

# APPROVED DRUG PRODUCTS

WITH

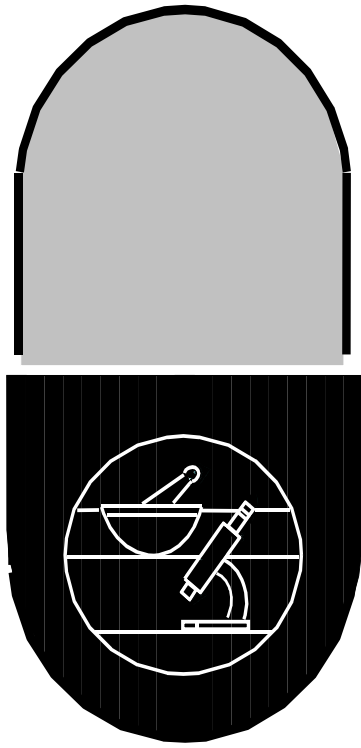
**THERAPEUTIC  
EQUIVALENCE  
EVALUATIONS**

**39<sup>th</sup> 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

**2019**



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**2019**

# 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, 2018.

## 39<sup>th</sup> EDITION



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
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2019

**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>INSULIN DETEMIR RECOMBINANT - LEVEMIR FLEXTOUCH</u>						
N 021536 005	9616180	Jan 20, 2026	DP			
	9687611	Feb 27, 2027	DP			
	9775953	Jul 17, 2026	DP			
	9861757	Jan 20, 2026	DP			
	RE46363	Aug 03, 2026	DP			
<u>INSULIN GLARGINE RECOMBINANT - LANTUS</u>						
N 021081 001	7476652	Jul 23, 2023	DP			
	7713930	Jun 13, 2023	DP			
	7918833	Sep 23, 2027	DP			
<u>INSULIN GLARGINE RECOMBINANT - LANTUS SOLOSTAR</u>						
N 021081 002	8512297	Sep 15, 2024	DP			
	8556864	Mar 03, 2024	DP			
	8603044	Mar 02, 2024	DP			
	8679069	Apr 12, 2025	DP			
	8992486	Jun 05, 2024	DP			
	9011391	Mar 26, 2024	DP	U-1832		
	9233211	Mar 02, 2024	DP			
	9408979	Mar 02, 2024	DP			
	9526844	Mar 02, 2024	DP			
	9533105	Aug 17, 2024	DP			
	9561331	Aug 28, 2024	DP			
	9604008	Mar 02, 2024	DP			
	9604009	Aug 16, 2024	DP			
	9610409	Mar 02, 2024	DP			
	9623189	Aug 19, 2024	DP			
	9717852	Apr 08, 2033	DP			
	9775954	Mar 02, 2024	DP			
	9827379	Mar 02, 2024	DP	U-2146		
<u>INSULIN GLARGINE RECOMBINANT - TOUJEO SOLOSTAR</u>						
N 206538 001	7918833	Sep 23, 2027	DP			
	7918833*PED	Mar 23, 2028				
	8512297	Sep 15, 2024	DP			
	8556864	Mar 03, 2024	DP			
	8603044	Mar 02, 2024	DP			
	8679069	Apr 12, 2025	DP			
	8992486	Jun 05, 2024	DP			
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	9345750	May 18, 2031	DP	U-1855		
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	9561331	Aug 28, 2024	DP			
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	9623189	Aug 19, 2024	DP			
	9775954	Mar 02, 2024	DP			
	9827379	Mar 02, 2024	DP	U-2146		
<u>INSULIN GLARGINE RECOMBINANT - TOUJEO MAX SOLOSTAR</u>						
N 206538 002	7918833	Sep 23, 2027	DP			
	8512297	Sep 15, 2024	DP			
	8556864	Mar 03, 2024	DP			
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	8679069	Apr 12, 2025	DP			
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	9408979	Mar 02, 2024	DP			
	9526844	Mar 02, 2024	DP			
	9533105	Aug 17, 2024	DP			
	9561331	Aug 28, 2024	DP			