Paragraph IV Patent Certifications

June 26, 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 **(http://sharepoint.fda.gov/orgs/CDER-OCOMM-DOC/CDERWebSupport/Lists/WebSupportCDER/Item/displayifs.aspx?List=61607bdc%2D5465%2D4f84%2Da459%2Df2a5edf81b3d&ID=1162&Web=3b7d4fca%2De6cb%2D4c79%2D87a0%2D7917df4a9610#)**, before making any decisions based on this information.

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Bendamustine Hydrochloride	Injection	100 mg/4 mL (25 mg/mL) multiple-dose vials	Bendeka	5/4/2017
Buprenorphine and Naloxone	Buccal Film	2.1mg/0.3 mg and 4.2 mg/0.7 mg	Bunavail	11/23/2016
Buprenorphine and Naloxone	Buccal Film	6.3 mg/1 mg	Bunavail	12/21/2015
Buprenorphine Hydrochloride and Naloxone Hydrochloride Dihydrate	Sublingual Tablets	0.7 mg/0.18 mg	Zubsolv	5/3/2017
Cyanocobalamin	Nasal Spray	500 mcg/spray	Nascobal	4/28/2017
Dronabinol	Oral Solution	5mg/ml	Syndros	4/17/2017
Emtricitabine and Tenofovir Disoproxil Fumarate	Tablets	100 mg/150 mg, 133 mg/200 mg, and 167 mg/250 mg	Truvada	5/19/2017

Related Information

- **Paragraph IV Patent Certifications (PPIV) (PDF - 1.7MB) (/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)

Paragraph IV Patent Certifications (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm047676.htm)

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