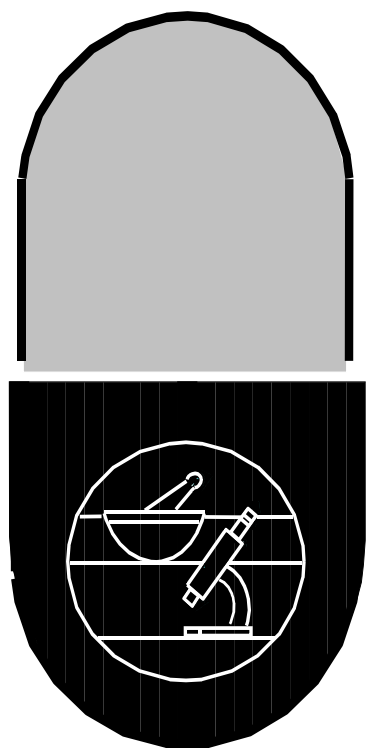




APPROVED DRUG PRODUCTS

WITH

**THERAPEUTIC
EQUIVALENCE
EVALUATIONS**

39th EDITION

**THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER
SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS
OFFICE OF GENERIC DRUG POLICY

2019

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>SAXAGLIPTIN HYDROCHLORIDE - ONGLYZA</u>						
N 022350 001	7951400	Nov 30, 2028	DP		M-175	Apr 05, 2019
	RE44186	Jul 31, 2023	DS DP U-1837		M-198	Feb 27, 2020
	RE44186	Jul 31, 2023	DS DP U-995			
<u>SAXAGLIPTIN HYDROCHLORIDE - ONGLYZA</u>						
N 022350 002	7951400	Nov 30, 2028	DP		M-175	Apr 05, 2019
	RE44186	Jul 31, 2023	DS DP U-1837		M-198	Feb 27, 2020
	RE44186	Jul 31, 2023	DS DP U-995			
<u>SECNIDAZOLE - SOLOSEC</u>						
N 209363 001					NCE GAIN	Sep 15, 2022 Sep 15, 2027
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 001	7205302	Apr 04, 2023	DS DP U-1797		NCE	Dec 21, 2020
	8791122	Aug 01, 2030	DS DP		ODE-106	Dec 21, 2022
	9173881	Aug 12, 2029	U-1798			
	9284280	Jun 25, 2030	U-1831			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 002	7205302	Apr 04, 2023	DS DP U-1797		NCE	Dec 21, 2020
	8791122	Aug 01, 2030	DS DP		ODE-106	Dec 21, 2022
	9173881	Aug 12, 2029	U-1798			
	9284280	Jun 25, 2030	U-1831			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 003	7205302	Apr 04, 2023	DS DP U-1797		NCE	Dec 21, 2020
	8791122	Aug 01, 2030	DS DP		ODE-106	Dec 21, 2022
	9173881	Aug 12, 2029	U-1798			
	9284280	Jun 25, 2030	U-1831			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 004	7205302	Apr 04, 2023	DS DP U-1797		NCE	Dec 21, 2020
	8791122	Aug 01, 2030	DS DP		ODE-106	Dec 21, 2022
	9173881	Aug 12, 2029	U-1798			
	9284280	Jun 25, 2030	U-1831			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 005	7205302	Apr 04, 2023	DS DP U-1797		NCE	Dec 21, 2020
	8791122	Aug 01, 2030	DS DP		ODE-106	Dec 21, 2022
	9173881	Aug 12, 2029	U-1798			
	9284280	Jun 25, 2030	U-1831			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 006	7205302	Apr 04, 2023	DS DP U-1797		NCE	Dec 21, 2020
	8791122	Aug 01, 2030	DS DP		ODE-106	Dec 21, 2022
	9173881	Aug 12, 2029	U-1798			
	9284280	Jun 25, 2030	U-1831			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 007	7205302	Apr 04, 2023	DS DP U-1797		NCE	Dec 21, 2020
	8791122	Aug 01, 2030	DS DP		ODE-106	Dec 21, 2022
	9173881	Aug 12, 2029	U-1798			
	9284280	Jun 25, 2030	U-1831			
<u>SELEXIPAG - UPTRAVI</u>						
N 207947 008	7205302	Apr 04, 2023	DS DP U-1797		NCE	Dec 21, 2020
	8791122	Aug 01, 2030	DS DP		ODE-106	Dec 21, 2022
	9173881	Aug 12, 2029	U-1798			
	9284280	Jun 25, 2030	U-1831			
<u>SEMAGLUTIDE - OZEMPIC</u>						
N 209637 001	6899699	Jan 02, 2022	DP		NCE	Dec 05, 2022
	7762994	May 23, 2024	DP			
	8114833	Aug 13, 2025	DP			
	8129343	Jan 29, 2029	DS DP U-2202			
	8536122	Mar 20, 2026	DS DP U-2202			
	8579869	Jun 30, 2023	DP			
	8672898	Jan 02, 2022	DP			

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

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APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE (S)	EXCLUSIVITY EXPIRATION DATE
<u>SEMAGLUTIDE - OZEMPIC</u>						
N 209637	001 8684969	Oct 20, 2025	DP			
	8920383	Jul 17, 2026	DP			
	9108002	Jan 20, 2026	DP			
	9132239	Feb 01, 2032	DP			
	9457154	Sep 27, 2027	DP			
	9486588	Jan 02, 2022	DP			
	9616180	Jan 20, 2026	DP			
	9687611	Feb 27, 2027	DP			
	9775953	Jul 17, 2026	DP			
	9861757	Jan 20, 2026	DP			
	RE46363	Aug 03, 2026	DP			
<u>SERTRALINE HYDROCHLORIDE - ZOLOFT</u>						
N 020990	001 6727283	Oct 11, 2019	DP U-580			
	7067555	Oct 11, 2019	DP			
	7067555*PED	Apr 11, 2020				
<u>SEVELAMER CARBONATE - RENVELA</u>						
N 022127	001 7985418	Oct 27, 2025	DP		NPP	Nov 25, 2019
<u>SEVELAMER CARBONATE - RENVELA</u>						
N 022318	001 9095509	Dec 06, 2030	DP		NPP	Nov 25, 2019
<u>SEVELAMER CARBONATE - RENVELA</u>						
N 022318	002 9095509	Dec 06, 2030	DP		NPP	Nov 25, 2019
<u>SEVELAMER HYDROCHLORIDE - RENAGEL</u>						
N 021179	001 6733780	Oct 18, 2020	DP			
<u>SEVELAMER HYDROCHLORIDE - RENAGEL</u>						
N 021179	002 6733780	Oct 18, 2020	DP			
<u>SILDENAFIL CITRATE - VIAGRA</u>						
N 020895	001 6469012	Oct 22, 2019	U-155			
<u>SILDENAFIL CITRATE - VIAGRA</u>						
N 020895	002 6469012	Oct 22, 2019	U-155			
<u>SILDENAFIL CITRATE - VIAGRA</u>						
N 020895	003 6469012	Oct 22, 2019	U-155			
<u>SIMEPREVIR SODIUM - OLYSIO</u>						
N 205123	001 7671032	May 19, 2025	DS DP		M-171	Feb 26, 2019
	8148399	Sep 05, 2029	DS DP U-1467		M-179	May 20, 2019
	8349869	Jul 28, 2026	DS DP U-1467			
	8741926	Jul 28, 2026	DS U-1467			
	8754106	Jul 28, 2026	DS U-1467			
	9040562	Jul 28, 2026	DS DP U-1467			
	9353103	Jul 28, 2026	U-1467			
	9623022	Jul 28, 2026	U-1467			
	9856265	Jul 28, 2026	DS DP U-1467			
<u>SIMVASTATIN - FLOLIPID</u>						
N 206679	001 9597289	Feb 23, 2030	DP			
<u>SIMVASTATIN - FLOLIPID</u>						
N 206679	002 9597289	Feb 23, 2030	DP			
<u>SIMVASTATIN; SITAGLIPTIN PHOSPHATE - JUVISYNC</u>						
N 202343	001 6699871	Jul 26, 2022	DS DP U-1188			
	6890898	Feb 02, 2019	U-1189			
	6890898	Feb 02, 2019	U-1190			
	6890898	Feb 02, 2019	U-1191			
	7078381	Feb 02, 2019	U-1188			
	7125873	Jul 26, 2022	DP U-1189			
	7125873	Jul 26, 2022	DP U-1190			
	7125873	Jul 26, 2022	DP U-1192			
	7125873	Jul 26, 2022	DP U-1193			
	7326708	Apr 11, 2026	DS DP U-1188			
	7459428	Feb 02, 2019	U-1189			