



APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC
EQUIVALENCE
EVALUATIONS

33rd 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

2013

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, 2012.

33rd EDITION



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**FOOD AND DRUG ADMINISTRATION
 CENTER FOR DRUG EVALUATION AND RESEARCH
 APPROVED DRUG PRODUCTS
 with
 Therapeutic Equivalence Evaluations**

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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>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	6004297	Jan 28, 2019		DP	M-115	Apr 06, 2015
	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			
	8114833	Aug 13, 2025		DP		
	RE41956	Jan 21, 2021		DP		
	RE43834	Jan 28, 2019		DP		
<u>LISDEXAMFETAMINE DIMESYLATE - VYVANSE</u>						
N021977 001	7105486	Jun 29, 2023		U-727	I-645	Jan 31, 2015
	7223735	Jun 29, 2023		DP		
	7655630	Feb 24, 2023	DS		M-82	Apr 05, 2013
	7659253	Feb 24, 2023	DS DP	U-727	NPP	Nov 10, 2013
	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 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		
	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>						
N021977 002	7105486	Jun 29, 2023		U-727	I-645	Jan 31, 2015
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	7662788	Feb 24, 2023		U-727		
	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		
	7713936	Feb 24, 2023		U-727		
	7718619	Feb 24, 2023		DP U-842		
	7723305	Feb 24, 2023		DP U-842		