

FDA Listing of Authorized Generics as of April 11, 2024

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	35 mg	Sun Pharmaceutical Industries, Inc.	12/2020
3	ABSORICA	Capsules	30 mg	Sun Pharmaceutical Industries, Inc.	12/2020
4	ABSORICA	Capsules	25 mg	Sun Pharmaceutical Industries, Inc.	12/2020
5	ABSORICA	Capsules	20 mg	Sun Pharmaceutical Industries, Inc.	12/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
6	ABSORICA	Capsules	10 mg	Sun Pharmaceutical Industries, Inc.	12/2020
7	ACANYA	Gel	1.2% / 2.5%	Bausch Health Americas, Inc.	07/2018
8	ACCOLATE	Tablets	20 mg	AstraZeneca Pharmaceuticals	11/19/2010
9	ACCOLATE	Tablets	10 mg	AstraZeneca Pharmaceuticals	11/19/2010
10	ACCUNEB	Solution	1.25 mg/3 mL	Mylan Specialty L.P.	02/2012
11	ACCUNEB	Solution	0.63 mg/3 mL	Mylan Specialty L.P.	02/2012
12	ACEPHEN	Suppositories	120 mg	G & W Laboratories, Inc.	Prior to 1/1/1999
13	ACETADOTE	Injection	6 g/30 mL (200 mg/mL)	Cumberland Pharmaceuticals, Inc.	1/7/2013
14	ACTICLATE	Tablets	150 mg	Almirall, LLC	02/2018
15	ACTICLATE	Tablets	75 mg	Almirall, LLC	02/2018
16	ACTIGALL	Capsules	300 mg	Allergan Sales, LLC	08/13/2003
17	ACTIQ	Lozenge	200 mcg	Cephalon, Inc.	09/26/2006
18	ACTIQ	Lozenge	1200 mcg	Cephalon, Inc.	09/26/2006
19	ACTIQ	Lozenge	600 mcg	Cephalon, Inc.	09/26/2006
20	ACTIQ	Lozenge	400 mcg	Cephalon, Inc.	09/26/2006
21	ACTIQ	Lozenge	800 mcg	Cephalon, Inc.	09/26/2006

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
22	ACTIQ	Lozenge	1600 mcg	Cephalon, Inc.	09/26/2006
23	ACTONEL	Tablets	150 mg	Allergan Pharmaceuticals International Ltd.	06/2014
24	ACULAR LS	Ophthalmic Solution	0.4%	Allergan, Inc.	11/11/2013
25	ACZONE	Gel	7.5%	Almirall, LLC	01/2020
26	ADDERALL XR	Extended-release Capsules	15 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
27	ADDERALL XR	Extended-release Capsules	25 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
28	ADDERALL XR	Extended-release Capsules	20 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
29	ADDERALL XR	Extended-release Capsules	25 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
30	ADDERALL XR	Extended-release Capsules	5 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
31	ADDERALL XR	Extended-release Capsules	10 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
32	ADDERALL XR	Extended-release Capsules	30 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
33	ADDERALL XR	Extended-release Capsules	20 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
34	ADDERALL XR	Extended-release Capsules	15 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
35	ADDERALL XR	Extended-release Capsules	10 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
36	ADDERALL XR	Extended-release Capsules	5 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
37	ADRENACLICK	Injection	0.3 mg	Impax Laboratories, LLC	04/01/2010
38	ADRENACLICK	Injection	0.15 mg	Impax Laboratories, LLC	04/01/2010
39	ADVAIR DISKUS	Inhalation Powder	500/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019
40	ADVAIR DISKUS	Inhalation Powder	250/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019
41	ADVAIR DISKUS	Inhalation Powder	100/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
42	ADVAIR HFA	Inhalation Aerosol	230/21 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	ADVAIR HFA	Inhalation Aresol	45/21 MCG	GlaxoSmithKline Intellectual Property Ltd. England	3/1/2023
45	AIRDUO RESPICLICK	Inhalation Powder	232 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
46	AIRDUO RESPICLICK	Inhalation Powder	55 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
47	AIRDUO RESPICLICK	Inhalation Powder	113 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
48	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2012
49	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
50	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
51	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020

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

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
65	AMBIEN CR	Extended-release Tablets	12.5 mg	Sanofi Aventis U.S. LLC	12/2010
66	AMICAR	Tablets	1000 mg	Clover Pharmaceuticals Corporation	06/01/2012
67	AMITIZA	Capsule	8 mcg	Sucampo Pharma Americas, LLC	1/1/2023
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	24 mcg	Sucampo Pharma Americas, LLC	1/1/2023
71	AMITIZA	Capsules	8 mcg	Sucampo Pharma Americas, LLC	01/2021
72	AMITIZA	Capsules	24 mcg	Sucampo Pharma Americas, LLC	01/2021
73	AMMONUL	Injection	10% / 10%	Bausch Health US, LLC	03/2017
74	AMPYRA	Tablets	10 mg	Acorda Therapeutics, Inc.	09/2018
75	AMRIX	Capsules	15 mg	Cephalon, Inc.	03/2019
76	AMRIX	Capsules	30 mg	Cephalon, Inc.	03/2019
77	AMRIX	Capsules	30 mg	Cephalon, Inc.	03/2019
78	AMRIX	Capsules	15 mg	Cephalon, Inc.	03/2019
79	ANAFRANIL	Capsules	50 mg	Mallinckrodt	07/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
80	ANAFRANIL	Capsules	25 mg	Mallinckrodt	07/2015
81	ANAFRANIL	Capsules	75 mg	Mallinckrodt	07/2015
82	ANAPROX DS	Tablets	550 mg	Atnahs Pharma US Limited	10/2018
83	ANCOBAN	Capsules	500 mg	Bausch Health US, LLC	01/17/2012
84	ANCOBAN	Capsules	250 mg	Bausch Health US, LLC	07/2017
85	ANGIOMAX	Powder, for injection solution, lyophilized	250 mg	Sandoz Inc.	02/2017
86	ANGIOMAX	Powder, for injection solution, lyophilized	250 mg	Sandoz Inc.	10/2015
87	ANTARA	Capsules	43 mg	Lupin, Inc.	02/22/2013
88	ANTARA	Capsules	130 mg	Lupin, Inc.	02/22/2013
89	ANTIVERT	Tablets	12.5 mg	Casper Pharma LLC	01/2020
90	ANTIVERT	Tablets	25 mg	Casper Pharma LLC	01/2020
91	APADAZ	Tablets	8.16 mg / 325 mg	KVK-Tech, Inc.	06/2019
92	APRISO	Extended-release Capsules	0.375 g	Salix Pharmaceuticals, Inc.	07/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
93	APTENSIO XR	Extended-release Capsules	20 mg	Rhodes Pharmaceuticals L.P.	04/2020
94	APTENSIO XR	Extended-release Capsules	15 mg	Rhodes Pharmaceuticals L.P.	04/2020
95	APTENSIO XR	Extended-release Capsules	10 mg	Rhodes Pharmaceuticals L.P.	04/2020
96	APTENSIO XR	Extended-release Capsules	30 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	60 mg	Rhodes Pharmaceuticals L.P.	04/2020
99	APTENSIO XR	Extended-release Capsules	50 mg	Rhodes Pharmaceuticals L.P.	04/2020
100	ARAVA	Tablets	20 mg	Sanofi Aventis US LLC	09/07/2015
101	ARAVA	Tablets	10 mg	Sanofi Aventis US LLC	09/07/2015
102	ARICEPT	Film coated tablets	5 mg	Eisai, Inc.	11/25/2009 - 11/24/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
103	ARICEPT	Film coated tablets	10 mg	Eisai, Inc.	11/25/2009 - 11/24/2010
104	ARICEPT ODT	Orally disintegrating tablets	10 mg	Eisai, Inc.	10/18/2009 - 11/24/2010
105	ARICEPT ODT	Orally distinegrating tablets	5 mg	Eisai, Inc.	10/18/2009 - 11/24/2010
106	ARIXTRA	Injection	2.5 mg / 0.5 mL	Mylan Ireland Limited	12/2014 - 12/2015
107	ARIXTRA	Injection	5 mg / 0.4 mL	Mylan Ireland Limited	12/2014 - 12/2015
108	ARIXTRA	Injection	7.5 mg / 0.6 mL	Mylan Ireland Limited	12/2014 - 12/2015
109	ARIXTRA	Injection	10 mg / 0.8 mL	Mylan Ireland Limited	12/2014 - 12/2015
110	AROMASIN	Tablets	25 mg	Pfizer Inc.	11/02/2010
111	ARTHROTEC	Tablets	75 mg/200 mcg	Pfizer Inc.	07/10/2011
112	ARTHROTEC	Tablets	50 mg/200 mcg	Pfizer Inc.	07/10/2011
113	ATACAND	Tablets	16 mg	ANI Pharmaceuticals, Inc.	05/21/2013
114	ATACAND	Tablets	8 mg	ANI Pharmaceuticals, Inc.	05/21/2013

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115	ATACAND	Tablets	4 mg	ANI Pharmaceuticals, Inc.	05/21/2013
116	ATACAND	Tablets	32 mg	ANI Pharmaceuticals, Inc.	05/21/2013
117	ATACAND HCT	Tablets	32 mg/25 mg	ANI Pharmaceuticals, Inc.	09/2018
118	ATACAND HCT	Tablets	32 mg/12.5 mg	ANI Pharmaceuticals, Inc.	09/2018
119	ATACAND HCT	Tablets	16 mg/12.5 mg	ANI Pharmaceuticals, Inc.	09/2018
120	ADELVIA	Delayed-release Tablets	35 mg	Allergan	2015
121	ATIVAN	Injection	2 mg/mL	Baxter Healthcare Corporation	10/31/2003
122	ATIVAN	Injection	4 mg/mL	Baxter Healthcare Corporation	10/31/2003
123	ATRALIN	Gel	0.05%	Bausch Health Americas, Inc.	07/26/2007
124	AUGMENTIN	Oral Suspension	200 mg/28.5 mg per 5 mL	Dr. Reddy's Laboratories Inc.	10/22/1990
125	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
126	AUGMENTIN	Powder for Oral Suspension	250mg/62.5mg/5mL	USAntibiotics, LLC	12/5/2022
127	AUGMENTIN	Tablets	250 mg	Dr. Reddy's Laboratories Inc.	10/22/1990
128	AUGMENTIN	Tablets	500 mg	Dr. Reddy's Laboratories Inc.	10/22/1990
129	AUGMENTIN	Tablets	875 mg	Dr. Reddy's Laboratories Inc.	10/02/1996
130	AVALIDE	Tablets	150 mg/12.5 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
131	AVALIDE	Tablets	300 mg/12.5 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
132	AVAPRO	Tablets	300 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
133	AVAPRO	Tablets	150 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	AVELOX	Tablets	400 mg	Bayer HealthCare LLC	01/2014
136	AVITA	Cream	0.025%	Mylan Pharmaceuticals, Inc., a Viatris Company	05/01/1998
137	AZILECT	Tablets	0.5 mg	Teva Pharmaceuticals USA	01/2017

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

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
151	BICNU	Powder for Injection	100 mg/vial	Avet Lifesciences Private Ltd.	10/2019
152	BIDIL	Tablets	20 mg/37.5 mg	Azurity Pharmaceuticals, Inc.	04/2022
153	BLOCADREN	Tablets	5 mg	Merck & Co., Inc.	Prior to 1/1/1999
154	BLOCADREN	Tablets	10 mg	Merck & Co., Inc.	Prior to 1/1/1999
155	BREVIBLOC	Injection	10 mg/mL	Baxter Healthcare Corporation	11/2002 - 10/2003
156	BRISDELLE	Capsules	7.5 mg	Sebela Ireland Limited	10/2017
157	BUMEX	Tablets	0.5 mg	Validus Pharmaceuticals LLC	10/2015
158	BUMEX	Tablets	1 mg	Validus Pharmaceuticals LLC	10/2015
159	BUMEX	Tablets	2 mg	Validus Pharmaceuticals LLC	10/2015
160	BUTRANS	Transdermal System	7.5 mcg/hour	Purdue Pharma L.P.	07/2017
161	BUTRANS	Transdermal System	5 mcg/hour	Purdue Pharma L.P.	07/2017
162	BUTRANS	Transdermal System	10 mcg/hour	Purdue Pharma L.P.	07/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
163	BUTRANS	Transdermal System	15 mcg/hour	Purdue Pharma L.P.	07/2017
164	BUTRANS	Transdermal System	20 mcg/hour	Purdue Pharma L.P.	07/2017
165	CADUET	Tablet	10/20 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
166	CADUET	Tablet	2.5/10 mg	Pharmacia & Upjohn Co. LLC	03/14/2022
167	CADUET	Tablet	2.5/20 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
168	CADUET	Tablet	10/80 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
169	CADUET	Tablet	10/40 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
170	CADUET	Tablet	2.5/40 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
171	CADUET	Tablet	5/10 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
172	CADUET	Tablet	5/20 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
173	CADUET	Tablet	5/40 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
174	CADUET	Tablet	5/80 mg	Pharmacia & Upjohn Co. LLC	3/14/2022
175	CADUET	Tablet	10/10 mg	Pharmacia & Upjohn Co. LLC	3/14/2022

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
176	CANASA	Suppository	1000 mg	AbbVie, Inc.	12/2018
177	CARAC	Cream	0.5%	Bausch Health US, LLC	08/2020
178	CARAFATE	Oral Suspension	1 g/10 mL	Allergan Sales, LLC	12/2019
179	CARAFATE	Tablets	1 g	Allergan Sales, LLC	11/01/1996
180	CARBATROL	Extended-Release Capsules	100 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
181	CARBATROL	Extended-Release Capsules	300 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
182	CARBATROL	Extended-Release Capsules	200 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
183	CARDIOLITE	Injection	(per label)	Lantheus Medical Imaging, Inc.	12/1990
184	CARDIZEM	Tablets	30 mg	Bausch Health US, LLC	Prior to 1/1/1999
185	CARDIZEM	Tablets	60 mg	Bausch Health US, LLC	Prior to 1/1/1999
186	CARDIZEM	Tablets	90 mg	Bausch Health US, LLC	Prior to 1/1/1999
187	CARDIZEM	Tablets	120 mg	Bausch Health US, LLC	Prior to 1/1/1999

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

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

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213	CIPRO	for Oral Suspension	500 mg/5 mL	Bayer Pharmaceuticals Corp.	06/2003
214	CIPRODEX	Otic Suspension	0.3% & 0.1%	Novartis Pharmaceuticals Corporation	08/2020
215	CLEOCIN	Vaginal Cream	2%	Pfizer	12/17/2005
216	CLEOCIN HCl	Capsules	150 mg	Pfizer	07/11/2003
217	CLEOCIN HCl	Capsules	300 mg	Pfizer	06/18/2003
218	CLEOCIN PHOSPHATE	Injection	600 mg/4 mL	Pfizer	06/2019
219	CLEOCIN PHOSPHATE	Injection	900 mg/6 mL	Pfizer	06/2019
220	CLEOCIN PHOSPHATE	Injection	300 mg/2 mL	Pfizer	06/2019
221	CLEOCIN PHOSPHATE	Injection	9,000/60 mL	Pfizer	06/2019
222	CLEOCIN T	Topical Gel	1%	Pfizer	06/11/2003
223	CLEOCIN T	Topical Lotion	1%	Pfizer	06/18/2003
224	CLIMARA	Transdermal System	0.06 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
225	CLIMARA	Transdermal System	1 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
226	CLIMARA	Transdermal System	0.05 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
227	CLIMARA	Transdermal System	0.025 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
228	CLIMARA	Transdermal System	0.075 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
229	CLIMARA	Transdermal System	0.375 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
230	CLINDAGEL	Gel	1%	Bausch Health U.S., LLC	06/2018
231	CLINORIL	Tablets	150 mg	Merck & Co., Inc.	Prior to 1/1/1999
232	CLINORIL	Tablets	200 mg	Merck & Co., Inc.	Prior to 1/1/1999
233	CLOBEX	Shampoo	0.05%	Galderma Laboratories, L.P.	1/2024
234	CLOBEX	Spray	0.05%	Galderma Laboratories, L.P.	08/2015
235	CLODERM	Cream	0.1%	EPI Health, LLC	02/17/2014
236	CLODERM	Cream	0.1%	EPI Health, LLC	09/2019
237	CLOLAR	Injection	20mg/20mL	Genzyme Corporation	05/2017
238	CLOMID	Tablets	50 mg	Hoechst Marion Roussel, Inc.	Prior to 1/1/1999
239	CLOZARIL	Tablets	200 mg	Heritage Life Sciences (USA), Inc.	05/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
240	CLOZARIL	Tablets	50 mg	Heritage Life Sciences (USA), Inc.	03/2019
241	CLOZARIL	Tablets	25 mg	Heritage Life Sciences (USA), Inc.	03/2019
242	CLOZARIL	Tablets	100 mg	Heritage Life Sciences (USA), Inc.	03/2019
243	COLCRYS	Tablets	0.6 mg	Takeda Pharmaceuticals U.S.A. Inc.	07/01/2018
244	COLESTID	Granules for Oral Suspension	5 g per dose	Pharmacia and Upjohn LLC	01/11/2016
245	COLESTID	Tablets	1 g	Pharmacia and Upjohn LLC	02/2007
246	COLY-MYCIN M	for Injection	150 mg/vial (single dose vial)	Par Sterile Products, LLC	06/01/2012
247	COMTAN	Tablets	200 mg	Orion Corporation	06/04/2014
248	COMTAN	Tablets	200 mg	Orion Corporation	6/26/2013
249	COMTAN	Tablets	200 mg	Orion Corporation	10/19/2021
250	CONCERTA	Extended-release Tablets	36 mg	Janssen Research and Development, LLC	02/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
251	CONCERTA	Extended-release Tablets	54 mg	Janssen Research and Development, LLC	02/2019
252	CONCERTA	Extended-release Tablets	18 mg	Janssen Research and Development, LLC	02/2019
253	CONCERTA	Extended-release Tablets	27 mg	Janssen Research and Development, LLC	02/2019
254	CONDYLOX	Topical Solution	0.5%	Teva Branded Pharmaceuticals Products R&D, Inc	12/16/2003
255	CONZIP	Extended-release Capsules	100 mg	Cipher Pharmaceuticals, Inc.	06/2015
256	CONZIP	Extended-release Capsules	300 mg	Cipher Pharmaceuticals, Inc.	06/2015
257	CONZIP	Extended-release Capsules	200 mg	Cipher Pharmaceuticals, Inc.	05/2015
258	COREG CR	Capsules	80 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
259	COREG CR	Capsules	10 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
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	CORGARD	Tablets	20 mg	US WorldMeds, LLC	05/05/2014
263	CORGARD	Tablets	40 mg	US WorldMeds, LLC	05/05/2014
264	CORGARD	Tablets	80 mg	US WorldMeds, LLC	05/05/2014
265	CORTEF	Tablets	10 mg	Pharmacia and Upjohn Company LLC	12/21/2012
266	CORTEF	Tablets	20 mg	Pharmacia and Upjohn Company LLC	12/22/2012
267	CORTEF	Tablets	5 mg	Pharmacia and Upjohn Company LLC	12/21/2012
268	CORTENEMA	Rectal Suspension	100 mg/60 mL	ANI Pharmaceuticals, Inc.	08/2012
269	CORTISPORIN OTIC	Otic Solution	eq. 3.5 mg base/g; 10,000 units/g; 1%	Monarch Pharmaceuticals Inc.	1/11/1999

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
270	COSMEGEN	Powder, for injection solution, lyophilized	500 mcg (0.5 mg)	Recordati Rare Diseases Inc.	12/2017
271	CUBICIN	Injection, powder, lyophilized, for solution	500 mg per vial	Cubist Pharmaceuticals, LLC	06/2016
272	CUPRIMINE	Capsules	250 mg	Bausch Health Americas, Inc.	12/1970
273	CUTIVATE	Cream	0.05%	GlaxoSmithKline Consumer Healthcare	11/2003 - 11/2004
274	CUTIVATE	Ointment	0.005%	GlaxoSmithKline Consumer Healthcare	11/2003 - 11/2004
275	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
276	CYTOMEL	Tablets	5 mcg	King Pharmaceuticals R&D LLC	02/2019
277	CYTOMEL	Tablets	50 mcg	King Pharmaceuticals R&D LLC	06/2019
278	CYTOMEL	Tablets	25 mcg	King Pharmaceuticals R&D LLC	06/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
279	CYTOTEC	Tablets	100 mcg	Pfizer Inc.	06/18/2003
280	CYTOTEC	Tablets	200 mcg	Pfizer Inc.	06/18/2003
281	DANTRIUM	Capsules	25 mg	Par Sterile Products, LLC	04/08/2013
282	DANTRIUM	Capsules	100 mg	Par Sterile Products, LLC	02/2016
283	DANTRIUM	Capsules	50 mg	Par Sterile Products, LLC	04/08/2013
284	DARAPRIM	Tablets	25 mg	Vyera Pharmaceuticals, LLC	03/2020
285	DAYPRO	Caplets	600 mg	Pfizer Inc.	03/28/2013
286	DDAVP	Nasal Solution	10 mcg / 0.1 mL	Ferring Pharmaceuticals, Inc.	07/2016
287	DDAVP	Tablets	0.1 mg	Ferring Pharmaceuticals, Inc.	12/2015
288	DDAVP	Tablets	0.2 mg	Ferring Pharmaceuticals, Inc.	12/2015
289	DDAVP, DESMOPRESSIN ACETATE	Injection	4 mcg/mL	Ferring Pharmaceuticals Inc.	01/2016
290	DELESTROGEN	Injection	40 mg/mL	Par Sterile Products	06/01/2012
291	DELESTROGEN	Injection	10 mg/mL	Par Sterile Products	06/01/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
292	DELESTROGEN	Injection	20 mg/mL	Par Sterile Products	06/01/2012
293	DEMSER	Capsules	250 mg	Bausch Health US, LLC	09/2020
294	DENAVIR	Cream	1%	Mylan Pharmaceuticals Inc.	11/16/2022
295	DEPAKOTE ER	Extended-release Tablets	500 mg	Abbvie Inc.	08/2013
296	DEPAKOTE ER	Extended-release Tablets	250 mg	Abbvie Inc.	08/2013
297	DEPAKOTE SPRINKLE CAPSULES	Capsules	125 mg	AbbVie Inc.	08/31/2015
298	DEPO-MEDROL	Injection	40 mg/mL	Pharmacia and Upjohn	05/2006 - 05/2007
299	DEPO-MEDROL	Injection	80 mg/mL	Pharmacia and Upjohn	05/2006 - 05/2007
300	DEPO-PROVERA	Injection	150 mg in 1 mL	Pharmacia and Upjohn LLC	09/16/2004
301	DERMA-SMOOTH/FS (Body Oil)	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
302	DERMA-SMOOTH/FS (Scalp Oil)	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
303	DERMOTIC	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
304	DERMOTIC OIL	Oil	0.01%	Hill Dermaceuticals Inc.	08/20/2013
305	DESMOPRESSIN ACETATE	Nasal Spray	10 mcg per 0.1 mL (5 mL bottle)	Ferring Pharmaceuticals, Inc.	11/20/2014
306	DESOWEN	Cream	0.05%	Galderma Laboratories, L.P.	07/2013
307	DETROL	Tablets	1 mg	Upjohn US 2 LLC	01/2014
308	DETROL	Tablets	2 mg	Upjohn US 2 LLC	01/2014, 01/2016
309	DETROL LA	Extended-release Capsules	2 mg	Upjohn US 2 LLC	01/2016
310	DETROL LA	Extended-release Capsules	4 mg	Upjohn US 2 LLC	12/2014
311	DEXEDRINE SPANSULE	Extended-release Capsules	5 mg	Impax Laboratories, LLC	08/1976
312	DEXEDRINE SPANSULE	Extended-release Capsules	15 mg	Impax Laboratories, LLC	08/1976
313	DEXEDRINE SPANSULE	Extended-release Capsules	10 mg	Impax Laboratories, LLC	08/1976
314	DEXILANT	Delayed-release Capsules	60 mg	Takeda Pharmaceuticals U.S.A., Inc.	01/2022

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
315	DEXILANT	Delayed-release Capsules	30 mg	Takeda Pharmaceuticals U.S.A., Inc.	01/2022
316	DIABETA	Tablets	2.5 mg	Sanofi-Aventis U.S., LLC	05/01/1984
317	DIABETA	Tablets	5 mg	Sanofi-Aventis U.S., LLC	05/01/1984
318	DIAMOX SEQUELS	Extended-release Capsules	500 mg	Teva Branded Pharmaceutical Products R&D, Inc.	12/2008
319	DIASTAT ACUDIAL	Gel	10 mg	Bausch Health US, LLC	07/1997
320	DIASTAT ACUDIAL	Gel	2.5 mg	Bausch Health US, LLC	07/1997
321	DIASTAT ACUDIAL	Gel	20 mg	Bausch Health US, LLC	07/1997
322	DIBENZYLINE	Capsules	10 mg	Concordia Pharmaceuticals Inc.	08/11/2015
323	DICLEGIS	Delayed-release Tablets	10 mg/10 mg	Duchesnay Inc.	11/2018
324	DIFFERIN CREAM 0.1%	Cream	0.1%	Galderma Laboratories, L.P.	10/2010
325	DIFFERIN GEL 0.1%	Gel	0.1%	Galderma Laboratories, L.P.	08/23/2010
326	DIFFERIN GEL 0.3%	Gel	0.3%	Galderma Laboratories, L.P.	01/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
327	DIFLUCAN	Powder for Oral Suspension	10 mg/mL when reconstituted	Pfizer Inc.	03/12/2004
328	DIFLUCAN	Powder for Oral Suspension	40 mg/mL when reconstituted	Pfizer Inc.	03/12/2004
329	DIFLUCAN	Tablets	100 mg	Pfizer Inc.	03/12/2004
330	DIFLUCAN	Tablets	150 mg	Pfizer Inc.	03/12/2004
331	DIFLUCAN	Tablets	200 mg	Pfizer Inc.	03/12/2004
332	DILANTIN	Tablet (INFATABS)	50 mg	Parke-Davis Division of Pfizer Inc.	12/27/2012
333	DILANTIN-125	Oral Suspension	125 mg/5 mL (237 mL bottle)	Viartis Specialty LLC	04/2020
334	DILAUDID	Solution	5 mg/5 mL (1 mg/mL)	Rhodes Pharmaceuticals L.P.	10/1/2012
335	DILAUDID	Tablets	2 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
336	DILAUDID	Tablets	4 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
337	DILAUDID	Tablets	8 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
338	DIPROLENE	Ointment	0.05%	Organon LLC	8/10/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
339	DITROPAN XL	Extended-release Tablets	5 mg	Janssen Research and Development, LLC	11/12/2015
340	DITROPAN XL	Extended-release Tablets	10 mg	Janssen Research and Development, LLC	11/12/2015
341	DIURIL	Injection	500 mg/vial, sterile lyophilized	Oak Pharmaceuticals Inc.	08/13/2012
342	DORAL	Tablets	15 mg	Galt Pharmaceuticals, LLC	8/8/13
343	DORIBAX	Powder for Injection	500 mg/vial	Shionogi Inc.	12/2016
344	DORIBAX	Powder for Injection	250 mg/vial	Shionogi Inc.	12/2016
345	DORYX	Delayed-Release Tablets	80 mg	Mayne Pharma International Pty Ltd.	07/08/2013
346	DORYX	Delayed-Release Tablets	150 mg	Mayne Pharma International Pty Ltd.	07/08/2013
347	DORYX	Delayed-Release Tablets	100 mg	Mayne Pharma International Pty Ltd.	07/08/2013
348	DORYX	Delayed-Release Tablets	200 mg	Mayne Pharma International Pty Ltd.	02/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
349	DORYX	Delayed-Release Tablets	75 mg	Mayne Pharma International Pty Ltd.	07/08/2013
350	DORYX	Delayed-Release Tablets	50 mg	Mayne Pharma International Pty Ltd.	05/2016
351	DOSTINEX	Tablets	0.5 mg	Pfizer Inc.	09/22/2014
352	DOVONEX	Cream	0.005%	LEO Pharma Inc.	2012
353	DOVONEX	Ointment	0.005%	LEO Pharma Inc.	07/01/2013
354	DOXIL	Injection (Liposomal formulation)	20 mg/10 mL single use vial	Janssen Research & Development, LLC	07/2017
355	DOXIL	Injection (Liposomal formulation)	50 mg/25 mL single use vial	Janssen Research & Development, LLC	07/2017
356	DOXORUBICIN	Injection	50 mg/25 mL	Pharmacia and Upjohn	03/17/2014
357	DOXORUBICIN	Injection	20 mg/10mL	Pharmacia and Upjohn	03/17/2014
358	DOXORUBICIN	Injection	10 mg/5 mL	Pharmacia and Upjohn	03/17/2014
359	DOXORUBICIN	Injection	10 mg/5 mL	Pharmacia and Upjohn	4/1/2013
360	DOXORUBICIN	Injection	200 mg/100 mL	Pharmacia and Upjohn	4/1/2013
361	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
362	DOXORUBICIN	Injection	50 mg/25 mL	Pharmacia and Upjohn	4/1/2013
363	DOXORUBICIN	Injection	150 mg/75 mL	Pharmacia and Upjohn	4/1/2013
364	DOXORUBICIN	Injection	200 mg/ 100 mL	Pharmacia and Upjohn	03/17/2014
365	DUETACT	Tablets	30 mg / 2 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/04/2015
366	DUETACT	Tablets	30 mg / 4 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/04/2015
367	DUEXIS	Tablets	800 mg and 26.6 mg	Horizon Medicines LLC	09/2021
368	DUREZOL	Ophthalmic Emulsion	0.05%	Novartis Pharmaceuticals Corporation	09/2021
369	DYMISTA	Nasal Spray	137 mcg/50 mcg per spray	Mylan Specialty, L.P.	04/2020
370	DYRENIUM	Capsules	100 mg	Concordia Pharmaceuticals Inc.	08/2019
371	DYRENIUM	Capsules	50 mg	Concordia Pharmaceuticals Inc.	08/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
372	E.E.S. GRANULES	Suspension	200 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	09/2016
373	EDECRIN	Powder, for Injection Solution, Lyophilized	50 mg/vial	Bausch Health Americas, Inc.	01/1967
374	EDECRIN	Tablets	25 mg	Bausch Health Americas, Inc.	01/2016 - 01/2017
375	EFUDEX	Cream	5%	Bausch Health Americas, Inc.	07/2013
376	ELDEPRYL	Capsules	5 mg	Somerset Pharmaceuticals, Inc.	05/1998 - 05/1999
377	ELDEPRYL	Tablets	5 mg	Somerset Pharmaceuticals, Inc.	06/1999 - 06/2000
378	ELIDEL	Cream	1%	Bausch Health US, LLC	12/2018
379	ELIMITE	Cream	5%	Mylan Pharmaceuticals, Inc.	06/2017
380	ELOXATIN	Injection	50 mg / 10 mL (5 mg/mL)	Sanofi-Aventis US LLC	07/07/2014
381	ELOXATIN	Injection	100 mg / 20 mL (5 mg/mL)	Sanofi-Aventis US LLC	07/07/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
382	ELOXATIN (PREMIERPro)	Injection	50 mg/10 mL (5 mg/mL)	Sanofi-Aventis US LLC	10/2015
383	ELOXATIN (PREMIERPro)	Injection	100 mg / 20 mL (5 mg/mL)	Sanofi-Aventis US LLC	10/2015
384	EMLA	Cream	2.5% and 2.5%	Teva Branded Pharmaceutical Products R&D, Inc.	11/12/2012
385	ENTOCORT EC	Capsules	3 mg	Padagis US LLC	08/18/2011
386	EPANED	Oral Solution	1 mg/mL	Azurity Pharmaceuticals, Inc.	03/2022
387	EPCLUSA	Tablets	400 mg / 100 mg	Gilead Sciences, Inc.	10/2018
388	EPIDUO	Topical Gel	0.1% / 2.5%	Galderma Laboratories, L.P.	08/2017
389	EPIDUO FORTE	Gel	0.3% and 2.5%	Galderma Laboratories, L.P.	02/2022
390	EPIPEN	Injection	0.3 mg/0.3 mL	Mylan Specialty L.P., a Viatris Company	12/15/2016
391	EPIPEN JR.	Injection	0.15/0.3 mL	Mylan Specialty L.P., a Viatris Company	12/15/2016
392	EPIVIR-HBV	Tablets	100 mg	GlaxoSmithKline LLC	09/05/2014
393	EPZICOM	Tablets	600 mg and 300 mg	ViiV Healthcare Company	09/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
394	ERYC	Delayed-Release Capsules	250 mg	Dr. Reddy's Laboratories, SA	07/29/2013
395	ERYGEL	Topical Gel	2%	Mylan Pharmaceuticals, Inc.	10/2018
396	ERYPED 200	Suspension	200 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	08/2020
397	ERYPED 400	Suspension	400 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	03/2019
398	EVOXAC	Capsules	30 mg	Daiichi Sankyo, Inc.	03/2016
399	EXALGO	Extended-release Tablets	32 mg	SpecGx LLC	06/12/2014
400	EXALGO	Extended-release Tablets	8 mg	SpecGx LLC	06/12/2014
401	EXALGO	Extended-release Tablets	12 mg	SpecGx LLC	06/12/2014
402	EXALGO	Extended-release Tablets	16 mg	SpecGx LLC	06/12/2014
403	EXELDERM	Cream	1.0%	Journey Medical Corporation	02/2020
404	EXELDERM	Solution	1.0%	Journey Medical Corporation	02/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
405	EXELON	Patch	9.5 mg/24 hours	Novartis Pharmaceuticals Corporation	09/2015
406	EXELON	Patch	4.6 mg/24 hours	Novartis Pharmaceuticals Corporation	09/2015
407	EXELON	Patch	13.3 mg/24 hours	Novartis Pharmaceuticals Corporation	09/2015
408	EXTINA	Aerosol Foam	2%	Mylan Pharmaceuticals Inc.	12/2018
409	FABIOR	Aerosol Foam	0.1%	Mayne Pharma LLC	04/2021
410	FAMVIR	Tablets	250 mg	Novartis	03/22/2011
411	FAMVIR	Tablets	125 mg	Novartis	03/22/2011
412	FAMVIR FAMVIR	Tablets	500 mg	Novartis	03/22/2011
413	FELBATOL	Oral Suspension	600 mg/5 mL	Mylan Specialty, L.P., a Viatris Company	1/2012
414	FELBATOL	Tablets	400 mg	Mylan Specialty, L.P., a Viatris Company	11/2011
415	FELBATOL	Tablets	600 mg	Mylan Specialty, L.P., a Viatris Company	11/2011
416	FELDENE	Capsules	20 mg	Pfizer Inc.	03/03/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
417	FELDENE	Capsules	10 mg	Pfizer Inc.	03/03/2014
418	FEMCON Fe	Chewable Tablets	0.4 mg/35 mcg	Allergan Pharmaceuticals International Ltd.	10/2011
419	FENOGLIDE	Tablets	40 mg	Salix Pharmaceuticals, Inc.	06/24/2015
420	FENOGLIDE	Tablets	120 mg	Salix Pharmaceuticals, Inc.	03/2021
421	FENOGLIDE	Tablets	120 mg	Salix Pharmaceuticals, Inc.	06/24/2015
422	FENOGLIDE	Tablets	40 mg	Salix Pharmaceuticals, Inc.	03/2021
423	FENTORA	Tablet	200 mcg	Cephalon, Inc.	06/2019
424	FENTORA	Tablet	800 mcg	Cephalon, Inc.	06/2019
425	FENTORA	Tablet	400 mcg	Cephalon, Inc.	06/2019
426	FENTORA	Tablet	600 mcg	Cephalon, Inc.	06/2019
427	FIBRICOR	Tablets	35 mg	Athena Biosciences, LLC	09/22/2010
428	FIBRICOR	Tablets	105 mg	Athena Biosciences, LLC	09/22/2010
429	FINACEA	Gel	15%	LEO Pharma Inc.	10/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
430	FIORICET with CODEINE	Capsules	50 mg / 325 mg / 40 mg / 30 mg	Teva Branded Pharmaceutical Products R&D, Inc.	10/01/2003
431	FIRAZYR	Injection	30 mg / 3.0ML	Shire Human Genetic Therapies, Inc.	07/2019
432	FLECTOR	Topical System	1.3%	Institut Biochimique SA (IBSA)	03/2019
433	FLECTOR	Topical System	1.3%	Institut Biochimique SA (IBSA)	03/2019
434	FLEQSUVY	Suspension	5 mg/mL	Azurity Pharmaceuticals, Inc.	04/01/2023
435	FLORONE	Cream	0.05%	Pharmacia and Upjohn Company	Prior to 1/1/1999
436	FLOVENT HFA	Inhalation Aerosol	44 mcg	GlaxoSmithKline Intellectual Property Ltd England	05/2022
437	FLOVENT HFA	Inhalation Aerosol	110 mcg	GlaxoSmithKline Intellectual Property Ltd England	05/2022
438	FLOVENT HFA	Inhalation Aerosol	220 mcg	GlaxoSmithKline Intellectual Property Ltd England	05/2022
439	FLUMADINE	Tablets	100 mg	Forest Laboratories, Inc.	09/2002 - 09/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
440	FLUOXETINE	Tablets	60 mg	Alvogen Group Holdings 3, LLC	09/2017
441	FML	Ophthalmic Suspension	0.1%	Allergan, Inc.	10/1997
442	FOCALIN XR	Extended-release Capsules	15 mg	Novartis Pharmaceuticals Corporation	01/2014
443	FOCALIN XR	Extended-release Capsules	20 mg	Novartis Pharmaceuticals Corporation	06/2015
444	FOCALIN XR	Extended-release Capsules	30 mg	Novartis Pharmaceuticals Corporation	01/2014
445	FOCALIN XR	Extended-release Capsules	10 mg	Novartis Pharmaceuticals Corporation	02/2015
446	FOCALIN XR	Extended-release Capsules	5 mg	Novartis Pharmaceuticals Corporation	11/2014
447	FOCALIN XR	Extended-release Capsules	35 mg	Novartis Pharmaceuticals Corporation	01/2014
448	FORFIVO XL	Extended-release Tablets	450 mg	Alvogen Group Holdings 3, LLC	08/2018
449	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
450	FORTESA	Gel	10 mg testosterone/actuation	Endo Pharmaceuticals, Inc.	08/25/2014
451	FOSRENOL	Chewable Tablets	1000 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/2017
452	FOSRENOL	Chewable Tablets	750 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/2017
453	FOSRENOL	Chewable Tablets	500 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/2017
454	FURADANTIN	Oral Suspension	25 mg / 5 mL	Casper Pharma LLC	12/2011 - 12/2012
455	GABITRIL	Tablets	4 mg	Cephalon Inc.	12/26/2012
456	GABITRIL	Tablets	16 mg	Cephalon, Inc.	12/2012
457	GABITRIL	Tablets	12 mg	Cephalon, Inc.	12/2012
458	GABITRIL	Tablets	2 mg	Cephalon, Inc	12/26/2012
459	GASTROCROM	Oral Concentrate	100 mg/5 mL (ampule)	Mylan Specialty, L.P.	06/2015
460	GENERESS FE	Chewable Tablets	0.8 mg/25 mcg	Allergan Pharmaceuticals International Ltd.	03/2015
461	GEODON	Capsules	60 mg	Viartis Specialty LLC	12/15/2011
462	GEODON	Capsules	40 mg	Viartis Specialty LLC	12/15/2011

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
463	GEODON	Capsules	20 mg	Viartis Specialty LLC	12/15/2011
464	GEODON	Capsules	80 mg	Viartis Specialty LLC	12/15/2011
465	GLUCOTROL XL	Extended-release Tablets	2.5 mg	Pfizer Inc.	03/11/2004
466	GLUCOTROL XL	Extended-release Tablets	5 mg	Pfizer Inc.	03/11/2004
467	GLUCOTROL XL	Extended-release Tablets	10 mg	Pfizer Inc.	03/11/2004
468	GLUMETZA	Extended-release Tablets	500 mg	Bausch Health US, LLC	06/2008
469	GLUMETZA	Extended-release Tablets	1000 mg	Bausch Health US, LLC	06/2008
470	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
471	GOPRELTO	Solution	4%	Genus Lifesciences Inc.	06/2018
472	GRIS-PEG	Tablets	250 mg	Bausch Health US, LLC	12/03/2012
473	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
474	HALCION	Tablets	0.25 mg	Pfizer Inc.	6/17/2003
475	HALCION	Tablets	0.125 mg	Pfizer Inc.	7/11/2003
476	HALDOL DECANOATE	Injection	50 mg/mL	Janssen Research & Development, LLC	08/2011
477	HALDOL DECANOATE	Injection	100 mg/mL	Janssen Research & Development, LLC	07/2011
478	HARVONI	Tablets	90 mg and 400 mg	Gilead Sciences, Inc.	01/2019
479	HECTOROL	Capsules, liquid filled	2.5 mcg	Genzyme Corporation	03/11/2014
480	HECTOROL	Capsules, liquid filled	0.5 mcg	Genzyme Corporation	03/11/2014
481	HECTOROL	Capsules, liquid filled	1 mcg	Genzyme Corporation	03/11/2014
482	IMITREX	Injection	4 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
483	IMITREX	Injection	6 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
484	IMITREX	Nasal Spray	5 mg	GlaxoSmithKline Intellectual Property Ltd. England	03/2020
485	IMITREX	Nasal Spray	20 mg	GlaxoSmithKline Intellectual Property Ltd. England	03/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
486	IMITREX (refill)	Injection	6 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
487	IMITREX (refill)	Injection	4 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
488	INDERAL LA	Extended-release Capsules	60 mg	ANI Pharmaceuticals, Inc.	12/2017
489	INDERAL LA	Extended-release Capsules	80 mg	ANI Pharmaceuticals, Inc.	12/2017
490	INDERAL LA	Extended-release Capsules	120 mg	ANI Pharmaceuticals, Inc.	12/2017
491	INDERAL LA	Extended-release Capsules	160 mg	ANI Pharmaceuticals, Inc.	12/2017
492	INDERAL LA	Extended-release Capsules	60 mg	ANI Pharmaceuticals, Inc.	2/25/2009
493	INDERAL LA	Extended-release Capsules	80 mg	ANI Pharmaceuticals, Inc.	2/25/2009
494	INDERAL LA	Extended-release Capsules	120 mg	ANI Pharmaceuticals, Inc.	2/25/2009

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
495	INDERAL LA	Extended-release Capsules	160 mg	ANI Pharmaceuticals, Inc.	2/25/2009
496	INSPIRA	Tablets	25 mg	Upjohn US 2 LLC	09/13/2007
497	INSPIRA	Tablets	50 mg	Upjohn US 2 LLC	09/13/2007
498	INVANZ	Injection, Powder, Lyophilized, for Solution	1 g	Merck Sharp & Dohme Corp.	07/2018
499	INVEGA	Extended-release Tablets	6 mg	Janssen Research & Development, LLC	09/24/2015
500	INVEGA	Extended-release Tablets	9 mg	Janssen Research & Development, LLC	09/24/2015
501	INVEGA	Extended-release Tablets	1.5 mg	Janssen Research & Development, LLC	09/24/2015
502	INVEGA	Extended-release Tablets	3 mg	Janssen Research & Development, LLC	09/24/2015
503	IOPIDINE	Ophthalmic Solution	0.5%	Novartis Pharmaceuticals Corporation	08/2009
504	ISOPTO CARPINE	Ophthalmic Solution	2%	Novartis Pharmaceuticals Corporation	02/21/1996
505	ISOPTO CARPINE	Ophthalmic Solution	4%	Novartis Pharmaceuticals Corporation	02/21/1996

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
506	ISOPTO CARPINE	Ophthalmic Solution	1%	Novartis Pharmaceuticals Corporation	02/21/1996
507	ISORDIL TITRADOSE	Tablets	40 mg	Bausch Health US, LLC	03/2020
508	ISORDIL TITRADOSE	Tablets	5 mg	Bausch Health US, LLC	03/2020
509	ISTALOL	Solution	0.5%	Bausch & Lomb Incorporated	05/2018
510	ISUPREL	Injection	0.2 mg/mL	Bausch Health US, LLC	11/2020
511	KADIAN	Extended-release Capsules	80 mg	Allergan Sales, LLC	11/11/2011
512	KADIAN	Extended-release Capsules	100 mg	Allergan Sales, LLC	11/11/2011
513	KADIAN	Extended-release Capsules	60 mg	Allergan Sales, LLC	11/11/2011
514	KADIAN	Extended-release Capsules	30 mg	Allergan Sales, LLC	11/11/2011
515	KADIAN	Extended-release Capsules	20 mg	Allergan Sales, LLC	11/11/2011

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
516	KADIAN	Extended-release Capsules	10 mg	Allergan Sales, LLC	11/11/2011
517	KADIAN	Extended-release Capsules	50 mg	Allergan Sales, LLC	11/11/2011
518	KAZANO	Tablets	12.5 mg/500 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
519	KAZANO	Tablets	12.5 mg/1000 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
520	K-DUR 10	Extended-release Tablets	10 mEq	Schering Corporation	06/2002 - 06/2003
521	K-DUR 20	Extended-release Tablets	20 mEq	Schering Corporation	06/1998 - 06/1999
522	KITABIS PAK	Inhalation Solution	300 mg/5 mL ampules	PulmoFlow Inc.	07/2016
523	KLARON	Lotion	10%	Bausch Health US, LLC	12/2005 - 12/2006
524	K-TAB	Extended-release Tablets	8 mEq (600 mg)	AbbVie Inc.	02/2011
525	K-TAB	Extended-release Tablets	10 mEq (750 mg)	AbbVie Inc.	02/2011
526	K-TAB	Extended-release Tablets	20 mEq (1500 mg)	AbbVie Inc.	01/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
527	LAC-HYDRIN	Cream	eq. 12% base	Bristol-Myers Squibb Company	07/2004 - 06/2005
528	LAC-HYDRIN	Lotion	eq. 12% base	Bristol-Myers Squibb Company	03/2004 - 02/2005
529	LESCOL XL	Extended-release Tablets	80 mg	Novartis Pharmaceuticals Corporation	05/2018
530	LEVO-T	Tablets	200 mg	CEDIPROF, Inc.	08/2020
531	LEVO-T	Tablets	137 mg	CEDIPROF, Inc.	08/2020
532	LEVO-T	Tablets	75 mg	CEDIPROF, Inc.	08/2020
533	LEVO-T	Tablets	175 mg	CEDIPROF, Inc.	08/2020
534	LEVO-T	Tablets	150 mg	CEDIPROF, Inc.	08/2020
535	LEVO-T	Tablets	300 mg	CEDIPROF, Inc.	08/2020
536	LEVO-T	Tablets	88 mg	CEDIPROF, Inc.	08/2020
537	LEVO-T	Tablets	125 mg	CEDIPROF, Inc.	08/2020
538	LEVO-T	Tablets	25 mg	CEDIPROF, Inc.	08/2020
539	LEVO-T	Tablets	50 mg	CEDIPROF, Inc.	08/2020
540	LEVO-T	Tablets	100 mg	CEDIPROF, Inc.	08/2020
541	LEVO-T	Tablets	112 mg	CEDIPROF, Inc.	08/2020
542	LEXETTE	Foam	0.05%	Mayne Pharma LLC	02/2019
543	LIALDA	Delayed Release Tablets	1.2 g	Shire Development LLC	08/2017
544	LIBRAX	Capsules	5 mg/2.5 mg	Bausch Health US, LLC	09/2016 - 08/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
545	LIDEX	Topical Solution	0.05%	County Line Pharmaceuticals, LLC	03/2018
546	LIDODERM	Patch	700 mg (50 mg per gram adhesive) in an aqueous base	Teikoku Pharma USA, Inc.	05/2014
547	LIMBITROL	Tablets	5 mg; eq. 12.5 mg base	Valeant Pharmaceuticals International	01/2006 - 12/2006
548	LIMBITROL DS	Tablets	10 mg; eq. 25 mg base	Valeant Pharmaceuticals International	01/2007 - 12/2007
549	LIPOFEN	Capsules	150 mg	Cipher Pharmaceuticals, Inc.	04/2016
550	LIPOFEN	Capsules	50 mg	Cipher Pharmaceuticals, Inc.	04/2016
551	LITHOBID	Extended-release Tablets	300 mg	ANI Pharmaceuticals, Inc.	12/2016
552	LOCOID	Cream	0.1%	Bausch Health U.S., LLC	07/2013
553	LOCOID	Lotion	0.1%	Bausch Health US, LLC	06/2018
554	LOCOID (Ointment)	Ointment	0.1%	Bausch Health US, LLC	10/2015 - 10/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
555	LOCOID LIPOCREAM	Cream	0.1%	Bausch Health US, LLC	07/03/2013
556	LODOSYN	Tablets	25 mg	Bausch Health Americas, Inc.	04/2014
557	LOMOTIL	Tablets	2.5 mg/0.025 mg	Pfizer Inc.	07/2011, 02/2013
558	LOPRESSOR HCT	Tablets	1 mg/mL	Novartis Pharmaceuticals Corporation	03/1998 - 03/1999
559	LOPRESSOR HCT	Tablets	50mg / 25mg	Novartis Pharmaceuticals Corporation	11/25/2009
560	LOPRESSOR HCT	Tablets	100 mg / 25 mg	Novartis Pharmaceuticals Corporation	11/25/2009
561	LOPROX	Cream	0.77%	Medicis Pharmaceutical Corporation	12/2004 - 11/2005
562	LOPROX	Gel	0.77%	Alvogen, Inc.	07/2007 - 06/2008
563	LOPROX	Shampoo	1%	Medicis Pharmaceutical Corporation	12/2012
564	LoSEASONIQUE	Tablets	0.1 mg/0.02 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	12/07/2010
565	LoSEASONIQUE	Tablets	0.1 mg/0.02 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	11/10/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
566	LOTEMAX	Ophthalmic Suspension	0.5%	Bausch & Lomb Incorporated	07/2019
567	LOTENSIN HCT	Tablets	10 mg; 12.5 mg	Validus Pharmaceuticals LLC	04/2019
568	LOTENSIN HCT	Tablets	20 mg; 12.5 mg	Validus Pharmaceuticals LLC	04/2019
569	LOTENSIN HCT	Tablets	20 mg; 25 mg	Validus Pharmaceuticals LLC	04/2019
570	LOTRIMIN AF	Cream	1%	Schering-Plough HealthCare Products, Inc	03/1998 - 03/1999
571	LOTRONEX	Tablets	0.5 mg	Sebela Ireland Limited	05/2015
572	LOTRONEX	Tablets	1 mg	Sebela Ireland Limited	05/2015
573	LOTRONEX	Tablets	1 mg	Sebela Ireland Limited	05/2015
574	LOTRONEX	Tablets	0.5 mg	Sebela Ireland Limited	05/2015
575	LOVENOX	Injection	30 mg/0.3 mL prefilled syringe	Sanofi Aventis US LLC	10/2011
576	LOVENOX	Injection	120 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US LLC	05/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
577	LOVENOX	Injection	150 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	05/2015
578	LOVENOX	Injection	100 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	03/2015
579	LOVENOX	Injection	300 mg/3 mL multi-dose vial	Sanofi Aventis US LLC	03/2015
580	LOVENOX	Injection	40 mg/0.4 mL prefilled syringe	Sanofi Aventis US, LLC	03/2015
581	LOVENOX	Injection	120 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
582	LOVENOX	Injection	80 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US, LLC	03/2015
583	LOVENOX	Injection	30 mg/0.3 mL prefilled syringe	Sanofi Aventis US LLC	03/2015
584	LOVENOX	Injection	40 mg/0.4 mL prefilled syringe	Sanofi Aventis US LLC	10/2011
585	LOVENOX	Injection	60 mg/0.6 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
586	LOVENOX	Injection	80 mg/0.8 mL graduated prefilled syringe	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	300 mg/3 mL multi-dose vial	Sanofi Aventis US LLC	10/2011
589	LOVENOX	Injection	150 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
590	LOVENOX	Injection	60 mg/0.6 mL graduated prefilled syringe	Sanofi Aventis US LLC	03/2015
591	LOZOL	Tablets	2.5 mg	Rhone-Poulenc Rorer Pharmaceuticals Inc.	Prior to 1/1/1999
592	LUVOX	Tablets	25 mg	ANI Pharmaceuticals, Inc.	08/09/2011
593	LUVOX	Tablets	50 mg	ANI Pharmaceuticals, Inc.	08/09/2011
594	LUVOX	Tablets	100 mg	ANI Pharmaceuticals, Inc.	08/09/2011
595	LUXIQ	Foam	0.12%	Mylan Pharmaceuticals, Inc.	04/2017
596	LUZU	Cream	1%	Bausch Health US, LLC	07/2018
597	LYRICA	Capsules	75 mg	Upjohn US 2 LLC	07/2019
598	LYRICA	Capsules	300 mg	Upjohn US 2 LLC	07/2019
599	LYRICA	Capsules	25 mg	Upjohn US 2 LLC	07/2019
600	LYRICA	Capsules	50 mg	Upjohn US 2 LLC	07/2019
601	LYRICA	Capsules	225 mg	Upjohn US 2 LLC	07/2019
602	LYRICA	Capsules	200 mg	Upjohn US 2 LLC	07/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
603	LYRICA	Capsules	150 mg	Upjohn US 2 LLC	07/2019
604	LYRICA	Capsules	100 mg	Upjohn US 2 LLC	07/2019
605	LYRICA	Oral Solution	20 mg/mL	Upjohn US 2 LLC	07/2019
606	LYSTEDA	Tablets	650 mg	Amring Pharmaceuticals Inc.	03/17/2016
607	MACROBID	Capsules	100 mg	Almatica Pharma LLC	02/2011
608	MACRODANTIN	Capsules	50 mg	Almatica Pharma LLC	08/2011
609	MACRODANTIN	Capsules	100 mg	Almatica Pharma LLC	08/2011
610	MACRODANTIN	Capsules	25 mg	Almatica Pharma LLC	09/2010
611	MALARONE	Tablets	250 mg/100 mg	GlaxoSmithKline LLC	7/31/2012
612	MARINOL	Capsules	10 mg	AbbVie Inc.	05/2017
613	MARINOL	Capsules	5 mg	AbbVie Inc.	05/2017
614	MARINOL	Capsules	2.5 mg	AbbVie Inc.	05/2017
615	MAXIMUM STRENGTH MUCINEX DM	Extended-release Tablets	1200 mg and 60 mg	RB Health (US) LLC	10/2017
616	MAXIMUM STRENGTH MUCINEX DM	Extended-release Tablets	1200 mg and 60 mg	RB Health (US) LLC	09/2017
617	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
618	MAXITROL	Ophthalmic Ointment	3.5 mg and 10000 units and 0.1% / gram	Novartis Pharmaceuticals Corporation	03/04/1996
619	MAXZIDE	Tablets	75 mg and 50 mg	Mylan Pharmaceuticals Inc.	Prior to 1/1/1999
620	MAXZIDE-25	Tablets	37.5 mg and 25 mg	Mylan Pharmaceuticals Inc.	Prior to 1/1/1999
621	MEDROL	Tablets	8 mg	Pfizer Inc.	4/22/2013
622	MEDROL	Tablets	32 mg	Pfizer Inc.	4/22/2013
623	MEDROL	Tablets	4 mg	Pfizer Inc.	11/16/2011
624	MEDROL	Tablets	16 mg	Pfizer Inc.	4/22/2013
625	MEGACE ES	Oral Suspension	625 mg/5 mL (125 mg/mL)	Endo Pharmaceuticals, Inc.	07/2015
626	MEPHYTON	Tablets	5 mg	Bausch Health Americas, Inc.	04/2018
627	MESNEX	Injection	100 mg/mL	Baxter Healthcare Corporation	12/2003 - 12/2004
628	MESTINON	Oral Solution	60 mg / 5 mL	Bausch Health US, LLC	07/2019
629	MESTINON	Tablets	60 mg	Bausch Health US, LLC	04/2002 - 03/2003
630	MESTINON TIMESPAN	Tablets	180 mg	Bausch Health US, LLC	11/2015

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

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
642	METROGEL VAGINAL GEL	Vaginal Gel	0.75%	Bausch Health US, LLC	04/01/2015
643	METROLOTION	Lotion	0.75%	Galderma Laboratories, L.P.	6/16/2009
644	MIACALCIN	Nasal Spray	200 I.U. per actuation	Sebela Ireland Ltd.	12/09/2008
645	MICRONASE	Tablets	2.5 mg	Pharmacia and Upjohn	Prior to 1/1/1999
646	MICRONASE	Tablets	5 mg	Pharmacia and Upjohn	Prior to 1/1/1999
647	MICROZIDE	Capsules	12.5 mg	Teva Branded Pharmaceutical Products R&D, Inc.	10/05/2001
648	MIDAMOR	Tablets	5 mg	Padagis US LLC	04/06/2009
649	MIGRANAL	Nasal Spray	4 mg in 1 mL	Bausch Health US, LLC	03/18/2013
650	MINIPRESS	Capsules	1 mg	Pfizer Inc.	08/2021
651	MINIPRESS	Capsules	1 mg	Pfizer Inc.	01/2017
652	MINIPRESS	Capsules	2 mg	Pfizer Inc.	01/2017
653	MINIPRESS	Capsules	2 mg	Pfizer Inc.	03/2022
654	MINIPRESS	Capsules	5 mg	Pfizer Inc.	01/2017
655	MINIPRESS	Capsules	5 mg	Pfizer Inc.	03/2022
656	MINIVELLE	Film, Extended Release	0.1 mg per day	Noven Pharmaceuticals, Inc.	01/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
657	MINIVELLE	Film, Extended Release	0.075 mg per day	Noven Pharmaceuticals, Inc.	01/2018
658	MINIVELLE	Film, Extended Release	0.025 mg per day	Noven Pharmaceuticals, Inc.	01/2018
659	MINIVELLE	Film, Extended Release	0.0375 mg per day	Noven Pharmaceuticals, Inc.	01/2018
660	MINIVELLE	Film, Extended Release	0.05 mg per day	Noven Pharmaceuticals, Inc.	01/2018
661	MITIGARE	Capsules	0.6 mg	Hikma International Pharmaceuticals LLC	10/01/2014
662	MONODOX	Capsules	75 mg	Aqua Pharmaceuticals LLC	10/2014
663	MONODOX	Capsules	50 mg	Aqua Pharmaceuticals LLC	02/07/2005
664	MONODOX	Capsules	100 mg	Aqua Pharmaceuticals LLC	02/07/2005
665	MONOKET	Tablets	10 mg	ECI Pharmaceuticals LLC	06/30/1996 - 06/29/1997

	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	MUCINEX	Extended-release Tablets	600 mg	RB Health (US), LLC	02/2018
676	MUCINEX	Extended-release Tablets	600 mg	RB Health (US), LLC	02/2018
677	MUCINEX	Extended-release Tablets	600 mg	RB Health (US), LLC	02/2021
678	MUCINEX	Extended-release Tablets	600 mg	RB Health (US), LLC	02/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
679	MUCINEX (MAXIMUM STRENGTH)	Extended Release Tablets	1200 mg & 60 mg	RB Health (US) LLC	9/5/2017
680	MUCINEX (MAXIMUM STRENGTH)	Extended Release Tablets	1200 mg & 60 mg	RB Health (US) LLC	9/5/2017
681	MUCINEX (MAXIMUM STRENGTH)	Extended-release Tablets	1200 mg	RB Health (US), LLC	08/2017
682	MUCINEX (MAXIMUM STRENGTH)	Extended-release Tablets	1200 mg	RB Health (US), LLC	10/2017
683	MUCINEX DM	Extended-release Tablets	600 mg and 30 mg	RB Health (US) LLC	10/2019
684	MUCINEX DM	Extended-release Tablets	600 mg and 30 mg	RB Health (US) LLC	05/2019
685	MYAMBUTOL	Tablets	100 mg	STI Pharma LLC	12/15/2006
686	MYAMBUTOL	Tablets	400 mg	STI Pharma LLC	12/15/2006
687	MYCOBUTIN	Capsules	150 mg	Pfizer	05/13/2014
688	MYSOLINE	Tablets	250 mg	Bausch Health US, LLC	05/2018
689	MYSOLINE	Tablets	50 mg	Bausch Health US, LLC	05/2018
690	NALFON	Capsules	400 mg	Xspire Pharma LLC	05/2016
691	NALFON	Capsules	200 mg	Xspire Pharma LLC	04/2017
692	NALFON	Capsules	400 mg	Xspire Pharma LLC	08/05/2015
693	NAMENDA	Tablets	5 mg and 10 mg (titration pak)	Allergan Sales, LLC	04/01/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
694	NAMENDA	Tablets	10 mg	Allergan Sales, LLC	04/01/2015
695	NAMENDA	Tablets	5 mg	Allergan Sales, LLC	04/01/2015
696	NAPRELAN	Controlled-Release Tablets	500 mg	Almatica Pharma LLC	03/2015
697	NAPRELAN	Controlled-Release Tablets	375 mg	Almatica Pharma LLC	09/2015
698	NAPRELAN	Controlled-Release Tablets	750 mg	Almatica Pharma LLC	03/2015
699	NAPROSYN	Suspension	125 mg/5 mL	Atnahs Pharma US Limited	11/2016
700	NAPROSYN EC (EC-NAPROSYN)	Delayed-Release Tablets	500 mg	Atnahs Pharma US Limited	10/2018
701	NARDIL	Tablets	15 mg	Parke-Davis	3/23/2011
702	NASACORT AQ	Nasal Spray Spray Bottle	55 mcg/spray	Sanofi Aventis US, LLC	06/15/2011
703	NATROBA	Topical Suspension	0.9%	ParaPRO LLC	06/2014
704	NEOPROFEN	Injection	20mg/2mL (10mg/mL)	Recordati Rare Diseases Inc.	04/2016
705	NESINA	Tablets	25 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
706	NESINA	Tablets	12.5 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
707	NESINA	Tablets	6.25 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
708	NEURONTIN	Capsules	100 mg	Viartis Specialty LLC	3/17/2004
709	NEURONTIN	Capsules	300 mg	Viartis Specialty LLC	03/17/2004
710	NEURONTIN	Capsules	400 mg	Viartis Specialty LLC	3/17/2004
711	NEURONTIN	Oral Solution	250 mg per 5 mL	Viartis Specialty LLC	3/24/2011
712	NEURONTIN	Tablets	600 mg	Viartis Specialty LLC	3/17/2004
713	NEURONTIN	Tablets	800 mg	Viartis Specialty LLC	3/17/2004
714	NIASPAN	Extended-release Tablets	500 mg	AbbVie Inc.	06/30/2014
715	NIASPAN	Extended-release Tablets	750 mg	AbbVie Inc.	06/30/2014
716	NIASPAN	Extended-release Tablets	1000 mg	AbbVie Inc.	06/30/2014
717	NICORETTE	Chewing Gum	2 mg	GlaxoSmithKline Consumer Healthcare L.P.	01/2002 - 01/2003
718	NICORETTE	Chewing Gum	4 mg	GlaxoSmithKline Consumer Healthcare L.P.	06/2001 - 06/2002

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
719	NILANDRON	Tablets	150 mg	Concordia Pharmaceuticals Inc.	11/2019
720	NITRO-DUR	Transdermal	0.6 mg/hr	USpharma Ltd.	04/2020
721	NITRO-DUR	Transdermal	0.1 mg/hr	USpharma Ltd.	04/2020
722	NITRO-DUR	Transdermal	0.4 mg/hr	USpharma Ltd.	04/2020
723	NITRO-DUR	Transdermal	0.2 mg/hr	USpharma Ltd.	04/2020
724	NITROLINGUAL PUMPSPRAY	Lingual Spray	400 mcg per Spray	G. Pohl-Boskamp GmbH & Co.	02/01/2011
725	NITROSTAT	Tablets	0.4 mg	Viartis Speciality LLC	08/26/2016
726	NITROSTAT	Tablets	0.3 mg	Viartis Speciality LLC	08/26/2016
727	NITROSTAT	Tablets	0.6 mg	Viartis Speciality LLC	08/26/2016
728	NORPACE	Capsules	150 mg	Pfizer Inc.	04/2019
729	NORPACE	Capsules	100 mg	Pfizer Inc.	04/2019
730	NORPRAMIN	Tablets	10 mg	Sanofi-Aventis US LLC	04/2014
731	NORPRAMIN	Tablets	150 mg	Sanofi-Aventis US LLC	04/2014
732	NORPRAMIN	Tablets	25 mg	Sanofi-Aventis US LLC	04/2014
733	NORPRAMIN	Tablets	50 mg	Sanofi-Aventis US LLC	Prior to 1/1/1999

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
734	NORPRAMIN	Tablets	75 mg	Sanofi-Aventis US LLC	04/2014
735	NORPRAMIN	Tablets	100 mg	Sanofi-Aventis US LLC	04/2014
736	NOR-QD	Tablets	0.35 mg	Teva Branded Pharmaceuticals Products R&D, Inc	06/06/2003
737	NORVASC	Tablets	2.5 mg	Viartis Specialty LLC	6/15/2006
738	NORVASC	Tablets	5 mg	Viartis Specialty LLC	6/15/2006
739	NORVASC	Tablets	10 mg	Viartis Specialty LLC	6/15/2006
740	NOXAFIL	Delayed-release Tablets	100 mg	Merck Sharp & Dohme Corp.	08/2019
741	NOXAFIL	Oral Suspension	40 mg/mL	Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.	3/29/2023
742	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
743	NUMBRINO	Nasal Solution	4%	Lannett Company, Inc.	09/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
744	NUVARING	Vaginal Ring	11.7 mg / 2.7 mg (delivers 0.120 mg/0.015 mg per day)	Organon USA LLC	12/2019
745	NUVIGIL	Tablets	250 mg	Teva Pharmaceuticals USA	12/2016
746	NUVIGIL	Tablets	200 mg	Teva Pharmaceuticals USA	11/2016
747	NUVIGIL	Tablets	250 mg	Teva Pharmaceuticals USA	11/2016
748	NUVIGIL	Tablets	150 mg	Teva Pharmaceuticals USA	12/2016
749	NUVIGIL	Tablets	200 mg	Teva Pharmaceuticals USA	12/2016
750	NUVIGIL	Tablets	150 mg	Teva Pharmaceuticals USA	11/2016
751	NUVIGIL	Tablets	50 mg	Teva Pharmaceuticals USA	11/2016
752	OLUX	Foam	0.05%	Mylan Pharmaceuticals Inc.	12/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
753	OLUX-E	Emulsion, Aerosol Foam	0.05%	Mylan Pharmaceuticals Inc., a Viatris Company	01/2019
754	OMNIPRED	Ophthalmic Suspension	1%	Novartis Pharmaceuticals Corporation	01/1995
755	OPTIVAR	Ophthalmic Solution	0.05%	Meda Pharmaceuticals, Inc.	03/10/2011
756	ORABLOC	Injection	4% and 1:100,000	Pierrel S.p.A.	04/2021
757	ORABLOC	Injection	4% and 1:200,000	Pierrel S.p.A.	04/2021
758	ORABLOC	Injection	4% and 1:200,000	Pierrel S.p.A.	10/2016
759	ORABLOC	Injection	4% and 1:100,000	Pierrel S.p.A.	10/2016
760	ORACEA	Capsule	40mg	Galderma Laboratories, L.P.	2/27/2023
761	ORACEA	Capsules	40 mg	Galderma Laboratories, L.P.	04/2015
762	ORAPRED ODT	Orally Disintegrating Tablets	30 mg	Concordia Pharmaceuticals Inc.	10/2015
763	ORAPRED ODT	Orally Disintegrating Tablets	15 mg	Concordia Pharmaceuticals Inc.	10/2015
764	ORAPRED ODT	Orally Disintegrating Tablets	10 mg	Concordia Pharmaceuticals Inc.	10/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
765	OSENI	Tablets	12.5 mg/30 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
766	OSENI	Tablets	25 mg/15 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
767	OSENI	Tablets	25 mg/30 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
768	OSENI	Tablets	25 mg/45 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
769	OTOVEL	Otic Solution	0.3% / 0.025%	Laboratorios SALVAT, S.A.	11/2019
770	OVIDE	Lotion	0.5%	Taro Pharmaceuticals USA, Inc.	08/02/2008 - 08/01/2009
771	OXANDRIN	Tablets	2.5 mg	Savient Pharmaceuticals, Inc.	06/2006 - 05/2007
772	OXANDRIN	Tablets	10 mg	Savient Pharmaceuticals, Inc.	06/2006 - 05/2007
773	OXYCODONE HYDROCHLORIDE	Oral Solution	5 mg/5 mL	Genus Lifesciences, Inc.	09/2013
774	OXYCONTIN	Extended-release Tablets	20 mg	Purdue Pharma L.P.	03/24/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
775	OXYCONTIN	Extended-release Tablets	10 mg	Purdue Pharma L.P.	03/24/2015
776	OXYCONTIN	Extended-release Tablets	80 mg	Purdue Pharma L.P.	04/2022
777	OXYCONTIN	Extended-release Tablets	40 mg	Purdue Pharma L.P.	04/2022
778	OXYCONTIN	Extended-release Tablets	20 mg	Purdue Pharma L.P.	04/2022
779	OXYCONTIN	Extended-release Tablets	10 mg	Purdue Pharma L.P.	04/2022
780	OXYCONTIN	Extended-release Tablets	40 mg	Purdue Pharma L.P.	03/24/2015
781	OZOBAX	Solution	5mg/5mL	Metacel Pharmaceuticals, LLC	03/15/2022
782	PARAPLATIN	for Injection	50 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
783	PARAPLATIN	for Injection	150 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
784	PARAPLATIN	for Injection	450 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
785	PARAPLATIN AQ	Injection	eq. 50 mg/5 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
786	PARAPLATIN AQ	Injection	eq. 150 mg/15 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
787	PARAPLATIN AQ	Injection	eq. 450 mg/45 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
788	PARAPLATIN AQ	Injection	eq. 600 mg/60 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
789	PARNATE	Tablets	10 mg	Concordia Pharmaceuticals Inc.	02/05/2016
790	PATADAY	Ophthalmic Solution	0.2%	Alcon Laboratories	06/2017
791	PATADAY	Ophthalmic Solution	0.1%	Alcon Laboratories, Inc.	09/2015
792	PATANASE	Nasal Spray	665 mcg in 100 mg solution	Novartis Pharmaceuticals Corporation	04/2015
793	PATANOL	Ophthalmic Solution	0.1%	Novartis Pharmaceuticals Corporation	09/15/2015
794	PAXIL CR	Tablets	12.5 mg	GlaxoSmithKline	10/21/2010
795	PAXIL CR	Tablets	25 mg	GlaxoSmithKline	10/21/2010
796	PAXIL CR	Tablets	37.5 mg	GlaxoSmithKline	10/21/2010
797	PEDIAPRED	Oral Solution	5 mg / 5 mL	Seton Pharmaceuticals, LLC	02/2002
798	PENNSAID	Solution, Metered	2%	Horizon Therapeutics Ireland DAC	11/22/2022
799	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
800	PERFOROMIST	Inhalation Solution	20 mcg/2 mL	Mylan Specialty L.P.	07/2021
801	PHOSLO	Gelcaps	667 mg	Fresenius Medical Care North America	03/2014 - 03/2015
802	PLAN B ONE-STEP	Tablets	1.5 mg	Foundation Consumer Healthcare, LLC	02/12/2014
803	PLAQUENIL	Tablets	200 mg	Concordia Pharmaceuticals Inc.	05/1999 - 04/2000
804	PLENDIL	Extended-release Tablets	2.5 mg	AstraZeneca LP	10/2008
805	PLENDIL	Extended-release Tablets	5 mg	AstraZeneca LP	10/2008
806	PLENDIL	Extended-release Tablets	10 mg	AstraZeneca LP	10/2008
807	PLIAGLIS	Cream	7%/7%	Taro Pharmaceuticals USA, Inc.	11/2017
808	POLYTRIM	Ophthalmic Solution	10 mL unit	Allergan, Inc.	04/29/1997
809	PONSTEL	Capsules	250 mg	Shionogi, Inc.	07/11/2011
810	POTASSIUM CHLORIDE FOR ORAL SOLUTION	Powder for Solution	20 mEq	Pharma Research Software Solution, LLC	01/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
811	POTASSIUM CHLORIDE FOR ORAL SOLUTION	Powder for Solution	20 mEq	Pharma Research Software Solution, LLC	09/2015
812	POTASSIUM CHLORIDE ORAL SOLUTION, USP, 10%	Oral Solution	20 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
813	POTASSIUM CHLORIDE ORAL SOLUTION, USP, 10%	Oral Solution	20 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
814	POTASSIUM CHLORIDE ORAL SOLUTION, USP, 20%	Oral Solution	40 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
815	PRAVACHOL	Tablets	10 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
816	PRAVACHOL	Tablets	20 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
817	PRAVACHOL	Tablets	40 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
818	PRAVACHOL	Tablets	80 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
819	PRED FORTE	Ophthalmic Suspension	1%	Allergan, Inc.	08/1997
820	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
821	PREVACID	Delayed-Release Capsules	30 mg	Takeda Global Research & Development Center, Inc.	11/2009
822	PREVPAC	Delayed-Release Capsules, Capsules, and Tablets	30 mg, 500 mg, and 500 mg	Takeda Pharmaceuticals U.S.A., Inc.	03/02/2015
823	PRISTIQ	Extended-Release Tablets	100 mg	PF Prism C.V.	03/2017
824	PRISTIQ	Extended-Release Tablets	50 mg	PF Prism C.V.	03/2017
825	PRISTIQ	Extended-Release Tablets	25 mg	PF Prism C.V.	03/2017
826	PROAIR HFA	Inhalation Aerosol	90 mcg per acutation	Teva Branded Pharmaceutical Products R&D, Inc.	01/2019
827	PROCARDIA	Capsules	10 mg	Pfizer Inc.	3/25/2013
828	PROMETRIUM	Capsules	100 mg	Virtus Pharmaceuticals, LLC	07/2016
829	PROMETRIUM	Capsules	200 mg	Virtus Pharmaceuticals, LLC	07/2016
830	PROTOPIC	Ointment	0.03%	LEO Pharma Inc.	11/2014
831	PROTOPIC	Ointment	0.1%	LEO Pharma Inc.	11/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
832	PROVENTIL HFA	Inhalation Aerosol	90 mcg per actuation	Kindeva Drug Delivery L.P.	03/2021
833	PROVERA	Tablets	5 mg	Pharmacia and Upjohn	6/18/2003
834	PROVERA	Tablets	2.5 mg	Pharmacia and Upjohn	6/18/2003
835	PROVERA	Tablets	10 mg	Pharmacia and Upjohn	6/18/2003
836	PROVIGIL	Tablets	100 mg	Cephalon, Inc.	03/29/2012
837	PROVIGIL	Tablets	200 mg	Cephalon Inc.	03/29/2012
838	PURINETHOL	Tablets	50 mg	Stason Pharmaceuticals Inc.	11/2016
839	QUALAQUIN	Capsules	324 mg	Sun Pharmaceutical Industries, Inc.	07/23/2012
840	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
841	QUDEXY XR	Extended-release Capsules	100 mg	Upsher-Smith Laboratories, LLC	07/07/2014
842	QUDEXY XR	Extended-release Capsules	200 mg	Upsher-Smith Laboratories, LLC	07/07/2014
843	QUDEXY XR	Extended-release Capsules	50 mg	Upsher-Smith Laboratories, LLC	07/07/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
844	QUDEXY XR	Extended-release Capsules	25 mg	Upsher-Smith Laboratories, LLC	07/07/2014
845	QUDEXY XR	Extended-release Capsules	150 mg	Upsher-Smith Laboratories, LLC	07/07/2014
846	RAPAMUNE	Oral Solution	1 mg/mL	PF Prism C.V.	07/2019
847	RAPAMUNE	Tablets	0.5 mg	PF Prism C.V.	01/16/2014
848	RAPAMUNE	Tablets	1 mg	PF Prism CV	10/27/2014
849	RAPAMUNE	Tablets	2 mg	PF Prism CV	10/27/2014
850	RAZADYNE	Tablets	4 mg	Janssen Research & Development, LLC	08/28/2008
851	RAZADYNE	Tablets	8 mg	Janssen Research & Development, LLC	08/28/2008
852	RAZADYNE ER	Capsules	8 mg	Janssen Research & Development, LLC	10/13/2008
853	RAZADYNE ER	Capsules	16 mg	Janssen Research & Development, LLC	10/13/2008
854	RAZADYNE ER	Capsules	24 mg	Janssen Research & Development, LLC	10/13/2008
855	REGLAN	Injection	eq. 5 mg base/mL	Baxter Healthcare Corporation	02/2003 - 02/2004
856	REGLAN	Tablets	5 mg	ANI Pharmaceuticals, Inc.	12/2021

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
857	REGLAN	Tablets	10 mg	ANI Pharmaceuticals, Inc.	12/2021
858	RENVELA	Tablets	800 mg	Genzyme Corporation	04/16/2014
859	RESTORIL	Capsules	22.5 mg	Mallinckrodt Inc.	07/21/2008
860	RESTORIL	Capsules	7.5 mg	Mallinckrodt Inc.	07/22/2008
861	RETIN-A	Cream	0.1%	Bausch Health US, LLC	07/2019
862	RETIN-A	Cream	0.05%	Bausch Health US, LLC	12/2018
863	RETIN-A	Cream	0.025%	Bausch Health US, LLC	04/2019
864	RETIN-A	Cream	0.05%	Bausch Health US, LLC	07/19/1974
865	RETIN-A	Cream	0.1 %	Bausch Health US, LLC	01/26/1973
866	RETIN-A	Gel	0.01 %	Bausch Health US, LLC	08/2019
867	RETIN-A	Gel	0.025%	Bausch Health US, LLC	06/2005
868	RETIN-A MICRO	Gel	0.1 %	Bausch Health US, LLC	03/2013
869	RETIN-A MICRO	Gel	0.04%	Bausch Health US, LLC	03/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
870	RETIN-A MICRO	Gel	0.04 %	Bausch Health US, LLC	08/2019
871	RETIN-A MICRO	Gel	0.1 %	Bausch Health US, LLC	08/2019
872	REVATIO	Powder for Suspension	10 mg/mL	Upjohn 1 US LLC	09/2019
873	REVATIO	Tablets	20 mg	Upjohn 1 US LLC	11/2012, 11/2020
874	RISPERDAL	Oral Solution	1 mg/mL	Janssen Research & Development, LLC	06/30/2008
875	RITALIN	Tablet	20 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
876	RITALIN	Tablet	5 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
877	RITALIN	Tablet	10 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
878	RITALIN LA	Capsules	30 mg	Novartis Pharmaceuticals Corp	11/2015
879	RITALIN LA	Capsules	40 mg	Novartis Pharmaceuticals Corp	11/2015
880	RITALIN LA	Capsules	20 mg	Novartis Pharmaceuticals Corp	11/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
881	RITALIN LA	Capsules	10 mg	Novartis Pharmaceuticals Corp	02/2018
882	ROBINUL	Injection	0.2 mg/mL	Eurohealth International Sarl	02/06/1975
883	ROBINUL	Tablets	1 mg	Casper Pharma LLC	01/13/2005
884	ROBINUL FORTE	Tablets	2 mg	Casper Pharma LLC	01/13/2005
885	ROCALTROL	Oral Solution	1 mcg/mL (15 mL bottle)	Validus Pharmaceuticals LLC	08/26/2009
886	ROGAINE (FOR MEN)	Topical Solution	2%	McNeil-PPC, Inc.	06/1998 - 05/1999
887	ROGAINE (FOR WOMEN)	Topical Solution	2%	McNeil-PPC, Inc.	06/1998 - 05/1999
888	ROGAINE EXTRA STRENGTH (FOR MEN)	Topical Solution	5%	McNeil-PPC, Inc.	2004
889	ROSZET	Tablets	5 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
890	ROSZET	Tablets	40 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
891	ROSZET	Tablets	20 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
892	ROSZET	Tablets	10 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
893	ROWASA	Rectal Suspension Enema	4 g/60 mL	Mylan Specialty, L.P., a Viatris Company	2/2011
894	SAFRYAL	Tablets	3 mg / 0.03 mg / 0.451 mg	Bayer HealthCare LLC	08/2015
895	SALAGEN	Tablets	5 mg	Concordia Pharmaceuticals Inc.	12/2004
896	SALAGEN	Tablets	7.5 mg	Concordia Pharmaceuticals Inc.	03/2006 - 01/2007
897	SAMSCA	Tablets	15 mg	Otsuka Pharmaceutical Company, Ltd.	10/2020
898	SAPHRIS SAPHRIS	Sublingual Tablets	5 mg	Allergan Sales, LLC	05/2020
899	SAPHRIS SAPHRIS	Sublingual Tablets	10 mg	Allergan Sales, LLC	12/2020
900	SAPHRIS SAPHRIS	Sublingual Tablets	2.5 mg	Allergan Sales, LLC	05/2020
901	SEASONALE	Tablets	0.15 mg/0.03 mg	Teva Branded Pharmaceutical Products R&D, Inc.	9/7/2006

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
902	SEASONIQUE	Tablets	0.15 mg/0.03 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	07/28/2010
903	SECTRAL	Capsules	eq. 200 mg base	Wyeth Laboratories, Inc.	Prior to 1/1/1999
904	SECTRAL	Capsules	eq. 400 mg base	Wyeth Laboratories, Inc.	Prior to 1/1/1999
905	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	04/2019
906	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	04/2016
907	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2016
908	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
909	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	01/2015
910	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	01/2015
911	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	04/2019
912	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
913	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
914	SEROQUEL XR	Extended-release Tables	200 mg	AstraZeneca UK Limited	05/2017
915	SEROQUEL XR	Extended-release Tablets	200 mg	AstraZeneca UK Limited	11/2016
916	SEROQUEL XR	Extended-release Tablets	300 mg	AstraZeneca UK Limited	11/2016
917	SEROQUEL XR	Extended-release Tablets	50 mg	AstraZeneca UK Limited	05/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
918	SEROQUEL XR	Extended-release Tablets	150 mg	AstraZeneca UK Limited	11/2016
919	SEROQUEL XR	Extended-release Tablets	50 mg	AstraZeneca UK Limited	11/2016
920	SEROQUEL XR	Extended-release Tablets	400 mg	AstraZeneca UK Limited	05/2017
921	SEROQUEL XR	Extended-release Tablets	300 mg	AstraZeneca UK Limited	05/2017
922	SEROQUEL XR	Extended-release Tablets	150 mg	AstraZeneca UK Limited	05/2017
923	SILENOR	Tablets	3 mg	Currax Pharmaceuticals LLC	08/2010
924	SILENOR	Tablets	6 mg	Currax Pharmaceuticals LLC	08/2010
925	SILVADENE	Cream	1%	King Pharmaceuticals LLC	01/2018
926	SKELAXIN	Tablets	800 mg	King Pharmaceuticals R&D, LLC	08/2018
927	SOLARAZE	Gel	3%	Fougera Pharmaceuticals, Inc.	11/21/2013
928	SOMA	Tablet	250 mg	Mylan Specialty, L.P.	9/13/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
929	SOOLANTRA	Cream	1%	Galderma Laboratories, L.P.	1/8/2024
930	SOOLANTRA	Cream	1%	Galderma Laboratories, L.P.	06/2021
931	SORILUX	Foam	0.005%	Mayne Pharma LLC	02/2021
932	SPECTRACEF	Tablets	400 mg	Vansen Pharma, Inc.	Unknown
933	SPECTRACEF	Tablets	200 mg	Vansen Pharma, Inc.	Unknown
934	SPORANOX	Capsule	100 mg	Janssen Research & Development, LLC	2/2005; 6/2005
935	SPORANOX	Oral Solution	10 mg/mL	Janssen Research & Development, LLC	10/2018
936	STALEVO 100	Film-coated Tablets	25 mg, 100 mg, 200 mg	Orion Corporation	06/2014
937	STALEVO 125	Film-coated Tablets	31.25 mg, 125 mg, 200 mg	Orion Corporation	06/2014
938	STALEVO 150	Film-coated Tablets	37.5 mg, 150 mg, 200 mg	Orion Corporation	06/2014
939	STALEVO 200	Film-coated Tablets	50 mg, 200 mg, 200 mg	Orion Corporation	06/2014
940	STALEVO 50	Film-coated Tablets	12.5 mg, 50 mg, 200 mg	Orion Corporation	06/2014
941	STALEVO 75	Film-coated Tablets	18.75 mg, 75 mg, 200 mg	Orion Corporation	06/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
942	SULAR	Extended-release Tablets	34 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
943	SULAR	Extended-release Tablets	8.5 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
944	SULAR	Extended-release Tablets	17 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
945	SUPRAX	Capsules	400 mg	Lupin Limited	10/2020
946	SUPREP	Oral Solution (concentrate)	17.5g / 3.13g / 1.6g	Braintree Laboratories, Inc.	08/2010
947	SYMBICORT	Metered Dose Inhaler	80/4.5 mcg	AstraZeneca Pharmaceuticals LP	01/2020
948	SYMBICORT	Metered Dose Inhaler	160/4.5 mcg	AstraZeneca Pharmaceuticals LP	01/2020
949	SYNALAR	Solution	0.01%	Medimetriks Pharmaceuticals, Inc.	11/2012
950	SYNALGOS-DC	Capsules	356.4 mg/30 mg/16 mg	Sun Pharmaceutical Industries, Inc.	10/01/2012
951	SYPRINE	Capsules	250 mg	Bausch Health Americas, Inc.	02/2018
952	TACLONEX	Ointment	0.005%/0.064%	LEO Pharma A/S	01/2020
953	TAMBOCOR	Tablets	50 mg	3M Pharmaceuticals	10/2002

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
954	TAMBOCOR	Tablets	100 mg	3M Pharmaceuticals	10/2002
955	TAMBOCOR	Tablets	150 mg	3M Pharmaceuticals	10/2002
956	TARGRETIN	Gel	1%	Bausch Health Ireland Limited	06/2000
957	TASMAR	Tablets	100 mg	Bausch Health US, LLC	07/2004
958	TAXOTERE	Injection Concentrate	20 mg/mL	Sanofi Aventis US LLC	03/2011
959	TAXOTERE	Injection Concentrate	80 mg/4 mL (20 mg/mL)	Sanofi Aventis US LLC	03/2011
960	TAXOTERE	Injection Concentrate	160 mg/8 mL (20 mg/mL)	Sanofi Aventis US LLC	10/2016
961	TAYTULLA	Capsules	1 mg/20 mcg	Allergan Pharmaceuticals International Ltd	11/2020
962	TAZORAC	Cream	0.1%	Allergan Aesthetics, an Abbvie Company	10/2016
963	TAZORAC	Cream	0.05%	Allergan Aesthetics, an Abbvie Company	10/2016
964	TEGRETOL XR	Tablets	100 mg	Novartis Pharmaceuticals Corporation	07/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
965	TEGRETOL XR	Tablets	200 mg	Novartis Pharmaceuticals Corporation	06/15/2009
966	TEGRETOL XR	Tablets	400 mg	Novartis Pharmaceuticals Corporation	06/15/2009
967	TESSALON	Perles	100 mg	Pfizer Inc.	01/2020
968	TESTIM	Gel	50 mg in 5 g	Auxilium Pharmaceuticals, Inc.	06/09/2014
969	TETRACAINE HYDROCHLORIDE	Ophthalmic Solution	0.5%	Bausch Health Ireland Limited	06/2019
970	TIAZAC	Extended-release Capsules	120 mg	Bausch Health US, LLC Bausch Health US, LLC	08/20/2014
971	TIAZAC	Extended-release Capsules	180 mg	Bausch Health US, LLC	08/20/2014
972	TIAZAC	Extended-release Capsules	240 mg	Bausch Health US, LLC	08/20/2014
973	TIAZAC	Extended-release Capsules	300 mg	Bausch Health US, LLC Bausch Health US, LLC	08/20/2014
974	TIAZAC	Extended-release Capsules	360 mg	Bausch Health US, LLC	08/20/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
975	TIAZAC	Extended-release Capsules	420 mg	Bausch Health US, LLC	08/20/2014
976	TIGAN	Injection	100 mg/mL	Par Sterile Products, LLC	06/01/2012
977	TIMOPTIC	Ophthalmic Solution	0.5%	Bausch Health America, Inc.	06/2020
978	TIMOPTIC in OCUDOSE	Solution	0.5%	Bausch & Lomb Incorporated	04/2021
979	TIMOPTIC-XE	Solution	0.5%	Bausch Health US, LLC	02/2018
980	TIMOPTIC-XE	Solution	0.25%	Bausch Health US, LLC	02/2018
981	TIROSINT	Capsules	137 mcg	IBSA Pharma Inc.	11/2020
982	TIROSINT	Capsules	125 mcg	IBSA Pharma Inc.	11/2020
983	TIROSINT	Capsules	175 mcg	IBSA Pharma Inc.	11/2020
984	TIROSINT	Capsules	112 mcg	IBSA Pharma Inc.	11/2020
985	TIROSINT	Capsules	150 mcg	IBSA Pharma Inc.	11/2020
986	TIROSINT	Capsules	100 mcg	IBSA Pharma Inc.	11/2020
987	TIROSINT	Capsules	88 mcg	IBSA Pharma Inc.	11/2020
988	TIROSINT	Capsules	200 mcg	IBSA Pharma Inc.	11/2020
989	TIROSINT	Capsules	13 mcg	IBSA Pharma Inc.	11/2020
990	TIROSINT	Capsules	75 mcg	IBSA Pharma Inc.	11/2020
991	TIROSINT	Capsules	25 mcg	IBSA Pharma Inc.	11/2020
992	TIROSINT	Capsules	50 mcg	IBSA Pharma Inc.	11/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
993	TIVORBEX	Capsules	40 mg	Genus Lifesciences Inc.	01/2020
994	TIVORBEX	Capsules	20 mg	Genus Lifesciences Inc.	01/2020
995	TOBI	Solution for Inhalation	300 mg/5 mL ampule	Mylan Specialty, L.P., a Viatris Company	07/2014
996	TOBRADEX	Ophthalmic Suspension	0.3% and 0.1%	Novartis Pharmaceuticals Corporation	01/02/2009
997	TOFRONIL PM	Capsules	125 mg	Mallinckrodt Inc.	4/2006
998	TOFRONIL PM	Capsules	100 mg	Mallinckrodt Inc.	4/2006
999	TOFRONIL PM	Capsules	75 mg	Mallinckrodt Inc.	4/2006
1000	TOFRONIL PM	Capsules	150 mg	Mallinckrodt Inc.	4/2006
1001	TOPROL XL	Extended-release Tablets	25 mg	Toprol Acquisition LLC	01/2018
1002	TOPROL XL	Extended-release Tablets	50 mg	Toprol Acquisition LLC	01/2018
1003	TOPROL XL	Extended-release Tablets	100 mg	Toprol Acquisition LLC	01/2018
1004	TOPROL XL	Extended-release Tablets	200 mg	Toprol Acquisition LLC	01/2018
1005	TRANDATE	Tablets	300 mg	Alvogen, Inc.	03/2018
1006	TRANDATE	Tablets	100 mg	Alvogen, Inc.	12/01/2014
1007	TRANDATE	Tablets	200 mg	Alvogen, Inc.	03/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1008	TRAVATAN Z	Ophthalmic Solution	0.004%	Novartis Pharmaceuticals Corporation	12/2019
1009	TREXIMET	Tablets	85 mg/500 mg	Currax Pharmaceuticals LLC	02/2018
1010	TRIBENZOR	Tablets	40 mg/10 mg/25 mg	Cosette Pharmaceuticals, Inc.	10/2016
1011	TRIBENZOR	Tablets	40 mg/5 mg/25 mg	Cosette Pharmaceuticals, Inc.	10/2016
1012	TRIBENZOR	Tablets	40 mg/10 mg/12.5 mg	Cosette Pharmaceuticals, Inc.	10/2016
1013	TRIBENZOR	Tablets	40 mg/5 mg/12.5 mg	Cosette Pharmaceuticals, Inc.	10/2016
1014	TRIBENZOR	Tablets	20 mg/5 mg/12.5 mg	Cosette Pharmaceuticals, Inc.	10/2016
1015	TRILEPTAL	Oral Suspension	300 mg/5 mL	Novartis Pharmaceuticals Corporation	12/2009
1016	TRILIPIX	Delayed Release Capsules	135 mg	AbbVie Inc.	07/15/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1017	TRI-NORINYL	Tablets	0.5 mg and 0.035 mg, 1 mg and 0.035 mg	Mayne Pharma LLC	1/12/2005
1018	TUSSIONEX	Extended-Release Suspension	10 mg hydrocodone bitartrate & 8 mg chlorpheniramine maleate per 5 mL	UCB, Inc.	10/2010
1019	UCERIS	Extended-Release Tablets	9 mg	Salix Pharmaceuticals Inc.	07/2018
1020	ULTRAVATE	Cream	0.05%	Bristol-Myers Squibb Company	11/2004 - 10/2005
1021	ULTRAVATE	Ointment	0.05%	Bristol-Myers Squibb Company	11/2004 - 10/2005
1022	UNITHROID	Tablets	137 mcg (0.137 mg)	Jerome Stevens Pharmaceuticals, Inc.	unknown
1023	UNITHROID	Tablets	25 mcg (0.025 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1024	UNITHROID	Tablets	50 mcg (0.05 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1025	UNITHROID	Tablets	75 mcg (0.075 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1026	UNITHROID	Tablets	88 mcg (0.088 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1027	UNITHROID	Tablets	100 mcg (0.1 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1028	UNITHROID	Tablets	112 mcg (0.112 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1029	UNITHROID	Tablets	125 mcg (0.125 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1030	UNITHROID	Tablets	150 mcg (0.15 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1031	UNITHROID	Tablets	175 mcg (0.175 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1032	UNITHROID	Tablets	200 mcg (0.2 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1033	UNITHROID	Tablets	300 mcg (0.3 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1034	UREX	Tablets	1 gram	County Line Pharmaceuticals, LLC	05/2010
1035	UROCIT-K	Extended-release Tablets	15 mEq (1620 mg) per tablet	Mission Pharmacal Company	12/23/2013
1036	UROCIT-K	Extended-release Tablets	540 mg (5 mEq per tablet)	Mission Pharmacal Company	11/2007

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1037	URSO 250	Tablets	250 mg	Allergan Sales, LLC	07/06/2009
1038	URSO FORTE	Tablets	500 mg	Allergan Sales, LLC	07/06/2009
1039	VAGISTAT-1	Vaginal Ointment	6.50%	Bristol-Myers Squibb Company	02/1998 - 02/1999
1040	VANCOCIN	Capsules	125 mg	ANI Pharmaceuticals Inc.	10/26/2015
1041	VANCOCIN	Capsules	250 mg	ANI Pharmaceuticals Inc.	10/26/2015
1042	VASERETIC	Tablets	10 mg/25 mg	Valeant Pharmaceuticals North America, LLC	10/31/1986
1043	VASOTEC	Tablets	5 mg	Bausch Health US, LLC	12/24/1985
1044	VASOTEC	Tablets	20 mg	Bausch Health US, LLC	12/24/1985
1045	VASOTEC	Tablets	2.5 mg	Bausch Health US, LLC	07/26/1988
1046	VASOTEC	Tablets	10 mg	Bausch Health US, LLC	12/24/1985
1047	VECTICAL	Ointment	3 mcg/g	Galderma Laboratories, L.P.	02/28/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1048	VECTICAL	Ointment	3 mcg/g	Galderma Laboratories, L.P.	7/21/2023
1049	VELTIN	Gel	1.2%/0.025%	Almirall, LLC	06/2018
1050	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	37.5 mg	Osmotica Pharmaceutical US LLC	04/2010
1051	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	225 mg	Osmotica Pharmaceutical US LLC	04/2010
1052	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	75 mg	Osmotica Pharmaceutical US LLC	04/2010
1053	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	150 mg	Osmotica Pharmaceutical US LLC	04/2010
1054	VENOFER	Injection	2% w/v iron (Fe)	Luitpold Pharmaceuticals, Inc.	10/02/08
1055	VENTOLIN HFA	Metered-dose Inhaler	90 mcg per actuation	GlaxoSmithKline Intellectual Property Mgmt Ltd	01/2019
1056	VERELAN	Sustained- release Capsules	120 mg	Societal CDMO Gainesville, LLC	5/17/1999

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1057	VERELAN	Sustained-release Capsules	180 mg	Societal CDMO Gainesville, LLC	5/17/1999
1058	VERELAN	Sustained-release Capsules	240 mg	Societal CDMO Gainesville, LLC	5/17/1999
1059	VERELAN	Sustained-release Capsules	360 mg	Societal CDMO Gainesville, LLC	5/17/1999
1060	VERELAN PM	Extended-release Capsules	100 mg	Societal CDMO Gainesville, LLC	11/2006 - 11/2007
1061	VERELAN PM	Extended-release Capsules	200 mg	Societal CDMO Gainesville, LLC	11/2006 - 11/2007
1062	VERELAN PM	Extended-release Capsules	300 mg	Societal CDMO Gainesville, LLC	11/2006 - 11/2007
1063	VFEND	Powder for Oral Suspension	40 mg/mL (75 mL when reconstituted)	PF Prism C.V.	12/16/2013
1064	VIAGRA	Tablets	50 mg	Upjohn US 1 LLC	12/2017
1065	VIAGRA	Tablets	25 mg	Upjohn US 1 LLC	12/2017
1066	VIAGRA	Tablets	100 mg	Upjohn US 1 LLC	12/2017
1067	VIBRAMYCIN	Capsules	100 mg	Pfizer Inc.	05/2015
1068	VIGAMOX	Ophthalmic Solution	0.5%	Novartis Pharmaceuticals Corporation	01/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1069	VIMOVO	Delayed-release Tablets	375 mg /20 mg	Horizon Medicines, LLC	03/2020
1070	VIMOVO	Delayed-release Tablets	500 mg/20 mg	Horizon Medicines, LLC	03/2020
1071	VIRAZOLE	Inhalation Solution, USP	100 mL/6G Vial	Bausch Health US, LLC	4/15/2020
1072	VIRAZOLE	Powder for Solution	6g/100 mL vial, to be reconstituted	Bausch Health US, LLC	04/2017
1073	VISTARIL	Capsules	50 mg	Pfizer Inc.	07/2020
1074	VOGELXO	Gel	50 mg	Upsher-Smith Laboratories, LLC	06/2014
1075	VOLTAREN	Delayed-release Tablets	25 mg	Novartis Pharmaceuticals Corporation	Prior to 1/1/1999
1076	VOLTAREN	Delayed-release Tablets	50 mg	Novartis Pharmaceuticals Corporation	Prior to 1/1/1999
1077	VOLTAREN	Gel	1%	GlaxoSmithKline Consumer Healthcare	07/2016
1078	VOLTAREN XR	Extended-release Tablets	100 mg	Novartis Pharmaceuticals Corporation	05/22/2000
1079	VUSION	Ointment	0.25%, 15%, and 81.35%	Mylan Pharmaceuticals Inc., a Viatris Company	11/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1080	WELCHOL	Powder for Oral Suspension	3.75 g packet	Cosette Pharmaceuticals, Inc.	08/2022
1081	WELCHOL	Powder for Oral Suspension	3.75 g packet	Cosette Pharmaceuticals, Inc.	07/2018
1082	WELCHOL	Tablets	625mg	Cosette Pharmaceuticals, Inc.	8/1/2022
1083	XALATAN	Ophthalmic Solution	0.005% (125 mcg/2.5 mL)	Upjohn US 2, LLC	11/15/2010
1084	XANAX	Tablets	0.25 mg	Upjohn US 2 LLC	06/17/2003
1085	XANAX	Tablets	0.5 mg	Upjohn US 2 LLC	06/18/2003
1086	XANAX	Tablets	1 mg	Upjohn US 2 LLC	06/18/2003
1087	XANAX	Tablets	2 mg	Upjohn US 2 LLC	06/18/2003
1088	XANAX XR	Extended-release Tablets	0.5 mg	Upjohn US 2 LLC	11/16/2005
1089	XANAX XR	Extended-release Tablets	1 mg	Upjohn US 2 LLC	11/16/2005
1090	XANAX XR	Extended-release Tablets	2 mg	Upjohn US 2 LLC	11/16/2005
1091	XANAX XR	Extended-release Tablets	3 mg	Upjohn US 2 LLC	11/16/2005
1092	XENAZINE	Tablets	25 mg	Bausch Health US LLC	07/20/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1093	XENAZINE	Tablets	12.5 mg	Bausch Health US LLC	07/20/2015
1094	XENICAL	Capsules	120 mg	CHEPLAPHARM Arzneimittel GmbH	6/1/2022
1095	XIMINO	Extended-release Capsules	135 mg	Journey Medical Corporation	04/2020
1096	XIMINO	Extended-release Capsules	90 mg	Journey Medical Corporation	04/2020
1097	XIMINO	Extended-release Capsules	45 mg	Journey Medical Corporation	04/2020
1098	XOPENEX	Inhalation Solution	0.31 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1099	XOPENEX	Inhalation Solution	1.25 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1100	XOPENEX	Inhalation Solution	0.63 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1101	XOPENEX HFA	Aerosol, metered	45 mcg/actuation 45 mcg/actuation	Lupin Inc	10/2016
1102	XYREM	Oral Solution	.5g/mL	Jazz Pharmaceuticals, Inc.	1/3/2023

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1103	XYREM	Oral Solution	.5g/mL	Jazz Pharmaceuticals, Inc.	7/3/2023
1104	YASMIN	Tablets	3 mg; 0.03 mg	Bayer HealthCare Pharmaceuticals Inc.	05/09/2008
1105	ZANAFLEX	Capsule	6 mg	Covis Pharma GmbH	10/2011
1106	ZANAFLEX	Capsule	4 mg	Covis Pharma GmbH	10/2011
1107	ZARONTIN	Capsules	250 mg	Parke-Davis Division of Pfizer Inc.	10/12/2015
1108	ZAROXOLYN	Tablets	2.5 mg	Lannett Company, Inc.	10/2018
1109	ZAROXOLYN	Tablets	10 mg	Lannett Company, Inc.	10/2018
1110	ZAROXOLYN	Tablets	5 mg	Lannett Company, Inc.	11/2002 - 10/2003
1111	ZAVESCA	Capsules	100 mg	Actelion Pharmaceuticals Ltd.	04/2018
1112	ZEBETA	Tablets	5 mg	Lederle Laboratories	08/2000 - 08/2001
1113	ZEBETA	Tablets	10 mg	Lederle Laboratories	08/2000 - 08/2001

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1114	ZEGERID	Capsules	20 mg/1100 mg	Salix Pharmaceuticals, Inc.	02/27/2006
1115	ZEGERID	Capsules	40 mg/1100 mg	Salix Pharmaceuticals, Inc.	02/27/2006
1116	ZEGERID	Powder for Oral Suspension	20 mg/1680 mg	Salix Pharmaceuticals, Inc.	06/2014
1117	ZEGERID	Powder for Oral Suspension	40 mg/1680 mg	Salix Pharmaceuticals, Inc.	06/2014
1118	ZEMPLAR	Capsules	2 mcg	AbbVie Inc.	03/2014
1119	ZEMPLAR	Capsules	1 mcg	AbbVie Inc.	03/2014
1120	ZENPEP	Delayed Release Capsules	5000 lipase USP units	Eurand Pharmaceuticals, Ltd.	12/2/2009
1121	ZIAC	Tablets	2.5 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D, Inc.	08/2019
1122	ZIAC	Tablets	5 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D, Inc.	08/2019
1123	ZIAC	Tablets	10 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D, Inc.	08/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1124	ZIANA	Gel	1.2% and 0.025%	Bausch Health US, LLC	09/2020
1125	ZIOPTAN	Sterile Ophthalmic Solution	0.0015%	Thea Pharma Inc.	11/18/2022
1126	ZITHROMAX	Powder for Oral Suspension	300 mg (15 mL when mixed)	Pfizer Inc.	02/01/2005
1127	ZITHROMAX	Powder for Oral Suspension	600 mg (15 mL when mixed)	Pfizer Inc.	02/1/2005
1128	ZITHROMAX	Powder for Oral Suspension	900 mg (22.5 mL when mixed)	Pfizer Inc.	02/01/2005
1129	ZITHROMAX	Powder for Oral Suspension	1 gram (single dose packet)	Pfizer Inc.	2/1/2005
1130	ZITHROMAX	Powder for Oral Suspension	1200 mg (30 mL when mixed)	Pfizer Inc.	02/01/2005
1131	ZITHROMAX	Tablets	250 mg	Pfizer Inc.	02/01/2005
1132	ZOLOFT	Oral Solution, Concentrate	20 mg/mL	Viartis Specialty LLC	03/20/2006
1133	ZONALON and PRUDOXIN	Cream	5%	Mylan Pharmaceuticals, Inc.	01/2019
1134	ZORIVAX	Cream	5%	Bausch Health US, LLC	08/2019
1135	ZOVIRAX	Ointment	5%	Bausch Health US, LLC	04/2014
1136	ZYCLARA	Cream	3.75%	Bausch Health US, LLC	07/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1137	ZYCLARA	Cream	3.75%	Bausch Health US, LLC	08/2018
1138	ZYMAXID	Ophthalmic Solution	0.5 %	Allergan Sales, LLC	04/2015
1139	ZYVOX	Oral Suspension	100 mg/5 mL	Pharmacia and Upjohn Company	12/2015
1140	ZYVOX	Tablets	600 mg	Pharmacia and Upjohn LLC	12/2015