



APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC
EQUIVALENCE
EVALUATIONS

40th 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

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, 2019.

40th EDITION



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PRESCRIPTION AND OTC DRUG PRODUCT 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>LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO XR</u>						
N 208026 001	8883805	Nov 26, 2025	DP			
	9155705	May 21, 2030	DP			
	9173859	May 04, 2027	DP U-1503			
	9415016	Apr 02, 2029	DP			
	9555001	Mar 06, 2033	DP U-1967			
	9555001	Mar 06, 2033	DP U-1968			
<u>LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO XR</u>						
N 208026 002	10022379	Apr 02, 2029			U-2339	
	6488962	Jun 20, 2020	DP			
	7407955	May 02, 2025	DS DP			
	8119648	Aug 12, 2023			U-802	
	8178541	Aug 12, 2023	DP U-1853			
	8673927	May 04, 2027			U-1503	
	8883805	Nov 26, 2025	DP			
	9155705	May 21, 2030	DP			
	9173859	May 04, 2027	DP U-1503			
	9415016	Apr 02, 2029	DP			
	9555001	Mar 06, 2033	DP U-1967			
	9555001	Mar 06, 2033	DP U-1968			
<u>LINEZOLID - ZYVOX</u>						
N 021130 001	6514529	Mar 15, 2021	DP			
	6559305	Jan 29, 2021	DS			
<u>LINEZOLID - ZYVOX</u>						
N 021130 002	6514529	Mar 15, 2021	DP			
	6559305	Jan 29, 2021	DS			
<u>LINEZOLID - ZYVOX</u>						
N 021131 001	6559305	Jan 29, 2021	DS			
<u>LINEZOLID - ZYVOX</u>						
N 021131 002	6559305	Jan 29, 2021	DS			
	6559305*PED	Jul 29, 2021				
<u>LINEZOLID - ZYVOX</u>						
N 021131 003	6559305	Jan 29, 2021	DS			
	6559305*PED	Jul 29, 2021				
<u>LINEZOLID - ZYVOX</u>						
N 021132 001	6559305	Jan 29, 2021	DS			
<u>LIRAGLUTIDE RECOMBINANT - VICTOZA</u>						
N 022341 001	6268343	Aug 22, 2022	DS DP U-968		I-750	Aug 25, 2020
	6268343*PED	Feb 22, 2023			NPP	Jun 17, 2022
	7762994	May 23, 2024	DP		PED	Dec 17, 2022
	7762994*PED	Nov 23, 2024				
	8114833	Aug 13, 2025	DS DP			
	8114833*PED	Feb 13, 2026				
	8579869	Jun 30, 2023	DP			
	8579869*PED	Dec 30, 2023				
	8846618	Jun 27, 2022	DP			
	8846618*PED	Dec 27, 2022				
	9265893	Sep 23, 2032	DP			
	9265893*PED	Mar 23, 2033				
	9968659	Jan 09, 2037			U-2313	
	9968659*PED	Jul 09, 2037				
	RE41956	Jan 21, 2021	DP			
	RE41956*PED	Jul 21, 2021				
<u>LIRAGLUTIDE RECOMBINANT - SAXENDA</u>						
N 206321 001	10220155	Jul 17, 2026	DP			
	10220155*PED	Jan 17, 2027				
	10357616	Jan 20, 2026	DP			
	10376652	Jan 20, 2026	DP			