

FDA Listing of Authorized Generics as of April 6, 2026

Note:

This list of authorized generic drugs (AGs) was created from a manual review of FDA’s database of annual reports submitted to the FDA since January 1, 1999 by sponsors of new drug applications (NDAs). Because the annual reports seldom indicate the date an AG initially entered the market, the column headed “Date Authorized Generic Entered Market” reflects the period covered by the annual report in which the AG was first reported. Subsequent marketing dates by the same firm or other firms are not included in this listing. As noted, in many cases FDA does not have information on whether the AG is still marketed and, if not still marketed, the date marketing ceased. Although attempts have been made to ensure that this list is as accurate as possible, given the volume of data reviewed and the possibility of database limitations or errors, users of this list are cautioned to independently verify the information on the list. We welcome comments on and suggested changes (e.g., additions and deletions) to the list, but the list may include only information that is included in an annual report. Please send suggested changes to the list, along with any supporting documentation to: AuthorizedGenerics@FDA.HHS.GOV

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	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1	ABSORICA	Capsules	25 mg	Sun Pharmaceutical Industries, Inc.	12/2020
2	ABSORICA	Capsules	20 mg	Sun Pharmaceutical Industries, Inc.	12/2020
3	ABSORICA	Capsules	30 mg	Sun Pharmaceutical Industries, Inc.	12/2020
4	ABSORICA	Capsules	35 mg	Sun Pharmaceutical Industries, Inc.	12/2020
5	ABSORICA	Capsules	40 mg	Sun Pharmaceutical Industries, Inc.	12/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
6	ABSORICA	Capsules	10 mg	Sun Pharmaceutical Industries, Inc.	12/2020
7	ACANYA	Gel	1.2% / 2.5%	Bausch Health Americas, Inc.	07/02/2018
8	ACANYA	Gel	1.2% / 3.75%	Bausch Health Americas, Inc.	10/02/2023
9	ACCOLATE	Tablets	10 mg	AstraZeneca Pharmaceuticals	11/19/2010
10	ACCOLATE	Tablets	20 mg	AstraZeneca Pharmaceuticals	11/19/2010
11	ACEPHEN	Suppositories	120 mg	G & W Laboratories, Inc.	Prior to 1/1/1999
12	ACETADOTE	Injection	6 g/30 mL (200 mg/mL)	Cumberland Pharmaceuticals, Inc.	1/7/2013
13	ACTICLATE	Tablets	150 mg	Almirall, LLC	02/2018
14	ACTICLATE	Tablets	75 mg	Almirall, LLC	02/2018
15	ACTIGALL	Capsules	300 mg	Teva Branded Pharmaceutical Products R&D LLC	08/13/2003
16	ACTIQ	Lozenge	200 mcg	Cephalon, LLC	09/26/2006
17	ACTIQ	Lozenge	400 mcg	Cephalon, LLC	09/26/2006
18	ACTIQ	Lozenge	600 mcg	Cephalon, LLC	09/26/2006
19	ACTIQ	Lozenge	800 mcg	Cephalon, LLC	09/26/2006
20	ACTIQ	Lozenge	1200 mcg	Cephalon, LLC	09/26/2006

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
21	ACTIQ	Lozenge	1600 mcg	Cephalon, LLC	09/26/2006
22	ACTONEL	Tablets	150 mg	Allergan Pharmaceuticals International Ltd.	06/2014
23	ACULAR LS	Ophthalmic Solution	0.4%	Allergan, Inc.	11/11/2013
24	ACZONE	Gel	7.5%	Almirall, LLC	01/2020
25	ADDERALL XR	Extended-release Capsules	5 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
26	ADDERALL XR	Extended-release Capsules	10 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
27	ADDERALL XR	Extended-release Capsules	15 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
28	ADDERALL XR	Extended-release Capsules	20 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
29	ADDERALL XR	Extended-release Capsules	25 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
30	ADDERALL XR	Extended-release Capsules	30 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
31	ADDERALL XR	Extended-release Capsules	30 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
32	ADDERALL XR	Extended-release Capsules	25 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
33	ADDERALL XR	Extended-release Capsules	20 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
34	ADDERALL XR	Extended-release Capsules	15 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
35	ADDERALL XR	Extended-release Capsules	5 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
36	ADDERALL XR	Extended-release Capsules	10 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
37	ADRENACLICK	Injection	0.15 mg	Impax Laboratories, LLC	04/01/2010
38	ADRENACLICK	Injection	0.3 mg	Impax Laboratories, LLC	04/01/2010
39	ADVAIR DISKUS	Inhalation Powder	100/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019
40	ADVAIR DISKUS	Inhalation Powder	250/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
41	ADVAIR DISKUS	Inhalation Powder	500/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019
42	ADVAIR HFA	Inhalation Aerosol	230/21 MCG	GlaxoSmithKline Intellectual Property Ltd. England	3/1/2023
43	ADVAIR HFA	Inhalation Aresol	45/21 MCG	GlaxoSmithKline Intellectual Property Ltd. England	3/1/2023
44	ADVAIR HFA	Inhalation Aresol	115/21 MCG	GlaxoSmithKline Intellectual Property Ltd. England	3/1/2023
45	AGGRASTAT	Solution for Injection Premixed	0.05 mg/mL	Medicure Pharma	3/2024
46	AGGRASTAT	Solution for Injection Premixed	0.25 mg/mL	Medicure Pharma	02/2025
47	AIRDUO RESPICLICK	Inhalation Powder	55 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
48	AIRDUO RESPICLICK	Inhalation Powder	113 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
49	AIRDUO RESPICLICK	Inhalation Powder	232 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
50	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
51	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
52	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
53	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
54	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2012
55	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
56	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
57	ALDACTAZIDE	Tablet	25 mg/25 mg	Pfizer Inc.	12/01/2021
58	ALINIA	Tablets	500 mg	Romark Laboratories, L.C.	02/2021
59	ALLEGRA	Tablets	30 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
60	ALLEGRA	Tablets	60 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
61	ALLEGRA	Tablets	180 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
62	ALLEGRA-D 12 HOUR	Extended-release Tablets	60 mg/120 mg	Sanofi Aventis US LLC	12/2004 - 12/2005

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
63	ALREX	Ophthalmic Suspension	0.2%	Bausch & Lomb Incorporated	02/09/2024
64	AMARYL	Tablets	1 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
65	AMARYL	Tablets	2 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
66	AMARYL	Tablets	4 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
67	AMBIEN CR	Extended-release Tablets	12.5 mg	Sanofi Aventis U.S. LLC	12/2010
68	AMBIEN CR	Extended-release Tablets	6.25 mg	Sanofi Aventis U.S. LLC	10/2010
69	AMICAR	Tablets	1000 mg	Clover Pharmaceuticals Corporation	06/01/2012
70	AMITIZA	Capsule	24 mcg	Sucampo Pharma Americas LLC	1/1/2023
71	AMITIZA	Capsule	24 mcg	Sucampo Pharma Americas, LLC	04/10/2024
72	AMITIZA	Capsule	8 mcg	Sucampo Pharma Americas, LLC	04/10/2024
73	AMITIZA	Capsule	24 mcg	Sucampo Pharma Americas, LLC	1/1/2023
74	AMITIZA	Capsule	8 mcg	Sucampo Pharma Americas, LLC	1/1/2023
75	AMITIZA	Capsule	8 mcg	Sucampo Pharma Americas, LLC	1/1/2023

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
76	AMITIZA	Capsules	8 mcg	Sucampo Pharma Americas, LLC	01/2021
77	AMITIZA	Capsules	24 mcg	Sucampo Pharma Americas, LLC	01/2021
78	AMMONUL	Injection	10% / 10%	Bausch Health US, LLC	03/15/2017
79	AMOXIL	Powder for Oral Suspension	400 mg/5 mL when reconstituted	USAntibiotics, LLC	04/01/2024
80	AMPYRA	Tablets	10 mg	Acorda Therapeutics, Inc.	09/2018
81	AMRIX	Capsules	30 mg	Cephalon, Inc.	03/2019
82	AMRIX	Capsules	15 mg	Cephalon, Inc.	03/2019
83	AMRIX	Capsules	30 mg	Cephalon, Inc.	03/2019
84	AMRIX	Capsules	15 mg	Cephalon, Inc.	03/2019
85	ANAFRANIL	Capsules	25 mg	Mallinckrodt	07/2015
86	ANAFRANIL	Capsules	50 mg	Mallinckrodt	07/2015
87	ANAFRANIL	Capsules	75 mg	Mallinckrodt	07/2015
88	ANAPROX DS	Tablets	550 mg	Atnahs Pharma US Limited	10/2018
89	ANCOBON	Capsules	500 mg	Bausch Health US, LLC	07/26/2017
90	ANCOBON	Capsules	250 mg	Bausch Health US, LLC	07/26/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
91	ANGIOMAX	Powder, for injection solution, lyophilized	250 mg	Sandoz Inc.	02/2017
92	ANGIOMAX	Powder, for injection solution, lyophilized	250 mg	Sandoz Inc.	10/2015
93	ANORO ELLIPTA	Inhalation Powder	62.5/25 mcg	GlaxoSmithKline Intellectual Prop Dev Ltd	04/11/2025
94	ANTARA	Capsules	43 mg	Lupin Inc.	02/22/2013
95	ANTARA	Capsules	130 mg	Lupin Inc.	02/22/2013
96	ANTIVERT	Chewable Tablets	50 mg	Casper Pharma LLC	01/15/2020
97	ANTIVERT	Tablets	12.5 mg	Casper Pharma LLC	01/2020
98	ANTIVERT	Tablets	25 mg	Casper Pharma LLC	01/2020
99	APADAZ	Tablets	8.16 mg / 325 mg	KVK-Tech, Inc.	06/2019
100	APRISO	Extended-release Capsules	0.375 g	Salix Pharmaceuticals, Inc.	07/19/2018
101	APTENSIO XR	Extended-release Capsules	30 mg	Rhodes Pharmaceuticals L.P.	04/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
102	APTENSIO XR	Extended-release Capsules	20 mg	Rhodes Pharmaceuticals L.P.	04/2020
103	APTENSIO XR	Extended-release Capsules	40 mg	Rhodes Pharmaceuticals L.P.	04/2020
104	APTENSIO XR	Extended-release Capsules	50 mg	Rhodes Pharmaceuticals L.P.	04/2020
105	APTENSIO XR	Extended-release Capsules	10 mg	Rhodes Pharmaceuticals L.P.	04/2020
106	APTENSIO XR	Extended-release Capsules	15 mg	Rhodes Pharmaceuticals L.P.	04/2020
107	APTENSIO XR	Extended-release Capsules	60 mg	Rhodes Pharmaceuticals L.P.	04/2020
108	ARAVA	Tablets	20 mg	Sanofi Aventis US LLC	09/07/2015
109	ARAVA	Tablets	10 mg	Sanofi Aventis US LLC	09/07/2015
110	ARICEPT	Film coated tablets	5 mg	Eisai, Inc.	11/25/2009 - 11/24/2010
111	ARICEPT	Film coated tablets	10 mg	Eisai, Inc.	11/25/2009 - 11/24/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
112	ARICEPT ODT	Orally disintegrating tablets	10 mg	Eisai, Inc.	10/18/2009 - 11/24/2010
113	ARICEPT ODT	Orally distinegrating tablets	5 mg	Eisai, Inc.	10/18/2009 - 11/24/2010
114	ARIXTRA	Injection	2.5 mg / 0.5 mL	Mylan Ireland Limited	12/2014 - 12/2015
115	ARIXTRA	Injection	5 mg / 0.4 mL	Mylan Ireland Limited	12/2014 - 12/2015
116	ARIXTRA	Injection	7.5 mg / 0.6 mL	Mylan Ireland Limited	12/2014 - 12/2015
117	ARIXTRA	Injection	10 mg / 0.8 mL	Mylan Ireland Limited	12/2014 - 12/2015
118	AROMASIN	Tablets	25 mg	Pfizer Inc.	11/02/2010
119	ARTHROTEC	Tablets	75 mg/200 mcg	Pfizer Inc.	11/01/2012
120	ARTHROTEC	Tablets	50 mg/200 mcg	Pfizer Inc.	11/01/2012
121	ATACAND	Tablets	32 mg	ANI Pharmaceuticals, Inc.	05/21/2013
122	ATACAND	Tablets	8 mg	ANI Pharmaceuticals, Inc.	05/21/2013
123	ATACAND	Tablets	16 mg	ANI Pharmaceuticals, Inc.	05/21/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
124	ATACAND	Tablets	4 mg	ANI Pharmaceuticals, Inc.	05/21/2013
125	ATACAND HCT	Tablets	16 mg/12.5 mg	ANI Pharmaceuticals, Inc.	09/2018
126	ATACAND HCT	Tablets	32 mg/12.5 mg	ANI Pharmaceuticals, Inc.	09/2018
127	ATACAND HCT	Tablets	32 mg/25 mg	ANI Pharmaceuticals, Inc.	09/2018
128	ATELVIA	Delayed-release Tablets	35 mg	Allergan	2015
129	ATIVAN	Injection	2 mg/mL	Baxter Healthcare Corporation	10/31/2003
130	ATIVAN	Injection	4 mg/mL	Baxter Healthcare Corporation	10/31/2003
131	ATRALIN	Gel	0.05%	Bausch Health Americas, Inc.	07/26/2007
132	ATROPINE SULFATE OPHTHALMIC SOLUTION	Sterile Ophthalmic Solution	1%	Bausch & Lomb Incorporated	4/23/2023
133	AUGMENTIN	Oral Suspension	200 mg/28.5 mg per 5 mL	USAntibiotics, LLC	10/22/1990
134	AUGMENTIN	Oral Suspension	400 mg/57 mg per 5 mL	USAntibiotics, LLC	10/22/1990

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
135	AUGMENTIN	Powder for Oral Suspension	250mg/62.5mg/5mL	USAntibiotics, LLC	12/5/2022
136	AUGMENTIN	Tablets	250 mg	USAntibiotics, LLC	10/22/1990
137	AUGMENTIN	Tablets	500 mg	USAntibiotics, LLC	10/22/1990
138	AUGMENTIN	Tablets	875 mg/125 mg	USAntibiotics, LLC	11/21/2022
139	AUGMENTIN ES-600	Powder for Oral Suspension	600 mg/42.9 mg per 5 mL	USAntibiotics, LLC	9/19/2022
140	AUGMENTIN XR	Tablets	1000mg/62.5mg	USAntibiotics	12/15/2025
141	AVALIDE	Tablets	150 mg/12.5 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
142	AVALIDE	Tablets	300 mg/12.5 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
143	AVELOX	Tablets	400 mg	Bayer HealthCare LLC	01/2014
144	AVITA	Cream	0.025%	Mylan Pharmaceuticals, Inc., a Viatris Company	05/01/1998
145	AZILECT	Tablets	0.5 mg	Teva Pharmaceuticals USA	01/2017
146	AZILECT	Tablets	1 mg	Teva Pharmaceuticals USA	01/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
147	AZOPT	Ophthalmic Suspension	1%	Novartis Pharmaceuticals Corporation	03/2021
148	AZULFIDINE	Tablets	500 mg	Pfizer Inc.	07/14/2003
149	AZULFIDINE EN-TABS	Delayed Release Tablets	500mg ECT	Pfizer Inc.	3/2022
150	BENICAR HCT	Tablets	40 mg/25 mg	Daiichi Sankyo, Inc	10/2016
151	BENICAR HCT	Tablets	20 mg/12.5 mg	Daiichi Sankyo, Inc	10/2016
152	BENICAR HCT	Tablets	40 mg/12.5 mg	Daiichi Sankyo, Inc	10/2016
153	BENZACLIN	Topical Gel	1% / 5%	Bausch Health US, LLC	05/2017
154	BENZAMYCIN	Topical Gel	3% Erythromycin, 5% Benzoyl Peroxide	Bausch Health US, LLC	10/2014 - 10/2015
155	BEPREVE	Solution	1.5%	Bausch & Lomb Incorporated	05/28/2021
156	BETHKIS	Inhalation Solution	300 mg/4 mL	Chiesi USA, Inc.	09/2020
157	BETOPTIC	Ophthalmic Solution	eq. 0.5% base	Alcon Laboratories, Inc.	05/08/2000
158	BICNU	Lyophilized Powder for Injection	100 mg/vial	Avet Lifesciences Private Limited	03/01/2021
159	BiCNU	Powder for Injection	100 mg/vial	Avet Lifesciences Private Limited	10/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
160	BIDIL	Tablets	20 mg/37.5 mg	Azurity Pharmaceuticals, Inc.	04/2022
161	BLOCADREN	Tablets	5 mg	Merck & Co., Inc.	Prior to 1/1/1999
162	BLOCADREN	Tablets	10 mg	Merck & Co., Inc.	Prior to 1/1/1999
163	BREO ELLIPTA	Inhalation Powder	100 ug/1, 25ug/1	GlaxoSmithKline Intellectual Property Development	5/23/2022
164	BREO ELLIPTA	Inhalation Powder	200ug/1, 25 ug/1	GlaxoSmithKline Intellectual Property Development	05/23/2022
165	BREVIBLOC	Injection	10 mg/mL	Baxter Healthcare Corporation	11/2002 - 10/2003
166	BRISDELLE	Capsules	7.5 mg	Sebela Ireland Limited	10/2017
167	BUMEX	Tablets	0.5 mg	Validus Pharmaceuticals LLC	10/2015
168	BUMEX	Tablets	1 mg	Validus Pharmaceuticals LLC	10/2015
169	BUMEX	Tablets	2 mg	Validus Pharmaceuticals LLC	10/2015
170	BUTRANS	Transdermal System	7.5 mcg/hour	Purdue Pharma L.P.	07/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
171	BUTRANS	Transdermal System	10 mcg/hour	Purdue Pharma L.P.	07/2017
172	BUTRANS	Transdermal System	20 mcg/hour	Purdue Pharma L.P.	07/2017
173	BUTRANS	Transdermal System	15 mcg/hour	Purdue Pharma L.P.	07/2017
174	BUTRANS	Transdermal System	5 mcg/hour	Purdue Pharma L.P.	07/2017
175	CADUET	Tablet	10/20 mg	Pfizer Inc.	3/14/2022
176	CADUET	Tablet	2.5/10 mg	Pfizer Inc.	03/14/2022
177	CADUET	Tablet	10/40 mg	Pfizer Inc.	3/14/2022
178	CADUET	Tablet	2.5/20 mg	Pfizer Inc.	3/14/2022
179	CADUET	Tablet	10/80 mg	Pfizer Inc.	3/14/2022
180	CADUET	Tablet	5/10 mg	Pfizer Inc.	3/14/2022
181	CADUET	Tablet	5/20 mg	Pfizer Inc.	3/14/2022
182	CADUET	Tablet	5/40 mg	Pfizer Inc.	3/14/2022
183	CADUET	Tablet	5/80 mg	Pfizer Inc.	3/14/2022
184	CADUET	Tablet	10/10 mg	Pfizer Inc.	3/14/2022
185	CADUET	Tablet	2.5/40 mg	Pfizer Inc.	3/14/2022
186	CANASA	Suppository	1000 mg	AbbVie, Inc.	12/2018
187	CARAFATE	Oral Suspension	1 g/10 mL	Allergan Sales, LLC	12/2019
188	CARAFATE	Tablets	1 g	Allergan Sales, LLC	11/01/1996

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
189	CARBATROL	Extended-Release Capsules	100 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
190	CARBATROL	Extended-Release Capsules	300 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
191	CARBATROL	Extended-Release Capsules	200 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
192	CARDIOLITE	Injection	(per label)	Lantheus Medical Imaging, Inc.	12/1990
193	CARDIZEM	Tablets	30 mg	Bausch Health US, LLC	12/25/2010
194	CARDIZEM	Tablets	60 mg	Bausch Health US, LLC	12/25/2010
195	CARDIZEM	Tablets	90 mg	Bausch Health US, LLC	12/25/2010
196	CARDIZEM	Tablets	120 mg	Bausch Health US, LLC	12/25/2010
197	CARDIZEM CD	Capsules	360 mg	Bausch Health US, LLC	04/11/2001
198	CARDIZEM LA	Tablets	180 mg	Bausch Health US, LLC	02/06/2014
199	CARDIZEM LA	Tablets	240 mg	Bausch Health US, LLC	02/06/2014
200	CARDIZEM LA	Tablets	300 mg	Bausch Health US, LLC	02/06/2014

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201	CARDIZEM LA	Tablets	360 mg	Bausch Health US, LLC	02/06/2014
202	CARDIZEM LA	Tablets	120 mg	Bausch Health US, LLC	2/6/2014
203	CARDIZEM LA	Tablets	420 mg	Bausch Health US, LLC	02/06/2014
204	CARDURA	Tablets	8 mg	Viartis Specialty LLC	07/07/2014, 10/19/2021
205	CARDURA	Tablets	4 mg	Viartis Specialty LLC	07/07/2014, 01/18/2023
206	CARDURA	Tablets	2 mg	Viartis Specialty LLC	07/07/2014, 10/19/2021
207	CARDURA	Tablets	1 mg	Viartis Specialty LLC	07/07/2014, 11/03/2021
208	CARNITOR	Oral Solution	1 g/10 mL	Leadiant Biosciences, Inc.	04/2005 - 04/2006
209	CARNITOR	Tablets	330 mg	Leadiant Biosciences, Inc.	1/2005 - 12/2005
210	CASODEX	Tablets	50 mg	ANI Pharmaceuticals, Inc.	10/2020
211	CASPORYN HC	Otic Suspension	10mg/mL, 3.5 mg/mL, 10000 [USP'U]/mL	Casper Pharma LLC	03/15/2019
212	CEDAX	Capsules	400 mg	Pernix Therapeutics LLC	10/22/2013

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213	CEDAX	Powder, for Oral Suspension	60 mL when reconstituted (180 mg per 5 mL)	Pernix Therapeutics LLC	10/22/2013
214	CELEBREX	Capsules	100 mg	Upjohn US 2 LLC	12/10/2014
215	CELEBREX	Capsules	400 mg	Upjohn US 2 LLC	12/10/2014
216	CELEBREX	Capsules	200 mg	Upjohn US 2 LLC	12/10/2014
217	CETRAXAL	Otic Solution	0.2%	Laboratorios Salvat SA	08/2012
218	CHILDREN'S MOTRIN	Suspension	100 mg/5 mL	McNeil Consumer Healthcare	06/1998 - 06/1999
219	CHILDREN'S MOTRIN (aka INFANT'S MOTRIN)	Suspension/ Drops	40 mg/mL	McNeil Consumer Healthcare	Prior to 1/1/1999
220	CILOXAN	Ophthalmic Solution	0.3%	Novartis Pharmaceuticals Corporation	05/28/2004
221	CIPRO	for Oral Suspension	250 mg/5 mL	Bayer Pharmaceuticals Corp.	06/2003
222	CIPRO	for Oral Suspension	500 mg/5 mL	Bayer Pharmaceuticals Corp.	06/2003
223	CIPRODEX	Otic Suspension	0.3% & 0.1%	Novartis Pharmaceuticals Corporation	08/2020
224	CLEOCIN	Vaginal Cream	2%	Pfizer Inc.	12/17/2005
225	CLEOCIN HCl	Capsules	150 mg	Pfizer Inc.	07/11/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
226	CLEOCIN HCl	Capsules	300 mg	Pfizer Inc.	06/18/2003
227	CLEOCIN PHOSPHATE	Injection	600 mg/4 mL	Pfizer	06/2019
228	CLEOCIN PHOSPHATE	Injection	900 mg/6 mL	Pfizer	06/2019
229	CLEOCIN PHOSPHATE	Injection	300 mg/2 mL	Pfizer	06/2019
230	CLEOCIN PHOSPHATE	Injection	9,000/60 mL	Pfizer	06/2019
231	CLEOCIN T	Topical Gel	1%	Pfizer Inc.	06/11/2003, 06/18/2003
232	CLEOCIN T	Topical Lotion	1%	Pfizer Inc.	06/18/2003
233	CLIMARA	Transdermal System	0.025 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
234	CLIMARA	Transdermal System	0.375 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
235	CLIMARA	Transdermal System	0.05 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
236	CLIMARA	Transdermal System	1 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
237	CLIMARA	Transdermal System	0.06 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
238	CLIMARA	Transdermal System	0.075 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
239	CLINDAGEL	Gel	1%	Bausch Health U.S., LLC	06/08/2018
240	CLINORIL	Tablets	150 mg	Merck & Co., Inc.	Prior to 1/1/1999
241	CLINORIL	Tablets	200 mg	Merck & Co., Inc.	Prior to 1/1/1999
242	CLOBEX	Shampoo	0.05%	Galderma Laboratories, L.P.	1/2024
243	CLOBEX	Spray	0.05%	Galderma Laboratories, L.P.	08/2015
244	CLODERM	Cream	0.1%	EPI Health, LLC	09/2019
245	CLODERM	Cream	0.1%	EPI Health, LLC	02/17/2014
246	CLOLAR	Injection	20mg/20mL	Genzyme Corporation	05/2017
247	CLOMID	Tablets	50 mg	Hoechst Marion Roussel, Inc.	Prior to 1/1/1999
248	CLOZARIL	Tablets	100 mg	Heritage Life Sciences (USA), Inc.	03/2019
249	CLOZARIL	Tablets	200 mg	Heritage Life Sciences (USA), Inc.	05/2020
250	CLOZARIL	Tablets	50 mg	Heritage Life Sciences (USA), Inc.	03/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
251	CLOZARIL	Tablets	25 mg	Heritage Life Sciences (USA), Inc.	03/2019
252	COLCRYS	Tablets	0.6 mg	Takeda Pharmaceuticals U.S.A. Inc.	07/01/2018
253	COLESTID	Granules for Oral Suspension	5 g	Pfizer Inc.	01/11/2016
254	COLESTID	Tablets	1 g	Pfizer Inc.	02/2007
255	COLY-MYCIN M	for Injection	150 mg/vial (single dose vial)	Par Sterile Products, LLC	06/01/2012
256	COMTAN	Tablets	200 mg	Orion Corporation	06/04/2014
257	CONZIP	Extended-release Capsules	300 mg	Cipher Pharmaceuticals, Inc.	06/2015
258	CONZIP	Extended-release Capsules	100 mg	Cipher Pharmaceuticals, Inc.	06/2015
259	CONZIP	Extended-release Capsules	200 mg	Cipher Pharmaceuticals, Inc.	05/2015
260	COREG CR	Capsules	80 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
261	COREG CR	Capsules	40 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
262	COREG CR	Capsules	20 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
263	COREG CR	Capsules	10 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
264	CORGARD	Tablets	80 mg	US WorldMeds, LLC	05/05/2014
265	CORGARD	Tablets	40 mg	US WorldMeds, LLC	05/05/2014
266	CORGARD	Tablets	20 mg	US WorldMeds, LLC	05/05/2014
267	CORTEF	Tablets	20 mg	Pharmacia and Upjohn Company LLC	12/22/2012
268	CORTEF	Tablets	5 mg	Pharmacia and Upjohn Company LLC	12/21/2012
269	CORTEF	Tablets	10 mg	Pharmacia and Upjohn Company LLC	12/21/2012
270	CORTENEMA	Rectal Suspension	100 mg/60 mL	ANI Pharmaceuticals, Inc.	08/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
271	CORTISPORIN OTIC	Otic Solution	eq. 3.5 mg base/g; 10,000 units/g; 1%	Monarch Pharmaceuticals Inc.	1/11/1999
272	COSMEGEN	Powder, for injection solution, lyophilized	500 mcg (0.5 mg)	Recordati Rare Diseases Inc.	12/2017
273	CUPRIMINE	Capsules	250 mg	Bausch Health Americas, Inc.	12/1970
274	CUTIVATE	Cream	0.05%	GlaxoSmithKline Consumer Healthcare	11/2003 - 11/2004
275	CUTIVATE	Ointment	0.005%	GlaxoSmithKline Consumer Healthcare	11/2003 - 11/2004
276	CYCLESSA	Tablets	0.1 mg, 0.125 mg, 0.15 mg; 0.025 mg, 0.025 mg, 0.025 mg	Organon USA Inc.	9/15/2004
277	CYTOMEL	Tablets	50 mcg	King Pharmaceuticals R&D LLC	06/2019
278	CYTOMEL	Tablets	25 mcg	King Pharmaceuticals R&D LLC	06/2019
279	CYTOMEL	Tablets	5 mcg	King Pharmaceuticals R&D LLC	02/2019
280	CYTOTEC	Tablets	100 mcg	Pfizer Inc.	06/18/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
281	CYTOTEC	Tablets	200 mcg	Pfizer Inc.	06/18/2003
282	DANTRIUM	Capsules	25 mg	Par Sterile Products, LLC	04/08/2013
283	DANTRIUM	Capsules	100 mg	Par Sterile Products, LLC	02/2016
284	DANTRIUM	Capsules	50 mg	Par Sterile Products, LLC	04/08/2013
285	DARAPRIM	Tablets	25 mg	Vyera Pharmaceuticals, LLC	03/2020
286	DAYTRANA	Patches	27.5 mg	Noven Pharmaceuticals, Inc.	06/05/2023
287	DAYTRANA	Patches	82.5 mg	Noven Pharmaceuticals, Inc.	06/05/2023
288	DAYTRANA	Patches	55.0 mg	Noven Pharmaceuticals, Inc.	06/05/2023
289	DAYTRANA	Patches	41.3 mg	Noven Pharmaceuticals, Inc.	06/05/2023
290	DDAVP	Nasal Solution	10 mcg / 0.1 mL	Ferring Pharmaceuticals, Inc.	07/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
291	DDAVP	Tablets	0.1 mg	Ferring Pharmaceuticals, Inc.	12/2015
292	DDAVP	Tablets	0.2 mg	Ferring Pharmaceuticals, Inc.	12/2015
293	DDAVP, DESMOPRESSIN ACETATE	Injection	40 mcg/10 mL	Ferring Pharmaceuticals Inc.	01/2016
294	DELESTROGEN	Injection	10 mg/mL	Par Sterile Products	06/01/2012
295	DELESTROGEN	Injection	40 mg/mL	Par Sterile Products	06/01/2012
296	DELESTROGEN	Injection	20 mg/mL	Par Sterile Products	06/01/2012
297	DEMSER	Capsules	250 mg	Bausch Health US, LLC	09/07/2020
298	DENAVIR	Cream	1%	Mylan Pharmaceuticals Inc.	11/16/2022
299	DEPAKOTE ER	Extended-release Tablets	500 mg	Abbvie Inc.	08/2013
300	DEPAKOTE ER	Extended-release Tablets	250 mg	Abbvie Inc.	08/2013
301	DEPAKOTE SPRINKLE CAPSULES	Capsules	125 mg	AbbVie Inc.	08/31/2015
302	DEPO-MEDROL	Injection	40 mg/mL	Pharmacia and Upjohn	05/2006 - 05/2007

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
303	DEPO-MEDROL	Injection	80 mg/mL	Pharmacia and Upjohn	05/2006 - 05/2007
304	DEPO-PROVERA	Injection	150 mg in 1 mL	Pfizer	7/13/2021
305	DEPO-PROVERA	Injection	150 mg in 1 mL	Pfizer	09/16/2004
306	DERMA-SMOOTH/FS (Body Oil)	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
307	DERMA-SMOOTH/FS (Scalp Oil)	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
308	DERMOTIC	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
309	DERMOTIC OIL	Oil	0.01%	Hill Dermaceuticals Inc.	08/20/2013
310	DESMOPRESSIN ACETATE	Nasal Spray	10 mcg per 0.1 mL (5 mL bottle)	Ferring Pharmaceuticals, Inc.	11/20/2014
311	DESOWEN	Cream	0.05%	Galderma Laboratories, L.P.	08/01/2013
312	DETROL	Tablets	1 mg	Upjohn US 2 LLC	01/2014
313	DETROL	Tablets	2 mg	Upjohn US 2 LLC	01/2014, 01/2016
314	DETROL LA	Extended-release Capsules	2 mg	Upjohn US 2 LLC	01/2016
315	DETROL LA	Extended-release Capsules	4 mg	Upjohn US 2 LLC	12/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
316	DEXEDRINE SPANSULE	Extended-release Capsules	5 mg	Impax Laboratories, LLC	08/1976
317	DEXEDRINE SPANSULE	Extended-release Capsules	15 mg	Impax Laboratories, LLC	08/1976
318	DEXEDRINE SPANSULE	Extended-release Capsules	10 mg	Impax Laboratories, LLC	08/1976
319	DEXILANT	Delayed-release Capsules	30 mg	Takeda Pharmaceuticals U.S.A., Inc.	01/2022
320	DEXILANT	Delayed-release Capsules	60 mg	Takeda Pharmaceuticals U.S.A., Inc.	01/2022
321	DIABETA	Tablets	2.5 mg	Sanofi-Aventis U.S., LLC	05/01/1984
322	DIABETA	Tablets	5 mg	Sanofi-Aventis U.S., LLC	05/01/1984
323	DIAMOX SEQUELS	Extended-release Capsules	500 mg	Teva Branded Pharmaceutical Products R&D, Inc.	12/2008
324	DIASTAT ACUDIAL	Gel	10 mg	Bausch Health US, LLC	07/1997
325	DIASTAT ACUDIAL	Gel	20 mg	Bausch Health US, LLC	07/1997

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
326	DIASTAT ACUDIAL	Gel	2.5 mg	Bausch Health US, LLC	07/1997
327	DIBENZYLINE	Capsules	10 mg	Advanz Pharma (US) Corp.	08/11/2015
328	DICLEGIS	Delayed-release Tablets	10 mg/10 mg	Duchesnay Inc.	11/2018
329	DIFFERIN CREAM 0.1%	Cream	0.1%	Galderma Laboratories, L.P.	10/2010
330	DIFFERIN GEL	Gel	0.3%	Galderma Laboratories, L.P.	04/2024
331	DIFLUCAN	Powder for Oral Suspension	40 mg	Pfizer Inc.	03/12/2004
332	DIFLUCAN	Powder for Oral Suspension	10 mg/mL when reconstituted	Pfizer Inc.	03/12/2004
333	DIFLUCAN	Powder for Oral Suspension	40 mg/mL when reconstituted	Pfizer Inc.	03/12/2004
334	DILANTIN	Tablet (INFATABS)	50 mg	Parke-Davis Division of Pfizer Inc.	12/27/2012
335	DILANTIN-125	Oral Suspension	125 mg/5 mL (237 mL bottle)	Viartis Specialty LLC	04/2020
336	DILAUDID	Solution	5 mg/5 mL (1 mg/mL)	Rhodes Pharmaceuticals L.P.	10/1/2012
337	DILAUDID	Tablets	4 mg	Rhodes Pharmaceuticals L.P.	11/23/2009

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
338	DILAUDID	Tablets	2 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
339	DILAUDID	Tablets	8 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
340	DIPROLENE	Ointment	0.05%	Organon LLC	8/10/2012
341	DITROPAN XL	Extended-release Tablets	5 mg	Janssen Research and Development, LLC	11/12/2015
342	DITROPAN XL	Extended-release Tablets	10 mg	Janssen Research and Development, LLC	11/12/2015
343	DIURIL	Injection	500 mg/vial, sterile lyophilized	Oak Pharmaceuticals Inc.	08/13/2012
344	DIVIGEL	Gel	0.1%/0.75 mg	Vertical Pharmaceuticals, LLC	10/10/2022
345	DIVIGEL	Gel	0.1%/1.25 mg	Vertical Pharmaceuticals, LLC	10/10/2022
346	DIVIGEL	Gel	0.1%/0.5 mg	Vertical Pharmaceuticals, LLC	10/10/2022
347	DIVIGEL	Gel	0.1%/0.25 mg	Vertical Pharmaceuticals, LLC	10/10/2022

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
348	DIVIGEL	Gel	0.1%/1.0 mg	Vertical Pharmaceuticals, LLC	10/10/2022
349	DORAL	Tablets	15 mg	Galt Pharmaceuticals, LLC	03/20/2018
350	DORIBAX	Powder for Injection	500 mg/vial	Shionogi Inc.	12/2016
351	DORIBAX	Powder for Injection	250 mg/vial	Shionogi Inc.	12/2016
352	DORYX	Delayed-Release Tablets	75 mg	Mayne Pharma International Pty Ltd.	07/08/2013
353	DORYX	Delayed-Release Tablets	80 mg	Mayne Pharma International Pty Ltd.	07/08/2013
354	DORYX	Delayed-Release Tablets	50 mg	Mayne Pharma International Pty Ltd.	05/2016
355	DORYX	Delayed-Release Tablets	200 mg	Mayne Pharma International Pty Ltd.	02/2016
356	DORYX	Delayed-Release Tablets	100 mg	Mayne Pharma International Pty Ltd.	07/08/2013
357	DORYX	Delayed-Release Tablets	150 mg	Mayne Pharma International Pty Ltd.	07/08/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
358	DOSTINEX	Tablets	0.5 mg	Pfizer Inc.	09/22/2014
359	DOVONEX	Cream	0.005%	LEO Pharma Inc.	2012
360	DOVONEX	Ointment	0.005%	LEO Pharma Inc.	07/01/2013
361	DOXIL	Injection (Liposomal formulation)	20 mg/10 mL single use vial	Janssen Research & Development, LLC	07/2017
362	DOXIL	Injection (Liposomal formulation)	50 mg/25 mL single use vial	Janssen Research & Development, LLC	07/2017
363	DOXORUBICIN	Injection	20 mg/10 mL	Pharmacia and Upjohn	4/1/2013
364	DOXORUBICIN	Injection	200 mg/100 mL	Pharmacia and Upjohn	4/1/2013
365	DOXORUBICIN	Injection	10 mg/5 mL	Pharmacia and Upjohn	03/17/2014
366	DOXORUBICIN	Injection	10 mg/5 mL	Pharmacia and Upjohn	4/1/2013
367	DOXORUBICIN	Injection	20 mg/10mL	Pharmacia and Upjohn	03/17/2014
368	DOXORUBICIN	Injection	50 mg/25 mL	Pharmacia and Upjohn	03/17/2014
369	DOXORUBICIN	Injection	150 mg/75 mL	Pharmacia and Upjohn	4/1/2013
370	DOXORUBICIN	Injection	50 mg/25 mL	Pharmacia and Upjohn	4/1/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
371	DOXORUBICIN	Injection	200 mg/ 100 mL	Pharmacia and Upjohn	03/17/2014
372	DUETACT	Tablets	30 mg / 4 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/04/2015
373	DUETACT	Tablets	30 mg / 2 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/04/2015
374	DUEXIS	Tablets	800 mg and 26.6 mg	Horizon Medicines LLC	09/2021
375	DUREZOL	Ophthalmic Emulsion	0.05%	Novartis Pharmaceuticals Corporation	09/2021
376	DYMISTA	Nasal Spray	137 mcg/50 mcg per spray	Viartis Specialty, LLC	04/14/2020
377	DYRENIUM	Capsules	50 mg	Advanz Pharma (US) Corp.	08/2019
378	DYRENIUM	Capsules	100 mg	Advanz Pharma (US) Corp.	08/2019
379	E.E.S. GRANULES	Suspension	200 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	09/2016
380	EDECIN	Powder, for Injection Solution, Lyophilized	50 mg/vial	Bausch Health Americas, Inc.	01/1967

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
381	EDECIN	Tablets	25 mg	Bausch Health Americas, Inc.	01/2016 - 01/2017
382	EFUDEX	Cream	5%	Extrovis AG	07/2013
383	ELDEPRYL	Capsules	5 mg	Somerset Pharmaceuticals, Inc.	05/1998 - 05/1999
384	ELDEPRYL	Tablets	5 mg	Somerset Pharmaceuticals, Inc.	06/1999 - 06/2000
385	ELIDEL	Cream	1%	Bausch Health US, LLC	12/2018
386	ELIMITE	Cream	5%	Aurobindo Pharma USA Inc.	06/2017
387	ELOXATIN	Injection	50 mg / 10 mL (5 mg/mL)	Sanofi-Aventis US LLC	07/07/2014
388	ELOXATIN	Injection	100 mg / 20 mL (5 mg/mL)	Sanofi-Aventis US LLC	07/07/2014
389	ELOXATIN (PREMIERPro)	Injection	100 mg / 20 mL (5 mg/mL)	Sanofi-Aventis US LLC	10/2015
390	ELOXATIN (PREMIERPro)	Injection	50 mg/10 mL (5 mg/mL)	Sanofi-Aventis US LLC	10/2015
391	EMLA	Cream	2.5% and 2.5%	Teva Branded Pharmaceutical Products R&D, Inc.	11/12/2012
392	ENTOCORT EC	Capsules	3 mg	Padagis US LLC	08/18/2011

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
393	EPANED	Oral Solution	1 mg/mL	Azurity Pharmaceuticals, Inc.	03/23/2022
394	EPCLUSA	Tablets	400 mg / 100 mg	Gilead Sciences, Inc.	10/2018
395	EPIDUO FORTE	Gel	0.3% and 2.5%	Galderma Laboratories, L.P.	02/2022
396	EPIPEN	Injection	0.3 mg/0.3 mL	Mylan Specialty L.P., a Viatris Company	12/15/2016
397	EPIPEN JR.	Injection	0.15/0.3 mL	Mylan Specialty L.P., a Viatris Company	12/15/2016
398	EPIVIR-HBV	Tablets	100 mg	GlaxoSmithKline LLC	09/05/2014
399	EPZICOM	Tablets	600 mg and 300 mg	ViiV Healthcare Company	09/2016
400	ERYC	Delayed-Release Capsules	250 mg	Dr. Reddy's Laboratories, Inc.	07/29/2013
401	ERYPED 200	Suspension	200 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	08/2020
402	ERYPED 400	Suspension	400 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	03/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
403	EVOXAC	Capsules	30 mg	Daiichi Sankyo, Inc.	03/2016
404	EXALGO	Extended-release Tablets	16 mg	SpecGx LLC	06/12/2014
405	EXALGO	Extended-release Tablets	12 mg	SpecGx LLC	06/12/2014
406	EXALGO	Extended-release Tablets	32 mg	SpecGx LLC	06/12/2014
407	EXALGO	Extended-release Tablets	8 mg	SpecGx LLC	06/12/2014
408	EXELDERM	Cream	1.0%	Journey Medical Corporation	02/2020
409	EXELDERM	Solution	1.0%	Journey Medical Corporation	02/2020
410	EXELON	Patch	9.5 mg/24 hours	Novartis Pharmaceuticals Corporation	09/2015
411	EXELON	Patch	13.3 mg/24 hours	Novartis Pharmaceuticals Corporation	09/2015
412	EXELON	Patch	4.6 mg/24 hours	Novartis Pharmaceuticals Corporation	09/2015
413	EXTINA	Aerosol Foam	2%	Mylan Pharmaceuticals Inc.	12/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
414	FABIOR	Aerosol Foam	0.1%	Mayne Pharma LLC	04/2021
415	FAMVIR	Tablets	125 mg	Novartis	03/22/2011
416	FAMVIR	Tablets	250 mg	Novartis	03/22/2011
417	FAMVIR FAMVIR	Tablets	500 mg	Novartis	03/22/2011
418	FARXIGA	Tablets	10 mg	AstraZeneca AB	01/03/2024
419	FARXIGA	Tablets	5 mg	AstraZeneca AB	01/03/2024
420	FEMCON Fe	Chewable Tablets	0.4 mg/35 mcg	Allergan Pharmaceuticals International Ltd.	10/2011
421	FENOGLIDE	Tablets	120 mg	Salix Pharmaceuticals, Inc.	06/24/2015
422	FENOGLIDE	Tablets	40 mg	Salix Pharmaceuticals, Inc.	06/24/2015
423	FENTORA	Tablet	200 mcg	Cephalon, Inc.	06/2019
424	FENTORA	Tablet	400 mcg	Cephalon, Inc.	06/2019
425	FENTORA	Tablet	800 mcg	Cephalon, Inc.	06/2019
426	FENTORA	Tablet	600 mcg	Cephalon, Inc.	06/2019
427	FINACEA	Gel	15%	LEO Pharma Inc.	10/2018
428	FIORICET with CODEINE	Capsules	50 mg / 325 mg / 40 mg / 30 mg	Teva Branded Pharmaceutical Products R&D, Inc.	10/01/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
429	FIRAZYR	Injection	30 mg / 3.0ML	Shire Human Genetic Therapies, Inc.	07/2019
430	FLECTOR	Topical System	1.3%	Institut Biochimique SA (IBSA)	03/2019
431	FLECTOR	Topical System	1.3%	Institut Biochimique SA (IBSA)	03/2019
432	FLEQSUVY	Suspension	5 mg/mL	Azurity Pharmaceuticals, Inc.	04/01/2023
433	FLORONE	Cream	0.05%	Pharmacia and Upjohn Company	Prior to 1/1/1999
434	FLOVENT DISKUS	Inhalation Powder	50 mcg	GlaxoSmithKline Intellectual Property Ltd England	10/30/2023
435	FLOVENT DISKUS	Inhalation Powder	100 mcg	GlaxoSmithKline Intellectual Property Ltd England	10/30/2023
436	FLOVENT DISKUS	Inhalation Powder	250 mcg	GlaxoSmithKline Intellectual Property Ltd England	10/30/2023
437	FLOVENT HFA	Inhalation Aerosol	110 mcg	GlaxoSmithKline Intellectual Property Ltd England	05/23/2022

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
438	FLOVENT HFA	Inhalation Aerosol	220 mcg	GlaxoSmithKline Intellectual Property Ltd England	05/23/2022
439	FLOVENT HFA	Inhalation Aerosol	44 mcg	GlaxoSmithKline Intellectual Property Ltd England	05/23/2022
440	FLUMADINE	Tablets	100 mg	Forest Laboratories, Inc.	09/2002 - 09/2003
441	FLUORESCEIN SODIUM AND BENOXINATE HYDROCHLORIDE	Ophthalmic Solution	0.3%/0.4%	Bausch + Lomb Ireland Limited	03/20/2020
442	FLUORESCEIN SODIUM AND BENOXINATE HYDROCHLORIDE	Ophthalmic Solution	0.3%/0.4%	Bausch + Lomb Ireland Limited	03/25/2021
443	FLUOXETINE	Tablets	60 mg	Alvogen Group Holdings 3, LLC	09/2017
444	FML	Ophthalmic Suspension	0.1%	Allergan, Inc.	10/1997
445	FOCALIN XR	Extended-release Capsules	15 mg	Novartis Pharmaceuticals Corporation	01/2014
446	FOCALIN XR	Extended-release Capsules	20 mg	Novartis Pharmaceuticals Corporation	06/2015
447	FOCALIN XR	Extended-release Capsules	30 mg	Novartis Pharmaceuticals Corporation	01/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
448	FOCALIN XR	Extended-release Capsules	5 mg	Novartis Pharmaceuticals Corporation	11/2014
449	FOCALIN XR	Extended-release Capsules	35 mg	Novartis Pharmaceuticals Corporation	01/2014
450	FOCALIN XR	Extended-release Capsules	10 mg	Novartis Pharmaceuticals Corporation	02/2015
451	FORFIVO XL	Extended-release Tablets	450 mg	TWi Pharmaceuticals, Inc.	08/2018
452	FORFIVO XL	Extended-release Tablets	450 mg	TWi Pharmaceuticals, Inc.	09/2018
453	FORTEO	Injection Solution	560 mcg/2.24 mL (250 mcg/mL)	Eli Lilly and Company	11/17/2023
454	FORTESA	Gel	10 mg testosterone/actuation	Endo Pharmaceuticals, Inc.	08/25/2014
455	FOSRENOL	Chewable Tablets	500 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/30/2017
456	FOSRENOL	Chewable Tablets	1000 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
457	FOSRENOL	Chewable Tablets	750 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/2017
458	FURADANTIN	Oral Suspension	25 mg / 5 mL, 50 mg / 5 mL	Casper Pharma LLC	12/23/2020, 02/01/2024
459	GABITRIL	Tablets	12 mg	Cephalon, Inc.	12/2012
460	GABITRIL	Tablets	4 mg	Cephalon Inc.	12/26/2012
461	GABITRIL	Tablets	16 mg	Cephalon, Inc.	12/2012
462	GABITRIL	Tablets	2 mg	Cephalon, Inc	12/26/2012
463	GASTROCROM	Oral Concentrate	100 mg/5 mL (ampule)	Viartis Specialty LLC	06/2015
464	GENERESS FE	Chewable Tablets	0.8 mg/25 mcg	Teva Branded Pharmaceuticals R&D LLC	03/2015
465	GEODON	Capsules	20 mg	Viartis Specialty LLC	12/15/2011
466	GEODON	Capsules	60 mg	Viartis Specialty LLC	12/15/2011
467	GEODON	Capsules	80 mg	Viartis Specialty LLC	12/15/2011
468	GEODON	Capsules	40 mg	Viartis Specialty LLC	12/15/2011
469	GLUCOTROL XL	Extended-release Tablets	2.5 mg	Pfizer Inc.	03/11/2004
470	GLUCOTROL XL	Extended-release Tablets	5 mg	Pfizer Inc.	03/11/2004

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
471	GLUCOTROL XL	Extended-release Tablets	10 mg	Pfizer Inc.	03/11/2004
472	GLUMETZA	Extended-release Tablets	1000 mg	Bausch Health US, LLC	06/2008
473	GLUMETZA	Extended-release Tablets	500 mg	Bausch Health US, LLC	06/2008
474	GOLYTELY	Powder for Oral Solution	PEG-3350 17.6 mmol/L, sodium 125 mmol/L, sulfate 40 mmol/L, chloride 35 mmol/L, bicarbonate 20 mmol/L and potassium 10 mmol/L (per 4 liter jug w/water)	Braintree Laboratories, Inc.	07/2009
475	GOPRELTO	Solution	4%	Genus Lifesciences Inc.	06/2018
476	GRIS-PEG	Tablets	250 mg	Bausch Health US, LLC	12/03/2012
477	GRIS-PEG	Tablets	125 mg	Bausch Health US, LLC	12/03/2012
478	HALCION	Tablets	0.25 mg	Pfizer Inc.	6/17/2003
479	HALCION	Tablets	0.125 mg	Pfizer Inc.	7/11/2003
480	HALDOL DECANOATE	Injection	50 mg/mL	Janssen Research & Development, LLC	08/2011
481	HALDOL DECANOATE	Injection	100 mg/mL	Janssen Research & Development, LLC	07/2011
482	HARVONI	Tablets	90 mg and 400 mg	Gilead Sciences, Inc.	01/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
483	HECTOROL	Capsules, liquid filled	2.5 mcg	Genzyme Corporation	03/11/2014
484	HECTOROL	Capsules, liquid filled	0.5 mcg	Genzyme Corporation	03/11/2014
485	HECTOROL	Capsules, liquid filled	1 mcg	Genzyme Corporation	03/11/2014
486	IMITREX	Injection	6 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
487	IMITREX	Injection	4 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
488	IMITREX	Nasal Spray	20 mg	GlaxoSmithKline Intellectual Property Ltd. England	03/2020
489	IMITREX	Nasal Spray	5 mg	GlaxoSmithKline Intellectual Property Ltd. England	03/2020
490	IMITREX (refill)	Injection	6 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
491	IMITREX (refill)	Injection	4 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
492	INDERAL LA	Extended-release Capsules	80 mg	ANI Pharmaceuticals, Inc.	12/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
493	INDERAL LA	Extended-release Capsules	160 mg	ANI Pharmaceuticals, Inc.	12/2017
494	INDERAL LA	Extended-release Capsules	60 mg	ANI Pharmaceuticals, Inc.	12/2017
495	INDERAL LA	Extended-release Capsules	120 mg	ANI Pharmaceuticals, Inc.	12/2017
496	INDERAL LA	Extended-release Capsules	60 mg	ANI Pharmaceuticals, Inc.	2/25/2009
497	INDERAL LA	Extended-release Capsules	80 mg	ANI Pharmaceuticals, Inc.	2/25/2009
498	INDERAL LA	Extended-release Capsules	120 mg	ANI Pharmaceuticals, Inc.	2/25/2009
499	INDERAL LA	Extended-release Capsules	160 mg	ANI Pharmaceuticals, Inc.	2/25/2009
500	INSPRA	Tablets	25 mg	Upjohn US 2 LLC	09/27/2002
501	INSPRA	Tablets	50 mg	Upjohn US 2 LLC	09/13/2007
502	INVANZ	Injection, Powder, Lyophilized, for Solution	1 g	Merck Sharp & Dohme LLC	07/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
503	INVEGA	Extended-release Tablets	6 mg	Janssen Research & Development, LLC	09/24/2015
504	INVEGA	Extended-release Tablets	9 mg	Janssen Research & Development, LLC	09/24/2015
505	INVEGA	Extended-release Tablets	3 mg	Janssen Research & Development, LLC	09/24/2015
506	INVEGA	Extended-release Tablets	1.5 mg	Janssen Research & Development, LLC	09/24/2015
507	IOPIDINE	Ophthalmic Solution	0.5%	Harrow Eye, LLC	08/2009
508	ISOPTO CARPINE	Ophthalmic Solution	4%	Novartis Pharmaceuticals Corporation	02/21/1996
509	ISOPTO CARPINE	Ophthalmic Solution	2%	Novartis Pharmaceuticals Corporation	02/21/1996
510	ISOPTO CARPINE	Ophthalmic Solution	1%	Novartis Pharmaceuticals Corporation	02/21/1996
511	ISORDIL TITRADOSE	Tablets	40 mg	Bausch Health US, LLC	03/02/2020
512	ISORDIL TITRADOSE	Tablets	5 mg	Bausch Health US, LLC	03/02/2020
513	ISTALOL	Solution	0.5%	Bausch & Lomb Incorporated	05/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
514	KADIAN	Extended-release Capsules	10 mg	Allergan Sales, LLC	11/11/2011
515	KADIAN	Extended-release Capsules	100 mg	Allergan Sales, LLC	11/11/2011
516	KADIAN	Extended-release Capsules	80 mg	Allergan Sales, LLC	11/11/2011
517	KADIAN	Extended-release Capsules	60 mg	Allergan Sales, LLC	11/11/2011
518	KADIAN	Extended-release Capsules	50 mg	Allergan Sales, LLC	11/11/2011
519	KADIAN	Extended-release Capsules	20 mg	Allergan Sales, LLC	11/11/2011
520	KADIAN	Extended-release Capsules	30 mg	Allergan Sales, LLC	11/11/2011
521	KAZANO	Tablets	12.5 mg/1000 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
522	KAZANO	Tablets	12.5 mg/500 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
523	K-DUR 10	Extended-release Tablets	10 mEq	Schering Corporation	06/2002 - 06/2003
524	K-DUR 20	Extended-release Tablets	20 mEq	Schering Corporation	06/1998 - 06/1999
525	KITABIS PAK	Inhalation Solution	300 mg/5 mL ampules	PulmoFlow Inc.	07/2016
526	KLARON	Lotion	10%	Bausch Health US, LLC	12/2005 - 12/2006
527	KORLYM	Tablets	300 mg	Corcept Therapeutics Incorporated	05/28/2024
528	K-TAB	Extended-release Tablets	20 mEq (1500 mg)	AbbVie Inc.	01/2014
529	K-TAB	Extended-release Tablets	8 mEq (600 mg)	AbbVie Inc.	02/2011
530	K-TAB	Extended-release Tablets	10 mEq (750 mg)	AbbVie Inc.	02/2011
531	LAC-HYDRIN	Cream	eq. 12% base	Bristol-Myers Squibb Company	07/2004 - 06/2005
532	LAC-HYDRIN	Lotion	eq. 12% base	Bristol-Myers Squibb Company	03/2004 - 02/2005
533	LESCOL XL	Extended-release Tablets	80 mg	Sandoz Inc.	05/2018
534	LEVO-T	Tablets	112 mcg	CEDIPROF, Inc.	08/2020
535	LEVO-T	Tablets	200 mcg	CEDIPROF, Inc.	08/2020
536	LEVO-T	Tablets	175 mcg	CEDIPROF, Inc.	08/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
537	LEVO-T	Tablets	150 mcg	CEDIPROF, Inc.	08/2020
538	LEVO-T	Tablets	50 mcg	CEDIPROF, Inc.	08/2020
539	LEVO-T	Tablets	25 mcg	CEDIPROF, Inc.	08/2020
540	LEVO-T	Tablets	300 mcg	CEDIPROF, Inc.	08/2020
541	LEVO-T	Tablets	125 mcg	CEDIPROF, Inc.	08/2020
542	LEVO-T	Tablets	100 mcg	CEDIPROF, Inc.	08/2020
543	LEVO-T	Tablets	88 mcg	CEDIPROF, Inc.	08/2020
544	LEVO-T	Tablets	75 mcg	CEDIPROF, Inc.	08/2020
545	LEVO-T	Tablets	137 mcg	CEDIPROF, Inc.	08/2020
546	LEXETTE	Foam	0.05%	Mayne Pharma LLC	02/2019
547	LIDEX	Topical Solution	0.05%	County Line Pharmaceuticals, LLC	03/2018
548	LIDODERM	Patch	700 mg (50 mg per gram adhesive) in an aqueous base	Teikoku Pharma USA, Inc.	05/2014
549	LIMBITROL	Tablets	5 mg; eq. 12.5 mg base	Valeant Pharmaceuticals International	01/2006 - 12/2006
550	LIMBITROL DS	Tablets	10 mg; eq. 25 mg base	Valeant Pharmaceuticals International	01/2007 - 12/2007
551	LIPOFEN	Capsules	150 mg	Cipher Pharmaceuticals Inc.	04/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
552	LIPOFEN	Capsules	50 mg	Cipher Pharmaceuticals Inc.	04/2016
553	LITHOBID	Extended-release Tablets	300 mg	ANI Pharmaceuticals, Inc.	12/2016
554	LOCOID	Cream	0.1%	Bausch Health U.S., LLC	07/2013
555	LOCOID	Lotion	0.1%	Bausch Health US, LLC	06/2018
556	LOCOID (Ointment)	Ointment	0.1%	Bausch Health US, LLC	10/2015 - 10/2016
557	LOCOID LIPOCREAM	Cream	0.1%	Bausch Health US, LLC	07/03/2013
558	LODOSYN	Tablets	25 mg	Bausch Health Americas, Inc.	04/04/2014
559	LOMOTIL	Tablets	2.5 mg/0.025 mg	Pfizer Inc.	08/07/2012, 03/06/2013
560	LOPRESSOR HCT	Tablets	1 mg/mL	Novartis Pharmaceuticals Corporation	03/1998 - 03/1999
561	LOPRESSOR HCT	Tablets	50mg / 25mg	Novartis Pharmaceuticals Corporation	11/25/2009
562	LOPRESSOR HCT	Tablets	100 mg / 25 mg	Novartis Pharmaceuticals Corporation	11/25/2009

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
563	LOPROX	Cream	0.77%	Medicis Pharmaceutical Corporation	12/2004 - 11/2005
564	LOPROX	Gel	0.77%	Alvogen, Inc.	07/2007 - 06/2008
565	LOPROX	Shampoo	1%	Medicis Pharmaceutical Corporation	12/2012
566	LoSEASONIQUE	Tablets	0.1 mg/0.02 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D LLC	12/07/2011
567	LOTEMAX	Gel	0.5%	Bausch & Lomb Incorporated	02/17/2021
568	LOTEMAX	Gel	0.5%	Bausch & Lomb Incorporated	06/30/2023
569	LOTEMAX	Ophthalmic Suspension	0.5%	Bausch & Lomb Incorporated	07/01/2019
570	LOTENSIN HCT	Tablets	20 mg; 25 mg	Validus Pharmaceuticals LLC	04/2019
571	LOTENSIN HCT	Tablets	20 mg; 12.5 mg	Validus Pharmaceuticals LLC	04/2019
572	LOTENSIN HCT	Tablets	10 mg; 12.5 mg	Validus Pharmaceuticals LLC	04/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
573	LOTRIMIN AF	Cream	1%	Schering-Plough HealthCare Products, Inc	03/1998 - 03/1999
574	LOTRONEX	Tablets	1 mg	Sebela Ireland Limited	05/2015
575	LOTRONEX	Tablets	1 mg	Sebela Ireland Limited	05/2015
576	LOTRONEX	Tablets	0.5 mg	Sebela Ireland Limited	05/2015
577	LOTRONEX	Tablets	0.5 mg	Sebela Ireland Limited	05/2015
578	LOVENOX	Injection	100 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
579	LOVENOX	Injection	120 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
580	LOVENOX	Injection	60 mg/0.6 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
581	LOVENOX	Injection	80 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
582	LOVENOX	Injection	30 mg/0.3 mL prefilled syringe	Sanofi Aventis US LLC	10/2011
583	LOVENOX	Injection	150 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
584	LOVENOX	Injection	300 mg/3 mL multi-dose vial	Sanofi Aventis US LLC	10/2011
585	LOVENOX	Injection	40 mg/0.4 mL prefilled syringe	Sanofi Aventis US LLC	10/2011

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
586	LOZOL	Tablets	2.5 mg	Rhone-Poulenc Rorer Pharmaceuticals Inc.	Prior to 1/1/1999
587	LUVOX	Tablets	50 mg	ANI Pharmaceuticals, Inc.	08/09/2011
588	LUVOX	Tablets	100 mg	ANI Pharmaceuticals, Inc.	08/09/2011
589	LUVOX	Tablets	25 mg	ANI Pharmaceuticals, Inc.	08/09/2011
590	LUZU	Cream	1%	Bausch Health US, LLC	07/2018
591	LYRICA	Capsules	25 mg	Upjohn US 2 LLC	07/2019
592	LYRICA	Capsules	75 mg	Upjohn US 2 LLC	07/2019
593	LYRICA	Capsules	50 mg	Upjohn US 2 LLC	07/2019
594	LYRICA	Capsules	225 mg	Upjohn US 2 LLC	07/2019
595	LYRICA	Capsules	200 mg	Upjohn US 2 LLC	07/2019
596	LYRICA	Capsules	150 mg	Upjohn US 2 LLC	07/2019
597	LYRICA	Capsules	100 mg	Upjohn US 2 LLC	07/2019
598	LYRICA	Capsules	300 mg	Upjohn US 2 LLC	07/2019
599	LYRICA	Oral Solution	20 mg/mL	Upjohn US 2 LLC	07/2019
600	LYSTEDA	Tablets	650 mg	Nordic Pharma Inc.	03/17/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
601	MACROBID	Capsules	100 mg	Almatica Pharma, LLC	05/25/2011
602	MACRODANTIN	Capsules	100 mg	Almatica Pharma LLC	08/2011
603	MACRODANTIN	Capsules	50 mg	Almatica Pharma LLC	08/2011
604	MACRODANTIN	Capsules	25 mg	Almatica Pharma LLC	09/2010
605	MALARONE	Tablets	250 mg/100 mg	GlaxoSmithKline LLC	7/31/2012
606	MARINOL	Capsules	10 mg	AbbVie Inc.	05/2017
607	MARINOL	Capsules	5 mg	AbbVie Inc.	05/2017
608	MARINOL	Capsules	2.5 mg	AbbVie Inc.	05/2017
609	MAXIMUM STRENGTH MUCINEX DM	Extended-release Tablets	1200 mg and 60 mg	RB Health (US) LLC	09/2017
610	MAXIMUM STRENGTH MUCINEX DM	Extended-release Tablets	1200 mg and 60 mg	RB Health (US) LLC	10/2017
611	MAXIMUM STRENGTH MUCINEX DM	Extended-release Tablets	1200 mg and 60 mg	RB Health (US) LLC	09/2017
612	MAXITROL	Ophthalmic Ointment	3.5 mg and 10000 units and 0.1% / gram	Novartis Pharmaceuticals Corporation	03/04/1996
613	MAXZIDE	Tablets	75 mg and 50 mg	Mylan Pharmaceuticals Inc.	Prior to 1/1/1999

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
614	MAXZIDE-25	Tablets	37.5 mg and 25 mg	Mylan Pharmaceuticals Inc.	Prior to 1/1/1999
615	MEDROL	Tablets	8 mg	Pfizer Inc.	4/22/2013
616	MEDROL	Tablets	16 mg	Pfizer Inc.	4/22/2013
617	MEDROL	Tablets	32 mg	Pfizer Inc.	4/22/2013
618	MEDROL	Tablets	4 mg	Pfizer Inc.	11/16/2011, 10/11/2011
619	MEGACE ES	Oral Suspension	625 mg/5 mL (125 mg/mL)	Endo Pharmaceuticals, Inc.	07/2015
620	MELOXICAM	Oral Suspension	7.5 mg / 5 mL	Avondale Pharmaceuticals, LLC	06/29/2022
621	MEPHYTON	Tablets	5 mg	Bausch Health Americas, Inc.	04/23/2018
622	MESNEX	Injection	100 mg/mL	Baxter Healthcare Corporation	12/2003 - 12/2004
623	MESTINON	Oral Solution	60 mg / 5 mL	Bausch Health US, LLC	07/2019
624	MESTINON	Tablets	60 mg	Bausch Health US, LLC	04/2002 - 03/2003
625	MESTINON TIMESPAN	Tablets	180 mg	Bausch Health US, LLC	11/2015
626	METADATE CD	Extended-release Capsules	10 mg	Lannett Company, Inc.	09/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
627	METADATE CD	Extended-release Capsules	20 mg	Lannett Company, Inc.	09/2012
628	METADATE CD	Extended-release Capsules	60 mg	Lannett Company, Inc.	09/2012
629	METADATE CD	Extended-release Capsules	50 mg	Lannett Company, Inc.	09/2012
630	METADATE CD	Extended-release Capsules	40 mg	Lannett Company, Inc.	09/2012
631	METADATE CD	Extended-release Capsules	30 mg	Lannett Company, Inc.	09/2012
632	METHYLIN	Oral Solution	5 mg/5 mL	Mallinckrodt Inc.	08/01/2013
633	METHYLIN	Oral Solution	10 mg/5 mL	Mallinckrodt Inc.	08/01/2013
634	METROCREAM	Cream	0.75%	Galderma Laboratories, L.P.	05/19/2025
635	METROCREAM	Cream	0.75%	Galderma Laboratories, L.P.	3/2009
636	METROGEL	Gel	1%	Galderma Laboratories, L.P.	11/10/2023, 05/19/2025
637	METROGEL	Gel	1%	Galderma Laboratories, L.P.	11/10/2023
638	METROGEL	Gel	1%	Galderma Laboratories, L.P.	02/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
639	METROGEL VAGINAL GEL	Vaginal Gel	0.75%	Bausch Health US, LLC	04/01/2015
640	METROLOTION	Lotion	0.75%	Galderma Laboratories, L.P.	02/10/2025
641	MIACALCIN	Nasal Spray	200 I.U. per actuation	Sebela Ireland Ltd.	12/09/2008
642	MICRONASE	Tablets	2.5 mg	Pharmacia and Upjohn	Prior to 1/1/1999
643	MICRONASE	Tablets	5 mg	Pharmacia and Upjohn	Prior to 1/1/1999
644	MICROZIDE	Capsules	12.5 mg	Teva Branded Pharmaceutical Products R&D LLC	10/05/2001
645	MIDAMOR	Tablets	5 mg	Padagis US LLC	04/06/2009
646	MIGRANAL	Nasal Spray	4 mg in 1 mL	Bausch Health US, LLC	03/18/2013
647	MINIPRESS	Capsules	1 mg	Pfizer Inc.	01/16/2017
648	MINIPRESS	Capsules	2 mg	Pfizer Inc.	01/16/2017
649	MINIPRESS	Capsules	2 mg	Pfizer Inc.	03/11/2022
650	MINIPRESS	Capsules	5 mg	Pfizer Inc.	01/16/2017
651	MINIPRESS	Capsules	1 mg	Pfizer Inc.	08/25/2021
652	MINIPRESS	Capsules	5 mg	Pfizer Inc.	03/11/2022
653	MINIVELLE	Film, Extended Release	0.075 mg per day	Noven Pharmaceuticals, Inc.	01/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
654	MINIVELLE	Film, Extended Release	0.1 mg per day	Noven Pharmaceuticals, Inc.	01/2018
655	MINIVELLE	Film, Extended Release	0.0375 mg per day	Noven Pharmaceuticals, Inc.	01/2018
656	MINIVELLE	Film, Extended Release	0.025 mg per day	Noven Pharmaceuticals, Inc.	01/2018
657	MINIVELLE	Film, Extended Release	0.05 mg per day	Noven Pharmaceuticals, Inc.	01/2018
658	MITIGARE	Capsules	0.6 mg	Hikma International Pharmaceuticals LLC	10/01/2014
659	MOBIC	Oral Suspension	7.5 mg/5 mL	Avondale Pharmaceuticals LLC	06/29/2022
660	MONODOX	Capsules	75 mg	Aqua Pharmaceuticals LLC	10/2014
661	MONODOX	Capsules	50 mg	Aqua Pharmaceuticals LLC	02/07/2005
662	MONODOX	Capsules	100 mg	Aqua Pharmaceuticals LLC	02/07/2005

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
663	MONOKET	Tablets	10 mg	ECI Pharmaceuticals LLC	06/30/1996 - 06/29/1997
664	MONUROL	Granules for Oral Solution	3 g	Zambon S.p.A.	01/27/2022
665	MOVIPREP	Powder for Oral Solution	100 g/7.5 g/2.691 g/1.015 g/5.9 g/4.7 g	Salix Pharmaceuticals, Inc.	09/2020
666	MOXATAG	Extended-Release Tablets	775 mg	Vernalis (R&D) Limited	08/20/2014
667	MOZOBIL	Injection, Solution	24 mg/1.2 mL	Genzyme Corporation	07/24/2023
668	MS CONTIN	Extended-release Tablets	15 mg	Purdue Pharma L.P.	05/2005 - 05/2006
669	MS CONTIN	Extended-release Tablets	30 mg	Purdue Pharma L.P.	05/2005 - 05/2006
670	MS CONTIN	Extended-release Tablets	60 mg	Purdue Pharma L.P.	05/2005 - 05/2006
671	MS CONTIN	Extended-release Tablets	100 mg	Purdue Pharma L.P.	05/2005 - 05/2006
672	MS CONTIN	Extended-release Tablets	200 mg	Purdue Pharma L.P.	05/2005 - 05/2006
673	MUCINEX	Extended-release Tablets	600 mg	RB Health (US), LLC	02/2018
674	MYAMBUTOL	Tablets	100 mg	STI Pharma LLC	12/15/2006
675	MYAMBUTOL	Tablets	400 mg	STI Pharma LLC	12/15/2006

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
676	MYCOBUTIN	Capsules	150 mg	Pfizer Inc.	05/13/2014
677	MYSOLINE	Tablets	250 mg	Bausch Health US, LLC	05/2018
678	MYSOLINE	Tablets	50 mg	Bausch Health US, LLC	05/2018
679	NALFON	Capsules	200 mg	Xspire Pharma LLC	04/2017
680	NALFON	Capsules	400 mg	Xspire Pharma LLC	05/2016
681	NALFON	Capsules	400 mg	Xspire Pharma LLC	08/05/2015
682	NAMENDA	Tablets	10 mg	Allergan Sales, LLC	04/01/2015
683	NAMENDA	Tablets	5 mg	Allergan Sales, LLC	04/01/2015
684	NAMENDA	Tablets	5 mg and 10 mg (titration pak)	Allergan Sales, LLC	04/01/2015
685	NAPRELAN	Controlled Release Tablets	375 mg	TWi Pharmaceuticals, Inc.	04/25/2024
686	NAPRELAN	Controlled Release Tablets	500 mg	TWi Pharmaceuticals, Inc.	04/25/2024
687	NAPRELAN	Controlled Release Tablets	750 mg	TWi Pharmaceuticals, Inc.	04/25/2024

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
688	NAPRELAN	Controlled-Release Tablets	375 mg	TWi Pharmaceuticals, Inc.	03/11/2015
689	NAPRELAN	Controlled-Release Tablets	500 mg	TWi Pharmaceuticals, Inc.	03/11/2015
690	NAPRELAN	Controlled-Release Tablets	750 mg	TWi Pharmaceuticals, Inc.	04/30/2026
691	NAPROSYN	Suspension	125 mg/5 mL	Atnahs Pharma US Limited	11/2016
692	NAPROSYN EC (EC-NAPROSYN)	Delayed-Release Tablets	500 mg	Atnahs Pharma US Limited	10/2018
693	NARDIL	Tablets	15 mg	Parke Davis	03/23/2011
694	NASACORT AQ	Nasal Spray Spray Bottle	55 mcg/spray	Sanofi Aventis US, LLC	06/15/2011
695	NATROBA	Topical Suspension	0.9%	ParaPRO LLC	06/2014
696	NEOPROFEN	Injection	20mg/2mL (10mg/mL)	Recordati Rare Diseases Inc.	04/2016
697	NESINA	Tablets	12.5 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/08/2016
698	NESINA	Tablets	6.25 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
699	NESINA	Tablets	25 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/08/2016
700	NEURONTIN	Capsules	100 mg	Viartis Specialty LLC	3/17/2004
701	NEURONTIN	Capsules	300 mg	Viartis Specialty LLC	03/17/2004
702	NEURONTIN	Capsules	400 mg	Viartis Specialty LLC	3/17/2004
703	NEURONTIN	Oral Solution	250 mg per 5 mL	Viartis Specialty LLC	3/24/2011
704	NEURONTIN	Tablets	600 mg	Viartis Specialty LLC	3/17/2004
705	NEURONTIN	Tablets	800 mg	Viartis Specialty LLC	3/17/2004
706	NIASPAN	Extended-release Tablets	750 mg	AbbVie Inc.	06/30/2014
707	NIASPAN	Extended-release Tablets	500 mg	AbbVie Inc.	06/30/2014
708	NIASPAN	Extended-release Tablets	1000 mg	AbbVie Inc.	06/30/2014
709	NICORETTE	Chewing Gum	2 mg	GlaxoSmithKline Consumer Healthcare L.P.	01/2002 - 01/2003
710	NICORETTE	Chewing Gum	4 mg	GlaxoSmithKline Consumer Healthcare L.P.	06/2001 - 06/2002

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
711	NILANDRON	Tablets	150 mg	Advanz Pharma (US) Corp.	11/2019
712	NITRO-DUR	Transdermal	0.4 mg/hr	USpharma Ltd.	04/2020
713	NITRO-DUR	Transdermal	0.2 mg/hr	USpharma Ltd.	04/2020
714	NITRO-DUR	Transdermal	0.6 mg/hr	USpharma Ltd.	04/2020
715	NITRO-DUR	Transdermal	0.1 mg/hr	USpharma Ltd.	04/2020
716	NITROLINGUAL PUMPSPRAY	Lingual Spray	400 mcg per Spray	G. Pohl-Boskamp GmbH & Co.	02/01/2011
717	NITROSTAT	Tablets	0.6 mg	Viartis Speciality LLC	08/26/2016
718	NITROSTAT	Tablets	0.4 mg	Viartis Speciality LLC	08/26/2016
719	NITROSTAT	Tablets	0.3 mg	Viartis Speciality LLC	08/26/2016
720	NORPACE	Capsules	100 mg	Pfizer Inc.	04/23/2019
721	NORPACE	Capsules	150 mg	Pfizer Inc.	04/23/2019
722	NORPRAMIN	Tablets	150 mg	Sanofi-Aventis US LLC	04/2014
723	NORPRAMIN	Tablets	10 mg	Sanofi-Aventis US LLC	04/2014
724	NORPRAMIN	Tablets	25 mg	Sanofi-Aventis US LLC	04/2014
725	NORPRAMIN	Tablets	50 mg	Sanofi-Aventis US LLC	Prior to 1/1/1999
726	NORPRAMIN	Tablets	75 mg	Sanofi-Aventis US LLC	04/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
727	NORPRAMIN	Tablets	100 mg	Sanofi-Aventis US LLC	04/2014
728	NOR-QD	Tablets	0.35 mg	Teva Branded Pharmaceutical Products R&D LLC	06/06/2003
729	NORVASC	Tablets	2.5 mg	Viartis Specialty LLC	6/15/2006
730	NORVASC	Tablets	5 mg	Viartis Specialty LLC	6/15/2006
731	NORVASC	Tablets	10 mg	Viartis Specialty LLC	6/15/2006
732	NOXAFIL	Delayed-release Tablets	100 mg	Merck Sharp & Dohme LLC	08/30/2019
733	NOXAFIL	Oral Suspension	40 mg/mL	Merck Sharp & Dohme LLC	3/29/2023
734	NULYTELY	Powder (for reconstitution with water)	Per 4 liter jug: polyethylene glycol 3350 420 g, sodium bicarbonate 5.72 g, sodium chloride 11.2 g, potassium chloride 1.48 g, flavoring 2 g	Braintree Laboratories, Inc.	02/2013
735	NUMBRINO	Nasal Solution	4%	Lannett Company, Inc.	09/2020
736	NUVARING	Vaginal Ring	11.7 mg / 2.7 mg (delivers 0.12 mg/0.015 mg per day)	Organon USA LLC	12/16/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
737	NUVIGIL	Tablets	150 mg	Teva Pharmaceuticals USA	11/2016
738	NUVIGIL	Tablets	250 mg	Teva Pharmaceuticals USA	12/2016
739	NUVIGIL	Tablets	50 mg	Teva Pharmaceuticals USA	11/2016
740	NUVIGIL	Tablets	200 mg	Teva Pharmaceuticals USA	12/2016
741	NUVIGIL	Tablets	150 mg	Teva Pharmaceuticals USA	12/2016
742	NUVIGIL	Tablets	250 mg	Teva Pharmaceuticals USA	11/2016
743	NUVIGIL	Tablets	200 mg	Teva Pharmaceuticals USA	11/2016
744	OLUX	Foam	0.05%	Mylan Pharmaceuticals Inc.	12/2018
745	OLUX-E	Emulsion, Aerosol Foam	0.05%	Mylan Pharmaceuticals Inc., a Viatris Company	01/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
746	OMNIPRED	Ophthalmic Suspension	1%	Novartis Pharmaceuticals Corporation	01/1995
747	OPTIVAR	Ophthalmic Solution	0.05%	Meda Pharmaceuticals, Inc.	03/10/2011
748	ORABLOC	Injection	4% and 1:200,000	Pierrel S.p.A.	10/2016
749	ORABLOC	Injection	4% and 1:100,000	Pierrel S.p.A.	10/2016
750	ORACEA	Capsule	40mg	Galderma Laboratories, L.P.	2/27/2023
751	ORAPRED ODT	Orally Disintegrating Tablets	15 mg	Concordia Pharmaceuticals Inc.	10/2015
752	ORAPRED ODT	Orally Disintegrating Tablets	30 mg	Concordia Pharmaceuticals Inc.	10/2015
753	ORAPRED ODT	Orally Disintegrating Tablets	10 mg	Concordia Pharmaceuticals Inc.	10/2015
754	OSENI	Tablets	25 mg/30 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
755	OSENI	Tablets	25 mg/45 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
756	OSENI	Tablets	12.5 mg/30 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
757	OSENI	Tablets	25 mg/15 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
758	OTOVEL	Otic Solution	0.3% / 0.025%	Laboratorios SALVAT, S.A.	11/2019
759	OVIDE	Lotion	0.5%	Taro Pharmaceuticals USA, Inc.	08/02/2008 - 08/01/2009
760	OXANDRIN	Tablets	2.5 mg	Savient Pharmaceuticals, Inc.	06/2006 - 05/2007
761	OXANDRIN	Tablets	10 mg	Savient Pharmaceuticals, Inc.	06/2006 - 05/2007
762	OXYCODONE HYDROCHLORIDE	Oral Solution	5 mg/5 mL	Genus Lifesciences, Inc.	09/2013
763	OXYCONTIN	Extended-release Tablets	40 mg	Purdue Pharma L.P.	04/2022
764	OXYCONTIN	Extended-release Tablets	10 mg	Purdue Pharma L.P.	04/2022
765	OXYCONTIN	Extended-release Tablets	20 mg	Purdue Pharma L.P.	04/2022
766	OXYCONTIN	Extended-release Tablets	20 mg	Purdue Pharma L.P.	03/24/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
767	OXYCONTIN	Extended-release Tablets	40 mg	Purdue Pharma L.P.	03/24/2015
768	OXYCONTIN	Extended-release Tablets	80 mg	Purdue Pharma L.P.	03/24/2015
769	OXYCONTIN	Extended-release Tablets	80 mg	Purdue Pharma L.P.	04/2022
770	OXYCONTIN	Extended-release Tablets	10 mg	Purdue Pharma L.P.	03/24/2015
771	OZOBAX	Solution	10mg/5mL	Metacel Pharmaceuticals, LLC	10/12/2023
772	OZOBAX	Solution	10mg/5mL	Metacel Pharmaceuticals, LLC	03/05/2024
773	OZOBAX	Solution	5mg/5mL	Metacel Pharmaceuticals, LLC	03/15/2022
774	PARAPLATIN	for Injection	50 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
775	PARAPLATIN	for Injection	150 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
776	PARAPLATIN	for Injection	450 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
777	PARAPLATIN AQ	Injection	eq. 50 mg/5 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
778	PARAPLATIN AQ	Injection	eq. 150 mg/15 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
779	PARAPLATIN AQ	Injection	eq. 450 mg/45 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
780	PARAPLATIN AQ	Injection	eq. 600 mg/60 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
781	PARNATE	Tablets	10 mg	ADVANZ PHARMA (US) Corp.	02/05/2016
782	PATADAY	Ophthalmic Solution	0.2%	Alcon Laboratories	06/2017
783	PATADAY	Ophthalmic Solution	0.1%	Alcon Laboratories, Inc.	09/2015
784	PATANOL	Ophthalmic Solution	0.1%	Novartis Pharmaceuticals Corporation	09/15/2015
785	PAXIL CR	Controlled-Release Tablets	12.5 mg	Apotex Inc.	08/09/2019
786	PAXIL CR	Controlled-Release Tablets	25 mg	Apotex Inc.	08/09/2019
787	PAXIL CR	Controlled-Release Tablets	37.5 mg	Apotex, Inc.	08/09/2019
788	PEDIAPRED	Oral Solution	5 mg / 5 mL	Seton Pharmaceuticals, LLC	02/2002
789	PERFOROMIST	Inhalation Solution	20 mcg/2 mL	Mylan Specialty L.P.	07/2021

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
790	PHOSLO	Gelcaps	667 mg	Fresenius Medical Care North America	03/2014 - 03/2015
791	PLAN B ONE-STEP	Tablets	1.5 mg	Foundation Consumer Healthcare, LLC	02/12/2014
792	PLAQUENIL	Tablets	200 mg	Concordia Pharmaceuticals Inc.	05/1999 - 04/2000
793	PLENDIL	Extended-release Tablets	2.5 mg	AstraZeneca LP	10/2008
794	PLENDIL	Extended-release Tablets	5 mg	AstraZeneca LP	10/2008
795	PLENDIL	Extended-release Tablets	10 mg	AstraZeneca LP	10/2008
796	PLIAGLIS	Cream	7%/7%	Taro Pharmaceuticals USA, Inc.	11/2017
797	POLYTRIM	Ophthalmic Solution	10 mL unit	Allergan, Inc.	04/29/1997
798	PONSTEL	Capsules	250 mg	Shionogi, Inc.	07/11/2011
799	POTASSIUM CHLORIDE FOR ORAL SOLUTION	Powder for Solution	20 mEq	Pharma Research Software Solution, LLC	01/2017
800	POTASSIUM CHLORIDE FOR ORAL SOLUTION	Powder for Solution	20 mEq	Pharma Research Software Solution, LLC	09/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
801	POTASSIUM CHLORIDE ORAL SOLUTION, USP, 10%	Oral Solution	20 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
802	POTASSIUM CHLORIDE ORAL SOLUTION, USP, 10%	Oral Solution	20 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
803	POTASSIUM CHLORIDE ORAL SOLUTION, USP, 20%	Oral Solution	40 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
804	PRAVACHOL	Tablets	10 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
805	PRAVACHOL	Tablets	20 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
806	PRAVACHOL	Tablets	40 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
807	PRAVACHOL	Tablets	80 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
808	PRED FORTE	Ophthalmic Suspension	1%	Allergan, Inc.	08/1997
809	PREVACID	Delayed-Release Capsules	15 mg	Takeda Global Research & Development Center, Inc.	11/2009
810	PREVACID	Delayed-Release Capsules	30 mg	Takeda Global Research & Development Center, Inc.	11/2009

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
811	PREVPAC	Delayed-Release Capsules, Capsules, and Tablets	30 mg, 500 mg, and 500 mg	Takeda Pharmaceuticals U.S.A., Inc.	03/02/2015
812	PROAIR HFA	Inhalation Aerosol	90 mcg per acutation	Teva Branded Pharmaceuticals Products R&D LLC	01/2019
813	PROLENSA	Solution	0.07%	Bausch & Lomb Incorporated	1/8/2024
814	PROTOPIC	Ointment	0.03%	LEO Pharma Inc.	11/2014
815	PROTOPIC	Ointment	0.1%	LEO Pharma Inc.	11/2014
816	PROVENTIL HFA	Inhalation Aerosol	108 mcg per actuation	Kindeva Drug Delivery L.P.	03/2021
817	PROVERA	Tablets	2.5 mg	Pfizer	6/18/2003
818	PROVERA	Tablets	10 mg	Pfizer	6/18/2003
819	PROVERA	Tablets	5 mg	Pfizer	6/18/2003
820	PROVIGIL	Tablets	200 mg	Cephalon Inc.	03/29/2012
821	PROVIGIL	Tablets	100 mg	Cephalon, Inc.	03/29/2012
822	PURIXAN	Oral Suspension	20 mg/mL	Nova Laboratories Limited	12/04/2025
823	QUALAQUIN	Capsules	324 mg	Sun Pharmaceutical Industries, Inc.	07/23/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
824	QUARTETTE	Tablets	0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg, and 0.01 mg	Teva Branded Pharmaceutical Products R&D LLC	04/2017
825	QUDEXY XR	Extended-release Capsules	200 mg	Upsher-Smith Laboratories, LLC	07/07/2014
826	QUDEXY XR	Extended-release Capsules	50 mg	Upsher-Smith Laboratories, LLC	07/07/2014
827	QUDEXY XR	Extended-release Capsules	25 mg	Upsher-Smith Laboratories, LLC	07/07/2014
828	QUDEXY XR	Extended-release Capsules	100 mg	Upsher-Smith Laboratories, LLC	07/07/2014
829	QUDEXY XR	Extended-release Capsules	150 mg	Upsher-Smith Laboratories, LLC	07/07/2014
830	RAPAMUNE	Oral Solution	1 mg/mL	PF Prism C.V.	07/2019
831	RAPAMUNE	Tablets	2 mg	PF Prism C.V.	10/27/2014
832	RAPAMUNE	Tablets	0.5 mg	PF Prism C.V.	01/16/2014
833	RAPAMUNE	Tablets	1 mg	PF Prism C.V.	10/27/2014
834	RAZADYNE	Tablets	4 mg	Janssen Research & Development, LLC	08/28/2008
835	RAZADYNE	Tablets	8 mg	Janssen Research & Development, LLC	08/28/2008

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
836	RAZADYNE ER	Capsules	8 mg	Janssen Research & Development, LLC	10/13/2008
837	RAZADYNE ER	Capsules	16 mg	Janssen Research & Development, LLC	10/13/2008
838	RAZADYNE ER	Capsules	24 mg	Janssen Research & Development, LLC	10/13/2008
839	REGLAN	Injection	eq. 5 mg base/mL	Baxter Healthcare Corporation	02/2003 - 02/2004
840	REGLAN	Tablets	5 mg	ANI Pharmaceuticals, Inc.	12/2021
841	REGLAN	Tablets	10 mg	ANI Pharmaceuticals, Inc.	12/2021
842	RELEXXII	Extended-release Tablets	54 mg	Osmotica Pharmaceutical US LLC	11/01/2023, 08/12/2024
843	RELEXXII	Extended-release Tablets	27 mg	Osmotica Pharmaceutical US LLC	11/01/2023, 08/12/2024
844	RELEXXII	Extended-release Tablets	18 mg	Osmotica Pharmaceutical US LLC	11/01/2023, 08/12/2024
845	RELEXXII	Extended-release Tablets	45 mg	Osmotica Pharmaceutical US LLC	06/23/2022

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
846	RELEXXII	Extended-release Tablets	63 mg	Osmotica Pharmaceutical US LLC	06/23/2022
847	RELEXXII	Extended-release Tablets	36 mg	Osmotica Pharmaceutical US LLC	11/01/2023, 08/12/2024
848	RELEXXII	Extended-release Tablets	72 mg	Osmotica Pharmaceutical US LLC	06/23/2022
849	REVELA	Tablets	800 mg	Genzyme Corporation	04/16/2014
850	RESTORIL	Capsules	15 mg	Mallinckrodt Pharmaceuticals	04/20/2020
851	RESTORIL	Capsules	30 mg	Mallinckrodt Pharmaceuticals	08/02/2021
852	RESTORIL	Capsules	22.5 mg	Mallinckrodt Pharmaceuticals	07/21/2008
853	RESTORIL	Capsules	7.5 mg	Mallinckrodt Pharmaceuticals	07/22/2008
854	RETIN-A	Cream	0.05%	Bausch Health US, LLC	07/19/1974
855	RETIN-A	Cream	0.1 %	Bausch Health US, LLC	01/26/1973
856	RETIN-A	Cream	0.05%	Bausch Health US, LLC	12/2018
857	RETIN-A	Cream	0.025%	Bausch Health US, LLC	04/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
858	RETIN-A	Cream	0.1%	Bausch Health US, LLC	07/2019
859	RETIN-A	Gel	0.01%	Bausch Health US, LLC	08/2019
860	RETIN-A	Gel	0.025%	Bausch Health US, LLC	06/2005
861	RETIN-A MICRO	Gel	0.04 %	Bausch Health US, LLC	08/2019
862	RETIN-A MICRO	Gel	0.04%	Bausch Health US, LLC	03/2013
863	RETIN-A MICRO	Gel	0.1 %	Bausch Health US, LLC	03/2013
864	RETIN-A MICRO	Gel	0.1 %	Bausch Health US, LLC	08/2019
865	REVATIO	Tablets	20 mg	Viartis Specialty LLC	09/27/2012, 11/09/2020
866	RITALIN	Tablet	10 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
867	RITALIN	Tablet	20 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
868	RITALIN	Tablet	5 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
869	RITALIN LA	Capsules	40 mg	Novartis Pharmaceuticals Corp	11/2015
870	RITALIN LA	Capsules	20 mg	Novartis Pharmaceuticals Corp	11/2015
871	RITALIN LA	Capsules	30 mg	Novartis Pharmaceuticals Corp	11/2015
872	RITALIN LA	Capsules	10 mg	Novartis Pharmaceuticals Corp	02/2018
873	ROBINUL	Injection	0.2 mg/mL	Eurohealth International Sarl	02/06/1975
874	ROBINUL	Tablets	1 mg	Casper Pharma LLC	01/13/2005
875	ROBINUL FORTE	Tablets	2 mg	Casper Pharma LLC	01/13/2005
876	ROCALTROL	Oral Solution	1 mcg/mL (15 mL bottle)	Validus Pharmaceuticals LLC	08/26/2009
877	ROGAINE (FOR MEN)	Topical Solution	2%	McNeil-PPC, Inc.	06/1998 - 05/1999
878	ROGAINE (FOR WOMEN)	Topical Solution	2%	McNeil-PPC, Inc.	06/1998 - 05/1999
879	ROGAINE EXTRA STRENGTH (FOR MEN)	Topical Solution	5%	McNeil-PPC, Inc.	2004

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
880	ROSZET	Tablets	5 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
881	ROSZET	Tablets	40 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
882	ROSZET	Tablets	20 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
883	ROSZET	Tablets	10 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
884	ROWASA	Rectal Suspension Enema	4 g/60 mL	Viartis Specialty LLC	05/13/2016
885	SAFRYAL	Tablets	3 mg / 0.03 mg / 0.451 mg	Bayer HealthCare LLC	08/2015
886	SALAGEN	Tablets	5 mg	Concordia Pharmaceuticals Inc.	12/2004
887	SALAGEN	Tablets	7.5 mg	Concordia Pharmaceuticals Inc.	03/2006 - 01/2007
888	SAMSCA	Tablets	15 mg	Otsuka Pharmaceutical Company, Ltd.	10/2020
889	SAPHRIS SAPHRIS	Sublingual Tablets	5 mg	Allergan Sales, LLC	05/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
890	SAPHRIS SAPHRIS	Sublingual Tablets	2.5 mg	Allergan Sales, LLC	05/2020
891	SAPHRIS SAPHRIS	Sublingual Tablets	10 mg	Allergan Sales, LLC	12/2020
892	SEASONALE	Tablets	0.15 mg/0.03 mg	Teva Branded Pharmaceutical Products R&D LLC	9/7/2006
893	SEASONIQUE	Tablets	0.15 mg/0.03 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D LLC	07/28/2011
894	SECTRAL	Capsules	eq. 200 mg base	Wyeth Laboratories, Inc.	Prior to 1/1/1999
895	SECTRAL	Capsules	eq. 400 mg base	Wyeth Laboratories, Inc.	Prior to 1/1/1999
896	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2016
897	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
898	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	01/2015
899	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	01/2015
900	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	04/2016
901	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
902	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	04/2019
903	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	04/2019
904	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
905	SEROQUEL XR	Extended-release Tablets	200 mg	AstraZeneca UK Limited	05/2017
906	SEROQUEL XR	Extended-release Tablets	50 mg	AstraZeneca UK Limited	11/2016
907	SEROQUEL XR	Extended-release Tablets	200 mg	AstraZeneca UK Limited	11/2016
908	SEROQUEL XR	Extended-release Tablets	50 mg	AstraZeneca UK Limited	05/2017
909	SEROQUEL XR	Extended-release Tablets	150 mg	AstraZeneca UK Limited	11/2016
910	SEROQUEL XR	Extended-release Tablets	300 mg	AstraZeneca UK Limited	05/2017
911	SEROQUEL XR	Extended-release Tablets	400 mg	AstraZeneca UK Limited	05/2017
912	SEROQUEL XR	Extended-release Tablets	150 mg	AstraZeneca UK Limited	05/2017
913	SEROQUEL XR	Extended-release Tablets	300 mg	AstraZeneca UK Limited	11/2016
914	SERTRALINE	Capsules	150 mg	Almatica Pharma, LLC	09/22/2025
915	SERTRALINE	Capsules	200 mg	Almatica Pharma, LLC	09/22/2025
916	SILENOR	Tablets	3 mg	Currax Pharmaceuticals LLC	08/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
917	SILENOR	Tablets	6 mg	Currax Pharmaceuticals LLC	08/2010
918	SILVADENE	Cream	1%	King Pharmaceuticals LLC	01/16/2018, 02/09/2018
919	SOLARAZE	Gel	3%	Fougera Pharmaceuticals, Inc.	11/21/2013
920	SOMA	Tablet	250 mg	Viartis Specialty LLC	9/13/2010
921	SOOLANTRA	Cream	1%	Galderma Laboratories, L.P.	1/8/2024
922	SORILUX	Foam	0.005%	Mayne Pharma LLC	02/2021
923	SPECTRACEF	Tablets	200 mg	Vansen Pharma, Inc.	Unknown
924	SPECTRACEF	Tablets	400 mg	Vansen Pharma, Inc.	Unknown
925	SPORANOX	Capsule	100 mg	Janssen Pharmaceuticals, Inc.	2/01/2005
926	SPORANOX	Oral Solution	10 mg/mL	Janssen Research & Development, LLC	10/2018
927	STALEVO 100	Film-coated Tablets	25 mg, 100 mg, 200 mg	Orion Corporation	06/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
928	STALEVO 125	Film-coated Tablets	31.25 mg, 125 mg, 200 mg	Orion Corporation	06/2014
929	STALEVO 150	Film-coated Tablets	37.5 mg, 150 mg, 200 mg	Orion Corporation	06/2014
930	STALEVO 200	Film-coated Tablets	50 mg, 200 mg, 200 mg	Orion Corporation	06/2014
931	STALEVO 50	Film-coated Tablets	12.5 mg, 50 mg, 200 mg	Orion Corporation	06/2014
932	STALEVO 75	Film-coated Tablets	18.75 mg, 75 mg, 200 mg	Orion Corporation	06/2014
933	SULAR	Extended-release Tablets	8.5 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
934	SULAR	Extended-release Tablets	17 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
935	SULAR	Extended-release Tablets	34 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
936	SUPRAX	Capsules	400 mg	Lupin Limited	10/2020
937	SUPREP	Oral Solution (concentrate)	17.5g / 3.13g / 1.6g	Braintree Laboratories, Inc.	08/2010
938	SYMBICORT	Metered Dose Inhaler	80/4.5 mcg	AstraZeneca Pharmaceuticals LP	01/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
939	SYMBICORT	Metered Dose Inhaler	160/4.5 mcg	AstraZeneca Pharmaceuticals LP	01/2020
940	SYNALAR	Cream	.1 mg/g	Medimetriks Pharmaceuticals, Inc.	5/7/2024
941	SYNALAR	Cream	.25 mg/g	Medimetriks Pharmaceuticals, Inc.	5/7/2024
942	SYNALAR	Ointment	0.025%	Medimetriks Pharmaceuticals, Inc.	11/2023
943	SYNALAR	Ointment	0.025%	Medimetriks Pharmaceuticals, Inc.	11/16/2023
944	SYNALGOS-DC	Capsules	356.4 mg/30 mg/16 mg	Sun Pharmaceutical Industries, Inc.	10/01/2012
945	SYPRINE	Capsules	250 mg	Bausch Health Americas, Inc.	02/2018
946	TACLONEX	Ointment	0.005%/0.064%	LEO Pharma A/S	01/2020
947	TAMBOCOR	Tablets	50 mg	3M Pharmaceuticals	10/2002
948	TAMBOCOR	Tablets	100 mg	3M Pharmaceuticals	10/2002
949	TAMBOCOR	Tablets	150 mg	3M Pharmaceuticals	10/2002

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
950	TARGRETIN	Gel	1%	Bausch Health Ireland Limited	06/2022
951	TASMAR	Tablets	100 mg	Bausch Health US, LLC	07/27/2004
952	TAXOTERE	Injection Concentrate	160 mg/8 mL (20 mg/mL)	Sanofi Aventis US LLC	10/2016
953	TAXOTERE	Injection Concentrate	80 mg/4 mL (20 mg/mL)	Sanofi Aventis US LLC	03/2011
954	TAXOTERE	Injection Concentrate	20 mg/mL	Sanofi Aventis US LLC	03/2011
955	TAYTULLA	Capsules	1 mg/20 mcg	Allergan Pharmaceuticals International Ltd	11/2020
956	TAZORAC	Cream	0.1%	Allergan Aesthetics, an Abbvie Company	10/2016
957	TAZORAC	Cream	0.05%	Allergan Aesthetics, an Abbvie Company	10/2016
958	TEGRETOL XR	Tablets	100 mg	Novartis Pharmaceuticals Corporation	07/2018
959	TEGRETOL XR	Tablets	200 mg	Novartis Pharmaceuticals Corporation	06/15/2009

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
960	TEGRETOL XR	Tablets	400 mg	Novartis Pharmaceuticals Corporation	06/15/2009
961	TESTIM	Gel	50 mg in 5 g	Auxilium Pharmaceuticals, Inc.	06/09/2014
962	TETRACAINE HYDROCHLORIDE	Ophthalmic Solution	0.5%	Bausch + Lomb Ireland Limited	06/2019
963	THIOLA EC	Tablets	100 mg	Mission Pharmacal Company	12/05/2024
964	THIOLA EC	Tablets	300 mg	Mission Pharmacal Company	12/05/2024
965	TIAZAC	Extended-release Capsules	180 mg	Bausch Health US, LLC	08/20/2014
966	TIAZAC	Extended-release Capsules	240 mg	Bausch Health US, LLC	08/20/2014
967	TIAZAC	Extended-release Capsules	300 mg	Bausch Health US, LLC Bausch Health US, LLC	08/20/2014
968	TIAZAC	Extended-release Capsules	360 mg	Bausch Health US, LLC	08/20/2014
969	TIAZAC	Extended-release Capsules	420 mg	Bausch Health US, LLC	08/20/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
970	TIAZAC	Extended-release Capsules	120 mg	Bausch Health US, LLC	08/20/2014
971	TIGAN	Injection	100 mg/mL	Par Sterile Products, LLC	06/01/2012
972	TIMOPTIC	Ophthalmic Solution	0.5%	Bausch & Lomb Incorporated	06/2020
973	TIMOPTIC	Ophthalmic Solution	0.5%	Bausch & Lomb Incorporated	06/2020
974	TIMOPTIC in OCUDOSE	Solution	0.5%	Bausch & Lomb Incorporated	04/2021
975	TIMOPTIC-XE	Solution	0.5%	Bausch & Lomb Incorporated	02/14/2018
976	TIMOPTIC-XE	Solution	0.25%	Bausch & Lomb Incorporated	02/14/2018
977	TIROSINT	Capsules	125 mcg	IBSA Pharma Inc.	03/01/2023
978	TIROSINT	Capsules	88 mcg	IBSA Pharma Inc.	03/01/2023
979	TIROSINT	Capsules	75 mcg	IBSA Pharma Inc.	03/01/2023
980	TIROSINT	Capsules	50 mcg	IBSA Pharma Inc.	03/01/2023
981	TIROSINT	Capsules	13 mcg	IBSA Pharma Inc.	03/01/2023
982	TIROSINT	Capsules	25 mcg	IBSA Pharma Inc.	03/01/2023
983	TIROSINT	Capsules	150 mcg	IBSA Pharma Inc.	03/01/2023
984	TIROSINT	Capsules	175 mcg	IBSA Pharma Inc.	03/01/2023
985	TIROSINT	Capsules	100 mcg	IBSA Pharma Inc.	03/01/2023
986	TIROSINT	Capsules	200 mcg	IBSA Pharma Inc.	03/01/2023

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
987	TIROSINT	Capsules	112 mcg	IBSA Pharma Inc.	03/01/2023
988	TIROSINT	Capsules	137 mcg	IBSA Pharma Inc.	03/01/2023
989	TIVORBEX	Capsules	20 mg	Genus Lifesciences Inc.	01/2020
990	TIVORBEX	Capsules	40 mg	Genus Lifesciences Inc.	01/2020
991	TOBI	Solution for Inhalation	300 mg/5 mL ampule	Mylan Specialty, L.P., a Viatris Company	07/2014
992	TOBRADEX	Ophthalmic Suspension	0.3% and 0.1%	Novartis Pharmaceuticals Corporation	01/02/2009
993	TOFRONIL PM	Capsules	75 mg	Mallinckrodt Inc.	4/2006
994	TOFRONIL PM	Capsules	100 mg	Mallinckrodt Inc.	4/2006
995	TOFRONIL PM	Capsules	125 mg	Mallinckrodt Inc.	4/2006
996	TOFRONIL PM	Capsules	150 mg	Mallinckrodt Inc.	4/2006
997	TOPROL XL	Extended-release Tablets	200 mg	Melinta Therapeutics, LLC	01/2018
998	TOPROL XL	Extended-release Tablets	100 mg	Melinta Therapeutics, LLC	01/2018
999	TOPROL XL	Extended-release Tablets	50 mg	Melinta Therapeutics, LLC	01/2018
1000	TOPROL XL	Extended-release Tablets	25 mg	Melinta Therapeutics, LLC	01/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1001	TRAVATAN Z	Ophthalmic Solution	0.004%	Novartis Pharmaceuticals Corporation	12/2019
1002	TREXIMET	Tablets	85 mg/500 mg	Currax Pharmaceuticals LLC	02/2018
1003	TRIBENZOR	Tablets	20 mg/5 mg/12.5 mg	Cosette Pharmaceuticals, Inc.	10/2016
1004	TRIBENZOR	Tablets	40 mg/10 mg/25 mg	Cosette Pharmaceuticals, Inc.	10/2016
1005	TRIBENZOR	Tablets	40 mg/10 mg/12.5 mg	Cosette Pharmaceuticals, Inc.	10/2016
1006	TRIBENZOR	Tablets	40 mg/5 mg/25 mg	Cosette Pharmaceuticals, Inc.	10/2016
1007	TRIBENZOR	Tablets	40 mg/5 mg/12.5 mg	Cosette Pharmaceuticals, Inc.	10/2016
1008	TRILEPTAL	Oral Suspension	300 mg/5 mL	Novartis Pharmaceuticals Corporation	12/2009
1009	TRILIPIX	Delayed Release Capsules	45 mg	AbbVie Inc.	09/12/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1010	TRILIPIX	Delayed Release Capsules	135 mg	AbbVie Inc.	09/12/2016
1011	TRI-NORINYL	Tablets	0.5 mg and 0.035 mg, 1 mg and 0.035 mg	Mayne Pharma LLC	1/12/2005
1012	TUSSIONEX	Extended-Release Suspension	10 mg hydrocodone bitartrate & 8 mg chlorpheniramine maleate per 5 mL	UCB, Inc.	10/2010
1013	UCERIS	Extended-Release Tablets	9 mg	Salix Pharmaceuticals Inc.	07/2018
1014	ULTRAVATE	Cream	0.05%	Bristol-Myers Squibb Company	11/2004 - 10/2005
1015	ULTRAVATE	Ointment	0.05%	Bristol-Myers Squibb Company	11/2004 - 10/2005
1016	UNITHROID	Tablets	137 mcg (0.137 mg)	Jerome Stevens Pharmaceuticals, Inc.	unknown
1017	UNITHROID	Tablets	25 mcg (0.025 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1018	UNITHROID	Tablets	50 mcg (0.05 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1019	UNITHROID	Tablets	75 mcg (0.075 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1020	UNITHROID	Tablets	88 mcg (0.088 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1021	UNITHROID	Tablets	100 mcg (0.1 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1022	UNITHROID	Tablets	112 mcg (0.112 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1023	UNITHROID	Tablets	125 mcg (0.125 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1024	UNITHROID	Tablets	150 mcg (0.15 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1025	UNITHROID	Tablets	175 mcg (0.175 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1026	UNITHROID	Tablets	200 mcg (0.2 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1027	UNITHROID	Tablets	300 mcg (0.3 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1028	UREX	Tablets	1 gram	County Line Pharmaceuticals, LLC	05/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1029	UROCIT-K	Extended-release Tablets	540 mg (5 mEq per tablet)	Mission Pharmacal Company	11/2007
1030	UROCIT-K	Extended-release Tablets	15 mEq (1620 mg) per tablet	Mission Pharmacal Company	12/23/2013
1031	URSO 250	Tablets	250 mg	Allergan Sales, LLC	07/06/2009
1032	URSO FORTE	Tablets	500 mg	Allergan Sales, LLC	07/06/2009
1033	VAGISTAT-1	Vaginal Ointment	6.50%	Bristol-Myers Squibb Company	02/1998 - 02/1999
1034	VANCOGIN	Capsules	125 mg	ANI Pharmaceuticals Inc.	10/26/2015
1035	VANCOGIN	Capsules	250 mg	ANI Pharmaceuticals Inc.	10/26/2015
1036	VASERETIC	Tablets	10 mg/25 mg	Valeant Pharmaceuticals North America, LLC	10/31/1986
1037	VASOTEC	Tablets	20 mg	Bausch Health US, LLC	12/24/1985
1038	VASOTEC	Tablets	10 mg	Bausch Health US, LLC	12/24/1985
1039	VASOTEC	Tablets	5 mg	Bausch Health US, LLC	12/24/1985

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1040	VASOTEC	Tablets	2.5 mg	Bausch Health US, LLC	07/26/1988
1041	VECTICAL	Ointment	3 mcg/g	Galderma Laboratories, L.P.	02/28/2012
1042	VECTICAL	Ointment	3 mcg/g	Galderma Laboratories, L.P.	7/21/2023
1043	VELTIN	Gel	1.2%/0.025%	Almirall, LLC	06/2018
1044	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	37.5 mg	Osmotica Pharmaceutical US LLC	04/2010
1045	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	225 mg	Osmotica Pharmaceutical US LLC	04/2010
1046	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	150 mg	Osmotica Pharmaceutical US LLC	04/2010
1047	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	75 mg	Osmotica Pharmaceutical US LLC	04/2010
1048	VENOFER	Injection	2% w/v iron (Fe)	Luitpold Pharmaceuticals, Inc.	10/02/08
1049	VENTOLIN HFA	Metered-dose Inhaler	90 mcg per actuation	GlaxoSmithKline Intellectual Property Mgmt Ltd	01/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1050	VERELAN	Sustained-release Capsules	120 mg	Azurity Pharmaceuticals, Inc.	5/17/1999
1051	VERELAN	Sustained-release Capsules	180 mg	Azurity Pharmaceuticals, Inc.	5/17/1999
1052	VERELAN	Sustained-release Capsules	240 mg	Azurity Pharmaceuticals, Inc.	5/17/1999
1053	VERELAN	Sustained-release Capsules	360 mg	Azurity Pharmaceuticals, Inc.	5/17/1999
1054	VERELAN PM	Extended-release Capsules	100 mg	Azurity Pharmaceuticals, Inc.	11/2006 - 11/2007
1055	VERELAN PM	Extended-release Capsules	200 mg	Azurity Pharmaceuticals, Inc.	11/2006 - 11/2007
1056	VERELAN PM	Extended-release Capsules	300 mg	Azurity Pharmaceuticals, Inc.	11/2006 - 11/2007
1057	VFEND	Powder for Oral Suspension	40 mg/mL (75 mL when reconstituted)	PF Prism C.V.	12/16/2013
1058	VIAGRA	Tablets	100 mg	Viartis Specialty LLC	12/01/2017
1059	VIAGRA	Tablets	50 mg	Viartis Specialty LLC	12/01/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1060	VIAGRA	Tablets	25 mg	Viatrix Specialty LLC	12/01/2017
1061	VIBRAMYCIN	Capsules	100 mg	Pfizer Inc.	05/2015
1062	VIGAMOX	Ophthalmic Solution	0.5%	Harrow Eye, LLC	07/01/2017
1063	VIRAZOLE	Inhalation Solution, USP	100 mL/6G Vial	Bausch Health US, LLC	4/15/2020
1064	VIRAZOLE	Powder for Solution	6g/100 mL vial, to be reconstituted	Bausch Health US, LLC	04/2017
1065	VISTARIL	Capsules	50 mg	Pfizer Inc.	07/15/2020
1066	VIVELLE-DOT	Transdermal System	0.1 mg	Sandoz Inc	12/2014
1067	VIVELLE-DOT	Transdermal System	0.0375 mg	Sandoz, Inc	12/2014
1068	VIVELLE-DOT	Transdermal System	0.025 mg	Sandoz Inc	12/2014
1069	VIVELLE-DOT	Transdermal System	0.05 mg	Sandoz Inc	12/2014
1070	VIVELLE-DOT	Transdermal System	0.075 mg	Novartis Pharmaceuticals Corporation	12/2014
1071	VOGELXO	Gel	50 mg	Upsher-Smith Laboratories, LLC	06/2014
1072	VOLTAREN	Delayed-release Tablets	25 mg	Novartis Pharmaceuticals Corporation	Prior to 1/1/1999

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1073	VOLTAREN	Delayed-release Tablets	50 mg	Novartis Pharmaceuticals Corporation	Prior to 1/1/1999
1074	VOLTAREN	Gel	1%	GlaxoSmithKline Consumer Healthcare	07/2016
1075	VOLTAREN XR	Extended-release Tablets	100 mg	Novartis Pharmaceuticals Corporation	05/22/2000
1076	VUEWAY	Injection	50 mL vial label	Guerbet	09/21/2022
1077	VUEWAY	Injection	30 mL vial label	Guerbet	09/21/2022
1078	VUEWAY	Injection	10 mL vial label	Guerbet	09/21/2022
1079	VUEWAY	Injection	3 mL vial label	Guerbet	09/21/2022
1080	VUEWAY	Injection	100 mL vial label	Guerbet	09/21/2022
1081	VUEWAY	Injection	7.5 mL vial label	Guerbet	09/21/2022
1082	VUSION	Ointment	0.25%, 15%, and 81.35%	Mylan Pharmaceuticals Inc., a Viatris Company	11/06/2018
1083	WELCHOL	Powder for Oral Suspension	3.75 g packet	Cosette Pharmaceuticals, Inc.	08/01/2022
1084	WELCHOL	Tablets	625mg	Cosette Pharmaceuticals, Inc.	8/1/2022
1085	XALATAN	Ophthalmic Solution	0.005% (125 mcg/2.5 mL)	Upjohn US 2 LLC, a Viatris company	11/15/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1086	XANAX	Tablets	0.25 mg	Upjohn US 2 LLC	06/17/2003
1087	XANAX	Tablets	0.5 mg	Upjohn US 2 LLC	06/18/2003
1088	XANAX	Tablets	1 mg	Upjohn US 2 LLC	06/18/2003
1089	XANAX	Tablets	2 mg	Upjohn US 2 LLC	06/18/2003
1090	XANAX XR	Extended-release Tablets	0.5 mg	Upjohn US 2 LLC	01/17/2003
1091	XANAX XR	Extended-release Tablets	1 mg	Upjohn US 2 LLC	01/17/2003
1092	XANAX XR	Extended-release Tablets	2 mg	Upjohn US 2 LLC	01/17/2003
1093	XANAX XR	Extended-release Tablets	3 mg	Upjohn US 2 LLC	01/17/2003
1094	XENAZINE	Tablets	25 mg	Bausch Health US, LLC	07/20/2015
1095	XENAZINE	Tablets	12.5 mg	Bausch Health US, LLC	07/20/2015
1096	XENICAL	Capsules	120 mg	CHEPLAPHARM Arzneimittel GmbH	6/1/2022
1097	XIGDUO XR	Tablets	5 mg/1000 mg	AstraZeneca Pharmaceuticals LP	01/03/2024
1098	XIGDUO XR	Tablets	10 mg/1000 mg	AstraZeneca Pharmaceuticals LP	01/03/2024

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1099	XIMINO	Extended-release Capsules	90 mg	Journey Medical Corporation	04/2020
1100	XIMINO	Extended-release Capsules	135 mg	Journey Medical Corporation	04/2020
1101	XIMINO	Extended-release Capsules	45 mg	Journey Medical Corporation	04/2020
1102	XOPENEX	Inhalation Solution	1.25 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1103	XOPENEX	Inhalation Solution	0.63 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1104	XOPENEX	Inhalation Solution	0.31 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1105	XOPENEX HFA	Aerosol, metered	45 mcg/actuation 45 mcg/actuation	Lupin Inc	10/2016
1106	XYREM	Oral Solution	.5g/mL	Jazz Pharmaceuticals, Inc.	7/3/2023
1107	XYREM	Oral Solution	.5g/mL	Jazz Pharmaceuticals, Inc.	1/3/2023

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1108	YASMIN	Tablets	3 mg; 0.03 mg	Bayer HealthCare Pharmaceuticals Inc.	05/09/2008
1109	ZANAFLEX	Capsule	6 mg	Covis Pharma GmbH	10/2011
1110	ZANAFLEX	Capsule	4 mg	Covis Pharma GmbH	10/2011
1111	ZAROXOLYN	Tablets	10 mg	Lannett Company, Inc.	10/2018
1112	ZAROXOLYN	Tablets	2.5 mg	Lannett Company, Inc.	10/2018
1113	ZAROXOLYN	Tablets	5 mg	Lannett Company, Inc.	11/2002 - 10/2003
1114	ZAVESCA	Capsules	100 mg	Actelion Pharmaceuticals Ltd.	04/2018
1115	ZEBETA	Tablets	5 mg	Lederle Laboratories	08/2000 - 08/2001
1116	ZEBETA	Tablets	10 mg	Lederle Laboratories	08/2000 - 08/2001
1117	ZEGERID	Capsules	40 mg/1100 mg	Salix Pharmaceuticals, Inc.	02/27/2006
1118	ZEGERID	Capsules	20 mg/1100 mg	Salix Pharmaceuticals, Inc.	02/27/2006

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1119	ZEGERID	Powder for Oral Suspension	40 mg/1680 mg	Salix Pharmaceuticals, Inc.	06/2014
1120	ZEGERID	Powder for Oral Suspension	20 mg/1680 mg	Salix Pharmaceuticals, Inc.	06/2014
1121	ZEMPLAR	Capsules	2 mcg	AbbVie Inc.	03/2014
1122	ZEMPLAR	Capsules	1 mcg	AbbVie Inc.	03/2014
1123	ZENPEP	Delayed Release Capsules	5000 lipase USP units	Eurand Pharmaceuticals, Ltd.	12/2/2009
1124	ZIAC	Tablets	2.5 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D LLC	08/2019
1125	ZIAC	Tablets	5 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D LLC	08/2019
1126	ZIAC	Tablets	10 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D LLC	08/2019
1127	ZIANA	Gel	1.2% and 0.025%	Bausch Health US, LLC	09/2020
1128	ZIOPTAN	Sterile Ophthalmic Solution	0.0015%	Thea Pharma Inc.	11/18/2022

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1129	ZITHROMAX	Powder for Oral Suspension	600 mg (15 mL when mixed)	Pfizer Inc.	02/1/2005
1130	ZITHROMAX	Powder for Oral Suspension	900 mg (22.5 mL when mixed)	Pfizer Inc.	02/01/2005
1131	ZITHROMAX	Powder for Oral Suspension	1 gram (single dose packet)	Pfizer Inc.	2/1/2005
1132	ZITHROMAX	Powder for Oral Suspension	1200 mg (30 mL when mixed)	Pfizer Inc.	02/01/2005
1133	ZITHROMAX	Tablets	250 mg	Pfizer Inc.	02/01/2005
1134	ZOLOFT	Oral Solution, Concentrate	20 mg/mL	Viartis Specialty LLC	05/15/2018
1135	ZOMIG	Nasal Spray	5 mg	Amneal Pharmaceuticals LLC	07/15/2024
1136	ZOMIG	Nasal Spray	2.5 mg	Amneal Pharmaceuticals LLC	07/15/2024
1137	ZONALON and PRUDOXIN	Cream	5%	Mylan Pharmaceuticals, Inc.	01/04/2019
1138	ZOVIRAX	Cream	5%	Bausch Health US, LLC	08/2019
1139	ZOVIRAX	Ointment	5%	Bausch Health US, LLC	04/2014
1140	ZYCLARA	Cream	3.75%	Bausch Health US, LLC	07/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1141	ZYCLARA	Cream	3.75%	Bausch Health US, LLC	08/2018
1142	ZYLOPRIM	Tablet	300 mg	Casper Pharma LLC	11/17/2022
1143	ZYLOPRIM	Tablets	200 mg	Casper Pharma LLC	11/17/2022
1144	ZYLOPRIM	Tablets	100 mg	Casper Pharma LLC	11/17/2022
1145	ZYMAXID	Ophthalmic Solution	0.5%	Allergan Sales, LLC	04/2015
1146	ZYVOX	Oral Suspension	100 mg/5 mL	Pfizer Inc.	12/21/2015
1147	ZYVOX	Tablets	600 mg	Pfizer Inc.	12/21/2015