



APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC
EQUIVALENCE
EVALUATIONS

38th 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

2018

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	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>LINAGLIPTIN; METFORMIN HYDROCHLORIDE - JENTADUETO XR</u>						
N 208026 002	6488962	Jun 20, 2020	DP			
	6890898	Feb 02, 2019	U-803			
	7078381	Feb 02, 2019	U-803			
	7407955	May 02, 2025	DS DP			
	7459428	Feb 02, 2019	U-803			
	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	6004297	Jan 28, 2019	DP		I-750	Aug 25, 2020
	6268343	Aug 22, 2022	DS DP U-968		M-176	Apr 22, 2019
	6458924	Aug 22, 2017	DS DP U-968			
	7235627	Aug 22, 2017	DS DP			
	8114833	Aug 13, 2025	DP			
	8846618	Jun 27, 2022	DP			
	9265893	Sep 23, 2032	DP			
	RE41956	Jan 21, 2021	DP			
	RE43834	Jan 28, 2019	DP			
<u>LIRAGLUTIDE RECOMBINANT - SAXENDA</u>						
N 206321 001	6268343	Aug 22, 2022	DS DP U-1255			
	6458924	Aug 22, 2017	DS DP U-1255			
	6899699	Jan 01, 2022	DP			
	7235627	Aug 22, 2017	DS DP			
	8114833	Aug 13, 2025	DP			
	8672898	Jan 02, 2022	DP			
	8684969	Oct 20, 2025	DP			
	8846618	Jun 27, 2022	DP			

See report footnote for information regarding report content

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<u>LIRAGLUTIDE RECOMBINANT - SAXENDA</u>						
N 206321 001	9108002	Jan 26, 2026	DP			
	9132239	Feb 01, 2032	DP			
	9457154	Sep 27, 2027	DP			
	9486588	Jan 02, 2022	DP			
	9687611	Feb 27, 2027	DP			
	9775953	Jul 17, 2026	DP			
	RE46363	Aug 03, 2026	DP			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N 021977 001	7105486	Feb 24, 2023		U-727	I-703	Jan 30, 2018
	7223735	Feb 24, 2023	DP		M-188	Oct 14, 2019
	7655630	Feb 24, 2023	DS			
	7659253	Feb 24, 2023	DS DP	U-727		
	7659254	Feb 24, 2023		U-1034		
	7662787	Feb 24, 2023	DS			
	7662788	Feb 24, 2023		U-727		
	7671030	Feb 24, 2023	DP	U-727		
	7671031	Feb 24, 2023		U-727		
	7674774	Feb 24, 2023	DP	U-842		
	7678770	Feb 24, 2023		U-842		
	7678771	Feb 24, 2023	DP	U-842		
	7687466	Feb 24, 2023	DP			
	7687467	Feb 24, 2023	DP	U-842		
	7700561	Feb 24, 2023	DP			
	7713936	Feb 24, 2023		U-727		
	7718619	Feb 24, 2023	DP	U-842		
	7723305	Feb 24, 2023	DP	U-842		
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N 021977 002	7105486	Feb 24, 2023		U-727	I-703	Jan 30, 2018
	7223735	Feb 24, 2023	DP		M-188	Oct 14, 2019
	7655630	Feb 24, 2023	DS			
	7659253	Feb 24, 2023	DS DP	U-727		
	7659254	Feb 24, 2023		U-1034		
	7662787	Feb 24, 2023	DS			
	7662788	Feb 24, 2023		U-727		
	7671030	Feb 24, 2023	DP	U-727		
	7671031	Feb 24, 2023		U-727		
	7674774	Feb 24, 2023	DP	U-842		
	7678770	Feb 24, 2023		U-842		
	7678771	Feb 24, 2023	DP	U-842		
	7687466	Feb 24, 2023	DP			
	7687467	Feb 24, 2023	DP	U-842		
	7700561	Feb 24, 2023	DP			
	7713936	Feb 24, 2023		U-727		
	7718619	Feb 24, 2023	DP	U-842		
	7723305	Feb 24, 2023	DP	U-842		
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N 021977 003	7105486	Feb 24, 2023		U-727	I-703	Jan 30, 2018
	7223735	Feb 24, 2023	DP		M-188	Oct 14, 2019
	7655630	Feb 24, 2023	DS			
	7659253	Feb 24, 2023	DS DP	U-727		
	7659254	Feb 24, 2023		U-1034		
	7662787	Feb 24, 2023	DS			
	7662788	Feb 24, 2023		U-727		
	7671030	Feb 24, 2023	DP	U-727		
	7671031	Feb 24, 2023		U-727		
	7674774	Feb 24, 2023	DP	U-842		
	7678770	Feb 24, 2023		U-842		
	7678771	Feb 24, 2023	DP	U-842		
	7687466	Feb 24, 2023	DP			
	7687467	Feb 24, 2023	DP	U-842		
	7700561	Feb 24, 2023	DP			
	7713936	Feb 24, 2023		U-727		
	7718619	Feb 24, 2023	DP	U-842		

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 001	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>SELEXIPAG - UPTRAVI</u>						
N 207947 002	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>SELEXIPAG - UPTRAVI</u>						
N 207947 003	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>SELEXIPAG - UPTRAVI</u>						
N 207947 004	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>SELEXIPAG - UPTRAVI</u>						
N 207947 005	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>SELEXIPAG - UPTRAVI</u>						
N 207947 006	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>SELEXIPAG - UPTRAVI</u>						
N 207947 007	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>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>SEMAGLUTIDE - OZEMPIC</u>						
N 209637 001	6899699	Jan 02, 2022	DP		NCE	Dec 05, 2022
	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			
	9687611	Feb 27, 2027	DP			
	9775953	Jul 17, 2026	DP			
	RE46363	Aug 03, 2026	DP			
<u>SERTRALINE HYDROCHLORIDE - ZOLOFT</u>						
N 020990 001	6727283	Oct 11, 2019	DP U-580			
	7067555	Oct 11, 2019	DP			