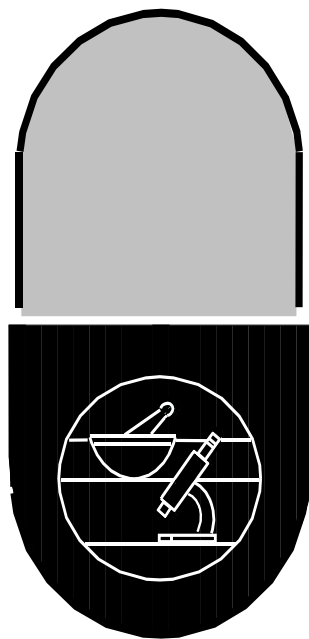


**CUMULATIVE
SUPPLEMENT 12
DECEMBER 2017**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

37th EDITION

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**

2017

PATENT AND EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 12 - December 2017

See List footnote for information regarding List content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>SEMAGLUTIDE - OZEMPIC</u>						
N 209637 001	>A> 6899699	Jan 02, 2022	DP		>A> NCE	Dec 05, 2022
	>A> 7762994	May 23, 2024	DP			
	>A> 8114833	Aug 13, 2025	DP			
	>A> 8129343	Jan 29, 2029	DS DP U-2202			
	>A> 8536122	Mar 20, 2026	DS DP U-2202			
	>A> 8579869	Jun 30, 2023	DP			
	>A> 8672898	Jan 02, 2022	DP			
	>A> 8684969	Oct 20, 2025	DP			
	>A> 8920383	Jul 17, 2026	DP			
	>A> 9108002	Jan 20, 2026	DP			
	>A> 9132239	Feb 01, 2032	DP			
	>A> 9457154	Sep 27, 2027	DP			
	>A> 9486588	Jan 02, 2022	DP			
	>A> 9687611	Feb 27, 2027	DP			
	>A> 9775953	Jul 17, 2026	DP			
	>A> RE46363	Aug 03, 2026	DP			
<u>SILDENAFIL CITRATE - SILDENAFIL CITRATE</u>						
A 077342 001					>A> PC	Jun 09, 2018
<u>SILDENAFIL CITRATE - SILDENAFIL CITRATE</u>						
A 077342 002					>A> PC	Jun 09, 2018
<u>SILDENAFIL CITRATE - SILDENAFIL CITRATE</u>						
A 077342 003					>A> PC	Jun 09, 2018
<u>SIMEPREVIR SODIUM - OLYSIO</u>						
N 205123 001	9623022	Jul 28, 2026	U-1467			
<u>SIMVASTATIN - FLOLIPID</u>						
N 206679 001	9597289	Feb 23, 2030	DP			
<u>SIMVASTATIN - FLOLIPID</u>						
N 206679 002	9597289	Feb 23, 2030	DP			
<u>SINECATECHINS - VEREGEN</u>						
N 021902 001	9770406	Jul 12, 2025	DP U-172			
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N 021995 001	6303661	Apr 24, 2017	U-1996			
	6890898	Feb 02, 2019	U-1997			
	7078381	Feb 02, 2019	U-1997			
	7459428	Feb 02, 2019	U-1945			
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N 021995 002	6303661	Apr 24, 2017	U-1996			
	6890898	Feb 02, 2019	U-1997			
	7078381	Feb 02, 2019	U-1997			
	7459428	Feb 02, 2019	U-1945			
<u>SITAGLIPTIN PHOSPHATE - JANUVIA</u>						
N 021995 003	6303661	Apr 24, 2017	U-1996			
	6890898	Feb 02, 2019	U-1997			
	7078381	Feb 02, 2019	U-1997			
	7459428	Feb 02, 2019	U-1945			
<u>SODIUM NITRITE; SODIUM THIOSULFATE - NITHIODOTE</u>						
N 201444 001	9345724	Mar 29, 2031	DS DP U-2015			
	9585912	Mar 29, 2031	DS DP			