



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

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		
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		9284280	Jun 25, 2030	U-1831		
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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		
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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		

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<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		