Patent Certifications and Suitability Petitions

FDA aspires to continually improve its pre-ANDA (abbreviated new drug application) interactions with applicants. To facilitate these interactions and keep stakeholders as informed as possible, the agency regularly publishes information on suitability petitions and Paragraph IV patent certifications.

- **Paragraph IV Patent Certifications**
- **Paragraph IV Certifications List**
- **New Paragraph IV Certifications as of February 1, 2018**
- **Suitability Petitions**
- **Contact Us**

Paragraph IV Patent Certifications

Under the **Drug Price Competition and Patent Term Restoration Act of 1984 (https://www.congress.gov/bill/98th-congress/senate-bill/01538)**, also known as the Hatch-Waxman Amendments, a company can seek FDA approval to market a generic drug before the expiration of patents related to the brand-name drug that the generic seeks to copy. To seek this approval, a generic applicant must provide in its application a "certification" that a patent submitted to FDA by the brand-name drug's sponsor and listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) is, in the generic applicant's opinion and to the best of its knowledge, invalid, unenforceable, or will not be infringed by the generic product. This certification is called a "paragraph IV certification." The first company or companies to submit an application that (1) is determined by the agency to be "substantially complete" upon submission and (2) contains a paragraph IV certification to at least one of the patents listed in the Orange Book is generally eligible for the exclusive right to market the generic drug for 180 days.

In order to challenge a patent in court, the generic applicant that submitted a paragraph IV certification must notify the brand product sponsor and any patent holder of the submission of the ANDA and patent challenge. If the brand product sponsor or patent holder files an infringement suit against the generic applicant within 45 days of the ANDA notification, FDA approval to market the generic drug is generally postponed for 30 months unless the patent expires or is judged to be invalid or not infringed before that time. This 30-month postponement, commonly referred to as the "30-month stay," gives the brand product sponsor and patent holder a prescribed amount of time to assert patent rights in court before a generic competitor is approved and can market the drug.

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Paragraph IV Certifications List

As part of its ongoing efforts to assist generic drug applicants in preparing their applications, FDA regularly publishes a **list of drug products for which an ANDA has been received by the Office of Generic Drugs (OGD) containing a Paragraph IV patent certification (/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM293268.pdf)** (PDF - 476KB). This list includes the name of the drug product, dosage form, strength, reference listed drug (RLD), and the date on which the first substantially complete generic drug application was submitted to the agency that contained a paragraph IV certification (on a prospective basis, beginning March 2, 2004). The agency will not disclose the identity of the applicant(s). The Agency will make every effort to ensure the accuracy of the information disclosed in this list. However, before making any decisions based on this information, any discrepancies or disparities should be discussed with the Patent and Exclusivities Team (PET) by emailing **CDER-OGDPET@fda.hhs.gov (mailto:CDER-OGDPET@fda.hhs.gov)**.

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New Paragraph IV Certifications as of February 1, 2018

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Mifepristone	Tablets	300 mg	Korlym 202107	12/15/2017
Sofosbuvir	Tablets	400 mg	Sovaldi 204671	12/6/2017

Additional Resource

- **Paragraph IV Patent Certifications (PPIV) (/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM293268.pdf)** as of February 1, 2018 (PDF - 1 MB)

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Suitability Petitions

Certain differences between a reference listed drug (RLD) and a proposed generic drug product may be permitted in an abbreviated new drug application (ANDA) if these differences are the subject of an approved suitability petition submitted under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act, and pursuant to 21 CFR 314.93.

An applicant may submit a suitability petition to the FDA requesting permission to submit an ANDA for a generic drug product that differs from an RLD in its:

- route of administration,
- dosage form,
- strength, or
- if it has one different active ingredient in a fixed-combination drug product.

An ANDA citing a suitability petition that has not been approved will not be received for review because the application lacks a legal basis for the submission.

A generic applicant cannot submit an ANDA for such a product until FDA has approved the related petition. The grounds for FDA approval of such a petition are set out in 21 CFR 314.93(e). The determination that an ANDA will be approved is not made until the ANDA itself is submitted and is reviewed by the Agency.

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Accessing and Tracking Suitability Petitions

You may view copies of submitted suitability petitions and responses from FDA at **www.regulations.gov (https://www.regulations.gov/)**, which is searchable by docket number or drug product name. You may also submit comments to pending suitability petitions through this site.

The Office of Generic Drugs (OGD) has previously posted suitability petition tracking reports; however, these lists are not regularly updated as they are burdensome to maintain. For the most up-to-date information, OGD recommends searching for suitability petitions on regulations.gov.

- **OGD Suitability Tracking Report Sorted by Drug Name (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM458481)** (PDF – 1.3 MB) (updated August 2015)
- **OGD Suitability Tracking Report Sorted by Petition Number (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM458482)** (PDF – 1.3 MB) (updated August 2015)

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Contact Us

Questions about suitability petitions can be directed to
FDA's Division of Dockets Management
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

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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)**
- **Generic Drugs Program (/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/default.htm)**
- **Industry Resources (/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/ucm567283.htm)**

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

Generic Drug Development (/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 Drugs Program (FY 2018) Monthly Performance (/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm375079.htm)

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