

Paragraph IV Patent Certifications
January 11, 2022

| 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 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 |
| Abiraterone Acetate | Tablets | 125 mg | Yonsa 210308 | 7/23/2018 | 1 | | | | | 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 |
| 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 | 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 | | | | | | |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--|--------------------------|---|----------------------|--------------------|---------------------------|-------------------------|-------------------------------|----------------------------------|---|---|
| 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/ Ipratropium Bromide | Inhalation Solution | 0.083%/ 0.017% | Duoneb 20950 | Pre-MMA | | | | | | |
| 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% | Lastacast 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 | | | | | | |
| 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 | 2/11/2020 | 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|----------------------------------|---|--------------------|--------------------|---------------------------|--------------------------|-------------------------------|----------------------------------|---|---|
| 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 | | | | | 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 |
| 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 |
| Amlodipine Benzoate | Oral Suspension | 1 mg/mL | Katerzia 211340 | 12/29/2020 | 1 | | | | | 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 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 |
| 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 | | | | | 1/28/2032 |
| Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate | Extended-release Capsules | 37.5 mg and 50 mg | Mydayis 22063 | 8/3/2017 | 1 | | | | | 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 | | | | | 8/24/2029 |
| Apixaban | Tablets | 2.5 mg and 5 mg | Eliquis 202155 | 12/28/2016 | 25 | Eligible | 1/14/2020 | 12/23/2019 | | 2/24/2031 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|-----------------------------------|-------------------------------|---|------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Apremilast | Tablets | 10 mg, 20 mg and 30 mg | Otezla 205437 | 3/22/2018 | 10 | 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 |
| 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 |
| 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 | | 4/6/2026 |
| Aspirin and Omeprazole | Delayed-release Tablets | 81 mg/40 mg and 325 mg/40 mg | Yosprala 205103 | 10/14/2016 | 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 |
| Atazanavir Sulfate and Cobicistat | Tablets | 300 mg/150 mg | Evotaz 206353 | 9/13/2017 | 1 | | | | | 9/3/2029 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|---------------------|---|---|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | | | | | 4/27/2025 |
| 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 | | | | | 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 | | | | | 6/4/2028 |
| Azelastine Hydrochloride | Nasal Spray | 205.5 mcg/spray | Children's Astepro Allergy (OTC) 213872 | 7/12/2021 | 1 | | | | | 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 |

**Paragraph IV Patent Certifications
January 11, 2022**

| 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 |
|-----------------------------|---------------------|---|--|--------------------|---------------------------|--------------------------|-------------------------------|----------------------------------|---|---|
| Azilsartan Kamedoxomil | Tablets | 40 mg and 80 mg | Edarbi 200796 | 4/10/2020 | 1 | | | | | 3/26/2028 |
| 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 | | | | | 8/30/2039 |
| Balsalazide Disodium | Tablets | 1.1 g | Giazo 22205 | 11/5/2013 | 1 | Eligible | 2/11/2020 | 9/8/2015 | | 6/23/2031 |
| Beclomethasone Dipropionate | Inhalation Aerosol | 40 mcg/actuation and 80 mcg/actuation | Qvar 20911 | 1/10/2020 | 1 | | | | | 5/18/2031 |
| Belinostat | Injection | 500 mg/vial | Beleodaq 206256 | 7/3/2018 | 1 | | | | | 10/27/2027 |
| Bendamustine Hydrochloride | Injection | 25 mg/vial and 100 mg/vial | Treanda 22249 | 6/4/2013 | | | | | | |
| Bendamustine Hydrochloride | Injection | 90 mg/mL, 0.5 mL and 2 mL in single- dose vials | Treanda 22249 | 6/19/2014 | | | | | | |
| Bendamustine Hydrochloride | Injection | 100 mg/4 mL (25 mg/mL) multiple- dose vials | Bendeka 208194 | 5/4/2017 | | | | | | |
| Bendamustine Hydrochloride | Injection | 100 mg/4 mL (25 mg/mL) multiple- dose vials | Bendamustine Hydrochloride Injection 205580 | 7/17/2018 | | | | | | |
| 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 | 3/5/219 | | 9/19/2019 |
| 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% | Semivo 208079 | 2/15/2018 | 1 | Eligible | 7/13/2020 | 6/17/2020 | | 8/31/2030 |
| Betaxolol | Ophthalmic Solution | 0.5%(base) | Betoptol 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 |
| Bimatoprost | Ophthalmic Solution | 0.01% | Lumigan 22184 | 4/5/2011 | 1 | | | | | 6/13/2027 |
| Bimatoprost | Ophthalmic Solution | 0.03% | Lumigan 21275 | 12/22/2008 | 1 | Extinguished | 2/11/2020 | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|---------------------|--|------------------------|--------------------|---------------------------|--------------------------|-------------------------------|----------------------------------|---|---|
| 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 |
| 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 | | | | | 12/28/2027 |
| Bosutinib | Tablets | 100 mg and 500 mg | Bosulif 203341 | 9/6/2016 | 2 | | | | | 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 |
| Brexipiprazole | Tablets | 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg | Rexulti 205422 | 7/10/2019 | 18 | | | | | 10/12/2032 |
| 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 | | | | | 1/28/2022 |
| Brimonidine Tartrate | Ophthalmic Solution | 0.15% | Alphagan P 21262 | 11/03/2006 | 1 | Extinguished | 2/11/2020 | | | 1/28/2022 |
| Brimonidine Tartrate | Ophthalmic Solution | 0.2% | Alphagan 20613 | Pre-MMA | | | | | | |
| Brimonidine Tartrate | Ophthalmic Solution | 0.025% | Lumify (OTC) 208144 | 7/12/2021 | 1 | | | | | 7/14/2030 |
| Brimonidine Tartrate and Timolol Maleate | Ophthalmic Solution | 0.2%/0.5% | Combigan 21398 | 11/21/2008 | 1 | | | | | 4/19/2022 |
| Brivaracetam | Injection | 50 mg/5 mL | Briviact 205837 | 5/12/2020 | 2 | | | | | 2/21/2021 |
| Brivaracetam | Oral Solution | 10 mg/mL | Briviact 205838 | 5/12/2020 | 1 | | | | | 2/21/2021 |
| Brivaracetam | Tablets | 10 mg, 25 mg, 50 mg, 75 mg and 100 mg | Briviact 205836 | 5/12/2020 | 7 | | | | | 2/21/2021 |
| Bromfenac Sodium | Ophthalmic Solution | 0.07% | Prolensa 203168 | 7/26/2013 | 1 | Eligible | 11/19/2019 | | | 9/11/2025 |
| Bromfenac Sodium | Ophthalmic Solution | 0.075% | Bromsite 206911 | 10/25/2017 | 1 | | | | | 8/7/2029 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--|--------------------------|--|--------------------------|--------------------|---------------------------|-----------------------------|-------------------------------|----------------------------------|---|---|
| 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 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 | | | | | 10/16/2028 |
| Bupivacaine Liposome | Injectable Suspension | 266 mg/20 mL | Exparel 22496 | 8/20/2021 | 1 | | | | | 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 |
| 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 | | | | | 5/22/2030 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 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 | | | | | 9/18/2032 |
| Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate | Sublingual Tablets | 2.9 mg/7.1 mg | Zubsolv 204242 | 12/21/2015 | 1 | | | | | 9/18/2032 |
| Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate | Sublingual Tablets | 0.7 mg/0.18 mg | Zubsolv 204242 | 5/4/2017 | 1 | | | | | 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 | | | | | | |
| 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--|--------------------------|--|--------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Cabazitaxel | Injection | 60 mg/1.5 mL | Jevtana 201023 | 6/17/2014 | 8 | | | | | 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 | | | | | 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 |
| Calcium Acetate | Oral Solution | 667 mg/5 mL | Phoslyra 22581 | 12/5/2013 | 2 | | | | | 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|---------------------------|--|-----------------------------------|--------------------|---------------------------|--------------------------|-------------------------------|----------------------------------|---|---|
| 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 |
| Capecitabine | Tablets | 150 mg and 500 mg | Xeloda 20896 | 11/10/2008 | 1 | Extinguished | 3/10/2020 | 8/8/2014 | | 12/14/2013 |
| 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 |
| 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 | 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/ 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--------------------------------|---------------------------|--|----------------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 |
| 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 | | | | | | |
| 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 | | | 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 | | | | | 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | 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 | | | | | | |
| 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 | Evovac 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 | | | | | | |
| Clarithromycin | Extended-release Tablets | 500 mg | Biaxin XL 50775 | PIV received prior to 2/5/2009 | | | | | | |
| Clevipidine | Injectable Emulsion | 25 mg/50 mL and 50 mg/100 mL | Cleviprex 22156 | 7/2/2019 | 1 | | | | | 10/10/2031 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | | 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 | 1.1 mg/day 1.2 mg/day 1.3 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 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | 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 | | | | | 9/3/2029 |
| Colchicine | Capsules | 0.6 mg | Mitigare 204820 | 6/10/2016 | 1 | Eligible | 8/27/2019 | 11/29/2018 | | 8/22/2033 |
| Colchicine | Tablets | 0.3 mg | Colcrys 22352 | 7/19/2019 | 1 | Eligible | 4/7/2020 | 11/14/2019 | | 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 | | | | | 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 | | | | | | |
| Cyanocobalamin | Nasal Spray | 500 mcg/spray | Nascobal 21642 | 4/28/2017 | 1 | Extinguished | 4/6/2021 | | | 8/1/2024 |
| Crisaborole | Topical Ointment | 2% | Eucrisa 207695 | 6/14/2021 | 5 | | | | | 1/20/2030 |
| 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 | | 5/13/2011 | 2/26/2025 |
| Cyclophosphamide | For Injection | 100 mg/vial 200 mg/vial 500 mg/vial 1 g/vial 2 g/vial | Cytosan 12142 | Pre-MMA | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|--------------------------|--|------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Cysteamine Bitartrate | Delayed-release Capsules | 25 mg and 75 mg | Procysbi 203389 | 5/11/2020 | 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 | 5/6/2020 | | 8/31/2027 |
| Dabigatran Etexilate Mesylate | Capsules | eq. to 110 mg base | Pradaxa 22512 | 12/15/2015 | 2 | | | | | |
| 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 |
| Dapagliflozin and Metformin Hydrochloride | Extended-release Tablets | 5 mg/500 mg 5 mg/1000 mg 10 mg/500 mg 10 mg/1000 mg | Xigduo XR 205649 | 1/8/2018 | 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 | | | |
| Darifenacin Hydrobromide | Extended-release Tablets | 7.5 mg and 15 mg | Enblex 21513 | 12/22/2008 | 3 | Deferred | 4/7/2020 | 3/13/2015 | 3/15/2016 | 8/21/2016 |
| Darunavir Ethanolate | Tablets | 75 mg, 150 mg and 300 mg | Prezista 21976 | 6/23/2010 | 1 | | | | | 12/26/2026 |
| Darunavir Ethanolate | Tablets | 400 mg | Prezista 21976 | 6/23/2010 | 2 | | | | | 12/26/2026 |
| Darunavir Ethanolate | Tablets | 600 mg | Prezista 21976 | 6/23/2010 | 3 | Deferred | 7/2/2019 | 11/21/2017 | | 12/26/2026 |
| Darunavir Ethanolate | Tablets | 800 mg | Prezista 21976 | 5/14/2013 | 1 | | | | | 12/26/2026 |
| Darunavir and Cobicistat | Tablets | 800 mg/150 mg | Prezcobix 205395 | 7/24/2020 | 1 | | | | | 10/6/2032 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|-------------------------------|--------------------------------|--------------------------|--------------------|---------------------------|-------------------------|-------------------------------|----------------------------------|---|---|
| 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 | | 3/28/2026 |
| 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 | | 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 |
| 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|----------------------------------|---------------------------|----------------------------------|------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Desonide | Gel | 0.05% | Desonate 21844 | 12/1/2010 | 1 | Deferred | 6/15/2020 | 5/11/2020 | 7/9/2020 | 8/3/2020 |
| 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 | | | | | 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 | Deferred | 4/7/2020 | 4/19/2017 | | 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 | 1/4/2023 |
| 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
January 11, 2022

| 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 Quinidine Sulfate | Capsules | 20 mg/10 mg | Nuedexta 21879 | 3/7/2011 | 1 | Extinguished | 3/10/2020 | | | 8/13/2026 |
| 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 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 Sodium | Topical Solution | 2.0% | Pennsaid 204623 | 6/3/2014 | 1 | | | | | 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 | 3/15/2010 | 6/25/2013 |
| Dimethyl Fumarate | Delayed-release Capsules | 120 mg and 240 mg | Tecfidera 204063 | 3/27/2017 | 29 | Deferred | 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 |

**Paragraph IV Patent Certifications
January 11, 2022**

| 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 |
|---|-------------------------------|-------------------------------|-------------------|--------------------------------|---------------------------|-----------------------|-------------------------------|----------------------------------|---|---|
| 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 |
| 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 | | | | | | |
| 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 | | | | | 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--|--------------------------|------------------------------------|-----------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | Eligible | 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 | | | | | 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 | | | | | 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 | | | | | 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 | Eligible | 4/7/2020 | 3/30/2009 | 6/1/2020 | 12/20/2021 |
| 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 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--|--------------------------|---|--------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 |
| 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 | Deferred | 10/5/2021 | 9/8/2021 | | 6/26/2026 |
| Eltrombopag Olamine | Tablets | 50 mg and 75 mg | Promacta 22291 | 1/7/2014 | 1 | | | | | 2/1/2028 |
| Eltrombopag Olamine | Tablets | 12.5 mg and 25 mg | Promacta 22291 | 2/4/2014 | 1 | | | | | 2/1/2028 |
| Elvitegravir, Cobicistat, Emtricitabine, Tenofovir Disoproxil Fumarate | Tablets | 150 mg, 150 mg, 200 mg, 300 mg | Stribild 203100 | 10/4/2018 | 1 | | | | | 4/24/2030 |
| Eluxadoline | Tablets | 75 mg and 100 mg | Viberzi 206940 | 5/28/2019 | 6 | | | | | 3/14/2033 |
| Empagliflozin | Tablets | 10 mg and 25 mg | Jardiance 204629 | 8/1/2018 | 14 | | | | | 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 | | | | | 4/3/2034 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|--------------------------|---|--------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 |
| Emtricitabine and Tenofovir Alafenamide Fumarate | Tablets | 200 mg/25 mg | Descovy 208215 | 11/5/2019 | 6 | | | | | 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 | | | | | 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 |
| 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 | Deferred | 6/15/2021 | 5/14/2021 | | 8/13/2027 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
| Ephedrine Sulfate | Injection | 50 mg/10 mL | Emerphed 213407 | 10/14/2021 | 1 | | | | | 5/16/2040 |
| 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 | | 3/13/2035 |
| Epinephrine | Injection | 30 mg/30 mL | Adrenalin 204640 | 8/20/2018 | 1 | | | | | 3/13/2035 |
| Epinephrine | Injection | 1 mg/mL | Epinephrine Injection 205029 | 8/13/2020 | 1 | | | | | 8/15/2034 |
| 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 |
| Eribulin Mesylate | Injection | 1 mg/2 mL | Halaven 201532 | 12/20/2019 | 1 | | | | | 1/8/2027 |
| 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 |
| 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|-------------------------|-------------------------------------|---|--------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Eslicarbazepine Acetate | Tablets | 200 mg, 400 mg, 600 mg and 800 mg | Aptiom 22416 | 11/8/2017 | 7 | Deferred | 7/13/2021 | 6/29/2021 | | 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 | | | | | | |
| 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 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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; 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 | | | | | 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 |
| 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 | | | | | | |
| Everolimus | Tablets | 0.25 mg, 0.5 mg, and 0.75 mg | Zortress 21560 | 9/30/2013 | 3 | Extinguished Deferred | 4/7/2020 | 4/12/2018 | | 3/9/2020 |
| 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 | | 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|----------------------------|-----------------------------------|---|----------------------------|--------------------|---------------------------|-----------------------|-------------------------------|----------------------------------|---|---|
| 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 |
| Felodipine | Extended-release Tablets | 2.5 mg, 5 mg and 10 mg | Plendil ER 19834 | Pre-MMA | | | | | | |
| Fenfluramine Hydrochloride | Oral Solution | 2.2 mg/mL | Fintepla NDA 212102 | 6/21/2021 | 1 | | | | | 8/2/2037 |
| 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | 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 | | | | | 4/27/2030 |
| Fentanyl | Sublingual Spray | 1.1 mg/spray, 1.2 mg/spray, 0.6 mg/spray, 0.8 mg/spray, 1.2 mg/spray, 1.6 mg/spray | Subsys 202788 | 12/7/2017 | 1 | | | | | 4/27/2030 |
| 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 | 750 mg/15 mL | Injectafer 203565 | 3/27/2019 | 1 | | | | | 2/13/2027 |
| 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 | | 6/7/2027 |
| Fexofenadine Hydrochloride | Oral Suspension | 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 | | | | | 7/31/2027 |
| Finasteride | Tablets | 1 mg | Propecia 20788 | Pre-MMA | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--------------------------|--------------------------|----------------------------------|------------------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Finasteride | Tablets | 5 mg | Proscar 20180 | Pre-MMA | | | | | | |
| Fingolimod | Capsules | 0.5 mg | Gilenya 22527 | 9/22/2014 | 19 | Deferred | 1/2/2020 | 12/4/2019 | | 3/29/2026 |
| 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 | Veramyst | 7/15/2011 | 1 | Extinguished | 6/15/2020 | | | 8/3/2021 |
| 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 mcg/inh | Flovent HFA 21433 | 12/23/2016 | 1 | | | | | 2/26/2026 |
| Fluticasone Propionate | Inhalation Aerosol | 0.22 mcg/inh | Flovent HFA 21433 | 10/29/2021 | 1 | | | | | 2/26/2026 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|---------------------------|-----------------------------------|--------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | 11/1/2021 | 1 | | | | | 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 | | | | | | |
| 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 | | | | | | |
| Gabapentin | Tablets | 600 mg and 800 mg | Neurontin 20882 | Pre-MMA | | | | | | |
| Gabapentin | Tablets | 300 mg and 600 mg | Gralise 22544 | 10/31/2011 | 1 | | | | | 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 |

**Paragraph IV Patent Certifications
January 11, 2022**

| 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 |
|--|---------------------------|---|-------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 |
| 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 |
| 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|-----------------------------|---|------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | | | | | 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 |
| 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 | | | | | 11/30/2036 |
| Halobetasol Propionate and Tazarotene | Lotion | 0.01%/0.045% | Duobrii 209354 | 6/11/2020 | 1 | | | | | 6/6/2036 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--------------------------------------|---------------------------|--|------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | | | 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 |
| 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 | | | | | | |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | Capsules | 70 mg | Imbruvica 205552 | 12/14/2018 | 1 | Eligible | 4/6/2021 | 3/31/2021 | | 10/30/2033 |
| Ibuprofen | Capsules | 140 mg | Imbruvica 205552 | 11/13/2017 | 8 | Deferred | 4/6/2021 | 3/31/2021 | | 10/24/2034 |
| Ibuprofen | Tablets | 140 mg and 560 mg | Imbruvica 210563 | 11/5/2018 | 1 | | | | | 3/3/2036 |
| Ibuprofen | 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 | | | | | | |
| 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 | Deferred | 6/29/2020 | 3/30/2016 | | 3/20/2021 |
| 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 | | | | | 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 | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---------------------------------------|---------------------------------|--|---------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | Deferred | 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 | | 4/29/2030 |
| 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 | | | | | | |
| 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 | | | | | | |
| lloperidone | 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 |
| 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 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|------------------------------------|---------------------|---|-------------------|--------------------|---------------------------|-----------------------|-------------------------------|----------------------------------|---|---|
| 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 |
| Isotretinoin | Capsules | 30 mg | Absorica 21951 | 12/31/2012 | 1 | Eligible Deferred | 4/20/2021 4/6/2021 | 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 | | 9/21/2021 |
| Isotretinoin | Capsules | 20 mg | Absorica 21951 | 1/7/2013 | 1 | Eligible Deferred | 4/20/2021 4/6/2021 | 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 | | 9/21/2021 |
| Isotretinoin | Capsules | 35 mg | Absorica 21951 | 11/25/2015 | 1 | Deferred | 4/6/2021 | 3/31/2021 | | 9/21/2021 |
| Isotretinoin | Capsules | 25 mg | Absorica 21951 | 5/16/2016 | 1 | Deferred | 4/6/2021 | 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 | | 2/22/2026 |
| Ivacaftor | Tablets | 150 mg | Kalydeco 203188 | 6/10/2020 | 1 | | | | | 8/13/2029 |
| 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 |
| Ixabepilone | Injection | 15 mg/vial and 45 mg/vial, single-use vials | Ixempra Kit 22065 | 4/16/2012 | 1 | | | | | 2/8/2022 |
| Ixazomib Citrate | Capsules | 2.3 mg, 3 mg and 4 mg | Ninlaro 208462 | 11/20/2019 | 1 | | | | | 11/20/2029 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---------------------------|---|--|--------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | | | | | 3/17/2022 |
| Lacosamide | Tablets | 50 mg, 100 mg, 150 mg, and 200 mg | Vimpat 22253 | 10/29/2012 | 14 | | | | | 3/17/2022 |
| Lacosamide | Injection | 10 mg/mL, 20 mL | Vimpat 22254 | 6/30/2016 | 1 | Extinguished | 3/10/2020 | | | 3/17/2022 |
| 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 | | | | | | |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--------------------------------|--------------------------|----------------------------|----------------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 |
| Latanoprost | Ophthalmic Solution | 0.005% | Xalatan 20597 | Pre-MMA | | | | | | |
| Lenalidomide | Capsules | 5 mg, 10 mg and 15 mg | Revlimid 21880 | 8/30/2010 | 1 | Non-Forfeiture | 11/17/2020 | 5/21/2021 | | 4/27/2027 |
| Lenalidomide | Capsules | 25 mg | Revlimid 21880 | 7/12/2010 | 1 | Non-Forfeiture | 11/17/2020 | 5/21/2021 | | 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 | | 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 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--|---------------------------|--|--|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | Non-Forfeiture | 10/5/2021 | 6/6/2011 | | |
| Levonorgestrel and Ethinyl Estradiol | Tablets | 0.15 mg/0.03 mg | Seasonale 21544 | 3/29/2004 | | | | | | |
| Levonorgestrel and Ethinyl Estradiol | Tablets | 0.1 mg/0.02 mg | Balcoltra 208612 | 7/14/2020 | 1 | | | | | 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 | | | | | | |
| 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | 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 | Deferred | 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 | Eligible | 1/12/2021 | 1/6/2021 | | 3/14/2024 |
| Levothyroxine Sodium | Capsules | 112 mcg | Tirosint 21924 | 12/18/2020 | 1 | | | | | 3/14/2024 |
| Lidocaine | Topical Patch | 5% | Lidoderm 20612 | 11/13/2009 | 1 | Deferred | 10/5/2021 | 8/23/2012 | | 10/27/2015 |
| Lifitegrast | Ophthalmic Solution | 5% | Xiidra 208073 | 7/13/2020 | 4 | | | | | 7/25/2033 |
| Linacotide | Capsules | 145 mcg and 290 mcg | Linzess 202811 | 8/30/2016 | 4 | Deferred | 2/22/2021 | 2/9/2021 | | 10/30/2031 |
| Linacotide | Capsules | 72 mcg | Linzess 202811 | 11/7/2017 | 1 | | | | | 8/16/2033 |
| Linagliptin | Tablets | 5 mg | Tradjenta 201280 | 5/4/2015 | 11 | Deferred | 12/14/2021 | 8/31/2021 | | 6/4/2030 |
| 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 | Deferred | 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 | | | 6/3/2015 | | 11/18/2014 |
| Linezolid | Tablets | 600 mg | Zyvox 21130 | 12/21/2005 | 1 | Eligible | 10/5/2021 | 5/18/2015 | | 11/18/2014 |
| Liraglutide | Injection | 18 mg/3 mL prefilled syringe | Victoza 22341 | 12/12/2016 | 1 | | | | | 1/9/2037 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | Saxenda 206321 | 8/16/2021 | 1 | | | | | 1/9/2037 |
| Lisdexamfetamine Dimesylate | Capsules | 10 mg | Vyvanse 21977 | 4/9/2020 | 1 | | | | | 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 | | | | | 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 | 6/27/2016 | 4 | Extinguished | 5/19/2020 | | | 2/7/2033 |
| Losartan Potassium | Tablets | 25 mg, 50 mg, and 100 mg | Cozaar 20386 | Pre-MMA | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 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 | | | | | |
| 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 | | 1/4/2021 | 8/30/2022 |
| 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 |
| 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 | | | | | | |
| Maraviroc | Tablets | 150 mg and 300 mg | Selzentry 22128 | 8/8/2011 | 2 | | | | | 11/25/2022 |
| Mefloquine Hydrochloride | Tablets | 250 mg | Lariam 19591 | Pre-MMA | | | | | | |
| 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 | | 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 |
| 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 | | | | | | |
| Memantine Hydrochloride | Extended-release Capsules | 7 mg, 14 mg, 21 mg, and 28 mg | Namenda XR 22525 | 6/10/2013 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--|---------------------------|-----------------------------|---------------------|--------------------|---------------------------|-----------------------------|-------------------------------|----------------------------------|---|---|
| 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 | | 12/5/2029 |
| Memantine Hydrochloride Extended-release and Donepezil Hydrochloride | Capsules | 21 mg/10 mg | Namzaric 206439 | 9/23/2016 | 1 | | | | | 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 | Deferred | 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 | | | | | | |
| 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 | | | | | | |
| 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 | | | | | |
| Methylnaltrexone Bromide | Injection | 12 mg/0.6 mL | Relistor 21964 | 7/22/2015 | 1 | | | | | 12/31/2030 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|-------------------------------|--|--|------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Methylalntrexone Bromide | Injection | 8 mg/0.4 mL | Relistor 21964 | 9/8/2015 | 1 | | | | | 12/31/2030 |
| Methylalntrexone 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 |
| 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|------------------------------|-------------------------------|-----------------------------------|--|--------------------------------|---------------------------|-----------------------|-------------------------------|----------------------------------|---|---|
| Metoclopramide Hydrochloride | Orally Disintegrating Tablets | 5 mg and 10 mg | Metozolv ODT 22246 | 8/24/2010 | | | | | | |
| 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 | | | | | | |
| Metronidazole | Topical Gel | 1% | Metrogel 21789 | 10/21/2008 | 1 | Eligible | 5/4/2021 | 7/22/2011 | 7/1/2013 | 2/21/2022 |
| 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 | | | | | | |
| 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 | | | | | 6/20/2038 |
| Midostaurin | Capsules | 25 mg | Rydapt 207997 | 4/28/2021 | 4 | | | | | 12/2/2030 |
| Mifepristone | Tablets | 300 mg | Korlym 202107 | 12/15/2017 | | | | | | |
| Milnacipran Hydrochloride | Tablets | 12.5 mg, 25 mg, 50 mg, and 100 mg | Savella 22256 | 1/14/2013 | | | | | | |
| 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 | | | | | | |
| 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 | | | | | | |
| Minocycline Hydrochloride | Extended-release Tablet | 105 mg | Solodyn 50808 | 12/13/2010 | | | | | | |
| Minocycline Hydrochloride | Injection | 100 mg/vial | Minocin NDA 50444 | 10/16/2020 | 1 | | | | | 5/12/2031 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|-------------------------------|--|----------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Minocycline Hydrochloride | Topical Aerosol Foam | 4% | Amzeeq NDA 212379 | 5/11/2021 | 1 | | | | | 9/8/2037 |
| Minoxidil | Topical Aerosol Foam | 5% | Men's Rogaine 21812 | 4/6/2009 | | | | | | |
| Mirabegron | Extended-release Tablets | 25 mg and 50 mg | Myrbetriq 202611 | 6/28/2016 | 7 | | | | | 11/4/2023 |
| 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 | | | | | | |
| 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 | | | | | | |
| Mometasone Furoate | Nasal Spray | 50 mcg/ Spray | Nasonex 20762 | 8/7/2009 | | | | | | |
| Mometasone Furoate | Topical Solution (Cream) | 0.1% | Elocon 19625 | Pre-MMA | | | | | | |
| Mometasone Furoate | Topical Solution (Lotion) | 0.1% | Elocon 19796 | 6/10/2004 | | | | | | |
| Montelukast | Tablets | 10 mg | Singulair 20829 | 2/20/2007 | | | | | | |
| Montelukast Sodium | Chewable Tablets | 4 mg and 5 mg | Singulair 20830 | 12/26/2006 | | | | | | |
| 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 |
| Morphine Sulfate | Extended-release Tablets | 15 mg, 30 mg and 60 mg | Arymo ER 208603 | 12/29/2017 | | | | | | |
| Morphine Sulfate | Extended-release Tablets | 15 mg, 30 mg, 60 mg and 100 mg | Morphabond ER 206544 | 1/28/2019 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 and Naltrexone Hydrochloride | Extended-release Capsules | 20 mg/0.8 mg | Embeda 22321 | 8/16/2018 | | | | | | |
| Morphine Sulfate and Naltrexone Hydrochloride | Extended-release Capsules | 100 mg/4 mg | Embeda 22321 | 5/3/2010 | 1 | Extinguished | 6/15/2020 | | | |
| Morphine Sulfate and Naltrexone Hydrochloride | Extended-release Capsules | 60 mg/2.4 mg | Embeda 22321 | 5/25/2010 | 1 | Extinguished | 6/15/2020 | | | |
| 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 | | | |
| 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 | | | | | | |
| 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 | | | | | | |
| Mycophenolic Acid | Delayed-release Tablets | 360 mg | Myfortic 50791 | 2/2/2009 | | | | | | |
| Mycophenolic Mofetil | For Oral Suspension | 200 mg/mL | Cellcept 50759 | 3/25/2011 | | | | | | |
| 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 | | 1/31/2033 |
| Naloxegol | Tablets | 12.5 mg and 25 mg | Movantik 204760 | 9/17/2018 | 2 | | | | | 4/2/2032 |
| 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 |
| Naltrexone | Extended-release Injectable Suspension | 380 mg/vial | Vivitrol 21897 | 6/18/2020 | 1 | | | | | 10/15/2029 |
| Naltrexone Hydrochloride and Bupropion Hydrochloride | Extended-release Tablets | 8 mg/90 mg | Contrave 200063 | 3/12/2015 | 1 | | | | | 2/2/2030 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|--------------------------|--|-----------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | 917/2021 | 12/17/2021 |
| Nebivolol Hydrochloride and Valsartan | Tablets | 5 mg/80 mg | Byvalson 206302 | 6/9/2017 | 1 | | | | | 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 |
| Nevirapine | Extended-release Tablets | 400 mg | Viramune XR 201152 | 6/21/2013 | | | | | | |
| 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 | | | | | | |
| 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---------------------------|--------------------------|---|--|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | | | | | 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 | | | | | | |
| 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 | | | | | | |
| Nilotinib | Capsules | 50 mg | Tasigna 22068 | 10/17/2019 | 1 | | | | | 4/7/2032 |
| Nilotinib | Capsules | 150 mg and 200 mg | Tasigna 22068 | 11/8/2013 | 1 | | | | | 7/18/2026 |
| Nimodipine | Oral Solution | 6 mg/mL | Nymalize 203340 | 11/29/2021 | 1 | | | | | 4/16/2038 |
| Nintedanib | Capsules | 100 mg and 150 mg | Ofev 205832 | 10/15/2018 | 4 | | | | | 6/7/2029 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|--------------------------|--|------------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Nisoldipine | Extended-release Tablets | 8.5 mg and 17 mg | Sular 20356 | 3/2/2009 | | | | | | |
| Nisoldipine | Extended-release Tablets | 20 mg and 30 mg | Sular 20356 | 11/7/2007 | | | | | | |
| Nisoldipine | Extended-release Tablets | 25.5 mg and 34 mg | Sular 20356 | 11/28/2008 | | | | | | |
| Nisoldipine | Extended-release Tablets | 40 mg | Sular 20356 | 6/11/2007 | | | | | | |
| 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 | 1.1 mg/hr 1.2 mg/hr 1.3 mg/hr 1.4 mg/hr 0.6 mg/hr 0.8 mg/hr | Nitro-dur 20145 | Pre-MMA | | | | | | |
| Nitroglycerin | Sublingual Spray | 400 mcg/spray, 4.9 g and 12 g bottles | Nitrolingual Pumpspray 18705 | 4/17/2012 | | | | | | |
| Nizatidine | Capsules | 150 mg and 300 mg | Axid 19508 | Pre-MMA | | | | | | |
| Nizatidine | Oral Solution | 15 mg/mL | Axid 21494 | 5/14/2008 | | | | | | |
| 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 |
| 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 / Ethinyl Estradiol and Ferrous Fumarate | Tablets | 1 mg/0.01 mg, 0.01 mg and 75 mg | Lo Loestrin Fe 22501 | 4/29/2011 | | | | | | |
| Norethindrone and Ethinyl Estradiol and Ferrous Fumarate | Chewable Tablets | 0.4 mg/0.035 mg | Ovcon-35 Fe Femcon Fe NDA 21-490 | 4/27/2007 | | | | | | |
| Norethindrone and Ethinyl Estradiol and Ferrous Fumarate | Chewable Tablets | 0.8 mg/0.025 mg and 75 mg | Generess Fe | 8/5/2011 | | | | | | |
| Norethindrone Acetate and Ethinyl Estradiol and Ferrous Fumarate | Chewable Tablets | 1 mg/0.02 mg and 75 mg | Minastrin 24 Fe 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 | | | | | 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|----------------------------------|--|---|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | | | | | | |
| 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 | | | | | | |
| Olmesartan Medoxomil | Tablets | 5 mg, 20 mg and 40 mg | Benicar 21286 | 4/25/2006 | | | | | | |
| Olmesartan Medoxomil and Hydrochlorothiazide | Tablets | 20 mg/12.5 mg | Benicar HCT 21532 | 5/11/2007 | | | | | | |
| Olmesartan Medoxomil and Hydrochlorothiazide | Tablets | 40 mg/12.5 mg and 40 mg/25 mg | Benicar HCT 21532 | 2/15/2007 | | | | | | |
| Olopatadine Hydrochloride | Nasal Spray | 0.665 mg/ Spray | Patanase 21861 | 6/29/2009 | | | | | | |
| 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 | | | | | | |
| Omega-3-Acid Ethyl Esters | Capsules | 1 g | Lovaza 21654 | 11/10/2008 | | | | | | |
| Omeprazole | Delayed-release Capsules | 10 mg, 20 mg and 40 mg | Prilosec 19810 | Pre-MMA | | | | | | |
| Omeprazole and Sodium Bicarbonate | Capsules | 20 mg/1100 mg and 40 mg/1100 mg | Zegerid 21849 | 4/30/2007 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | Zegerid OTC 22281 | 4/20/2010 | | | | | | |
| Omeprazole and Sodium Bicarbonate | Powder for Oral Suspension | 20mg/1680mg per packet | Zegerid 21636 | 11/13/2007 | | | | | | |
| Omeprazole and Sodium Bicarbonate | Powder for Oral Suspension | 40 mg/1680 mg per packet | Zegerid 21636 | 8/24/2007 | | | | | | |
| Omeprazole Magnesium | Delayed-release Capsules | 20 mg | Prilosec OTC 21229 | 3/19/2007 | | | | | | |
| Omeprazole Magnesium | Delayed-release Tablets | 20 mg | Prilosec OTC 21229 | 3/30/2012 | | | | | | |
| 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 | | | | | | |
| 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 | | | | | | |
| Oseltamivir Phosphate | Capsules | 30 mg and 45 mg | Tamiflu 21087 | 8/2/2011 | | | | | | |
| Oseltamivir Phosphate | Capsules | 75 mg | Tamiflu 21087 | 11/15/2010 | | | | | | |
| 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 |
| Ospemifene | Tablets | 60 mg | Ospheña 203505 | 12/29/2020 | 1 | | | | | 7/9/2028 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|-------------------------|-------------------------------------|---------------------------------------|------------------------|--------------------|---------------------------|-----------------------|-------------------------------|----------------------------------|---|---|
| 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 | | | | | | |
| 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 | | | | | | |
| 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 | | | | | | |
| 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 | | | | | | |
| Oxycodone Hydrochloride | Extended-release Tablets | 30 mg and 60 mg | Oxycontin (NDA 020553) | 1/3/2007 | | | | | | |
| Oxycodone Hydrochloride | Extended-release Tablets | 10 mg | Oxycontin (NDA 022272) | 10/25/2010 | 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 |
| Oxycodone Hydrochloride | Extended-release Tablets | 40 mg | Oxycontin (NDA 022272) | 10/4/2010 | 1 | Extinguished | 10/8/2019 | | | 4/19/2025 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | 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 | | | | | | |
| Oxymorphone Hydrochloride | Extended-release Tablets | 7.5 mg and 15 mg | Opana ER | 5/29/2008 | | | | | | |
| Oxymorphone Hydrochloride | Extended-release Tablets | 30 mg | Opana ER | 6/12/2008 | | | | | | |
| Oxymorphone Hydrochloride | Extended-release Tablets | 7.5 mg, 10 mg, and 15 mg | Opana ER (NDA 201655) | 3/23/2012 | 1 | Extinguished | 3/10/2020 | | | 7/10/2029 |
| Oxymorphone Hydrochloride | Extended-release Tablets | 5 mg | Opana ER (NDA 201655) | 3/26/2012 | | | | | | |
| Oxymorphone Hydrochloride | Extended-release Tablets | 20 mg, 30 mg and 40 mg | Opana ER (NDA 201655) | 4/3/2012 | | | | | | |
| Paclitaxel | Injection | 6 mg/mL, 5 mL, 16.7 mL, 25 mL, 33.3 mL and 50 mL vials | Taxol 20262 | Pre-MMA | | | | | | |
| Paclitaxel Protein-Bound Particles | For Injection Suspension | 100 mg/vial | Abraxane 21660 | 12/11/2015 | 1 | | | | | 10/27/2024 |
| Palbociclib | Capsules | 75 mg, 100 mg and 125 mg | Ibrance 207103 | 2/4/2019 | | | | | | |
| Palbociclib | Tablets | 75 mg, 100 mg and 125 mg | Ibrance 212436 | 11/24/2020 | 1 | | | | | 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 | Deferred | 8/24/2021 | 7/6/2021 | | 1/26/2031 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|----------------------------|--|---|----------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | | | | | | |
| 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 | Prontonix 20987 | 2/2/2004 | | | | | | |
| Pantoprazole Sodium | for Delayed-release Oral Suspension | 40 mg | Prontonix 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 | | | | | | |
| Paricalcitol | Capsules | 4 mcg | Zemplar 21606 | 8/25/2008 | | | | | | |
| Paroxetine Hydrochloride | Capsules | 10 mg and 20 mg | Paxil 20885 | Pre-MMA | | | | | | |
| 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 | | | | | | |
| Paroxetine Hydrochloride | Extended-release Tablets | 37.5 mg | Paxil CR 20936 | 5/19/2009 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | 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 | | | | | | |
| Perampanel | Tablets | 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg | Fycompa 202834 | 10/24/2016 | 2 | | | | | 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 | | | | | 10/5/2029 |
| Perindopril Erbumine | Tablets | 2 mg, 4 mg and 8 mg | Aceon 20184 | 6/6/2006 | | | | | | |
| Phentermine Hydrochloride | Orally Disintegrating Tablets | 15 mg and 30 mg | Suprenza 202088 | 10/19/2012 | | | | | | |
| Phentermine Hydrochloride | Orally Disintegrating Tablets | 37.5 mg | Suprenza 202088 | 3/22/2013 | | | | | | |
| Phentermine Hydrochloride and Topiramate | Extended-release Capsules | 3.75 mg/23 mg 7.5 mg/46 mg 11.25 mg/69 mg 15 mg/92 mg | Qsymia 22580 | 7/18/2013 | | | | | | |
| Phenylephrine and Ketorolac | Injection | 1%/0.3% | Omidria 205388 | 5/29/2015 | 1 | Extinguished | 8/13/2019 | | | 7/30/2023 |
| Pimavanserin | Capsules | 34 mg | Nuplazid 210793 | 4/29/2020 | 5 | | | | | 8/27/2038 |
| Pimavanserin | Tablets | 10 mg | Nuplazid 207318 | 4/29/2020 | 1 | | | | | 6/3/2028 |
| Pioglitazone Hydrochloride | Tablets | 15 mg, 30 mg and 45 mg | Actos 21073 | Pre-MMA | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|---|---|--------------------------|--------------------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Pioglitazone Hydrochloride and Glimepiride | Tablets | 30 mg/2 mg and 30 mg/4 mg | Duetact 21925 | 12/22/2009 | | | | | | |
| 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 | | | | | | |
| 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 | | | | | | |
| 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 | | | | | |
| Pirfenidone | Tablets | 267 mg, 534 mg and 801 mg | Esbriet 208780 | 10/15/2018 | 17 | | | | | 8/30/2033 |
| Pitavastatin Calcium | Tablets | 1 mg, 2 mg, and 4 mg | Livalo 22363 | 8/5/2013 | | | | | | |
| 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 | | | | | | |
| 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 | | | | | | |
| 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 | | | | | | |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|---------------------------|--|------------------|--------------------|---------------------------|-------------------------|-------------------------------|----------------------------------|---|---|
| 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 |
| 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 |
| Ponatinib Hydrochloride | Tablets | 15 mg and 45 mg | Iclusig 203469 | 3/31/2021 | 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 | 7/30/2019 | | | 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 | | | | | | |
| Pramipexole Dihydrochloride | Tablets | 0.125 mg, 0.5 mg, 1 mg and 1.5 mg | Mirapex 20667 | 6/24/2005 | | | | | | |
| Pramipexole Dihydrochloride | Tablets | 0.25 mg | Mirapex 20667 | 5/27/2005 | | | | | | |
| Pramipexole Dihydrochloride | Tablets | 0.75 mg | Mirapex 20667 | 7/31/2008 | | | | | | |
| Pramipexole Dihydrochloride | Extended-release Tablets | 0.375 mg, 0.75 mg, 1.5 mg, 3 mg and 4.5 mg | Mirapex ER 22421 | 6/1/2010 | | | | | | |
| Pramipexole Dihydrochloride | Extended-release Tablets | 2.25 mg and 3.75 mg | Mirapex ER 22421 | 7/26/2011 | | | | | | |
| Prasugrel Hydrochloride | Tablets | 5 mg and 10 mg | Effient 22307 | 7/10/2013 | 17 | Eligible | 6/29/2020 | | 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 | | | | | | |

**Paragraph IV Patent Certifications
January 11, 2022**

| 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 |
|-------------------------------|-------------------------------|--|-------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Prazosin Hydrochloride | Capsules | 1 mg, 2 mg and 5 mg | Minipress 17442 | Pre-MMA | | | | | | |
| 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, 2 mg, and 5 mg | Rayos 202020 | 11/26/2012 | | | | | | |
| Pregabalin | Capsules | 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg | Lyrica 21446 | 12/30/2008 | | | | | | |
| Pregablin | Oral Solution | 20 mg/mL | Lyrica 22488 | 5/19/2010 | | | | | | |
| Pregabalin | Extended-release Tablets | 330 mg | Lyrica CR 209501 | 1/29/2018 | 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 | | | | | | |
| Propafenone Hydrochloride | Extended-release Capsules | 225 mg and 425 mg | Rythmol SR 21416 | 10/11/2006 | | | | | | |
| 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 | | | | | | |
| 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 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | 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 | Tablets | 400 mg | Isentress 22145 | 10/12/2011 | 1 | | | | | 3/11/2029 |
| 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 21461 | 5/17/2010 | 5 | Eligible | 3/23/2021 | 9/12/2013 | 1/2/2017 | 12/5/2026 |
| Regadenoson | Injection | 0.08 mg/mL, 5 mL vial | Lexiscan 22161 | 4/10/2012 | 1 | Extinguished | 1/12/2021 | | | 6/22/2019 |
| Regorafenib | Tablets | 40 mg | Stivarga 203085 | 9/27/2016 | 2 | | | | | 2/16/2031 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|-------------------------------|---------------------------------------|-------------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 |
| 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 | 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 | | | | | 3/12/2029 |
| Riociguat | Tablets | 0.5 mg, 1 mg, 1.5 mg, 2 mg and 2.5 mg | Adempas 204819 | 10/10/2017 | 3 | | | | | 12/4/2026 |
| 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 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--------------------------|-------------------------------------|--------------------------------|------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 |
| Rivaroxaban | Tablets | 2.5 mg | Xarelto 22406 | 11/19/2018 | 4 | | | | | 11/13/2024 |
| Rivaroxaban | Tablets | 10 mg, 15 mg, and 20 mg | Xarelto 22406 | 7/1/2015 | 8 | | | | | 8/28/2024 |
| 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 | | 3/8/2024 |
| Roflumilast | Tablets | 250 mcg | Daliresp 22522 | 1/25/2019 | 1 | | | | | 3/8/2024 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|-----------------------------------|--|-----------------|--------------------|---------------------------|----------------|-------------------------------|------------------------------------|---|---|
| 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 |
| 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, 200 mg and 400 mg | Banzel 21911 | 11/14/2012 | 5 | Eligible | 3/23/2021 | 5/16/2016: 200 mg and 400mg | 6/1/2021: 200 mg and 400 mg | 11/14/2022 |
| Rufinamide | Oral Suspension | 40 mg/mL | Banzel 201367 | 6/16/2014 | 1 | Extinguished | 10/8/2019 | | | 11/14/2022 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---|----------------------------|---|----------------------|--------------------|---------------------------|-------------------|-------------------------------|----------------------------------|---|---|
| Ruxolitinib | 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 | | | | | 5/27/2027 |
| Safinamide Mesylate | Tablets | 50 mg and 100 mg | Xadago 2071454 | 3/22/2021 | 6 | | | | | 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 | | | | | 11/30/2028 |
| 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 | | | | | 7/31/2023 |
| 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 | Upravi 207947 | 12/23/2019 | 4 | | | | | 8/1/2030 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 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 | | 3/7/2023 |
| Sodium Oxybate | Oral Solution | 500 mg/mL | Xyrem 21196 | 7/8/2010 | 1 | Eligible | 7/2/2019 | 1/17/2017 | | 6/16/2024 |
| 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 |
| Sofosbuvir | Tablets | 400 mg | Sovaldi 204671 | 12/6/2017 | 2 | | | | | 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 | | | | | 10/28/2036 |
| Sugammadex Sodium | Injection | 200 mg/2 mL and 500 mg/5 mL | Bridion 22225 | 12/16/2019 | 14 | | | | | 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 |
| 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 |
| 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 |
| Tafuprost | Ophthalmic Solution | 0.0015% | Zioptan 202514 | 2/10/2016 | 2 | Deferred | 12/14/2021 | 8/19/2019 | | 12/18/2022 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|-------------------------------------|--------------------------|---|--------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | | | | | 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 | | | | | 6/27/2025 |
| Tapentadol | Oral Solution | 20 mg/mL | Nucynta 203794 | 12/20/2013 | 1 | | | | | 6/27/2025 |
| Tasimelteon | Capsules | 20 mg | Hetlioz 205677 | 1/31/2018 | 3 | | | | | 5/17/2034 |
| Tavaborole | Topical Solution | 5% | Kerydin 204427 | 7/9/2018 | 13 | Eligible | 11/17/2020 | 10/13/2020 | 10/19/2020 | 5/26/2027 |
| Teduglutide | Injection | 5 mg/vial | Gattex Kit 203411 | 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 |
| 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 | | | | | 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|---------------------------|---------------------|----------------------------------|----------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | | 2/4/2034 |
| Teriparatide | Injection | 250 mcg/mL, 2.4 mL prefilled Pen | Forteo 21318 | 7/27/2015 | 1 | | | | | 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 |
| 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 | 2/9/2021 | | | 10/23/2020 |
| 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 | | 4/17/2030 |
| Ticagrelor | Tablets | 60 mg | Brilinta 22433 | 9/30/2015 | 3 | Eligible | 8/13/2019 | 9/4/2018 | | 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|--------------------------|----------------------------|---|------------------------------|--------------------|---------------------------|--------------------------------|-------------------------------|----------------------------------|---|---|
| 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 |
| Tiotropium Bromide | Inhalation Powder Capsules | 18 mcg | Spiriva 21395 | 5/11/2018 | 1 | | | | | 4/19/2030 |
| Tirofiban Hydrochloride | Injection | 12.5 mg/250 mL | Aggrastat 20913 | 10/3/2018 | 1 | Deferred | 5/4/2021 | 4/8/2021 | | 5/1/2023 |
| Tirofiban Hydrochloride | Injection | 5 mg/100 mL | Aggrastat 20913 | 8/29/2019 | 1 | | | | | 5/1/2023 |
| 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 | Eligible | 7/2/2019 | 6/26/2019 | | 9/22/2022 |
| Tofacitinib | Tablets | 5 mg | Xeljanz 203214 | 11/7/2016 | 3 | | | | | 12/8/2025 |
| Tofacitinib | Tablets | 10 mg | Xeljanz 203214 | 7/24/2019 | 1 | Eligible | 7/13/2021 | 6/1/2021 | | 12/8/2025 |
| Tofacitinib | Extended-release Tablets | 11 mg | Xeljanz XR 208246 | 11/7/2016 | 1 | Extinguished | 8/10/2020 | | | 3/25/2023 |
| Tofacitinib | Extended-release Tablets | 22 mg | Xeljanz XR 208246 | 12/28/2020 | 1 | Eligible | 8/24/2021 | 8/19/2021 | | 3/14/2034 |
| Tofacitinib New | Oral Solution | 1 mg/mL | Xeljanz 213082 | 11/12/2021 | 1 | | | | | 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 | | | 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 | | | | | 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 | | | | | | |

Paragraph IV Patent Certifications
January 11, 2022

| 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 | Tablets | 50 mg | Topamax 20505 | 9/8/2005 | 1 | Extinguished | 8/10/2020 | 3/27/2009 | | 9/26/2008 |
| 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 | 8/27/2019 | | | 3/19/2033 |
| Topiramate | Extended-release Capsules | 200 mg | Trokendi XR 201635 | 4/3/2014 | 1 | | | | | 3/18/2029 |
| Topiramate | Extended-release Capsules | 25 mg, 50 mg, and 100 mg | Trokendi XR 201635 | 5/12/2014 | 1 | Deferred | 11/19/2019 | 11/24/2017 | | 3/18/2029 |
| Torseamide | 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 |
| 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 |
| 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 |

Paragraph IV Patent Certifications
January 11, 2022

| 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 |
|-------------------------------------|---------------------------|---|------------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| Trazodone Hydrochloride | Tablets | 150 mg | Desyrel 18207 | Pre-MMA | | | | | | |
| Trazodone Hydrochloride | Extended-release Tablets | 150 mg and 300 mg | Olepro 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 |
| 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 | | | | | | |
| Trifluridine and Tipiracil | Tablets | 15 mg/6.14 mg and 20 mg/8.19 mg | Lonsurf 207981 | 9/23/2019 | 4 | | | | | 6/17/2034 |
| Tropium 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 |
| 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 |
| Valacyclovir Hydrochloride | Tablets | 500 mg and 1000 mg | Valtrex 20487 | Pre-MMA | | | | | | |

**Paragraph IV Patent Certifications
January 11, 2022**

| 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 |
|-----------------------------------|----------------------------------|---|-----------------------|--------------------|---------------------------|----------------------------|-------------------------------|----------------------------------|---|---|
| Valbenazine Tosylate | Capsules | 40 mg and 80 mg | Ingrezza 209241 | 4/12/2021 | 4 | | | | | 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 |
| 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 | | | | | 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 | Deferred | 9/7/2021 | 8/11/2021 | 9/21/2021 | 8/3/2022 |
| Vasopressin | Injection | 20 units/mL, 1 mL | Vasostrict 204485 | 3/23/2018 | 1 | Non-Forfeiture Deferred | 12/28/2021 | 12/15/2021 | | 1/30/2035 |
| Vasopressin | Injection | 20 units/mL, 10 mL | Vasostrict 204485 | 6/29/2018 | 1 | | | | | 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
January 11, 2022**

| 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 |
| Vilazodone Hydrochloride | Tablets | 10 mg, 20 mg, and 40 mg | VIIBRYD 22567 | 1/21/2015 | 5 | Eligible | 7/27/2020 | 9/13/2019 | | 6/5/2022 |
| Vincristine Sulfate | Injection | 1 mg/mL, 1 mL, 2 mL and 5 mL vials | Oncovin 14103 | Pre-MMA | | | | | | |
| 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 |
| 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 | Deferred | 10/5/2021 | 9/17/2021 | | 6/30/2031 |
| 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 |
| 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 |

**Paragraph IV Patent Certifications
January 11, 2022**

| 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 |
|---|-----------------------------|-----------------------------|---------------------|--------------------|---------------------------|----------------|-------------------------------|----------------------------------|---|---|
| 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 | 12/6/2020 | 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 |
| * ANDA withdrawn or exclusivity relinquished | | | | | | | | | | |