



APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC
EQUIVALENCE
EVALUATIONS

44th 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

2024

APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2023.

44th EDITION



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2024

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>SELPERCATINIB - RETEVMO</u>						
N 213246 002	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			
	10584124	Oct 10, 2038	DS U-3450			
	10584124	Oct 10, 2038	DS U-3451			
	10584124	Oct 10, 2038	DS U-3452			
	10584124	Oct 10, 2038	DS U-3453			
	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			
	10786489	Oct 10, 2038	DP U-3450			
	10786489	Oct 10, 2038	DP U-3451			
	10786489	Oct 10, 2038	DP U-3452			
	10786489	Oct 10, 2038	DP U-3453			
<u>SELUMETINIB SULFATE - KOSELUGO</u>						
N 213756 001	11813246	Mar 26, 2029	DP		NCE	Apr 10, 2025
	7425637	Mar 13, 2024	DS		ODE-288	Apr 10, 2027
	9156795	Dec 12, 2026	DS DP			
	9562017	Dec 12, 2026	DS U-2800			
<u>SELUMETINIB SULFATE - KOSELUGO</u>						
N 213756 002	11813246	Mar 26, 2029	DP		NCE	Apr 10, 2025
	7425637	Mar 13, 2024	DS		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			
	10335462	Jun 21, 2033	U-2580			
	10357616	Jan 20, 2026	DP			
	10376652	Jan 20, 2026	DP			
	11097063	Jul 17, 2026	DP			
	11311679	Jan 20, 2026	DP			
	11446443	Oct 20, 2025	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			
	8684969	Oct 20, 2025	DP			
	8920383	Jul 17, 2026	DP			
	9108002	Jan 20, 2026	DP			

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<u>SEMAGLUTIDE - OZEMPIC</u>						
N 209637 001	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			
	10335462	Jun 21, 2033	U-2580			
	10357616	Jan 20, 2026	DP			
	10376652	Jan 20, 2026	DP			
	11097063	Jul 17, 2026	DP			
	11311679	Jan 20, 2026	DP			
	11446443	Oct 20, 2025	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		
	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			
	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 003	10220155	Jul 17, 2026	DP		D-185	Mar 28, 2025
	10357616	Jan 20, 2026	DP			
	10376652	Jan 20, 2026	DP			
	11097063	Jul 17, 2026	DP			
	11311679	Jan 20, 2026	DP			
	11446443	Oct 20, 2025	DP			
	7762994	May 23, 2024	DP			
	8114833	Aug 13, 2025	DP			
	8129343	Dec 05, 2031	DS DP	U-3355		
	8536122	Mar 20, 2026	DS DP	U-3355		
	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			
	9616180	Jan 20, 2026	DP			
	9687611	Feb 27, 2027	DP			
	9775953	Jul 17, 2026	DP			
	9861757	Jan 20, 2026	DP			

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<u>SEMAGLUTIDE - OZEMPIC</u>						
N 209637 004	10220155	Jul 17, 2026	DP			
	10335462	Jun 21, 2033	DP U-2580			
	10357616	Jan 20, 2026	DP			
	10376652	Jan 20, 2026	DP			
	11097063	Jul 17, 2026	DP			
	11311679	Jan 20, 2026	DP			
	11446443	Oct 20, 2025	DP			
	7762994	May 23, 2024	DP			
	8114833	Aug 13, 2025	DP			
	8129343	Dec 05, 2031	DS DP U-3469			
	8536122	Mar 20, 2026	DS DP U-3469			
	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			
	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			
	10278923	May 02, 2034	U-2628			
	10933120	Mar 15, 2033	DP			
	10960052	Dec 16, 2031	DP			
	11382957	Dec 16, 2031	DP			
	11759501	Mar 15, 2033	DP			
	11759502	Mar 15, 2033	DP			
	11759503	Mar 15, 2033	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			
	10278923	May 02, 2034	U-2628			
	10933120	Mar 15, 2033	DP			
	10960052	Dec 16, 2031	DP			
	11382957	Dec 16, 2031	DP			
	11759501	Mar 15, 2033	DP			
	11759502	Mar 15, 2033	DP			
	11759503	Mar 15, 2033	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>						