



APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC
EQUIVALENCE
EVALUATIONS

35th 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 MEDICAL PRODUCTS AND TOBACCO
OFFICE OF GENERIC DRUGS

2015

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>EVEROLIMUS - AFINITOR</u>						
N 022334 001	5665772	Sep 09, 2019	DS DP		I-650	Apr 26, 2015
	6004973	Jul 12, 2016	DP		I-655	Jul 20, 2015
	7297703	Dec 06, 2019	DP		ODE	Oct 29, 2017
	7741338	Dec 06, 2019	DP		ODE	May 05, 2018
	8410131	May 22, 2025	DS DP U-1368		ODE	Apr 26, 2019
	8410131*PED	Nov 22, 2025			PED	Sep 30, 2014
	8436010	Feb 22, 2022	DS DP U-1396		PED	Nov 05, 2014
	8436010*PED	Aug 22, 2022			PED	Oct 26, 2015
	8778962	Feb 18, 2022		U-1541	PED	Apr 29, 2018
	8778962*PED	Aug 18, 2022			PED	Nov 05, 2018
					PED	Oct 26, 2019
<u>EVEROLIMUS - AFINITOR</u>						
N 022334 002	5665772	Sep 09, 2019	DS DP		I-650	Apr 26, 2015
	6004973	Jul 12, 2016	DP		I-655	Jul 20, 2015
	7297703	Dec 06, 2019	DP		ODE	Oct 29, 2017
	7741338	Dec 06, 2019	DP		ODE	May 05, 2018
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	8778962	Feb 18, 2022		U-1541	PED	Apr 29, 2018
	8778962*PED	Aug 18, 2022			PED	Nov 05, 2018
					PED	Oct 26, 2019
<u>EVEROLIMUS - AFINITOR</u>						
N 022334 003	5665772	Sep 09, 2019	DS DP		I-650	Apr 26, 2015
	6004973	Jul 12, 2016	DP		I-655	Jul 20, 2015
	7297703	Dec 06, 2019	DP		ODE	Oct 29, 2017
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