

U.S. Food and Drug Administration
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First-Time Generic Drug Approvals - March 2016

	ANDA Number	Generic Drug Name	Generic Manufacturer/Applicant	Brand Name	Approval Date
1	207349	MAGNESIUM SULFATE IN 5% DEXTROSE INJECTION USP, 1G/100 ML	HQ SPECIALTY PHARMA CORPORATION	MAGNESIUM SULFATE IN 5% DEXTROSE INJECTION	3/2/2016
2	205076	OXICONAZOLE NITRATE CREAM, 1%	TARO PHARMACEUTICALS USA, INC.	OXISTAT CREAM	3/7/2016
3	077342	SILDENAFIL CITRATE TABLETS, 25 MG (BASE), 50 MG (BASE), 100 MG (BASE)	TEVA PHARMACEUTICALS USA, INC.	VIAGRA (SILDENAFIL CITRATE) TABLETS, 25 MG, 50 MG, 100 MG	3/9/2016
4	206485	MAGNESIUM SULFATE IN WATER FOR INJECTION, 40 MG/ML, 80 MG/ML	FRESENIUS KABI USA, LLC	MAGNESIUM SULFATE IN WATER FOR INJECTION	3/15/2016
5	208077	DICLOFENAC SODIUM TOPICAL GEL, 1%	AMNEAL PHARMACEUTICALS	VOLTAREN GEL, 1%	3/18/2016
6	091161	MOMETASONE FUROATE NASAL SPRAY, 50 MCG	APOTEX CORP	NASONEX NASAL SPRAY	3/22/2016
7	204771	BENDAMUSTINE HYDROCHLORIDE FOR INJECTION, 25 MG/VIAL, 100 MG/VIAL (SINGLE DOSE VIAL)	GLENMARK PHARMACEUTICALS LIMITED	TREANDA FOR INJECTION, 25MG/VIAL, 100MG/VIAL	3/24/2016
8	205476	BENDAMUSTINE HYDROCHLORIDE FOR INJECTION, 25 MG/VIAL, 100 MG/VIAL (SINGLE DOSE VIAL)	INNOPHARMA LICENSING LLC	TREANDA FOR INJECTION, 25MG/VIAL, 100MG/VIAL	3/24/2016
9	091039	DAPTOMYCIN FOR INJECTION, 500 MG/VIAL	TEVA PHARMACEUTICALS USA	CUBICIN FOR INJECTION	3/24/2016
10	205943	LEVONORGESTREL/ETHINYL ESTRADIOL TABS USP/ETHINYL ESTRADIOL 0.15 MG/0.02 MG/0.01 MG 0.15 MG/0.025 MG/0.01 MG 0.15 MG/0.03 MG/0.01 MG	LUPIN LIMITED	QUARTETTE TABLETS	3/29/2016
11	202402	IBUPROFEN LYSINE INJECTION, 20 MG/2 ML (10 MG/ML) SDV	EXELA PHARMA SCIENCES, LLC	NEOPROFEN INJECTION	3/30/2016

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ANDA (Generic) Drug Approvals - Previous Years

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Argentum Pharmaceuticals LLC v. Cipla Ltd.

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