

FDA Listing of Authorized Generics as of July 1, 2022

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	ABRAXANE	Injection	100 mg per vial	Abraxis Bioscience LLC	04/2022
2	ABRAXANE	Injection	100 mg per vial	Abraxis Bioscience LLC	04/2022
3	ACANYA	Gel	1.2% / 2.5%	Bausch Health Americas, Inc.	07/2018
4	ACCOLATE	Tablets	20 mg	AstraZeneca Pharmaceuticals	11/19/2010
5	ACCOLATE	Tablets	10 mg	AstraZeneca Pharmaceuticals	11/19/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
6	ACCUNEB	Solution	1.25 mg/3 mL	Mylan Specialty L.P.	02/2012
7	ACCUNEB	Solution	0.63 mg/3 mL	Mylan Specialty L.P.	02/2012
8	ACCURETIC	Tablets	20 mg/12.5 mg	Pfizer Pharmaceuticals Ltd.	02/06/2006
9	ACEPHEN	Suppositories	120 mg	G & W Laboratories, Inc.	Prior to 1/1/1999
10	ACETADOTE	Injection	6 g/30 mL (200 mg/mL)	Cumberland Pharmaceuticals, Inc.	1/7/2013
11	ACTICLATE	Tablets	150 mg	Almirall, LLC	02/2018
12	ACTICLATE	Tablets	75 mg	Almirall, LLC	02/2018
13	ACTIGALL	Capsules	300 mg	Allergan Sales, LLC	08/13/2003
14	ACTIQ	Lozenge	400 mcg	Cephalon, Inc.	09/26/2006
15	ACTIQ	Lozenge	600 mcg	Cephalon, Inc.	09/26/2006
16	ACTIQ	Lozenge	800 mcg	Cephalon, Inc.	09/26/2006
17	ACTIQ	Lozenge	1200 mcg	Cephalon, Inc.	09/26/2006
18	ACTIQ	Lozenge	1600 mcg	Cephalon, Inc.	09/26/2006
19	ACTIQ	Lozenge	200 mcg	Cephalon, Inc.	09/26/2006
20	ACTIVELLA	Tablets	1 mg / 0.5 mg	Amneal Pharmaceuticals LLC	01/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
21	ACTONEL	Tablets	150 mg	Allergan Pharmaceuticals International Ltd.	06/2014
22	ACTOS	Tablets	15 mg	Takeda Pharmaceuticals USA	08/17/2012
23	ACTOS	Tablets	45 mg	Takeda Pharmaceuticals USA	08/17/2012
24	ACTOS	Tablets	30 mg	Takeda Pharmaceuticals USA	08/17/2012
25	ACULAR LS	Ophthalmic Solution	0.4%	Allergan, Inc.	11/11/2013
26	ACZONE	Gel	7.5%	Almirall, LLC	01/2020
27	ADDERALL XR	Extended-release Capsules	5 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
28	ADDERALL XR	Extended-release Capsules	25 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
29	ADDERALL XR	Extended-release Capsules	20 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
30	ADDERALL XR	Extended-release Capsules	15 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
31	ADDERALL XR	Extended-release Capsules	10 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
32	ADDERALL XR	Extended-release Capsules	10 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
33	ADDERALL XR	Extended-release Capsules	25 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
34	ADDERALL XR	Extended-release Capsules	15 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
35	ADDERALL XR	Extended-release Capsules	20 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
36	ADDERALL XR	Extended-release Capsules	30 mg	Takeda Pharmaceuticals USA Inc.	10/2016 - 10/2017
37	ADDERALL XR	Extended-release Capsules	30 mg	Takeda Pharmaceuticals USA Inc.	04/02/2009
38	ADRENACLICK	Injection	0.3 mg	Impax Laboratories, LLC	04/01/2010
39	ADRENACLICK	Injection	0.15 mg	Impax Laboratories, LLC	04/01/2010
40	ADVAIR DISKUS	Inhalation Powder	250/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
41	ADVAIR DISKUS	Inhalation Powder	100/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019
42	ADVAIR DISKUS	Inhalation Powder	500/50 mcg	GlaxoSmithKline Intellectual Prop. Ltd. England	02/2019
43	AIRDUORESPICLICK	Inhalation Powder	113 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
44	AIRDUORESPICLICK	Inhalation Powder	55 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
45	AIRDUORESPICLICK	Inhalation Powder	232 mcg / 14 mcg	Teva Branded Pharmaceutical Products R&D Inc.	04/2017
46	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
47	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2012
48	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
49	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
50	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014
51	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
52	ALAWAY	Ophthalmic Solution	0.035%	Bausch & Lomb Incorporated	2020
53	ALBENZA	Tablets	200 mg	Impax Laboratories, LLC	09/2018
54	ALBENZA	Tablets	200 mg	Impax Laboratories, LLC	unknown
55	ALDACTAZIDE	Tablets	25 mg/25 mg	Pfizer Inc.	10/06/2003
56	ALLEGRA	Tablets	30 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
57	ALLEGRA	Tablets	60 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
58	ALLEGRA	Tablets	180 mg	Sanofi Aventis US LLC	02/2005 - 02/2006
59	ALLEGRA-D 12 HOUR	Extended-release Tablets	60 mg/120 mg	Sanofi Aventis US LLC	12/2004 - 12/2005
60	AMARYL	Tablets	1 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
61	AMARYL	Tablets	2 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
62	AMARYL	Tablets	4 mg	Sanofi Aventis US LLC	11/2004 - 11/2005
63	AMBIEN	Tablets	5 mg	Sanofi Aventis US LLC	12/2006 - 12/2007
64	AMBIEN	Tablets	10 mg	Sanofi Aventis US LLC	12/2006 - 12/2007
65	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
66	AMBIEN CR	Extended-release Tablets	12.5 mg	Sanofi Aventis U.S. LLC	12/2010
67	AMICAR	Tablets	1000 mg	Clover Pharmaceuticals Corporation	06/01/2012
68	AMMONUL	Injection	10% / 10%	Bausch Health US, LLC	03/2017
69	AMPYRA	Tablets	10 mg	Acorda Therapeutics, Inc.	09/2018
70	AMRIX	Capsules	30 mg	Cephalon, Inc.	03/2019
71	AMRIX	Capsules	15 mg	Cephalon, Inc.	03/2019
72	AMRIX	Capsules	30 mg	Cephalon, Inc.	03/2019
73	AMRIX	Capsutls	15 mg	Cephalon, Inc.	03/2019
74	ANAFRANIL	Capsules	75 mg	Mallinckrodt	07/2015
75	ANAFRANIL	Capsules	50 mg	Mallinckrodt	07/2015
76	ANAFRANIL	Capsules	25 mg	Mallinckrodt	07/2015
77	ANAPROX DS	Tablets	550 mg	Atnahs Pharma US Limited	10/2018
78	ANCOBAN	Capsules	500 mg	Bausch Health US, LLC	01/17/2012
79	ANCOBAN	Capsules	250 mg	Bausch Health US, LLC	07/2017
80	ANGIOMAX	Powder, for injection solution, lyophilized	250 mg	Sandoz Inc.	02/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
81	ANGIOMAX	Powder, for injection solution, lyophilized	250 mg	Sandoz Inc.	10/2015
82	ANTARA	Capsules	43 mg	Lupin, Inc.	02/22/2013
83	ANTARA	Capsules	30 mg	Lupin, Inc.	12/2020
84	ANTARA	Capsules	90 mg	Lupin, Inc.	12/2020
85	ANTARA	Capsules	130 mg	Lupin, Inc.	02/22/2013
86	APADAZ	Tablets	8.16 mg / 325 mg	KVK-Tech, Inc.	06/2019
87	APRISO	Extended-release Capsules	0.375 g	Salix Pharmaceuticals, Inc.	07/2018
88	APTENSIO XR	Extended-release Capsules	30 mg	Rhodes Pharmaceuticals L.P.	04/2020
89	APTENSIO XR	Extended-release Capsules	50 mg	Rhodes Pharmaceuticals L.P.	04/2020
90	APTENSIO XR	Extended-release Capsules	60 mg	Rhodes Pharmaceuticals L.P.	04/2020
91	APTENSIO XR	Extended-release Capsules	40 mg	Rhodes Pharmaceuticals L.P.	04/2020
92	APTENSIO XR	Extended-release Capsules	20 mg	Rhodes Pharmaceuticals L.P.	04/2020

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93	APTENSIO XR	Extended-release Capsules	15 mg	Rhodes Pharmaceuticals L.P.	04/2020
94	APTENSIO XR	Extended-release Capsules	10 mg	Rhodes Pharmaceuticals L.P.	04/2020
95	ARAVA	Tablets	20 mg	Sanofi Aventis US LLC	09/07/2015
96	ARAVA	Tablets	10 mg	Sanofi Aventis US LLC	09/07/2015
97	ARICEPT	Film coated tablets	5 mg	Eisai, Inc.	11/25/2009 - 11/24/2010
98	ARICEPT	Film coated tablets	10 mg	Eisai, Inc.	11/25/2009 - 11/24/2010
99	ARICEPT ODT	Orally disintegrating tablets	10 mg	Eisai, Inc.	10/18/2009 - 11/24/2010
100	ARICEPT ODT	Orally distinegrating tablets	5 mg	Eisai, Inc.	10/18/2009 - 11/24/2010
101	ARIXTRA	Injection	10 mg / 0.8 mL	Mylan Ireland Limited	12/2014 - 12/2015
102	ARIXTRA	Injection	5 mg / 0.4 mL	Mylan Ireland Limited	12/2014 - 12/2015
103	ARIXTRA	Injection	2.5 mg / 0.5 mL	Mylan Ireland Limited	12/2014 - 12/2015
104	ARIXTRA	Injection	7.5 mg / 0.6 mL	Mylan Ireland Limited	12/2014 - 12/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
105	AROMASIN	Tablets	25 mg	Pfizer Inc.	11/02/2010
106	ARTHROTEC	Tablets	50 mg/200 mcg	Pfizer Inc.	07/10/2011
107	ARTHROTEC	Tablets	75 mg/200 mcg	Pfizer Inc.	07/10/2011
108	ATACAND	Tablets	4 mg	ANI Pharmaceuticals, Inc.	05/21/2013
109	ATACAND	Tablets	8 mg	ANI Pharmaceuticals, Inc.	05/21/2013
110	ATACAND	Tablets	16 mg	ANI Pharmaceuticals, Inc.	05/21/2013
111	ATACAND	Tablets	32 mg	ANI Pharmaceuticals, Inc.	05/21/2013
112	ATACANDHCT	Tablets	16 mg/12.5 mg	ANI Pharmaceuticals, Inc.	09/2018
113	ATACANDHCT	Tablets	32 mg/25 mg	ANI Pharmaceuticals, Inc.	09/2018
114	ATACANDHCT	Tablets	32 mg/12.5 mg	ANI Pharmaceuticals, Inc.	09/2018
115	ATELVIA	Tablets	35 mg	Allergan	2015
116	ATIVAN	Injection	2 mg/mL	Baxter Healthcare Corporation	10/31/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
117	ATIVAN	Injection	4 mg/mL	Baxter Healthcare Corporation	10/31/2003
118	ATRALIN	Gel	0.05%	Bausch Health Americas, Inc.	06/19/2014
119	ATRALIN	Gel	0.05%	Bausch Health Americas, Inc.	07/26/2007
120	AUGMENTIN	Oral Suspension	250 mg/62.5 mg per 5 mL	Dr. Reddy's Laboratories Inc.	10/1990
121	AUGMENTIN	Oral Suspension	200 mg/28.5 mg per 5 mL	Dr. Reddy's Laboratories Inc.	10/22/1990
122	AUGMENTIN	Oral Suspension	400 mg/57 mg per 5 mL	Dr. Reddy's Laboratories Inc.	10/22/1990
123	AUGMENTIN	Tablets	250 mg	Dr. Reddy's Laboratories Inc.	10/22/1990
124	AUGMENTIN	Tablets	500 mg	Dr. Reddy's Laboratories Inc.	10/22/1990
125	AUGMENTIN	Tablets	875 mg	Dr. Reddy's Laboratories Inc.	10/02/1996
126	AUGMENTINES-600	Powder for Oral Suspension	600 mg/42.9 mg per 5 mL	Dr. Reddy's Laboratories Inc.	06/22/2001
127	AVALIDE	Tablets	150 mg/12.5 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
128	AVALIDE	Tablets	300 mg/12.5 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
129	AVAPRO	Tablets	75 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
130	AVAPRO	Tablets	300 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
131	AVAPRO	Tablets	150 mg	Sanofi-Aventis LLC	09/01/2011 - 08/31/2012, 09/2019
132	AVELOX	Tablets	400 mg	Bayer HealthCare LLC	01/2014
133	AVITA	Cream	0.025%	Mylan Pharmaceuticals, Inc., a Viatris Company	05/01/1998
134	AXERT	Tablets	12.5 mg	Janssen Research & Development, LLC	07/2015
135	AXERT	Tablets	6.25 mg	Janssen Research & Development, LLC	07/2015
136	AZILECT	Tablets	0.5 mg	Teva Pharmaceuticals USA	01/2017
137	AZILECT	Tablets	1 mg	Teva Pharmaceuticals USA	01/2017
138	AZOPT	Ophthalmic Suspension	1%	Novartis Pharmaceuticals Corporation	03/2021
139	AZULFIDINE	Tablets	500 mg	Pfizer Inc.	07/14/2003
140	AZULFIDINE EN-TABS	Delayed-release Tablets	500 mg	Pfizer Inc.	06/17/2003
141	BENICAR HCT	Tablets	40 mg/25 mg	Daiichi Sankyo, Inc	10/2016
142	BENICAR HCT	Tablets	40 mg/12.5 mg	Daiichi Sankyo, Inc	10/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
143	BENICAR HCT	Tablets	20 mg/12.5 mg	Daiichi Sankyo, Inc	10/2016
144	BENZACLIN	Topical Gel	1% / 5%	Bausch Health US, LLC	05/2017
145	BENZAMYCIN	Topical Gel	3% Erythromycin, 5% Benzoyl Peroxide	Bausch Health US, LLC	10/2014 - 10/2015
146	BETHKIS	Inhalation Solution	300 mg/4 mL	Chiesi USA, Inc.	09/2020
147	BETOPTIC	Ophthalmic Solution	eq. 0.5% base	Alcon Laboratories, Inc.	05/08/2000
148	BIAXIN	Granules for Oral Suspension	250 mg per 5 mL when reconstituted (100 mL bottle)	AbbVie Inc.	05/2012
149	BIAXIN	Granules for Oral Suspension	125 mg per 5 mL when reconstituted (50 mL bottle)	AbbVie Inc.	05/2012
150	BiCNU	Powder for Injection	100 mg/vial	Avet Lifesciences Private Ltd.	10/2019
151	BLOCADREN	Tablets	5 mg	Merck & Co., Inc.	Prior to 1/1/1999
152	BLOCADREN	Tablets	10 mg	Merck & Co., Inc.	Prior to 1/1/1999
153	BREVIBLOC	Injection	10 mg/mL	Baxter Healthcare Corporation	11/2002 - 10/2003
154	BRISDELLE	Capsules	7.5 mg	Sebela Ireland Limited	10/2017
155	BUMEX	Tablets	0.5 mg	Validus Pharmaceuticals LLC	10/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
156	BUMEX	Tablets	1 mg	Validus Pharmaceuticals LLC	10/2015
157	BUMEX	Tablets	2 mg	Validus Pharmaceuticals LLC	10/2015
158	BUTRANS	Transdermal System	7.5 mcg/hour	Purdue Pharma L.P.	07/2017
159	BUTRANS	Transdermal System	10 mcg/hour	Purdue Pharma L.P.	07/2017
160	BUTRANS	Transdermal System	5 mcg/hour	Purdue Pharma L.P.	07/2017
161	BUTRANS	Transdermal System	15 mcg/hour	Purdue Pharma L.P.	07/2017
162	BUTRANS	Transdermal System	20 mcg/hour	Purdue Pharma L.P.	07/2017
163	CADUET	Tablet	10 mg/10 mg	Pharmacia & Upjohn Company LLC	04/04/2014
164	CADUET	Tablet	5 mg/20 mg	Pharmacia & Upjohn Company LLC	04/04/2014
165	CADUET	Tablet	10 mg/80 mg	Pharmacia & Upjohn Company LLC	04/04/2014
166	CADUET	Tablet	2.5 mg/40 mg	Pharmacia & Upjohn Company LLC	04/04/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
167	CADUET	Tablet	5 mg/80 mg	Pharmacia & Upjohn Company LLC	04/04/2014
168	CADUET	Tablet	5 mg/40 mg	Pharmacia & Upjohn Company LLC	04/04/2014
169	CADUET	Tablet	5 mg/10 mg	Pharmacia & Upjohn Company LLC	04/04/2014
170	CADUET	Tablet	10 mg/20 mg	Pharmacia & Upjohn Company LLC	04/04/2014
171	CADUET	Tablet	2.5 mg/20 mg	Pharmacia & Upjohn Company LLC	04/04/2014
172	CADUET	Tablet	2.5 mg/10 mg	Pharmacia & Upjohn Company LLC	04/04/2014
173	CADUET	Tablet	10 mg/40 mg	Pharmacia & Upjohn Company LLC	04/04/2014
174	CANASA	Suppository	1000 mg	Allergan Sales, LLC	12/2018
175	CARAC	Cream	0.5%	Bausch Health US, LLC	08/2020
176	CARAFATE	Oral Suspension	1 g/10 mL	Allergan Sales, LLC	12/2019

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177	CARAFATE	Tablets	1 g	Allergan Sales, LLC	11/01/1996
178	CARBATROL	Extended-Release Capsules	200 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
179	CARBATROL	Extended-Release Capsules	100 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
180	CARBATROL	Extended-Release Capsules	300 mg	Takeda Pharmaceuticals U.S.A., Inc.	12/15/2011
181	CARDIOLITE	Injection	(per label)	Lantheus Medical Imaging, Inc.	12/1990
182	CARDIZEM	Tablets	30 mg	Bausch Health US, LLC	Prior to 1/1/1999
183	CARDIZEM	Tablets	60 mg	Bausch Health US, LLC	Prior to 1/1/1999
184	CARDIZEM	Tablets	90 mg	Bausch Health US, LLC	Prior to 1/1/1999
185	CARDIZEM	Tablets	120 mg	Bausch Health US, LLC	Prior to 1/1/1999
186	CARDIZEMCD	Capsules	360 mg	Bausch Health US, LLC	08/09/2012
187	CARDIZEMLA	Tablets	360 mg	Bausch Health US, LLC	02/06/2014
188	CARDIZEMLA	Tablets	180 mg	Bausch Health US, LLC	02/06/2014

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189	CARDIZEMLA	Tablets	240 mg	Bausch Health US, LLC	02/06/2014
190	CARDIZEMLA	Tablets	420 mg	Bausch Health US, LLC	02/06/2014
191	CARDIZEMLA	Tablets	300 mg	Bausch Health US, LLC	02/06/2014
192	CARDURA	Tablets	1 mg	Viatis Specialty LLC	07/2014, 11/2021
193	CARDURA	Tablets	4 mg	Viatis Specialty LLC	07/2014
194	CARDURA	Tablets	2 mg	Viatis Specialty LLC	07/2014, 10/2021
195	CARDURA	Tablets	8 mg	Viatis Specialty LLC	07/2014, 10/2021
196	CARNITOR	Oral Solution	1 g/10 mL	Leadiant Biosciences, Inc.	04/2005 - 04/2006
197	CARNITOR	Tablets	330 mg	Leadiant Biosciences, Inc.	1/2005 - 12/2005
198	CASODEX	Tablets	50 mg	ANI Pharmaceuticals, Inc.	10/2020
199	CEDAX	Capsules	400 mg	Pernix Therapeutics LLC	10/22/2013
200	CEDAX	Powder, for Oral Suspension	60 mL when reconstituted (180 mg per 5 mL)	Pernix Therapeutics LLC	10/22/2013
201	CELEBREX	Capsules	50 mg	Upjohn US 2 LLC	12/10/2014
202	CELEBREX	Capsules	200 mg	Upjohn US 2 LLC	12/10/2014

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203	CELEBREX	Capsules	400 mg	Upjohn US 2 LLC	12/10/2014
204	CELEBREX	Capsules	100 mg	Upjohn US 2 LLC	12/10/2014
205	CELESTONE SOLUSPAN	Injection	30 mg/5 mL (6 mg/mL)	Organon LLC	02/2019
206	CHILDREN'S MOTRIN	Suspension	100 mg/5 mL	McNeil Consumer Healthcare	06/1998 - 06/1999
207	CHILDREN'S MOTRIN (aka INFANTS MOTRIN)	Suspension/ Drops	40 mg/mL	McNeil Consumer Healthcare	Prior to 1/1/1999
208	CILOXAN	Ophthalmic Solution	0.3%	Novartis Pharmaceuticals Corporation	05/28/2004
209	CIPRO	for Oral Suspension	250 mg/5 mL	Bayer Pharmaceuticals Corp.	06/2003
210	CIPRO	for Oral Suspension	500 mg/5 mL	Bayer Pharmaceuticals Corp.	06/2003
211	CIPRODEX	Otic Suspension	0.3% & 0.1%	Novartis Pharmaceuticals Corporation	08/2020
212	CLEOCIN	Vaginal Cream	2%	Pharmacia and Upjohn LLC	12/17/2005
213	CLEOCIN HCl	Capsules	150 mg	Pharmacia and Upjohn LLC	07/11/2003
214	CLEOCIN HCl	Capsules	300 mg	Pharmacia and Upjohn LLC	06/18/2003
215	CLEOCIN PHOSPHATE	Injection	9,000/60 mL	Pharmacia and Upjohn LLC	06/2019

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216	CLEOCIN PHOSPHATE	Injection	900 mg/6 mL	Pharmacia and Upjohn LLC	06/2019
217	CLEOCIN PHOSPHATE	Injection	300 mg/2 mL	Pharmacia and Upjohn LLC	06/2019
218	CLEOCIN PHOSPHATE	Injection	600 mg/4 mL	Pharmacia and Upjohn LLC	06/2019
219	CLEOCINT	Topical Gel	1%	Pharmacia and Upjohn LLC	06/11/2003
220	CLEOCINT	Topical Lotion	1%	Pharmacia and Upjohn LLC	06/18/2003
221	CLIMARA	Transdermal System	0.025 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
222	CLIMARA	Transdermal System	0.375 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
223	CLIMARA	Transdermal System	0.06 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018
224	CLIMARA	Transdermal System	0.05 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	0.075 mg/day	Bayer HealthCare Pharmaceuticals, Inc.	08/2018

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227	CLINDAGEL	Gel	1%	Bausch Health U.S., LLC	06/2018
228	CLINORIL	Tablets	150 mg	Merck & Co., Inc.	Prior to 1/1/1999
229	CLINORIL	Tablets	200 mg	Merck & Co., Inc.	Prior to 1/1/1999
230	CLOBEX	Shampoo	0.05%	Galderma Laboratories, LP	01/2020
231	CLOBEX	Spray	0.05%	Galderma Laboratories, L.P.	08/2015
232	CLODERM	Cream	0.1%	EPI Health, LLC	02/17/2014
233	CLODERM	Cream	0.1%	EPI Health, LLC	09/2019
234	CLOLAR	Injection	20mg/20mL	Genzyme Corporation	05/2017
235	CLOMID	Tablets	50 mg	Hoechst Marion Roussel, Inc.	Prior to 1/1/1999
236	CLOZARIL	Tablets	25 mg	Heritage Life Sciences (USA), Inc.	03/2019
237	CLOZARIL	Tablets	50 mg	Heritage Life Sciences (USA), Inc.	03/2019
238	CLOZARIL	Tablets	100 mg	Heritage Life Sciences (USA), Inc.	03/2019
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	COLCRYS	Tablets	0.6 mg	Takeda Pharmaceuticals U.S.A. Inc.	07/01/2018
241	COLESTID	Granules for Oral Suspension	5 g per dose	Pharmacia and Upjohn LLC	01/11/2016
242	COLESTID	Tablets	1 g	Pharmacia and Upjohn LLC	02/2007
243	COLY-MYCINM	for Injection	150 mg/vial (single dose vial)	Par Sterile Products, LLC	06/01/2012
244	COMTAN	Tablets	200 mg	Orion Corporation	06/04/2014
245	COMTAN	Tablets	200 mg	Orion Corporation	10/1/2012
246	COMTAN	Tablets	200 mg	Orion Corporation	6/26/2013
247	CONCERTA	Extended-release Tablets	36 mg	Janssen Research and Development, LLC	02/2019
248	CONCERTA	Extended-release Tablets	18 mg	Janssen Research and Development, LLC	02/2019
249	CONCERTA	Extended-release Tablets	27 mg	Janssen Research and Development, LLC	02/2019
250	CONCERTA	Extended-release Tablets	54 mg	Janssen Research and Development, LLC	02/2019
251	CONDYLOX	Topical Solution	0.5%	Teva Branded Pharmaceuticals Products R&D, Inc	12/16/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
252	CONZIP	Extended-release Capsules	100 mg	Cipher Pharmaceuticals, Inc.	06/2015
253	CONZIP	Extended-release Capsules	200 mg	Cipher Pharmaceuticals, Inc.	05/2015
254	CONZIP	Extended-release Capsules	300 mg	Cipher Pharmaceuticals, Inc.	06/2015
255	COREG CR	Capsules	40 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
256	COREG CR	Capsules	20 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
257	COREG CR	Capsules	10 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
258	COREG CR	Capsules	80 mg	SmithKline Beecham (Cork) Ltd, Ireland	11/2017
259	CORGARD	Tablets	20 mg	US WorldMeds, LLC	05/05/2014
260	CORGARD	Tablets	40 mg	US WorldMeds, LLC	05/05/2014
261	CORGARD	Tablets	80 mg	US WorldMeds, LLC	05/05/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
262	CORTEF	Tablets	20 mg	Pharmacia and Upjohn Company LLC	12/22/2012
263	CORTEF	Tablets	5 mg	Pharmacia and Upjohn Company LLC	12/21/2012
264	CORTEF	Tablets	10 mg	Pharmacia and Upjohn Company LLC	12/21/2012
265	CORTENEMA	Rectal Suspension	100 mg/60 mL	ANI Pharmaceuticals, Inc.	08/2012
266	CORTISPORINOTIC	Otic Solution	eq. 3.5 mg base/g; 10,000 units/g; 1%	Monarch Pharmaceuticals Inc.	1/11/1999
267	COSMEGEN	Powder, for injection solution, lyophilized	500 mcg (0.5 mg)	Recordati Rare Diseases Inc.	12/2017
268	CUBICIN	Injection, powder, lyophilized, for solution	500 mg per vial	Cubist Pharmaceuticals, LLC	06/2016
269	CUPRIMINE	Capsules	250 mg	Bausch Health Americas, Inc.	12/1970
270	CUTIVATE	Cream	0.05%	GlaxoSmithKline Consumer Healthcare	11/2003 - 11/2004

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
271	CUTIVATE	Ointment	0.005%	GlaxoSmithKline Consumer Healthcare	11/2003 - 11/2004
272	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
273	CYTOMEL	Tablets	5 mcg	King Pharmaceuticals R&D LLC	02/2019
274	CYTOMEL	Tablets	50 mcg	King Pharmaceuticals R&D LLC	06/2019
275	CYTOMEL	Tablets	25 mcg	King Pharmaceuticals R&D LLC	06/2019
276	CYTOTEC	Tablets	100 mcg	Pfizer Inc.	06/18/2003
277	CYTOTEC	Tablets	200 mcg	Pfizer Inc.	06/18/2003
278	DANTRIUM	Capsules	50 mg	Par Sterile Products, LLC	04/08/2013
279	DANTRIUM	Capsules	25 mg	Par Sterile Products, LLC	04/08/2013
280	DANTRIUM	Capsules	100 mg	Par Sterile Products, LLC	02/2016
281	DARAPRIM	Tablets	25 mg	Vyera Pharmaceuticals, LLC	03/2020
282	DAYPRO	Caplets	600 mg	Pfizer Inc.	03/28/2013

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
283	DDAVP	Nasal Solution	10 mcg / 0.1 mL	Ferring Pharmaceuticals, Inc.	07/2016
284	DDAVP	Tablets	0.1 mg	Ferring Pharmaceuticals, Inc.	12/2015
285	DDAVP	Tablets	0.2 mg	Ferring Pharmaceuticals, Inc.	12/2015
286	DDAVP, DESMOPRESSIN ACETATE	Injection	4 mcg/mL	Ferring Pharmaceuticals Inc.	01/2016
287	DELESTROGEN	Injection	10 mg/mL	Par Sterile Products	06/01/2012
288	DELESTROGEN	Injection	20 mg/mL	Par Sterile Products	06/01/2012
289	DELESTROGEN	Injection	40 mg/mL	Par Sterile Products	06/01/2012
290	DEMSER	Capsules	250 mg	Bausch Health US, LLC	09/2020
291	DEPAKOTE ER	Extended-release Tablets	500 mg	Abbvie Inc.	08/2013
292	DEPAKOTE ER	Extended-release Tablets	250 mg	Abbvie Inc.	08/2013
293	DEPAKOTE SPRINKLE CAPSULES	Capsules	125 mg	AbbVie Inc.	08/31/2015
294	DEPO-MEDROL	Injection	40 mg/mL	Pharmacia and Upjohn	05/2006 - 05/2007

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
295	DEPO-MEDROL	Injection	80 mg/mL	Pharmacia and Upjohn	05/2006 - 05/2007
296	DEPO-PROVERA	Injection	150 mg in 1 mL	Pharmacia and Upjohn LLC	09/16/2004
297	DERMA-SMOOTH/FS (Body Oil)	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
298	DERMA-SMOOTH/FS (Scalp Oil)	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
299	DERMOTIC	Oil	0.01%	Hill Dermaceuticals Inc.	08/2013
300	DERMOTICOIL	Oil	0.01%	Hill Dermaceuticals Inc.	08/20/2013
301	DESMOPRESSIN ACETATE	Nasal Spray	10 mcg per 0.1 mL (5 mL bottle)	Ferring Pharmaceuticals, Inc.	11/20/2014
302	DESOWEN	Cream	0.05%	Galderma Laboratories, L.P.	07/2013
303	DETROL	Tablets	1 mg	Upjohn US 2 LLC	01/2014
304	DETROL	Tablets	2 mg	Upjohn US 2 LLC	01/2014, 01/2016
305	DETROL LA	Extended-release Capsules	2 mg	Pharmacia and Upjohn LLC	01/2016
306	DETROL LA	Extended-release Capsules	4 mg	Pharmacia and Upjohn LLC	12/2014
307	DEXEDRINE SPANSULE	Extended-release Capsules	5 mg	Impax Laboratories, LLC	08/1976

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

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
318	DIBENZYLINE	Capsules	10 mg	Concordia Pharmaceuticals Inc.	08/11/2015
319	DICLEGIS	Delayed-release Tablets	10 mg/10 mg	Duchesnay Inc.	11/2018
320	DIFFERIN CREAM 0.1%	Cream	0.1%	Galderma Laboratories, L.P.	10/2010
321	DIFFERIN GEL 0.1%	Gel	0.1%	Galderma Laboratories, L.P.	08/23/2010
322	DIFFERIN GEL 0.3%	Gel	0.3%	Galderma Laboratories, L.P.	01/2014
323	DIFLUCAN	Powder for Oral Suspension	10 mg/mL when reconstituted	Pfizer Inc.	03/12/2004
324	DIFLUCAN	Powder for Oral Suspension	40 mg/mL when reconstituted	Pfizer Inc.	03/12/2004
325	DIFLUCAN	Tablets	100 mg	Pfizer Inc.	03/12/2004
326	DIFLUCAN	Tablets	150 mg	Pfizer Inc.	03/12/2004
327	DIFLUCAN	Tablets	200 mg	Pfizer Inc.	03/12/2004
328	DILANTIN	Tablet (INFATABS)	50 mg	Parke-Davis Division of Pfizer Inc.	12/27/2012
329	DILANTIN-125	Oral Suspension	125 mg/5 mL (237 mL bottle)	Viatrix Specialty LLC	04/2020
330	DILAUDID	Solution	5 mg/5 mL (1 mg/mL)	Rhodes Pharmaceuticals L.P.	10/1/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
331	DILAUDID	Tablets	2 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
332	DILAUDID	Tablets	4 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
333	DILAUDID	Tablets	8 mg	Rhodes Pharmaceuticals L.P.	11/23/2009
334	DIPROLENE	Ointment	0.05%	Merck Sharp & Dohme Corporation	8/10/2012
335	DITROPAN XL	Extended-release Tablets	5 mg	Janssen Research and Development, LLC	11/12/2015
336	DITROPAN XL	Extended-release Tablets	10 mg	Janssen Research and Development, LLC	11/12/2015
337	DIURIL	Injection	500 mg/vial, sterile lyophilized	Oak Pharmaceuticals Inc.	08/13/2012
338	DORAL	Tablets	15 mg	Galt Pharmaceuticals, LLC	8/8/13
339	DORIBAX	Powder for Injection	250 mg/vial	Shionogi Inc.	12/2016
340	DORIBAX	Powder for Injection	500 mg/vial	Shionogi Inc.	12/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
341	DORYX	Delayed-Release Tablets	50 mg	Mayne Pharma International Pty Ltd.	05/2016
342	DORYX	Delayed-Release Tablets	100 mg	Mayne Pharma International Pty Ltd.	07/08/2013
343	DORYX	Delayed-Release Tablets	150 mg	Mayne Pharma International Pty Ltd.	07/08/2013
344	DORYX	Delayed-Release Tablets	200 mg	Mayne Pharma International Pty Ltd.	02/2016
345	DORYX	Delayed-Release Tablets	80 mg	Mayne Pharma International Pty Ltd.	07/08/2013
346	DORYX	Delayed-Release Tablets	75 mg	Mayne Pharma International Pty Ltd.	07/08/2013
347	DOSTINEX	Tablets	0.5 mg	Pfizer Inc.	09/22/2014
348	DOVONEX	Cream	0.005%	LEO Pharma Inc.	2012
349	DOVONEX	Ointment	0.005%	LEO Pharma Inc.	07/01/2013
350	DOXIL	Injection (Liposomal formulation)	50 mg/25 mL single use vial	Janssen Research & Development, LLC	07/2017
351	DOXIL	Injection (Liposomal formulation)	20 mg/10 mL single use vial	Janssen Research & Development, LLC	07/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
352	DOXORUBICIN	Injection	200 mg/100 mL	Pharmacia and Upjohn	4/1/2013
353	DOXORUBICIN	Injection	10 mg/5 mL	Pharmacia and Upjohn	4/1/2013
354	DOXORUBICIN	Injection	50 mg/25 mL	Pharmacia and Upjohn	03/17/2014
355	DOXORUBICIN	Injection	10 mg/5 mL	Pharmacia and Upjohn	03/17/2014
356	DOXORUBICIN	Injection	20 mg/10mL	Pharmacia and Upjohn	03/17/2014
357	DOXORUBICIN	Injection	150 mg/75 mL	Pharmacia and Upjohn	4/1/2013
358	DOXORUBICIN	Injection	50 mg/25 mL	Pharmacia and Upjohn	4/1/2013
359	DOXORUBICIN	Injection	200 mg/ 100 mL	Pharmacia and Upjohn	03/17/2014
360	DOXORUBICIN	Injection	20 mg/10 mL	Pharmacia and Upjohn	4/1/2013
361	DRISDOL	Capsules	1.25 mg (50,000 IU)	Sanofi Aventis US LLC	11/10/2009
362	DUETACT	Tablets	30 mg / 4 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/04/2015
363	DUETACT	Tablets	30 mg / 2 mg	Takeda Pharmaceuticals U.S.A., Inc.	08/04/2015
364	DUEXIS	Tablets	800 mg and 26.6 mg	Horizon Medicines LLC	09/2021

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
365	DYMISTA	Nasal Spray	137 mcg/50 mcg per spray	Mylan Specialty, L.P.	04/2020
366	DYRENIUM	Capsules	100 mg	Concordia Pharmaceuticals Inc.	08/2019
367	DYRENIUM	Capsules	50 mg	Concordia Pharmaceuticals Inc.	08/2019
368	E.E.S. GRANULES	Suspension	200 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	09/2016
369	EDECRIN	Powder, for Injection Solution, Lyophilized	50 mg/vial	Bausch Health Americas, Inc.	01/1967
370	EDECRIN	Tablets	25 mg	Bausch Health Americas, Inc.	01/2016 - 01/2017
371	ELDEPRYL	Capsules	5 mg	Somerset Pharmaceuticals, Inc.	05/1998 - 05/1999
372	ELDEPRYL	Tablets	5 mg	Somerset Pharmaceuticals, Inc.	06/1999 - 06/2000
373	ELIDEL	Cream	1%	Bausch Health US, LLC	12/2018
374	ELIMITE	Cream	5%	Mylan Pharmaceuticals, Inc.	06/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
375	ELOXATIN	Injection	50 mg / 10 mL (5 mg/mL)	Sanofi-Aventis US LLC	07/07/2014
376	ELOXATIN	Injection	100 mg / 20 mL (5 mg/mL)	Sanofi-Aventis US LLC	07/07/2014
377	ELOXATIN (PREMIERPro)	Injection	50 mg/10 mL (5 mg/mL)	Sanofi-Aventis US LLC	10/2015
378	ELOXATIN (PREMIERPro)	Injection	100 mg / 20 mL (5 mg/mL)	Sanofi-Aventis US LLC	10/2015
379	EMLA	Cream	2.5% and 2.5%	Teva Branded Pharmaceutical Products R&D, Inc.	11/12/2012
380	ENTOCORTEC	Capsules	3 mg	Paddock Laboratories, LLC	08/18/2011
381	EPCLUSA	Tablets	400 mg / 100 mg	Gilead Sciences, Inc.	10/2018
382	EPIDUO	Topical Gel	0.1% / 2.5%	Galderma Laboratories, L.P.	08/2017
383	EPIPEN	Injection	0.3 mg/0.3 mL	Mylan Specialty L.P., a Viatris Company	12/15/2016
384	EPIPEN JR.	Injection	0.15/0.3 mL	Mylan Specialty L.P., a Viatris Company	12/15/2016
385	EPIVIR-HBV	Tablets	100 mg	GlaxoSmithKline LLC	09/05/2014
386	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
387	ERYC	Delayed-Release Capsules	250 mg	Mayne Pharma International Pty Ltd	07/29/2013
388	ERYGEL	Topical Gel	2%	Mylan Pharmaceuticals, Inc.	10/2018
389	ERYPED 200	Suspension	200 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	08/2020
390	ERYPED 400	Suspension	400 mg per 5 mL when reconstituted	Azurity Pharmaceuticals, Inc.	03/2019
391	EVOXAC	Capsules	30 mg	Daiichi Sankyo, Inc.	03/2016
392	EXALGO	Extended-release Tablets	8 mg	SpecGx LLC	06/12/2014
393	EXALGO	Extended-release Tablets	12 mg	SpecGx LLC	06/12/2014
394	EXALGO	Extended-release Tablets	16 mg	SpecGx LLC	06/12/2014
395	EXALGO	Extended-release Tablets	32 mg	SpecGx LLC	06/12/2014
396	EXELDERM	Cream	1.0%	Journey Medical Corporation	02/2020
397	EXELDERM	Solution	1.0%	Journey Medical Corporation	02/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
398	EXTINA	Aerosol Foam	2%	Mylan Pharmaceuticals Inc.	12/2018
399	FAMVIR	Tablets	250 mg	Novartis	03/22/2011
400	FAMVIR	Tablets	125 mg	Novartis	03/22/2011
401	FAMVIR FAMVIR	Tablets	500 mg	Novartis	03/22/2011
402	FELBATOL	Oral Suspension	600 mg/5 mL	Mylan Specialty, L.P., a Viatris Company	1/2012
403	FELBATOL	Tablets	600 mg	Mylan Specialty, L.P., a Viatris Company	11/2011
404	FELBATOL	Tablets	400 mg	Mylan Specialty, L.P., a Viatris Company	11/2011
405	FELDENE	Capsules	20 mg	Pfizer Inc.	03/03/2014
406	FELDENE	Capsules	10 mg	Pfizer Inc.	03/03/2014
407	FEMCONFe	Chewable Tablets	0.4 mg/35 mcg	Allergan Pharmaceuticals International Ltd.	10/2011
408	FENOGLIDE	Tablets	120 mg	Salix Pharmaceuticals, Inc.	03/2021
409	FENOGLIDE	Tablets	40 mg	Salix Pharmaceuticals, Inc.	03/2021

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
410	FENOGLIDE	Tablets	40 mg	Salix Pharmaceuticals, Inc.	06/24/2015
411	FENOGLIDE	Tablets	120 mg	Salix Pharmaceuticals, Inc.	06/24/2015
412	FENTORA	Tablet	600 mcg	Cephalon, Inc.	06/2019
413	FENTORA	Tablet	100 mg	Cephalon, Inc.	06/2019
414	FENTORA	Tablet	400 mcg	Cephalon, Inc.	06/2019
415	FIBRICOR	Tablets	105 mg	Athena Biosciences, LLC	09/22/2010
416	FIBRICOR	Tablets	35 mg	Athena Biosciences, LLC	09/22/2010
417	FINACEA	Gel	15%	LEO Pharma Inc.	10/2018
418	FIORICET with CODEINE	Capsules	50 mg / 325 mg / 40 mg / 30 mg	Teva Branded Pharmaceutical Products R&D, Inc.	10/01/2003
419	FIORINAL	Capsules	50 mg / 325 mg / 40 mg	Allergan Sales, LLC	10/6/2003
420	FIORINAL with CODEINE	Capsules	50 mg / 325 mg / 40 mg / 30 mg	Allergan Sales, LLC	10/26/2006
421	FIRAZYR	Injection	30 mg / 3.0ML	Shire Human Genetic Therapies, Inc.	07/2019
422	FLECTOR	Topical System	1.3%	Institut Biochimique SA (IBSA)	03/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
423	FLECTOR	Topical System	1.3%	Institut Biochimique SA (IBSA)	03/2019
424	FLORONE	Cream	0.05%	Pharmacia and Upjohn Company	Prior to 1/1/1999
425	FLUMADINE	Tablets	100 mg	Forest Laboratories, Inc.	09/2002 - 09/2003
426	FLUOXETINE	Tablets	60 mg	Alvogen Group Holdings 3, LLC	09/2017
427	FML	Ophthalmic Suspension	0.1%	Allergan, Inc.	10/1997
428	FOCALIN XR	Extended-release Capsules	30 mg	Novartis Pharmaceuticals Corporation	01/2014
429	FOCALIN XR	Extended-release Capsules	15 mg	Novartis Pharmaceuticals Corporation	01/2014
430	FOCALIN XR	Extended-release Capsules	40 mg	Novartis Pharmaceuticals Corporation	03/2014
431	FOCALIN XR	Extended-release Capsules	5 mg	Novartis Pharmaceuticals Corporation	11/2014
432	FOCALIN XR	Extended-release Capsules	10 mg	Novartis Pharmaceuticals Corporation	02/2015
433	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
434	FORFIVOXL	Extended-release Tablets	450 mg	Alvogen Group Holdings 3, LLC	08/2018
435	FORTESA	Gel	10 mg testosterone/actuation	Endo Pharmaceuticals, Inc.	08/25/2014
436	FURADANTIN	Oral Suspension	25 mg / 5 mL	Casper Pharma LLC	12/2011 - 12/2012
437	GABITRIL	Tablets	2 mg	Cephalon, Inc	12/26/2012
438	GABITRIL	Tablets	4 mg	Cephalon Inc.	12/26/2012
439	GABITRIL	Tablets	16 mg	Cephalon, Inc.	12/2012
440	GABITRIL	Tablets	12 mg	Cephalon, Inc.	12/2012
441	GASTROCROM	Oral Concentrate	100 mg/5 mL (ampule)	Mylan Specialty, L.P.	06/2015
442	GENERESS FE	Chewable Tablets	0.8 mg/25 mcg	Allergan Pharmaceuticals International Ltd.	03/2015
443	GEODON	Capsules	20 mg	Upjohn US 1 LLC	12/15/2011
444	GEODON	Capsules	40 mg	Upjohn US 1 LLC	12/15/2011
445	GEODON	Capsules	60 mg	Upjohn US 1 LLC	12/15/2011
446	GEODON	Capsules	80 mg	Upjohn US 1 LLC	12/15/2011
447	GLUCOTROL XL	Extended-release Tablets	2.5 mg	Pfizer Inc.	03/11/2004
448	GLUCOTROL XL	Extended-release Tablets	5 mg	Pfizer Inc.	03/11/2004
449	GLUCOTROL XL	Extended-release Tablets	10 mg	Pfizer Inc.	03/11/2004

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
450	GLUMETZA	Extended-release Tablets	500 mg	Bausch Health US, LLC	06/2008
451	GLUMETZA	Extended-release Tablets	1000 mg	Bausch Health US, LLC	06/2008
452	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
453	GOPRELTO	Solution	4%	Genus Lifesciences Inc.	06/2018
454	GRIS-PEG	Tablets	250 mg	Bausch Health US, LLC	12/03/2012
455	GRIS-PEG	Tablets	125 mg	Bausch Health US, LLC	12/03/2012
456	HALCION	Tablets	0.125 mg	Pfizer Inc.	7/11/2003
457	HALCION	Tablets	0.25 mg	Pfizer Inc.	6/17/2003
458	HALDOL	Injection	5 mg/mL	Janssen Research & Development, LLC	7/2011
459	HALDOL DECANOATE	Injection	50 mg/mL	Janssen Research & Development, LLC	08/2011
460	HALDOL DECANOATE	Injection	100 mg/mL	Janssen Research & Development, LLC	07/2011
461	HARVONI	Tablets	90 mg and 400 mg	Gilead Sciences, Inc.	01/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
462	HECTOROL	Capsules, liquid filled	2.5 mcg	Genzyme Corporation	03/11/2014
463	HECTOROL	Capsules, liquid filled	1 mcg	Genzyme Corporation	03/11/2014
464	HECTOROL	Capsules, liquid filled	0.5 mcg	Genzyme Corporation	03/11/2014
465	IMITREX	Injection	4 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
466	IMITREX	Injection	6 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
467	IMITREX	Nasal Spray	5 mg	GlaxoSmithKline Intellectual Property Ltd. England	03/2020
468	IMITREX	Nasal Spray	20 mg	GlaxoSmithKline Intellectual Property Ltd. England	03/2020
469	IMITREX (refill)	Injection	6 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
470	IMITREX (refill)	Injection	4 mg/0.5 mL	GlaxoSmithKline Intellectual Prop. Ltd. England	06/2020
471	INDERAL LA	Extended-release Capsules	60 mg	ANI Pharmaceuticals, Inc.	12/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
472	INDERAL LA	Extended-release Capsules	120 mg	ANI Pharmaceuticals, Inc.	12/2017
473	INDERAL LA	Extended-release Capsules	160 mg	ANI Pharmaceuticals, Inc.	12/2017
474	INDERAL LA	Extended-release Capsules	80 mg	ANI Pharmaceuticals, Inc.	12/2017
475	INDERAL LA	Extended-release Capsules	60 mg	ANI Pharmaceuticals, Inc.	2/25/2009
476	INDERAL LA	Extended-release Capsules	80 mg	ANI Pharmaceuticals, Inc.	2/25/2009
477	INDERAL LA	Extended-release Capsules	120 mg	ANI Pharmaceuticals, Inc.	2/25/2009
478	INDERAL LA	Extended-release Capsules	160 mg	ANI Pharmaceuticals, Inc.	2/25/2009
479	INSpra	Tablets	25 mg	Upjohn US 2 LLC	09/13/2007
480	INSpra	Tablets	50 mg	Upjohn US 2 LLC	09/13/2007
481	INVANZ	Injection, Powder, Lyophilized, for Solution	1 g	Merck Sharp & Dohme Corp.	07/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
482	INVEGA	Extended-release Tablets	9 mg	Janssen Research & Development, LLC	09/24/2015
483	INVEGA	Extended-release Tablets	6 mg	Janssen Research & Development, LLC	09/24/2015
484	INVEGA	Extended-release Tablets	3 mg	Janssen Research & Development, LLC	09/24/2015
485	INVEGA	Extended-release Tablets	1.5 mg	Janssen Research & Development, LLC	09/24/2015
486	IOPIDINE	Ophthalmic Solution	0.5%	Novartis Pharmaceuticals Corporation	08/2009
487	ISOPTOCARPINE	Ophthalmic Solution	2%	Novartis Pharmaceuticals Corporation	02/21/1996
488	ISOPTOCARPINE	Ophthalmic Solution	4%	Novartis Pharmaceuticals Corporation	02/21/1996
489	ISOPTOCARPINE	Ophthalmic Solution	1%	Novartis Pharmaceuticals Corporation	02/21/1996
490	ISORDIL TITRADOSE	Tablets	5 mg	Bausch Health US, LLC	03/2020
491	ISORDIL TITRADOSE	Tablets	40 mg	Bausch Health US, LLC	03/2020
492	ISTALOL	Solution	0.5%	Bausch & Lomb Incorporated	05/2018
493	ISUPREL	Injection	0.2 mg/mL	Bausch Health US, LLC	11/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
494	KADIAN	Extended-release Capsules	30 mg	Allergan Sales, LLC	11/11/2011
495	KADIAN	Extended-release Capsules	100 mg	Allergan Sales, LLC	11/11/2011
496	KADIAN	Extended-release Capsules	80 mg	Allergan Sales, LLC	11/11/2011
497	KADIAN	Extended-release Capsules	50 mg	Allergan Sales, LLC	11/11/2011
498	KADIAN	Extended-release Capsules	20 mg	Allergan Sales, LLC	11/11/2011
499	KADIAN	Extended-release Capsules	10 mg	Allergan Sales, LLC	11/11/2011
500	KADIAN	Extended-release Capsules	60 mg	Allergan Sales, LLC	11/11/2011
501	KAZANO	Tablets	12.5 mg/500 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
502	KAZANO	Tablets	12.5 mg/1000 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
503	K-DUR 10	Extended-release Tablets	10 mEq	Schering Corporation	06/2002 - 06/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
504	K-DUR 20	Extended-release Tablets	20 mEq	Schering Corporation	06/1998 - 06/1999
505	KEFLEX	Capsules	750 mg	Pragma Pharmaceuticals, LLC	06/2017
506	KITABISPAK	Inhalation Solution	300 mg/5 mL ampules	PulmoFlow Inc.	07/2016
507	KLARON	Lotion	10%	Bausch Health US, LLC	12/2005 - 12/2006
508	K-TAB	Extended-release Tablets	20 mEq (1500 mg)	AbbVie Inc.	01/2014
509	K-TAB	Extended-release Tablets	8 mEq (600 mg)	AbbVie Inc.	02/2011
510	K-TAB	Extended-release Tablets	10 mEq (750 mg)	AbbVie Inc.	02/2011
511	LAC-HYDRIN	Cream	eq. 12% base	Bristol-Myers Squibb Company	07/2004 - 06/2005
512	LAC-HYDRIN	Lotion	eq. 12% base	Bristol-Myers Squibb Company	03/2004 - 02/2005
513	LESCOL XL	Extended-release Tablets	80 mg	Novartis Pharmaceuticals Corporation	05/2018
514	LEVO-T	Tablets	200 mg	CEDIPROF, Inc.	08/2020
515	LEVO-T	Tablets	150 mg	CEDIPROF, Inc.	08/2020
516	LEVO-T	Tablets	300 mg	CEDIPROF, Inc.	08/2020
517	LEVO-T	Tablets	175 mg	CEDIPROF, Inc.	08/2020
518	LEVO-T	Tablets	125 mg	CEDIPROF, Inc.	08/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
519	LEVO-T	Tablets	112 mg	CEDIPROF, Inc.	08/2020
520	LEVO-T	Tablets	100 mg	CEDIPROF, Inc.	08/2020
521	LEVO-T	Tablets	88 mg	CEDIPROF, Inc.	08/2020
522	LEVO-T	Tablets	75 mg	CEDIPROF, Inc.	08/2020
523	LEVO-T	Tablets	50 mg	CEDIPROF, Inc.	08/2020
524	LEVO-T	Tablets	25 mg	CEDIPROF, Inc.	08/2020
525	LEVO-T	Tablets	137 mg	CEDIPROF, Inc.	08/2020
526	LEXETTE	Foam	0.05%	Mayne Pharma LLC	02/2019
527	LIALDA	Delayed Release Tablets	1.2 g	Shire Development LLC	08/2017
528	LIBRAX	Capsules	5 mg/2.5 mg	Bausch Health US, LLC	09/2016 - 08/2017
529	LIDEX	Topical Solution	0.05%	County Line Pharmaceuticals, LLC	03/2018
530	LIDODERM	Patch	700 mg (50 mg per gram adhesive) in an aqueous base	Teikoku Pharma USA, Inc.	05/2014
531	LIMBITROL	Tablets	5 mg; eq. 12.5 mg base	Valeant Pharmaceuticals International	01/2006 - 12/2006
532	LIMBITROL DS	Tablets	10 mg; eq. 25 mg base	Valeant Pharmaceuticals International	01/2007 - 12/2007
533	LIORESAL	Injection	0.5 mg/mL	Medtronic Inc	06/1999 - 05/2000
534	LIORESAL	Injection	2 mg/mL	Medtronic Inc	06/1999 - 05/2000

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
535	LIPITOR	Tablets	40 mg	Upjohn Manufacturing Ireland Unlimited	1/28/2013
536	LIPITOR	Tablets	80 mg	Upjohn Manufacturing Ireland Unlimited	1/28/2013
537	LIPITOR	Tablets	20 mg	Upjohn Manufacturing Ireland Unlimited	1/28/2013
538	LIPITOR	Tablets	10 mg	Upjohn Manufacturing Ireland Unlimited	1/28/2013
539	LIPOFEN	Capsules	50 mg	Cipher Pharmaceuticals, Inc.	04/2016
540	LIPOFEN	Capsules	150 mg	Cipher Pharmaceuticals, Inc.	04/2016
541	LITHOBID	Extended-release Tablets	300 mg	ANI Pharmaceuticals, Inc.	12/2016
542	LOCOID	Cream	0.1%	Bausch Health U.S., LLC	07/2013
543	LOCOID	Lotion	0.1%	Bausch Health US, LLC	06/2018
544	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
545	LOCOID LIPOCREAM	Cream	0.1%	Bausch Health US, LLC	07/03/2013
546	LODOSYN	Tablets	25 mg	Bausch Health Americas, Inc.	04/2014
547	LOESTRIN 24 Fe Fe	Tablets	1 mg/20 mcg	Allergan Pharmaceuticals International Ltd.	11/05/2015
548	LOMOTIL	Tablet	2.5 mg/0.025 mg	Pfizer Inc.	07/2011, 02/2013
549	LOPID	Tablets	600 mg	Pfizer Pharmaceuticals Ltd.	11/2020
550	LOPRESSOR HCT	Tablets	1 mg/mL	Novartis Pharmaceuticals Corporation	03/1998 - 03/1999
551	LOPRESSOR HCT	Tablets	50mg / 25mg	Novartis Pharmaceuticals Corporation	11/25/2009
552	LOPRESSOR HCT	Tablets	100 mg / 25 mg	Novartis Pharmaceuticals Corporation	11/25/2009
553	LOPROX	Cream	0.77%	Medicis Pharmaceutical Corporation	12/2004 - 11/2005
554	LOPROX	Gel	0.77%	Alvogen, Inc.	07/2007 - 06/2008
555	LOPROX	Shampoo	1%	Medicis Pharmaceutical Corporation	12/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
556	LOPROX	Topical Suspension	0.77%	Medimetriks Pharmaceuticals, Inc.	12/2003 - 11/2004
557	LoSEASONIQUE	Tablets	0.1 mg/0.02 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	11/10/2016
558	LoSEASONIQUE	Tablets	0.1 mg/0.02 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	12/07/2010
559	LOTEMAX	Ophthalmic Suspension	0.5%	Bausch & Lomb Incorporated	07/2019
560	LOTENSINHCT	Tablets	20 mg; 25 mg	Validus Pharmaceuticals LLC	04/2019
561	LOTENSINHCT	Tablets	20 mg; 12.5 mg	Validus Pharmaceuticals LLC	04/2019
562	LOTENSINHCT	Tablets	10 mg; 12.5 mg	Validus Pharmaceuticals LLC	04/2019
563	LOTORNEX	Tablets	0.5 mg	Sebela Ireland Limited	05/2015
564	LOTRIMIN AF	Cream	1%	Schering-Plough HealthCare Products, Inc	03/1998 - 03/1999
565	LOTRONEX	Tablets	0.5 mg	Sebela Ireland Limited	05/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
566	LOTRONEX	Tablets	1 mg	Sebel Ireland Limited	05/2015
567	LOVENOX	Injection	150 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
568	LOVENOX	Injection	150 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	05/2015
569	LOVENOX	Injection	120 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US LLC	05/2015
570	LOVENOX	Injection	30 mg/0.3 mL prefilled syringe	Sanofi Aventis US LLC	10/2011
571	LOVENOX	Injection	40 mg/0.4 mL prefilled syringe	Sanofi Aventis US LLC	10/2011
572	LOVENOX	Injection	60 mg/0.6 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
573	LOVENOX	Injection	80 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
574	LOVENOX	Injection	100 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
575	LOVENOX	Injection	40 mg/0.4 mL prefilled syringe	Sanofi Aventis US, LLC	03/2015
576	LOVENOX	Injection	120 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US LLC	10/2011
577	LOVENOX	Injection	300 mg/3 mL multi-dose vial	Sanofi Aventis US LLC	03/2015
578	LOVENOX	Injection	60 mg/0.6 mL graduated prefilled syringe	Sanofi Aventis US LLC	03/2015
579	LOVENOX	Injection	80 mg/0.8 mL graduated prefilled syringe	Sanofi Aventis US, LLC	03/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
580	LOVENOX	Injection	100 mg/1 mL graduated prefilled syringe	Sanofi Aventis US LLC	03/2015
581	LOVENOX	Injection	300 mg/3 mL multi-dose vial	Sanofi Aventis US LLC	10/2011
582	LOVENOX	Injection	30 mg/0.3 mL prefilled syringe	Sanofi Aventis US LLC	03/2015
583	LOZOL	Tablets	2.5 mg	Rhone-Poulenc Rorer Pharmaceuticals Inc.	Prior to 1/1/1999
584	LUVOX	Tablets	50 mg	ANI Pharmaceuticals, Inc.	08/09/2011
585	LUVOX	Tablets	25 mg	ANI Pharmaceuticals, Inc.	08/09/2011
586	LUVOX	Tablets	100 mg	ANI Pharmaceuticals, Inc.	08/09/2011
587	LUXIQ	Foam	0.12%	Mylan Pharmaceuticals, Inc.	04/2017
588	LUZU	Cream	1%	Bausch Health US, LLC	07/2018
589	LYRICA	Capsules	200 mg	Upjohn US 2 LLC	07/2019
590	LYRICA	Capsules	225 mg	Upjohn US 2 LLC	07/2019
591	LYRICA	Capsules	150 mg	Upjohn US 2 LLC	07/2019
592	LYRICA	Capsules	100 mg	Upjohn US 2 LLC	07/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
593	LYRICA	Capsules	300 mg	Upjohn US 2 LLC	07/2019
594	LYRICA	Capsules	75 mg	Upjohn US 2 LLC	07/2019
595	LYRICA	Capsules	25 mg	Upjohn US 2 LLC	07/2019
596	LYRICA	Capsules	50 mg	Upjohn US 2 LLC	07/2019
597	LYRICA	Oral Solution	20 mg per mL	Upjohn US 2 LLC	07/2019
598	LYSTEDA	Tablets	650 mg	Amring Pharmaceuticals Inc.	03/17/2016
599	MACROBID	Capsules	100 mg	Almatica Pharma LLC	02/2011
600	MACRODANTIN	Capsules	50 mg	Almatica Pharma LLC	08/2011
601	MACRODANTIN	Capsules	25 mg	Almatica Pharma LLC	09/2010
602	MACRODANTIN	Capsules	100 mg	Almatica Pharma LLC	08/2011
603	MALARONE	Tablets	250 mg/100 mg	GlaxoSmithKline LLC	7/31/2012
604	MARINOL	Capsules	2.5 mg	AbbVie Inc.	05/2017
605	MARINOL	Capsules	5 mg	AbbVie Inc.	05/2017
606	MARINOL	Capsules	10 mg	AbbVie Inc.	05/2017
607	MAXIMUM STRENGTH MUCINEX DM	Extended-release Tablets	1200 mg and 60 mg	RB Health (US) LLC	09/2017
608	MAXIMUM STRENGTH MUCINEX DM	Extended-release Tablets	1200 mg and 60 mg	RB Health (US) LLC	10/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
609	MAXIMUM STRENGTH MUCINEX DM	Extended-release Tablets	1200 mg and 60 mg	RB Health (US) LLC	09/2017
610	MAXITROL	Ophthalmic Ointment	3.5 mg and 10000 units and 0.1% / gram	Novartis Pharmaceuticals Corporation	03/04/1996
611	MAXZIDE	Tablets	75 mg and 50 mg	Mylan Pharmaceuticals Inc.	Prior to 1/1/1999
612	MAXZIDE-25	Tablets	37.5 mg and 25 mg	Mylan Pharmaceuticals Inc.	Prior to 1/1/1999
613	MEDROL	Tablets	8 mg	Pfizer Inc.	4/22/2013
614	MEDROL	Tablets	16 mg	Pfizer Inc.	4/22/2013
615	MEDROL	Tablets	4 mg	Pfizer Inc.	11/16/2011
616	MEDROL	Tablets	32 mg	Pfizer Inc.	4/22/2013
617	MEGACE ES	Oral Suspension	625 mg/5 mL (125 mg/mL)	Endo Pharmaceuticals, Inc.	07/2015
618	MEPHYTON	Tablets	5 mg	Bausch Health Americas, Inc.	04/2018
619	MESNEX	Injection	100 mg/mL	Baxter Healthcare Corporation	12/2003 - 12/2004
620	MESTINON	Oral Solution	60 mg / 5 mL	Bausch Health US, LLC	07/2019
621	MESTINON	Tablets	60 mg	Bausch Health US, LLC	04/2002 - 03/2003

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

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
634	METROGEL VAGINAL GEL	Vaginal Gel	0.75%	Bausch Health US, LLC	04/01/2015
635	METROLOTION	Lotion	0.75%	Galderma Laboratories, L.P.	6/16/2009
636	MIACALCIN	Nasal Spray	200 I.U. per actuation	Sebela Ireland Ltd.	12/09/2008
637	MICARDIS	Tablets	40 mg	Boehringer Ingelheim Pharmaceuticals, Inc.	11/13/2013
638	MICARDISHCT	Tablets	80 mg/12.5 mg	Boehringer Ingelheim Pharmaceuticals, Inc.	02/28/2014
639	MICARDISHCT	Tablets	80 mg/25 mg	Boehringer Ingelheim Pharmaceuticals, Inc.	02/28/2014
640	MICARDISHCT	Tablets	40 mg/12.5 mg	Boehringer Ingelheim Pharmaceuticals, Inc.	02/28/2014
641	MICRO-K EXTENCAPS	Extended-Release Capsules	8 mEq (600 mg)	Nesher Pharmaceuticals USA LLC	03/10/2011
642	MICRO-K EXTENCAPS	Extended-Release Capsules	10 mEq (750 mg)	Nesher Pharmaceuticals USA LLC	01/19/2011
643	MICRONASE	Tablets	2.5 mg	Pharmacia and Upjohn	Prior to 1/1/1999

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
644	MICRONASE	Tablets	5 mg	Pharmacia and Upjohn	Prior to 1/1/1999
645	MICROZIDE	Capsules	12.5 mg	Teva Branded Pharmaceutical Products R&D, Inc.	10/05/2001
646	MIDAMOR	Tablets	5 mg	Paddock Laboratories	04/06/2009
647	MIGRANAL	Nasal Spray	4 mg in 1 mL	Bausch Health US, LLC	03/18/2013
648	MINASTRIN 24 FE	Tablets	1 mg/20 mcg	Allergan Pharmaceuticals International Limited	03/2017
649	MINIPRESS	Capsules	5 mg	Pfizer Inc.	01/2017
650	MINIPRESS	Capsules	1 mg	Pfizer Inc.	08/2021
651	MINIPRESS	Capsules	5 mg	Pfizer Inc.	03/2022
652	MINIPRESS	Capsules	2 mg	Pfizer Inc.	03/2022
653	MINIPRESS	Capsules	1 mg	Pfizer Inc.	01/2017
654	MINIPRESS	Capsules	2 mg	Pfizer Inc.	01/2017
655	MINIVELLE	Film, Extended Release	0.05 mg per day	Noven Pharmaceuticals, Inc.	01/2018
656	MINIVELLE	Film, Extended Release	0.0375 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	0.025 mg per day	Noven Pharmaceuticals, Inc.	01/2018
658	MINIVELLE	Film, Extended Release	0.1 mg per day	Noven Pharmaceuticals, Inc.	01/2018
659	MINIVELLE	Film, Extended Release	0.075 mg per day	Noven Pharmaceuticals, Inc.	01/2018
660	MITIGARE	Capsules	0.6 mg	Hikma International Pharmaceuticals LLC	10/01/2014
661	MOBIC	Oral Suspension	7.5 mg/5 mL	Boehringer Ingelheim Pharmaceuticals Inc.	6/12/2006
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	Kremers Urban Pharmaceuticals, Inc.	06/30/1996 - 06/29/1997

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
666	MONOKET	Tablets	20 mg	Kremers Urban Pharmaceuticals, Inc.	06/30/1996 - 06/29/1997
667	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
668	MOXATAG	Extended-Release Tablets	775 mg	Vernalis (R&D) Limited	08/20/2014
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	02/2018
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	Extended-release Tablets	600 mg	RB Health (US), LLC	02/2018
680	MUCINEX (MAXIMUM STRENGTH)	Extended-release Tablets	1200 mg	RB Health (US), LLC	08/2017
681	MUCINEX (MAXIMUM STRENGTH)	Extended-release Tablets	1200 mg	RB Health (US), LLC	12/2017
682	MUCINEX (MAXIMUM STRENGTH)	Extended-release Tablets	1200 mg	RB Health (US), LLC	02/2018
683	MUCINEX (MAXIMUM STRENGTH)	Extended-release Tablets	1200 mg	RB Health (US) LLC	08/2017
684	MUCINEX (MAXIMUM STRENGTH)	Extended-release Tablets	1200 mg	RB Health (US), LLC	10/2017
685	MUCINEX (MAXIMUM STRENGTH)	Extended-release Tablets	1200 mg	RB Health (US), LLC	08/2017
686	MUCINEX (MAXIMUM STRENGTH)	Extended-release Tablets	1200 mg	RB Health (US), LLC	08/2017
687	MUCINEXDM	Extended-release Tablets	600 mg and 30 mg	RB Health (US) LLC	10/2019
688	MUCINEXDM	Extended-release Tablets	600 mg and 30 mg	RB Health (US) LLC	05/2019
689	MYAMBUTOL	Tablets	100 mg	STI Pharma LLC	12/15/2006
690	MYAMBUTOL	Tablets	400 mg	STI Pharma LLC	12/15/2006
691	MYCOBUTIN	Capsules	150 mg	Pharmacia and Upjohn LLC	05/13/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
692	MYSOLINE	Tablets	250 mg	Bausch Health US, LLC	05/2018
693	MYSOLINE	Tablets	50 mg	Bausch Health US, LLC	05/2018
694	NALFON	Capsules	400 mg	Xspire Pharma LLC	08/05/2015
695	NALFON	Capsules	200 mg	Xspire Pharma LLC	04/2017
696	NALFON	Capsules	400 mg	Xspire Pharma LLC	05/2016
697	NAMENDA	Tablets	5 mg and 10 mg (titration pak)	Allergan Sales, LLC	04/01/2015
698	NAMENDA	Tablets	10 mg	Allergan Sales, LLC	04/01/2015
699	NAMENDA	Tablets	5 mg	Allergan Sales, LLC	04/01/2015
700	NAMENDA XR	Capsules	7 mg	Allergan Sales, LLC	05/2019
701	NAMENDA XR	Capsules	14 mg	Allergan Sales, LLC	05/2019
702	NAMENDA XR	Capsules	21 mg	Allergan Sales, LLC	05/2019
703	NAMENDA XR	Capsules	28 mg	Allergan Sales, LLC	05/2019
704	NAPRELAN	Controlled-Release Tablets	500 mg	Almatica Pharma LLC	03/2015
705	NAPRELAN	Controlled-Release Tablets	750 mg	Almatica Pharma LLC	03/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
706	NAPRELAN	Controlled-Release Tablets	375 mg	Almatica Pharma LLC	09/2015
707	NAPROSYN	Suspension	125 mg/5 mL	Atnahs Pharma US Limited	11/2016
708	NAPROSYN EC (EC-NAPROSYN)	Delayed-Release Tablets	375 mg	Atnahs Pharma US Limited	10/2018
709	NAPROSYN EC (EC-NAPROSYN)	Delayed-Release Tablets	500 mg	Atnahs Pharma US Limited	10/2018
710	NARDIL	Tablets	15 mg	Parke-Davis	3/23/2011
711	NASACORT AQ	Nasal Spray Spray Bottle	55 mcg/spray	Sanofi Aventis US, LLC	06/15/2011
712	NATROBA	Topical Suspension	0.9%	ParaPRO LLC	06/2014
713	NEOPROFEN	Injection	20mg/2mL (10mg/mL)	Recordati Rare Diseases Inc.	04/2016
714	NESINA	Tablets	6.25 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
715	NESINA	Tablets	12.5 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
716	NESINA	Tablets	25 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
717	NEURONTIN	Capsules	100 mg	Viartis Specialty LLC	3/17/2004
718	NEURONTIN	Capsules	300 mg	Viartis Specialty LLC	03/17/2004

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
719	NEURONTIN	Capsules	400 mg	Viartis Specialty LLC	3/17/2004
720	NEURONTIN	Oral Solution	250 mg per 5 mL	Viartis Specialty LLC	3/24/2011
721	NEURONTIN	Tablets	600 mg	Viartis Specialty LLC	3/17/2004
722	NEURONTIN	Tablets	800 mg	Viartis Specialty LLC	3/17/2004
723	NIASPAN	Extended-release Tablets	1000 mg	AbbVie Inc.	06/30/2014
724	NIASPAN	Extended-release Tablets	500 mg	AbbVie Inc.	06/30/2014
725	NIASPAN	Extended-release Tablets	750 mg	AbbVie Inc.	06/30/2014
726	NICORETTE	Chewing Gum	2 mg	GlaxoSmithKline Consumer Healthcare L.P.	01/2002 - 01/2003
727	NICORETTE	Chewing Gum	4 mg	GlaxoSmithKline Consumer Healthcare L.P.	06/2001 - 06/2002
728	NILANDRON	Tablets	150 mg	Concordia Pharmaceuticals Inc.	11/2019
729	NITRO-DUR	Transdermal	0.6 mg/hr	USpharma Ltd.	04/2020
730	NITRO-DUR	Transdermal	0.4 mg/hr	USpharma Ltd.	04/2020
731	NITRO-DUR	Transdermal	0.2 mg/hr	USpharma Ltd.	04/2020
732	NITRO-DUR	Transdermal	0.1 mg/hr	USpharma Ltd.	04/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
733	NITROLINGUAL PUMPSPRAY	Lingual Spray	400 mcg per Spray	G. Pohl-Boskamp GmbH & Co.	02/01/2011
734	NITROSTAT	Tablets	0.3 mg	Upjohn US 1 LLC	08/26/2016
735	NITROSTAT	Tablets	0.4 mg	Upjohn US 1 LLC	08/26/2016
736	NITROSTAT	Tablets	0.6 mg	Upjohn US 1 LLC	08/26/2016
737	NORFLEX	Extended-release Tablets	100 mg	3M Pharmaceuticals	Prior to 1/1/1999
738	NORPACE	Capsules	100 mg	Pfizer Inc.	04/2019
739	NORPACE	Capsules	150 mg	Pfizer Inc.	04/2019
740	NORPRAMIN	Tablets	10 mg	Sanofi-Aventis US LLC	04/2014
741	NORPRAMIN	Tablets	150 mg	Sanofi-Aventis US LLC	04/2014
742	NORPRAMIN	Tablets	25 mg	Sanofi-Aventis US LLC	04/2014
743	NORPRAMIN	Tablets	50 mg	Sanofi-Aventis US LLC	Prior to 1/1/1999
744	NORPRAMIN	Tablets	75 mg	Sanofi-Aventis US LLC	04/2014
745	NORPRAMIN	Tablets	100 mg	Sanofi-Aventis US LLC	04/2014
746	NOR-QD	Tablets	0.35 mg	Teva Branded Pharmaceuticals Products R&D, Inc	06/06/2003
747	NORVASC	Tablets	2.5 mg	Viatis Specialty LLC	6/15/2006

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
748	NORVASC	Tablets	5 mg	Viartis Specialty LLC	6/15/2006
749	NORVASC	Tablets	10 mg	Viartis Specialty LLC	6/15/2006
750	NOXAFIL	Delayed-release Tablets	100 mg	Merck Sharp & Dohme Corp.	08/2019
751	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
752	NUMBRINO	Nasal Solution	4%	Lannett Company, Inc.	09/2020
753	NUVARING	Vaginal Ring	11.7 mg / 2.7 mg (delivers 0.120 mg/0.015 mg per day)	Organon USA Inc.	12/2019
754	NUVIGIL	Tablets	200 mg	Teva Pharmaceuticals USA	12/2016
755	NUVIGIL	Tablets	50 mg	Teva Pharmaceuticals USA	12/2016
756	NUVIGIL	Tablets	150 mg	Teva Pharmaceuticals USA	12/2016
757	NUVIGIL	Tablets	200 mg	Teva Pharmaceuticals USA	11/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
758	NUVIGIL	Tablets	250 mg	Teva Pharmaceuticals USA	11/2016
759	NUVIGIL	Tablets	50 mg	Teva Pharmaceuticals USA	11/2016
760	NUVIGIL	Tablets	150 mg	Teva Pharmaceuticals USA	11/2016
761	NUVIGIL	Tablets	250 mg	Teva Pharmaceuticals USA	12/2016
762	OLUX	Foam	0.05%	Mylan Pharmaceuticals Inc.	12/2018
763	OLUX-E	Emulsion, Aerosol Foam	0.05%	Mylan Pharmaceuticals Inc., a Viatris Company	01/2019
764	OMNIPRED	Ophthalmic Suspension	1%	Novartis Pharmaceuticals Corporation	01/1995
765	OPTIVAR	Ophthalmic Solution	0.05%	Meda Pharmaceuticals, Inc.	03/10/2011
766	ORABLOC	Injection	4% and 1:100,000	Pierrel S.p.A.	04/2021
767	ORABLOC	Injection	4% and 1:200,000	Pierrel S.p.A.	10/2016
768	ORABLOC	Injection	4% and 1:100,000	Pierrel S.p.A.	10/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
769	ORABLOC	Injection	4% and 1:200,000	Pierrel S.p.A.	04/2021
770	ORACEA	Capsules	40 mg	Galderma Laboratories, L.P.	04/2015
771	ORAPREDOOT	Orally Disintegrating Tablets	10 mg	Concordia Pharmaceuticals Inc.	10/2015
772	ORAPREDOOT	Orally Disintegrating Tablets	30 mg	Concordia Pharmaceuticals Inc.	10/2015
773	ORAPREDOOT	Orally Disintegrating Tablets	15 mg	Concordia Pharmaceuticals Inc.	10/2015
774	OSENI	Tablets	12.5 mg/30 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
775	OSENI	Tablets	25 mg/15 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
776	OSENI	Tablets	25 mg/30 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
777	OSENI	Tablets	25 mg/45 mg	Takeda Pharmaceuticals U.S.A., Inc.	04/2016
778	OTOVEL	Otic Solution	0.3% / 0.025%	Laboratorios SALVAT, S.A.	11/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
779	OVIDE	Lotion	0.5%	Taro Pharmaceuticals USA, Inc.	08/02/2008 - 08/01/2009
780	OXANDRIN	Tablets	2.5 mg	Savient Pharmaceuticals, Inc.	06/2006 - 05/2007
781	OXANDRIN	Tablets	10 mg	Savient Pharmaceuticals, Inc.	06/2006 - 05/2007
782	OXYCODONE HYDROCHLORIDE	Oral Solution	5 mg/5 mL	Genus Lifesciences, Inc.	09/2013
783	OXYCONTIN	Extended-release Tablets	80 mg	Purdue Pharma L.P.	04/2022
784	OXYCONTIN	Extended-release Tablets	80 mg	Purdue Pharma L.P.	03/24/2015
785	OXYCONTIN	Extended-release Tablets	10 mg	Purdue Pharma L.P.	04/2022
786	OXYCONTIN	Extended-release Tablets	10 mg	Purdue Pharma L.P.	03/24/2015
787	OXYCONTIN	Extended-release Tablets	20 mg	Purdue Pharma L.P.	03/24/2015
788	OXYCONTIN	Extended-release Tablets	20 mg	Purdue Pharma L.P.	04/2022
789	OXYCONTIN	Extended-release Tablets	40 mg	Purdue Pharma L.P.	03/24/2015
790	OXYCONTIN	Extended-release Tablets	40 mg	Purdue Pharma L.P.	04/2022

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
791	PARAPLATIN	for Injection	50 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
792	PARAPLATIN	for Injection	150 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
793	PARAPLATIN	for Injection	450 mg/vial	Bristol-Myers Squibb Company	03/2004 - 02/2005
794	PARAPLATIN AQ	Injection	eq. 50 mg/5 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
795	PARAPLATIN AQ	Injection	eq. 150 mg/15 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
796	PARAPLATIN AQ	Injection	eq. 450 mg/45 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
797	PARAPLATIN AQ	Injection	eq. 600 mg/60 mL (10 mg/mL)	Bristol-Myers Squibb Company	07/2004 - 06/2005
798	PARLODEL	Capsules	5 mg	Validus Pharmaceuticals LLC	12/1998, 4/2006
799	PARLODEL	Tablets	2.5 mg	Validus Pharmaceuticals LLC	Prior to 1/1/1999
800	PARNATE	Tablets	10 mg	Concordia Pharmaceuticals Inc.	02/05/2016
801	PATADAY	Ophthalmic Solution	0.1%	Alcon Laboratories, Inc.	09/2015
802	PATADAY	Ophthalmic Solution	0.2%	Alcon Laboratories	06/2017

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
803	PATANASE	Nasal Spray	665 mcg in 100 mg solution	Novartis Pharmaceuticals Corporation	04/2015
804	PATANOL	Ophthalmic Solution	0.1%	Novartis Pharmaceuticals Corporation	09/15/2015
805	PAXIL CR	Tablets	12.5 mg	GlaxoSmithKline	10/21/2010
806	PAXIL CR	Tablets	25 mg	GlaxoSmithKline	10/21/2010
807	PAXIL CR	Tablets	37.5 mg	GlaxoSmithKline	10/21/2010
808	PEDIAPRED	Oral Solution	5 mg / 5 mL	Seton Pharmaceuticals, LLC	02/2002
809	PHOSLO	Gelcaps	667 mg	Fresenius Medical Care North America	03/2014 - 03/2015
810	PLAN B ONE-STEP	Tablets	1.5 mg	Foundation Consumer Healthcare, LLC	02/12/2014
811	PLAQUENIL	Tablets	200 mg	Concordia Pharmaceuticals Inc.	05/1999 - 04/2000
812	PLENDIL	Extended-release Tablets	2.5 mg	AstraZeneca LP	10/2008
813	PLENDIL	Extended-release Tablets	5 mg	AstraZeneca LP	10/2008
814	PLENDIL	Extended-release Tablets	10 mg	AstraZeneca LP	10/2008

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
815	PLIAGLIS	Cream	7%/7%	Taro Pharmaceuticals USA, Inc.	11/2017
816	POLYTRIM	Ophthalmic Solution	10 mL unit	Allergan, Inc.	04/29/1997
817	PONSTEL	Capsules	250 mg	Shionogi, Inc.	07/11/2011
818	POTASSIUM CHLORIDE FOR ORAL SOLUTION	Powder for Solution	20 mEq	Pharma Research Software Solution, LLC	01/2017
819	POTASSIUM CHLORIDE FOR ORAL SOLUTION	Powder for Solution	20 mEq	Pharma Research Software Solution, LLC	09/2015
820	POTASSIUM CHLORIDE ORAL SOLUTION, USP, 10%	Oral Solution	20 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
821	POTASSIUM CHLORIDE ORAL SOLUTION, USP, 10%	Oral Solution	20 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
822	POTASSIUM CHLORIDE ORAL SOLUTION, USP, 20%	Oral Solution	40 mEq per 15 mL	Lehigh Valley Technologies	05/14/2015
823	PRAVACHOL	Tablets	10 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
824	PRAVACHOL	Tablets	20 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
825	PRAVACHOL	Tablets	40 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006
826	PRAVACHOL	Tablets	80 mg	Bristol-Myers Squibb Company	10/2005 - 09/2006

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
827	PREDFORTE	Ophthalmic Suspension	1%	Allergan, Inc.	08/1997
828	PREVACID	Delayed-Release Capsules	15 mg	Takeda Global Research & Development Center, Inc.	11/2009
829	PREVACID	Delayed-Release Capsules	30 mg	Takeda Global Research & Development Center, Inc.	11/2009
830	PREVPAC	Delayed-Release Capsules, Capsules, and Tablets	30 mg, 500 mg, and 500 mg	Takeda Pharmaceuticals U.S.A., Inc.	03/02/2015
831	PRISTIQ	Extended-Release Tablets	50 mg	PF Prism C.V.	03/2017
832	PRISTIQ	Extended-Release Tablets	100 mg	PF Prism C.V.	03/2017
833	PRISTIQ	Extended-Release Tablets	25 mg	PF Prism C.V.	03/2017
834	PROAIR HFA	Inhalation Aerosol	90 mcg per acutation	Teva Branded Pharmaceutical Products R&D, Inc.	01/2019
835	PROCARDIA	Capsules	10 mg	Pfizer Inc.	3/25/2013
836	PROMETRIUM	Capsules	200 mg	Virtus Pharmaceuticals, LLC	07/30/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
837	PROMETRIUM	Capsules	200 mg	Virtus Pharmaceuticals, LLC	07/2016
838	PROMETRIUM	Capsules	100 mg	Virtus Pharmaceuticals, LLC	07/30/2010
839	PROMETRIUM	Capsules	100 mg	Virtus Pharmaceuticals, LLC	07/2016
840	PROTOPIC	Ointment	0.03%	LEO Pharma Inc.	11/2014
841	PROTOPIC	Ointment	0.1%	LEO Pharma Inc.	11/2014
842	PROVENTIL HFA	Inhalation Aerosol	90 mcg per actuation	Kindeva Drug Delivery L.P.	03/2021
843	PROVENTIL HFA	Inhalation Aerosol	90 mcg per actuation	Kindeva Drug Delivery L.P.	04/2019
844	PROVERA	Tablets	2.5 mg	Pharmacia and Upjohn	6/18/2003
845	PROVERA	Tablets	5 mg	Pharmacia and Upjohn	6/18/2003
846	PROVERA	Tablets	10 mg	Pharmacia and Upjohn	6/18/2003
847	PROVIGIL	Tablets	200 mg	Cephalon Inc.	03/29/2012
848	PROVIGIL	Tablets	100 mg	Cephalon, Inc.	03/29/2012
849	PURINETHOL	Tablets	50 mg	Stason Pharmaceuticals Inc.	11/2016
850	QUALAQUIN	Capsules	324 mg	Sun Pharmaceutical Industries, Inc.	07/23/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
851	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
852	QUDEXY XR	Extended-release Capsules	50 mg	Upsher-Smith Laboratories, LLC	07/07/2014
853	QUDEXY XR	Extended-release Capsules	25 mg	Upsher-Smith Laboratories, LLC	07/07/2014
854	QUDEXY XR	Extended-release Capsules	150 mg	Upsher-Smith Laboratories, LLC	07/07/2014
855	QUDEXY XR	Extended-release Capsules	100 mg	Upsher-Smith Laboratories, LLC	07/07/2014
856	QUDEXY XR	Extended-release Capsules	200 mg	Upsher-Smith Laboratories, LLC	07/07/2014
857	RAPAMUNE	Oral Solution	1 mg/mL	PF Prism C.V.	07/2019
858	RAPAMUNE	Tablets	0.5 mg	PF Prism C.V.	01/16/2014
859	RAPAMUNE	Tablets	2 mg	PF Prism CV	10/27/2014
860	RAPAMUNE	Tablets	1 mg	PF Prism CV	10/27/2014
861	RAZADYNE	Tablets	4 mg	Janssen Research & Development, LLC	08/28/2008
862	RAZADYNE	Tablets	8 mg	Janssen Research & Development, LLC	08/28/2008

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
863	RAZADYNE ER	Capsules	8 mg	Janssen Research & Development, LLC	10/13/2008
864	RAZADYNE ER	Capsules	16 mg	Janssen Research & Development, LLC	10/13/2008
865	RAZADYNE ER	Capsules	24 mg	Janssen Research & Development, LLC	10/13/2008
866	REGLAN	Injection	eq. 5 mg base/mL	Baxter Healthcare Corporation	02/2003 - 02/2004
867	REGLAN	Tablets	5 mg	ANI Pharmaceuticals, Inc.	12/2021
868	REGLAN	Tablets	10 mg	ANI Pharmaceuticals, Inc.	12/2021
869	RELPAX	Tablets	40 mg	Upjohn Manufacturing Ireland Unltd	07/2017
870	RELPAX	Tablets	20 mg	Upjohn Manufacturing Ireland Unltd	07/2017
871	REVELA	Tablets	800 mg	Genzyme Corporation	04/16/2014
872	RESTORIL	Capsules	22.5 mg	Mallinckrodt Inc.	07/21/2008
873	RESTORIL	Capsules	7.5 mg	Mallinckrodt Inc.	07/22/2008
874	RETIN-A	Cream	0.1 %	Bausch Health US, LLC	01/26/1973
875	RETIN-A	Cream	0.1%	Bausch Health US, LLC	07/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
876	RETIN-A	Cream	0.025%	Bausch Health US, LLC	09/2014 - 09/2015
877	RETIN-A	Cream	0.05%	Bausch Health US, LLC	02/06/2014
878	RETIN-A	Cream	0.025%	Bausch Health US, LLC	04/2019
879	RETIN-A	Cream	0.05%	Bausch Health US, LLC	12/2018
880	RETIN-A	Cream	0.05%	Valeant Pharmaceuticals North America, LLC	07/19/1974
881	RETIN-A	Gel	0.01 %	Bausch Health US, LLC	08/2019
882	RETIN-A	Gel	0.025%	Bausch Health US, LLC	06/2005
883	RETIN-A MICRO	Gel	0.04 %	Bausch Health US, LLC	08/2019
884	RETIN-A MICRO	Gel	0.1 %	Bausch Health US, LLC	08/2019
885	RETIN-A MICRO	Gel	0.04%	Bausch Health US, LLC	03/2013
886	RETIN-A MICRO	Gel	0.1 %	Bausch Health US, LLC	03/2013
887	REVATIO	Powder for Suspension	10 mg/mL	Upjohn 1 US LLC	09/2019
888	REVATIO	Tablets	20 mg	Upjohn 1 US LLC	11/2012, 11/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
889	RISPERDAL	Oral Solution	1 mg/mL	Janssen Research & Development, LLC	06/30/2008
890	RITALIN	Tablet	20 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
891	RITALIN	Tablet	5 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
892	RITALIN	Tablet	10 mg	Novartis Pharmaceuticals Corp	Prior to 1/1/1999
893	RITALINLA	Capsules	40 mg	Novartis Pharmaceuticals Corp	11/2015
894	RITALINLA	Capsules	30 mg	Novartis Pharmaceuticals Corp	11/2015
895	RITALINLA	Capsules	20 mg	Novartis Pharmaceuticals Corp	11/2015
896	RITALINLA	Capsules	10 mg	Novartis Pharmaceuticals Corp	02/2018
897	ROBINUL	Injection	0.2 mg/mL	Eurohealth International Sarl	02/06/1975
898	ROBINUL	Tablets	1 mg	Shionogi Pharma, Inc.	01/13/2005

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
899	ROBINUL FORTE	Tablets	2 mg	Shionogi Pharma, Inc.	01/13/2005
900	ROCALTROL	Oral Solution	1 mcg/mL (15 mL bottle)	Validus Pharmaceuticals LLC	08/26/2009
901	ROGAINE (FOR MEN)	Topical Solution	2%	McNeil-PPC, Inc.	06/1998 - 05/1999
902	ROGAINE (FOR WOMEN)	Topical Solution	2%	McNeil-PPC, Inc.	06/1998 - 05/1999
903	ROGAINE EXTRA STRENGTH (FOR MEN)	Topical Solution	5%	McNeil-PPC, Inc.	2004
904	ROSZET	Tablets	5 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
905	ROSZET	Tablets	10 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
906	ROSZET	Tablets	20 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
907	ROSZET	Tablets	40 mg/10 mg	Althera Pharmaceuticals, LLC	10/2021
908	ROWASA	Rectal Suspension Enema	4 g/60 mL	Mylan Specialty, L.P., a Viatris Company	2/2011
909	SAFRYAL	Tablets	3 mg / 0.03 mg / 0.451 mg	Bayer HealthCare LLC	08/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
910	SALAGEN	Tablets	5 mg	Concordia Pharmaceuticals Inc.	12/2004
911	SALAGEN	Tablets	7.5 mg	Concordia Pharmaceuticals Inc.	03/2006 - 01/2007
912	SAMSCA	Tablets	30 mg	Otsuka Pharmaceutical Company, Ltd.	05/2020
913	SAMSCA	Tablets	15 mg	Otsuka Pharmaceutical Company, Ltd.	10/2020
914	SAPHRIS SAPHRIS	Sublingual Tablets	10 mg	Allergan Sales, LLC	12/2020
915	SEASONALE	Tablets	0.15 mg/0.03 mg	Teva Branded Pharmaceutical Products R&D, Inc.	9/7/2006
916	SEASONIQUE	Tablets	0.15 mg/0.03 mg and 0.01 mg	Teva Branded Pharmaceutical Products R&D, Inc.	07/28/2010
917	SECTRAL	Capsules	eq. 200 mg base	Wyeth Laboratories, Inc.	Prior to 1/1/1999
918	SECTRAL	Capsules	eq. 400 mg base	Wyeth Laboratories, Inc.	Prior to 1/1/1999
919	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2016
920	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
921	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	04/2019
922	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	01/2015
923	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	04/2019
924	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
925	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	04/2016
926	SEPTOCAINE	Injection	4% and 1:200,000	Deproco, Inc.	01/2015
927	SEPTOCAINE	Injection	4% and 1:100,000	Deproco, Inc.	01/2015
928	SEROQUEL XR	Extended-release Tables	200 mg	AstraZeneca UK Limited	05/2017
929	SEROQUEL XR	Extended-release Tablets	50 mg	AstraZeneca UK Limited	11/2016
930	SEROQUEL XR	Extended-release Tablets	150 mg	AstraZeneca UK Limited	05/2017
931	SEROQUEL XR	Extended-release Tablets	300 mg	AstraZeneca UK Limited	05/2017
932	SEROQUEL XR	Extended-release Tablets	50 mg	AstraZeneca UK Limited	05/2017
933	SEROQUEL XR	Extended-release Tablets	300 mg	AstraZeneca UK Limited	11/2016
934	SEROQUEL XR	Extended-release Tablets	200 mg	AstraZeneca UK Limited	11/2016
935	SEROQUEL XR	Extended-release Tablets	400 mg	AstraZeneca UK Limited	05/2017
936	SEROQUEL XR	Extended-release Tablets	150 mg	AstraZeneca UK Limited	11/2016

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
937	SILENOR	Tablets	6 mg	Currax Pharmaceuticals LLC	08/2010
938	SILENOR	Tablets	3 mg	Currax Pharmaceuticals LLC	08/2010
939	SILVADENE	Cream	1%	King Pharmaceuticals LLC	01/2018
940	SKELAXIN	Tablets	800 mg	King Pharmaceuticals R&D, LLC	08/2018
941	SODIUM EDECRIN	Powder, for Solution	50 mg/vial (single dose vial for preparation of IV solution)	Aton Pharma, Inc.	01/2015 - 01/2016
942	SOLARAZE	Gel	3%	Fougera Pharmaceuticals, Inc.	11/21/2013
943	SOLODYN	Extended-release Tablets	55 mg	Bausch Health US, LLC	10/2018
944	SOLODYN	Extended-release Tablets	105 mg	Bausch Health US, LLC	10/2018
945	SOLODYN	Extended-release Tablets	80 mg	Bausch Health US, LLC	10/2018
946	SOLODYN	Extended-release Tablets	115 mg	Bausch Health US, LLC	02/2018
947	SOLODYN	Extended-release Tablets	65 mg	Bausch Health US, LLC	02/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
948	SOMA	Tablet	250 mg	Mylan Specialty, L.P.	9/13/2010
949	SOOLANTRA	Cream	1%	Galderma Laboratories, L.P.	06/2021
950	SORILUX	Foam	0.005%	Mayne Pharma LLC	08/2020
951	SORILUX	Foam	0.005%	Mayne Pharma LLC	02/2021
952	SPECTRACEF	Tablets	200 mg	Vansen Pharma, Inc.	Unknown
953	SPECTRACEF	Tablets	400 mg	Vansen Pharma, Inc.	Unknown
954	SPORANOX	Capsule	100 mg	Janssen Research & Development, LLC	2/2005; 6/2005
955	SPORANOX	Oral Solution	10 mg/mL	Janssen Research & Development, LLC	10/2018
956	STALEVO 100	Film-coated Tablets	25 mg, 100 mg, 200 mg	Orion Corporation	06/2014
957	STALEVO 125	Film-coated Tablets	31.25 mg, 125 mg, 200 mg	Orion Corporation	06/2014
958	STALEVO 150	Film-coated Tablets	37.5 mg, 150 mg, 200 mg	Orion Corporation	06/2014
959	STALEVO 200	Film-coated Tablets	50 mg, 200 mg, 200 mg	Orion Corporation	06/2014
960	STALEVO 50	Film-coated Tablets	12.5 mg, 50 mg, 200 mg	Orion Corporation	06/2014
961	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
962	STRATTERA	Capsules	10 mg	Eli Lilly and Company	05/2017
963	STRATTERA	Capsules	100 mg	Eli Lilly and Company	05/2017
964	STRATTERA	Capsules	18 mg	Eli Lilly and Company	05/2017
965	STRATTERA	Capsules	25 mg	Eli Lilly and Company	05/2017
966	STRATTERA	Capsules	40 mg	Eli Lilly and Company	05/2017
967	STRATTERA	Capsules	60 mg	Eli Lilly and Company	05/2017
968	STRATTERA	Capsules	80 mg	Eli Lilly and Company	05/2017
969	SULAR	Extended-release Tablets	17 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
970	SULAR	Extended-release Tablets	8.5 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
971	SULAR	Extended-release Tablets	34 mg	Covis Pharma GmbH/Cardinal Health Regulatory	2/2012 - 2/2013
972	SUPRAX	Capsules	400 mg	Lupin Limited	10/2020
973	SYMBICORT	Metered Dose Inhaler	160/4.5 mcg	AstraZeneca Pharmaceuticals LP	01/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
974	SYMBICORT	Metered Dose Inhaler	80/4.5 mcg	AstraZeneca Pharmaceuticals LP	01/2020
975	SYNALAR	Cream	0.025%	Medimetriks Pharmaceuticals, Inc.	12/2012
976	SYNALAR	Cream	0.01%	Medimetriks Pharmaceuticals, Inc.	12/2012
977	SYNALAR	Ointment	0.025%	Medimetriks Pharmaceuticals, Inc.	12/2012
978	SYNALGOS-DC	Capsules	356.4 mg/30 mg/16 mg	Sun Pharmaceutical Industries, Inc.	10/01/2012
979	SYPRINE	Capsules	250 mg	Bausch Health Americas, Inc.	02/2018
980	TACLONEX	Ointment	0.005%/0.064%	LEO Pharma A/S	01/2020
981	TACLONEX	Topical Suspension	0.005%/0.064%	LEO Pharma Inc.	01/2020
982	TAMBOCOR	Tablets	50 mg	3M Pharmaceuticals	10/2002
983	TAMBOCOR	Tablets	100 mg	3M Pharmaceuticals	10/2002
984	TAMBOCOR	Tablets	150 mg	3M Pharmaceuticals	10/2002
985	TARGRETIN	Capsules	75 mg	Bausch Health Ireland, Limited	12/2015

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
986	TARKA	Extended-release Tablets	4 mg Trandolapril, 240 mg Verapamil Hydrochloride	AbbVie	02/25/2015
987	TARKA	Extended-release Tablets	2 mg Trandolapril, 240 mg Verapamil Hydrochloride	AbbVie	02/25/2015
988	TARKA	Extended-release Tablets	2 mg Trandolapril, 180 mg Verapamil Hydrochloride	AbbVie	02/25/2015
989	TASMAR	Tablets	100 mg	Bausch Health US, LLC	07/2004
990	TAXOTERE	Injection Concentrate	160 mg/8 mL (20 mg/mL)	Sanofi Aventis US LLC	10/2016
991	TAXOTERE	Injection Concentrate	80 mg/4 mL (20 mg/mL)	Sanofi Aventis US LLC	03/2011
992	TAXOTERE	Injection Concentrate	20 mg/mL	Sanofi Aventis US LLC	03/2011
993	TAYTULLA	Capsules	1 mg/20 mcg	Allergan Pharmaceuticals International Ltd	11/2020
994	TAZORAC	Cream	0.1%	Allergan Aesthetics, an Abbvie Company	10/2016
995	TAZORAC	Cream	0.05%	Allergan Aesthetics, an Abbvie Company	10/2016
996	TEGRETOL XR	Tablets	100 mg	Novartis Pharmaceuticals Corporation	07/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
997	TEGRETOL XR	Tablets	200 mg	Novartis Pharmaceuticals Corporation	06/15/2009
998	TEGRETOL XR	Tablets	400 mg	Novartis Pharmaceuticals Corporation	06/15/2009
999	TESSALON	Perles	100 mg	Pfizer Inc.	01/2020
1000	TESTIM	Gel	50 mg in 5 g	Auxilium Pharmaceuticals, Inc.	06/09/2014
1001	TETRACAINE HYDROCHLORIDE	Ophthalmic Solution	0.5%	Bausch Health Ireland Limited	06/2019
1002	TIAZAC	Extended-release Capsules	420 mg	Bausch Health US, LLC	08/20/2014
1003	TIAZAC	Extended-release Capsules	300 mg	Bausch Health US, LLC Bausch Health US, LLC	08/20/2014
1004	TIAZAC	Extended-release Capsules	240 mg	Bausch Health US, LLC	08/20/2014
1005	TIAZAC	Extended-release Capsules	180 mg	Bausch Health US, LLC	08/20/2014
1006	TIAZAC	Extended-release Capsules	120 mg	Bausch Health US, LLC Bausch Health US, LLC	08/20/2014

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1007	TIAZAC	Extended-release Capsules	360 mg	Bausch Health US, LLC	08/20/2014
1008	TIGAN	Injection	100 mg/mL	Par Sterile Products, LLC	06/01/2012
1009	TIMOPTIC	Ophthalmic Solution	0.5%	Bausch Health America, Inc.	06/2020
1010	TIMOPTIC in OCUDOSE	Solution	0.5%	Bausch Health Americas, Inc.	04/2021
1011	TIROSINT	Capsules	13 mcg	IBSA Pharma Inc.	11/2020
1012	TIROSINT	Capsules	25 mcg	IBSA Pharma Inc.	11/2020
1013	TIROSINT	Capsules	50 mcg	IBSA Pharma Inc.	11/2020
1014	TIROSINT	Capsules	150 mcg	IBSA Pharma Inc.	11/2020
1015	TIROSINT	Capsules	75 mcg	IBSA Pharma Inc.	11/2020
1016	TIROSINT	Capsules	100 mcg	IBSA Pharma Inc.	11/2020
1017	TIROSINT	Capsules	112 mcg	IBSA Pharma Inc.	11/2020
1018	TIROSINT	Capsules	125 mcg	IBSA Pharma Inc.	11/2020
1019	TIROSINT	Capsules	88 mcg	IBSA Pharma Inc.	11/2020
1020	TIROSINT	Capsules	175 mcg	IBSA Pharma Inc.	11/2020
1021	TIROSINT	Capsules	137 mcg	IBSA Pharma Inc.	11/2020
1022	TIROSINT	Capsules	200 mcg	IBSA Pharma Inc.	11/2020
1023	TIVORBEX	Capsules	20 mg	Genus Lifesciences Inc.	01/2020
1024	TIVORBEX	Capsules	40 mg	Genus Lifesciences Inc.	01/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1025	TOBI	Solution for Inhalation	300 mg/5 mL ampule	Mylan Specialty, L.P., a Viatris Company	07/2014
1026	TOBRADEX	Ophthalmic Suspension	0.3%, 0.1%	Novartis Pharmaceuticals Corporation	01/02/2009
1027	TOFRONIL PM	Capsules	150 mg	Mallinckrodt Inc.	4/2006
1028	TOFRONIL PM	Capsules	75 mg	Mallinckrodt Inc.	4/2006
1029	TOFRONIL PM	Capsules	125 mg	Mallinckrodt Inc.	4/2006
1030	TOFRONIL PM	Capsules	100 mg	Mallinckrodt Inc.	4/2006
1031	TOPROL XL	Extended-release Tablets	25 mg	Toprol Acquisition LLC	01/2018
1032	TOPROL XL	Extended-release Tablets	50 mg	Toprol Acquisition LLC	01/2018
1033	TOPROL XL	Extended-release Tablets	100 mg	Toprol Acquisition LLC	01/2018
1034	TOPROL XL	Extended-release Tablets	200 mg	Toprol Acquisition LLC	01/2018
1035	TORADOL	Tablets	10 mg	Syntex (U.S.A.) Inc.	Prior to 1/1/1999
1036	TRANDATE	Tablets	200 mg	Alvogen, Inc.	03/2018
1037	TRANDATE	Tablets	300 mg	Alvogen, Inc.	03/2018
1038	TRANDATE	Tablets	100 mg	Alvogen, Inc.	12/01/2014
1039	TRAVATANZ	Ophthalmic Solution	0.004%	Novartis Pharmaceuticals Corporation	12/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1040	TREXIMET	Tablets	85 mg/500 mg	Curax Pharmaceuticals LLC	02/2018
1041	TRIBENZOR	Tablets	40 mg/5 mg/25 mg	Daiichi Sankyo, Inc.	10/2016
1042	TRIBENZOR	Tablets	40 mg/10 mg/25 mg	Daiichi Sankyo, Inc.	10/2016
1043	TRIBENZOR	Tablets	40 mg/10 mg/12.5 mg	Daiichi Sankyo, Inc.	10/2016
1044	TRIBENZOR	Tablets	20 mg/5 mg/12.5 mg	Daiichi Sankyo, Inc.	10/2016
1045	TRIBENZOR	Tablets	40 mg/5 mg/12.5 mg	Daiichi Sankyo, Inc.	10/2016
1046	TRILEPTAL	Oral Suspension	300 mg/5 mL	Novartis Pharmaceuticals Corporation	12/2009
1047	TRILIPIX	Delayed Release Capsules	135 mg	AbbVie Inc.	07/15/2013
1048	TRILIPIX	Delayed Release Capsules	45 mg	AbbVie Inc.	07/15/2013
1049	TRI-NORINYL	Tablets	0.5 mg and 0.035 mg, 1 mg and 0.035 mg	Mayne Pharma LLC	1/12/2005
1050	TUSSIONEX	Extended-Release Suspension	10 mg hydrocodone bitartrate & 8 mg chlorpheniramine maleate per 5 mL	UCB, Inc.	10/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1051	UCERIS	Extended-Release Tablets	9 mg	Salix Pharmaceuticals Inc.	07/2018
1052	ULTRAVATE	Cream	0.05%	Bristol-Myers Squibb Company	11/2004 - 10/2005
1053	ULTRAVATE	Ointment	0.05%	Bristol-Myers Squibb Company	11/2004 - 10/2005
1054	UNITHROID	Tablets	137 mcg (0.137 mg)	Jerome Stevens Pharmaceuticals, Inc.	unknown
1055	UNITHROID	Tablets	25 mcg (0.025 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1056	UNITHROID	Tablets	50 mcg (0.05 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1057	UNITHROID	Tablets	75 mcg (0.075 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1058	UNITHROID	Tablets	88 mcg (0.088 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1059	UNITHROID	Tablets	100 mcg (0.1 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1060	UNITHROID	Tablets	112 mcg (0.112 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1061	UNITHROID	Tablets	125 mcg (0.125 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1062	UNITHROID	Tablets	150 mcg (0.15 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1063	UNITHROID	Tablets	175 mcg (0.175 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1064	UNITHROID	Tablets	200 mcg (0.2 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1065	UNITHROID	Tablets	300 mcg (0.3 mg)	Jerome Stevens Pharmaceuticals, Inc.	08/2002 - 07/2003
1066	UREX	Tablets	1 gram	County Line Pharmaceuticals, LLC	05/2010
1067	UROCIT-K	Extended-release Tablets	540 mg (5 mEq per tablet)	Mission Pharmacal Company	11/2007
1068	UROCIT-K	Extended-release Tablets	15 mEq (1620 mg) per tablet	Mission Pharmacal Company	12/23/2013
1069	URSO 250	Tablets	250 mg	Allergan Sales, LLC	07/06/2009
1070	URSO FORTE	Tablets	500 mg	Allergan Sales, LLC	07/06/2009
1071	VAGISTAT-1	Vaginal Ointment	6.50%	Bristol-Myers Squibb Company	02/1998 - 02/1999

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1072	VANCOCIN	Capsules	250 mg	ANI Pharmaceuticals Inc.	10/26/2015
1073	VANCOCIN	Capsules	125 mg	ANI Pharmaceuticals Inc.	10/26/2015
1074	VASERETIC	Tablets	10 mg/25 mg	Valeant Pharmaceuticals North America, LLC	10/31/1986
1075	VASOTEC	Tablets	2.5 mg	Bausch Health US, LLC	07/26/1988
1076	VASOTEC	Tablets	5 mg	Bausch Health US, LLC	12/24/1985
1077	VASOTEC	Tablets	10 mg	Bausch Health US, LLC	12/24/1985
1078	VASOTEC	Tablets	20 mg	Bausch Health US, LLC	12/24/1985
1079	VECTICAL	Ointment	3 mcg/g	Galderma Laboratories, L.P.	02/28/2012
1080	VELTIN	Gel	1.2%/0.025%	Almirall, LLC	06/2018
1081	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	75 mg	Osmotica Pharmaceutical US LLC	04/2010
1082	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	37.5 mg	Osmotica Pharmaceutical US LLC	04/2010

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1083	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	150 mg	Osmotica Pharmaceutical US LLC	04/2010
1084	VENLAFAXINE HYDROCHLORIDE EXTENDED RELEASE TABLETS	Tablet, Extended Release	225 mg	Osmotica Pharmaceutical US LLC	04/2010
1085	VENOFER	Injection	2% w/v iron (Fe)	Luitpold Pharmaceuticals, Inc.	10/02/08
1086	VENTOLIN HFA	Metered-dose Inhaler	90 mcg per actuation	GlaxoSmithKline Intellectual Property Mgmt Ltd	01/2019
1087	VERELAN	Sustained- release Capsules	120 mg	Recro Gainesville LLC	5/17/1999
1088	VERELAN	Sustained- release Capsules	180 mg	Recro Gainesville LLC	5/17/1999
1089	VERELAN	Sustained- release Capsules	240 mg	Recro Gainesville LLC	5/17/1999
1090	VERELAN	Sustained- release Capsules	360 mg	Recro Gainesville LLC	5/17/1999
1091	VERELAN PM	Extended- release Capsules	100 mg	Recro Gainesville LLC	11/2006 - 11/2007

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1092	VERELANPM	Extended-release Capsules	200 mg	Recro Gainesville LLC	11/2006 - 11/2007
1093	VERELANPM	Extended-release Capsules	300 mg	Recro Gainesville LLC	11/2006 - 11/2007
1094	VFEND	Powder for Oral Suspension	40 mg/mL (75 mL when reconstituted)	PF Prism C.V.	12/16/2013
1095	VFEND	Tablets	200 mg	PF Prism C.V.	07/08/2010
1096	VFEND	Tablets	50 mg	PF Prism C.V.	07/08/2010
1097	VIAGRA	Tablets	50 mg	Upjohn US 1 LLC	12/2017
1098	VIAGRA	Tablets	100 mg	Upjohn US 1 LLC	12/2017
1099	VIAGRA	Tablets	25 mg	Upjohn US 1 LLC	12/2017
1100	VIBRAMYCIN	Capsules	100 mg	Pfizer Inc.	05/2015
1101	VIDAZA	Injection, Powder, Lyophilized, for Solution	100 mg single-dose vial	Celgene Corporation	09/16/2013
1102	VIGAMOX	Ophthalmic Solution	0.5%	Novartis Pharmaceuticals Corporation	01/2017
1103	VIMOVO	Delayed-release Tablets	375 mg/20 mg	Horizon Medicines, LLC	03/2020
1104	VIMOVO	Delayed-release Tablets	500 mg/20 mg	Horizon Medicines, LLC	03/2020
1105	VIRAMUNE	Oral Suspension	50 mg/5 mL	Boehringer-Ingelheim	05/21/2012

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
				Pharmaceuticals, Inc.	
1106	VIRAMUNE	Tablets	200 mg	Boehringer-Ingelheim Pharmaceuticals, Inc.	05/21/2012
1107	VIRAZOLE	Powder for Solution	6g/100 mL vial, to be reconstituted	Bausch Health US, LLC	04/2017
1108	VISTARIL	Capsules	50 mg	Pfizer Inc.	07/2020
1109	VOGELXO	Gel	50 mg	Upsher-Smith Laboratories, LLC	06/2014
1110	VOLTAREN	Delayed-release Tablets	25 mg	Novartis Pharmaceuticals Corporation	Prior to 1/1/1999
1111	VOLTAREN	Delayed-release Tablets	50 mg	Novartis Pharmaceuticals Corporation	Prior to 1/1/1999
1112	VOLTAREN	Gel	1%	GlaxoSmithKline Consumer Healthcare	07/2016
1113	VOLTAREN XR	Extended-release Tablets	100 mg	Novartis Pharmaceuticals Corporation	05/22/2000
1114	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
1115	WELCHOL	Oral Solution	3.75 g packet	Daiichi Sankyo Inc.	07/2018
1116	WELCHOL	Tablets	625 mg	Daiichi Sankyo, Inc.	05/2018
1117	XALATAN	Ophthalmic Solution	0.005% (125 mcg/2.5 mL)	Upjohn US 2, LLC	11/15/2010
1118	XANAX	Tablets	0.25 mg	Upjohn US 2 LLC	06/17/2003
1119	XANAX	Tablets	0.5 mg	Upjohn US 2 LLC	06/18/2003
1120	XANAX	Tablets	1 mg	Upjohn US 2 LLC	06/18/2003
1121	XANAX	Tablets	2 mg	Upjohn US 2 LLC	06/18/2003
1122	XANAX XR	Extended-release Tablets	0.5 mg	Upjohn US 2 LLC	11/16/2005
1123	XANAX XR	Extended-release Tablets	1 mg	Upjohn US 2 LLC	11/16/2005
1124	XANAX XR	Extended-release Tablets	2 mg	Upjohn US 2 LLC	11/16/2005
1125	XANAX XR	Extended-release Tablets	3 mg	Upjohn US 2 LLC	11/16/2005
1126	XIMINO	Extended-release Capsules	90 mg	Journey Medical Corporation	04/2020
1127	XIMINO	Extended-release Capsules	135 mg	Journey Medical Corporation	04/2020
1128	XIMINO	Extended-release Capsules	45 mg	Journey Medical Corporation	04/2020

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1129	XOPENEX	Inhalation Solution	0.63 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1130	XOPENEX	Inhalation Solution	1.25 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1131	XOPENEX	Inhalation Solution	0.31 mg/3 mL	Oak Pharmaceuticals, Inc.	08/2012
1132	XOPENEX HFA	Aerosol, metered	45 mcg/actuation 45 mcg/actuation	Sunovion Pharmaceuticals Inc.	10/2016
1133	YASMIN	Tablets	3 mg; 0.03 mg	Bayer HealthCare Pharmaceuticals Inc.	05/09/2008
1134	ZANAFLEX	Capsule	2 mg	Covis Pharma GmbH	10/2011
1135	ZANAFLEX	Capsule	4 mg	Covis Pharma GmbH	10/2011
1136	ZANAFLEX	Capsule	6 mg	Covis Pharma GmbH	10/2011
1137	ZARONTIN	Capsules	250 mg	Parke-Davis Division of Pfizer Inc.	10/12/2015
1138	ZAROXOLYN	Tablets	10 mg	Lannett Company, Inc.	10/2018
1139	ZAROXOLYN	Tablets	2.5 mg	Lannett Company, Inc.	10/2018

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1140	ZAROXOLYN	Tablets	5 mg	Lannett Company, Inc.	11/2002 - 10/2003
1141	ZAVESCA	Capsules	100 mg	Actelion Pharmaceuticals Ltd.	04/2018
1142	ZEBETA	Tablets	5 mg	Lederle Laboratories	08/2000 - 08/2001
1143	ZEBETA	Tablets	10 mg	Lederle Laboratories	08/2000 - 08/2001
1144	ZEGERID	Capsules	40 mg/1100 mg	Salix Pharmaceuticals, Inc.	02/27/2006
1145	ZEGERID	Capsules	20 mg/1100 mg	Salix Pharmaceuticals, Inc.	02/27/2006
1146	ZEGERID	Powder for Oral Suspension	20 mg/1680 mg	Salix Pharmaceuticals, Inc.	06/2014
1147	ZEGERID	Powder for Oral Suspension	40 mg/1680 mg	Salix Pharmaceuticals, Inc.	06/2014
1148	ZEMPLAR	Capsules	1 mcg	AbbVie Inc.	03/2014
1149	ZEMPLAR	Capsules	2 mcg	AbbVie Inc.	03/2014
1150	ZENPEP	Delayed Release Capsules	5000 lipase USP units	Eurand Pharmaceuticals, Ltd.	12/2/2009
1151	ZIAC	Tablets	2.5 mg; 6.25 mg	Teva Branded Pharmaceutical	08/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
				Products R&D, Inc.	
1152	ZIAC	Tablets	5 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D, Inc.	08/2019
1153	ZIAC	Tablets	10 mg; 6.25 mg	Teva Branded Pharmaceutical Products R&D, Inc.	08/2019
1154	ZIANA	Gel	1.2% and 0.025%	Bausch Health US, LLC	09/2020
1155	ZITHROMAX	Powder for Oral Suspension	300 mg (15 mL when mixed)	Pfizer Inc.	02/01/2005
1156	ZITHROMAX	Powder for Oral Suspension	600 mg (15 mL when mixed)	Pfizer Inc.	02/1/2005
1157	ZITHROMAX	Powder for Oral Suspension	900 mg (22.5 mL when mixed)	Pfizer Inc.	02/01/2005
1158	ZITHROMAX	Powder for Oral Suspension	1 gram (single dose packet)	Pfizer Inc.	2/1/2005
1159	ZITHROMAX	Powder for Oral Suspension	1200 mg (30 mL when mixed)	Pfizer Inc.	02/01/2005
1160	ZITHROMAX	Tablets	250 mg	Pfizer Inc.	02/01/2005
1161	ZOLOFT	Oral Solution, Concentrate	20 mg/mL	Viartis Specialty LLC	03/20/2006
1162	ZONALON and PRUDOXIN	Cream	5%	Mylan Pharmaceuticals, Inc.	01/2019

	Proprietary Name	Dosage Form	Strength	NDA Applicant Name	Date Authorized Generic Entered the Market
1163	ZORIVAX	Cream	5%	Bausch Health US, LLC	08/2019
1164	ZOVIRAX	Ointment	5%	Bausch Health US, LLC	04/2014
1165	ZOVIRAX	Oral Suspension	200 mg per 5 mL	Mylan Pharmaceuticals Inc., a Viatris Company	10/2018
1166	ZYCLARA	Cream	3.75%	Bausch Health US, LLC	07/2020
1167	ZYCLARA	Cream	3.75%	Bausch Health US, LLC	08/2018
1168	ZYFLOCR	Extended-release Tablets	600 mg	Chiesi USA, Inc.	04/2017
1169	ZYMAXID	Ophthalmic Solution	0.5 %	Allergan Sales, LLC	04/2015
1170	ZYVOX	Oral Suspension	100 mg/5 mL	Pharmacia and Upjohn Company	12/2015
1171	ZYVOX	Tablets	600 mg	Pharmacia and Upjohn LLC	12/2015