



# APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC  
EQUIVALENCE  
EVALUATIONS

40<sup>th</sup> 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

2020

**PRESCRIPTION AND OTC DRUG 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>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>SELINEXOR - XPOVIO</u>						
N 212306 001	8999996	Sep 15, 2032	DS DP		NCE	Jul 03, 2024
	9079865	Jul 26, 2032		U-2584	ODE-257	Jul 03, 2026
	9714226	Jul 26, 2032	DS DP			
<u>SEMAGLUTIDE - OZEMPIC</u>						
N 209637 001	10220155	Jul 17, 2026	DP		NCE	Dec 05, 2022
	10335462	Jun 21, 2033		U-2580		
	10357616	Jan 20, 2026	DP			
	10376652	Jan 20, 2026	DP			
	6899699	Jan 02, 2022	DP			
	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			
	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>SEMAGLUTIDE - RYBELSUS</u>						
N 213051 001	10086047	Dec 16, 2031	DP		NCE	Dec 05, 2022
	10278923	May 02, 2034		U-2628	NP	Sep 20, 2022
	8129343	Jan 29, 2029	DS DP	U-2628		
	8536122	Mar 20, 2026	DS DP	U-2628		
	9278123	Dec 16, 2031	DP	U-2628		
<u>SEMAGLUTIDE - RYBELSUS</u>						
N 213051 002	10086047	Dec 16, 2031	DP		NCE	Dec 05, 2022
	10278923	May 02, 2034		U-2628	NP	Sep 20, 2022
	8129343	Jan 29, 2029	DS DP	U-2628		
	8536122	Mar 20, 2026	DS DP	U-2628		
	9278123	Dec 16, 2031	DP	U-2628		
<u>SEMAGLUTIDE - RYBELSUS</u>						
N 213051 003	10086047	Dec 16, 2031	DP		NCE	Dec 05, 2022
	10278923	May 02, 2034		U-2628	NP	Sep 20, 2022
	8129343	Jan 29, 2029	DS DP	U-2628		
	8536122	Mar 20, 2026	DS DP	U-2628		
	9278123	Dec 16, 2031	DP	U-2628		
<u>SERTRALINE HYDROCHLORIDE - ZOLOFT</u>						
N 020990 001	7067555*PED	Apr 11, 2020				
<u>SEVELAMER CARBONATE - RENVELA</u>						
N 022127 001	7985418	Oct 27, 2025	DP			
<u>SEVELAMER CARBONATE - RENVELA</u>						
N 022318 001	9095509	Dec 06, 2030	DP			
<u>SEVELAMER CARBONATE - RENVELA</u>						
N 022318 002	9095509	Dec 06, 2030	DP			