



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.

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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 - RYBELSUS</u>						
N 213051 003	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 - WEGOVY</u>						
N 215256 001	10888605	Aug 24, 2038	DP U-3162		NP	Jun 04, 2024
	11318191	Feb 17, 2041	DP U-3162		NPP	Dec 23, 2025
	11752198	Aug 24, 2038	DP U-3162			
	8129343	Dec 05, 2031	DS DP			
	8536122	Mar 20, 2026	DS DP			
	9764003	Jun 21, 2033	U-3161			
<u>SEMAGLUTIDE - WEGOVY</u>						
N 215256 002	10888605	Aug 24, 2038	DP U-3162		NP	Jun 04, 2024
	11318191	Feb 17, 2041	DP U-3162		NPP	Dec 23, 2025
	11752198	Aug 24, 2038	DP U-3162			
	8129343	Dec 05, 2031	DS DP			
	8536122	Mar 20, 2026	DS DP			
	9764003	Jun 21, 2033	U-3161			
<u>SEMAGLUTIDE - WEGOVY</u>						
N 215256 003	10888605	Aug 24, 2038	DP U-3162		NP	Jun 04, 2024
	11318191	Feb 17, 2041	DP U-3162		NPP	Dec 23, 2025
	11752198	Aug 24, 2038	DP U-3162			
	8129343	Dec 05, 2031	DS DP			
	8536122	Mar 20, 2026	DS DP			
	9764003	Jun 21, 2033	U-3161			
<u>SEMAGLUTIDE - WEGOVY</u>						
N 215256 004	10888605	Aug 24, 2038	DP U-3162		D-190	Jul 21, 2026
	11318191	Feb 17, 2041	DP U-3162		NP	Jun 04, 2024
	11752198	Aug 24, 2038	DP U-3162		NPP	Dec 23, 2025
	8129343	Dec 05, 2031	DS DP			
	8536122	Mar 20, 2026	DS DP			
	9764003	Jun 21, 2033	U-3161			
<u>SEMAGLUTIDE - WEGOVY</u>						
N 215256 005	10888605	Aug 24, 2038	DP U-3162		NP	Jun 04, 2024
	11318191	Feb 17, 2041	DP U-3162		NPP	Dec 23, 2025
	11752198	Aug 24, 2038	DP U-3162			
	8129343	Dec 05, 2031	DS DP			
	8536122	Mar 20, 2026	DS DP			
	9764003	Jun 21, 2033	U-3161			
<u>SETMELANOTIDE ACETATE - IMCIVREE</u>						