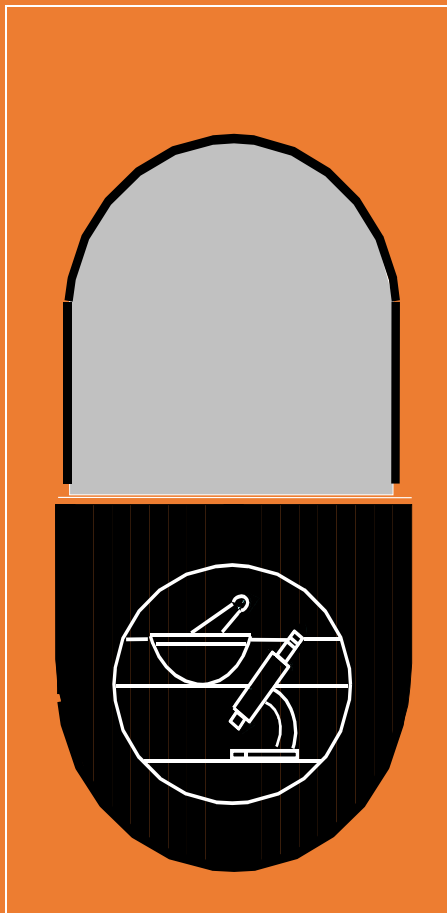




APPROVED DRUG PRODUCTS

WITH

**THERAPEUTIC
EQUIVALENCE
EVALUATIONS**

42nd 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**

2022

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>SELINEXOR - XPOVIO</u>						
N 212306 004	11034660	Jul 26, 2032	U-3018			
	8999996	Sep 15, 2032	DS DP			
	9079865	Jul 26, 2032	U-2584			
	9079865	Jul 26, 2032	U-2855			
	9079865	Jul 26, 2032	U-3018			
	9714226	Jul 26, 2032	DS DP			
<u>SELPERCATINIB - RETEVMO</u>						
N 213246 001	10112942	Oct 10, 2037	DS DP		NCE	May 08, 2025
	10137124	Oct 10, 2037	U-2826		ODE-301	May 08, 2027
	10137124	Oct 10, 2037	U-2827		ODE-302	May 08, 2027
	10137124	Oct 10, 2037	U-2828		ODE-303	May 08, 2027
	10172851	Oct 10, 2037	U-2826			
	10172851	Oct 10, 2037	U-2827			
	10172851	Oct 10, 2037	U-2828			
	10584124	Oct 10, 2038	DS U-2826			
	10584124	Oct 10, 2038	DS U-2827			
	10584124	Oct 10, 2038	DS U-2828			
	10786489	Oct 10, 2038	DP U-2971			
	10786489	Oct 10, 2038	DP U-2972			
	10786489	Oct 10, 2038	DP U-2973			
	10786489	Oct 10, 2038	DP U-2974			
	10786489	Oct 10, 2038	DP U-2975			
	10786489	Oct 10, 2038	DP U-2976			
	10786489	Oct 10, 2038	DP U-2977			
<u>SELPERCATINIB - RETEVMO</u>						
N 213246 002	10112942	Oct 10, 2037	DS DP		NCE	May 08, 2025
	10137124	Oct 10, 2037	U-2826		ODE-301	May 08, 2027
	10137124	Oct 10, 2037	U-2827		ODE-302	May 08, 2027
	10137124	Oct 10, 2037	U-2828		ODE-303	May 08, 2027
	10172851	Oct 10, 2037	U-2826			
	10172851	Oct 10, 2037	U-2827			
	10172851	Oct 10, 2037	U-2828			
	10584124	Oct 10, 2038	DS U-2826			
	10584124	Oct 10, 2038	DS U-2827			
	10584124	Oct 10, 2038	DS U-2828			
	10786489	Oct 10, 2038	DP U-2971			
	10786489	Oct 10, 2038	DP U-2972			
	10786489	Oct 10, 2038	DP U-2973			
	10786489	Oct 10, 2038	DP U-2974			
	10786489	Oct 10, 2038	DP U-2975			
	10786489	Oct 10, 2038	DP U-2976			
	10786489	Oct 10, 2038	DP U-2977			
<u>SELMETINIB SULFATE - KOSELUGO</u>						
N 213756 001	7425637	Apr 11, 2024	DS		NCE	Apr 10, 2025
	8178693	Mar 13, 2023	DS DP		ODE-288	Apr 10, 2027
	9156795	Dec 12, 2026	DS DP			
	9562017	Dec 12, 2026	DS U-2800			
<u>SELMETINIB SULFATE - KOSELUGO</u>						
N 213756 002	7425637	Apr 11, 2024	DS		NCE	Apr 10, 2025
	8178693	Mar 13, 2023	DS DP		ODE-288	Apr 10, 2027
	9156795	Dec 12, 2026	DS DP			
	9562017	Dec 12, 2026	DS U-2800			
<u>SEMAGLUTIDE - OZEMPIC</u>						
N 209637 001	10220155	Jul 17, 2026	DP		I-822	Jan 16, 2023
	10335462	Jun 21, 2033	U-2580		NCE	Dec 05, 2022
	10357616	Jan 20, 2026	DP			
	10376652	Jan 20, 2026	DP			
	11097063	Jul 17, 2026	DP			
	6899699	Jan 02, 2022	DP			
	7762994	May 23, 2024	DP			
	8114833	Aug 13, 2025	DP			
	8129343	Dec 05, 2031	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

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>SEMAGLUTIDE - OZEMPIC</u>						
N 209637 002	10220155	Jul 17, 2026	DP		I-822	Jan 16, 2023
	10335462	Jun 21, 2033	U-2580		NCE	Dec 05, 2022
	10357616	Jan 20, 2026	DP			
	10376652	Jan 20, 2026	DP			
	11097063	Jul 17, 2026	DP			
	6899699	Jan 02, 2022	DP			
	7762994	May 23, 2024	DP			
	8114833	Aug 13, 2025	DP			
	8129343	Dec 05, 2031	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 29, 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		M-252	Jan 16, 2023
	10278923	May 02, 2034	U-2628		NCE	Dec 05, 2022
	10933120	Mar 15, 2033	DP		NP	Sep 20, 2022
	10960052	Dec 16, 2031	DP			
	8129343	Dec 05, 2031	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		M-252	Jan 16, 2023
	10278923	May 02, 2034	U-2628		NCE	Dec 05, 2022
	10933120	Mar 15, 2033	DP		NP	Sep 20, 2022
	10960052	Dec 16, 2031	DP			
	8129343	Dec 05, 2031	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		M-252	Jan 16, 2023
	10278923	May 02, 2034	U-2628		NCE	Dec 05, 2022
	10933120	Mar 15, 2033	DP		NP	Sep 20, 2022
	10960052	Dec 16, 2031	DP			
	8129343	Dec 05, 2031	DS DP U-2628			
	8536122	Mar 20, 2026	DS DP U-2628			
	9278123	Dec 16, 2031	DP U-2628			
<u>SEMAGLUTIDE - WEGOVY</u>						
N 215256 001	10888605	Aug 24, 2038	DP U-3162		NCE	Dec 05, 2022
	8129343	Dec 05, 2031	DS DP		NP	Jun 04, 2024
	8536122	Mar 20, 2026	DS DP			
	9764003	Jun 21, 2033	U-3161			