

FDA Listing of Authorized Generics as of January 8, 2025

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	40 mg	Sun Pharmaceutical Industries, Inc.	12/2020
2	ABSORICA	Capsules	10 mg	Sun Pharmaceutical Industries, Inc.	12/2020
3	ABSORICA	Capsules	35 mg	Sun Pharmaceutical Industries, Inc.	12/2020
4	ABSORICA	Capsules	30 mg	Sun Pharmaceutical Industries, Inc.	12/2020
5	ABSORICA	Capsules	25 mg	Sun Pharmaceutical Industries, Inc.	12/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
6	ABSORICA	Capsules	20 mg	Sun Pharmaceutical Industries, Inc.	12/2020
7	ACANYA	Gel	1.2% / 2.5%	Bausch Health Americas, Inc.	07/2018
8	ACCOLATE	Tablets	10 mg	AstraZeneca Pharmaceuticals	11/19/2010
9	ACCOLATE	Tablets	20 mg	AstraZeneca Pharmaceuticals	11/19/2010
10	ACEPHEN	Suppositories	120 mg	G & W Laboratories, Inc.	Prior to 1/1/1999
11	ACETADOTE	Injection	6 g/30 mL (200 mg/mL)	Cumberland Pharmaceuticals, Inc.	1/7/2013
12	ACTICLATE	Tablets	75 mg	Almirall, LLC	02/2018
13	ACTICLATE	Tablets	150 mg	Almirall, LLC	02/2018
14	ACTIGALL	Capsules	300 mg	Allergan Sales, LLC	08/13/2003
15	ACTIQ	Lozenge	800 mcg	Cephalon, LLC	09/26/2006
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	1200 mcg	Cephalon, LLC	09/26/2006
20	ACTIQ	Lozenge	1600 mcg	Cephalon, LLC	09/26/2006
21	ACTONEL	Tablets	150 mg	Allergan Pharmaceuticals International Ltd.	06/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
22	ACULAR LS	Ophthalmic Solution	0.4%	Allergan, Inc.	11/11/2013
23	ACZONE	Gel	7.5%	Almirall, LLC	01/2020
24	ADDERALL XR	Extended-release Capsules	5 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
25	ADDERALL XR	Extended-release Capsules	15 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
26	ADDERALL XR	Extended-release Capsules	15 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
27	ADDERALL XR	Extended-release Capsules	30 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
28	ADDERALL XR	Extended-release Capsules	25 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
29	ADDERALL XR	Extended-release Capsules	20 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
30	ADDERALL XR	Extended-release Capsules	10 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
31	ADDERALL XR	Extended-release Capsules	25 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
32	ADDERALL XR	Extended-release Capsules	20 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
33	ADDERALL XR	Extended-release Capsules	30 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
34	ADDERALL XR	Extended-release Capsules	10 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
35	ADDERALL XR	Extended-release Capsules	5 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
36	ADRENACLICK	Injection	0.3 mg	Impax Laboratories, LLC	04/01/2010
37	ADRENACLICK	Injection	0.15 mg	Impax Laboratories, LLC	04/01/2010
38	ADVAIR DISKUS	Inhalation Powder	500/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019
39	ADVAIR DISKUS	Inhalation Powder	250/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019
40	ADVAIR DISKUS	Inhalation Powder	100/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019
41	ADVAIR HFA	Inhalation Aerosol	230/21 MCG	GlaxoSmithKline Intellectual Property Ltd. England	3/1/2023

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
42	ADVAIR HFA	Inhalation Aresol	45/21 MCG	GlaxoSmithKline Intellectual Property Ltd. England	3/1/2023
43	ADVAIR HFA	Inhalation Aresol	115/21 MCG	GlaxoSmithKline Intellectual Property Ltd. England	3/1/2023
44	AGGRASTAT	Solution for Injection Premixed	0.25 mg/mL	Medicure International Inc.	3/2024
45	AIRDUO RESPICLICK	Inhalation Powder	232 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
46	AIRDUO RESPICLICK	Inhalation Powder	113 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
47	AIRDUO RESPICLICK	Inhalation Powder	55 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
48	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
49	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
50	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2012
51	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
52	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
53	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
54	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
55	ALDACTAZIDE	Tablet	25 mg/25 mg	Pfizer Inc.	12/01/2021
56	ALDACTAZIDE	Tablets	25 mg/25 mg	Pfizer Inc.	10/06/2003
57	ALINIA	Tablets	500 mg	Romark Laboratories, L.C.	02/2021
58	ALLEGRA	Tablets	30 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
59	ALLEGRA	Tablets	60 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
60	ALLEGRA	Tablets	180 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
61	ALLEGRA-D 12 HOUR	Extended-release Tablets	60 mg/120 mg	Sanofi Aventis US LLC	12/2004 - 12/2005
62	AMARYL	Tablets	1 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
63	AMARYL	Tablets	2 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
64	AMARYL	Tablets	4 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
65	AMBIEN CR	Extended-release Tablets	6.25 mg	Sanofi Aventis U.S. LLC	10/2010
66	AMBIEN CR	Extended-release Tablets	12.5 mg	Sanofi Aventis U.S. LLC	12/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
67	AMICAR	Tablets	1000 mg	Clover Pharmaceuticals Corporation	06/01/2012
68	AMITIZA	Capsule	24 mcg	Sucampo Pharma Americas, LLC	1/1/2023
69	AMITIZA	Capsule	8 mcg	Sucampo Pharma Americas, LLC	1/1/2023
70	AMITIZA	Capsule	8 mcg	Sucampo Pharma Americas, LLC	1/1/2023
71	AMITIZA	Capsule	24 mcg	Sucampo Pharma Americas LLC	1/1/2023
72	AMITIZA	Capsules	24 mcg	Sucampo Pharma Americas, LLC	01/2021
73	AMITIZA	Capsules	8 mcg	Sucampo Pharma Americas, LLC	01/2021
74	AMMONUL	Injection	10% / 10%	Bausch Health US, LLC	03/2017
75	AMPYRA	Tablets	10 mg	Acorda Therapeutics, Inc.	09/2018
76	AMRIX	Capsules	15 mg	Cephalon, Inc.	03/2019
77	AMRIX	Capsules	15 mg	Cephalon, Inc.	03/2019
78	AMRIX	Capsules	30 mg	Cephalon, Inc.	03/2019
79	AMRIX	Capsules	30 mg	Cephalon, Inc.	03/2019
80	ANAFRANIL	Capsules	75 mg	Mallinckrodt	07/2015
81	ANAFRANIL	Capsules	50 mg	Mallinckrodt	07/2015
82	ANAFRANIL	Capsules	25 mg	Mallinckrodt	07/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
83	ANAPROX DS	Tablets	550 mg	Atnahs Pharma US Limited	10/2018
84	ANCOBAN	Capsules	500 mg	Bausch Health US, LLC	01/17/2012
85	ANCOBAN	Capsules	250 mg	Bausch Health US, LLC	07/2017
86	ANGIOMAX	Powder, for injection solution, lyophilized	250 mg	Sandoz Inc.	10/2015
87	ANGIOMAX	Powder, for injection solution, lyophilized	250 mg	Sandoz Inc.	02/2017
88	ANTARA	Capsules	130 mg	Lupin, Inc.	02/22/2013
89	ANTARA	Capsules	43 mg	Lupin, Inc.	02/22/2013
90	ANTIVERT	Tablets	12.5 mg	Casper Pharma LLC	01/2020
91	ANTIVERT	Tablets	25 mg	Casper Pharma LLC	01/2020
92	APADAZ	Tablets	8.16 mg / 325 mg	KVK-Tech, Inc.	06/2019
93	APRISO	Extended-release Capsules	0.375 g	Salix Pharmaceuticals, Inc.	07/19/2018
94	APTENSIO XR	Extended-release Capsules	10 mg	Rhodes Pharmaceuticals L.P.	04/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
95	APTENSIO XR	Extended-release Capsules	60 mg	Rhodes Pharmaceuticals L.P.	04/2020
96	APTENSIO XR	Extended-release Capsules	50 mg	Rhodes Pharmaceuticals L.P.	04/2020
97	APTENSIO XR	Extended-release Capsules	40 mg	Rhodes Pharmaceuticals L.P.	04/2020
98	APTENSIO XR	Extended-release Capsules	30 mg	Rhodes Pharmaceuticals L.P.	04/2020
99	APTENSIO XR	Extended-release Capsules	20 mg	Rhodes Pharmaceuticals L.P.	04/2020
100	APTENSIO XR	Extended-release Capsules	15 mg	Rhodes Pharmaceuticals L.P.	04/2020
101	ARAVA	Tablets	10 mg	Sanofi Aventis US LLC	09/07/2015
102	ARAVA	Tablets	20 mg	Sanofi Aventis US LLC	09/07/2015
103	ARICEPT	Film coated tablets	5 mg	Eisai, Inc.	11/25/2009 - 11/24/2010
104	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
105	ARICEPT ODT	Orally disintegrating tablets	10 mg	Eisai, Inc.	10/18/2009 - 11/24/2010
106	ARICEPT ODT	Orally distinegrating tablets	5 mg	Eisai, Inc.	10/18/2009 - 11/24/2010
107	ARIXTRA	Injection	7.5 mg / 0.6 mL	Mylan Ireland Limited	12/2014 - 12/2015
108	ARIXTRA	Injection	5 mg / 0.4 mL	Mylan Ireland Limited	12/2014 - 12/2015
109	ARIXTRA	Injection	2.5 mg / 0.5 mL	Mylan Ireland Limited	12/2014 - 12/2015
110	ARIXTRA	Injection	10 mg / 0.8 mL	Mylan Ireland Limited	12/2014 - 12/2015
111	AROMASIN	Tablets	25 mg	Pfizer Inc.	11/02/2010
112	ARTHROTEC	Tablets	75 mg/200 mcg	Pfizer Inc.	07/10/2011
113	ARTHROTEC	Tablets	50 mg/200 mcg	Pfizer Inc.	07/10/2011
114	ATACAND	Tablets	4 mg	ANI Pharmaceuticals, Inc.	05/21/2013
115	ATACAND	Tablets	16 mg	ANI Pharmaceuticals, Inc.	05/21/2013
116	ATACAND	Tablets	32 mg	ANI Pharmaceuticals, Inc.	05/21/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
117	ATACAND	Tablets	8 mg	ANI Pharmaceuticals, Inc.	05/21/2013
118	ATACAND HCT	Tablets	32 mg/25 mg	ANI Pharmaceuticals, Inc.	09/2018
119	ATACAND HCT	Tablets	16 mg/12.5 mg	ANI Pharmaceuticals, Inc.	09/2018
120	ATACAND HCT	Tablets	32 mg/12.5 mg	ANI Pharmaceuticals, Inc.	09/2018
121	ATELVIA	Delayed-release Tablets	35 mg	Allergan	2015
122	ATIVAN	Injection	2 mg/mL	Baxter Healthcare Corporation	10/31/2003
123	ATIVAN	Injection	4 mg/mL	Baxter Healthcare Corporation	10/31/2003
124	ATRALIN	Gel	0.05%	Bausch Health Americas, Inc.	07/26/2007
125	ATROPINE SULFATE OPHTHALMIC SOLUTION	Sterile Ophthalmic Solution	1%	Bausch & Lomb Incorporated	4/23/2023
126	AUGMENTIN	Oral Suspension	200 mg/28.5 mg per 5 mL	Dr. Reddy's Laboratories Inc.	10/22/1990
127	AUGMENTIN	Oral Suspension	400 mg/57 mg per 5 mL	Dr. Reddy's Laboratories Inc.	10/22/1990

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
128	AUGMENTIN	Powder for Oral Suspension	250mg/62.5mg/5mL	USAntibiotics, LLC	12/5/2022
129	AUGMENTIN	Tablets	250 mg	Dr. Reddy's Laboratories Inc.	10/22/1990
130	AUGMENTIN	Tablets	500 mg	Dr. Reddy's Laboratories Inc.	10/22/1990
131	AUGMENTIN	Tablets	875 mg	Dr. Reddy's Laboratories Inc.	10/02/1996
132	AVALIDE	Tablets	150 mg/12.5 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
133	AVALIDE	Tablets	300 mg/12.5 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
134	AVAPRO	Tablets	75 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
135	AVAPRO	Tablets	300 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
136	AVAPRO	Tablets	150 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
137	AVELOX	Tablets	400 mg	Bayer HealthCare LLC	01/2014
138	AVITA	Cream	0.025%	Mylan Pharmaceuticals, Inc., a Viatris Company	05/01/1998
139	AZILECT	Tablets	1 mg	Teva Pharmaceuticals USA	01/2017

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

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

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166	BUTRANS	Transdermal System	15 mcg/hour	Purdue Pharma L.P.	07/2017
167	BUTRANS	Transdermal System	5 mcg/hour	Purdue Pharma L.P.	07/2017
168	BUTRANS	Transdermal System	10 mcg/hour	Purdue Pharma L.P.	07/2017
169	CADUET	Tablet	2.5/10 mg	Pharmacia & Upjohn Co. LLC	03/14/2022
170	CADUET	Tablet	10/20 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
171	CADUET	Tablet	10/10 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
172	CADUET	Tablet	2.5/20 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
173	CADUET	Tablet	5/80 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
174	CADUET	Tablet	5/40 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
175	CADUET	Tablet	10/40 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
176	CADUET	Tablet	10/80 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
177	CADUET	Tablet	5/10 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
178	CADUET	Tablet	5/20 mg	Pharmacia & Upjohn Co. LLC	3/14/2022

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179	CADUET	Tablet	2.5/40 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
180	CANASA	Suppository	1000 mg	AbbVie, Inc.	12/2018
181	CARAFATE	Oral Suspension	1 g/10 mL	Allergan Sales, LLC	12/2019
182	CARAFATE	Tablets	1 g	Allergan Sales, LLC	11/01/1996
183	CARBATROL	Extended-Release Capsules	300 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
184	CARBATROL	Extended-Release Capsules	200 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
185	CARBATROL	Extended-Release Capsules	100 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
186	CARDIOLITE	Injection	(per label)	Lantheus Medical Imaging, Inc.	12/1990
187	CARDIZEM	Tablets	30 mg	Bausch Health US, LLC	12/25/2010
188	CARDIZEM	Tablets	60 mg	Bausch Health US, LLC	12/25/2010
189	CARDIZEM	Tablets	90 mg	Bausch Health US, LLC	12/25/2010
190	CARDIZEM	Tablets	120 mg	Bausch Health US, LLC	12/25/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
191	CARDIZEM CD	Capsules	360 mg	Bausch Health US, LLC	08/09/2012
192	CARDIZEM LA	Extended Release Tablets	120 mg	Bausch Health US, LLC	2/6/2014
193	CARDIZEM LA	Tablets	180 mg	Bausch Health US, LLC	02/06/2014
194	CARDIZEM LA	Tablets	420 mg	Bausch Health US, LLC	02/06/2014
195	CARDIZEM LA	Tablets	360 mg	Bausch Health US, LLC	02/06/2014
196	CARDIZEM LA	Tablets	300 mg	Bausch Health US, LLC	02/06/2014
197	CARDIZEM LA	Tablets	240 mg	Bausch Health US, LLC	02/06/2014
198	CARDURA	Tablets	2 mg	Viartis Specialty LLC	07/2014, 10/2021
199	CARDURA	Tablets	4 mg	Viartis Specialty LLC	07/2014
200	CARDURA	Tablets	8 mg	Viartis Specialty LLC	07/2014, 10/2021
201	CARDURA	Tablets	1 mg	Viartis Specialty LLC	07/2014, 11/2021
202	CARNITOR	Oral Solution	1 g/10 mL	Leadiant Biosciences, Inc.	04/2005 - 04/2006
203	CARNITOR	Tablets	330 mg	Leadiant Biosciences, Inc.	1/2005 - 12/2005

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204	CASODEX	Tablets	50 mg	ANI Pharmaceuticals, Inc.	10/2020
205	CASPORYN HC	Otic Suspension	3.5 mg	Casper Pharma LLC	03/15/2019
206	CEDAX	Capsules	400 mg	Pernix Therapeutics LLC	10/22/2013
207	CEDAX	Powder, for Oral Suspension	60 mL when reconstituted (180 mg per 5 mL)	Pernix Therapeutics LLC	10/22/2013
208	CELEBREX	Capsules	200 mg	Upjohn US 2 LLC	12/10/2014
209	CELEBREX	Capsules	400 mg	Upjohn US 2 LLC	12/10/2014
210	CELEBREX	Capsules	50 mg	Upjohn US 2 LLC	12/10/2014
211	CELEBREX	Capsules	100 mg	Upjohn US 2 LLC	12/10/2014
212	CETRAXAL	Otic Solution	0.2%	Wraser Pharmaceuticals, LLC	08/2012
213	CHILDREN'S MOTRIN	Suspension	100 mg/5 mL	McNeil Consumer Healthcare	06/1998 - 06/1999
214	CHILDREN'S MOTRIN (aka INFANT'S MOTRIN)	Suspension/Drops	40 mg/mL	McNeil Consumer Healthcare	Prior to 1/1/1999
215	CILOXAN	Ophthalmic Solution	0.3%	Novartis Pharmaceuticals Corporation	05/28/2004
216	CIPRO	for Oral Suspension	250 mg/5 mL	Bayer Pharmaceuticals Corp.	06/2003

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217	CIPRO	for Oral Suspension	500 mg/5 mL	Bayer Pharmaceuticals Corp.	06/2003
218	CIPRODEX	Otic Suspension	0.3% & 0.1%	Novartis Pharmaceuticals Corporation	08/2020
219	CLEOCIN	Vaginal Cream	2%	Pfizer	12/17/2005
220	CLEOCIN HCl	Capsules	150 mg	Pfizer	07/11/2003
221	CLEOCIN HCl	Capsules	300 mg	Pfizer	06/18/2003
222	CLEOCIN PHOSPHATE	Injection	300 mg/2 mL	Pfizer	06/2019
223	CLEOCIN PHOSPHATE	Injection	9,000/60 mL	Pfizer	06/2019
224	CLEOCIN PHOSPHATE	Injection	900 mg/6 mL	Pfizer	06/2019
225	CLEOCIN PHOSPHATE	Injection	600 mg/4 mL	Pfizer	06/2019
226	CLEOCIN T	Topical Gel	1%	Pfizer	06/11/2003
227	CLEOCIN T	Topical Lotion	1%	Pfizer	06/18/2003
228	CLIMARA	Transdermal System	0.375 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
229	CLIMARA	Transdermal System	0.05 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
230	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
231	CLIMARA	Transdermal System	0.075 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
232	CLIMARA	Transdermal System	1 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
233	CLIMARA	Transdermal System	0.025 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
234	CLINDAGEL	Gel	1%	Bausch Health U.S., LLC	06/2018
235	CLINORIL	Tablets	150 mg	Merck & Co., Inc.	Prior to 1/1/1999
236	CLINORIL	Tablets	200 mg	Merck & Co., Inc.	Prior to 1/1/1999
237	CLOBEX	Shampoo	0.05%	Galderma Laboratories, L.P.	1/2024
238	CLOBEX	Spray	0.05%	Galderma Laboratories, L.P.	08/2015
239	CLODERM	Cream	0.1%	EPI Health, LLC	09/2019
240	CLODERM	Cream	0.1%	EPI Health, LLC	02/17/2014
241	CLOLAR	Injection	20mg/20mL	Genzyme Corporation	05/2017
242	CLOMID	Tablets	50 mg	Hoechst Marion Roussel, Inc.	Prior to 1/1/1999
243	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
244	CLOZARIL	Tablets	200 mg	Heritage Life Sciences (USA), Inc.	05/2020
245	CLOZARIL	Tablets	100 mg	Heritage Life Sciences (USA), Inc.	03/2019
246	CLOZARIL	Tablets	25 mg	Heritage Life Sciences (USA), Inc.	03/2019
247	COLCRYS	Tablets	0.6 mg	Takeda Pharmaceuticals U.S.A. Inc.	07/01/2018
248	COLESTID	Granules for Oral Suspension	5 g per dose	Pharmacia and Upjohn LLC	01/11/2016
249	COLESTID	Tablets	1 g	Pharmacia and Upjohn LLC	02/2007
250	COLY-MYCIN M	for Injection	150 mg/vial (single dose vial)	Par Sterile Products, LLC	06/01/2012
251	COMTAN	Tablets	200 mg	Orion Corporation	06/04/2014
252	CONCERTA	Extended-release Tablets	18 mg	Janssen Research & Development, LLC	02/2019
253	CONCERTA	Extended-release Tablets	27 mg	Janssen Research & Development, LLC	02/2019
254	CONCERTA	Extended-release Tablets	36 mg	Janssen Research & Development, LLC	02/2019
255	CONCERTA	Extended-release Tablets	54 mg	Janssen Research & Development, LLC	02/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
256	CONDYLOX	Topical Solution	0.5%	Teva Branded Pharmaceuticals Products R&D, Inc	12/16/2003
257	CONZIP	Extended-release Capsules	300 mg	Cipher Pharmaceuticals, Inc.	06/2015
258	CONZIP	Extended-release Capsules	200 mg	Cipher Pharmaceuticals, Inc.	05/2015
259	CONZIP	Extended-release Capsules	100 mg	Cipher Pharmaceuticals, Inc.	06/2015
260	COREG CR	Capsules	20 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
261	COREG CR	Capsules	40 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
262	COREG CR	Capsules	80 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
263	COREG CR	Capsules	10 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
264	CORGARD	Tablets	20 mg	US WorldMeds, LLC	05/05/2014
265	CORGARD	Tablets	40 mg	US WorldMeds, LLC	05/05/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
266	CORGARD	Tablets	80 mg	US WorldMeds, LLC	05/05/2014
267	CORTEF	Tablets	5 mg	Pharmacia and Upjohn Company LLC	12/21/2012
268	CORTEF	Tablets	10 mg	Pharmacia and Upjohn Company LLC	12/21/2012
269	CORTEF	Tablets	20 mg	Pharmacia and Upjohn Company LLC	12/22/2012
270	CORTENEMA	Rectal Suspension	100 mg/60 mL	ANI Pharmaceuticals, Inc.	08/2012
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

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
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	5 mcg	King Pharmaceuticals R&D LLC	02/2019
278	CYTOMEL	Tablets	50 mcg	King Pharmaceuticals R&D LLC	06/2019
279	CYTOMEL	Tablets	25 mcg	King Pharmaceuticals R&D LLC	06/2019
280	CYTOTEC	Tablets	100 mcg	Pfizer Inc.	06/18/2003
281	CYTOTEC	Tablets	200 mcg	Pfizer Inc.	06/18/2003
282	DANTRIUM	Capsules	100 mg	Par Sterile Products, LLC	02/2016
283	DANTRIUM	Capsules	50 mg	Par Sterile Products, LLC	04/08/2013
284	DANTRIUM	Capsules	25 mg	Par Sterile Products, LLC	04/08/2013
285	DARAPRIM	Tablets	25 mg	Vyera Pharmaceuticals, LLC	03/2020
286	DAYPRO	Caplets	600 mg	Pfizer Inc.	03/28/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
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	DAYTRANA	Patches	27.5 mg	Noven Pharmaceuticals, Inc.	06/05/2023
291	DDAVP	Nasal Solution	10 mcg / 0.1 mL	Ferring Pharmaceuticals, Inc.	07/2016
292	DDAVP	Tablets	0.1 mg	Ferring Pharmaceuticals, Inc.	12/2015
293	DDAVP	Tablets	0.2 mg	Ferring Pharmaceuticals, Inc.	12/2015
294	DDAVP, DESMOPRESSIN ACETATE	Injection	4 mcg/mL	Ferring Pharmaceuticals Inc.	01/2016
295	DELESTROGEN	Injection	20 mg/mL	Par Sterile Products	06/01/2012
296	DELESTROGEN	Injection	10 mg/mL	Par Sterile Products	06/01/2012
297	DELESTROGEN	Injection	40 mg/mL	Par Sterile Products	06/01/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
298	DEMSER	Capsules	250 mg	Bausch Health US, LLC	09/07/2020
299	DENAVIR	Cream	1%	Mylan Pharmaceuticals Inc.	11/16/2022
300	DEPAKOTE ER	Extended-release Tablets	500 mg	Abbvie Inc.	08/2013
301	DEPAKOTE ER	Extended-release Tablets	250 mg	Abbvie Inc.	08/2013
302	DEPAKOTE SPRINKLE CAPSULES	Capsules	125 mg	AbbVie Inc.	08/31/2015
303	DEPO-MEDROL	Injection	40 mg/mL	Pharmacia and Upjohn	05/2006 - 05/2007
304	DEPO-MEDROL	Injection	80 mg/mL	Pharmacia and Upjohn	05/2006 - 05/2007
305	DEPO-PROVERA	Injection	150 mg in 1 mL	Pfizer	7/13/2021
306	DEPO-PROVERA	Injection	150 mg in 1 mL	Pfizer	09/16/2004
307	DERMA-SMOOTH/FS (Body Oil)	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
308	DERMA-SMOOTH/FS (Scalp Oil)	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
309	DERMOTIC	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
310	DERMOTIC OIL	Oil	0.01%	Hill Dermaceuticals Inc.	08/20/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
311	DESMOPRESSIN ACETATE	Nasal Spray	10 mcg per 0.1 mL (5 mL bottle)	Ferring Pharmaceuticals, Inc.	11/20/2014
312	DESOWEN	Cream	0.05%	Galderma Laboratories, L.P.	07/2013
313	DETROL	Tablets	2 mg	Upjohn US 2 LLC	01/2014, 01/2016
314	DETROL	Tablets	1 mg	Upjohn US 2 LLC	01/2014
315	DETROL LA	Extended-release Capsules	4 mg	Upjohn US 2 LLC	12/2014
316	DETROL LA	Extended-release Capsules	2 mg	Upjohn US 2 LLC	01/2016
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	DEXEDRINE SPANSULE	Extended-release Capsules	5 mg	Impax Laboratories, LLC	08/1976
320	DEXILANT	Delayed-release Capsules	60 mg	Takeda Pharmaceuticals U.S.A., Inc.	01/2022
321	DEXILANT	Delayed-release Capsules	30 mg	Takeda Pharmaceuticals U.S.A., Inc.	01/2022

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
322	DIABETA	Tablets	2.5 mg	Sanofi-Aventis U.S., LLC	05/01/1984
323	DIABETA	Tablets	5 mg	Sanofi-Aventis U.S., LLC	05/01/1984
324	DIAMOX SEQUELS	Extended-release Capsules	500 mg	Teva Branded Pharmaceutical Products R&D, Inc.	12/2008
325	DIASTAT ACUDIAL	Gel	20 mg	Bausch Health US, LLC	07/1997
326	DIASTAT ACUDIAL	Gel	2.5 mg	Bausch Health US, LLC	07/1997
327	DIASTAT ACUDIAL	Gel	10 mg	Bausch Health US, LLC	07/1997
328	DIBENZYLINE	Capsules	10 mg	Concordia Pharmaceuticals Inc.	08/11/2015
329	DICLEGIS	Delayed-release Tablets	10 mg/10 mg	Duchesnay Inc.	11/2018
330	DIFFERIN CREAM 0.1%	Cream	0.1%	Galderma Laboratories, L.P.	10/2010
331	DIFFERIN GEL	Gel	0.3%	Galderma Laboratories, L.P.	04/2024
332	DIFFERIN GEL 0.1%	Gel	0.1%	Galderma Laboratories, L.P.	08/23/2010
333	DIFLUCAN	Powder for Oral Suspension	10 mg/mL when reconstituted	Pfizer Inc.	03/12/2004

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
334	DIFLUCAN	Powder for Oral Suspension	40 mg/mL when reconstituted	Pfizer Inc.	03/12/2004
335	DIFLUCAN	Tablets	100 mg	Pfizer Inc.	03/12/2004
336	DIFLUCAN	Tablets	150 mg	Pfizer Inc.	03/12/2004
337	DIFLUCAN	Tablets	200 mg	Pfizer Inc.	03/12/2004
338	DILANTIN	Tablet (INFATABS)	50 mg	Parke-Davis Division of Pfizer Inc.	12/27/2012
339	DILANTIN-125	Oral Suspension	125 mg/5 mL (237 mL bottle)	Viartis Specialty LLC	04/2020
340	DILAUDID	Solution	5 mg/5 mL (1 mg/mL)	Rhodes Pharmaceuticals L.P.	10/1/2012
341	DILAUDID	Tablets	2 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
342	DILAUDID	Tablets	4 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
343	DILAUDID	Tablets	8 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
344	DIPROLENE	Ointment	0.05%	Organon LLC	8/10/2012
345	DITROPAN XL	Extended-release Tablets	5 mg	Janssen Research and Development, LLC	11/12/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
346	DITROPAN XL	Extended-release Tablets	10 mg	Janssen Research and Development, LLC	11/12/2015
347	DIURIL	Injection	500 mg/vial, sterile lyophilized	Oak Pharmaceuticals Inc.	08/13/2012
348	DORAL	Tablets	15 mg	Galt Pharmaceuticals, LLC	8/8/13
349	DORIBAX	Powder for Injection	500 mg/vial	Shionogi Inc.	12/2016
350	DORIBAX	Powder for Injection	250 mg/vial	Shionogi Inc.	12/2016
351	DORYX	Delayed-Release Tablets	80 mg	Mayne Pharma International Pty Ltd.	07/08/2013
352	DORYX	Delayed-Release Tablets	200 mg	Mayne Pharma International Pty Ltd.	02/2016
353	DORYX	Delayed-Release Tablets	50 mg	Mayne Pharma International Pty Ltd.	05/2016
354	DORYX	Delayed-Release Tablets	75 mg	Mayne Pharma International Pty Ltd.	07/08/2013
355	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
356	DORYX	Delayed-Release Tablets	100 mg	Mayne Pharma International Pty Ltd.	07/08/2013
357	DOSTINEX	Tablets	0.5 mg	Pfizer Inc.	09/22/2014
358	DOVONEX	Cream	0.005%	LEO Pharma Inc.	2012
359	DOVONEX	Ointment	0.005%	LEO Pharma Inc.	07/01/2013
360	DOXIL	Injection (Liposomal formulation)	50 mg/25 mL single use vial	Janssen Research & Development, LLC	07/2017
361	DOXIL	Injection (Liposomal formulation)	20 mg/10 mL single use vial	Janssen Research & Development, LLC	07/2017
362	DOXORUBICIN	Injection	50 mg/25 mL	Pharmacia and Upjohn	4/1/2013
363	DOXORUBICIN	Injection	20 mg/10mL	Pharmacia and Upjohn	03/17/2014
364	DOXORUBICIN	Injection	50 mg/25 mL	Pharmacia and Upjohn	03/17/2014
365	DOXORUBICIN	Injection	150 mg/75 mL	Pharmacia and Upjohn	4/1/2013
366	DOXORUBICIN	Injection	200 mg/ 100 mL	Pharmacia and Upjohn	03/17/2014
367	DOXORUBICIN	Injection	10 mg/5 mL	Pharmacia and Upjohn	03/17/2014
368	DOXORUBICIN	Injection	20 mg/10 mL	Pharmacia and Upjohn	4/1/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
369	DOXORUBICIN	Injection	10 mg/5 mL	Pharmacia and Upjohn	4/1/2013
370	DOXORUBICIN	Injection	200 mg/100 mL	Pharmacia and Upjohn	4/1/2013
371	DUETACT	Tablets	30 mg / 2 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/04/2015
372	DUETACT	Tablets	30 mg / 4 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/04/2015
373	DUEXIS	Tablets	800 mg and 26.6 mg	Horizon Medicines LLC	09/2021
374	DUREZOL	Ophthalmic Emulsion	0.05%	Novartis Pharmaceuticals Corporation	09/2021
375	DYMISTA	Nasal Spray	137 mcg/50 mcg per spray	Mylan Specialty, L.P.	04/2020
376	DYRENIUM	Capsules	100 mg	Concordia Pharmaceuticals Inc.	08/2019
377	DYRENIUM	Capsules	50 mg	Concordia Pharmaceuticals Inc.	08/2019
378	E.E.S. GRANULES	Suspension	200 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	09/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
379	EDECIN	Powder, for Injection Solution, Lyophilized	50 mg/vial	Bausch Health Americas, Inc.	01/1967
380	EDECIN	Tablets	25 mg	Bausch Health Americas, Inc.	01/2016 - 01/2017
381	EFUDEX	Cream	5%	Bausch Health Americas, Inc.	07/2013
382	ELDEPRYL	Capsules	5 mg	Somerset Pharmaceuticals, Inc.	05/1998 - 05/1999
383	ELDEPRYL	Tablets	5 mg	Somerset Pharmaceuticals, Inc.	06/1999 - 06/2000
384	ELIDEL	Cream	1%	Bausch Health US, LLC	12/2018
385	ELIMITE	Cream	5%	Mylan Pharmaceuticals, Inc.	06/2017
386	ELOXATIN	Injection	100 mg / 20 mL (5 mg/mL)	Sanofi-Aventis US LLC	07/07/2014
387	ELOXATIN	Injection	50 mg / 10 mL (5 mg/mL)	Sanofi-Aventis US LLC	07/07/2014
388	ELOXATIN (PREMIERPro)	Injection	50 mg/10 mL (5 mg/mL)	Sanofi-Aventis US LLC	10/2015
389	ELOXATIN (PREMIERPro)	Injection	100 mg / 20 mL (5 mg/mL)	Sanofi-Aventis US LLC	10/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
390	EMLA	Cream	2.5% and 2.5%	Teva Branded Pharmaceutical Products R&D, Inc.	11/12/2012
391	ENTOCORT EC	Capsules	3 mg	Padagis US LLC	08/18/2011
392	EPANED	Oral Solution	1 mg/mL	Azurity Pharmaceuticals, Inc.	03/2022
393	EPCLUSA	Tablets	400 mg / 100 mg	Gilead Sciences, Inc.	10/2018
394	EPIDUO	Topical Gel	0.1% / 2.5%	Galderma Laboratories, L.P.	08/2017
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, SA	07/29/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
401	ERYGEL	Topical Gel	2%	Mylan Pharmaceuticals, Inc.	10/19/2018
402	ERYPED 200	Suspension	200 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	08/2020
403	ERYPED 400	Suspension	400 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	03/2019
404	EVOXAC	Capsules	30 mg	Daiichi Sankyo, Inc.	03/2016
405	EXALGO	Extended-release Tablets	32 mg	SpecGx LLC	06/12/2014
406	EXALGO	Extended-release Tablets	12 mg	SpecGx LLC	06/12/2014
407	EXALGO	Extended-release Tablets	8 mg	SpecGx LLC	06/12/2014
408	EXALGO	Extended-release Tablets	16 mg	SpecGx LLC	06/12/2014
409	EXELDERM	Cream	1.0%	Journey Medical Corporation	02/2020
410	EXELDERM	Solution	1.0%	Journey Medical Corporation	02/2020
411	EXELON	Patch	4.6 mg/24 hours	Novartis Pharmaceuticals Corporation	09/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
412	EXELON	Patch	9.5 mg/24 hours	Novartis Pharmaceuticals Corporation	09/2015
413	EXELON	Patch	13.3 mg/24 hours	Novartis Pharmaceuticals Corporation	09/2015
414	EXTINA	Aerosol Foam	2%	Mylan Pharmaceuticals Inc.	12/2018
415	FABIOR	Aerosol Foam	0.1%	Mayne Pharma LLC	04/2021
416	FAMVIR	Tablets	125 mg	Novartis	03/22/2011
417	FAMVIR	Tablets	250 mg	Novartis	03/22/2011
418	FAMVIR FAMVIR	Tablets	500 mg	Novartis	03/22/2011
419	FELBATOL	Oral Suspension	600 mg/5 mL	Mylan Specialty, L.P., a Viatris Company	1/2012
420	FELBATOL	Tablets	400 mg	Mylan Specialty, L.P., a Viatris Company	11/2011
421	FELBATOL	Tablets	600 mg	Mylan Specialty, L.P., a Viatris Company	11/2011
422	FELDENE	Capsules	20 mg	Pfizer Inc.	03/03/2014
423	FELDENE	Capsules	10 mg	Pfizer Inc.	03/03/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
424	FEMCON Fe	Chewable Tablets	0.4 mg/35 mcg	Allergan Pharmaceuticals International Ltd.	10/2011
425	FENOGLIDE	Tablets	120 mg	Salix Pharmaceuticals, Inc.	06/24/2015
426	FENOGLIDE	Tablets	40 mg	Salix Pharmaceuticals, Inc.	06/24/2015
427	FENOGLIDE	Tablets	40 mg	Salix Pharmaceuticals, Inc.	03/2021
428	FENOGLIDE	Tablets	120 mg	Salix Pharmaceuticals, Inc.	03/2021
429	FENTORA	Tablet	800 mcg	Cephalon, Inc.	06/2019
430	FENTORA	Tablet	600 mcg	Cephalon, Inc.	06/2019
431	FENTORA	Tablet	200 mcg	Cephalon, Inc.	06/2019
432	FENTORA	Tablet	400 mcg	Cephalon, Inc.	06/2019
433	FINACEA	Gel	15%	LEO Pharma Inc.	10/2018
434	FIORICET with CODEINE	Capsules	50 mg / 325 mg / 40 mg / 30 mg	Teva Branded Pharmaceutical Products R&D, Inc.	10/01/2003
435	FIRAZYR	Injection	30 mg / 3.0ML	Shire Human Genetic Therapies, Inc.	07/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
436	FLECTOR	Topical System	1.3%	Institut Biochimique SA (IBSA)	03/2019
437	FLECTOR	Topical System	1.3%	Institut Biochimique SA (IBSA)	03/2019
438	FLEQSUVY	Suspension	5 mg/mL	Azurity Pharmaceuticals, Inc.	04/01/2023
439	FLORONE	Cream	0.05%	Pharmacia and Upjohn Company	Prior to 1/1/1999
440	FLOVENT DISKUS	Inhalation Powder	50 mcg	GlaxoSmithKline Intellectual Property Ltd England	10/30/2023
441	FLOVENT DISKUS	Inhalation Powder	250 mcg	GlaxoSmithKline Intellectual Property Ltd England	10/30/2023
442	FLOVENT DISKUS	Inhalation Powder	100 mcg	GlaxoSmithKline Intellectual Property Ltd England	10/30/2023
443	FLOVENT HFA	Inhalation Aerosol	220 mcg	GlaxoSmithKline Intellectual Property Ltd England	05/2022
444	FLOVENT HFA	Inhalation Aerosol	110 mcg	GlaxoSmithKline Intellectual Property Ltd England	05/2022
445	FLOVENT HFA	Inhalation Aerosol	44 mcg	GlaxoSmithKline Intellectual Property Ltd England	05/2022

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
446	FLUMADINE	Tablets	100 mg	Forest Laboratories, Inc.	09/2002 - 09/2003
447	FLUOXETINE	Tablets	60 mg	Alvogen Group Holdings 3, LLC	09/2017
448	FML	Ophthalmic Suspension	0.1%	Allergan, Inc.	10/1997
449	FOCALIN XR	Extended-release Capsules	30 mg	Novartis Pharmaceuticals Corporation	01/2014
450	FOCALIN XR	Extended-release Capsules	15 mg	Novartis Pharmaceuticals Corporation	01/2014
451	FOCALIN XR	Extended-release Capsules	5 mg	Novartis Pharmaceuticals Corporation	11/2014
452	FOCALIN XR	Extended-release Capsules	10 mg	Novartis Pharmaceuticals Corporation	02/2015
453	FOCALIN XR	Extended-release Capsules	35 mg	Novartis Pharmaceuticals Corporation	01/2014
454	FOCALIN XR	Extended-release Capsules	20 mg	Novartis Pharmaceuticals Corporation	06/2015
455	FORFIVO XL	Extended-release Tablets	450 mg	Alvogen Group Holdings 3, LLC	08/2018
456	FORFIVO XL	Extended-release Tablets	450 mg	Alvogen Group Holdings 3, LLC	09/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
457	FORTEO	Injection Solution	560 mcg/2.24 mL (250 mcg/mL)	Eli Lilly and Company	11/17/2023
458	FORTESA	Gel	10 mg testosterone/actuation	Endo Pharmaceuticals, Inc.	08/25/2014
459	FOSRENOL	Chewable Tablets	500 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/30/2017
460	FOSRENOL	Chewable Tablets	750 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/2017
461	FOSRENOL	Chewable Tablets	1000 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/2017
462	FURADANTIN	Oral Suspension	25 mg / 5 mL	Casper Pharma LLC	12/2011 - 12/2012
463	GABITRIL	Tablets	16 mg	Cephalon, Inc.	12/2012
464	GABITRIL	Tablets	4 mg	Cephalon Inc.	12/26/2012
465	GABITRIL	Tablets	12 mg	Cephalon, Inc.	12/2012
466	GABITRIL	Tablets	2 mg	Cephalon, Inc	12/26/2012
467	GASTROCROM	Oral Concentrate	100 mg/5 mL (ampule)	Mylan Specialty, L.P.	06/2015
468	GENERESS FE	Chewable Tablets	0.8 mg/25 mcg	Allergan Pharmaceuticals International Ltd.	03/2015
469	GEODON	Capsules	80 mg	Viartis Specialty LLC	12/15/2011

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
470	GEODON	Capsules	60 mg	Viartis Specialty LLC	12/15/2011
471	GEODON	Capsules	40 mg	Viartis Specialty LLC	12/15/2011
472	GEODON	Capsules	20 mg	Viartis Specialty LLC	12/15/2011
473	GLUCOTROL XL	Extended-release Tablets	2.5 mg	Pfizer Inc.	03/11/2004
474	GLUCOTROL XL	Extended-release Tablets	5 mg	Pfizer Inc.	03/11/2004
475	GLUCOTROL XL	Extended-release Tablets	10 mg	Pfizer Inc.	03/11/2004
476	GLUMETZA	Extended-release Tablets	1000 mg	Bausch Health US, LLC	06/2008
477	GLUMETZA	Extended-release Tablets	500 mg	Bausch Health US, LLC	06/2008
478	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
479	GOPRELTO	Solution	4%	Genus Lifesciences Inc.	06/2018
480	GRIS-PEG	Tablets	125 mg	Bausch Health US, LLC	12/03/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
481	GRIS-PEG	Tablets	250 mg	Bausch Health US, LLC	12/03/2012
482	HALCION	Tablets	0.125 mg	Pfizer Inc.	7/11/2003
483	HALCION	Tablets	0.25 mg	Pfizer Inc.	6/17/2003
484	HALDOL DECANOATE	Injection	100 mg/mL	Janssen Research & Development, LLC	07/2011
485	HALDOL DECANOATE	Injection	50 mg/mL	Janssen Research & Development, LLC	08/2011
486	HARVONI	Tablets	90 mg and 400 mg	Gilead Sciences, Inc.	01/2019
487	HECTOROL	Capsules, liquid filled	0.5 mcg	Genzyme Corporation	03/11/2014
488	HECTOROL	Capsules, liquid filled	1 mcg	Genzyme Corporation	03/11/2014
489	HECTOROL	Capsules, liquid filled	2.5 mcg	Genzyme Corporation	03/11/2014
490	IMITREX	Injection	6 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
491	IMITREX	Injection	4 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
492	IMITREX	Nasal Spray	5 mg	GlaxoSmithKline Intellectual Property Ltd. England	03/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
493	IMITREX	Nasal Spray	20 mg	GlaxoSmithKline Intellectual Property Ltd. England	03/2020
494	IMITREX (refill)	Injection	6 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
495	IMITREX (refill)	Injection	4 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
496	INDERAL LA	Extended-release Capsules	120 mg	ANI Pharmaceuticals, Inc.	12/2017
497	INDERAL LA	Extended-release Capsules	60 mg	ANI Pharmaceuticals, Inc.	12/2017
498	INDERAL LA	Extended-release Capsules	80 mg	ANI Pharmaceuticals, Inc.	12/2017
499	INDERAL LA	Extended-release Capsules	160 mg	ANI Pharmaceuticals, Inc.	12/2017
500	INDERAL LA	Extended-release Capsules	60 mg	ANI Pharmaceuticals, Inc.	2/25/2009
501	INDERAL LA	Extended-release Capsules	80 mg	ANI Pharmaceuticals, Inc.	2/25/2009

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
502	INDERAL LA	Extended-release Capsules	120 mg	ANI Pharmaceuticals, Inc.	2/25/2009
503	INDERAL LA	Extended-release Capsules	160 mg	ANI Pharmaceuticals, Inc.	2/25/2009
504	INSpra	Tablets	25 mg	Upjohn US 2 LLC	09/13/2007
505	INSpra	Tablets	50 mg	Upjohn US 2 LLC	09/13/2007
506	INVANZ	Injection, Powder, Lyophilized, for Solution	1 g	Merck Sharp & Dohme Corp.	07/2018
507	INVEGA	Extended-release Tablets	1.5 mg	Janssen Research & Development, LLC	09/24/2015
508	INVEGA	Extended-release Tablets	3 mg	Janssen Research & Development, LLC	09/24/2015
509	INVEGA	Extended-release Tablets	6 mg	Janssen Research & Development, LLC	09/24/2015
510	INVEGA	Extended-release Tablets	9 mg	Janssen Research & Development, LLC	09/24/2015
511	IOPIDINE	Ophthalmic Solution	0.5%	Harrow Eye, LLC	08/2009
512	ISOPTO CARPINE	Ophthalmic Solution	2%	Novartis Pharmaceuticals Corporation	02/21/1996
513	ISOPTO CARPINE	Ophthalmic Solution	1%	Novartis Pharmaceuticals Corporation	02/21/1996

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
514	ISOPTO CARPINE	Ophthalmic Solution	4%	Novartis Pharmaceuticals Corporation	02/21/1996
515	ISORDIL TITRADOSE	Tablets	5 mg	Bausch Health US, LLC	03/2020
516	ISORDIL TITRADOSE	Tablets	40 mg	Bausch Health US, LLC	03/2020
517	ISTALOL	Solution	0.5%	Bausch & Lomb Incorporated	05/2018
518	KADIAN	Extended-release Capsules	80 mg	Allergan Sales, LLC	11/11/2011
519	KADIAN	Extended-release Capsules	50 mg	Allergan Sales, LLC	11/11/2011
520	KADIAN	Extended-release Capsules	60 mg	Allergan Sales, LLC	11/11/2011
521	KADIAN	Extended-release Capsules	100 mg	Allergan Sales, LLC	11/11/2011
522	KADIAN	Extended-release Capsules	20 mg	Allergan Sales, LLC	11/11/2011
523	KADIAN	Extended-release Capsules	10 mg	Allergan Sales, LLC	11/11/2011

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
524	KADIAN	Extended-release Capsules	30 mg	Allergan Sales, LLC	11/11/2011
525	KAZANO	Tablets	12.5 mg/500 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
526	KAZANO	Tablets	12.5 mg/1000 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
527	K-DUR 10	Extended-release Tablets	10 mEq	Schering Corporation	06/2002 - 06/2003
528	K-DUR 20	Extended-release Tablets	20 mEq	Schering Corporation	06/1998 - 06/1999
529	KITABIS PAK	Inhalation Solution	300 mg/5 mL ampules	PulmoFlow Inc.	07/2016
530	KLARON	Lotion	10%	Bausch Health US, LLC	12/2005 - 12/2006
531	K-TAB	Extended-release Tablets	8 mEq (600 mg)	AbbVie Inc.	02/2011
532	K-TAB	Extended-release Tablets	10 mEq (750 mg)	AbbVie Inc.	02/2011
533	K-TAB	Extended-release Tablets	20 mEq (1500 mg)	AbbVie Inc.	01/2014
534	LAC-HYDRIN	Cream	eq. 12% base	Bristol-Myers Squibb Company	07/2004 - 06/2005
535	LAC-HYDRIN	Lotion	eq. 12% base	Bristol-Myers Squibb Company	03/2004 - 02/2005

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
536	LESCOL XL	Extended-release Tablets	80 mg	Novartis Pharmaceuticals Corporation	05/2018
537	LEVO-T	Tablets	125 mg	CEDIPROF, Inc.	08/2020
538	LEVO-T	Tablets	100 mg	CEDIPROF, Inc.	08/2020
539	LEVO-T	Tablets	300 mg	CEDIPROF, Inc.	08/2020
540	LEVO-T	Tablets	200 mg	CEDIPROF, Inc.	08/2020
541	LEVO-T	Tablets	175 mg	CEDIPROF, Inc.	08/2020
542	LEVO-T	Tablets	137 mg	CEDIPROF, Inc.	08/2020
543	LEVO-T	Tablets	112 mg	CEDIPROF, Inc.	08/2020
544	LEVO-T	Tablets	25 mg	CEDIPROF, Inc.	08/2020
545	LEVO-T	Tablets	150 mg	CEDIPROF, Inc.	08/2020
546	LEVO-T	Tablets	88 mg	CEDIPROF, Inc.	08/2020
547	LEVO-T	Tablets	75 mg	CEDIPROF, Inc.	08/2020
548	LEVO-T	Tablets	50 mg	CEDIPROF, Inc.	08/2020
549	LEXETTE	Foam	0.05%	Mayne Pharma LLC	02/2019
550	LIBRAX	Capsules	5 mg/2.5 mg	Bausch Health US, LLC	09/2016 - 08/2017
551	LIDEX	Topical Solution	0.05%	County Line Pharmaceuticals, LLC	03/2018
552	LIDODERM	Patch	700 mg (50 mg per gram adhesive) in an aqueous base	Teikoku Pharma USA, Inc.	05/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
553	LIMBITROL	Tablets	5 mg; eq. 12.5 mg base	Valeant Pharmaceuticals International	01/2006 - 12/2006
554	LIMBITROL DS	Tablets	10 mg; eq. 25 mg base	Valeant Pharmaceuticals International	01/2007 - 12/2007
555	LIPOFEN	Capsules	150 mg	Cipher Pharmaceuticals, Inc.	04/2016
556	LIPOFEN	Capsules	50 mg	Cipher Pharmaceuticals, Inc.	04/2016
557	LITHOBID	Extended-release Tablets	300 mg	ANI Pharmaceuticals, Inc.	12/2016
558	LOCOID	Cream	0.1%	Bausch Health U.S., LLC	07/2013
559	LOCOID	Lotion	0.1%	Bausch Health US, LLC	06/2018
560	LOCOID (Ointment)	Ointment	0.1%	Bausch Health US, LLC	10/2015 - 10/2016
561	LOCOID LIPOCREAM	Cream	0.1%	Bausch Health US, LLC	07/03/2013
562	LODOSYN	Tablets	25 mg	Bausch Health Americas, Inc.	04/2014
563	LOMOTIL	Tablets	2.5 mg/0.025 mg	Pfizer Inc.	07/2011, 02/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
564	LOPRESSOR HCT	Tablets	1 mg/mL	Novartis Pharmaceuticals Corporation	03/1998 - 03/1999
565	LOPRESSOR HCT	Tablets	50mg / 25mg	Novartis Pharmaceuticals Corporation	11/25/2009
566	LOPRESSOR HCT	Tablets	100 mg / 25 mg	Novartis Pharmaceuticals Corporation	11/25/2009
567	LOPROX	Cream	0.77%	Medicis Pharmaceutical Corporation	12/2004 - 11/2005
568	LOPROX	Gel	0.77%	Alvogen, Inc.	07/2007 - 06/2008
569	LOPROX	Shampoo	1%	Medicis Pharmaceutical Corporation	12/2012
570	LoSEASONIQUE	Tablets	0.1 mg/0.02 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	12/07/2011
571	LoSEASONIQUE	Tablets	0.1 mg/0.02 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	11/10/2016
572	LOTEMAX	Ophthalmic Suspension	0.5%	Bausch & Lomb Incorporated	07/2019
573	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
574	LOTENSIN HCT	Tablets	20 mg; 12.5 mg	Validus Pharmaceuticals LLC	04/2019
575	LOTENSIN HCT	Tablets	20 mg; 25 mg	Validus Pharmaceuticals LLC	04/2019
576	LOTRIMIN AF	Cream	1%	Schering-Plough HealthCare Products, Inc	03/1998 - 03/1999
577	LOTRONEX	Tablets	0.5 mg	Sebela Ireland Limited	05/2015
578	LOTRONEX	Tablets	1 mg	Sebela Ireland Limited	05/2015
579	LOTRONEX	Tablets	0.5 mg	Sebela Ireland Limited	05/2015
580	LOTRONEX	Tablets	1 mg	Sebela Ireland Limited	05/2015
581	LOVENOX	Injection	150 mg/1 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	120 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
584	LOVENOX	Injection	80 mg/0.8 mL graduated prefilled syringe	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	LOVENOX	Injection	300 mg/3 mL multi-dose vial	Sanofi Aventis US LLC	10/2011
587	LOVENOX	Injection	100 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
588	LOVENOX	Injection	60 mg/0.6 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
589	LOZOL	Tablets	2.5 mg	Rhone-Poulenc Rorer Pharmaceuticals Inc.	Prior to 1/1/1999
590	LUVOX	Tablets	25 mg	ANI Pharmaceuticals, Inc.	08/09/2011
591	LUVOX	Tablets	100 mg	ANI Pharmaceuticals, Inc.	08/09/2011
592	LUVOX	Tablets	50 mg	ANI Pharmaceuticals, Inc.	08/09/2011
593	LUZU	Cream	1%	Bausch Health US, LLC	07/2018
594	LYRICA	Capsules	50 mg	Upjohn US 2 LLC	07/2019
595	LYRICA	Capsules	25 mg	Upjohn US 2 LLC	07/2019
596	LYRICA	Capsules	100 mg	Upjohn US 2 LLC	07/2019
597	LYRICA	Capsules	300 mg	Upjohn US 2 LLC	07/2019
598	LYRICA	Capsules	150 mg	Upjohn US 2 LLC	07/2019
599	LYRICA	Capsules	200 mg	Upjohn US 2 LLC	07/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
600	LYRICA	Capsules	225 mg	Upjohn US 2 LLC	07/2019
601	LYRICA	Capsules	75 mg	Upjohn US 2 LLC	07/2019
602	LYRICA	Oral Solution	20 mg/mL	Upjohn US 2 LLC	07/2019
603	LYSTEDA	Tablets	650 mg	Amring Pharmaceuticals Inc.	03/17/2016
604	MACROBID	Capsules	100 mg	Almatica Pharma LLC	02/2011
605	MACRODANTIN	Capsules	100 mg	Almatica Pharma LLC	08/2011
606	MACRODANTIN	Capsules	50 mg	Almatica Pharma LLC	08/2011
607	MACRODANTIN	Capsules	25 mg	Almatica Pharma LLC	09/2010
608	MALARONE	Tablets	250 mg/100 mg	GlaxoSmithKline LLC	7/31/2012
609	MARINOL	Capsules	2.5 mg	AbbVie Inc.	05/2017
610	MARINOL	Capsules	5 mg	AbbVie Inc.	05/2017
611	MARINOL	Capsules	10 mg	AbbVie Inc.	05/2017
612	MAXIMUM STRENGTH MUCINEX DM	Extended-release Tablets	1200 mg and 60 mg	RB Health (US) LLC	09/2017
613	MAXIMUM STRENGTH MUCINEX DM	Extended-release Tablets	1200 mg and 60 mg	RB Health (US) LLC	10/2017
614	MAXIMUM STRENGTH MUCINEX DM	Extended-release Tablets	1200 mg and 60 mg	RB Health (US) LLC	09/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
615	MAXITROL	Ophthalmic Ointment	3.5 mg and 10000 units and 0.1% / gram	Novartis Pharmaceuticals Corporation	03/04/1996
616	MAXZIDE	Tablets	75 mg and 50 mg	Mylan Pharmaceuticals Inc.	Prior to 1/1/1999
617	MAXZIDE-25	Tablets	37.5 mg and 25 mg	Mylan Pharmaceuticals Inc.	Prior to 1/1/1999
618	MEDROL	Tablets	8 mg	Pfizer Inc.	4/22/2013
619	MEDROL	Tablets	16 mg	Pfizer Inc.	4/22/2013
620	MEDROL	Tablets	32 mg	Pfizer Inc.	4/22/2013
621	MEDROL	Tablets	4 mg	Pfizer Inc.	11/16/2011
622	MEGACE ES	Oral Suspension	625 mg/5 mL (125 mg/mL)	Endo Pharmaceuticals, Inc.	07/2015
623	MELOXICAM	Oral Suspension	7.5 mg / 5 mL	Avondale Pharmaceuticals LLC	06/29/2022
624	MEPHYTON	Tablets	5 mg	Bausch Health Americas, Inc.	04/23/2018
625	MESNEX	Injection	100 mg/mL	Baxter Healthcare Corporation	12/2003 - 12/2004
626	MESTINON	Oral Solution	60 mg / 5 mL	Bausch Health US, LLC	07/2019
627	MESTINON	Tablets	60 mg	Bausch Health US, LLC	04/2002 - 03/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
628	MESTINON TIMESPAN	Tablets	180 mg	Bausch Health US, LLC	11/2015
629	METADATE CD	Extended-release Capsules	30 mg	Lannett Company, Inc.	09/2012
630	METADATE CD	Extended-release Capsules	60 mg	Lannett Company, Inc.	09/2012
631	METADATE CD	Extended-release Capsules	40 mg	Lannett Company, Inc.	09/2012
632	METADATE CD	Extended-release Capsules	10 mg	Lannett Company, Inc.	09/2012
633	METADATE CD	Extended-release Capsules	50 mg	Lannett Company, Inc.	09/2012
634	METADATE CD	Extended-release Capsules	20 mg	Lannett Company, Inc.	09/2012
635	METHYLIN	Oral Solution	5 mg/5 mL	Mallinckrodt Inc.	08/01/2013
636	METHYLIN	Oral Solution	10 mg/5 mL	Mallinckrodt Inc.	08/01/2013
637	METROCREAM	Cream	0.75%	Galderma Laboratories, L.P.	3/2009
638	METROGEL	Gel	1%	Galderma Laboratories, L.P.	02/2017
639	METROGEL	Gel	0.75%	Galderma Laboratories, L.P.	03/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
640	METROGEL	Gel	1%	Galderma Laboratories, L.P.	11/10/2023
641	METROGEL VAGINAL GEL	Vaginal Gel	0.75%	Bausch Health US, LLC	04/01/2015
642	METROLOTION	Lotion	0.75%	Galderma Laboratories, L.P.	6/16/2009
643	MIACALCIN	Nasal Spray	200 I.U. per actuation	Sebela Ireland Ltd.	12/09/2008
644	MICRONASE	Tablets	2.5 mg	Pharmacia and Upjohn	Prior to 1/1/1999
645	MICRONASE	Tablets	5 mg	Pharmacia and Upjohn	Prior to 1/1/1999
646	MICROZIDE	Capsules	12.5 mg	Teva Branded Pharmaceutical Products R&D, Inc.	10/05/2001
647	MIDAMOR	Tablets	5 mg	Padagis US LLC	04/06/2009
648	MIGRANAL	Nasal Spray	4 mg in 1 mL	Bausch Health US, LLC	03/18/2013
649	MINIPRESS	Capsules	1 mg	Pfizer Inc.	01/2017
650	MINIPRESS	Capsules	5 mg	Pfizer Inc.	01/2017
651	MINIPRESS	Capsules	2 mg	Pfizer Inc.	01/2017
652	MINIPRESS	Capsules	5 mg	Pfizer Inc.	03/2022
653	MINIPRESS	Capsules	1 mg	Pfizer Inc.	08/2021
654	MINIPRESS	Capsules	2 mg	Pfizer Inc.	03/2022
655	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
656	MINIVELLE	Film, Extended Release	0.05 mg per day	Noven Pharmaceuticals, Inc.	01/2018
657	MINIVELLE	Film, Extended Release	0.025 mg per day	Noven Pharmaceuticals, Inc.	01/2018
658	MINIVELLE	Film, Extended Release	0.0375 mg per day	Noven Pharmaceuticals, Inc.	01/2018
659	MINIVELLE	Film, Extended Release	0.1 mg per day	Noven Pharmaceuticals, Inc.	01/2018
660	MITIGARE	Capsules	0.6 mg	Hikma International Pharmaceuticals LLC	10/01/2014
661	MONODOX	Capsules	75 mg	Aqua Pharmaceuticals LLC	10/2014
662	MONODOX	Capsules	50 mg	Aqua Pharmaceuticals LLC	02/07/2005
663	MONODOX	Capsules	100 mg	Aqua Pharmaceuticals LLC	02/07/2005
664	MONOKET	Tablets	10 mg	ECI Pharmaceuticals LLC	06/30/1996 - 06/29/1997
665	MONUROL	Granules for Oral Solution	3 g	Zambon S.p.A.	01/27/2022

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
666	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
667	MOXATAG	Extended-Release Tablets	775 mg	Vernalis (R&D) Limited	08/20/2014
668	MOZOBIL	Injection, Solution	24 mg/1.2 mL	Genzyme Corporation	7/24/2023
669	MS CONTIN	Extended-release Tablets	15 mg	Purdue Pharma L.P.	05/2005 - 05/2006
670	MS CONTIN	Extended-release Tablets	30 mg	Purdue Pharma L.P.	05/2005 - 05/2006
671	MS CONTIN	Extended-release Tablets	60 mg	Purdue Pharma L.P.	05/2005 - 05/2006
672	MS CONTIN	Extended-release Tablets	100 mg	Purdue Pharma L.P.	05/2005 - 05/2006
673	MS CONTIN	Extended-release Tablets	200 mg	Purdue Pharma L.P.	05/2005 - 05/2006
674	MUCINEX	Extended-release Tablets	600 mg	RB Health (US), LLC	02/2018
675	MYAMBUTOL	Tablets	100 mg	STI Pharma LLC	12/15/2006
676	MYAMBUTOL	Tablets	400 mg	STI Pharma LLC	12/15/2006
677	MYCOBUTIN	Capsules	150 mg	Pfizer Inc.	05/13/2014
678	MYSOLINE	Tablets	250 mg	Bausch Health US, LLC	05/2018
679	MYSOLINE	Tablets	50 mg	Bausch Health US, LLC	05/2018
680	NALFON	Capsules	400 mg	Xspire Pharma LLC	08/05/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
681	NALFON	Capsules	400 mg	Xspire Pharma LLC	05/2016
682	NALFON	Capsules	200 mg	Xspire Pharma LLC	04/2017
683	NAMENDA	Tablets	5 mg and 10 mg (titration pak)	Allergan Sales, LLC	04/01/2015
684	NAMENDA	Tablets	10 mg	Allergan Sales, LLC	04/01/2015
685	NAMENDA	Tablets	5 mg	Allergan Sales, LLC	04/01/2015
686	NAPRELAN	Controlled-Release Tablets	375 mg	Almatica Pharma LLC	09/2015
687	NAPRELAN	Controlled-Release Tablets	750 mg	Almatica Pharma LLC	03/2015
688	NAPRELAN	Controlled-Release Tablets	500 mg	Almatica Pharma LLC	03/2015
689	NAPROSYN	Suspension	125 mg/5 mL	Atnahs Pharma US Limited	11/2016
690	NAPROSYN EC (EC-NAPROSYN)	Delayed-Release Tablets	500 mg	Atnahs Pharma US Limited	10/2018
691	NARDIL	Tablets	15 mg	Parke-Davis	3/23/2011
692	NASACORT AQ	Nasal Spray Spray Bottle	55 mcg/spray	Sanofi Aventis US, LLC	06/15/2011
693	NATROBA	Topical Suspension	0.9%	ParaPRO LLC	06/2014
694	NEOPROFEN	Injection	20mg/2mL (10mg/mL)	Recordati Rare Diseases Inc.	04/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
695	NESINA	Tablets	6.25 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
696	NESINA	Tablets	25 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
697	NESINA	Tablets	12.5 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
698	NEURONTIN	Capsules	100 mg	Viartis Specialty LLC	3/17/2004
699	NEURONTIN	Capsules	300 mg	Viartis Specialty LLC	03/17/2004
700	NEURONTIN	Capsules	400 mg	Viartis Specialty LLC	3/17/2004
701	NEURONTIN	Oral Solution	250 mg per 5 mL	Viartis Specialty LLC	3/24/2011
702	NEURONTIN	Tablets	600 mg	Viartis Specialty LLC	3/17/2004
703	NEURONTIN	Tablets	800 mg	Viartis Specialty LLC	3/17/2004
704	NIASPAN	Extended-release Tablets	500 mg	AbbVie Inc.	06/30/2014
705	NIASPAN	Extended-release Tablets	750 mg	AbbVie Inc.	06/30/2014
706	NIASPAN	Extended-release Tablets	1000 mg	AbbVie Inc.	06/30/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
707	NICORETTE	Chewing Gum	2 mg	GlaxoSmithKline Consumer Healthcare L.P.	01/2002 - 01/2003
708	NICORETTE	Chewing Gum	4 mg	GlaxoSmithKline Consumer Healthcare L.P.	06/2001 - 06/2002
709	NILANDRON	Tablets	150 mg	Concordia Pharmaceuticals Inc.	11/2019
710	NITRO-DUR	Transdermal	0.4 mg/hr	USpharma Ltd.	04/2020
711	NITRO-DUR	Transdermal	0.2 mg/hr	USpharma Ltd.	04/2020
712	NITRO-DUR	Transdermal	0.6 mg/hr	USpharma Ltd.	04/2020
713	NITRO-DUR	Transdermal	0.1 mg/hr	USpharma Ltd.	04/2020
714	NITROLINGUAL PUMPSPRAY	Lingual Spray	400 mcg per Spray	G. Pohl-Boskamp GmbH & Co.	02/01/2011
715	NITROSTAT	Tablets	0.6 mg	Viartis Speciality LLC	08/26/2016
716	NITROSTAT	Tablets	0.4 mg	Viartis Speciality LLC	08/26/2016
717	NITROSTAT	Tablets	0.3 mg	Viartis Speciality LLC	08/26/2016
718	NORPACE	Capsules	150 mg	Pfizer Inc.	04/2019
719	NORPACE	Capsules	100 mg	Pfizer Inc.	04/2019
720	NORPRAMIN	Tablets	10 mg	Sanofi-Aventis US LLC	04/2014
721	NORPRAMIN	Tablets	150 mg	Sanofi-Aventis US LLC	04/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
722	NORPRAMIN	Tablets	25 mg	Sanofi-Aventis US LLC	04/2014
723	NORPRAMIN	Tablets	50 mg	Sanofi-Aventis US LLC	Prior to 1/1/1999
724	NORPRAMIN	Tablets	75 mg	Sanofi-Aventis US LLC	04/2014
725	NORPRAMIN	Tablets	100 mg	Sanofi-Aventis US LLC	04/2014
726	NOR-QD	Tablets	0.35 mg	Teva Branded Pharmaceuticals Products R&D, Inc	06/06/2003
727	NORVASC	Tablets	2.5 mg	Viartis Specialty LLC	6/15/2006
728	NORVASC	Tablets	5 mg	Viartis Specialty LLC	6/15/2006
729	NORVASC	Tablets	10 mg	Viartis Specialty LLC	6/15/2006
730	NOXAFIL	Delayed-release Tablets	100 mg	Merck Sharp & Dohme Corp.	08/2019
731	NOXAFIL	Oral Suspension	40 mg/mL	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.	3/29/2023
732	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

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
733	NUMBRINO	Nasal Solution	4%	Lannett Company, Inc.	09/2020
734	NUVARING	Vaginal Ring	11.7 mg / 2.7 mg (delivers 0.12 mg/0.015 mg per day)	Organon USA LLC	12/2019
735	NUVIGIL	Tablets	200 mg	Teva Pharmaceuticals USA	11/2016
736	NUVIGIL	Tablets	50 mg	Teva Pharmaceuticals USA	11/2016
737	NUVIGIL	Tablets	250 mg	Teva Pharmaceuticals USA	11/2016
738	NUVIGIL	Tablets	150 mg	Teva Pharmaceuticals USA	11/2016
739	NUVIGIL	Tablets	150 mg	Teva Pharmaceuticals USA	12/2016
740	NUVIGIL	Tablets	250 mg	Teva Pharmaceuticals USA	12/2016
741	NUVIGIL	Tablets	200 mg	Teva Pharmaceuticals USA	12/2016
742	OLUX	Foam	0.05%	Mylan Pharmaceuticals Inc.	12/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
743	OLUX-E	Emulsion, Aerosol Foam	0.05%	Mylan Pharmaceuticals Inc., a Viatris Company	01/2019
744	OMNIPRED	Ophthalmic Suspension	1%	Novartis Pharmaceuticals Corporation	01/1995
745	OPTIVAR	Ophthalmic Solution	0.05%	Meda Pharmaceuticals, Inc.	03/10/2011
746	ORABLOC	Injection	4% and 1:100,000	Pierrel S.p.A.	10/2016
747	ORABLOC	Injection	4% and 1:200,000	Pierrel S.p.A.	10/2016
748	ORACEA	Capsule	40mg	Galderma Laboratories, L.P.	2/27/2023
749	ORACEA	Capsules	40 mg	Galderma Laboratories, L.P.	04/2015
750	ORAPRED ODT	Orally Disintegrating Tablets	30 mg	Concordia Pharmaceuticals Inc.	10/2015
751	ORAPRED ODT	Orally Disintegrating Tablets	15 mg	Concordia Pharmaceuticals Inc.	10/2015
752	ORAPRED ODT	Orally Disintegrating Tablets	10 mg	Concordia Pharmaceuticals Inc.	10/2015
753	OSENI	Tablets	12.5 mg/30 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
754	OSENI	Tablets	25 mg/30 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
755	OSENI	Tablets	25 mg/15 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
756	OSENI	Tablets	25 mg/45 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
757	OTOVEL	Otic Solution	0.3% / 0.025%	Laboratorios SALVAT, S.A.	11/2019
758	OVIDE	Lotion	0.5%	Taro Pharmaceuticals USA, Inc.	08/02/2008 - 08/01/2009
759	OXANDRIN	Tablets	2.5 mg	Savient Pharmaceuticals, Inc.	06/2006 - 05/2007
760	OXANDRIN	Tablets	10 mg	Savient Pharmaceuticals, Inc.	06/2006 - 05/2007
761	OXYCODONE HYDROCHLORIDE	Oral Solution	5 mg/5 mL	Genus Lifesciences, Inc.	09/2013
762	OXYCONTIN	Extended-release Tablets	10 mg	Purdue Pharma L.P.	04/2022
763	OXYCONTIN	Extended-release Tablets	80 mg	Purdue Pharma L.P.	03/24/2015
764	OXYCONTIN	Extended-release Tablets	40 mg	Purdue Pharma L.P.	03/24/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
765	OXYCONTIN	Extended-release Tablets	20 mg	Purdue Pharma L.P.	03/24/2015
766	OXYCONTIN	Extended-release Tablets	10 mg	Purdue Pharma L.P.	03/24/2015
767	OXYCONTIN	Extended-release Tablets	40 mg	Purdue Pharma L.P.	04/2022
768	OXYCONTIN	Extended-release Tablets	20 mg	Purdue Pharma L.P.	04/2022
769	OXYCONTIN	Extended-release Tablets	80 mg	Purdue Pharma L.P.	04/2022
770	OZOBAX	Solution	5mg/5mL	Metacel Pharmaceuticals, LLC	03/15/2022
771	OZOBAX	Solution	10mg/5mL	Metacel Pharmaceuticals, LLC	10/12/2023
772	OZOBAX	Solution	10mg/5mL	Metacel Pharmaceuticals, LLC	03/05/2024
773	PARAPLATIN	for Injection	50 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
774	PARAPLATIN	for Injection	150 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
775	PARAPLATIN	for Injection	450 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
776	PARAPLATIN AQ	Injection	eq. 50 mg/5 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
777	PARAPLATIN AQ	Injection	eq. 150 mg/15 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
778	PARAPLATIN AQ	Injection	eq. 450 mg/45 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
779	PARAPLATIN AQ	Injection	eq. 600 mg/60 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
780	PARNATE	Tablets	10 mg	Concordia Pharmaceuticals Inc.	02/05/2016
781	PATADAY	Ophthalmic Solution	0.2%	Alcon Laboratories	06/2017
782	PATADAY	Ophthalmic Solution	0.1%	Alcon Laboratories, Inc.	09/2015
783	PATANOL	Ophthalmic Solution	0.1%	Novartis Pharmaceuticals Corporation	09/15/2015
784	PAXIL CR	Controlled-Release Tablets	25 mg	Apotex Inc.	08/09/2019
785	PAXIL CR	Controlled-Release Tablets	37.5 mg	Apotex, Inc.	08/09/2019
786	PAXIL CR	Controlled-Release Tablets	12.5 mg	Apotex Inc.	08/09/2019
787	PEDIAPRED	Oral Solution	5 mg / 5 mL	Seton Pharmaceuticals, LLC	02/2002
788	PENNSAID	Solution, Metered	2%	Horizon Therapeutics Ireland DAC	12/05/2022

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
789	PENNSAID	Solution, Metered	2%	Horizon Therapeutics Ireland DAC	11/22/2022
790	PERFOROMIST	Inhalation Solution	20 mcg/2 mL	Mylan Specialty L.P.	07/2021
791	PHOSLO	Gelcaps	667 mg	Fresenius Medical Care North America	03/2014 - 03/2015
792	PLAN B ONE-STEP	Tablets	1.5 mg	Foundation Consumer Healthcare, LLC	02/12/2014
793	PLAQUENIL	Tablets	200 mg	Concordia Pharmaceuticals Inc.	05/1999 - 04/2000
794	PLENDIL	Extended-release Tablets	2.5 mg	AstraZeneca LP	10/2008
795	PLENDIL	Extended-release Tablets	5 mg	AstraZeneca LP	10/2008
796	PLENDIL	Extended-release Tablets	10 mg	AstraZeneca LP	10/2008
797	PLIAGLIS	Cream	7%/7%	Taro Pharmaceuticals USA, Inc.	11/2017
798	POLYTRIM	Ophthalmic Solution	10 mL unit	Allergan, Inc.	04/29/1997
799	PONSTEL	Capsules	250 mg	Shionogi, Inc.	07/11/2011
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 FOR ORAL SOLUTION	Powder for Solution	20 mEq	Pharma Research Software Solution, LLC	01/2017
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, 10%	Oral Solution	20 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
804	POTASSIUM CHLORIDE ORAL SOLUTION, USP, 20%	Oral Solution	40 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
805	PRAVACHOL	Tablets	10 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
806	PRAVACHOL	Tablets	20 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
807	PRAVACHOL	Tablets	40 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
808	PRAVACHOL	Tablets	80 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
809	PRED FORTE	Ophthalmic Suspension	1%	Allergan, Inc.	08/1997
810	PREVACID	Delayed-Release Capsules	15 mg	Takeda Global Research & Development Center, Inc.	11/2009

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
811	PREVACID	Delayed-Release Capsules	30 mg	Takeda Global Research & Development Center, Inc.	11/2009
812	PREVPAC	Delayed-Release Capsules, Capsules, and Tablets	30 mg, 500 mg, and 500 mg	Takeda Pharmaceuticals U.S.A., Inc.	03/02/2015
813	PRISTIQ	Extended-Release Tablets	50 mg	PF Prism C.V.	03/2017
814	PRISTIQ	Extended-Release Tablets	100 mg	PF Prism C.V.	03/2017
815	PRISTIQ	Extended-Release Tablets	25 mg	PF Prism C.V.	03/2017
816	PROAIR HFA	Inhalation Aerosol	90 mcg per acutation	Teva Branded Pharmaceutical Products R&D, Inc.	01/2019
817	PROCARDIA	Capsules	10 mg	Pfizer Inc.	3/25/2013
818	PROLENSA	Solution	0.07%	Bausch & Lomb Incorporated	1/8/2024
819	PROTOPIC	Ointment	0.03%	LEO Pharma Inc.	11/2014
820	PROTOPIC	Ointment	0.1%	LEO Pharma Inc.	11/2014
821	PROVENTIL HFA	Inhalation Aerosol	108 mcg per actuation	Kindeva Drug Delivery L.P.	03/2021
822	PROVERA	Tablets	5 mg	Pfizer	6/18/2003
823	PROVERA	Tablets	2.5 mg	Pfizer	6/18/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
824	PROVERA	Tablets	10 mg	Pfizer	6/18/2003
825	PROVIGIL	Tablets	100 mg	Cephalon, Inc.	03/29/2012
826	PROVIGIL	Tablets	200 mg	Cephalon Inc.	03/29/2012
827	QUALAQUIN	Capsules	324 mg	Sun Pharmaceutical Industries, Inc.	07/23/2012
828	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, Inc.	04/2017
829	QUDEXY XR	Extended-release Capsules	50 mg	Upsher-Smith Laboratories, LLC	07/07/2014
830	QUDEXY XR	Extended-release Capsules	100 mg	Upsher-Smith Laboratories, LLC	07/07/2014
831	QUDEXY XR	Extended-release Capsules	200 mg	Upsher-Smith Laboratories, LLC	07/07/2014
832	QUDEXY XR	Extended-release Capsules	25 mg	Upsher-Smith Laboratories, LLC	07/07/2014
833	QUDEXY XR	Extended-release Capsules	150 mg	Upsher-Smith Laboratories, LLC	07/07/2014
834	RAPAMUNE	Oral Solution	1 mg/mL	PF Prism C.V.	07/2019
835	RAPAMUNE	Tablets	0.5 mg	PF Prism C.V.	01/16/2014
836	RAPAMUNE	Tablets	2 mg	PF Prism C.V.	10/27/2014
837	RAPAMUNE	Tablets	1 mg	PF Prism C.V.	10/27/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
838	RAZADYNE	Tablets	4 mg	Janssen Research & Development, LLC	08/28/2008
839	RAZADYNE	Tablets	8 mg	Janssen Research & Development, LLC	08/28/2008
840	RAZADYNE ER	Capsules	8 mg	Janssen Research & Development, LLC	10/13/2008
841	RAZADYNE ER	Capsules	16 mg	Janssen Research & Development, LLC	10/13/2008
842	RAZADYNE ER	Capsules	24 mg	Janssen Research & Development, LLC	10/13/2008
843	REGLAN	Injection	eq. 5 mg base/mL	Baxter Healthcare Corporation	02/2003 - 02/2004
844	REGLAN	Tablets	5 mg	ANI Pharmaceuticals, Inc.	12/2021
845	REGLAN	Tablets	10 mg	ANI Pharmaceuticals, Inc.	12/2021
846	RENVELA	Tablets	800 mg	Genzyme Corporation	04/16/2014
847	RESTORIL	Capsule	30 mg	Mallinckrodt Pharmaceuticals	08/02/2021
848	RESTORIL	Capsule	15 mg	Mallinckrodt Pharmaceuticals	04/20/2020
849	RESTORIL	Capsules	22.5 mg	Mallinckrodt Inc.	07/21/2008
850	RESTORIL	Capsules	7.5 mg	Mallinckrodt Inc.	07/22/2008

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
851	RETIN-A	Cream	0.1%	Bausch Health US, LLC	07/2019
852	RETIN-A	Cream	0.025%	Bausch Health US, LLC	04/2019
853	RETIN-A	Cream	0.05%	Bausch Health US, LLC	12/2018
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	Gel	0.01 %	Bausch Health US, LLC	08/2019
857	RETIN-A	Gel	0.025%	Bausch Health US, LLC	06/2005
858	RETIN-A MICRO	Gel	0.1 %	Bausch Health US, LLC	08/2019
859	RETIN-A MICRO	Gel	0.1 %	Bausch Health US, LLC	03/2013
860	RETIN-A MICRO	Gel	0.04 %	Bausch Health US, LLC	08/2019
861	RETIN-A MICRO	Gel	0.04%	Bausch Health US, LLC	03/2013
862	REVATIO	Powder for Suspension	10 mg/mL	Upjohn 1 US LLC	09/2019
863	REVATIO	Tablets	20 mg	Viartis Specialty LLC	09/27/2012, 11/09/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
864	RISPERDAL	Oral Solution	1 mg/mL	Janssen Research & Development, LLC	06/30/2008
865	RITALIN	Tablet	5 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
866	RITALIN	Tablet	20 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
867	RITALIN	Tablet	10 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
868	RITALIN LA	Capsules	20 mg	Novartis Pharmaceuticals Corp	11/2015
869	RITALIN LA	Capsules	10 mg	Novartis Pharmaceuticals Corp	02/2018
870	RITALIN LA	Capsules	40 mg	Novartis Pharmaceuticals Corp	11/2015
871	RITALIN LA	Capsules	30 mg	Novartis Pharmaceuticals Corp	11/2015
872	ROBINUL	Injection	0.2 mg/mL	Eurohealth International Sarl	02/06/1975
873	ROBINUL	Tablets	1 mg	Casper Pharma LLC	01/13/2005

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
874	ROBINUL FORTE	Tablets	2 mg	Casper Pharma LLC	01/13/2005
875	ROCALTROL	Oral Solution	1 mcg/mL (15 mL bottle)	Validus Pharmaceuticals LLC	08/26/2009
876	ROGAINE (FOR MEN)	Topical Solution	2%	McNeil-PPC, Inc.	06/1998 - 05/1999
877	ROGAINE (FOR WOMEN)	Topical Solution	2%	McNeil-PPC, Inc.	06/1998 - 05/1999
878	ROGAINE EXTRA STRENGTH (FOR MEN)	Topical Solution	5%	McNeil-PPC, Inc.	2004
879	ROSZET	Tablets	20 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
880	ROSZET	Tablets	10 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
881	ROSZET	Tablets	5 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
882	ROSZET	Tablets	40 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
883	ROWASA	Rectal Suspension Enema	4 g/60 mL	Mylan Specialty, L.P., a Viatris Company	2/2011

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
884	SAFRYAL	Tablets	3 mg / 0.03 mg / 0.451 mg	Bayer HealthCare LLC	08/2015
885	SALAGEN	Tablets	5 mg	Concordia Pharmaceuticals Inc.	12/2004
886	SALAGEN	Tablets	7.5 mg	Concordia Pharmaceuticals Inc.	03/2006 - 01/2007
887	SAMSCA	Tablets	15 mg	Otsuka Pharmaceutical Company, Ltd.	10/2020
888	SAPHRIS SAPHRIS	Sublingual Tablets	2.5 mg	Allergan Sales, LLC	05/2020
889	SAPHRIS SAPHRIS	Sublingual Tablets	5 mg	Allergan Sales, LLC	05/2020
890	SAPHRIS SAPHRIS	Sublingual Tablets	10 mg	Allergan Sales, LLC	12/2020
891	SEASONALE	Tablets	0.15 mg/0.03 mg	Teva Branded Pharmaceutical Products R&D, Inc.	9/7/2006
892	SEASONIQUE	Tablets	0.15 mg/0.03 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	07/28/2010
893	SECTRAL	Capsules	eq. 200 mg base	Wyeth Laboratories, Inc.	Prior to 1/1/1999
894	SECTRAL	Capsules	eq. 400 mg base	Wyeth Laboratories, Inc.	Prior to 1/1/1999
895	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	01/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
896	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	04/2016
897	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	04/2019
898	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
899	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
900	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2016
901	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	04/2019
902	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	01/2015
903	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
904	SEROQUEL XR	Extended-release Tables	200 mg	AstraZeneca UK Limited	05/2017
905	SEROQUEL XR	Extended-release Tablets	400 mg	AstraZeneca UK Limited	05/2017
906	SEROQUEL XR	Extended-release Tablets	200 mg	AstraZeneca UK Limited	11/2016
907	SEROQUEL XR	Extended-release Tablets	150 mg	AstraZeneca UK Limited	11/2016
908	SEROQUEL XR	Extended-release Tablets	300 mg	AstraZeneca UK Limited	05/2017
909	SEROQUEL XR	Extended-release Tablets	150 mg	AstraZeneca UK Limited	05/2017
910	SEROQUEL XR	Extended-release Tablets	300 mg	AstraZeneca UK Limited	11/2016
911	SEROQUEL XR	Extended-release Tablets	50 mg	AstraZeneca UK Limited	05/2017
912	SEROQUEL XR	Extended-release Tablets	50 mg	AstraZeneca UK Limited	11/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
913	SILENOR	Tablets	6 mg	Currax Pharmaceuticals LLC	08/2010
914	SILENOR	Tablets	3 mg	Currax Pharmaceuticals LLC	08/2010
915	SILVADENE	Cream	1%	King Pharmaceuticals LLC	01/2018
916	SKELAXIN	Tablets	800 mg	King Pharmaceuticals R&D, LLC	08/2018
917	SOLARAZE	Gel	3%	Fougera Pharmaceuticals, Inc.	11/21/2013
918	SOMA	Tablet	250 mg	Mylan Specialty, L.P.	9/13/2010
919	SOOLANTRA	Cream	1%	Galderma Laboratories, L.P.	06/2021
920	SOOLANTRA	Cream	1%	Galderma Laboratories, L.P.	1/8/2024
921	SORILUX	Foam	0.005%	Mayne Pharma LLC	02/2021
922	SPECTRACEF	Tablets	200 mg	Vansen Pharma, Inc.	Unknown
923	SPECTRACEF	Tablets	400 mg	Vansen Pharma, Inc.	Unknown

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
924	SPORANOX	Capsule	100 mg	Janssen Research & Development, LLC	2/2005; 6/2005
925	SPORANOX	Oral Solution	10 mg/mL	Janssen Research & Development, LLC	10/2018
926	STALEVO 100	Film-coated Tablets	25 mg, 100 mg, 200 mg	Orion Corporation	06/2014
927	STALEVO 125	Film-coated Tablets	31.25 mg, 125 mg, 200 mg	Orion Corporation	06/2014
928	STALEVO 150	Film-coated Tablets	37.5 mg, 150 mg, 200 mg	Orion Corporation	06/2014
929	STALEVO 200	Film-coated Tablets	50 mg, 200 mg, 200 mg	Orion Corporation	06/2014
930	STALEVO 50	Film-coated Tablets	12.5 mg, 50 mg, 200 mg	Orion Corporation	06/2014
931	STALEVO 75	Film-coated Tablets	18.75 mg, 75 mg, 200 mg	Orion Corporation	06/2014
932	SULAR	Extended-release Tablets	17 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
933	SULAR	Extended-release Tablets	34 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
934	SULAR	Extended-release Tablets	8.5 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
935	SUPRAX	Capsules	400 mg	Lupin Limited	10/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
936	SUPREP	Oral Solution (concentrate)	17.5g / 3.13g / 1.6g	Braintree Laboratories, Inc.	08/2010
937	SYMBICORT	Metered Dose Inhaler	160/4.5 mcg	AstraZeneca Pharmaceuticals LP	01/2020
938	SYMBICORT	Metered Dose Inhaler	80/4.5 mcg	AstraZeneca Pharmaceuticals LP	01/2020
939	SYNALAR	Cream	.25 mg/g	Medimetriks Pharmaceuticals, Inc.	5/7/2024
940	SYNALAR	Cream	.1 mg/g	Medimetriks Pharmaceuticals, Inc.	5/7/2024
941	SYNALAR	Ointment	0.025%	Medimetriks Pharmaceuticals, Inc.	11/2023
942	SYNALGOS-DC	Capsules	356.4 mg/30 mg/16 mg	Sun Pharmaceutical Industries, Inc.	10/01/2012
943	SYPRINE	Capsules	250 mg	Bausch Health Americas, Inc.	02/2018
944	TACLONEX	Ointment	0.005%/0.064%	LEO Pharma A/S	01/2020
945	TAMBOCOR	Tablets	50 mg	3M Pharmaceuticals	10/2002
946	TAMBOCOR	Tablets	100 mg	3M Pharmaceuticals	10/2002
947	TAMBOCOR	Tablets	150 mg	3M Pharmaceuticals	10/2002

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
948	TARGRETIN	Gel	1%	Bausch Health Ireland Limited	06/2022
949	TASMAR	Tablets	100 mg	Bausch Health US, LLC	07/2004
950	TAXOTERE	Injection Concentrate	80 mg/4 mL (20 mg/mL)	Sanofi Aventis US LLC	03/2011
951	TAXOTERE	Injection Concentrate	20 mg/mL	Sanofi Aventis US LLC	03/2011
952	TAXOTERE	Injection Concentrate	160 mg/8 mL (20 mg/mL)	Sanofi Aventis US LLC	10/2016
953	TAYTULLA	Capsules	1 mg/20 mcg	Allergan Pharmaceuticals International Ltd	11/2020
954	TAZORAC	Cream	0.1%	Allergan Aesthetics, an Abbvie Company	10/2016
955	TAZORAC	Cream	0.05%	Allergan Aesthetics, an Abbvie Company	10/2016
956	TEGRETOL XR	Tablets	100 mg	Novartis Pharmaceuticals Corporation	07/2018
957	TEGRETOL XR	Tablets	200 mg	Novartis Pharmaceuticals Corporation	06/15/2009
958	TEGRETOL XR	Tablets	400 mg	Novartis Pharmaceuticals Corporation	06/15/2009

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
959	TESTIM	Gel	50 mg in 5 g	Auxilium Pharmaceuticals, Inc.	06/09/2014
960	TETRACAINE HYDROCHLORIDE	Ophthalmic Solution	0.5%	Bausch Health Ireland Limited	06/2019
961	TIAZAC	Extended-release Capsules	240 mg	Bausch Health US, LLC	08/20/2014
962	TIAZAC	Extended-release Capsules	120 mg	Bausch Health US, LLC	08/20/2014
963	TIAZAC	Extended-release Capsules	180 mg	Bausch Health US, LLC	08/20/2014
964	TIAZAC	Extended-release Capsules	420 mg	Bausch Health US, LLC	08/20/2014
965	TIAZAC	Extended-release Capsules	300 mg	Bausch Health US, LLC Bausch Health US, LLC	08/20/2014
966	TIAZAC	Extended-release Capsules	360 mg	Bausch Health US, LLC	08/20/2014
967	TIGAN	Injection	100 mg/mL	Par Sterile Products, LLC	06/01/2012
968	TIMOPTIC	Ophthalmic Solution	0.5%	Bausch & Lomb Incorporated	06/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
969	TIMOPTIC	Ophthalmic Solution	0.5%	Bausch & Lomb Incorporated	06/2020
970	TIMOPTIC in OCUDOSE	Solution	0.5%	Bausch & Lomb Incorporated	04/2021
971	TIMOPTIC-XE	Solution	0.25%	Bausch & Lomb Incorporated	02/2018
972	TIMOPTIC-XE	Solution	0.5%	Bausch & Lomb Incorporated	02/2018
973	TIROSINT	Capsules	25 mcg	IBSA Pharma Inc.	03/01/2023
974	TIROSINT	Capsules	13 mcg	IBSA Pharma Inc.	03/01/2023
975	TIROSINT	Capsules	50 mcg	IBSA Pharma Inc.	03/01/2023
976	TIROSINT	Capsules	75 mcg	IBSA Pharma Inc.	03/01/2023
977	TIROSINT	Capsules	88 mcg	IBSA Pharma Inc.	03/01/2023
978	TIROSINT	Capsules	100 mcg	IBSA Pharma Inc.	03/01/2023
979	TIROSINT	Capsules	200 mcg	IBSA Pharma Inc.	03/01/2023
980	TIROSINT	Capsules	125 mcg	IBSA Pharma Inc.	03/01/2023
981	TIROSINT	Capsules	137 mcg	IBSA Pharma Inc.	03/01/2023
982	TIROSINT	Capsules	175 mcg	IBSA Pharma Inc.	11/2020
983	TIROSINT	Capsules	175 mcg	IBSA Pharma Inc.	03/01/2023
984	TIROSINT	Capsules	150 mcg	IBSA Pharma Inc.	03/01/2023
985	TIROSINT	Capsules	112 mcg	IBSA Pharma Inc.	03/01/2023
986	TIROSINT	Capsules	75 mcg	IBSA Pharma Inc.	11/2020
987	TIROSINT	Capsules	200 mcg	IBSA Pharma Inc.	11/2020
988	TIROSINT	Capsules	150 mcg	IBSA Pharma Inc.	11/2020
989	TIROSINT	Capsules	137 mcg	IBSA Pharma Inc.	11/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
990	TIROSINT	Capsules	125 mcg	IBSA Pharma Inc.	11/2020
991	TIROSINT	Capsules	112 mcg	IBSA Pharma Inc.	11/2020
992	TIROSINT	Capsules	100 mcg	IBSA Pharma Inc.	11/2020
993	TIROSINT	Capsules	88 mcg	IBSA Pharma Inc.	11/2020
994	TIROSINT	Capsules	50 mcg	IBSA Pharma Inc.	11/2020
995	TIROSINT	Capsules	25 mcg	IBSA Pharma Inc.	11/2020
996	TIROSINT	Capsules	13 mcg	IBSA Pharma Inc.	11/2020
997	TIVORBEX	Capsules	20 mg	Genus Lifesciences Inc.	01/2020
998	TIVORBEX	Capsules	40 mg	Genus Lifesciences Inc.	01/2020
999	TOBI	Solution for Inhalation	300 mg/5 mL ampule	Mylan Specialty, L.P., a Viatris Company	07/2014
1000	TOBRADEX	Ophthalmic Suspension	0.3% and 0.1%	Novartis Pharmaceuticals Corporation	01/02/2009
1001	TOFRONIL PM	Capsules	75 mg	Mallinckrodt Inc.	4/2006
1002	TOFRONIL PM	Capsules	100 mg	Mallinckrodt Inc.	4/2006
1003	TOFRONIL PM	Capsules	125 mg	Mallinckrodt Inc.	4/2006
1004	TOFRONIL PM	Capsules	150 mg	Mallinckrodt Inc.	4/2006
1005	TOPROL XL	Extended-release Tablets	25 mg	Toprol Acquisition LLC	01/2018
1006	TOPROL XL	Extended-release Tablets	200 mg	Toprol Acquisition LLC	01/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1007	TOPROL XL	Extended-release Tablets	100 mg	Toprol Acquisition LLC	01/2018
1008	TOPROL XL	Extended-release Tablets	50 mg	Toprol Acquisition LLC	01/2018
1009	TRANDATE	Tablets	300 mg	Alvogen, Inc.	03/2018
1010	TRANDATE	Tablets	100 mg	Alvogen, Inc.	12/01/2014
1011	TRANDATE	Tablets	200 mg	Alvogen, Inc.	03/2018
1012	TRAVATAN Z	Ophthalmic Solution	0.004%	Novartis Pharmaceuticals Corporation	12/2019
1013	TREXIMET	Tablets	85 mg/500 mg	Currax Pharmaceuticals LLC	02/2018
1014	TRIBENZOR	Tablets	40 mg/5 mg/12.5 mg	Cosette Pharmaceuticals, Inc.	10/2016
1015	TRIBENZOR	Tablets	40 mg/10 mg/12.5 mg	Cosette Pharmaceuticals, Inc.	10/2016
1016	TRIBENZOR	Tablets	40 mg/10 mg/25 mg	Cosette Pharmaceuticals, Inc.	10/2016
1017	TRIBENZOR	Tablets	40 mg/5 mg/25 mg	Cosette Pharmaceuticals, Inc.	10/2016
1018	TRIBENZOR	Tablets	20 mg/5 mg/12.5 mg	Cosette Pharmaceuticals, Inc.	10/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1019	TRILEPTAL	Oral Suspension	300 mg/5 mL	Novartis Pharmaceuticals Corporation	12/2009
1020	TRILIPIX	Delayed Release Capsules	135 mg	AbbVie Inc.	07/15/2013
1021	TRI-NORINYL	Tablets	0.5 mg and 0.035 mg, 1 mg and 0.035 mg	Mayne Pharma LLC	1/12/2005
1022	TUSSIONEX	Extended-Release Suspension	10 mg hydrocodone bitartrate & 8 mg chlorpheniramine maleate per 5 mL	UCB, Inc.	10/2010
1023	UCERIS	Extended-Release Tablets	9 mg	Salix Pharmaceuticals Inc.	07/2018
1024	ULTRAVATE	Cream	0.05%	Bristol-Myers Squibb Company	11/2004 - 10/2005
1025	ULTRAVATE	Ointment	0.05%	Bristol-Myers Squibb Company	11/2004 - 10/2005
1026	UNITHROID	Tablets	137 mcg (0.137 mg)	Jerome Stevens Pharmaceuticals, Inc.	unknown
1027	UNITHROID	Tablets	25 mcg (0.025 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1028	UNITHROID	Tablets	50 mcg (0.05 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1029	UNITHROID	Tablets	75 mcg (0.075 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1030	UNITHROID	Tablets	88 mcg (0.088 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1031	UNITHROID	Tablets	100 mcg (0.1 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1032	UNITHROID	Tablets	112 mcg (0.112 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1033	UNITHROID	Tablets	125 mcg (0.125 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1034	UNITHROID	Tablets	150 mcg (0.15 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1035	UNITHROID	Tablets	175 mcg (0.175 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1036	UNITHROID	Tablets	200 mcg (0.2 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1037	UNITHROID	Tablets	300 mcg (0.3 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1038	UREX	Tablets	1 gram	County Line Pharmaceuticals, LLC	05/2010
1039	UROCIT-K	Extended-release Tablets	540 mg (5 mEq per tablet)	Mission Pharmacal Company	11/2007
1040	UROCIT-K	Extended-release Tablets	15 mEq (1620 mg) per tablet	Mission Pharmacal Company	12/23/2013
1041	URSO 250	Tablets	250 mg	Allergan Sales, LLC	07/06/2009
1042	URSO FORTE	Tablets	500 mg	Allergan Sales, LLC	07/06/2009
1043	VAGISTAT-1	Vaginal Ointment	6.50%	Bristol-Myers Squibb Company	02/1998 - 02/1999
1044	VANCOCIN	Capsules	125 mg	ANI Pharmaceuticals Inc.	10/26/2015
1045	VANCOCIN	Capsules	250 mg	ANI Pharmaceuticals Inc.	10/26/2015
1046	VASERETIC	Tablets	10 mg/25 mg	Valeant Pharmaceuticals North America, LLC	10/31/1986
1047	VASOTEC	Tablets	2.5 mg	Bausch Health US, LLC	07/26/1988
1048	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
1049	VASOTEC	Tablets	10 mg	Bausch Health US, LLC	12/24/1985
1050	VASOTEC	Tablets	20 mg	Bausch Health US, LLC	12/24/1985
1051	VECTICAL	Ointment	3 mcg/g	Galderma Laboratories, L.P.	7/21/2023
1052	VECTICAL	Ointment	3 mcg/g	Galderma Laboratories, L.P.	02/28/2012
1053	VELTIN	Gel	1.2%/0.025%	Almirall, LLC	06/2018
1054	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	37.5 mg	Osmotica Pharmaceutical US LLC	04/2010
1055	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	225 mg	Osmotica Pharmaceutical US LLC	04/2010
1056	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	75 mg	Osmotica Pharmaceutical US LLC	04/2010
1057	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	150 mg	Osmotica Pharmaceutical US LLC	04/2010
1058	VENOFER	Injection	2% w/v iron (Fe)	Luitpold Pharmaceuticals, Inc.	10/02/08
1059	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
1060	VERELAN	Sustained-release Capsules	120 mg	Societal CDMO Gainesville, LLC	5/17/1999
1061	VERELAN	Sustained-release Capsules	180 mg	Societal CDMO Gainesville, LLC	5/17/1999
1062	VERELAN	Sustained-release Capsules	240 mg	Societal CDMO Gainesville, LLC	5/17/1999
1063	VERELAN	Sustained-release Capsules	360 mg	Societal CDMO Gainesville, LLC	5/17/1999
1064	VERELAN PM	Extended-release Capsules	100 mg	Societal CDMO Gainesville, LLC	11/2006 - 11/2007
1065	VERELAN PM	Extended-release Capsules	200 mg	Societal CDMO Gainesville, LLC	11/2006 - 11/2007
1066	VERELAN PM	Extended-release Capsules	300 mg	Societal CDMO Gainesville, LLC	11/2006 - 11/2007
1067	VFEND	Powder for Oral Suspension	40 mg/mL (75 mL when reconstituted)	PF Prism C.V.	12/16/2013
1068	VIAGRA	Tablets	100 mg	Viatis Specialty LLC	12/1/2017
1069	VIAGRA	Tablets	50 mg	Viatis Specialty LLC	12/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1070	VIAGRA	Tablets	25 mg	Viartis Specialty LLC	12/2017
1071	VIBRAMYCIN	Capsules	100 mg	Pfizer Inc.	05/2015
1072	VIGAMOX	Ophthalmic Solution	0.5%	Novartis Pharmaceuticals Corporation	01/2017
1073	VIMOVO	Delayed-release Tablets	375 mg /20 mg	Horizon Medicines, LLC	03/2020
1074	VIMOVO	Delayed-release Tablets	500 mg/20 mg	Horizon Medicines, LLC	03/2020
1075	VIRAZOLE	Inhalation Solution, USP	100 mL/6G Vial	Bausch Health US, LLC	4/15/2020
1076	VIRAZOLE	Powder for Solution	6g/100 mL vial, to be reconstituted	Bausch Health US, LLC	04/2017
1077	VISTARIL	Capsules	50 mg	Pfizer Inc.	07/2020
1078	VIVELLE-DOT	Transdermal System	0.1 mg	Sandoz Inc	12/2014
1079	VIVELLE-DOT	Transdermal System	0.0375 mg	Sandoz, Inc	12/2014
1080	VIVELLE-DOT	Transdermal System	0.05 mg	Sandoz Inc	12/2014
1081	VIVELLE-DOT	Transdermal System	0.075 mg	Novartis Pharmaceuticals Corporation	12/2014
1082	VIVELLE-DOT	Transdermal System	0.025 mg	Sandoz Inc	12/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1083	VOGELXO	Gel	50 mg	Upsher-Smith Laboratories, LLC	06/2014
1084	VOLTAREN	Delayed-release Tablets	25 mg	Novartis Pharmaceuticals Corporation	Prior to 1/1/1999
1085	VOLTAREN	Delayed-release Tablets	50 mg	Novartis Pharmaceuticals Corporation	Prior to 1/1/1999
1086	VOLTAREN	Gel	1%	GlaxoSmithKline Consumer Healthcare	07/2016
1087	VOLTAREN XR	Extended-release Tablets	100 mg	Novartis Pharmaceuticals Corporation	05/22/2000
1088	VUSION	Ointment	0.25%, 15%, and 81.35%	Mylan Pharmaceuticals Inc., a Viatris Company	11/2018
1089	WELCHOL	Powder for Oral Suspension	3.75 g packet	Cosette Pharmaceuticals, Inc.	08/2022
1090	WELCHOL	Tablets	625mg	Cosette Pharmaceuticals, Inc.	8/1/2022
1091	XALATAN	Ophthalmic Solution	0.005% (125 mcg/2.5 mL)	Upjohn US 2, LLC	11/15/2010
1092	XANAX	Tablets	0.25 mg	Upjohn US 2 LLC	06/17/2003
1093	XANAX	Tablets	0.5 mg	Upjohn US 2 LLC	06/18/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1094	XANAX	Tablets	1 mg	Upjohn US 2 LLC	06/18/2003
1095	XANAX	Tablets	2 mg	Upjohn US 2 LLC	06/18/2003
1096	XANAX XR	Extended-release Tablets	0.5 mg	Upjohn US 2 LLC	11/16/2005
1097	XANAX XR	Extended-release Tablets	1 mg	Upjohn US 2 LLC	11/16/2005
1098	XANAX XR	Extended-release Tablets	2 mg	Upjohn US 2 LLC	11/16/2005
1099	XANAX XR	Extended-release Tablets	3 mg	Upjohn US 2 LLC	11/16/2005
1100	XENAZINE	Tablets	25 mg	Bausch Health US, LLC	07/20/2015
1101	XENAZINE	Tablets	12.5 mg	Bausch Health US, LLC	07/20/2015
1102	XENICAL	Capsules	120 mg	CHEPLAPHARM Arzneimittel GmbH	6/1/2022
1103	XIMINO	Extended-release Capsules	45 mg	Journey Medical Corporation	04/2020
1104	XIMINO	Extended-release Capsules	135 mg	Journey Medical Corporation	04/2020
1105	XIMINO	Extended-release Capsules	90 mg	Journey Medical Corporation	04/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1106	XOPENEX	Inhalation Solution	0.63 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1107	XOPENEX	Inhalation Solution	0.31 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1108	XOPENEX	Inhalation Solution	1.25 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1109	XOPENEX HFA	Aerosol, metered	45 mcg/actuation 45 mcg/actuation	Lupin Inc	10/2016
1110	XYREM	Oral Solution	.5g/mL	Jazz Pharmaceuticals, Inc.	7/3/2023
1111	XYREM	Oral Solution	.5g/mL	Jazz Pharmaceuticals, Inc.	1/3/2023
1112	YASMIN	Tablets	3 mg; 0.03 mg	Bayer HealthCare Pharmaceuticals Inc.	05/09/2008
1113	ZANAFLEX	Capsule	6 mg	Covis Pharma GmbH	10/2011
1114	ZANAFLEX	Capsule	4 mg	Covis Pharma GmbH	10/2011
1115	ZARONTIN	Capsules	250 mg	Parke-Davis Division of Pfizer Inc.	10/12/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1116	ZAROXOLYN	Tablets	2.5 mg	Lannett Company, Inc.	10/2018
1117	ZAROXOLYN	Tablets	10 mg	Lannett Company, Inc.	10/2018
1118	ZAROXOLYN	Tablets	5 mg	Lannett Company, Inc.	11/2002 - 10/2003
1119	ZAVESCA	Capsules	100 mg	Actelion Pharmaceuticals Ltd.	04/2018
1120	ZEBETA	Tablets	5 mg	Lederle Laboratories	08/2000 - 08/2001
1121	ZEBETA	Tablets	10 mg	Lederle Laboratories	08/2000 - 08/2001
1122	ZEGERID	Capsules	20 mg/1100 mg	Salix Pharmaceuticals, Inc.	02/27/2006
1123	ZEGERID	Capsules	40 mg/1100 mg	Salix Pharmaceuticals, Inc.	02/27/2006
1124	ZEGERID	Powder for Oral Suspension	20 mg/1680 mg	Salix Pharmaceuticals, Inc.	06/2014
1125	ZEGERID	Powder for Oral Suspension	40 mg/1680 mg	Salix Pharmaceuticals, Inc.	06/2014
1126	ZEMPLAR	Capsules	1 mcg	AbbVie Inc.	03/2014
1127	ZEMPLAR	Capsules	2 mcg	AbbVie Inc.	03/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1128	ZENPEP	Delayed Release Capsules	5000 lipase USP units	Eurand Pharmaceuticals, Ltd.	12/2/2009
1129	ZIAC	Tablets	2.5 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D, Inc.	08/2019
1130	ZIAC	Tablets	5 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D, Inc.	08/2019
1131	ZIAC	Tablets	10 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D, Inc.	08/2019
1132	ZIANA	Gel	1.2% and 0.025%	Bausch Health US, LLC	09/2020
1133	ZIOPTAN	Sterile Ophthalmic Solution	0.0015%	Thea Pharma Inc.	11/18/2022
1134	ZITHROMAX	Powder for Oral Suspension	300 mg (15 mL when mixed)	Pfizer Inc.	02/01/2005
1135	ZITHROMAX	Powder for Oral Suspension	600 mg (15 mL when mixed)	Pfizer Inc.	02/1/2005
1136	ZITHROMAX	Powder for Oral Suspension	900 mg (22.5 mL when mixed)	Pfizer Inc.	02/01/2005
1137	ZITHROMAX	Powder for Oral Suspension	1 gram (single dose packet)	Pfizer Inc.	2/1/2005
1138	ZITHROMAX	Powder for Oral Suspension	1200 mg (30 mL when mixed)	Pfizer Inc.	02/01/2005
1139	ZITHROMAX	Tablets	250 mg	Pfizer Inc.	02/01/2005

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1140	ZOLOFT	Oral Solution, Concentrate	20 mg/mL	Viartis Specialty LLC	03/20/2006
1141	ZOMIG	Nasal Spray	5 mg	Amneal Pharmaceuticals LLC	07/15/2024
1142	ZOMIG	Nasal Spray	2.5 mg	Amneal Pharmaceuticals LLC	07/15/2024
1143	ZONALON and PRUDOXIN	Cream	5%	Mylan Pharmaceuticals, Inc.	01/2019
1144	ZORIVAX	Cream	5%	Bausch Health US, LLC	08/2019
1145	ZOVIRAX	Ointment	5%	Bausch Health US, LLC	04/2014
1146	ZYCLARA	Cream	3.75%	Bausch Health US, LLC	07/2020
1147	ZYCLARA	Cream	3.75%	Bausch Health US, LLC	08/2018
1148	ZYLOPRIM	Tablet	300 mg	Casper Pharma LLC	11/17/2022
1149	ZYLOPRIM	Tablets	200 mg	Casper Pharma LLC	11/17/2022
1150	ZYLOPRIM	Tablets	100 mg	Casper Pharma LLC	11/17/2022
1151	ZYMAXID	Ophthalmic Solution	0.5 %	Allergan Sales, LLC	04/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1152	ZYVOX	Oral Suspension	100 mg/5 mL	Pharmacia and Upjohn Company	12/2015
1153	ZYVOX	Tablets	600 mg	Pharmacia and Upjohn LLC	12/2015