



APPROVED DRUG PRODUCTS

WITH

**THERAPEUTIC
EQUIVALENCE
EVALUATIONS**

31st 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
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF PHARMACEUTICAL SCIENCE
OFFICE OF GENERIC DRUGS

2011

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>LINEZOLID - ZYVOX</u>						
N021130 002	5688792	Nov 18, 2014	DS U-319			
	5688792*PED	May 18, 2015				
	6514529	Mar 15, 2021	DP			
	6514529*PED	Sep 15, 2021				
	6559305	Jan 29, 2021	DS			
	6559305*PED	Jul 29, 2021				
<u>LINEZOLID - ZYVOX</u>						
N021131 001	5688792	Nov 18, 2014	U-319			
	5688792*PED	May 18, 2015				
	6559305	Jan 29, 2021	DS			
	6559305*PED	Jul 29, 2021				
<u>LINEZOLID - ZYVOX</u>						
N021132 001	5688792	Nov 18, 2014	DS U-319			
	5688792*PED	May 18, 2015				
	6559305	Jan 29, 2021	DS			
	6559305*PED	Jul 29, 2021				
<u>LIRAGLUTIDE RECOMBINANT - VICTOZA</u>						
N022341 001	6268343	Aug 22, 2017	DS DP U-968		NCE	Jan 25, 2015
	6458924	Aug 22, 2017	DS DP U-968			
	7235627	Aug 22, 2017	DS DP			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 001	7105486	Jun 29, 2023	U-727		M-82	Apr 05, 2013
	7223735	Jun 29, 2023	DP		NPP	Nov 10, 2013
	7655630	Feb 24, 2023	DS		NPP	Apr 23, 2011
	7659253	Feb 24, 2023	DS DP U-727		NCE	Feb 23, 2012
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	7671030	Feb 24, 2023	DP U-727			
	7671031	Feb 28, 2023	U-727			
	7674774	Mar 18, 2023	DP U-842			
	7678770	Mar 25, 2023	U-842			
	7678771	Mar 25, 2023	DP U-842			
	7687466	Feb 24, 2023	DP			
	7687467	Apr 08, 2023	DP U-842			
	7700561	Jun 29, 2023	DP			
	7718619	Feb 24, 2023	DP U-842			
	7723305	Feb 24, 2023	DP U-842			
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 002	7105486	Jun 29, 2023	U-727		M-82	Apr 05, 2013
	7223735	Jun 29, 2023	DP		NPP	Nov 10, 2013
	7655630	Feb 24, 2023	DS		NPP	Apr 23, 2011
	7659253	Feb 24, 2023	DS DP U-727		NCE	Feb 23, 2012
	7659254	Feb 24, 2023	U-1034			
	7662787	Feb 24, 2023	DS			
	7671030	Feb 24, 2023	DP U-727			
	7671031	Feb 28, 2023	U-727			
	7674774	Mar 18, 2023	DP U-842			
	7678770	Mar 25, 2023	U-842			
	7678771	Mar 25, 2023	DP U-842			
	7687466	Feb 24, 2023	DP			
	7687467	Apr 08, 2023	DP U-842			
	7700561	Jun 29, 2023	DP			
	7718619	Feb 24, 2023	DP U-842			
	7723305	Feb 24, 2023	DP U-842			