007	9/5/2018
Cinacalcet Hydrochloride	Tablets	30 mg, 60 mg and 90 mg	Sensipar 21688	3/10/2008	1	Extinguished	8/27/2019			12/14/2016
Ciprofloxacin	Oral Suspension	250 mg/5 mL and 500 mg/ 5 mL	Cipro 20780	10/16/2009	1	Deferred	4/7/2020	3/5/2014		12/9/2014
Ciprofloxacin Hydrochloride	Tablets	100 mg, 250 mg, 500 mg and 750 mg	Cipro 19537	Pre-MMA						
Ciprofloxacin and Dexamethasone	Otic Suspension	0.3%/0.1%	Ciprodex 21537	7/31/2012	1	Extinguished	11/17/2020			8/10/2020
Cisatracurium Besylate (multi-dose)	Injection	2 mg/mL, 10 mL vial	Nimbex 20551	8/12/2009	1	Eligible	4/7/2020	2/3/2012		9/26/2012
Cisatracurium Besylate (preserve free)	Injection	2 mg/mL, 5 mL vial and 10 mg/mL, 20 mL vial	Nimbex 20551	8/4/2009	1	Eligible	4/7/2020	2/3/2012		9/26/2012
Cisplatin	Injection	1 mg/mL, 10 mL, 50 mL, 100 mL and 200 mL vials	Platinol-AQ 18057	Pre-MMA						
Cisplatin	For Injection	10 mg/vial and 50 mg/vial	Platinol 18057	Pre-MMA						
Cladribine	Tablets	10 mg	Mavenclad 22561	4/7/2022	1					10/16/2026
Clarithromycin	Extended-release Tablets	500 mg	Biaxin XL 50775	PIV received prior to 2/5/2009						
Clascoterone	Cream	1%	Winlevi 213433	8/26/2024	1					7/25/2030
Clevidipine	Injectable Emulsion	25 mg/50 mL and 50 mg/100 mL	Cleviprex 22156	7/2/2019	1					10/10/2031

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Clindamycin Phosphate	Foam	1%	Evoclin 50801	PIV received prior to 2/5/2009	1	Eligible	3/10/2020	3/31/2010	3/31/2010	8/9/2026
Clindamycin Phosphate	Vaginal Cream	2%	Clindesse 50793	2/5/2015	1	Extinguished	4/7/2020			4/27/2023
Clindamycin Phosphate and Tretinoin	Gel	1.2%/0.025%	Ziana 50802	12/17/2010	1	Deferred	6/18/2019	6/12/2015	7/5/2016	8/3/2020
Clindamycin Phosphate and Benzoyl Peroxide	Gel	1% / 5%	Duac 50741	12/11/2008	1	Deferred	6/18/2019	6/26/2012	6/26/2012	11/14/2012
Clindamycin Phosphate and Benzoyl Peroxide	Gel	1.2%/2.5%	Acanya 50819	12/20/2012	1	Eligible	6/18/2019	6/19/2015	2/19/2019	8/5/2029
Clindamycin Phosphate and Benzoyl Peroxide	Gel	1.2%/3.75%	Onexton 50819	9/30/2015	1	Eligible	6/18/2019	6/5/2018	10/2/2023	8/5/2029
Clobetasol Propionate	Emulsion Foam	0.05%	Olux-E 22013	2/25/2010	1	Eligible	4/7/2020	8/14/2012	2/1/2013	9/8/2019
Clobetasol Propionate	Topical Foam	0.05%	Olux 21142	6/27/2005	1	Eligible	4/7/2020	3/10/2008		10/3/2017
Clobetasol Propionate	Lotion	0.05%	Clobex 21535	3/27/2006	1	Eligible	4/7/2020	12/4/2008	1/2/2012	9/22/2017
Clobetasol Propionate	Spray	0.05%	Clobex 21835	9/29/2008	1	Eligible	4/7/2020	6/16/2011	1/1/2015	3/24/2018
Clobetasol Propionate	Topical Shampoo	0.05%	Clobex 21644	1/9/2008	1	Non-Forfeiture	4/7/2020	6/7/2011	1/2/2012	6/17/2019
Clobetasol Propionate	Cream	0.025%	Impoyz 209483	12/6/2019	1					3/11/2035
Clofarabine	Injection	1 mg/mL, 20 mL vial	Clolar 21673	2/23/2012	1	Eligible	4/7/2020	5/9/2017	5/9/2017	1/14/2018
Clonidine Hydrochloride	Extended-release Tablets	0.1 mg and 0.2 mg	Jenloga 22331	3/4/2011	1	Extinguished	4/7/2020	4/2/2014		10/13/2013
Clonidine Hydrochloride	Extended-release Tablets	0.1 mg and 0.2 mg	Kapvay 22331	3/4/2011	1	Eligible	4/7/2020	9/30/2013	10/7/213	10/13/2013
Clonidine Hydrochloride	Transdermal System	0.1 mg/day 0.2 mg/day 0.3 mg/day	Catapres-TTS 18891	Pre-MMA						
Clopidogrel Bisulfate	Tablets	75 mg	Plavix 20839	Pre-MMA						
Clopidogrel Bisulfate	Tablets	300 mg	Plavix 20839	3/4/2009	1	Eligible	4/7/2020	5/17/2012	5/17/2012	6/10/2019
Clozapine	Orally Disintegrating Tablets	12.5 mg	Fazaclo 21590	6/5/2008	1	Extinguished	4/7/2020			4/9/2018

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Clozapine	Orally Disintegrating Tablets	25 mg and 100 mg	Fazaclo 21590	4/28/2008	1	Extinguished	4/7/2020	11/25/2015	8/30/2012	4/9/2018
Clozapine	Orally Disintegrating Tablets	150 mg	Fazaclo 21590	4/8/2011	1	Deferred	4/7/2020	11/25/2015	5/4/2015	4/9/2018
Clozapine	Orally Disintegrating Tablets	200 mg	Fazaclo 21590	4/18/2011	1	Deferred	4/7/2020	11/25/2015	5/4/2015	4/9/2018
Cobicistat	Tablets	150 mg	Tybost 203094	11/14/2016	1	Deferred	3/4/2024	2/7/2024		9/3/2029
Colchicine	Capsules	0.6 mg	Mitigare 204820	6/10/2016	1	Eligible	8/27/2019	11/29/2018	11/1/2023	8/22/2033
Colchicine	Tablets	0.3 mg	Colcrys 22352	7/19/2019	1	Eligible	4/7/2020	11/14/2019	8/1/2020	2/17/2029
Colchicine	Tablets	0.6 mg	Colcrys 22352	12/23/2011	1	Extinguished	4/7/2020		7/2/2018	2/17/2029
Colchicine	Oral Solution	0.6 mg/5 mL	Gloperba 210942	4/2/2020	1	Non-Forfeiture	1/10/2023			12/20/2037
Colesevelam Hydrochloride	Powder for Oral Suspension	1.875 g/Packet and 3.75 g/Packet	Welchol 22362	4/9/2010	1	Extinguished	3/10/2020			12/2/2014
Colesevelam Hydrochloride	Tablets	625 mg	Welchol 21176	7/1/2009	1	Extinguished	4/7/2020	5/16/2018		12/10/2014
Colestipol Hydrochloride	Tablets	1 g	Colestid 02222	8/23/2005	1			10/24/2006		
Conjugated Estrogen (Synthetic A)	Tablets	0.3 mg, 0.45 mg and 0.9 mg	Cenestin 20992	3/19/2009	1	Extinguished	4/7/2020			7/26/2015
Conjugated Estrogen (Synthetic A)	Tablets	1.25 mg	Cenestin 20992	11/3/2008	1	Extinguished	4/7/2020			7/26/2015
Conjugated Estrogen (Synthetic A)	Tablets	0.625 mg	Cenestin 20992	3/2/2009	1	Extinguished	4/7/2020			7/26/2015
Conjugated Estrogens	Tablets	0.3 mg and 0.625 mg	Premarin 04782	Pre-MMA						
Crisaborole	Topical Ointment	2%	Eucrisa 207695	6/14/2021	5					1/20/2030
Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate	Injection	60 mcg/mL, 3 mcg/mL, 6 mcg/mL, 1000 mcg/mL	Multrys 209376	11/14/2023	3					7/1/2041
Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate	Injection	0.3 mg/mL, 55 mcg/mL, 60 mcg/mL, 3 mg/mL (1 mL)	Tralement 209376	11/14/2023	3					7/1/2041

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Cupric Sulfate, Magnesium Sulfate, Selenious Acid, Zinc Sulfate	Injection	0.3 mg/mL, 55 mcg/mL, 60 mcg/mL, 3 mg/mL (5 mL)	Tralement 209376	11/14/2023	3					7/1/2041
Cyanocobalamin	Nasal Spray	500 mcg/spray	Nascobal 21642	4/28/2017	1	Extinguished	4/6/2021			8/1/2024
Cyclobenzaprine Hydrochloride	Tablets	10 mg	Flexeril 17821	Pre-MMA						
Cyclobenzaprine Hydrochloride	Extended-release Capsule	15 mg and 30 mg	Amrix 21777	8/11/2008	1	Extinguished Non-Forfeiture	4/7/2020 4/7/2020		5/13/2011	2/26/2025
Cyclophosphamide	For Injection	100 mg/vial 200 mg/vial 500 mg/vial 1 g/vial 2 g/vial	Cytoxan 12142	Pre-MMA						
Cyclophosphamide	Injection	500 mg/2.5 mL and 1 g/5 mL	Cyclophos 212501	3/7/2022	1	Eligible	11/11/2024	10/29/2024		2/15/2036
Cyclophosphamide	Injection	2 g/10 mL	Cyclophos 212501	1/17/2023	1					2/15/2036
Cyclosporine	Ophthalmic Emulsion	0.05%	Restasis 50790	1/13/2014	1	Extinguished	2/8/2022			5/17/2014
Cyclosporine	Ophthalmic Emulsion	0.05%	Restasis Multidose 50790	1/29/2020	1					5/11/2034
Cysteamine Bitartrate	Delayed-release Capsules	25 mg and 75 mg	Procysbi 203389	5/11/2020	1	Extinguished	3/17/2025			8/16/2036
Cysteamine Bitartrate	Delayed-release Granules	75 mg/Packet and 300 mg/Packet	Procysbi 213491	12/16/2021	1					8/16/2036
Cysteine Hydrochloride	Injection	500 mg/10 mL	Elcys 210660	12/10/2019	1					1/15/2039
Dabigatran Etexilate Mesylate	Capsules	eq. to 75 mg base and 150 mg base	Pradaxa 22512	10/20/2014	17	Eligible	6/15/2020	3/11/2020	75 mg - 7/1/2022 150 mg-3/11/2020	8/31/2027
Dabigatran Etexilate Mesylate	Capsules	eq. to 110 mg base	Pradaxa 22512	12/15/2015	2	Eligible	1/8/2024	12/15/2023	2/13/2024	1/20/2031
Dalbavancin Hydrochloride	Powder For Injection	500 mg/vial	Dalvance	5/23/2023	3					5/23/2028

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Dalfampridine	Extended-release Tablets	10 mg	Ampyra 22250	1/22/2014	8	Eligible	11/19/2019	1/23/2017	9/10/2018	5/26/2027
Dapagliflozin	Tablets	5 mg and 10 mg	Farxiga 202293	1/8/2018	20					5/26/2030
Dapagliflozin and Saxagliptan	Tablets	5 mg/5 mg	Qtern 209091	7/29/2020	1					12/16/2029
Dapagliflozin and Saxagliptan	Tablets	10 mg/5 mg	Qtern 209091	1/8/2018	5					12/16/2029
Dapagliflozin and Metformin Hydrochloride	Extended-release Tablets	2.5 mg/1000 mg	Xigduo XR 205649	10/29/2018	1					12/16/2029
Dapaglifozin 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	10					5/26/2030
Dapsone	Gel	7.5%	Aczone 207154	2/13/2017	1	Eligible	7/2/2019	6/26/2019	6/26/2019	11/18/2033
Daptomycin	For Injection	500 mg/vial	Cubicin 21572	11/19/2008	1	Extinguished	11/19/2019			9/24/2019
Darifenacin Hydrobromide	Extended-release Tablets	7.5 mg and 15 mg	Enablex 21513	12/22/2008	3	Deferred	4/7/2020	3/13/2015	3/15/2016	8/21/2016
Darolutamide	Tablets	300 mg	Nubeqa 212099	7/31/2023	1					2/27/2038
Darunavir Ethanolate	Tablets	75 mg, 150 mg and 300 mg	Prezista 21976	6/23/2010	1	Eligible	8/18/2025	7/22/2025		12/26/2026
Darunavir Ethanolate	Tablets	400 mg	Prezista 21976	6/23/2010	3	Eligible	11/13/2023	9/14/2023	10/18/2024	12/26/2026
Darunavir Ethanolate	Tablets	600 mg	Prezista 21976	6/23/2010	4	Eligible	7/2/2019	11/21/2017	6/1/2023	12/26/2026
Darunavir Ethanolate	Tablets	800 mg	Prezista 21976	5/14/2013	1	Eligible	10/4/2022	9/29/2022	6/1/2023	12/26/2026
Darunavir and Cobicistat	Tablets	800 mg/150 mg	Prezcobix 205395	7/24/2020	1					10/6/2032
Darunavir, Cobicistat, Emtricitabine, Tenofovir Alafenamide	Tablets	800 mg/150 mg/ 200 mg/10 mg	Symtuza 210455	8/16/2021	1					7/19/2038
Dasatinib	Tablets	80 mg and 140 mg	Sprycel 21986	6/17/2011	1	Non-Forfeiture	10/2/2021	11/23/2021	9/3/2024	3/28/2026

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Dasatinib	Tablets	20 mg, 50 mg, 70 mg and 100 mg	Sprycel 21986	6/28/2010	1	Non-Forfeiture Deferred	10/19/2021 4/7/2020	6/10/2016	9/3/2024	3/28/2026
Deferasirox	Tablets for Suspension	125 mg, 250 mg, and 500 mg	Exjade 21882	10/28/2011	1	Eligible	7/2/2019	1/26/2016	3/22/2019	4/5/2019
Deferasirox	Tablets	90 mg and 360 mg	Jadenu 206910	10/19/2015	1	Extinguished	7/16/2019			4/5/2019
Deferasirox	Tablets	180 mg	Jadenu 206910	4/21/2016	1	Eligible	7/16/2019	12/13/2019	12/17/2019	11/21/2034
Deferiprone	Tablets	500 mg	Ferriprox 21825	1/29/2016	1	Eligible	8/13/2019	2/8/2019	9/28/2020	6/28/2021
Defibrotide Sodium	Injection	200 mg/2.5 mL	Defitelio 208114	12/27/2024	1					6/22/2032
Degarelix Acetate	Powder for Injection	80 mg/vial and 120 mg/vial	Firmagon 22201	12/20/2019	1					4/27/2032
Deoxycholic Acid	Injection	10 mg/mL (2 mL)	Kybella 206333	7/13/2018	1	Deferred	5/4/2021	4/2/2021		3/2/2030
Desflurane	Inhalation	99.9%	Suprane 20118	9/11/2008	1	Extinguished	4/7/2020			4/8/2014
Desloratadine	Tablets	5 mg	Clarinex 21165	6/21/2006	11	Extinguished	4/7/2020	10/25/2010		7/7/2019
Desloratadine	Orally Disintegrating Tablets	2.5 mg and 5 mg	Clarinex 21165	6/21/2006	3	Extinguished	4/7/2020	7/12/2010		7/7/2019
Desloratadine	Oral Solution	0.5 mg/mL	Clarinex Syrup 21300	5/8/2008	1	Extinguished	4/7/2020			6/1/2018
Desloratadine and Pseudoephedrine Sulfate	Extended-release Tablets	2.5 mg/120 mg	Clarinex-D 24 Hour 21313	6/1/2007	1	Extinguished	4/7/2020			2/18/2021
Desloratadine and Pseudoephedrine Sulfate	Extended-release Tablets	5 mg/240 mg	Clarinex-D 24 Hour 21313	6/21/2006	1	Extinguished	4/7/2020	4/26/2011		3/28/2022
Desmopressin Acetate	Injection	4 mcg/mL, 1 mL and 10 mL vials	DDAVP 18938	Pre-MMA						
Desmopressin Acetate	Nasal Spray	0.01%	DDAVP 17922	Pre-MMA						
Desmopressin Acetate	Tablets	0.1 mg and 0.2 mg	DDAVP 19955	Pre-MMA						
Desogestrel; Ethinyl Estradiol Tablets	Tablets	0.15mg/ 0.02 mg and 0.01 mg	Mircette 20713	Pre-MMA						
Desonide	Gel	0.05%	Desonate 21844	12/1/2010	1	Deferred	6/15/2020	5/11/2020	7/9/2020	8/3/2020

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Desoximetasone	Topical Spray	0.25%	Topicort 204141	12/18/2013	1	Extinguished	4/7/2020	1/20/2017		4/23/2028
Desvenlafaxine Succinate	Extended-release Tablets	50 mg and 100 mg	Pristiq 21992	2/29/2012	12	Eligible	6/18/2019	6/29/2015	2/28/2017	2/11/2022
Desvenlafaxine Succinate	Extended-release Tablets	25 mg	Pristiq 21992	5/8/2015	1	Eligible	4/7/2020	7/29/2016	7/29/2016	7/5/2027
Deutetrabenazine	Tablets	6 mg, 9 mg and 12 mg	Austedo 208082	4/5/2021	2	Eligible	2/17/2025	12/26/2024		3/7/2036
Dexlansoprazole	Delayed-release Capsules	30 mg	Dexilant 22287	11/30/2010	1	Extinguished	4/7/2020			8/2/2026
Dexlansoprazole	Delayed-release Capsules	60 mg	Dexilant 2287	8/25/2010	1	Extinguished Deferred	9/20/2022 4/7/2020	4/19/2017	11/22/2022	8/2/2026
Dexmedetomidine	Injection	100 mcg/mL	Precedex 21038	4/8/2009	1	Eligible	4/7/2020	6/14/2016	9/22/2014	3/31/2019
Dexmedetomidine	Injection	4 mcg/mL, 50 mL and 100 mL vials	Precedex 21038	12/26/2013	1	Extinguished	8/13/2019	1/30/2020		1/4/2032
Dexmedetomidine	Injection	4 mcg/mL, 20 mL vials	Precedex 21038	9/30/2015	1	Eligible	7/2/2019	11/29/2018	6/3/2019	1/4/2032
Dexmethylphenidate Hydrochloride	Tablets	2.5 mg	Focalin 21278	7/27/2004	1	Eligible	4/7/2020	1/29/2007		12/4/2015
Dexmethylphenidate Hydrochloride	Tablets	5 mg and 10 mg	Focalin 21278	5/27/2004	1	Eligible	4/7/2020	1/29/2007		12/4/2015
Dexmethylphenidate Hydrochloride	Extended-release Capsules	15 mg	Focalin XR 21802	5/14/2007	1	Eligible	1/27/2020	11/18/2013		11/1/2019
Dexmethylphenidate Hydrochloride	Extended-release Capsules	5 mg, 10 mg and 20 mg	Focalin XR 21802	3/30/2007	1	Eligible	1/27/2020	11/19/2013	11/10/2014	11/1/2019
Dexmethylphenidate Hydrochloride	Extended-release Capsules	30 mg	Focalin XR 21802	12/15/2010	1	Eligible	1/27/2020	8/28/2013	11/18/2013	11/1/2019
Dexmethylphenidate Hydrochloride	Extended-release Capsules	40 mg	Focalin XR 21802	12/20/2010	1	Eligible	1/27/2020	11/19/2013	11/22/2013	11/1/2019
Dexmethylphenidate	Extended-release Capsules	35 mg	Focalin XR 21802	9/29/2011	1	Eligible	1/27/2020	11/30/2016	1/5/2017	11/1/2019
Dexmethylphenidate	Extended-release Capsules	25 mg	Focalin XR 21802	9/30/2011	1	Eligible	1/27/2020	11/30/2016	1/5/2017	11/1/2019
Dexrazoxane	For Injection	250 mg/vial	Zinecard 20212	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
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	Pre-MMA						
Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate	Tablets	5 mg, 10 mg, 20 mg, 30 mg	Adderall 11522	11/18/2009	1	Extinguished	4/7/2020			7/6/2020
Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate	Tablets	7.5 mg, 12.5 mg and 15 mg	Adderall 11522	Pre-MMA						
Dextromethorphan Polistirex	Extended-release Suspension	30 mg/5 mL	Delsym 18658	1/12/2009	1	Eligible	4/7/2020	5/25/2012	8/27/2012	4/16/2017
Dextromethorphan Hydrobromide and Bupropion Hydrochloride	Extended-release Tablet	45 mg/105 mg	Auvelity 215430	12/22/2022	1					1/7/2040
Dextromethorphan Hydrobromide and Quinidine Sulfate	Capsules	20 mg/10 mg	Nuedexta 21879	3/7/2011	1	Extinguished	3/10/2020			8/13/2026
Diazepam	Nasal Spray	5 mg/spray and 7.5 mg/spray	Valtoco 211635	4/3/2025	1					3/27/2029
Diazepam	Nasal Spray	10 mg/spray	Valtoco 211635	2/14/2024	1					3/27/2029
Diazepam	Tablets	2 mg, 5 mg and 10 mg	Valium 13263	Pre-MMA						
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	1	Extinguished	4/7/2020			10/31/2012
Diazepam	Rectal Gel	5 mg/mL, 4mL pre-filled syringe	Diastat Acudial 20648	12/8/2008	1	Extinguished	4/7/2020			9/17/2013
Diazepam	Rectal Gel	5 mg/mL, 2mL pre-filled syringe	Diastat Acudial 20648	12/23/2008	1	Extinguished	4/7/2020			9/17/2013

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Diclofenac Potassium	Oral Solution (Sachet)	50 mg	Cambia 22165	1/24/2011	1	Extinguished	4/7/2020			6/16/2026
Diclofenac Potassium	Capsules	25 mg	Zipsor 22202	11/14/2012	1	Extinguished	2/11/2020	2/23/2016		2/24/2029
Diclofenac Sodium	Injection	37.5 mg/mL, 1 mL single-dose vials	Dyloject 22396	12/15/2015	1	Eligible	7/2/2019	6/18/2019		3/22/2027
Diclofenac Sodium	Topical Gel	3%	Solaraze 21005	12/16/2009	1	Deferred	4/7/2020	10/28/2013	11/21/2013	8/11/2015
Diclofenac Sodium	Topical Solution	1.5%	Pennsaid 20947	7/11/2012	1	Eligible	4/7/2020	5/27/2014	5/27/2014	7/10/2029
Diclofenac Sodium	Topical Solution	2.0%	Pennsaid 204623	6/3/2014	1	Extinguished	5/5/2022			8/9/2030
Diclofenac	Capsules	18 mg and 35 mg	Zorvolex 204592	6/6/2014	1					4/23/2030
Diclofenac Epolamine	Topical Patch	1.3%	Flector 21234	6/26/2015	1	Extinguished	7/2/2019			4/13/2019
Diclofenac Sodium and Misoprostol	Delayed-release Tablets	50 mg/0.2 mg	Arthrotec 20607	6/29/2009	1	Extinguished	3/10/2020			2/11/2014
Diclofenac Sodium and Misoprostol	Delayed-release Tablets	75 mg/0.2 mg	Arthrotec 20607	11/28/2008	1	Extinguished	3/10/2020			2/11/2014
Didanosine	Delayed-release Capsules	200 mg, 250 mg and 400 mg	Videx EC 21183	6/1/2004	1	Eligible	4/7/2020	12/3/2004		3/1/2007
Difluprednate	Ophthalmic Emulsion	0.05%	Durezol 22212	5/1/2014	1	Extinguished	7/2/2019			5/18/2019
Diltiazem Hydrochloride	Extended-release Capsules	60 mg, 90 mg and 120 mg	Cardizem SR 19471	Pre-MMA						
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg and 240 mg	Dilacor XR 20092	Pre-MMA						
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg, 240 mg, 300 mg and 360 mg	Cardizem CD 20062	Pre-MMA						
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg, 240 mg, 300 mg, 360 mg and 420 mg	Tiazac 20401	Pre-MMA						
Diltiazem Hydrochloride	Extended-release Tablets	120 mg, 180 mg, 240 mg, 300 mg and 360 mg	Cardizem LA 21392	8/30/2005	1	Deferred	11/19/2019	3/15/2010	3/15/2010	6/25/2013
Diltiazem Hydrochloride	Extended-release Tablets	420 mg	Cardizem LA 21392	4/25/2005	1	Deferred	11/19/2019	3/15/2010	3/152010	6/25/2013

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Dimethyl Fumarate	Delayed-release Capsules	120 mg and 240 mg	Tecfidera 204063	3/27/2017	29	Eligible	8/24/2020	8/17/2020	8/18/2020	2/7/2028
Diroximel Fumarate	Delayed-release Capsules	231 mg	Vumerity 211855	12/23/2020	1					9/20/2033
Divalproex Sodium	Delayed-release Tablets	125 mg, 250 mg and 500 mg	Depakote 18723	Pre-MMA						
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	1	Extinguished	4/7/2020			11/22/2013
Dofetilide	Capsules	0.125 mg, 0.25 mg, and 0.5 mg	Tikosyn 20931	5/1/2014	1	Eligible	8/13/2019	6/6/2016	6/7/2016	10/9/2018
Dolutegravir Sodium	Tablets	10 mg, 25 mg and 50 mg	Tivicay 204790	8/14/2017	4					12/8/2029
Dolutegravir Sodium	Tablets for Suspension	5 mg	Tivicay PD 213983	7/21/2021	1					12/8/2029
Dolutegravir Sodium and Lamivudine	Tablets	50 mg/300 mg	Dovato 211994	7/30/2019	1					12/8/2029
Dolutegravir Sodium and Rilpivirine	Tablets	50 mg/25 mg	Juluca 210192	11/19/2019	1					1/24/2031
Donepezil Hydrochloride	Tablets	5 mg and 10 mg	Aricept 20690	Pre-MMA						
Donepezil Hydrochloride	Orally Disintegrating Tablets	5 mg and 10 mg	Aricept ODT 21720	6/30/2010	1	Extinguished	4/7/2020	11/26/2010		6/23/2022
Donepezil Hydrochloride	Tablets	23 mg	Aricept 22568	7/9/2013		Eligible	4/7/2020	7/24/2013	7/26/2013	10/4/2026
Doravirine, Lamivudine and Tenofovir Disoproxil Fumarate	Tablets	100 mg/300 mg/ 300 mg	Delstrigo 210807	8/30/2022	1					11/29/2036
Doripenem	Injection	250 mg/vial and 500 mg/vial	Doribax 22106	10/12/2011	1	Extinguished	4/7/2020			6/5/2015
Dorzolamide Hydrochloride	Ophthalmic Solution	2%	Trusopt 20408	10/11/2005	1	Extinguished	4/7/2020	10/28/2008		4/28/2008
Dorzolamide Hydrochloride and Timolol Maleate	Ophthalmic Solution	2%/0.5%	Cosopt 20869	10/11/2005	1	Extinguished	4/7/2020	10/28/2008		4/28/2008
Doxazosin Mesylate	Tablets	1 mg, 2 mg, 4 mg and 8 mg	Cardura 19668	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Doxepin Hydrochloride	Tablets	3 mg and 6 mg	Silenor 22036	9/16/2010	2	Extinguished Eligible	7/27/2020 6/18/2019	7/26/2013		2/17/2020
Doxercalciferol	Capsules	1 mcg	Hectorol 20862	2/12/2010	1	Extinguished	4/7/2020	9/9/2016		2/11/2014
Doxercalciferol	Capsules	0.5 mcg and 2.5 mcg	Hectorol 20862	3/25/2009	1	Eligible	4/7/2020	1/14/2014 9/23/2011		7/18/2021
Doxercalciferol	Injection	2 mcg/mL, 2 mL ampules	Hectorol 21027	10/15/2007	1	Extinguished	11/19/2019			
Doxercalciferol	Injection	2 mcg/mL, 1 mL in 2 mL vial	Hectorol 21027	12/28/2011	1	Extinguished	11/19/2019			
Doxycycline	Delayed-release Capsules	40 mg	Oracea 50805	12/12/2008	1	Extinguished	8/24/2022			4/5/2022
Doxycycline Hyclate	Delayed-release Tablets	75 mg and 100 mg	Doryx 50795	PIV received prior to 2/5/2009	1	Eligible	4/7/2020	12/28/2010	12/30/2010	12/15/2022
Doxycycline Hyclate	Delayed-release Tablets	150 mg	Doryx 50795	12/19/2008	1	Extinguished	4/7/2020			12/15/2022
Doxycycline Hyclate	Delayed-release Tablets	200 mg	Doryx 50795	5/19/2014	1	Eligible	4/7/2020	5/19/2016	5/19/2016	12/15/2022
Doxycycline Hyclate	Delayed-release Tablets	80 mg	Doryx 50795	7/1/2015	1	Extinguished Eligible	4/18/2023 4/7/2020	4/29/2016		12/15/2022
Doxycycline Hyclate	Delayed-release Tablets	50 mg	Doryx 50795	11/5/2015	1	Eligible	4/7/2020	5/23/2016	5/23/2016	2/3/2028
Doxycycline Hyclate	Delayed-release Tablets	60 mg and 120 mg	Doryx MPC 50795	9/28/2017	1	Extinguished	8/7/2023			12/23/2034
Doxylamine Succinate and Pyridoxine Hydrochloride	Delayed-release Tablets	10 mg/10 mg	Diclegis 21876	8/1/2013	1	Extinguished	7/2/2019	8/19/2016	6/21/2019	6/21/2021
Doxylamine Succinate and Pyridoxine Hydrochloride	Extended-release Tablets	20 mg/20 mg	Bonjesta 209661	8/28/2018	1	Deferred	5/5/2022	3/1/2022		2/18/2033
Dronabinol	Oral Solution	5 mg/mL	Syndros 205525	4/17/2017	1	Extinguished	1/12/2021			8/6/2028
Dronedarone Hydrochloride	Tablets	400 mg	Multaq 22425	7/1/2013	7	Eligible	2/6/2024	1/31/2024		4/16/2029
Drospirenone and Estradiol	Tablets	0.5 mg/1 mg	Angeliq 21355	12/26/2007	1	Extinguished	4/7/2020			8/11/2017
Drospirenone and Estradiol	Tablets	0.25 mg/0.5 mg	Angeliq 21355	1/8/2015	1	Extinguished	4/7/2020			10/22/2031
Drospirenone and Ethinyl Estradiol	Tablets	3 mg/0.02 mg	Yaz 21676	9/29/2006	1	Extinguished Deferred	11/17/2022 11/17/2022	3/30/2009	6/1/2010	12/20/2021

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Drospirenone and Ethinyl Estradiol	Tablets	3 mg/0.03 mg	Yasmin 21098	1/7/2005	1	Extinguished	4/7/2020	5/9/2008		8/31/2020
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	1	Extinguished	4/7/2020	10/11/2016		3/3/2022
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	1	Eligible	4/7/2020	10/11/2016	10/11/2016	3/3/2022
Drospirenone	Tablets	4 mg	Slynd 211367	1/7/2022	1					6/28/2031
Duloxetine Hydrochloride	Delayed-release Capsules	20 mg, 30 mg and 60 mg	Cymbalta 21427	8/4/2008	16	Eligible	4/7/2020	12/11/2013		7/18/2014
Duloxetine Hydrochloride	Delayed-release Capsules	40 mg	Cymbalta 21427	5/10/2012	1	Eligible	4/7/2020	12/11/2013	7/15/2015	7/18/2014
Dutasteride	Capsules	0.5 mg	Avodart 21319	10/29/2007	1	Deferred	4/7/2020	12/21/2010	10/9/2015	11/20/2015
Dutasteride and Tamsulosin Hydrochloride	Capsules	0.5 mg/0.4 mg	Jalyn 22460	10/26/2010	1	Eligible	4/7/2020	2/26/2014	11/18/2015	11/20/2015
Edaravone	Oral Suspension	105 mg/5 mL	Radicava ORS 215446	4/20/2023	1					11/1/2039
Edoxaban Tosylate	Tablets	15 mg, 30 mg and 60 mg	Savaysa 206316	1/28/2019	1					3/28/2028
Efavirenz	Tablets	600 mg	Sustiva 21360	4/9/2009	1	Eligible	4/7/2020	2/17/2016	1/30/2018	1/20/2018
Efavirenz	Capsules	50 mg, 100 mg and 200 mg	Sustiva 20972	11/3/2016	1	Eligible	7/2/2019	12/15/2017	12/21/2017	4/6/2019
Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate	Tablets	600 mg/200 mg/300 mg	Atripla 21937	12/29/2008	1	Extinguished	4/7/2020	11/9/2018		3/9/2021
Efinaconazole	Topical Solution	10%	Jublia 203567	6/6/2018	19	Eligible	2/9/2021	12/16/2020		10/2/2034
Elagolix Sodium	Tablets	150 mg and 200 mg	Orilissa 210450	7/25/2022	9					9/1/2036
Elagolix Sodium, Estradiol, Norethindrone Acetate; Elagolix Sodium	Capsules	300 mg/1 mg/ 0.5 mg; 300 mg	Oriahnn (Co-Packaged) 213388	11/3/2022	1					3/14/2034

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Eletriptan Hydrobromide	Tablets	20 mg and 40 mg	Relpax 21016	3/29/2010	1	Extinguished	3/10/2020			8/29/2017
Eliglustat Tartrate	Capsules	84 mg	Cerdelga 205494	8/20/2018	6	Eligible Deferred	2/17/2025 10/5/2021	9/8/2021		6/26/2026
Eltrombopag Olamine	Tablets	50 mg and 75 mg	Promacta 22291	1/7/2014	1	Eligible	2/17/2025	1/17/2025	5/13/2025	2/1/2028
Eltrombopag Olamine	Tablets	12.5 mg and 25 mg	Promacta 22291	2/4/2014	1	Eligible	2/17/2025	1/17/2025	5/13/2025	2/1/2028
Elrombopag Olamine	For Oral Suspension	12.5 mg/packet and 25 mg/packet	Promacta Kit 207027	4/22/2022	1	Eligible	5/13/2024	4/18/2024	5/13/2025	7/13/2025
Elvitegravir, Cobicistat, Emtricitabine, Tenofovir Disoproxil Fumarate	Tablets	150 mg/150 mg/ 200 mg/300 mg	Stribild 203100	10/4/2018	1					4/24/2030
Elvitegravir, Cobicistat, Emtricitabine, Tenofovir Alafenamide	Tablets	150 mg/150 mg/ 200 mg/10 mg	Genvoya 207561	4/12/2023	1					10/6/2032
Eluxadoline	Tablets	75 mg and 100 mg	Viberzi 206940	5/28/2019	6	Eligible	4/14/2025	3/14/2025		3/14/2033
Empagliflozin	Tablets	10 mg and 25 mg	Jardiance 204629	8/1/2018	14	Eligible	9/6/2022	8/3/2022		6/11/2034
Empagliflozin and Metformin Hydrochloride	Tablets	5 mg/500 mg 5 mg/1000 mg 12.5 mg/500 mg 12.5 mg/1000 mg	Synjardy 206111	8/1/2018	4	Eligible	9/6/2022	7/7/2022		8/1/2028
Empagliflozin and Metformin Hydrochloride	Extended-release Tablets	5 mg/1000 mg 10 mg/1000 mg 12.5 mg/1000 mg 25 mg/1000 mg	Synjardy XR 208658	8/1/2018	3					6/11/2034
Empagliflozin and Linagliptin	Tablets	10 mg/5 mg and 25 mg/5 mg	Glyxambi 206073	8/1/2018	9					6/11/2034
Empagliflozin, Linagliptan and Metformin Hydrochloride	Extended-release Tablets	5 mg/2.5 mg/1 g, 10 mg/5 mg/1 g, 12.5 mg/5 mg/1 g, 25 mg/5 mg/1 g	Trijardy XR 212614	5/26/2020	1					4/3/2034
Emtricitabine	Capsules	200 mg	Emtriva 21500	7/16/2012	1	Eligible	11/17/2020	7/2/2018	8/31/2020	3/9/2021

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Emtricitabine and Tenofovir Alafenamide Fumarate	Tablets	120 mg/15 mg	Descovy 208215	10/31/2022	1	Eligible	5/27/2024	5/17/2024		8/15/2032
Emtricitabine and Tenofovir Alafenamide Fumarate	Tablets	200 mg/25 mg	Descovy 208215	11/5/2019	6	Deferred	5/27/2024	5/17/2024		8/15/2032
Emtricitabine and Tenofovir Disoproxil Fumarate	Tablets	200 mg/300 mg	Truvada 21752	9/26/2008	1	Extinguished	8/13/2019	6/8/2017		3/9/2021
Emtricitabine and Tenofovir Disoproxil Fumarate	Tablets	100 mg/150 mg 133 mg/200 mg 167 mg/250 mg	Truvada 21752	5/19/2017	1	Eligible	8/13/2019	8/22/2018	1/18/2021	3/9/2021
Emtricitabine, Rilpivirine Hydrochloride and Tenofovir Disoproxil Fumarate	Tablets	200 mg/25 mg/ 300 mg	Complera 202123	5/20/2015	1	Eligible	5/27/2025	5/20/2025	5/27/2025	12/9/2025
Emtricitabine, Rilpivirine Hydrochloride and Tenofovir Alafenamide Fumarate	Tablets	200 mg/25 mg/ 25 mg	Odefsey 208351	11/5/2019	3					8/15/2032
Enalapril Maleate	Tablets	2.5 mg, 5 mg, 10 mg and 20 mg	Vasotec 18998	Pre-MMA						
Enalapril Maleate	Powder for Oral Solution	1 mg/mL	Epaned Kit 204308	6/21/2016	1					11/6/2032
Enalapril Maleate	Oral Solution	1 mg/mL	Epaned 208686	8/31/2018	1	Eligible	9/7/2021	8/10/2021	8/17/2021	3/25/2036
Encorafenib	Capsules	75 mg	Braftovi 210496	6/27/2022	3					11/21/2032
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	Pre-MMA						
Enoxaparin Sodium	Injection	150 mg/mL, 0.6 mL, 0.8 mL and 1 mL prefilled syringes	Lovenox 20164	Pre-MMA						
Enoxaparin Sodium	Injection	100 mg/mL, 3 mL vials	Lovenox 20164	12/7/2006	1	Non-Forfeiture	4/7/2020	11/28/2011		2/14/2012
Entacapone	Tablets	200 mg	Comtan 20796	4/11/2007	1	Extinguished	4/7/2020	8/16/2012		9/14/2018
Entecavir	Tablets	0.5 mg and 1 mg	Baraclude 21797	6/14/2010	1	Eligible	4/7/2020	8/26/2014	9/4/2014	8/21/2015
Enzalutamide	Capsules	40 mg	Xtandi 203415	8/31/2016	3	Non-Forfeiture Deferred	9/18/2023 6/15/2021	5/14/2021		8/13/2027

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Enzalutamide	Tablets	40 mg and 80 mg	Xtandi 213674	3/31/2021	1					8/13/2027
Enzalutamide	Tablets	120 mg and 160 mg	Xtandi 213674	12/27/2024	1					9/11/2033
Ephedrine Sulfate	Injection	50 mg/10 mL	Emerphed 213407	10/14/2021	1	Extinguished	10/3/2024			5/16/2040
Ephedrine Sulfate	Injection	25 mg/5 mL and 50 mg/10 mL	Ephedrine Sulfate 213994	3/17/2023	1	Eligible	3/17/2025	3/11/2025	8/25/2025	1/22/2040
Epinastine Hydrochloride	Ophthalmic Solution	0.05%	Elestat 21565	10/14/2008	1	Eligible	4/7/2020	3/14/2011	5/2/2011	11/29/2020
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	1	Deferred	8/27/2019	8/16/2018	8/19/2019	9/11/2025
Epinephrine	Injection	1 mg/mL ampules	Adrenalin 204200	3/9/2016	1	Deferred	4/7/2020	7/6/2018	1/31/2023	3/13/2035
Epinephrine	Injection	30 mg/30 mL	Adrenalin 204640	8/20/2018	1	Eligible	9/6/2022	4/24/2020	5/19/2020	3/13/2035
Epinephrine	Injection	1 mg/mL	Epinephrine Injection 205029	8/13/2020	1	Non-Forfeiture Deferred	3/17/2025 11/25/2024	11/20/2024	12/5/2024	8/15/2034
Epinephrine	Nasal Spray	2 mg/spray	Neffy 214697	6/30/2025	1					2/6/2039
Eplerenone	Tablets	25 mg and 50 mg	Inspra 21437	9/27/2006	2	Eligible	4/7/2020	7/30/2008	7/30/2008	4/10/2020
Epoprostenol Sodium	Injection	0. 5m/vial and 1.5 mg/vial	Veletri 22260	3/31/2017	1	Deferred	2/9/2021	1/15/2021	1/27/2021	3/15/2027
Eptifibatide	Injection	0.75 mg/mL, 100 mL vial	Integrilin 21437	6/5/2009	1	Eligible	4/7/2020	6/5/2015	12/14/2015	9/15/2015
Eptifibatide	Injection	2 mg/mL, 10 mL vial	Integrilin 20718	9/30/2008	1	Extinguished	4/7/2020	6/12/2015		9/15/2015
Eptifibatide	Injection	2 mg/mL, 100 mL vial	Integrilin 20718	12/18/2008	1	Extinguished	4/7/2020	6/12/2015		9/15/2015
Eprosartan Mesylate	Tablets	400 mg and 600 mg	Teveten 20738	5/10/2010	1	Eligible	4/7/2020	11/16/2011	12/20/2011	8/12/2014
Erdafitinib	Tablets	3 mg, 4 mg and 5 mg	Balversa 212018	4/12/2023	1					2/2/2038
Eribulin Mesylate	Injection	1 mg/2 mL	Halaven 201532	12/20/2019	1	Extinguished	4/15/2024			1/8/2027

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Erlotinib Hydrochloride	Tablets	100 mg and 150 mg	Tarceva 21743	11/18/2008	2	Eligible	6/18/2019	6/11/2014	5/9/2019	11/9/2020
Erlotinib Hydrochloride	Tablets	25 mg	Tarceva 21743	11/18/2008	1	Eligible	6/18/2019	6/11/2014	5/9/2019	11/9/2020
Ertapenem	Injection	1 g/vial	Invanz 21337	12/21/2012	1	Extinguished	3/10/2020			5/15/2017
Ertugliflozin	Tablets	5 mg and 15 mg	Steglatro 209803	12/20/2021	3	Eligible	8/7/2023	7/13/2023		7/13/2030
Escitalopram Oxalate	Capsules	5 mg	Lexapro 21323	8/17/2005	1	Eligible	4/7/2020	8/3/2007		7/25/2022
Escitalopram Oxalate	Capsules	10 mg and 20 mg	Lexapro 21323	3/30/2005	1	Eligible	4/7/2020	8/3/2007		7/25/2022
Escitalopram Oxalate	Tablets	5 mg, 10 mg and 20 mg	Lexapro 21323	Pre-MMA						
Esketamine Hydrochloride	Nasal Spray	28 mg	Spravato 211243	3/6/2023	3					9/10/2035
Eslicarbazepine Acetate	Tablets	200 mg, 400 mg, 600 mg and 800 mg	Aptiom 22416	11/8/2017	7	Eligible	7/13/2021	6/29/2021	5/6/2025	8/24/2032
Esmolol Hydrochloride	Injection	10 mg/mL, 10 mL vial	Brevibloc 19386	Pre-MMA						
Esmolol Hydrochloride	Injection	10 mg/mL, 250 mL infusion bags and 20 mg/mL, 100 mL infusion bags	Brevibloc 19386	1/31/2014	1	Extinguished	4/7/2020	6/8/2016		1/12/2021
Esomeprazole Magnesium	Delayed-release Capsules	20 mg and 40 mg	Nexium 21153	8/5/2005	1	Extinguished	4/7/2020			3/1/2008
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 21957	8/1/2013	1	Extinguished	10/4/2022			11/3/2019
Esomeprazole Magnesium	Delayed-release for Oral Suspension	10 mg	Nexium 22101	7/6/2018	1	Extinguished	1/27/2020	3/23/2020		11/3/2019
Esomeprazole Magnesium	Delayed-release for Oral Suspension	2.5 mg and 5 mg	Nexium 21957	9/24/2018	1	Extinguished	1/27/2020			11/3/2019
Esomeprazole	Delayed-release Tablets	20 mg	Nexium 24HR (OTC) 207920	9/9/2016	1	Eligible	7/2/2019	3/5/2019		11/3/2019
Esomeprazole Sodium	For Injection	20 mg/vial and 40 mg/vial	Nexium IV 21689	11/23/2009	1	Deferred	4/7/2020	3/18/2013	1/15/2014	5/27/2014

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
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	1	Extinguished	4/7/2020	12/19/2014		8/12/2014
Estradiol	Transdermal System	0.0375 mg/day and 0.06 mg/day	Climara 20375	Pre-MMA						
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	1	Eligible	4/7/2020	5/29/2015	10/17/2016	9/17/2022
Estradiol	Vaginal Inserts	4 mcg and 10 mcg	Imvexxy 208564	12/30/2019	1					12/20/2033
Estradiol	Transdermal System	0.0375 mg/day 0.05 mg/day 0.075 mg/day 0.1 mg/day	Minivelle 203752	8/18/2014	1	Deferred	10/8/2019	8/15/2018	11/1/2018	7/4/2030
Estradiol	Transdermal System	0.025 mg/day	Minivelle 203752	5/8/2015	1	Deferred	10/8/2019	8/15/2018	11/1/2018	7/4/2030
Estradiol; Estradiol and Norgestimate	Tablets	1 mg; 1 mg and 0.09 mg	Prefest 21040	Pre-MMA						
Estradiol and Progesterone	Capsules	1 mg/100 mg	Bijuva NDA 210132	1/6/2020	1	Eligible	5/31/2022	5/16/2022		11/21/2032
Estradiol Valerate and Dienogest	Tablets	3 mg;2 mg/2 mg; 2 mg/3 mg and 1 mg	Natazia 22252	10/22/2010	1	Extinguished	4/7/2020			10/25/2016
Estradiol, Norethindrone Acetate and Relugolix	Tablets	1 mg/0.5 mg/40 mg	Myfembree 214846	12/18/2024	1					5/3/2038
Eszopiclone	Tablets	1 mg, 2 mg and 3 mg	Lunesta 21476	12/15/2008	10	Eligible	4/7/2020	5/23/2011	4/15/2014	8/30/2012
Etelcalcetide	Injection	2.5 mg/0.5 mL 5 mg/mL 10 mg/2 mL	Parsabiv 208325	2/8/2021	2					6/27/2034
Ethinyl Estradiol and Etonogestrel	Vaginal Ring	0.015 mg/24 hour 0.12 mg/24 hour	Nuvaring 21187	6/17/2013	1	Extinguished	3/10/2020			4/8/2018
Etodolac	Extended-release Tablets	400 mg, 500 mg and 600 mg	Lodine XL 20584	Pre-MMA						
Etonogestrel	Implant	68 mg	Nexplanon 21529	12/31/2024	1					7/28/2030

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Everolimus	Tablets	0.25 mg, 0.5 mg, and 0.75 mg	Zortress 21560	9/30/2013	3	Extinguished Deferred	4/7/2020 4/7/2020	4/12/2018		9/9/2019
Everolimus	Tablets	10 mg	Afinitor 22334	6/18/2014	1	Extinguished	2/25/2020			12/6/2019
Everolimus	Tablets	2.5 mg, 5 mg, and 7.5 mg	Afinitor 22334	12/10/2014	1	Extinguished	2/25/2020	12/9/2019		12/6/2019
Everolimus	Tablets for Oral Suspension	2 mg, 3 mg and 5 mg	Afinitor Disperz 203985	12/30/2016	1	Eligible	1/27/2020	4/19/2019	10/1/2021	9/27/2022
Exenatide	Injection	250 mg/mL, 1.2 mL and 2.4 mL prefilled syringe	Byetta 21773	6/11/2014	1	Extinguished	2/11/2020			1/14/2020
Ezetimibe	Tablets	10 mg	Zetia 21445	10/25/2006	1	Eligible	6/18/2019	6/26/2015	12/12/2016	1/25/2022
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	1	Extinguished	3/10/2020			10/25/2016
Famciclovir	Tablets	125 mg, 250 mg and 500 mg	Famvir 20363	12/28/2004	1	Eligible	5/19/2020	8/24/2007		9/1/2015
Famotidine	Injection	10 mg/mL, 2 mL vials; unpreserved	Pepcid	Pre-MMA						
Famotidine	Injection	10 mg/mL, 4 mL and 20 mL vials; preserved	Pepcid	Pre-MMA						
Famotidine	Injection	10 mg/mL, 50 mL vial, pharmacy bulk package; unpreserved	Pepcid	Pre-MMA						
Famotidine	Tablets	10 mg (OTC)	Pepcid AC	Pre-MMA						
Famotidine	Tablets	20 mg and 40 mg	Pepcid 19462	Pre-MMA						
Famotidine	Tablets (Chewable)	10 mg (OTC)	Pepcid AC (chewable) 20801	Pre-MMA						
Febuxostat	Tablets	40 mg and 80 mg	Uloric 21856	2/13/2013	10	Eligible	8/27/2019	7/1/2019	7/1/2019	3/8/2024
Fedratinib Hydrochloride	Capsules	100 mg	Inrebic 212327	8/16/2023	1					9/24/2039
Felodipine	Extended-release Tablets	2.5 mg, 5 mg and 10 mg	Plendil ER 19834	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Fenfluramine Hydrochloride	Oral Solution	2.2 mg/mL	Fintepla 212102	6/21/2021	1					6/29/2038
Fenofibrate	Tablets	40 mg and 120 mg	Fenoglide 22118	3/17/2010	1	Extinguished	3/10/2020			12/9/2024
Fenofibrate	Capsules	43 mg and 130 mg	Antara 21695	9/15/2008	1	Extinguished	5/19/2020	3/1/2012		8/20/2020
Fenofibrate Choline	Delayed-release Capsules	45 mg	Trilipix 22224	9/2/2009	1	Extinguished	5/19/2020	9/7/2016		1/7/2025
Fenofibrate Choline	Delayed-release Capsules	135 mg	Trilipix 22224	9/1/2009	1	Extinguished	5/19/2020	9/7/2016		1/7/2025
Fenofibrate	Capsules	67 mg, 134 mg and 200 mg	Tricor 19304	Pre-MMA						
Fenofibrate	Tablets	48 mg	Tricor 21656	7/1/2008	1	Extinguished	4/7/2020	4/5/2012		2/21/2023
Fenofibrate	Tablets	54 mg, 107 mg and 160 mg	Tricor 21203	Pre-MMA						
Fenofibrate	Tablets	145 mg	Tricor 21656	10/19/2007	1	Extinguished	4/7/2020			2/21/2023
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	Pre-MMA						
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	1	Extinguished Deferred	3/10/2020 3/10/2020	1/7/2011		3/26/2019
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	1	Extinguished	9/4/2023			4/27/2030
Fentanyl	Sublingual Spray	0.1 mg/spray, 0.2 mg/spray, 0.6 mg/spray, 0.8 mg/spray, 1.2 mg/spray, 1.6 mg/spray	Subsys 202788	12/7/2017	1	Extinguished	9/4/2023			4/27/2030

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
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	1	Deferred	5/19/2020	11/17/2017		9/24/2019
Ferric Carboxymaltose	Injection	100 mg/2 mL	Injectafer 203565	9/23/2022	1					2/15/2028
Ferric Carboxymaltose	Injection	500 mg/10 mL	Injectafer 203565	2/22/2024	1					2/15/2028
Ferric Carboxymaltose	Injection	750 mg/15 mL	Injectafer 203565	3/27/2019	1					2/15/2028
Ferric Carboxymaltose	Injection	1 g/20 mL	Injectafer 203565	2/15/2022	1					2/15/2028
Ferumoxytol	Injection	30 mg/mL, 17 mL single-use vials	Feraheme 22180	12/4/2015	1	Deferred	2/9/2021	1/15/2021	7/15/2021	6/30/2023
Fesoterodine Fumarate	Extended-release Tablets	4 mg and 8 mg	Toviaz 22030	10/31/2012	16	Eligible	5/19/2020	12/10/2015	7/3/2022	6/7/2027
Fexofenadine Hydrochloride	Oral Suspension (OTC)	30 mg/5 mL	Allegra 201373	1/25/2010	1	Eligible	11/19/2019	11/18/2014	12/22/2014	3/14/2017
Fexofenadine Hydrochloride	Capsules	60 mg	Allegra 20625	Pre-MMA						
Fexofenadine Hydrochloride	Tablets	30 mg, 60 mg and 180 mg	Allegra 20872	Pre-MMA						
Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride	Extended-release Tablets	60 mg/120 mg	Allegra-D 20786	Pre-MMA						
Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride	Extended-release Tablets	180 mg/240 mg	Allegra-D 24 Hour 21704	6/6/2007	1	Eligible	5/19/2020	6/22/2011	1/28/2011	12/25/2020
Fidaxomicin	Tablets	200 mg	Dificid 201699	5/27/2015	1	Deferred	1/22/2024	1/16/2024	7/15/2025	7/31/2027
Finasteride	Tablets	1 mg	Propecia 20788	Pre-MMA						
Finasteride	Tablets	5 mg	Proscar 20180	Pre-MMA						
Finerenone New	Tablets	10 mg and 20 mg	Kerendia 215341	7/9/2025	9					7/29/2035
Fingolimod	Capsules	0.5 mg	Gilenya 22527	9/22/2014	19	Eligible	1/2/2020	12/4/2019	9/21/2022	3/29/2026

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Fingolimod	Capsules	0.25 mg	Gilenya 22527	7/19/2018	1	Eligible	11/15/2021	11/12/2021		3/30/2032
Flecainide Acetate	Tablets	50 mg, 100 mg and 150 mg	Tambocor 18830	Pre-MMA						
Fluconazole	For Oral Suspension	50 mg/5 mL and 200 mg/5 mL	Diflucan for Oral Suspension 20090	Pre-MMA						
Fluconazole	Tablets	50 mg, 100 mg, 150 mg and 200 mg	Diflucan 19949	Pre-MMA						
Flunisolide	Nasal Solution	0.025%	Nasalide 18148	Pre-MMA						
Fluocinonide	Cream	0.1%	Vanos 21758	1/31/2008	1	Eligible	6/1/2020	1/14/2014	1/14/2014	12/21/2021
Fluocinonide	Ointment	0.05%	Lidex 16909	Pre-MMA						
Fluorouracil	Cream	0.5%	Carac 20985	7/29/2011	1	Deferred	6/1/2020	4/20/2015	11/1/2014	6/2/2021
Fluoxetine Hydrochloride	Tablets	10 mg and 20 mg	Prozac 20974	Pre-MMA						
Fluoxetine Hydrochloride	Capsules	10 mg, 20 mg and 40 mg	Prozac 18936	Pre-MMA						
Fluoxetine Hydrochloride	Delayed-release Capsules	90 mg	Prozac Weekly 21235	Pre-MMA						
Fluoxetine Hydrochloride	Oral Solution	20 mg (base)/5 mL	Prozac 20101	Pre-MMA						
Fluoxetine Hydrochloride	Capsules	10 mg and 20 mg	Sarafem 18936	Pre-MMA						
Flutamide	Capsules	125 mg	Eulexin 18554	Pre-MMA						
Fluticasone Furoate	Nasal Spray	27.5 mcg	Flonase Sensimist Allergy Relief 22051	7/15/2011	1	Extinguished	6/15/2020			8/3/2021
Fluticasone Furoate and Vilanterol Trifenatate	Powder for Inhalation	100 mcg/25 mcg	Breo Ellipta 204275	6/16/2025	1					10/11/2030
Fluticasone Propionate	Lotion	0.05%	Cutivate 21152	7/28/2008	1	Eligible	6/15/2020	5/2/2011	3/26/2012	10/20/2019
Fluticasone Propionate	Inhalation Aerosol	0.11 mg/inh	Flovent HFA 21433	12/23/2016	1					2/26/2026

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Fluticasone Propionate	Inhalation Aerosol	0.22 mg/inh	Flovent HFA 21433	10/29/2021	1					2/26/2026
Fluvastatin	Capsules	20 mg and 40 mg	Lescol 20261	6/4/2008	1	Extinguished	6/15/2020	4/11/2012		12/12/2011
Fluvastatin Sodium	Extended-release Tablets	80 mg	Lescol XL 21192	3/15/2007	1	Extinguished	6/15/2020			4/13/2020
Fluvoxamine Maleate	Extended-release Capsules	100 mg	Luvox CR 22033	4/20/2009	1	Extinguished	6/15/2020	3/13/2013		5/10/2020
Fluvoxamine Maleate	Extended-release Capsules	150 mg	Luvox CR 22033	4/13/2009	1	Non-Forfeiture	6/15/2020	3/13/2013	3/13/2013	5/10/2020
Fomepizole	Injection	1.5 g/1.5 mL	Antizol 20696	4/14/2014	1	Extinguished	8/7/2023			6/30/2027
Formoterol Fumarate	Inhalation Solution	0.02 mg/2 mL	Perforomist 22007	1/21/2009	1	Extinguished	3/10/2020			6/22/2021
Fosamprenavir Calcium	Tablets	700 mg	Lexiva 21548	1/18/2012	1	Extinguished	6/15/2020	11/20/2019		7/15/2019
Fosaprepitant Dimeglumine	Injection	115 mg/vial	Emend 22023	1/25/2012	1	Extinguished	3/10/2020	9/5/2019		2/10/2015
Fosaprepitant Dimeglumine	Injection	150 mg/vial	Emend 22023	1/25/2012	2	Extinguished	3/10/2020			3/4/2019
Fosinopril Sodium	Tablets	10 mg, 20 mg and 40 mg	Monopril 19915	Pre-MMA						
Fosinopril Sodium and Hydrochlorothiazide	Tablets	10 mg/12.5 mg and 20 mg/12.5 mg	Monopril HCT 20286	Pre-MMA						
Fosnetupitant Chloride Hydrochloride and Palonosetron Hydrochloride	Solution in SDV	235 mg/0.25 mg per 20 mL	Akynzeo 210493	4/19/2022	1					6/2/2037
Fostamatinib Disodium	Tablets	100 mg and 150 mg	Tavalisse 209299	4/18/2022	1					7/27/2032
Frovatriptan Succinate	Tablets	2.5 mg	Frova 21006	3/9/2011	1	Eligible	6/15/2020	7/8/2014	4/29/2016	11/7/2015
Fulvestrant	Injection	50 mg/mL, 2.5 mL and 5 mL syringe	Faslodex 21344	10/1/2009	1	Extinguished	7/16/2019			1/9/2021
Gabapentin	Capsules	100 mg, 300 mg and 400 mg	Neurontin 20235	Pre-MMA						
Gabapentin	Tablets	100 mg, 300 mg and 400 mg	Neurontin 20235	Pre-MMA						
Gabapentin	Oral Solution	250 mg/5 mL	Neurontin 21129	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Gabapentin	Tablets	600 mg and 800 mg	Neurontin 20882	Pre-MMA						
Gabapentin	Tablets	300 mg and 600 mg	Gralise 22544	10/31/2011	1	Extinguished	1/22/2024			2/26/2024
Gabapentin Enacarbil	Extended-release Tablets	300 mg and 600 mg	Horizant 22399	4/29/2019	1					6/10/2029
Galantamine Hydrobromide	Extended-release Capsules	8 mg	Razadyne ER 21615	3/2/2006	1	Eligible	6/15/2020	9/15/2008	10/15/2008	12/20/2019
Galantamine Hydrobromide	Extended-release Capsules	16 mg and 24 mg	Razadyne ER 21615	3/11/2006	1	Eligible	6/15/2020	9/15/2008	10/15/2008	12/20/2019
Galantamine Hydrobromide	Tablets	4 mg, 8 mg and 12 mg	Razadyne 21169	2/28/2005	14	Eligible	6/15/2020	8/28/2008	8/28/2008	6/6/2017
Ganciclovir Sodium	Capsules	250 mg and 500 mg	Cytovene 20460	Pre-MMA						
Ganirelix Acetate	Injection	250 mcg/0.5 mL, 1 mL PFS	Ganirelix Acetate 21057	3/30/2012	1	Extinguished	1/27/2020	11/30/2018		6/16/2015
Gatifloxacin	Injection	10 mg/mL, 20 mL and 40 mL vials	Tequin	11/24/2004	1	Extinguished	6/15/2020			
Gatifloxacin	Ophthalmic Solution	0.3 %	Zymar 21493	7/19/2007	1	Eligible	6/15/2020	8/19/2011		8/20/2019
Gatifloxacin	Ophthalmic Solution	0.5 %	Zymaxid 22548	12/7/2010	1	Eligible	6/15/2020	8/28/2013	10/1/2013	8/20/2019
Gatifloxacin	Tablets	200 mg and 400 mg	Tequin	Pre-MMA						
Gatifloxacin in Dextrose 5% in Plastic Container	Injection	2 mg/mL, 100 mL and 200 mL containers (plastic)	Tequin	12/13/2004	2					
Gemcitabine	For Injection	200 mg/vial	Gemzar 20509	11/1/2005	1	Eligible	6/15/2020	12/18/2008		11/7/2012
Gemcitabine	For Injection	1g/vial	Gemzar 20509	11/14/2005	1	Eligible	6/15/2020	1/25/2011		11/7/2012
Gemcitabine	For Injection	2 g/vial	Gemzar	8/24/2007	1	Eligible	6/15/2020	11/15/2010	11/15/2010	11/7/2012
Gemifloxacin Mesylate	Tablets	320 mg	Factive 21158	3/4/2008	1	Eligible	6/18/2019	6/15/2015		9/21/2019
Gilteritinib Fumarate	Tablets	40 mg	Xospata 211349	11/28/2022	1					7/1/2036
Glatiramer Acetate	Injection	20 mg/mL, 1mL pre-filled syringe	Copaxone 20622	12/27/2007	1	Extinguished	2/25/2020	4/16/2015		5/24/2014

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Glatiramer Acetate	Injection	40 mg/mL, 1 mL pre-filled syringe	Copaxone 20622	2/26/2014	2	Deferred	2/25/2020	10/3/2017	10/4/2017	8/19/2030
Glimepiride and Rosiglitazone Maleate	Tablets	1 mg/4 mg 2 mg/4 mg 4 mg/4 mg	Avandaryl 21700	12/22/2006	1	Extinguished	6/15/2020	4/1/2016		10/21/2015
Glimepiride and Rosiglitazone Maleate	Tablets	8 mg/2 mg 8 mg/4 mg	Avandaryl 21700	5/30/2008	1	Eligible	6/15/2020	4/1/2016		10/19/2020
Glipizide	Extended-release Tablets	2.5 mg, 5 mg and 10 mg	Glucotrol XL 20329	Pre-MMA						
Glyburide	Tablets	1.5 mg, 3 mg, 4.5 mg and 6 mg	Glynase 20051	Pre-MMA						
Glyburide/ Metformin Hydrochloride	Tablets	1.25mg/250 mg 2.5 mg/500 mg 5 mg/500 mg	Glucovance 21178	Pre-MMA						
Glycerol Phenylbutyrate	Oral Liquid	1.1 g/mL	Ravicti 203284	11/19/2013	1	Eligible	1/11/2022	12/2/2021		3/9/2032
Glycopyrrolate	Tablets	1 mg	Robinul 12827	8/14/2009	1	Extinguished	3/10/2020	2/3/2014		4/24/2024
Glycopyrrolate	Tablets	1.5 mg	Robinul Forte	5/6/2009	1	Deferred	6/15/2020	3/12/2012		4/24/2024
Glycopyrrolate	Tablets	2 mg	Robinul Forte 12827	10/12/2010	1	Eligible	6/15/2020	2/3/2014	12/21/2015	4/24/2024
Glycopyrrolate	Oral Solution	1 mg/5 mL	Cuvposa 22571	6/20/2012	1	Eligible	8/24/2021	8/9/2021	1/4/2022	8/20/2023
Glycopyrronium Tosylate	Topical Cloth	2.4%	Qbrexza 210361	1/13/2020	1					2/28/2033
Granisetron Hydrochloride	Injection	0.1 mg/mL, 1 mL single dose vial	Kytril 20239	3/8/2007	1					
Granisetron Hydrochloride	Injection	1 mg/mL, 1 mL vials	Kytril 20239	6/1/2004	1	Eligible	6/15/2020	12/31/2007	12/31/2007	5/4/2019
Granisetron Hydrochloride	Injection	1 mg/mL, 4 mL multi-dose vials	Kytril 20239	7/19/2004	1	Eligible	6/15/2020	12/31/2007	12/31/2007	5/4/2019
Granisetron Hydrochloride	Transdermal System	3.1 mg/24 hrs	Sancuso 22198	10/9/2015	1	Extinguished				10/22/2024
Guaifenesin	Extended-release Tablets	600 mg and 1.2 gm	Mucinex 21282	6/9/2006	1	Extinguished	11/19/2019			4/28/2020
Guaifenesin and Dextromethorphan	Extended-release Tablets	600 mg/30 mg and 1200 mg/60 mg	Mucinex DM 21620	12/17/2008	1	Deferred	6/15/2020	8/31/2015	4/5/2016	4/28/2020

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Guaifenesin and Pseudoephedrine Hydrochloride	Extended-release Tablets	600 mg/60 mg and 1200 mg/120 mg	Mucinex-D 21585	12/29/2008	1	Deferred	6/15/2020	5/27/2015	12/16/2015	4/28/2020
Guanfacine Hydrochloride	Extended-release Tablets	1 mg, 2 mg, 3 mg and 4 mg	Intuniv 22037	12/29/2009	1	Eligible	6/29/2020	10/5/2012	12/1/2014	7/4/2022
Halobetasol Propionate	Lotion	0.05%	Ultavate 208183	1/24/2018	1	Eligible	7/13/2020	6/4/2020		6/19/2033
Halobetasol Propionate	Lotion	0.01%	Bryhali 209355	5/15/2019	1					11/2/2031
Halobetasol Propionate	Topical Foam	0.05%	Lexette 210566	1/28/2021	1	Eligible	9/4/2023	8/11/2023	12/27/2023	11/30/2036
Halobetasol Propionate and Tazarotene	Lotion	0.01%/0.045%	Duobrii 209354	6/11/2020	1	Extinguished	2/17/2025			6/6/2036
Hydrocodone Bitartrate	Extended-release Capsules	10 mg, 15 mg, 20 mg, 30 mg, 40 mg, and 50 mg	Zohydro ER 202880	2/26/2014	1	Extinguished	6/15/2020			11/1/2019
Hydrocodone Bitartrate and Ibuprofen	Tablets	2.5 mg/200 mg	Vicoprofen 20716	2/24/2006	1	Eligible	7/25/2022	10/19/2007		6/10/2017
Hydrocodone Bitartrate and Ibuprofen	Tablets	5 mg/200 mg	Vicoprofen	5/27/2005	1			3/18/2004		6/10/2017
Hydrocodone Bitartrate and Ibuprofen	Tablets	7.5 mg/200 mg	Vicoprofen 20716	Pre-MMA						
Hydrocodone Bitartrate and Ibuprofen	Tablets	10 mg/200 mg	Vicoprofen 20716	3/20/2006	1	Eligible	6/15/2020	11/6/2006		6/10/2017
Hydrocodone Bitartrate	Extended-release Tablets	20 mg, 60 mg, and 120 mg	Hysingla ER 206627	4/15/2015	1	Deferred	3/9/2021	3/1/2021	3/1/2021	12/21/2031
Hydrocodone Bitartrate	Extended-release Tablets	30 mg, 40 mg, 80 mg, and 100 mg	Hysingla ER 206627	5/8/2015	1	Deferred	3/9/2021	3/1/2021	3/1/2021	12/21/2031
Hydrocortisone Butyrate	Cream	0.10%	Locoid Lipocream 20769	6/28/2010	1	Eligible	6/29/2020	9/27/2013	12/5/2013	6/3/2014
Hydrocortisone Butyrate	Lotion	0.10%	Locoid 22076	8/31/2016	1	Eligible	6/29/2020	11/21/2017	2/12/2018	12/19/2026
Hydromorphone Hydrochloride	Extended-release Tablets	8 mg and 12 mg	Exlago 21217	9/2/2010	1	Deferred	6/29/2020	5/12/2014		7/7/2014
Hydromorphone Hydrochloride	Extended-release Tablets	16 mg	Exlago 21217	8/2/2010	1	Deferred	6/29/2020	5/12/2014		7/7/2014
Hydromorphone Hydrochloride	Oral Solution	5 mg/5mL	Dilaudid 19891	2/25/2011	1	Extinguished	1/27/2020			11/9/2020

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Hydromorphone Hydrochloride	Injection	10 mg/mL	Dilaudid-HP 19034	11/4/2011	1	Extinguished	6/29/2020			
Hydromorphone Hydrochloride	Injection	2 mg/mL	Dilaudid 19034	6/22/2011	1	Deferred	1/8/2024	4/27/2018	10/1/2018	11/9/2020
Hydromorphone Hydrochloride	Injection	0.5 mg/0.5 mL and 1 mg/mL	Dilaudid 19034	12/13/2022	1	Eligible	6/10/2024	2/9/2024	0.5 mg-5/15/2024 1 mg - 6/5/2024	3/12/2034
Hydromorphone Hydrochloride	Injection	0.2 mg/mL	Dilaudid 19034	12/19/2023	1	Eligible	6/10/2024	2/9/2024	10/14/2024	3/12/2034
Hydromorphone Hydrochloride	Tablets	2 mg, 4 mg, and 8 mg	Dilaudid 19892	8/5/2013	1	Deferred	6/29/2020	5/13/2016		11/9/2020
Hydroxyprogesterone Caproate	Injection (Auto-injector)	275 mg/1.1 mL	Makena 21945	9/28/2020	1					5/2/2036
Ibandronate Sodium	Injection	1 mg/mL, 3 mL Vial	Boniva 21858	8/31/2007	1	Extinguished	3/10/2020			9/2/2014
Ibandronate Sodium	Tablets	150 mg	Boniva 21455	5/16/2007	8	Deferred	6/29/2020	3/19/2012	3/19/2012	5/6/2023
Ibandronate Sodium	Tablets	2.5 mg	Boniva 21455	5/16/2007	1	Extinguished	6/29/2020			5/6/2023
Ibrutinib	Capsules	70 mg	Imbruvica 205552	12/14/2018	1	Eligible	4/6/2021	3/31/2021		10/30/2033
Ibrutinib	Capsules	140 mg	Imbruvica 205552	11/13/2017	8	Deferred	4/6/2021	3/31/2021		10/24/2034
Ibrutinib	Tablets	140 mg	Imbruvica 210563	11/5/2018	1					3/3/2036
Ibrutinib	Tablets	560 mg	Imbruvica 210563	11/5/2018	1	Extinguished	7/8/2024			3/3/2036
Ibrutinib	Tablets	280 mg and 420 mg	Imbruvica 210563	12/14/2018	1					3/3/2036
Ibuprofen	Oral Drops	40 mg/mL	Children's Motrin Drops 20603	Pre-MMA						
Ibuprofen	Oral Suspension	50 mg/1.25 mL	Concentrated Motrin Infant Drops 20812	6/29/2007	1					12/20/2011
Ibuprofen	Oral Suspension	100 mg/5 mL (Rx)	Motrin	Pre-MMA						
Ibuprofen	Oral Suspension	100 mg/5 mL (OTC)	Children's Motrin	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Ibuprofen	Chewable Tablets	50 mg and 100 mg	Children's Motrin, Junior Strength Motrin 20601	Pre-MMA						
Ibuprofen Lysine	Injection	10 mg/mL, 2 mL vials	Neoprofen 21903	10/1/2010	1	Extinguished Deferred	4/18/2023 6/29/2020	3/30/2016		3/20/2021
Ibuprofen and Acetaminophen	Tablets	125 mg/250 mg	Advil Dual Action with Acetaminophen 211733	3/28/2024	2	Eligible	5/13/2024	4/26/2024	5/7/2024	7/9/2041
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	1	Extinguished	4/18/2023			5/30/2022
Ibuprofen and Famotidine	Tablets	800 mg/26.6 mg	Duexis 22519	12/6/2011	1	Extinguished	8/24/2021			7/18/2026
Ibuprofen and Pseudoephedrine Hydrochloride	Oral Suspension	100 mg/ 15 mg per 5 mL	Children's Motrin Cold	Pre-MMA						
Ibuprofen and Pseudoephedrine Hydrochloride	Tablets	200 mg/30 mg	Advil Cold and Sinus	Pre-MMA						
Ibuprofen Potassium and Pseudoephedrine Hydrochloride	Capsules	200 mg/30 mg	Advil Cold and Sinus	12/27/2004	1	Extinguished	6/29/2020			
Icatibant	Injection	10 mg/mL	Firazyr 22150	8/25/2015	2	Extinguished	8/13/2019			7/15/2019
Icosapent Ethyl	Capsules	1 g	Vascepa 202057	7/26/2016	4	Eligible	6/15/2020	5/21/2020	11/4/2020	4/29/2030
Icosapent Ethyl	Capsules	500 mg	Vascepa 202057	8/29/2017	1	Non-Forfeiture	12/1/2020	9/11/2020	9/9/2022	4/29/2030
Idelalisib	Tablets	100 mg and 150 mg	Zydelig 205858	3/23/2022	1					9/2/2033
Ifosfamide	For Injection	1 g/vial and 3 g/vial	Ifex 19763	Pre-MMA						
Ifosfamide	Injection	50 mg/mL, 20 mL vials and 60 mL vials	Ifex	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
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	Pre-MMA						
Ifosfamide/ Mesna	Injection/ Injection Kit	50 mg/mL, 20 mL and 60 mL vials; 100 mg/mL, 10 mL vial	Ifex/ Mesnex Kit	Pre-MMA						
Iloperidone	Tablets	1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg	Fanapt 22192	5/6/2013	1	Extinguished	6/18/2019			11/15/2016
Imatinib Mesylate	Tablets	100 mg and 400 mg	Gleevec 21588	3/12/2007	1	Non-forfeiture	6/18/2019	12/3/2015	2/1/2016	11/23/2019
Imatinib Mesylate	Capsules	400 mg	Gleevec	1/24/2014	1	Extinguished	3/10/2020			1/16/2019
Imiquimod	Cream	5%	Aldara 20723	10/17/2006	1	Eligible	6/29/2020	2/25/2010	2/25/2010	8/24/2010
Imiquimod	Cream	2.5%	Zyclara 22483	6/17/2014	1					12/11/2029
Imiquimod	Cream	3.75%	Zyclara 22483	8/8/2012	1	Non-Forfeiture	7/16/2019		7/30/2020	12/11/2029
Indocyanine Green	For Injection	25 mg/vial	Spy Agent Green Kit 211580	11/28/2022	1	Extinguished	4/14/2025			8/4/2035
Indomethacin	Extended-release Capsules	75 mg	Indocin SR 18185	Pre-MMA						
Ingenol Mebutate	Gel	0.05%	Picato 202833	1/27/2016	2	Eligible	8/13/2019	1/9/2019		7/6/2027
Ingenol Mebutate	Gel	0.015%	Picato 202833	1/27/2016	2	Eligible	8/13/2019	1/7/2019		7/6/2027
Ipratropium Bromide	Inhalation Aerosol	0.21 mg/Inh	Atrovent HFA 21527	12/29/2023	1					1/17/2030
Irbesartan	Tablets	75 mg, 150 mg and 300 mg	Avapro 20757	5/25/2004	1	Non-Forfeiture	6/29/2020	3/30/2012	3/30/2012	6/7/2015
Irbesartan and Hydrochlorothiazide	Tablets	150 mg/12.5 mg and 300 mg/12.5 mg	Avalide 20758	11/10/2004	1	Eligible	6/29/2020	3/30/2012	3/30/2012	6/7/2015
Irbesartan and Hydrochlorothiazide	Tablets	300 mg/25 mg	Avalide 20758	6/6/2006	1	Eligible	6/29/2020	3/30/2012		6/7/2015
Irinotecan Hydrochloride	Injection	20 mg/mL, 2 mL and 5 mL vials	Camptosar 20571	7/26/2004	1	Extinguished	6/29/2020	2/20/2008		5/1/2020

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Isavuconazonium Sulfate	For Injection	372 mg/vial	Cresemba 207501	9/6/2024	2					10/31/2025
Isavuconazonium Sulfate	Capsules	74.5 mg	Cresemba 207500	9/6/2024	2					9/14/2027
Isavuconazonium Sulfate	Capsules	186 mg	Cresemba 207500	9/6/2024	4					9/14/2027
Isotretinoin	Capsules	30 mg	Absorica 21951	12/31/2012	1	Eligible Deferred	4/20/2021 4/6/2021	3/31/2021	3/31/2021	9/21/2021
Isotretinoin	Capsules	40 mg	Absorica 21951	12/31/2012	1	Extinguished Deferred	4/20/2021 4/6/2021	3/31/2021	3/31/2021	9/21/2021
Isotretinoin	Capsules	20 mg	Absorica 21951	1/7/2013	1	Eligible Deferred	4/20/2021 4/6/2021	3/31/2021	3/31/2021	9/21/2021
Isotretinoin	Capsules	10 mg	Absorica 21951	6/20/2013	1	Eligible Deferred	4/20/2021 4/6/2021	3/31/2021	3/31/2021	9/21/2021
Isotretinoin	Capsules	35 mg	Absorica 21951	11/25/2015	1	Deferred	4/6/2021	3/31/2021	3/31/2021	9/21/2021
Isotretinoin	Capsules	25 mg	Absorica 21951	5/16/2016	1	Deferred	4/6/2021	3/31/2021	3/31/2021	9/21/2021
Itraconazole	Capsules	100 mg	Sporanox 20083	Pre-MMA						
Itraconazole	Oral Solution	10 mg/mL	Sporanox 20657	5/3/2013	1	Eligible	6/29/2020	10/30/2015	9/18/2018	6/18/2019
Ivabradine	Tablets	5 mg and 7.5 mg	Corlanor 206143	10/15/2019	6	Eligible	1/11/2022	12/30/2021	10/5/2022	2/22/2026
Ivacaftor	Tablets	150 mg	Kalydeco 203188	6/10/2020	1					8/13/2029
Ivacaftor	Oral Granules	25 mg, 50 mg and 75 mg	Kalydeco 207925	4/13/2022	1					2/27/2033
Ivermectin	Lotion	0.50%	Sklice 202736	9/1/2017	1	Eligible	6/15/2020	5/6/2020	11/30/2020	10/12/2027
Ivermectin	Cream	1%	Soolantra 206255	12/30/2016	1	Eligible	1/2/2020	9/13/2019	10/14/2019	3/13/2034
Ivosidenib	Tablets	250 mg	Tibsovo 211192	7/20/2022	1					6/7/2039
Ixabepilon	Injection	15 mg/vial and 45 mg/vial, single-use vials	Ixempra Kit 22065	4/16/2012	1	Extinguished	4/18/2023			2/8/2022
Ixazomib Citrate	Capsules	2.3 mg, 3 mg and 4 mg	Ninlaro 208462	11/20/2019	1					11/20/2029

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Ketoconazole	Foam	2%	Extina 21738	7/30/2009	1	Eligible	6/29/2020	8/25/2011	8/25/2011	10/19/2018
Ketoprofen	Capsules	25 mg, 50 mg and 75 mg	Orudis 18754	Pre-MMA						
Ketorolac Tromethamine	Injection	15 mg/mL and 30 mg/mL	Toradol 19698	Pre-MMA						
Ketorolac Tromethamine	Ophthalmic Solution	0.45%	Acuvail 22427	8/24/2011	1	Eligible	6/29/2020	2/10/2014		8/15/2029
Ketorolac Tromethamine	Ophthalmic Solution	0.4%	Acular LS 21528	1/28/2005	1	Extinguished	6/29/2020	11/5/2009		5/5/2011
Ketorolac Tromethamine	Tablets	10 mg	Toradol 19645	Pre-MMA						
Ketorolac Tromethamine	Nasal Spray	15.75 mg/spray	Sprix 22382	3/12/2012	1	Extinguished	3/10/2020			12/25/2018
Ketotifen Fumarate	Ophthalmic Solution	0.025%	Zaditor 21066	12/23/2004	1	Eligible	7/27/2020	5/9/2006	7/3/2006	1/13/2019
Lacosamide	Oral Solution	10 mg/mL	Vimpat 22255	10/29/2012	3	Extinguished	4/18/2022			3/17/2022
Lacosamide	Tablets	50 mg, 100 mg, 150 mg, and 200 mg	Vimpat 22253	10/29/2012	14	Extinguished	4/18/2022	3/17/2022		3/17/2022
Lacosamide	Injection	10 mg/mL, 20 mL	Vimpat 22254	6/30/2016	1	Extinguished	3/10/2020			3/17/2022
Lactic Acid, Citric Acid and Potassium Bitartrate	Vaginal Gel	1.8%/1%/0.4%	Phexxi 208352	2/28/2023	1	Extinguished	7/8/2024			3/15/2033
Lactulose	Oral Syrup	10 g/15 mL	Cephulac 17657	Pre-MMA						
Lactulose	Oral Syrup	10 g/15 mL	Chronulac 17884	Pre-MMA						
Lamivudine	Tablets	100 mg	Epivir-HBV	10/31/2007	1	Extinguished	3/10/2020			5/18/2016
Lamivudine	Tablets	150 mg and 300 mg	Epivir	10/16/2007	1	Extinguished	10/5/2021			11/17/2009
Lamivudine and Zidovudine	Tablets	150 mg/300 mg	Combivir	6/26/2007	1	Eligible	10/5/2021	5/25/2011	2/3/2012	5/18/2016
Lamivudine	Oral Solution	10 mg/mL	Epivir	11/22/2011	1	Eligible	4/6/2021	10/31/2014	3/5/2015	3/20/2018
Lamotrigine	Tablets	25 mg, 100 mg, 150 mg and 200 mg	Lamictal 20241	Pre-MMA						
Lamotrigine	Chewable Tablets	2 mg, 5 mg and 25 mg	Lamictal CD 20764	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Lamotrigine	Orally Disintegrating Tablets	25 mg, 50 mg, 100 mg, and 200 mg	Lamictal ODT 22251	12/21/2009	1	Deferred	10/5/2021	7/15/2013		1/4/2029
Lamotrigine	Extended-release Tablets	25 mg, 50 mg, 100 mg, 200 mg, 250 mg, and 300 mg	Lamictal XR 22115	2/12/2014	1	Extinguished	4/7/2020			6/14/2028
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	1	Extinguished	10/5/2021	10/15/2010		5/10/2009
Lanthanum Carbonate	Chewable Tablet	500 mg, 750 mg and 1000 mg	Fosrenol 21468	10/27/2008	3	Deferred	7/16/2019	8/11/2017	8/30/2017	8/26/2024
Lanthanum Carbonate	Oral Powder	750 mg and 1000 mg	Fosrenol 204734	11/25/2015	1	Extinguished	6/15/2020			12/1/2030
Lapatinib Ditosylate	Tablets	250 mg	Tykerb 22059	3/14/2011	1	Deferred	11/17/2020	9/29/2020	9/29/2020	11/19/2021
Larotrectinib Sulfate	Capsules	25 mg and 100 mg	Vitrakvi 210861	5/6/2025	1					5/16/2037
Lasmiditan Succinate	Tablets	50 mg and 100 mg	Reyvow 211280	1/31/2024	1					12/5/2037
Latanoprost	Ophthalmic Solution	0.005%	Xalatan 20597	Pre-MMA						
Latanoprost and Netarsudil Dimesylate	Ophthalmic Solution	0.005%/0.02%	Rocklatan 208259	12/20/2021	2					3/14/2034
Latanoprostene Bunod	Ophthalmic Solution	0.024%	Vyzulta 207795	3/31/2022	1	Eligible	5/12/2025	4/29/2025		10/3/2025
Lenalidomide	Capsules	5 mg, 10 mg and 15 mg	Revlimid 21880	8/30/2010	1	Non-Forfeiture	11/17/2020	5/21/2021	3/3/2022	4/27/2027
Lenalidomide	Capsules	25 mg	Revlimid 21880	7/12/2010	1	Non-Forfeiture	11/17/2020	5/21/2021	3/3/2022	4/27/2027
Lenalidomide	Capsules	2.5 mg and 20 mg	Revlimid 21880	7/12/2016	1	Non-Forfeiture	11/17/2020	10/14/2021	9/7/2022	4/27/2027
Lenvatinib	Capsules	4 mg and 10 mg	Lenvima 206947	2/13/2019	2					7/27/2027
Letrozole	Tablets	2.5 mg	Femara 20726	3/2/2006	1	Eligible	4/6/2021	12/24/2008		6/3/2011
Leuprolide Acetate	Injection (depot)	7.5 mg/vial	Lupron Depot 19732	Pre-MMA						
Levalbuterol Hydrochloride	Inhalation Solution	0.0103%, 0.021% and 0.042%	Xopenex 20837	6/20/2005	1	Eligible	10/5/2021	4/9/2008		3/21/2021

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Levalbuterol Hydrochloride	Inhalation Solution	0.25%	Xopenex 20837	5/23/2006	1	Eligible	10/5/2021	3/20/2009		3/21/2021
Levalbuterol Tartrate	Inhalation Aerosol	0.045 mg/actuation	Xopenex HFA 21730	2/27/2012	1	Extinguished	3/10/2020			10/8/2024
Levetiracetam	Tablets	250 mg, 500 mg and 750 mg	Keppra 21035	Pre-MMA						
Levetiracetam	Tablets	1000 mg	Keppra 21035	1/24/2007	1			1/15/2009		7/14/2008
Levetiracetam	Extended-release Tablets	500 mg and 750 mg	Keppra XR 22285	1/7/2011	3	Eligible	6/15/2020	9/12/2011	9/12/2011	9/17/2028
Levetiracetam	Extended-release Tablets	1000 mg	Keppra XR 22285	1/7/2011	2	Extinguished	3/10/2020			9/17/2028
Levocetirizine Dihydrochloride	Oral Solution	0.5 mg/mL	Xyzal 22157	1/14/2009	1	Eligible	10/5/2021	11/7/2011		9/24/2012
Levocetirizine Dihydrochloride	Oral Solution	0.5 mg/mL	Xyzal Allergy 24 HR (OTC) 209090	1/4/2018	1	Deferred	10/5/2021			
Levocetirizine Dihydrochloride	Tablets	5 mg	Xyzal 22064	12/17/2007	1	Eligible	10/5/2021	11/26/2010		9/24/2012
Levofloxacin	Injection	5 mg/mL; 50 mL, 100 mL and 150 mL vials	Levaquin in Dextrose 5% in Plastic Container 20635	Pre-MMA						
Levofloxacin	Injection	25 mg/mL	Levaquin 20635	Pre-MMA						
Levofloxacin	Ophthalmic Solution	0.5%	Quixin 21199	Pre-MMA						
Levofloxacin	Oral Solution	25 mg/mL	Levaquin 21721	7/30/2009	1	Eligible	10/5/2021	6/20/2011		2/26/2022
Levofloxacin	Tablets	250 mg, 500 mg and 750 mg	Levaquin 20634	Pre-MMA						
Levoleucovorin Calcium	Injection	10 mg/mL, 17.5 mL vial and 25 mL vial	Fusilev 20140	10/26/2011	1	Eligible	10/5/2021	3/9/2015	4/23/2015	12/31/2019
Levoleucovorin Calcium	Injection	50 mg/vial	Fusilev 20140	12/19/2013	1					
Levomilnacipran	Extended-release Capsules	20 mg, 40 mg, 80 mg and 120 mg	Fetzima 204168	7/25/2017	6	Eligible	5/19/2020	2/4/2019		3/2/2031
Levonorgestrel and Ethinyl Estradiol	Tablets	0.09 mg/0.02 mg	Lybrel 21864	10/5/2007	1	Extinguished	10/5/2021	6/6/2011		9/3/2018

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Levonorgestrel and Ethinyl Estradiol	Tablets	0.15 mg/0.03 mg	Seasonale 21544	3/29/2004	1	Eligible	10/14/2024	9/6/2006		
Levonorgestrel and Ethinyl Estradiol	Tablets	0.1 mg/0.02 mg	Balcoltra 208612	7/14/2020	1	Extinguished	5/1/2023			8/16/2021
Levonorgestrel; Ethinyl Estradiol; Ethinyl Estradiol	Tablets	0.1 mg/0.02 mg and 0.01 mg	LoSeasonique 22262	11/16/2009	1	Eligible	10/5/2021	10/26/2011		6/15/2023
Levonorgestrel; Ethinyl Estradiol; Ethinyl Estradiol	Tablets	0.15 mg/0.03 mg/0.01 mg	Seasonique 21840	1/22/2008	1	Extinguished	10/14/2024	5/31/2011		1/30/2024
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	1	Extinguished	10/5/2021			
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	Pre-MMA						
Levothyroxine Sodium	for Injection	100 mcg/vial and 500 mcg/vial	Levothyroxine Sodium 202231	4/14/2015	2	Eligible	6/18/2019	6/29/2016	4/2/2018	10/3/2032
Levothyroxine Sodium	for Injection	200 mcg/vial	Levothyroxine Sodium 202231	5/1/2015	1	Deferred	6/18/2019	12/7/2015	7/5/2016	10/3/2032
Levothyroxine Sodium	Capsules	75 mcg and 150 mcg	Tirosint 21924	12/29/2017	1	Extinguished Deferred	3/18/2024 1/12/2021	10/28/2020		3/14/2024
Levothyroxine Sodium	Capsules	88 mcg, 100 mcg and 125 mcg	Tirosint 21924	8/1/2019	1	Extinguished Deferred	3/18/2024 1/12/2021	1/6/2021		3/14/2024
Levothyroxine Sodium	Capsules	112 mcg	Tirosint 21924	12/18/2020	1	Extinguished Deferred	3/18/2024 7/25/2022	4/16/2021		3/14/2024
Levothyroxine Sodium	Capsules	200 mcg	Tirosint 21924	12/30/2021	1	Extinguished Deferred	3/18/2024 11/15/2022	11/9/2022		3/14/2024
Levothyroxine Sodium	Capsules	137 mcg and 175 mcg	Tirosint 21924	11/4/2022	1	Extinguished Deferred	3/18/2024 5/1/2023	5/2/2023		3/14/2024

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Levothyroxine Sodium	Oral Solution	13 mcg/mL 25 mcg/mL 50 mcg/mL 75 mcg/mL 88 mcg/mL 100 mcg/mL 112 mcg/mL 125 mcg/mL 137 mcg/mL 150 mcg/mL 175 mcg/mL 200 mcg/mL	Tirosint-Sol 206977	9/30/2022	1					2/28/2037
Levothyroxine Sodium	Oral Solution	100 mcg/5 mL	Thyquidity 214047	12/28/2022	1	Extinguished	6/9/2025			8/6/2031
Lidocaine	Topical Patch	5%	Lidoderm 20612	11/13/2009	1	Deferred	10/5/2021	8/23/2012		10/27/2015
Lidocaine	Topical Patch	1.80%	Ztlido 207962	3/17/2022	1	Deferred	4/14/2025	3/25/2025		5/10/2031
Lifitegrast	Ophthalmic Solution	5%	Xiidra 208073	7/13/2020	4	Eligible	8/7/2023	8/4/2023		7/25/2033
Linaclotide	Capsules	145 mcg and 290 mcg	Linzess 202811	8/30/2016	4	Deferred	2/22/2021	2/9/2021		10/30/2031
Linaclotide	Capsules	72 mcg	Linzess 202811	11/7/2017	1					8/16/2033
Linagliptin	Tablets	5 mg	Tradjenta 201280	5/4/2015	11	Eligible	12/14/2021	8/31/2021		3/5/2031
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	8	Eligible	9/7/2021	8/30/2021		6/4/2030
Linagliptin and Metformin Hydrochloride	Extended-release Tablets	2.5 mg/1000 mg 5 mg/1000 mg	Jentadueto XR 208026	3/28/2018	1					5/21/2030
Linezolid	Injection	2 mg/mL, 100 mL bag	Zyvox 21131	12/29/2009	1	Extinguished	10/5/2021	7/16/2015		11/18/2014
Linezolid	Injection	2 mg/mL, 300 mL bag	Zyvox 21131	9/1/2009	1	Deferred	10/5/2021	6/27/2012		11/18/2014
Linezolid	Oral Suspension	100 mg/5 mL	Zyvox 21132	8/3/2009	1	Deferred	11/15/2022	6/3/2015	11/18/2015	1/29/2021
Linezolid	Tablets	600 mg	Zyvox 21130	12/21/2005	1	Eligible	10/5/2021	5/18/2015		11/18/2014

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Liraglutide	Injection	18 mg/3 mL prefilled syringe	Victoza 22341	12/12/2016	1	Non-Forfeiture	7/8/2024		6/24/2024	9/23/2032
Liraglutide	Injection	18 mg/3 mL prefilled syringe	Saxenda 206321	8/16/2021	1					1/9/2037
Lisdexamfetamine Dimesylate	Capsules	10 mg	Vyvanse 21977	4/9/2020	1	Extinguished	4/18/2023			2/24/2023
Lisdexamfetamine Dimesylate	Capsules	20 mg, 30 mg, 40 mg, 50 mg, 60 mg and 70 mg	Vyvanse 21977	2/23/2011	6	Extinguished	4/18/2023			2/24/2023
Lisinopril	Oral Solution	1 mg/mL	Qbrelis 208401	10/24/2019	1	Extinguished	6/15/2021			11/6/2035
Loperamide Hydrochloride and Simethicone	Chewable Tablets	2 mg/125 mg	Imodium Multi-Symptom Relief 20606	Pre-MMA						
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	1	Extinguished	6/15/2020			11/10/2020
Lopinavir and Ritonavir	Oral Solution	80 mg/20 mg per mL	Kaletra 21251	6/19/2014	1	Deferred	2/11/2020	12/27/2016	1/23/2017	11/28/2021
Loratadine	Syrup	1 mg/mL	Claritin 20641	Pre-MMA						
Loratadine	Tablets	10 mg	Claritin 19658	Pre-MMA						
Loratadine	Orally Disintegrating Tablets	10 mg	Claritin RediTabs 20704	Pre-MMA						
Loratadine/ Pseudoephedrine	Extended-release Tablets	5 mg/120 mg	Claritin D-12 hour 19670	Pre-MMA						
Loratadine/ Pseudoephedrine	Extended-release Tablets	10 mg/240 mg	Claritin D-24 hour 20470	Pre-MMA						
Lorcaserin Hydrochloride	Extended-release Tablets	20 mg	Belviq XR 208524	12/13/2016	1	Extinguished	5/19/2020			2/7/2033
Lorcaserin Hydrochloride	Tablets	10 mg	Belviq 22529	6/272016	4	Extinguished	5/19/2020			2/7/2033

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Losartan Potassium	Tablets	25 mg, 50 mg, and 100 mg	Cozaar 20386	Pre-MMA						
Losartan Potassium and Hydrochlorothiazide	Tablets	50 mg/12.5 mg and 100 mg/25 mg	Hyzaar 20387	5/24/2004	1	Eligible	10/5/2021	4/6/2010		9/4/2009
Losartan Potassium and Hydrochlorothiazide	Tablets	100 mg/12.5 mg	Hyzaar 20387	4/4/2006	1					
Loteprednol Etabonate	Ophthalmic Gel	0.38%	Lotemax SM 208219	11/14/2022	1	Eligible	7/7/2025	6/30/2025		12/23/2036
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	1	Extinguished	11/30/2021	6/27/2022	1/4/2021	8/30/2022
Lumateperone Tosylate	Capsules	10.5 mg and 21 mg	Caplyta 209500	12/20/2023	6					12/10/2040
Lumateperone Tosylate	Capsules	42 mg	Caplyta 209500	12/20/2023	7					12/10/2040
Lurasidone Hydrochloride	Tablets	20 mg, 40 mg, 60 mg, 80 mg, and 120 mg	Latuda 200603	10/28/2014	14	Extinguished Eligible	1/12/2021 8/27/2019	1/3/2019		5/26/2026
Lurbinectedin	Powder for Injection	4 mg/vial	Zepzelca 213702	6/17/2024	5					12/13/2029
Lutetium Lu 177 Dotatate	Injection	10 mCi/mL	Lutathera 208700	11/13/2023	1					7/25/2038
Macitentan	Tablets	10 mg	Opsumit 204410	10/18/2017	11	Eligible	5/4/2021	4/6/2021		4/18/2029
Malathion	Topical Lotion	0.50%	Ovide 18613	3/16/2011	1	Deferred	2/8/2022	5/23/2012		2/1/2027
Maraviroc	Tablets	150 mg and 300 mg	Selzentry 22128	8/8/2011	2	Eligible	2/22/2022	2/7/2022	2/7/2022	11/25/2022
Mefloquine Hydrochloride	Tablets	250 mg	Lariam 19591	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Megestrol Acetate	Oral Suspension	40 mg/mL	Megace 20264	Pre-MMA						
Megestrol Acetate	Oral Suspension	125 mg/mL	Megace ES 21778	4/27/2011	1	Eligible	10/5/2021	8/27/2014	7/1/2015	4/22/2024
Meloxicam	Oral Suspension	7.5 mg/5 mL	Mobic 21530	12/17/2009	1	Extinguished	3/10/2020			9/25/2019
Meloxicam	Capsules	5 mg and 10 mg	Vivlodex 207233	1/9/2017	1	Extinguished Deferred	3/9/2021 6/29/2020	6/1/2020	12/22/2020	3/31/2033
Meloxicam and Rizatriptan Benzoate	Tablets	20 mg/10 mg	Symbravo 215431	6/30/2025	1					5/28/2040
Melphalan Hydrochloride	Injection	50 mg/vial	Evomela 207155	9/8/2017	1	Eligible	5/19/2020	3/6/2020		2/27/2033
Memantine Hydrochloride	Tablets	5 mg and 10 mg	Namenda 21487	10/16/2007	14	Eligible	2/8/2022	1/30/2015		4/11/2015
Memantine Hydrochloride	Extended-release Capsules	7 mg, 14 mg, 21 mg, and 28 mg	Namenda XR 22525	6/10/2013	1	Extinguished	2/8/2022	10/12/2016		
Memantine Hydrochloride Extended-release and Donepezil Hydrochloride	Capsules	14 mg/10 mg and 28 mg/10 mg	Namzaric 206439	5/18/2015	1	Eligible	2/9/2021	1/27/2017	1/16/2025	12/5/2029
Memantine Hydrochloride Extended-release and Donepezil Hydrochloride	Capsules	21 mg/10 mg	Namzaric 206439	9/23/2016	1	Extinguished Deferred	3/3/2025 1/8/2024	12/15/2023	1/1/2025	12/5/2029
Memantine Hydrochloride Extended-release and Donepezil Hydrochloride	Capsules	7 mg/10 mg	Namzaric 206439	9/26/2016	1	Extinguished	2/9/2021			12/5/2029
Mesalamine	Delayed-release Tablets	400 mg	Asacol 19651	6/22/2007	1	Extinguished	2/11/2020			7/30/2013
Mesalamine	Delayed-release Tablets	800 mg	Asacol HD 21830	7/13/2011	1	Non-Forfeiture Deferred	11/8/2024 2/11/2020	7/21/2017	8/1/2016	11/15/2021
Mesalamine	Delayed-release Tablets	1.2 g	Lialda 22000	12/16/2009	1	Deferred	2/11/2020	6/5/2017	7/18/2017	6/8/2020
Mesalamine	Extended-release Capsules	0.375 g	Apriso 22301	4/3/2012	1	Extinguished	2/11/2020			4/20/2018
Mesalamine	Suppository	1000 mg	Canasa 21252	5/24/2013	1	Eligible	8/27/2019	11/24/2015	11/24/2015	6/6/2028
Mesalamine	Delayed-release Capsules	400 mg	Delzicol 204412	6/17/2014	1	Extinguished Non-Forfeiture	6/18/2019 6/18/2019			4/13/2020
Metaxalone	Tablets	400 mg	Skelaxin 13217	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Metaxalone	Tablets	800 mg	Skelaxin 13217	11/4/2004	1	Non-Forfeiture	9/8/2020	3/31/2010	3/31/2010	12/3/2021
Metformin Hydrochloride	Extended-release Tablets	500 mg	Glucophage XR 21202	Pre-MMA						
Metformin Hydrochloride	Extended-release Tablets	750 mg	Glucophage XR 21202	Pre-MMA						
Metformin Hydrochloride	Extended-release Tablets	500 mg and 1000 mg	Fortamet 21574	10/14/2008	1	Extinguished Eligible	4/17/2023 2/8/2022	6/29/2011		3/17/2021
Metformin Hydrochloride	Extended-release Tablets	500 mg and 1000 mg	Glumetza 21748	7/27/2009	1	Eligible	7/16/2019	7/19/2013	2/1/2016	500mg:10/25/2021 1 g: 6/20/2020
Metformin Hydrochloride	Oral Solution	500 mg/5 mL	Riomet 21591	2/2/2018	1	Eligible	11/15/2022	3/3/2020	4/20/2020	8/7/2021
Methylnaltrexone Bromide	Injection	12 mg/0.6 mL, Single Dose Vial	Relistor 21964	7/22/2015	1	Eligible	6/9/2025	5/28/2025		12/31/2030
Methylnaltrexone Bromide	Injection	12 mg/0.6 mL, Single Dose Prefilled Syringe	Relistor 21964	9/8/2015	1	Non-Forfeiture Deferred	2/17/2025 8/26/2024	8/26/2024		12/31/2030
Methylnaltrexone Bromide	Injection	8 mg/0.4 mL, Single Dose Prefilled Syringe	Relistor 21964	9/8/2015	1	Non-Forfeiture Deferred	5/27/2025 8/26/2024	8/26/2024		12/31/2030
Methylnaltrexone Bromide	Tablets	150 mg	Relistor 208271	9/6/2016	1					3/10/2031
Methylphenidate Hydrochloride	Extended-release Capsules	10 mg	Ritalin LA 21284	5/21/2007	1	Extinguished	3/10/2020			11/1/2019
Methylphenidate Hydrochloride	Extended-release Capsules	20 mg, 30 mg and 40 mg	Ritalin LA 21284	8/21/2006						
Methylphenidate Hydrochloride	Extended-release Capsules	10 mg, 20 mg and 30 mg	Metadate CD 21259	5/13/2005	1	Non-Forfeiture	9/8/2020	7/19/2012	9/27/2012	10/27/2020
Methylphenidate Hydrochloride	Extended-release Capsules	40 mg	Metadate CD 21259	3/15/2007	1	Non-Forfeiture	9/8/2020	7/19/2012	9/27/2012	10/27/2020
Methylphenidate Hydrochloride	Extended-release Chewable Tablets	20 mg, 30 mg and 40 mg	Quillichew ER 207960	4/25/2016	1					8/14/2033
Methylphenidate Hydrochloride	Extended-release Tablets	18 mg*, 27 mg, 36 mg and 54 mg	Concerta 21121	7/19/2005						
Methylphenidate Hydrochloride	Oral Solution	5 mg/5 mL 10 mg/5 mL	Methylin 21419	4/13/2010	1	Eligible	1/27/2020	7/23/2010	7/26/2010	10/7/2024

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Methylphenidate	Transdermal System	10 mg/9 hrs 15 mg/9 hrs 20 mg/9 hrs 30 mg/9 hrs	Daytrana 21514	4/13/2011	1	Extinguished	3/9/2021			9/30/2018
Methylphenidate Hydrochloride	Extended-release Oral Suspension	5 mg/mL	Quillivant XR 202100	8/2/2013						
Methylphenidate Hydrochloride	Extended-release Capsules	60 mg	Aptensio XR 205831	12/23/2015	1	Eligible	7/30/2019	12/13/2018	9/25/2020	12/16/2019
Methylphenidate Hydrochloride	Extended-release Capsules	10 mg	Aptensio XR 205831	12/24/2015	1	Eligible	7/30/2019	12/13/2018	9/25/2020	12/16/2019
Methylphenidate Hydrochloride	Extended-release Capsules	15 mg, 20 mg, 40 mg and 50 mg	Aptensio XR 205831	12/28/2015	1	Eligible	7/30/2019	12/13/2018	9/25/2020	12/16/2019
Methylphenidate Hydrochloride	Extended-release Capsules	30 mg	Aptensio XR 205831	3/28/2016	1	Eligible	7/30/2019	12/13/2018	9/25/2020	12/16/2019
Methylphenidate	Extended-release Orally Disintegrating Tablets	8.6 mg, 17.3 mg and 25.9 mg	Cotempla XR-ODT 205489	9/1/2017	1	Eligible	7/13/2020	6/19/2020		6/28/2032
Metoclopramide Hydrochloride	Injection	5 mg/mL, 2 mL, 10 mL, 20 mL and 30 mL vials	Reglan 17862	Pre-MMA						
Metoclopramide Hydrochloride	Orally Disintegrating Tablets	5 mg and 10 mg	Metozolv ODT 22246	8/24/2010	1	Extinguished Deferred	4/18/2023 2/8/2022	8/15/2014		7/11/2017
Metoclopramide Hydrochloride	Metered Nasal Spray	15 mg/spray	Gimoti 209388	12/30/2021	1					5/16/2030
Metoprolol Succinate	Extended-release Tablets	25 mg, 50 mg, 100 mg and 200 mg	Toprol XL 19962	Pre-MMA						
Metronidazole	Vaginal Gel	0.75%	MetroGel-Vaginal 20208	9/2/2004	1	Extinguished	2/8/2022			6/6/2006
Metronidazole	Topical Gel	1%	Metrogel 21789	10/21/2008	1	Eligible	5/4/2021	7/22/2011	7/1/2013	2/21/2022
Metronidazole	Vaginal Gel	1.30%	Nuvessa 205223	3/30/2022	1	Eligible	3/18/2024	3/18/2024		6/28/2032
Micafungin Sodium	For Injection	50 mg/vial 100 mg/vial	Mycamine 21506	6/16/2014	1	Eligible	6/1/2020	5/17/2019	5/8/2020	1/8/2021
Miconazole Nitrate	Vaginal Cream and Suppository	2% and 1.2 g	Monistat 1 Combination Pack 21308	12/5/2007	1	Extinguished Deferred	4/18/2023 2/8/2022	6/2/2010		11/28/2020

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Midazolam	Nasal Spray	5 mg/spray	Nayzilam 211321	6/1/2021	1					1/18/2028
Midazolam	Intravenous	50 mg/50 mL and 100 mg/100 mL	Midazolam in 0.9% Sodium Chloride 211844	9/29/2021	1	Eligible	4/18/2023	4/17/2023	7/6/2023	6/20/2038
Midostaurin	Capsules	25 mg	Rydapt 207997	4/28/2021	4	Eligible	5/13/2024	4/29/2024		12/2/2030
Mifepristone	Tablets	300 mg	Korlym 202107	12/15/2017	1	Eligible	2/8/2022	8/3/2020	1/19/2024	8/15/2036
Migalastat Hydrochloride	Capsules	123 mg	Galafold 208623	8/10/2022	3					2/6/2039
Milnacipran Hydrochloride	Tablets	12.5 mg, 25 mg, 50 mg, and 100 mg	Savella 22256	1/14/2013	8	Eligible	2/8/2022	1/27/2016		9/19/2029
Minocycline Hydrochloride	Extended-release Tablet	45 mg, 90 mg and 135 mg	Solodyn 50808	PIV received prior to 2/5/2009						
Minocycline Hydrochloride	Extended-release Tablet	55 mg	Solodyn 50808	12/2/2010	1	Eligible	12/13/2022	11/30/2011	2/22/2019	11/20/2025
Minocycline Hydrochloride	Extended-release Tablet	65 mg and 115 mg	Solodyn 50808	11/19/2009	1	Extinguished Eligible	6/18/2019 6/18/2019	5/18/2012	2/20/2018	2/19/2018
Minocycline Hydrochloride	Extended-release Tablet	80 mg	Solodyn 50808	10/27/2010	1	Non-Forfeiture	2/8/2022	9/25/2014		2/19/2018
Minocycline Hydrochloride	Extended-release Tablet	105 mg	Solodyn 50808	12/13/2010	1	Non-Forfeiture	2/8/2022			2/19/2018
Minocycline Hydrochloride	Injection	100 mg/vial	Minocin 50444	10/16/2020	1	Eligible	10/28/2024	10/24/2024		5/12/2031
Minocycline Hydrochloride	Topical Aerosol Foam	4%	Amzeeq 212379	5/11/2021	1					9/8/2037
Minocycline Hydrochloride	Topical Aerosol Foam	1.50%	Zilxi 213690	2/28/2022	1					10/1/2030
Minoxidil	Topical Aerosol Foam	5%	Men’s Rogaine 21812	4/6/2009	1	Eligible	2/8/2022	4/28/2011		4/20/2019
Minoxidil	Topical Aerosol Foam	5%	Women's Rogaine 21812	2/4/2015	1	Eligible	4/18/2022	7/27/2017		4/20/2019

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Mirabegron	Extended-release Tablets	25 mg	Myrbetriq 202611	6/28/2016	6	Extinguished Eligible	2/17/2025 10/4/2022	12/27/2019		11/4/2023
Mirabegron	Extended-release Tablets	50 mg	Myrbetriq 202611	6/28/2016	6	Extinguished Deferred	2/17/2025 10/4/2022	9/28/2022		11/4/2023
Mirabegron	Granules for Extended-release Suspension	8 mg/mL	Myrbetriq Granules 213801	1/12/2024	1					3/31/2036
Mirtazapine	Tablets	7.5 mg, 15 mg, 30 mg, and 45 mg	Remeron 20415	Pre-MMA						
Mirtazapine	Orally Disintegrating Tablets	15 mg, 30 mg and 45 mg	Remeron SolTab 21208	Pre-MMA						
Mitomycin	Powder for Injection	40 mg/vial	Jelmyto 211728	12/28/2023	1					1/20/2031
Modafinil	Tablets	100 mg and 200 mg	Provigil 20717	Pre-MMA						
Moexipril Hydrochloride	Tablets	7.5 mg and 15 mg	Univasc 20312	Pre-MMA						
Moexipril Hydrochloride and Hydrochlorothiazide	Tablets	7.5mg/12.5mg, 15 mg/25 mg and 15 mg/12.5 mg	Uniretic 20729	1/15/2004	1	Extinguished	2/8/2022	3/7/2007		2/24/2007
Mometasone Furoate	Nasal Spray	50 mcg/ Spray	Nasonex 20762	8/7/2009	1	Deferred	2/8/2022	3/22/2016	3/22/2016	10/3/2017
Mometasone Furoate	Topical Solution (Cream)	0.1%	Elocon 19625	Pre-MMA						
Mometasone Furoate	Topical Solution (Lotion)	0.1%	Elocon 19796	6/10/2004	1			4/6/2005		11/21/2007
Montelukast	Tablets	10 mg	Singulair 20829	2/20/2007	2	Extinguished	2/8/2022	8/3/2012		2/3/2012
Montelukast Sodium	Chewable Tablets	4 mg and 5 mg	Singulair 20830	12/26/2006	1	Extinguished	2/8/2022	8/3/2012		8/3/2012
Montelukast Sodium	Oral Granules	4 mg	Singular Granules 21409	10/17/2008	1	Extinguished	2/25/2020	8/3/2012		8/3/2012
Morphine Sulfate	Extended-release Capsules	30 mg, 60 mg, 90 mg and 120 mg	Avinza 21260	6/4/2007	1	Deferred	3/10/2020	1/16/2013		11/25/2017
Morphine Sulfate	Extended-release Capsules	45 mg and 75 mg	Avinza 21260	8/11/2009	1	Extinguished	3/10/2020			11/25/2017

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Morphine Sulfate	Extended-release Tablets	15 mg, 30 mg and 60 mg	Arymo ER 208603	12/29/2017	1	Extinguished	2/8/2022			11/25/2017
Morphine Sulfate	Extended-release Tablets	15 mg, 30 mg, 60 mg and 100 mg	Morphabond ER 206544	1/28/2019	1					8/21/2028
Morphine Sulfate and Naltrexone Hydrochloride	Extended-release Capsules	20 mg/0.8 mg	Embeda 22321	8/16/2018	1	Extinguished	2/8/2022			11/7/2029
Morphine Sulfate and Naltrexone Hydrochloride	Extended-release Capsules	100 mg/4 mg	Embeda 22321	5/3/2010	1	Extinguished	6/15/2020			6/19/2027
Morphine Sulfate and Naltrexone Hydrochloride	Extended-release Capsules	60 mg/2.4 mg	Embeda 22321	5/25/2010	1	Extinguished	6/15/2020			6/19/2027
Morphine Sulfate and Naltrexone Hydrochloride	Extended-release Capsules	30 mg/1.2 mg 50 mg/2 mg 80 mg/3.2 mg	Embeda 22321	5/28/2010	1	Extinguished	6/15/2020			6/19/2027
Moxifloxacin Hydrochloride	Ophthalmic Solution/Drops	0.5%	Vigamox 21598	12/22/2005	1	Extinguished	3/10/2020			9/20/2019
Moxifloxacin Hydrochloride	Ophthalmic Solution	0.5%	Moxeza 22428	2/29/2012	1	Eligible	2/8/2022	5/28/2015	5/28/2015	9/20/2019
Moxifloxacin Hydrochloride	Tablets	400 mg	Avelox 21085	Pre-MMA						
Moxifloxacin Hydrochloride	Injection	1.6 mg/mL	Avelox in Sodium Chloride 0.8% in plastic container 21277	2/7/2014	1	Deferred	10/8/2019	5/5/2017	10/3/2017	7/25/2020
Mycophenolic Acid	Delayed-release Tablets	180 mg	Myfortic 50791	6/3/2009	1	Extinguished	2/8/2022	1/8/2014		4/10/2017
Mycophenolic Acid	Delayed-release Tablets	360 mg	Myfortic 50791	2/2/2009	1	Non-Forfeiture	2/8/2022	1/8/2014	1/8/2014	4/10/2017
Mycophenolic Mofetil	For Oral Suspension	200 mg/mL	Cellcept 50759	3/25/2011	1	Deferred	2/8/2022	11/14/2014	11/17/2014	11/18/2014
Nabumetone	Tablets	500 mg and 750 mg	Relafen 19583	Pre-MMA						
Naftifine Hydrochloride	Gel	2%	Naftin Gel 204286	2/4/2015	1	Deferred	8/13/2019	4/10/2019	4/12/2023	1/31/2033
Nalmefene Hydrochloride	Nasal Spray	2.7 mg/spray	Opvee 217470	4/7/2025	1					7/10/2038
Naloxegol	Tablets	12.5 mg and 25 mg	Movantik 204760	9/17/2018	2					4/2/2032

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Naloxone Hydrochloride	Nasal Spray	2 mg/spray	Narcan 208411	12/28/2017	1					3/16/2035
Naloxone Hydrochloride	Nasal Spray	4 mg/spray	Narcan 208411	7/15/2016	1	Eligible	6/18/2019	4/19/2019	12/22/2021	3/16/2035
Naloxone Hydrochloride	Nasal Spray	8 mg/spray	Kloxxado 212045	3/30/2023	1	Eligible	5/12/2025	4/24/2025		8/26/2034
Naltrexone	Extended-release Injectable Suspension	380 mg/vial	Vivitrol 21897	6/18/2020	1	Deferred	87/2023	7/6/2023		10/15/2029
Naltrexone Hydrochloride and Bupropion Hydrochloride	Extended-release Tablets	8 mg/90 mg	Contrave 200063	3/12/2015	1					2/2/2030
Naproxen Sodium	Extended-release Tablets	375 mg (base) and 500 mg (base)	Naprelan 20353	Pre-MMA						
Naproxen Sodium	Capsules	200 mg	Naproxen Sodium 21920	11/15/2017	1	Extinguished	6/15/2020			3/3/2026
Naproxen and Esomeprazole Magnesium	Delayed-release Tablets	375 mg/20 mg and 500 mg/20 mg	Vimovo 22511	11/5/2010	1	Extinguished	2/25/2020			2/28/2023
Naproxen Sodium and Sumatriptan Succinate	Tablets	500 mg/85 mg	Treximet 21926	7/23/2008	1	Extinguished	3/10/2020			10/2/2025
Nateglinide	Tablets	60 mg and 120 mg	Starlix 21204	12/22/2004						
Nebivolol Hydrochloride	Tablets	2.5 mg, 5 mg, 10 mg, and 20 mg	Bystolic 21742	12/19/2011	7	Eligible	6/18/2019	4/16/2015	9/17/2021	12/17/2021
Nebivolol Hydrochloride and Valsartan	Tablets	5 mg/80 mg	Byvalson 206302	6/9/2017	1	Deferred	10/4/2022	9/19/2022		10/4/2027
Nefazodone Hydrochloride	Tablets	50 mg, 100 mg, 150 mg, 200 mg and 250 mg	Serzone 20152	Pre-MMA						
Nepafenac	Ophthalmic Suspension	0.3%	Ilevro 203491	12/21/2015	1					3/31/2032
Neratinib Maleate	Tablets	40 mg	Nerlynx 208051	7/19/2021	1					12/29/2025
Netarsudil Mesylate	Ophthalmic Solution	0.02%	Rhopressa 208254	12/20/2021	2					3/14/2034
Nevirapine	Extended-release Tablets	400 mg	Viramune XR 201152	6/21/2013	3	Eligible	12/13/2022	4/3/2014	4/15/2014	3/12/2029
Niacin	Extended-release Tablets	500 mg, 750 mg and 1000 mg	Niaspan 20381	Pre-MMA						
Niacin and Simvastatin	Extended-release Tablets	500 mg/20 mg	Simcor	2/12/2010						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
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 19734	12/27/2006	1					
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 19734	1/9/2013	1	Deferred	5/13/2024	4/17/2024		12/26/2027
Nicotine	Transdermal System	7 mg/day, 14 mg/day 21 mg/day	Habitrol 20076	Pre-MMA						
Nicotine	Transdermal System	7 mg/24 hrs 14 mg/24 hrs 21 mg/24 hrs	Nicoderm CQ 20165	5/30/2014	1	Extinguished	2/8/2022			5/22/2021
Nicotine Polacrilex	Troche/Lozenge	2 mg and 4 mg	Commit	Pre-MMA						
Nicotine Polacrilex	Troche/Lozenge (Mini)	2 mg and 4 mg	Nicorette 22360	12/2/2015	1	Eligible	10/8/2019	2/7/2019	4/4/2019	6/14/2029
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 18482	Pre-MMA						
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Adalat CC 20198	Pre-MMA						
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Procardia XL 19684	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Nilotinib	Capsules	50 mg	Tasigna 22068	10/17/2019	1	Non-Forfeiture Deferred	10/3/2024 1/8/2024	1/5/2024	5/23/2025	4/7/2032
Nilotinib	Capsules	150 mg and 200 mg	Tasigna 22068	11/8/2013	1	Non-Forfeiture Deferred	10/3/2024 1/8/2024	1/5/2024	5/23/2025	8/23/2028
Nimodipine	Oral Solution	6 mg/mL	Nymalize 203340	11/29/2021	1	Eligible				4/16/2038
Nintedanib Esylate	Capsules	100 mg and 150 mg	Ofev 205832	10/15/2018	4					6/7/2029
Niraparib Tosylate	Tablets	100 mg, 200 mg and 300 mg	Zejula 214876	6/17/2025	1					1/25/2039
Nisoldipine	Extended-release Tablets	8.5 mg and 17 mg	Sular 20356	3/2/2009	1	Eligible	2/8/2022	1/26/2011	1/28/2011	6/6/2012
Nisoldipine	Extended-release Tablets	20 mg and 30 mg	Sular 20356	11/7/2007	1	Extinguished	2/8/2022	7/25/2008		6/8/2008
Nisoldipine	Extended-release Tablets	25.5 mg and 34 mg	Sular 20356	11/28/2008	1	Eligible	2/8/2022	1/26/2011	1/28/2011	11/30/2014
Nisoldipine	Extended-release Tablets	40 mg	Sular 20356	6/11/2007	1	Extinguished	2/8/2022	7/25/2008		6/8/2008
Nitric Oxide	for Inhalation	100 ppm and 800 ppm	INOmax 20845	5/20/2014	1	Deferred	11/19/2019	10/2/2018	4/1/2019	1/6/2031
Nitrofurantoin Monohydrate/ Macrocrystals	Capsules	75 mg/25 mg	Macrobid 20064	Pre-MMA						
Nitroglycerin	Sublingual Tablets	0.3 mg, 0.4 mg, and 0.6 mg	Nitrostat 21134	10/19/2005	1	Extinguished	3/10/2020			9/16/2018
Nitroglycerin	Transdermal System	0.1 mg/hr	Transderm-Nitro 20144	Pre-MMA						
Nitroglycerin	Transdermal System	0.1 mg/hr 0.2 mg/hr 0.3 mg/hr 0.4 mg/hr 0.6 mg/hr 0.8 mg/hr	Nitro-dur 20145	Pre-MMA						
Nitroglycerin	Sublingual Spray	400 mcg/spray, 4.9 g and 12 g bottles	Nitrolingual Pumpspray 18705	4/17/2012	1	Eligible	2/8/2022	9/20/2013	9/23/2013	3/14/2028
Nizatidine	Capsules	150 mg and 300 mg	Axid 19508	Pre-MMA						
Nizatidine	Oral Solution	15 mg/mL	Axid 21494	5/14/2008	1	Extinguished Eligible	4/18/2023 2/22/2022	11/18/2009		7/17/2022

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Norelgestromin and Ethinyl Estradiol	Transdermal System	0.15 mg/0.02 mg per 24 hours	Ortho Evra 21180	3/22/2007	1	Extinguished	3/10/2020			11/20/2015
Norepinephrine Bitartrate in 0.9 % Sodium Chloride	Injection	4 mg/250 mL and 8 mg/250 mL	Norepinephrine Bitartrate in 0.9 % Sodium Chloride 215700	9/29/2023	1					4/26/2039
Norephinephrine Bitartrate in 0.9% Sodium Chloride	Injection	16 mg/250 mL	Norepinephrine Bitartrate in 0.9% Sodium Chloride 215700	1/21/2025	1					4/26/2039
Norepinephrine Bitartrate in 5% Dextrose	Injection	4 mg/250 mL and 8 mg/250 mL	Norepinephrine Bitartrate in 5% Dextrose 214313	10/7/2024	1					3/8/2041
Norepinephrine Bitartrate in 5% Dextrose	Injection	16 mg/250 mL	Norepinephrine Bitartrate in 5% Dextrose	5/12/2025	1					3/8/2041
Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/0.005 mg	Femhrt 21065	Pre-MMA						
Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/ 0.02 mg 1 mg/0.03 mg 1 mg /0.035 mg	Estrostep Fe 20130	Pre-MMA						
Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/0.02 mg 1 mg/ 0.03 mg and 1 mg /0.035 mg	Estrostep 21 20130	Pre-MMA						
Norethindrone Acetate/ Ethinyl Estradiol and Ferrous Fumarate	Tablets	1 mg/0.02 mg and 75 mg	Loestrin 24 Fe 21871	4/17/2006	1	Extinguished	2/8/2022	9/1/2009		7/22/2014
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 22501	4/29/2011	1	Extinguished	2/8/2022			2/2/2029
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	1	Non-Forfeiture	2/8/2022	8/5/2010	3/25/2011	4/6/2019
Norethindrone and Ethinyl Estradiol and Ferrous Fumarate	Chewable Tablets	0.8 mg/0.025 mg and 75 mg	Generess Fe	8/5/2011	1	Eligible	2/8/2022	4/23/2014	4/1/2015	4/16/2019

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Norethindrone Acetate and Ethinyl Estradiol and Ferrous Fumarate	Chewable Tablets	1 mg/0.02 mg and 75 mg	Minastrin 24 Fe 203667	4/23/2014	1	Eligible	10/8/2019	5/24/2016	3/15/2017	4/6/2019
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 18985	Pre-MMA						
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 21241	Pre-MMA						
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 19697	Pre-MMA						
Nortriptyline Hydrochloride	Capsules	10 mg, 25 mg, 50 mg and 75 mg	Pamelor 18013	Pre-MMA						
Obeticholic Acid	Tablets	5 mg and 10 mg	Ocaliva 207999	5/27/2020	5	Eligible	6/12/2023	5/30/2023		4/26/2036
Octreotide Acetate	Injection	0.05 mg /mL, 0.1 mg /mL and 0.5 mg/mL, 1 mL vials	Sandostatin (Preservative-free) 19667	Pre-MMA						
Octreotide Acetate	Injection	0.2 mg/mL and 1 mg /mL, 5 mL vials	Sandostatin 19667	Pre-MMA						
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 19667	1/17/2008	1	Extinguished Eligible	4/18/2023 2/8/2022	2/10/2011		5/19/2015
Octreotide Acetate	Delayed-release Capsules	20 mg	Mycapssa 208232	12/29/2023	1					12/28/2040
Ofloxacin	Otic Solution	0.3%	Floxin 20799	Pre-MMA						
Olanzapine	Tablets	2.5 mg, 5 mg, 7.5 mg, 10 mg and 15 mg	Zyprexa 20592	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Olanzapine	Tablets	20 mg	Zyprexa 20592	Pre-MMA						
Olanzapine	Orally Disintegrating Tablets	5 mg, 10 mg, 15 mg and 20 mg	Zyprexa Zydis 21086	Pre-MMA						
Olanzapine and Fluoxetine Hydrochloride	Capsules	6 mg/25 mg 12 mg/25 mg 6 mg/50 mg 12 mg/50 mg	Symbyax 21520	1/10/2005	1	Extinguished	2/8/2022	6/20/2012		11/1/2017
Olanzapine and Samidorphan L-Malate	Tablets	5 mg/10 mg 10 mg/10 mg 15 mg/10 mg 20 mg/10 mg	Lybalvi 213378	5/28/2025	3					11/12/2041
Olaparib	Tablets	100 mg and 150 mg	Lynparza 208558	11/1/2022	1					8/4/2031
Olmesartan Medoxomil	Tablets	5 mg, 20 mg and 40 mg	Benicar 21286	4/25/2006	1	Eligible	2/8/2022	10/26/2016	10/26/2016	11/19/2021
Olmesartan Medoxomil and Hydrochlorothiazide	Tablets	20 mg/12.5 mg	Benicar HCT 21532	5/11/2007	1	Eligible	2/8/2022	10/26/2016	10/26/2016	11/19/2021
Olmesartan Medoxomil and Hydrochlorothiazide	Tablets	40 mg/12.5 mg and 40 mg/25 mg	Benicar HCT 21532	2/15/2007	1	Eligible	2/8/2022	10/26/2016	10/26/2016	11/19/2021
Olopatadine Hydrochloride	Nasal Spray	0.665 mg/ Spray	Patanase 21861	6/29/2009	1	Extinguished	2/8/2022	10/8/2014		12/18/2010
Olopatadine Hydrochloride	Ophthalmic Solution	0.1%	Pataday Twice Daily Relief OTC 20688	7/17/2006	1	Extinguished	4/7/2020	12/7/2015		6/6/2015
Olopatadine Hydrochloride	Ophthalmic Solution	0.2%	Pataday Once Daily Relief OTC 21545	9/8/2008	1	Eligible	6/18/2019	7/13/2015	6/8/2017	11/12/2023
Olopatadine Hydrochloride	Ophthalmic Solution	0.7%	Pataday Once Daily Relief OTC 206276	9/10/2015	1	Non-forfeiture	6/18/2019	2/19/2020		5/19/2032
Omacetaxine Mepesuccinate	for Injection	3.5 mg/vial	Synribo 203585	10/26/2016	1	Extinguished	2/8/2022			6/28/2023
Omega-3-Acid Ethyl Esters	Capsules	1 g	Lovaza 21654	11/10/2008	3	Deferred	2/22/2022	4/7/2014		4/10/2017
Omeprazole	Delayed-release Capsules	10 mg, 20 mg and 40 mg	Prilosec 19810	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Omeprazole and Sodium Bicarbonate	Capsules	20 mg/1100 mg and 40 mg/1100 mg	Zegerid 21849	4/30/2007	1	Eligible	2/8/2022	5/25/2010	7/1/2010	7/16/2016
Omeprazole and Sodium Bicarbonate	Capsules	20 mg/1100 mg	Zegerid OTC 22281	4/20/2010	1	Extinguished	2/8/2022	7/15/2016		7/16/2016
Omeprazole and Sodium Bicarbonate	Powder for Oral Suspension	20mg/1680mg per packet	Zegerid 21636	11/13/2007	1	Deferred	2/8/2022	4/19/2013		7/16/2016
Omeprazole and Sodium Bicarbonate	Powder for Oral Suspension	40 mg/1680 mg per packet	Zegerid 21636	8/24/2007	1	Deferred	2/8/2022	4/19/2013		7/16/2016
Omeprazole Magnesium	Delayed-release Capsules	20 mg	Prilosec OTC 21229	3/19/2007	1	Eligible	2/8/2022	6/5/2009		11/15/2019
Omeprazole Magnesium	Delayed-release Tablets	20 mg	Prilosec OTC 21229	3/30/2012	1	Eligible	2/8/2022	7/30/2015	12/1/2017	11/15/2019
Omeprazole	Delayed-release Tablets	20 mg	Omeprazole 22032 (OTC)	6/3/2015	1	Extinguished Non-Forfeiture	2/11/2020 2/11/2020	10/12/2018		8/16/2025
Ondansetron Hydrochloride	Injection	2 mg/mL, 2 mL vials (Preservative-free)	Zofran 20007	Pre-MMA						
Ondansetron Hydrochloride	Injection	2 mg/mL, 20 mL vials	Zofran 20007	Pre-MMA						
Ondansetron Hydrochloride	Injection	0.64 mg/mL, 50 mL container (plastic)	Zofran in Plastic Container 20403	Pre-MMA						
Ondansetron Hydrochloride	Oral Solution	4 mg/5 mL	Zofran 20605	12/20/2004	1	Eligible	2/22/2022	12/26/2006		5/20/2016
Ondansetron Hydrochloride	Orally Disintegrating Tablets	4 mg and 8 mg	Zofran ODT 20781	Pre-MMA						
Ondansetron Hydrochloride	Tablets	4 mg, 8 mg, 16 mg and 24 mg	Zofran 20103	Pre-MMA						
Orlistat	Capsules	60 mg	Alli 21887	9/8/2010	1	Extinguished	2/8/2022			1/6/2018
Oseltamivir Phosphate	Capsules	30 mg and 45 mg	Tamiflu 21087	8/2/2011	1	Eligible	2/8/2022	8/3/2016	12/12/2016	12/27/2016
Oseltamivir Phosphate	Capsules	75 mg	Tamiflu 21087	11/15/2010	1	Eligible	2/8/2022	8/3/2016	12/12/2016	12/27/2016
Oseltamivir Phosphate	for Oral Suspension	6 mg/mL	Tamiflu 21246	6/18/2015	1	Extinguished	10/8/2019	2/20/2018		12/27/2016
Osimertinib Mesylate	Tablets	40 mg and 80 mg	Tagrisso 208065	11/13/2019	3					1/2/2035

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Ospemifene	Tablets	60 mg	Osphena 203505	12/29/2020	1	Eligible	2/19/2024	2/13/2024		7/9/2028
Oxaliplatin	Injection	5 mg/mL, 10 mL and 20 mL vials	Eloxatin 21759	2/9/2007	11	Eligible	3/10/2020	8/7/2009		2/9/2017
Oxaliplatin	Injection	5 mg/mL, 40 mL vials	Eloxatin 21759	7/16/2007	1	Extinguished	3/10/2020			8/7/2015
Oxandrolone	Tablets	2.5 mg and 10 mg	Oxandrin 13718	6/19/2006	1	Extinguished	2/8/2022			12/5/2017
Oxazepam	Capsules	10 mg, 15 mg and 30 mg	Serax 15539	Pre-MMA						
Oxcarbazepine	Tablets	150 mg, 300 mg and 600 mg	Trileptal 21014	5/5/2006	1	Eligible	2/8/2022	10/9/2007		2/12/2018
Oxcarbazepine	Oral Suspension	300 mg/5 mL	Trileptal 21285	12/26/2006	1	Eligible	6/15/2021	6/26/2009	12/14/2009	2/12/2018
Oxcarbazepine	Extended-release Tablets	600 mg	Oxtellar XR 202810	3/20/2013	1	Extinguished	3/10/2020			4/13/2027
Oxcarbazepine	Extended-release Tablets	150 mg and 300 mg	Oxtellar XR 202810	4/12/2013	1	Extinguished	3/10/2020			4/13/2027
Oxybutynin	Transdermal System Extended-release	3.9 mg/24 hrs	Oxytrol 21351	8/19/2008	1	Deferred	2/8/2022	3/4/2014		4/26/2020
Oxybutynin Chloride	Extended-release Tablets	5 mg, 10 mg and 15 mg	Ditropan XL 20897	Pre-MMA						
Oxybutynin Chloride	Gel	10%	Gelnique 22204	6/19/2014	1	Extinguished Deferred	6/15/2020 6/18/2019	5/31/2018		4/26/2020
Oxycodone	Extended-release Tablets	10 mg, 20 mg, 40 mg, 80 mg and 160 mg	Oxycontin (NDA 020553)	Pre-MMA						
Oxycodone Hydrochloride	Extended-release Tablets	15 mg	Oxycontin (NDA 020553)	2/15/2007	2	Extinguished	2/8/2022			4/16/2013
Oxycodone Hydrochloride	Extended-release Tablets	30 mg and 60 mg	Oxycontin (NDA 020553)	1/3/2007	1	Extinguished	2/8/2022			4/16/2013
Oxycodone Hydrochloride	Extended-release Tablets	10 mg	Oxycontin (NDA 022272)	10/25/2010	1	Extinguished	10/8/2019			4/19/2025
Oxycodone Hydrochloride	Extended-release Tablets	15 mg	Oxycontin (NDA 022272)	10/28/2010	1	Extinguished	10/8/2019			4/19/2025
Oxycodone Hydrochloride	Extended-release Tablets	20 mg	Oxycontin (NDA 022272)	10/29/2010	2	Extinguished	11/19/2019			4/19/2025
Oxycodone Hydrochloride	Extended-release Tablets	30 mg, 60 mg and 80 mg	Oxycontin (NDA 022272)	10/18/2010	1	Extinguished	6/18/2019			4/19/2025

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Oxycodone Hydrochloride	Extended-release Tablets	40 mg	Oxycontin (NDA 022272)	10/4/2010	1	Extinguished	10/8/2019			4/19/2025
Oxycodone Hydrochloride	Tablets	5 mg and 7.5 mg	Oxaydo 202080	2/7/2012	1	Extinguished	11/17/2020			3/16/2025
Oxycodone	Extended-release Capsules	9 mg, 13.5 mg, 18 mg, 27 mg and 36 mg	Xtampza ER 208090	11/15/2017	1					9/2/2036
Oxycodone Hydrochloride and Acetaminophen	Extended-release Tablets	7.5 mg/325 mg	Xartemis XR	4/3/2014	1	Extinguished	2/9/2021			12/21/2030
Oxymetazoline Hydrochloride	Topical Cream	1%	Rhofade 208552	6/20/2019	1	Eligible	11/2/2021	10/4/2021		6/11/2035
Oxymorphone Hydrochloride	Extended-release Tablets	5 mg, 10 mg, 20 mg and 40 mg	Opana ER	11/23/2007	1	Eligible	2/8/2022	6/14/2010	20 mg- 1/3/2013 5 mg, 10 mg and 40 mg -1/8/2013	7/3/2022
Oxymorphone Hydrochloride	Extended-release Tablets	7.5 mg and 15 mg	Opana ER	5/29/2008	1	Extinguished	2/8/2022	12/13/2010		7/3/2022
Oxymorphone Hydrochloride	Extended-release Tablets	30 mg	Opana ER	6/12/2008	1	Eligible	2/8/2022	7/22/2010	1/8/2013	2/4/2023
Oxymorphone Hydrochloride	Extended-release Tablets	7.5 mg, 10 mg, and 15 mg	Opana ER (NDA 201655)	3/23/2012	1	Extinguished	3/10/2020			7/10/2029
Oxymorphone Hydrochloride	Extended-release Tablets	5 mg	Opana ER (NDA 201655)	3/26/2012	1	Extinguished	2/8/2022			7/10/2029
Oxymorphone Hydrochloride	Extended-release Tablets	20 mg, 30 mg and 40 mg	Opana ER (NDA 201655)	4/3/2012	1	Extinguished	2/8/2022			7/10/2029
Ozanimod Hydrochloride	Capsules	0.23 mg, 0.46 mg and 0.92 mg	Zeposia	3/25/2024	3					9/30/2038
Paclitaxel	Injection	6 mg/mL, 5 mL, 16.7 mL, 25 mL, 33.3 mL and 50 mL vials	Taxol 20262	Pre-MMA						
Paclitaxel Protein-Bound Particles	For Injection Suspension	100 mg/vial	Abraxane 21660	12/11/2015	1	Extinguished	9/4/2023			10/27/2024
Palbociclib	Capsules	75 mg, 100 mg and 125 mg	Ibrance 207103	2/4/2019	12	Extinguished	4/18/2023			1/22/2023

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Palbociclib	Tablets	75 mg, 100 mg and 125 mg	Ibrance 212436	11/24/2020	1	Deferred	6/10/2024	6/5/2024		2/28/2034
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	1	Non-Forfeiture Deferred	1/22/2024 8/24/2021	7/6/2021		1/26/2031
Paliperidone Palmitate	Extended-release Injectable Suspension	546 mg/1.75 mL	Invega Trinza 207946	6/24/2020	1					4/5/2036
Paliperidone Palmitate	Extended-release Injectable Suspension	819 mg/2.625 mL	Invega Trinza 207946	4/30/2021	1					4/5/2036
Paliperidone Palmitate	Extended-release Injectable Suspension	273 mg/0.875 mL and 410 mg/1.315 mL	Invega Trinza 207946	7/14/2021	1					4/5/2036
Palonosetron Hydrochloride	Injection	0.05 mg/mL, 1.5 mL and 5 mL vials	Aloxi 21372	5/27/2011	3	Eligible	2/22/2022	10/13/2015	3/23/2018	1/30/2024
Pamidronate Disodium	For Injection	30 mg/vial 60 mg/vial 90 mg/vial	Aredia 20036	Pre-MMA						
Pamidronate Disodium	Injection	30 mg/vial 60 mg/vial 90 mg/vial	Aredia 20036	Pre-MMA						
Pantoprazole Sodium	For Injection	40 mg/vial	Prontonix IV 20988	4/7/2005	1	Extinguished	8/27/2019			11/17/2021
Pantoprazole Sodium	Delayed-release Tablets	20 mg and 40 mg	Protonix 20987	2/2/2004						
Pantoprazole Sodium	for Delayed-release Oral Suspension	40 mg	Protonix 22020	9/13/2019	1	Eligible	7/13/2020	6/30/2020	8/13/2020	6/7/2026
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 20819	11/28/2008	1	Eligible	3/10/2020	7/27/2011		10/8/2018
Paricalcitol	Capsules	1 mcg and 2 mcg	Zemplar 21606	10/14/2008	1	Eligible	2/22/2022	9/27/2013	9/30/2013	6/24/2014
Paricalcitol	Capsules	4 mcg	Zemplar 21606	8/25/2008	1	Eligible	2/22/2022	9/27/2013	9/30/2013	6/24/2014
Paroxetine Hydrochloride	Capsules	10 mg and 20 mg	Paxil 20885	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Paroxetine Hydrochloride	Oral Suspension	10 mg/5 mL	Paxil 20710	Pre-MMA						
Paroxetine Hydrochloride	Tablets	10 mg, 20 mg, 30 mg and 40 mg	Paxil 20031	Pre-MMA						
Paroxetine Hydrochloride	Extended-release Tablets	25 mg	Paxil CR 20936	9/9/2005	1	Eligible	2/22/2022	6/29/2007	5/14/2008	9/17/2017
Paroxetine Hydrochloride	Extended-release Tablets	37.5 mg	Paxil CR 20936	5/19/2009	1	Eligible	2/22/2022	4/14/2011	5/5/2011	3/17/2017
Paroxetine	Capsules	7.5 mg	Brisdelle 204516	4/7/2014	1	Extinguished	8/13/2019	3/13/2019		4/6/2029
Patiromer Sorbitex Calcium	for Oral Suspension	8.4 g, 16.8 g and 25.2 g	Veltassa 205739	10/21/2019	2					10/8/2033
Pemetrexed Disodium	For Injection	100 mg/vial	Alimta 21462	7/1/2008	1	Extinguished	3/10/2020			1/24/2017
Pemetrexed Disodium	For Injection	500 mg/vial	Alimta 21462	2/4/2008	2	Extinguished	3/10/2020			1/24/2017
Pemetrexed Disodium	For Injection	1000 mg/vial	Alimta 21462	6/27/2012	1	Extinguished	3/10/2020			11/24/2021
Pemetrexed Disodium	For Injection	750 mg/vial	Alimta 21462	10/6/2016	1	Extinguished	2/22/2022			11/24/2021
Pemigatinib	Tablets	4.5 mg, 9 mg and 13.5 mg	Pemazyre 213736	4/17/2024	1					8/30/2040
Perampanel	Tablets	2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg	Fycompa 202834	10/24/2016	2	Eligible	5/27/2025	5/23/2025	5/29/2025	7/1/2026
Perampanel	Oral Suspension	0.5 mg/mL	Fycompa 208277	12/20/2022	1					7/1/2026
Pergolide Mesylate	Tablets	0.05 mg, 0.25 mg and 1 mg	Permax 19385	Pre-MMA						
Perindopril Arginine and Amlodipine	Tablets	3.5 mg/2.5 mg, 7 mg/5 mg and 14 mg/10 mg	Prestalia 205003	11/4/2016	1	Extinguished	7/25/2022			10/5/2029
Perindopril Erbumine	Tablets	2 mg, 4 mg and 8 mg	Aceon 20184	6/6/2006	1	Extinguished	2/22/2022			11/10/2009
Phentermine Hydrochloride	Orally Disintegrating Tablets	15 mg and 30 mg	Suprenza 202088	10/19/2012	1	Deferred	2/22/2022	6/28/2017		7/23/2018
Phentermine Hydrochloride	Orally Disintegrating Tablets	37.5 mg	Suprenza 202088	3/22/2013	1	Deferred	2/22/2022	6/28/2017		7/23/2018

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
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 22580	7/18/2013	1	Extinguished	2/22/2022			6/14/2020
Phentolamine Mesylate	Ophthalmic Solution	0.75%	Ryzumvi 217064	12/16/2024	1					
Phenylephrine and Ketorolac	Injection	1%/0.3%	Omidria 205388	5/29/2015	1	Extinguished	8/13/2019			7/30/2023
Pilocarpine Hydrochloride	Ophthalmic Solution	1.25%	Vuity 214028	12/30/2022	1	Eligible	4/28/2025	4/28/2025		4/24/2039
Pimavanserin	Capsules	34 mg	Nuplazid 210793	4/29/2020	5	Eligible	1/22/2024	1/16/2024		8/27/2038
Pimavanserin	Tablets	10 mg	Nuplazid 207318	4/29/2020	1	Eligible	1/22/2024	1/16/2024		6/3/2028
Pimavanserin	Tablets	34 mg	Nuplazid 207318	1/2/2025	1					3/23/2037
Pioglitazone Hydrochloride	Tablets	15 mg, 30 mg and 45 mg	Actos 21073	Pre-MMA						
Pioglitazone Hydrochloride and Glimepiride	Tablets	30 mg/2 mg and 30 mg/4 mg	Duetact 21925	12/22/2009	1	Deferred	2/22/2022	1/4/2013	1/8/2013	6/8/2028
Pioglitazone Hydrochloride and Metformin Hydrochloride	Extended-release Tablets	15 mg/1000 mg and 30 mg/1000 mg	Actoplus Met XR 22024	9/23/2011	1	Extinguished	1/12/2021			7/31/2026
Pioglitazone Hydrochloride and Metformin Hydrochloride	Tablets	15 mg/500 mg and 15 mg/850 mg	Actoplus Met 21824	3/6/2008	1	Non-Forfeiture Extinguished	2/22/2022	2/25/2011	8/17/2012	6/19/2016
Piperacillin Sodium and Tazobactam Sodium	For Injection	2.25 g/vial 3.375 g/vial 4.5 g/vial	Zosyn 50684	PIV received prior to 2/5/2009						
Piperacillin Sodium and Tazobactam Sodium	For Injection	12 g/1.5 g per vial (pharmacy bulk)	Zosyn 50684	12/6/2011	1	Eligible	2/22/2022	10/29/2014	1/24/2017	4/14/2023
Piperacillin Sodium and Tazobactam Sodium	For Injection	36 mg/4.5 g per vial (pharmacy bulk)	Zosyn 50684	PIV received prior to 2/5/2009	1	Eligible	12/1/2020	9/15/2009	10/29/2009	4/14/2023
Pirfenidone	Capsules	267 mg	Esbriet 22535	10/15/2018	9	Eligible	1/25/2022	1/3/2022	6/13/2022	8/30/2033

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Pirfenidone	Tablets	267 mg and 801 mg	Esbriet 208780	10/15/2018	17	Eligible	2/8/2022	1/25/2022	5/2/2022	8/30/2033
Pirfenidone	Tablets	534 mg	Esbriet 208780	10/15/2018	2	Eligible	7/25/2022	7/19/2022		8/30/2033
Pitavastatin Calcium	Tablets	1 mg, 2 mg, and 4 mg	Livalo 22363	8/5/2013	7	Eligible	7/25/2022	12/20/2016	11/2/2023	2/19/2024
Pitolisant Hydrochloride	Tablets	4.45 mg and 17.8 mg	Wakix 211150	8/14/2023	7					3/7/2030
Plecanatide	Tablets	3 mg	Trulance 208745	1/19/2021	2					6/5/2034
Plerixafor	Injection	24 mg/1.2 mL vials (20 mg/mL)	Mozobil 22311	12/17/2012	3	Extinguished	87/2023			7/23/2023
Polyethylene Glycol 3350	Powder for Oral Solution	17g/Scoopful	Miralax 22015	Pre-MMA						
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	1	Eligible	2/22/2022	8/20/2014	4/21/2015	10/22/2022
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	1	Extinguished	2/22/2022			10/22/2022
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 21881	11/27/2007	1	Eligible	9/8/2020	1/25/2012	8/31/2020	9/1/2024
Polyethylene Glycol 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, Sodium Sulfate and Ascorbic Acid	For Oral Solution	140 g, 5.2 g, 2.2.g, 48.11 g, 9 g and 7.54 g per pouch	Plenvu 209381	12/6/2018	1					9/10/2033
Polyethylene Glycol 3350, Sodium Sulfate, Potassium Chloride, Magnesium Sulfate, Sodium Chloride	For Oral Solution	178.7 g/7.3 g/1.12 g/ 0.9g/0.5 g	Suflave 215344	4/4/2025	1					6/14/2044
Pomalidomide	Capsules	1 mg, 2 mg, 3 mg and 4 mg	Pomalyst 204026	2/8/2017	6	Non-Forfeiture Deferred	12/14/2021 1/12/2021	10/3/2020		6/21/2031

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Ponatinib Hydrochloride	Tablets	15 mg and 45 mg	Iclusig 203469	3/31/2021	1	Eligible	8/7/2023	7/14/2023		12/12/2033
Ponatinib Hydrochloride	Tablets	10 mg and 30 mg	Iclusig 203469	12/12/2022	1					12/12/2033
Posaconazole	Oral Suspension	40 mg/mL	Noxafil 22003	2/28/2011	1	Extinguished	7/30/2019			7/19/2019
Posaconazole	Delayed-release Tablets	100 mg	Noxafil 205053	6/16/2014	1	Extinguished	7/30/2019			7/19/2019
Posaconazole	Injection	18 mg/mL, 16.7 mL vials	Noxafil 205596	11/24/2015	1	Eligible	7/25/2022	5/25/2022	6/28/2023	7/4/2031
Potassium Chloride	Extended-release Capsules	8 mEq and 10 mEq	Micro K	Pre-MMA						
Potassium Chloride	Extended-release Tablets	10 mEq and 20 mEq	K-Dur	Pre-MMA						
Pralatrexate	Injection	20 mg/mL and 40 mg/2 mL	Folotyn 22468	9/24/2013	4	Extinguished Eligible	6/9/2025 3/17/2025	3/10/2025		5/31/2025
Pramipexole Dihydrochloride	Tablets	0.125 mg, 0.5 mg, 1 mg and 1.5 mg	Mirapex 20667	6/24/2005	1	Eligible	2/22/2022	2/19/2008	1/4/2010	3/25/2011
Pramipexole Dihydrochloride	Tablets	0.25 mg	Mirapex 20667	5/27/2005	1	Eligible	2/22/2022	2/19/2008	1/4/2010	3/25/2011
Pramipexole Dihydrochloride	Tablets	0.75 mg	Mirapex 20667	7/31/2008	1	Extinguished Eligible	4/18/2023 2/22/2022	4/9/2010		10/8/2010
Pramipexole Dihydrochloride	Extended-release Tablets	0.375 mg, 0.75 mg, 1.5 mg, 3 mg and 4.5 mg	Mirapex ER 22421	6/1/2010	1	Extinguished	2/8/2022			4/26/2028
Pramipexole Dihydrochloride	Extended-release Tablets	2.25 mg and 3.75 mg	Mirapex ER 22421	7/26/2011	1	Eligible	2/8/2022	2/6/2014	11/20/2015 - 2.25 mg 3.75 mg - 7/5/2016	4/26/2028
Prasugrel Hydrochloride	Tablets	5 mg and 10 mg	Effient 22307	7/10/2013	17	Eligible	6/29/2020	7/12/2017	8/15/2017	3/2/2022
Pravastatin Sodium	Tablets	10 mg, 20 mg, 40 mg and 80 mg	Pravachol 19898	Pre-MMA						
Pravastatin Sodium	Tablets	30 mg	Pravachol 19898	6/1/2005	1	Eligible	2/22/2022	11/28/2006		4/22/2014
Prazosin Hydrochloride	Capsules	1 mg, 2 mg and 5 mg	Minipress 17442	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Prednisolone Sodium Phosphate	Oral Solution	5 mg(base)/ 5 mL and 15 mg (base)/ 5 mL	Pediapred 19157	Pre-MMA						
Prednisolone Sodium Phosphate	Orally Disintegrating Tablets	10 mg, 15 mg and 30 mg	Orapred 21959	7/22/2010	1	Eligible	8/27/2019	4/10/2013	12/8/2014	11/24/2019
Prednisone	Delayed-release Tablets	1 mg and 2 mg	Rayos 202020	11/26/2012	1	Extinguished Deferred	8/5/2024 2/22/2022	4/25/2017		4/23/2024
Prednisone	Delayed-release Tablets	5 mg	Rayos 202020	11/26/2012	1	Non-Forfeiture Deferred	8/5/2024 2/22/2022	4/25/2017		1/7/2028
Pregabalin	Capsules	25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg	Lyrica 21446	12/30/2008	8	Extinguished	12/13/2022			12/30/2018
Pregablin	Oral Solution	20 mg/mL	Lyrica 22488	5/19/2010	1	Extinguished	7/25/2022			12/30/2018
Pregabalin	Extended-release Tablets	330 mg	Lyrica CR 209501	1/29/2018	1	Extinguished	4/20/2021	4/12/2021		11/2/2026
Pregabalin	Extended-release Tablets	82.5 mg and 165 mg	Lyrica CR 209501	2/2/2018	1	Extinguished	4/20/2021	4/12/2021		11/2/2026
Propafenone	Extended-release Capsules	325 mg	Rythmol SR 21416	11/07/2006	1	Deferred	7/25/2022	10/18/2010	1/3/2011	10/28/2014
Propafenone Hydrochloride	Extended-release Capsules	225 mg and 425 mg	Rythmol SR 21416	10/11/2006	1	Deferred	7/25/2022	10/18/2010	1/3/2011	10/28/2014
Propofol	Injection	10 mg/mL ; 20 mL, 50 mL and 100 mL vials and 20 mL syringe	Diprivan 19627	Pre-MMA						
Propranolol Hydrochloride	Extended-release Capsules	60 mg, 80 mg, 120 mg and 160 mg	Inderal LA 18553	Pre-MMA						
Propranolol Hydrochloride	Oral Solution	4.28 mg/mL	Hemangeol 205410	7/21/2022	1	Extinguished	2/17/2025			10/16/2028
Quetiapine Fumarate	Extended-release Tablets	400 mg	Seroquel XR 22047	6/18/2008	1	Eligible	8/24/2020	11/1/2016	11/1/2016	5/28/2017
Quetiapine Fumarate	Extended-release Tablets	150 mg	Seroquel XR 22047	11/17/2008	1	Eligible	8/24/2020	5/9/2017	11/1/2016	5/28/2017
Quetiapine Fumarate	Extended-release Tablets	200 mg and 300 mg	Seroquel XR 22047	6/12/2008	1	Eligible	8/24/2020	5/9/2017	11/1/2016	5/28/2017

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Quetiapine Fumarate	Extended-release Tablets	50 mg	Seroquel XR 22047	10/17/2008	1	Eligible	8/24/2020	5/9/2017	11/1/2016	5/28/2017
Quetiapine Fumarate	Tablets	25 mg	Seroquel 20639	8/12/2005	1	Extinguished	8/24/2020	3/27/2012		9/26/2011
Quetiapine Fumarate	Tablets	50 mg, 150 mg and 400 mg	Seroquel 20639	2/12/2007	1	Extinguished	8/24/2020	3/27/2012		9/26/2011
Quetiapine Fumarate	Tablets	100 mg, 200 mg and 300 mg	Seroquel 20639	2/21/2006	1	Extinguished	8/24/2020	3/27/2012		9/26/2011
Quinapril Hydrochloride	Tablets	5 mg, 10 mg, 20 mg and 40 mg	Accupril 19885	Pre-MMA						
Quinapril Hydrochloride/ Hydrochlorothiazide	Tablets	10 mg/12.5 mg 20 mg/12.5 mg 20mg/25 mg	Accuretic 20125	Pre-MMA						
Rabeprazole Sodium	Delayed-release Tablets	20 mg	Aciphex 20973	Pre-MMA						
Raltegravir Potassium	Tablets	400 mg	Isentress 22145	10/12/2011	1	Eligible	2/17/2025	12/19/2024		3/11/2029
Raltegravir Potassium	Tablets	600 mg	Isentress HD 22145	10/21/2022	1	Eligible	5/12/2025	5/8/2025		3/30/2032
Raloxifene Hydrochloride	Tablets	60 mg	Evista 20815	Pre-MMA						
Ramelteon	Tablets	8 mg	Rozerem 21782	7/22/2009	2	Deferred	6/18/2019	7/26/2013	7/22/2019	7/22/2019
Ramipril	Capsules	1.25 mg, 2.5 mg, 5 mg and 10 mg	Altace 19901	Pre-MMA						
Ranitidine	Capsules	150 mg and 300 mg	Zantac	Pre-MMA						
Ranitidine	Injection	25 mg/mL, 2 mL and 6 mL and 40 mL vials	Zantac	Pre-MMA						
Ranitidine	Oral Solution	15 mg/mL	Zantac	Pre-MMA						
Ranitidine	Tablets	75 mg, 150 mg and 300 mg	Zantac	Pre-MMA						
Ranitidine Hydrochloride	Tablets	150 mg	Zantac 150 (NDA 21698/Product 002)	10/30/2007	1	Extinguished	3/23/2021			12/20/2010
Ranolazine	Extended-release	500 mg and 1000 mg	Renexa 21526	5/17/2010	1	Eligible	3/23/2021	7/29/2013	1/27/2019	5/27/2019
Rasagiline Mesylate	Tablets	0.5 mg and 1 mg	Azilect 21641	5/17/2010	5	Eligible	3/23/2021	9/12/2013	1/2/2017	12/5/2026

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Regadenoson	Injection	0.08 mg/mL, 5 mL vial	Lexiscan 22161	4/10/2012	1	Extinguished	1/12/2021			2/2/2027
Regorafenib	Tablets	40 mg	Stivarga 203085	9/27/2016	2	Deferred	2/17/2025	1/13/2025		2/16/2031
Relugolix	Tablets	120 mg	Orgovyx 214621	12/18/2024	6					9/29/2037
Remdesivir	Powder for Injection	100 mg/vial	Veklury 214787	4/22/2025	1					5/28/2041
Remifentanil Hydrochloride	for Injection	1 mg/vial, 2 mg/vial and 5 mg/vial	Ultiva 20630	12/27/2013	1	Extinguished	7/2/2019	1/16/2018	1/26/2018	9/10/2017
Remimazolam Besylate	Powder for Injection	20 mg/vial	Byfavo 212295	10/7/2024	1					1/13/2034
Repaglinide	Tablets	0.5 mg*, 1 mg and 2 mg	Prandin 20741	2/10/2005	1	Eligible	3/23/2021	7/11/2013	7/24/2013	6/12/2018
Repaglinide and Metformin Hydrochloride	Tablets	1 mg/500 mg and 2 mg/500 mg	Prandimet 22386	4/9/2009	1	Extinguished	3/10/2020			6/12/2018
Revefenacin	Inhalation Solution	175 mcg/3 mL	Yupelri 210598	11/9/2022	7					10/23/2039
Ribavirin	Capsules	200 mg	Rebetol 20903	Pre-MMA						
Ribavirin	for Inhalation Solution	6 gm/vial	Virazole 18859	5/22/2014	1	Eligible	3/23/2021	10/6/2016	12/15/2016	11/21/2017
Ribociclib Succinate	Tablets	200 mg	Kisqali 209092	3/15/2021	4					4/14/2036
Ribociclib Succinate and Letrozole (Copackaged)	Tablets	200 mg and 2.5 mg	Kisqali Femara Co-Pack 209935	3/15/2021	4					4/14/2036
Rifaximin	Tablets	550 mg	Xifaxan 21361	12/18/2015	1	Non-Forfeiture Non-Forfeiture	2/17/2025 8/24/2021			10/2/2029
Rifaximin	Tablets	200 mg	Xifaxan 21361	1/28/2019	1					7/24/2029
Riluzole	Oral Suspension	50 mg/10 mL	Tiglutik Kit 209080	3/12/2021	1	Deferred	9/2/2024	8/22/2024		3/12/2029
Rimegepant Sulfate	Orally Disintegrating Tablets	75 mg	Nurtec ODT 212728	2/27/2024	7					3/25/2039
Riociguat	Tablets	0.5 mg, 1 mg, 1.5 mg, 2 mg and 2.5 mg	Adempas 204819	10/10/2017	3	Deferred	10/4/2022	9/1/2022		12/4/2026

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Risedronate Sodium	Tablets	5 mg, 30 mg and 35 mg	Actonel 20835	4/23/2004	1	Eligible	3/10/2020	10/5/2007	6/1/2015	6/10/2018 - 5 mg and 30 mg 7/17/2018 - 35 mg
Risedronate Sodium	Tablets	75 mg	Actonel 20835	9/7/2007	1	Extinguished	3/10/2020			6/10/2018
Risedronate Sodium	Tablets	150 mg	Actonel 20835	8/12/2008	1	Extinguished	3/10/2020	6/13/2014		5/6/2023
Risedronate Sodium	Delayed-release Tablets	35 mg	Atelvia 22560	6/9/2011	1	Deferred	3/23/2021	5/18/2015	5/18/2015	1/9/2028
Risedronate Sodium with Calcium Carbonate	Tablets	35 mg; 500 mg	Actonel with Calcium	12/18/2007	1	Extinguished	3/10/2020			7/17/2018
Risdiplam	For Oral Solution	0.75 mg/mL	Evrysdi 213535	8/7/2024	2					10/4/2038
Risperidone	Oral Solution	1 mg/mL	Risperdal 20588	Pre-MMA						
Risperidone	Tablets	0.25 mg, 1 mg, 2 mg, 3 mg and 4 mg	Risperdal 20272	Pre-MMA						
Risperidone	Orally Disintegrating Tablets	0.25 mg	Risperdal 21444	4/11/2005	1	Eligible	3/23/2021	4/30/2009	6/1/2009	6/10/2017
Risperidone	Orally Disintegrating Tablets	0.5 mg, 1 mg and 2 mg	Risperdal 21444	Pre-MMA						
Risperidone	Orally Disintegrating Tablets	3 mg and 4 mg	Risperdal 21444	3/23/2005	1	Eligible	3/23/2021	4/30/2009	6/1/2009	6/10/2017
Ritonavir	Tablets	100 mg	Norvir 22417	12/21/2010	1	Eligible	6/18/2019	1/15/2015	3/20/2018	5/10/2021
Ritonavir	Capsules	100 mg	Norvir	10/31/2012	1	Extinguished	2/9/2021			5/22/2020
Rivastigmine Tartrate	Capsules	1.5 mg, 3 mg, 4.5 mg and 6 mg	Exelon 20823	4/21/2004	3	Eligible	3/23/2021	10/22/2007		2/11/2014
Rivastigmine Tartrate	Oral Solution	2 mg/mL	Exelon 21025	11/5/2004	1	Extinguished	8/27/2019			2/11/2014
Rivastigmine	Transdermal System Extended-release	4.6 mg/24 hr and 9.5 mg/24 hr	Exelon 22083	4/27/2011	1	Extinguished	3/23/2021			1/8/2019
Rivastigmine	Transdermal System Extended-release	13.3 mg/24 hr	Exelon 22083	1/22/2013	1	Eligible	3/23/2021	8/31/2015	9/2/2015	1/8/2019

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Rivaroxaban	Tablets	2.5 mg	Xarelto 22406	11/19/2018	4	Extinguished	3/3/2025			11/13/2024
Rivaroxaban	Tablets	10 mg, 15 mg, and 20 mg	Xarelto 22406	7/1/2015	8	Extinguished	10/3/2024			8/28/2024
Rivaroxaban	Capsules	10 mg, 15 mg and 20 mg	Xarelto 22406	6/17/2022	1	Extinguished	6/9/2025			2/17/2034
Rizatriptan Benzoate	Tablets	5 mg and 10 mg	Maxalt 20864	9/2/2004	1	Extinguished	3/23/2021	12/31/2012		2/11/2014
Rizatriptan Benzoate	Orally Disintegrating Tablets	5 mg and 10 mg	Maxalt-MLT 20865	2/17/2006	1	Eligible	3/23/2021	12/31/2012	12/31/2012	2/11/2014
Rofecoxib	Tablets	12.5 mg, 25 mg and 50 mg	Vioxx 21052	Pre-MMA						
Roflumilast	Tablets	500 mcg	Daliresp 22522	3/2/2015	7	Eligible	6/18/2019	7/13/2018	10/19/2022	3/8/2024
Roflumilast	Tablets	250 mcg	Daliresp 22522	1/25/2019	1	Eligible	9/20/2022	9/7/2022	10/20/2022	3/8/2024
Roflumilast	Cream	0.3%	Zoryve 215985	12/27/2023	1					6/7/2037
Romidepsin	Injection	10 mg/vial	Istodax 22393	11/5/2013	1	Extinguished	11/2/2021	10/12/2021		8/22/2021
Ropinirole Hydrochloride	Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Requip 20658	12/22/2004	1	Extinguished	3/10/2020	5/5/2008		5/19/2008
Ropinirole Hydrochloride	Tablets	3 mg, 4 mg and 5 mg	Requip 20658	2/4/2005	1	Extinguished	3/10/2020	5/5/2008		5/19/2008
Ropinirole Hydrochloride	Extended-release Tablets	2 mg	Requip XL 22008	10/14/2008	1	Eligible	3/10/2020	5/17/2012	5/17/2012	6/6/2012
Ropinirole Hydrochloride	Extended-release Tablets	4 mg	Requip XL 22008	10/31/2008	1	Eligible	3/10/2020	5/17/2012	5/17/2012	6/6/2012
Ropinirole Hydrochloride	Extended-release Tablets	6 mg	Requip XL 22008	7/14/2009	1	Eligible	3/10/2020	5/17/2012	5/17/2012	6/6/2012
Ropinirole Hydrochloride	Extended-release Tablets	8 mg	Requip XL 22008	11/3/2008	1	Eligible	3/10/2020	5/17/2012	5/17/2012	6/6/2012
Ropinirole Hydrochloride	Extended-release Tablets	3 mg	Requip XL 22008	1/8/2009	1	Extinguished	3/10/2020			6/6/2012
Ropinirole Hydrochloride	Extended-release Tablets	12 mg	Requip XL 22008	2/5/2009	1	Eligible	3/10/2020	5/17/2012	5/17/2012	6/6/2012

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Ropivacaine Hydrochloride	Injection	2 mg/mL, 5 mg/mL and 10 mg/mL, 20 mL, 30 mL and 20 mL vials	Naropin 20533	11/13/2006	1	Extinguished	3/23/2021	7/17/2014		9/23/2014
Ropivacaine Hydrochloride	Injection	2 mg/mL, 100 mL	Naropin 20533	1/30/2015	1	Eligible	3/23/2021	7/13/2016	9/15/2016	11/28/2026
Ropivacaine Hydrochloride	Injection	2 mg/mL, 200 mL	Naropin 20533	9/3/2015	1	Extinguished	6/18/2019	3/16/2018		11/28/2026
Rosiglitazone Maleate	Tablets	2 mg, 4 mg and 8 mg	Avandia 21071	Pre-MMA						
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 21410	10/22/2004	1	Eligible	3/23/2021	5/7/2014 5/19/2017 1mg/500mg		2/11/2017
Rosuvastatin Calcium	Tablets	5 mg, 10 mg, 20 mg and 40 mg	Crestor 21366	8/13/2007	9	Non-Forfeiture	8/27/2019	4/29/2016	5/2/2016	8/4/2020
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 21829	11/26/2013	1					9/1/2027
Rufinamide	Tablets	100 mg	Banzel 21911	11/14/2012	1	Extinguished Deferred	4/18/2023 9/6/2022	8/17/2022		11/14/2022
Rufinamide	Tablets	200 mg and 400 mg	Banzel 21911	11/14/2012	5	Eligible	3/23/2021	5/16/2016	6/1/2021	11/14/2022
Rufinamide	Oral Suspension	40 mg/mL	Banzel 201367	6/16/2014	1	Extinguished	10/8/2019			11/14/2022
Ruxolitinib Phosphate	Cream	1.5%	Opzelura 215309	7/31/2023	1					5/5/2041
Ruxolitinib Phosphate	Tablets	5 mg, 10 mg, 15 mg, 20 mg, and 25 mg	Jakafi 202192	12/17/2015	1					6/12/2028
Sacubitril and Valsartan	Tablets	24 mg/26 mg, 49 mg/51 mg 97 mg/103 mg	Entresto 207620	7/8/2019	18	Deferred	6/10/2024	5/28/2024	7/23/2025	5/27/2027

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Safinamide Mesylate	Tablets	50 mg and 100 mg	Xadago 2071454	3/22/2021	6	Eligible	6/26/2023	6/14/2023		12/10/2028
Sapropterin Dihydrochloride	Tablets	100 mg	Kuvan 22181	6/5/2014	1	Eligible	11/19/2019	5/10/2019	10/1/2020	11/16/2025
Sapropterin Dihydrochloride	Powder for Oral Solution	100 mg per packet	Kuvan 205065	11/9/2015	1	Eligible Deferred	1/27/2020 8/27/2019	8/20/2019	10/1/2020	5/17/2025
Sapropterin Dihydrochloride	Powder for Oral Solution	500 mg per packet	Kuvan 205065	2/23/2017	1	Eligible	11/19/2019	8/20/2019	10/1/2020	11/1/2032
Saxagliptin Hydrochloride	Tablets	2.5 mg and 5 mg	Onglyza 22350	7/31/2013	8	Eligible	8/7/2023	7/31/2023	7/31/2023	11/302028
Saxagliptin Hydrochloride and Metformin Hydrochloride	Extended-release Tablets	5 mg/500 mg 2.5 mg/1000 mg 5 mg/1000 mg	Kombiglyze XR 200678	7/31/2013	3	Extinguished	8/7/2023			7/31/2023
Selenious Acid	Intravenous Solution	12 mcg/2 mL	Selenious Acid 209379	6/11/2024	4	Eligible	7/7/2025	6/11/2025		7/1/2041
Selenious Acid	Intravenous Solution	60 mcg/mL	Selenious Acid 209379	6/11/2024	5					7/1/2041
Selenious Acid	Intravenous Solution	600 mcg/10 mL	Selenious Acid 209379	6/11/2024	11	Eligible	3/3/2025	2/10/2025		7/1/2041
Selexipag	Tablets	0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1 mg, 1.2 mg, 1.4 mg and 1.6 mg	Uptravi 207947	12/23/2019	4	Eligible	1/10/2023	12/21/2022		8/1/2030
Selexipag	For Injection	1.8 mg/vial	Uptravi 214275	7/29/2022	1					8/1/2030
Selpercatinib	Capsules	40 mg and 80 mg	Retevmo 213246	5/8/2024	1	Extinguished	8/19/2024			10/10/2037
Semaglutide	Injection	2 mg/1.5 mL and 4 mg/3 mL	Ozempic 209637	12/6/2021	7					6/21/2033
Semaglutide	Injection	2 mg/3 mL	Ozempic 209637	4/11/2024	1					6/21/2033
Semaglutide	Injection	8 mg/3 mL	Ozempic 209637	12/21/2022	1					2/1/2032

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Semaglutide	Injection	0.25 mg/0.5 mL 0.5 mg/0.5 mL 1 mg/0.5 mL 1.7 mg/0.75 mL 2.4 mg/0.75 mL	Wegovy 215256	10/20/2022	1					2/17/2041
Semaglutide	Tablets	3 mg, 7 mg and 14 mg	Rybelsus 213051	7/15/2024	1					5/2/2034
Sertraline Hydrochloride	Oral Concentrate	20 mg/mL	Zoloft 20990	12/9/2003	1	Eligible	8/27/2019	6/30/2006	8/7/2007	10/11/2019
Sertraline Hydrochloride	Tablets	25 mg, 50 mg and 100 mg	Zoloft 19839	Pre-MMA						
Sertraline Hydrochloride	Tablets	150 mg and 200 mg	Zoloft 19839	11/9/2005	1	Eligible	8/24/2020	2/6/2007		8/13/2012
Sevelamer Carbonate	Powder for Oral Suspension	0.8 g/packet and 2.4 g/packet	Renvela 22318	12/30/2009	1	Extinguished	8/27/2019			9/16/2014
Sevelamer Carbonate	Tablets	800 mg	Renvela 22127	12/4/2008	1	Extinguished	8/27/2019	10/23/2017	4/16/2014	9/16/2014
Sevelamer Hydrochloride	Tablets	400 mg and 800 mg	Renagel 21179	5/22/2008	1	Extinguished	7/30/2019			10/18/2020
Sevoflurane	Inhalation	100%, 250 mL	Ultane 20478	Pre-MMA						
Sibutramine Hydrochloride	Capsules	10 mg and 15 mg	Meridia 20632	8/14/2009	1	Extinguished	8/24/2020			7/25/2012
Sildenafil Citrate	Tablets	25 mg and 50 mg	Viagra 20895	11/19/2004	1	Eligible	8/24/2020	3/9/2016	12/11/2017	10/22/2019
Sildenafil Citrate	Tablets	100 mg	Viagra 20895	10/25/2004	1	Eligible	8/24/2020	3/9/2016	12/11/2017	10/22/2019
Silodosin	Capsules	4 mg and 8 mg	Rapaflo 22206	10/9/2012	3	Deferred	8/24/2020	3/31/2017		12/1/2018
Silver Sulfadiazine	Cream	1%	Silvadene 17381	Pre-MMA						
Simvastatin	Tablets	5 mg, 10 mg, 20 mg, 40 mg and 80 mg	Zocor 19766	Pre-MMA						
Siponimod Fumaric Acid	Tablets	0.25 mg, 1 mg and 2 mg	Mayzent 209884	3/27/2023	5	Eligible	4/28/2025	4/22/2025		11/30/2030
Sirolimus	Tablets	0.5 mg	Rapamune 21110	9/28/2010	1	Eligible	3/10/2020	1/8/2014	1/16/2014	3/11/2018

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Sirolimus	Tablets	1 mg and 2 mg	Rapamune 21110	12/17/2009	1	Extinguished	3/10/2020			3/11/2018
Sitagliptin Phosphate	Tablets	25 mg, 50 mg and 100 mg	Januvia 21995	10/18/2010	6					11/24/2026
Sitagliptin Phosphate and Metformin Hydrochloride	Tablets	50 mg/500 mg and 50 mg/1000 mg	Janumet 22044	10/18/2010	5					11/24/2026
Sitagliptin Phosphate and Metformin Hydrochloride	Extended-release Tablets	50 mg/500 mg and 50 mg/1000 mg	Janumet XR 202270	3/16/2012	1	Eligible	6/9/2025	6/4/2025		11/24/2026
Sitagliptin Phosphate and Metformin Hydrochloride	Extended-release Tablets	100 mg/1000 mg	Janumet XR 202270	10/22/2012	1	Eligible	6/9/2025	6/4/2025		11/24/2026
Sitagliptin Phosphate and Simvastatin	Tablets	100 mg/10 mg and 100 mg/40 mg	Juvisync 202343	6/19/2012	1	Extinguished	8/24/2020			4/11/2026
Sitagliptin Phosphate and Simvastatin	Tablets	100 mg/20 mg	Juvisync 202343	6/25/2012	1	Extinguished	8/24/2020			4/11/2026
Sitagliptin Phosphate and Simvastatin	Tablets	50 mg/10 mg 50 mg/20 mg 50 mg/40 mg	Juvisync 202343	11/6/2012	1	Extinguished	8/24/2020			4/11/2026
Sodium Phosphate Monobasic Monohydrate and Sodium PhosphateDibasic Anhydrous, USP	Tablets	1.102 g and 0.398 g	Osmoprep 21892	4/9/2008	1	Eligible	8/24/2020	12/30/2011		5/18/2013
Sodium Picosulfate, Magnesium Oxide and Anhydrous Citric Acid	Oral Solution	10 mg, 3.5 g, and 12 g	Prepopik 202535	5/21/2014	1	Extinguished	8/13/2019			10/10/2028
Sodium Picosulfate, Magnesium Oxide and Anhydrous Citric Acid	Oral Solution	10 mg, 3.5 g, and 12 g	Clenpiq 209589	2/11/2019	1					6/26/2034
Sodium Sulfate, Potassium Sulfate and Magnesium Sulfate	Oral Solution	17.5 g/3.13 g/1.6 g	Suprep Bowel Prep Kit 22372	11/8/2010	1	Eligible	11/17/2020	2/23/2017	9/7/2022	3/7/2023
Sodium Sulfate, Magnesium Sulfate and Potassium Chloride	Tablets	1.479 g/0.225 g/ 0.188 g	Sutab 213135	3/3/2023	1					8/4/2037
Sodium Oxybate	Oral Solution	500 mg/mL	Xyrem 21196	7/8/2010	1	Eligible	7/2/2019	1/17/2017	1/17/2017	6/16/2024
Sodium Thiosulfate	Intravenous Injection	12.5 g/50 mL	Sodium Thiosulfate 203923	4/29/2022	1					3/29/2031

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Sodium Thiosulfate	Intravenous Injection	12.5 g/100 mL	Pedmark 212937	10/18/2022	1					7/1/2039
Sodium Zirconium Cyclosilicate	for Oral Suspension	5 g/packet and 10 g/packet	Lokelma 207078	5/18/2022	5					10/14/2035
Solifenacin Succinate	Tablets	5 mg and 10 mg	Vesicare 21518	4/8/2009	1	Deferred	8/24/2020	4/2/2014		11/9/2018
Solifenacin Succinate	Oral Suspension	1 mg/mL	Vesicare LS 209529	5/27/2021	1					5/18/2031
Solriamfetol Hydrochloride	Tablets	75 mg and 150 mg	Sunosi 211230	6/20/2023	6					3/19/2040
Sofosbuvir	Tablets	400 mg	Sovaldi 204671	12/6/2017	2	Deferred	2/8/2022	1/27/2022		12/11/2030
Sorafenib Tosylate	Tablets	200 mg	Nexavar 21923	2/28/2014	1	Eligible	11/17/2020	9/10/2020		2/11/2023
Spironolactone	Oral Suspension	25 mg/5 mL	Carospir 209478	12/31/2020	1	Eligible	9/18/2023	9/5/2023	10/31/2023	10/28/2036
Sugammadex Sodium	Injection	200 mg/2 mL and 500 mg/5 mL	Bridion 22225	12/16/2019	14	Eligible	6/12/2023	6/9/2023		1/27/2026
Sumatriptan Succinate	Injection	6 mg/0.5 mL, 0.5 mL vials	Imitrex	10/25/2004	1	Extinguished	8/24/2020	10/9/2009		8/6/2008
Sumatriptan Succinate	Injection	6 mg/0.5 mL, 0.5 mL (prefilled syringes)	Imitrex	5/9/2006	1	Extinguished	3/10/2020			8/6/2008
Sumatriptan Succinate	Tablets	25 mg, 50 mg and 100 mg	Imitrex 20132	Pre-MMA						
Sunitinib Malate	Capsules	12.5 mg, 25 mg, 37.5 mg and 50 mg	Sutent 21938	1/26/2010	1	Extinguished	9/7/2021			2/15/2021
Suvorexant	Tablets	5 mg, 10 mg, 15 mg and 20 mg	Belsomra 204569	3/4/2024	1					5/29/2033
Tacrolimus	Ointment	0.03%	Protopic 50777	11/22/2010	1	Extinguished	8/24/2020	9/9/2014		9/9/2014
Tacrolimus	Ointment	0.10%	Protopic 50777	9/9/2010	1	Extinguished	8/24/2020	9/9/2014		9/9/2014
Tacrolimus	Extended-release Capsules	0.5 mg, 1 mg, and 5 mg	Astagraf XL 204096	9/24/2013	1	Extinguished	8/24/2020			3/25/2019
Tacrolimus	Extended-release Tablets	0.75 mg, 1 mg and 4 mg	Envarsus XR 206406	3/31/2022	1					8/30/2028

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Tadalafil	Tablets	2.5 mg	Cialis 21368	10/14/2008	1	Eligible	6/18/2019	5/22/2018	9/27/2018	11/19/2020
Tadalafil	Tablets	5 mg, 10 mg and 20 mg	Cialis 21368	11/21/2007	1	Eligible	6/18/2019	5/22/2018	9/27/2018	11/19/2020
Tadalafil	Tablets	20 mg	Adcirca 22332	10/15/2009	1	Eligible	6/18/2019	8/3/2018	8/8/2018	4/26/2020
Tafamidis Meglumine	Capsules	20 mg	Vyndaqel 211996	5/3/2023	1	Extinguished	4/14/2025			4/27/2024
Tafamidis	Capsules	61 mg	Vyndamax 212161	5/3/2023	3					8/31/2035
Tafluprost	Ophthalmic Solution	0.0015%	Zioptan 202514	2/10/2016	2	Eligible Deferred	2/20/2023 12/14/2021	8/19/2019	12/6/2022	12/18/2022
Tamoxifen Citrate	Tablets	10 mg and 20 mg	Nolvadex 17970	Pre-MMA						
Tamsulosin Hydrochloride	Capsules	0.4 mg	Flomax 20579	12/20/2004	1	Extinguished	8/24/2020			
Tapentadol Hydrochloride	Tablets	50 mg, 75 mg, and 100 mg	Nucynta 22304	11/20/2012	4	Extinguished	7/7/2025			6/27/2025
Tapentadol Hydrochloride	Extended-release Tablets	50 mg, 100 mg, 150 mg, 200 mg, and 250 mg	Nucynta ER 200533	11/20/2012	2	Extinguished	7/7/2025			6/27/2025
Tapentadol	Oral Solution	20 mg/mL	Nucynta 203794	12/20/2013	1	Extinguished	7/7/2025			6/27/2025
Tasimelteon	Capsules	20 mg	Hetlioz 205677	1/31/2018	3	Eligible Deferred	1/10/2023 12/13/2022	12/12/2022	12/29/2022	5/17/2034
Tasimelteon	Oral Suspension	4 mg/mL	Hetlioz LQ 214517	4/1/2024	1					2/21/2041
Tavaborole	Topical Solution	5%	Kerydin 204427	7/9/2018	13	Eligible	11/17/2020	10/13/2020	10/19/2020	5/26/2027
Tazarotene	Topical Lotion	0.045%	Arazlo 211882	5/12/2022	1					5/11/2038
Technetium TC-99M Tetrofosmin Kit	Intravenous Injection	1.38 mg/vial	Myoview 30 mL 20372	2/20/2024	1					3/10/2030
Teduglutide	Injection	5 mg/vial	Gattex Kit 203441	12/21/2016	1					11/1/2025
Telmisartan	Tablets	20 mg, 40 mg and 80 mg	Micardis 20850	12/26/2006	1	Eligible	8/24/2020	1/8/2014	1/8/2014	1/10/2020
Telmisartan and Hydrochlorothiazide	Tablets	80 mg/12.5 mg and 40 mg/12.5 mg	Micardis HCT 21162	12/31/2008	1	Extinguished	8/24/2020			1/10/2020

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Temazepam	Capsules	7.5 mg	Restoril 18163	11/01/2006	1	Eligible	8/24/2020	9/8/2009		5/18/2010
Temozolomide	Capsules	5 mg, 20 mg, 100 mg and 250 mg	Temodar 21029	3/20/2007	1	Eligible	8/24/2020	3/1/2010	8/12/2013	8/11/2013
Temozolomide	Capsules	140 mg and 180 mg	Temodar 21029	3/24/2008	1	Eligible	8/24/2020	3/1/2010	8/12/2013	8/11/2013
Temsirolimus	Injection	25 mg/mL, 1.8 mL vial	Torisel 22088	5/25/2011	1	Extinguished	3/10/2020			4/18/2014
Tenofovir Alafenamide Fumarate	Tablets	25 mg	Vemlidy 208464	11/5/2019	6	Eligible	4/18/2023	3/30/2023		8/15/2032
Tenofovir Disoproxil Fumarate	Tablets	300 mg	Viread 21356	1/26/2010	1	Eligible	6/18/2019	3/18/2015	12/15/2017	1/25/2018
Tenofovir Disoproxil Fumarate	Tablets	150 mg, 200 mg, and 250 mg	Viread 21356	5/17/2012	1	Extinguished	6/18/2019			1/25/2018
Terazosin Hydrochloride	Capsules	1 mg, 2 mg, 5 mg and 10 mg	Hytrin 20347	Pre-MMA						
Terazosin Hydrochloride	Tablets	1 mg, 2 mg, 5 mg and 10 mg	Hytrin 19057	Pre-MMA						
Terbinafine Hydrochloride	Tablets	250 mg	Lamisil 20539	Pre-MMA						
Terfenadine	Tablets	60 mg	Seldane	Pre-MMA						
Teriflunomide	Tablets	7 mg and 14 mg	Aubagio 202992	9/12/2016	21	Eligible	6/18/2019	7/27/2018	3/12/2023	2/4/2034
Teriparatide	Injection	250 mcg/mL, 2.4 mL prefilled Pen	Forteo 21318	7/27/2015	1	Extinguished Non-Forfeiture	11/16/2023 11/16/2023	11/16/2023		3/25/2025
Testosterone	Gel	1%	Androgel	Pre-MMA						
Testosterone	Gel	1%	Testim 21454	8/21/2008	1	Extinguished	3/10/2020			6/11/2008
Testosterone	Gel	1% (pump)	Androgel	12/19/2008	1	Extinguished	8/24/2020			3/1/2021
Testosterone	Gel	1.62% (pump)	Androgel	4/6/2012	1	Eligible	10/8/2019	8/4/2015	10/12/2018	8/30/2020
Testosterone	Gel	1.62% (1.25 g and 2.5 g packets)	Androgel	Pre-MMA						
Testosterone	Gel	10 mg/actuation	Fortesta 21463	8/14/2012	1	Deferred	8/24/2020	8/5/2015		11/9/2018
Testosterone	Topical Solution	30 mg/1.5 mL	Axiron 22504	1/29/2013	1	Extinguished	8/24/2020	8/7/2017		2/19/2017

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Testosterone Undecanoate	Injection	250 mg/mL	Aveed 22219	6/11/2014	1					3/14/2027
Thalidomide	Capsules	50 mg and 100 mg	Thalomid 20785	12/18/2006	1	Extinguished	8/13/2019			10/23/2020
Thalidomide	Capsules	200 mg	Thalomid 20785	9/25/2006	1	Extinguished	8/13/2019			10/23/2020
Thalidomide	Capsules	150 mg	Thalomid 20785	2/3/2014	1	Extinguished	3/18/2024			12/9/2023
Tiagabine Hydrochloride	Tablets	2 mg and 4 mg	Gabitril 20646	2/1/2005	1	Eligible	8/24/2020	11/4/2011		6/10/2017
Tiagabine Hydrochloride	Tablets	12 mg and 16 mg	Gabitril 20646	1/24/2014	1	Extinguished	8/24/2020	10/13/2017		6/10/2017
Ticagrelor	Tablets	90 mg	Brilinta 22433	7/20/2015	16	Eligible	11/19/2019	9/4/2018	5/1/2025	4/17/2030
Ticagrelor	Tablets	60 mg	Brilinta 22433	9/30/2015	3	Eligible	8/13/2019	9/4/2018	5/1/2025	4/17/2030
Ticlopidine Hydrochloride	Tablets	250 mg	Ticlid	Pre-MMA						
Tigecycline	For Injection	50 mg per vial	Tygacil	6/15/2009	1	Extinguished	8/24/2020	5/27/2015		4/9/2016
Timolol Maleate	Ophthalmic Solution	0.25% and 0.5%	Timoptic	Pre-MMA						
Timolol Maleate	Ophthalmic Solution	0.5%	Istalol 21516	10/19/2012	1	Eligible	8/10/2020	4/17/2015	4/17/2015	11/16/2018
Tiopronin	Delayed-release Tablets	100 mg	Thiola EC 211843	10/11/2022	2	Eligible	3/6/2023	2/24/2023	2/24/2023	11/14/2038
Tiopronin	Delayed-release Tablets	300 mg	Thiola EC 211843	10/11/2022	2	Eligible	3/6/2023	2/24/2023	2/24/2023	11/14/2038
Tiotropium Bromide	Inhalation Powder Capsules	18 mcg	Spiriva 21395	5/11/2018	1	Deferred	6/26/2023	6/20/2023	8/16/2023	4/19/2030
Tiotropium Bromide	Inhalation Aerosol	2.5 mcg per actuation	Spiriva Respimat 21936	3/7/2023	1					4/16/2031
Tiotropium Bromide and Olodaterol Hydrochloride	Inhalation Spray	2.5 mcg/2.5 mcg per spray	Stiolto Respimat 206756	5/24/2024	1					10/16/2030
Tirbanibulin	Ointment	1%	Klisyri 213189	12/16/2024	1					9/7/2038
Tirofiban Hydrochloride	Injection	12.5 mg/250 mL	Aggrastat 20913	10/3/2018	1	Extinguished Non-Forfeiture Deferred	5/2/2023 2/6/2023 5/4/2021	4/8/2021		5/1/2023

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Tirofiban Hydrochloride	Injection	5 mg/100 mL	Aggrastat 20913	8/29/2019	1	Extinguished Deferred	5/2/2023 2/6/2023	2/7/2023		5/1/2023
Tivozanib Hydrochloride	Capsules	0.89 mg and 1.34 mg	Fotivda 212904	3/10/2025	3					11/5/2039
Tizanidine Hydrochloride	Capsules	2 mg, 4 mg and 6 mg	Zanaflex 21447	8/10/2007	1	Deferred	8/10/2020	2/3/2012	2/3/2012	11/28/2021
Tobramycin	Inhalation Solution	300 mg/5 mL	Tobi 50753	6/29/2009	1	Extinguished	8/10/2020	10/10/2013		10/19/2014
Tobramycin	Inhalation Solution	300 mg/4 mL	Bethkis 201820	8/31/2017	1	Extinguished Eligible	4/18/2023 7/2/2019	6/26/2019	6/26/2019	9/22/2022
Tofacitinib Citrate	Tablets	5 mg	Xeljanz 203214	11/7/2016	3	Eligible	3/20/2023	3/13/2023		12/8/2025
Tofacitinib Citrate	Tablets	10 mg	Xeljanz 203214	7/24/2019	1	Eligible	7/13/2021	6/1/2021		12/8/2025
Tofacitinib Citrate	Extended-release Tablets	11 mg	Xeljanz XR 208246	11/7/2016	1	Extinguished	8/10/2020			3/25/2023
Tofacitinib Citrate	Extended-release Tablets	22 mg	Xeljanz XR 208246	12/28/2020	1	Eligible	8/24/2021	8/19/2021		3/14/2034
Tofacitinib Citrate	Oral Solution	1 mg/mL	Xeljanz 213082	11/12/2021	1	Eligible	10/16/2023	9/25/2023		12/8/2025
Tolterodine Tartrate	Extended-release Capsules	2 mg and 4 mg	Detrol LA 21228	7/30/2007	1	Extinguished	8/10/2020	11/22/2016		11/11/2019
Tolterodine Tartrate	Tablets	1 mg and 2 mg	Detrol 20771							
Tolvaptan	Tablets	30mg	Samsca 22275	9/23/2013	1	Extinguished Non-Forfeiture	6/15/2020 6/15/2020			5/19/2020
Tolvaptan	Tablets	15 mg	Samsca 22275	10/10/2013	1	Non-Forfeiture	5/19/2020	2/15/2022	3/10/2022	9/1/2026
Tolvaptan	Tablets	60 mg	Samsca 22275	3/26/2018	1	Eligible	6/15/2020	5/19/2020		9/1/2026
Tolvaptan	Tablets	15 mg, 30 mg, 45 mg, 60 mg, 90 mg	Jynarque 204441	4/8/2021	1	Eligible	4/28/2025	4/23/2025	5/12/2025	4/7/2030
Topiramate	Capsules	15 mg and 25 mg	Topamax Sprinkle 20844	9/7/2005	1	Eligible	8/10/2020	4/15/2009	4/15/2009	9/1/2019
Topiramate	Tablets	25 mg, 100 mg and 200 mg	Topamax 20505	12/26/2001						
Topiramate	Tablets	50 mg	Topamax 20505	9/8/2005	1	Extinguished	8/10/2020	3/27/2009		9/26/2008

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Topiramate	Extended-release Capsules	25 mg, 50 mg, 100 mg, 150 mg, and 200 mg	Qudexy XR 205122	12/24/2015	1	Extinguished Non-Forfeiture	12/1/2020 8/27/2019			3/19/2033
Topiramate	Extended-release Capsules	200 mg	Trokendi XR 201635	4/3/2014	1	Extinguished	3/6/2023			3/18/2029
Topiramate	Extended-release Capsules	25 mg, 50 mg, and 100 mg	Trokendi XR 201635	5/12/2014	1	Extinguished Non-Forfeiture Deferred	3/20/2023 3/20/2023 11/19/2019	11/24/2017	1/4/2023	3/18/2029
Topiramate	Oral Solution	25 mg/mL	Epronita 214679	10/6/2022	1	Eligible	11/11/2024	10/31/2024	7/9/2025	8/21/2040
Torsemide	Tablets	5 mg, 10 mg, 20 mg, and 100 mg	Demadex 20136	Pre-MMA						
Trabectedin	Powder for Injection	1 mg/vial	Yondelis 207953	4/23/2020	2					1/7/2028
Tramadol Hydrochloride	Tablets	50 mg	Ultram 20281	Pre-MMA						
Tramadol Hydrochloride	Extended-release Tablets	100 mg	Ultram ER 21692	1/8/2007	1	Eligible	8/10/2020	11/13/2009	11/13/2009	5/10/2014
Tramadol Hydrochloride	Extended-release Tablets	200 mg	Ultram ER 21692	3/28/2007	1	Eligible	8/10/2020	11/13/2009	11/13/2009	5/10/2014
Tramadol Hydrochloride	Extended-release Tablets	300 mg	Ultram ER 21692	9/25/2007	1	Extinguished	8/10/2020	9/20/2011		5/10/2014
Tramadol Hydrochloride	Extended-release Tablets	100 mg, 200 mg and 300 mg	Ryzolt 21745	6/18/2009	1	Eligible	8/10/2020	12/30/2011	12/30/2011	6/29/2020
Tramadol Hydrochloride	Oral Solution	5 mg/mL	Qdolo 214044	9/16/2024	1					9/1/2040
Trametinib Dimethyl Sulfoxide	Tablets	0.5 mg and 2 mg	Mekinist 204114	9/28/2023	1	Eligible	8/19/2024	8/6/2024		1/28/2032
Trandolapril	Tablets	1 mg, 2 mg and 4 mg	Mavik 20528	10/4/2004	1	Extinguished	8/10/2020	6/12/2007		6/12/2007
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	2 mg/180 mg and 2 mg/240 mg	Tarka 20591	11/9/2007	1	Eligible	8/10/2020	5/26/2010		2/24/2015
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	1 mg/240 mg	Tarka 20591	2/20/2008	1	Eligible	8/10/2020	8/30/2010	9/20/2010	2/24/2015
Trandolapril and Verapamil Hydrochloride	Extended-release Tablets	4 mg/ 240 mg	Tarka 20591	7/24/2007	1	Eligible	8/10/2020	5/5/2010		2/24/2015
Tranexamic Acid	Tablets	650 mg	Lysteda 22430	5/24/2011	2	Eligible	8/10/2020	12/27/2012	1/3/2013	3/4/2025

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Travoprost	Ophthalmic Solution	0.003%	Izba 204822	12/30/2015	1	Extinguished	8/10/2020			10/10/2029
Travoprost	Ophthalmic Solution	0.004%	Travatan 21257	11/28/2008	1	Extinguished	8/10/2020			12/22/2014
Travoprost (Preserved)	Ophthalmic Solution	0.004%	Travatan Z 21994	2/19/2009	1	Extinguished	8/13/2019			12/2/2014
Trazodone Hydrochloride	Tablets	50 mg, 100 mg, 150 mg, 300 mg	Desyrel 18207	Pre-MMA						
Trazodone Hydrochloride	Extended-release Tablets	150 mg and 300 mg	Oleptro 22411	10/18/2010	1	Extinguished	8/10/2020			6/29/2020
Treprostinil Sodium	Injection	10 mg/mL, 20 mL vial	Remodulin 21272	12/2/2011	1	Eligible	6/18/2019	11/30/2017	3/25/2019	3/29/2029
Treprostinil Sodium	Injection	1 mg/mL, 2.5 mg/mL, and 5 mg/mL, 20 mL vial	Remodulin 21272	12/7/2012	1	Eligible	6/18/2019	11/30/2017	3/25/2019	3/29/2029
Treprostinil Sodium	Inhalation Solution	0.6 mg/mL, 2.9 mL ampules	Tyvaso 22387	4/13/2015	1	Extinguished	12/14/2021			12/15/2028
Treprostinil	Extended-release Tablets	2.5 mg	Orenitram 203496	12/24/2015	1					1/22/2031
Treprostinil	Extended-release Tablets	0.25 mg and 1 mg	Orenitram 203496	5/19/2016	1					1/22/2031
Treprostinil	Extended-release Tablets	0.125 mg and 5 mg	Orenitram 203496	12/28/2020	1					8/11/2031
Trientine Tetrahydrochloride	Tablets	300 mg	Cuvrior 215760	6/21/2023	1					5/3/2039
Tretinoin	Cream	0.025%, 0.05% and 0.1%	Retin-A	Pre-MMA						
Tretinoin	Gel	0.025%	Retin-A 17579	Pre-MMA						
Tretinoin	Gel	0.04%	Retin-A Micro 20475	12/20/2010	1	Eligible	8/10/2020	7/17/2013		9/21/2016
Tretinoin	Gel	0.1%	Retin-A Micro 20475	7/8/2010	1	Eligible	8/10/2020	7/17/2013	7/31/2013	9/21/2016
Triamcinolone Acetonide	Nasal Spray	0.055 mg/Spray	Nasacort AQ	12/29/2005	1	Deferred	8/10/2020	7/30/2009		7/3/2016
Triamterene/ Hydrochlorothiazide	Tablets	37.5 mg/25 mg and 75 mg/50 mg	Maxzide 19129	Pre-MMA						

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Trifarotene	Cream	0.005%	Aklief 211527	10/4/2023	2					5/30/2033
Trifluridine Hydrochloride and Tipiracil	Tablets	15 mg/6.14 mg and 20 mg/8.19 mg	Lonsurf 207981	9/23/2019	4	Deferred	6/26/2023	6/13/2023		6/17/2034
Triheptanoin	Oral Liquid	100% w/w	Dojolvi 213687	7/1/2024	3					4/28/2029
Trilaciclib Dihydrochloride	Powder for Injection	300 mg base/vial	Cosela 214200	2/12/2025	3					11/13/2040
Trospium Chloride	Extended-release Capsules	60 mg	Sanctura XR 22103	3/2/2009	1	Deferred	8/10/2020	10/12/2012	10/12/2012	2/1/2025
Ubrogepant	Tablets	50 mg and 100 mg	Ubrelvy 211765	12/26/2023	4					12/22/2041
Ulipristal Acetate	Tablets	30 mg	Ella 22474	8/13/2014	1	Eligible	8/10/2020	2/13/2017		6/12/2030
Unoprostone Isopropyl	Ophthalmic Solution	0.15%	Rescula 21214	5/12/2014	1	Extinguished	3/10/2020			7/9/2021
Upadacitinib	Extended-release Tablets	15 mg	Rinvoq 211675	8/16/2023	5					3/9/2038
Upadacitinib	Extended-release Tablets	30 mg	Rinvoq 211675	8/16/2023	4					3/9/2038
Upadacitinib	Extended-release Tablets	45 mg	Rinvoq 211675	8/16/2023	3					3/9/2038
Valacyclovir Hydrochloride	Tablets	500 mg and 1000 mg	Valtrex 20487	Pre-MMA						
Valbenazine Tosylate	Capsules	40 mg and 80 mg	Ingrezza 209241	4/12/2021	4	Eligible	4/15/2024	4/5/2024		8/10/2040
Valbenazine Tosylate	Capsules	60 mg	Ingrezza 209241	2/14/2022	1	Eligible	8/19/2024	8/7/2024		8/10/2040
Valbenazine Tosylate	Capsules	40 mg, 60 mg and 80 mg	Ingrezza Sprinkle 218390	1/7/2025	1					8/10/2040
Valganciclovir Hydrochloride	for Oral Solution	50 mg/mL	Valcyte 22257	3/21/2011	1	Extinguished	1/2/2020			3/29/2015
Valganciclovir Hydrochloride	Tablets	450 mg	Valcyte 21304	12/27/2005	1	Extinguished	7/27/2020			7/28/2014
Valsartan	Tablets	40 mg, 80 mg, 160 mg and 320 mg	Diovan 21283	12/28/2004	1	Non-Forfeiture	7/27/2020	6/26/2014	7/7/2014	6/18/2017

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Valsartan and Hydrochlorothiazide	Tablets	80 mg/12.5 mg 160 mg/12.5 mg 160 mg/25 mg	Diovan HCT 20818	12/2/2005	1	Eligible	7/27/2020	9/21/2012	9/21/2012	6/18/2017
Valsartan and Hydrochlorothiazide	Tablets	320 mg/12.5 mg and 320 mg/25 mg	Diovan HCT 20818	2/7/2007	1	Eligible	7/27/2020	9/21/2012	9/21/2012	6/18/2017
Vancomycin Hydrochloride	For Oral Solution	25 mg/mL and 50 mg/mL	Firvanq Kit 208910	5/18/2020	1	Eligible	12/13/2022	11/14/2022	8/29/2023	3/13/2035
Vardenafil Hydrochloride	Tablets	2.5 mg	Levitra 21400	9/4/2009	1	Deferred	7/27/2020	5/3/2012	10/3/2018	10/31/2018
Vardenafil Hydrochloride	Tablets	5 mg and 10 mg	Levitra 21400	7/10/2009	1	Deferred	7/27/2020	5/3/2012	10/3/2018	10/31/2018
Vardenafil Hydrochloride	Tablets	20 mg	Levitra 21400	3/5/2009	1	Deferred	7/27/2020	5/3/2012	10/3/2018	10/31/2018
Vardenafil Hydrochloride	Orally Disintegrating Tablets	10 mg	Staxyn 200179	12/22/2011	1	Extinguished Eligible	6/18/2019 6/18/2019	4/23/2015		10/31/2018
Varenicline Tartrate	Tablets	0.5 mg and 1 mg	Chantix 21928	5/10/2010	5	Eligible	9/7/2021	8/11/2021	9/21/2021	8/3/2022
Varenicline Tartrate	Nasal Spray	0.03 mg/spray	Tyrvaya 213978	4/21/2023	1					10/19/2035
Vasopressin	Injection	20 units/mL, 1 mL	Vasostrict 204485	3/23/2018	1	Non-Forfeiture Deferred	12/28/2021 12/28/2021	12/15/2021	1/18/2022	1/30/2035
Vasopressin	Injection	200 units/10 mL	Vasostrict 204485	6/29/2018	1	Non-Forfeiture	2/6/2023			1/30/2035
Vasopressin	Injection	20 units/100 mL	Vasostrict 204485	12/20/2022	1	Eligible	1/8/2024	12/6/2023		1/30/2035
Vasopressin	Injection	40 units/100 mL and 60 units/100 mL	Vasostrict 204485	2/28/2022	1	40 u/100 mL - Extinguished	8/18/2025			1/30/2035
Vecuronium Bromide	For Injection	10 mg/vial and 20 mg/vial	Norcuron 18776	Pre-MMA						
Venetoclax	Tablets	10 mg, 50 mg and 100 mg	Venclexta 208573	4/13/2020	2					1/29/2032
Venlafaxine Hydrochloride	Tablets	25 mg, 37.5 mg, 50 mg, 75 mg and 100 mg	Effexor 20151	11/03/2005	1			8/3/2006	6/15/2006	6/13/2008
Venlafaxine Hydrochloride	Extended-release Tablets	37.5 mg, 75 mg and 150 mg	Effexor XR 20699	5/3/2007	1	Extinguished	7/27/2020			3/20/2017

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Venlafaxine Hydrochloride	Extended-release Tablets	37.5 mg, 75 mg and 150 mg	Venlafaxine Hydrochloride 22104	2/12/2009	1	Eligible	7/27/2020	8/18/2010	6/15/2006	3/20/2017
Venlafaxine Hydrochloride	Extended-release Tablets	225 mg	Venlafaxine Hydrochloride 22104	1/10/2011	1	Extinguished	7/27/2020	1/8/2019		3/20/2017
Verapamil Hydrochloride	Extended-release Capsules	100 mg and 200 mg	Verelan PM 20943	7/20/2006	1	Extinguished	7/27/2020	8/9/2007		6/19/2007
Verapamil Hydrochloride	Extended-release Capsules	120 mg, 180 mg and 240 mg	Verelan SR	Pre-MMA						
Verapamil Hydrochloride	Extended-release Tablets	180 mg	Isoptin SR	Pre-MMA						
Verapamil Hydrochloride	Extended-release Tablets	240 mg	Covera HS 20552	Pre-MMA						
Verapamil Hydrochloride	Extended-release Capsules	300 mg	Verelan PM 20943	5/19/2006	1	Extinguished	7/27/2020	8/9/2007		6/17/2007
Vericiguat	Tablets	2.5 mg	Verquvo 214377	1/21/2025	5					11/26/2032
Vericiguat	Tablets	5 mg and 10 mg	Verquvo 214377	1/21/2025	4					11/26/2032
Vibegron	Tablets	75 mg	Gemtesa 213006	12/23/2024	4					3/22/2040
Vilazodone Hydrochloride	Tablets	10 mg, 20 mg, and 40 mg	VIIBRYD 22567	1/21/2015	5	Eligible	7/27/2020	9/13/2019	6/4/2022	6/5/2022
Viloxazine Hydrochloride	Extended-release Capsules	100 mg	Qelbree 211964	4/2/2025	7					4/2/2035
Viloxazine Hydrochloride	Extended-release Capsules	150 mg	Qelbree 211964	4/2/2025	7					4/2/20235
Viloxazine Hydrochloride	Extended-release Capsules	200 mg	Qelbree 211964	4/2/2025	8					4/2/2035
Vincristine Sulfate	Injection	1 mg/mL, 1 mL, 2 mL and 5 mL vials	Oncovin 14103	Pre-MMA						
Vismodegib	Capsules	150 mg	Erivedge 203388	3/27/20025	1					12/15/2028
Voclosporin	Capsules	7.9 mg	Lupkynis 213716	1/22/2025	8					12/7/2037
Voriconazole	For Injection	200 mg/vial	Vfend 21267	9/12/2008	1	Eligible	7/27/2020	5/30/2012	5/30/2012	6/2/2018

Paragraph IV Patent Certifications
September 1, 2025

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Voriconazole	Oral Suspension	40 mg/mL	Vfend 21630	10/8/2010	1	Eligible	7/27/2020	5/28/2013	9/25/2013	5/24/2016
Voriconazole	Tablets	50 mg and 200 mg	Vfend 21266	4/14/2008	1	Eligible	7/27/2020	4/22/2010	2/15/2011	5/24/2016
Vortioxetine	Tablets	5 mg, 10 mg, 15 mg and 20 mg	Trintellix 204447	10/2/2017	15					6/30/2031
Voxelotor	Tablets	300 mg and 500 mg	Oxbryta 213137	11/27/2023	2					10/12/2037
Voxelotor	Tablets for Oral Suspension	300 mg	Oxbryta 216157	11/27/2023	1					12/2/2036
Zafirlukast	Tablets	10 mg and 20 mg	Accolate 20547	2/29/2008	1	Eligible	7/27/2020	11/18/2010	11/18/2010	3/18/2014
Zaleplon	Capsules	5 mg and 10 mg	Sonata 20859	6/21/2005	1	Extinguished	7/27/2020	6/6/2008		6/6/2008
Zanubrutinib	Capsules	80 mg	Brukinsa 213217	11/14/2023	2					1/19/2043
Zidovudine	Capsules	100 mg	Retrovir 19665	Pre-MMA						
Ziprasidone Hydrochloride	Capsules	20 mg, 40 mg, 60 mg and 80 mg	Geodon 20825	2/7/2005	5	Eligible	7/27/2020	3/2/2012	3/2/2012	5/27/2019
Zoledronic Acid	Injection	0.05 mg/mL, 100 mL vial	Reclast 21817	8/29/2008	1	Extinguished	3/10/2020			9/2/2012
Zoledronic Acid	Injection	0.8 mg (base) /mL	Zometa 21223	6/11/2008	1	Extinguished	3/10/2020			9/2/2012
Zoledronic Acid	Injection	4 mg/100 mL, 100 mL vial	Zometa 21223	1/31/2012	1	Extinguished	3/10/2020			2/5/2028
Zolmitriptan	Nasal Spray	2.5 mg/spray	Zomig 21450	6/9/2016	1	Extinguished	7/27/2020			11/28/2020
Zolmitriptan	Nasal Spray	5 mg/spray	Zomig 21450	11/14/2013	1	Extinguished	1/12/2021			11/28/2020
Zolpidem Tartrate	Extended-release Tablets	6.25 mg	Ambien CR 21774	2/24/2006	1	Non-Forfeiture	7/27/2020	10/13/2010	10/13/2010	6/1/2020
Zolpidem Tartrate	Extended-release Tablets	12.5 mg	Ambien CR 21774	1/19/2006	1	Non-Forfeiture	7/27/2020	12/3/2010	12/6/2010	6/1/2020
Zolpidem Tartrate	Sublingual Tablets	5 mg and 10 mg	Edluar 21997	4/29/2010	1	Extinguished	7/27/2020	8/1/2016		9/24/2018
Zolpidem Tartrate	Sublingual Tablets	1.75 mg and 3.5 mg	Intermezzo 22328	4/10/2012	1	Eligible	7/27/2020	6/3/2015	3/23/2016	4/15/2027
Zonisamide	Oral Suspension	100 mg/5 mL	Zonisade 214273	2/4/2025	1					8/18/2038