Patents and Suitability Petitions

August 7, 2017

The PDF contains a list of drug products for which an Abbreviated New Drug Application (ANDA) has been received by the Office of Generic Drugs (OGD) containing a "Paragraph IV" patent certification. This list includes the name of the drug product, dosage form, strength (subject of Paragraph IV certification), reference listed drug (RLD), **and the date on which the first substantially complete generic drug application was submitted to the Agency (on a prospective basis beginning 3/2/2004**). The Agency will not disclose the identity of the applicant. This information will be updated twice a month and will be as current as the last update. This information should be used for reference only. The Agency will make every effort to ensure the accuracy of the information disclosed in this list. However, any discrepancies or disparities should be discussed with the Division of Filing Review at 240-402-8859, before making any decisions based on this information.

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Alvimopan	Capsules	12 mg	Entereg	6/16/2017
Isotretinoin	Capsules	35 mg	Absorica	11/25/2015
Isotretinoin	Capsules	25 mg	Absorica	5/16/2016
Memantine Hydrochloride Extended-release and Donepezil Hydrochloride	Capsules	21 mg/10 mg	Namzaric	9/23/2016
Memantine Hydrochloride Extended-release and Donepezil Hydrochloride	Capsules	7 mg/10 mg	Namzaric	9/26/2016
Nebivolol Hydrochloride and Valsartan	Tablets	5 mg/80 mg	Byvalson	6/9/2017

Related Information

- **Paragraph IV Patent Certifications (PPIV) (PDF - 476KB) (/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM293268.pdf)**

Resources for You

- **Office of Generic Drugs (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm119100.htm)**
- **Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) (/Drugs/InformationOnDrugs/ucm129662.htm)**
- **First Generic Drug Approvals (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/default.htm)**

More in Abbreviated New Drug Application (ANDA): Generics (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm)

Generic Drugs: Information for Industry (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm142112.htm)

Abbreviated New Drug Application (ANDA) Forms and Submission Requirements (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm120955.htm)

Activities Report of the Generic Drug Program (FY 2017) (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm375079.htm)

Patents and Suitability Petitions (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm047676.htm)

Suitability Petitions (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm120944.htm)