

Paragraph IV Patent Certifications
February 8, 2022

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/INDA	DATE OF SUBMISSION	NUMBER OF ANDAS SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Brivaracetam	Oral Solution	10 mg/mL	Briviact 205838	5/12/2020	1					2/21/2021
Brivaracetam	Tablets	10 mg, 25 mg, 50 mg, 75 mg and 100 mg	Briviact 205836	5/12/2020	7					2/21/2021
Bromfenac Sodium	Ophthalmic Solution	0.07%	Prolensa 203168	7/26/2013	1	Eligible	11/19/2019			9/11/2025
Bromfenac Sodium	Ophthalmic Solution	0.075%	Bromsite 206911	10/25/2017	1					8/7/2029
Budesonide	Enteric Coated Capsules	3 mg	Entocort EC 21324	2/1/2008	1	Extinguished	2/11/2020	4/2/2014		1/1/2015
Budesonide	Nasal Spray	0.032 mg (32 mcg)/spray	Rhinocort 20746	5/14/2007	1	Deferred	2/11/2020	5/12/2014	5/13/2014	10/29/2017
Budesonide	Inhalation Suspension	0.25 mg/2 mL and 0.5 mg/2 mL	Pulmicort Respules 20929	9/15/2005	1	Extinguished	4/7/2020	11/18/2008		2/27/2006
Budesonide	Inhalation Suspension	1 mg/2 mL	Pulmicort Respules 20929	5/28/2010	1	Eligible	2/11/2020	9/27/2013	7/27/2015	12/23/2018
Budesonide	Extended-release Tablets	9 mg	Uceris 203634	3/11/2013	1	Deferred	6/18/2019	7/3/2018	7/5/2018	6/9/2020
Budesonide and Formoterol Fumarate Dihydrate	Metered Inhalation	80 mcg/4.5 mcg per inhalation and 160 mcg/4.5 mcg per inhalation	Symbicort 21929	6/26/2018	1					10/16/2028
Bupivacaine Liposome	Injectable Suspension	266 mg/20 mL	Exparel 22496	8/20/2021	1					1/22/2041
Buprenorphine and Naloxone	Buccal Film	2.1 mg/0.3 mg and 4.2 mg/0.7 mg	Bunavail 205637	11/23/2016	1					8/20/2032
Buprenorphine and Naloxone	Buccal Film	6.3 mg/1 mg	Bunavail 205637	12/21/2015	1					8/20/2032
Buprenorphine Hydrochloride	Buccal Film	75 mcg and 150 mcg	Belbuca 207932	10/24/2016	1	Extinguished Non-Forfeiture	6/29/2021 2/9/2021			7/23/2027
Buprenorphine Hydrochloride	Buccal Film	300 mcg, 450 mcg, 600 mcg and 750 mcg	Belbuca 207932	10/4/2016	1	Extinguished Non-Forfeiture	6/29/2021 2/9/2021			7/23/2027
Buprenorphine Hydrochloride	Buccal Film	900 mcg	Belbuca 207932	9/12/2016	1	Extinguished Non-Forfeiture	6/29/2021 2/9/2021			7/23/2027
Buprenorphine Hydrochloride and Naloxone Hydrochloride	Sublingual Film	2 mg/0.5 mg* and 8 mg/2 mg	Suboxone 22410	10/15/2012	1	Extinguished	2/25/2020			2/13/2023