

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.

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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, the Food and Drug Administration (FDA or the Agency) regularly publishes information relevant to 180-day exclusivity for generic drug applicants provided under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Generally, this list describes drug products for which one or more substantially complete abbreviated new drug applications (ANDAs) containing a “paragraph IV” (PIV) patent certification have been submitted to FDA. (For more information on 180-day exclusivity, see FDA’s draft guidance for industry on *180-Day Exclusivity: Questions and Answers* (<https://www.fda.gov/media/102650/download>) (Jan. 2017).)

Historically, this list has included the name of the drug product, dosage form, strength(s), reference listed drug (RLD)/new drug application (NDA) number, and, beginning on March 2, 2004, the date on which the first substantially complete ANDA(s) (or amendment or supplement to one) was submitted to the Agency that contained a paragraph IV certification.

Under the FDA’s Drug Competition Action Plan (<https://www.fda.gov/news-events/fda-voices-perspectives-fda-experts/fda-working-lift-barriers-generic-drug-competition>) (DCAP), FDA committed to enhancing efficiency of the development and approval of ANDAs, with the ultimate goal of more approvals to help increase access to high-quality, lower cost generic drugs. FDA believes that additional information regarding 180-day exclusivity for specific drug products may support this DCAP goal by providing greater clarity to ANDA applicants regarding the earliest date when they may be able to obtain final approval. Accordingly, on a prospective basis beginning June 18, 2019, the Agency also will include the additional information described in detail below.

The newly added columns to the Paragraph IV Certification List will be updated retrospectively as practicable. Thus, entries in the newly added columns for drug products that reflect a date of first paragraph IV certification prior to June 18, 2019 may be blank because we have not updated that drug product’s information. By contrast, if entries for the newly added columns for drug products that reflect a date of paragraph IV certification after June 18, 2019 are blank, it means, in general, that FDA has not yet made a determination regarding or an event has not yet occurred for that column.

The Agency aims to provide accurate information in this list. However, FDA will make regulatory decisions based on the data and information in any relevant applications, and not the information on this list. Any discrepancies or disparities should be discussed with FDA’s Patent and Exclusivity Team (PET) by emailing CDER-OGDPET@fda.hhs.gov (mailto:CDER-OGDPET@fda.hhs.gov).

Beginning with the June 18, 2019 update, the Agency plans to include the following information for individual drug products on the Paragraph IV Certification List:

- **Active Ingredient Name**

This column reflects the established (nonproprietary) name of the active ingredient(s) in the drug product.

- **Dosage Form**

- **Strength**

- **RLD Name and NDA Number**

This column reflects the proprietary name, if any, of the RLD and its NDA number.

- **Date of First PIV Submission**

This column reflects the first date that a substantially complete application containing a paragraph IV certification(s) to at least one patent listed for the RLD in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (<https://www.fda.gov/orangebook>) (the Orange Book) was submitted. The date of first PIV submission may correspond to the date of submission of an original ANDA, an amendment to a pending ANDA, or a supplement to an approved ANDA.

Drug products on the list that have “pre-MMA” in the “Date of First PIV Submission” column are subject to the provisions of the FD&C Act in effect prior to the amendments made by the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (<https://www.congress.gov/bill/108th-congress/house-bill/1>) (MMA). Due to the “patent-by-patent” analysis needed to determine eligibility for 180-day exclusivity under the pre-MMA statutory scheme, listing individual dates of relevant submissions is not practical. (For more information on the applicability of the “pre-MMA” provisions of the FD&C Act related to 180-day exclusivity, see FDA's draft guidance for industry on *180-Day Exclusivity: Questions and Answers* (<https://www.fda.gov/media/102650/download>), at Q1.).

- **Number of Potential First Applicant ANDAs Submitted**

This column indicates the number of substantially complete ANDAs that contained a paragraph IV certification to at least one patent listed for the RLD in the Orange Book on the first date such a certification was submitted. FDA may adjust this number over time for a drug product, for example, if the agency grants a request for reconsideration of FDA's refusal to receive a relevant ANDA.

- **180-Day Decision Status**

This column indicates if FDA has made (or has deferred) a decision regarding eligibility for 180-day exclusivity for a drug product. Specifically, this column indicates whether: (1) FDA approved at least one first applicant's ANDA and considered that first applicant's drug product eligible for 180-day exclusivity at the time of approval (“eligible”); (2) FDA approved a first applicant but did not make a determination regarding eligibility for exclusivity at the time of approval (“deferred”); (3) FDA tentatively approved a subsequent applicant solely on the basis of a first applicant's eligibility for 180-day exclusivity at a time

that none of the grounds for forfeiture were found to apply (“non-forfeiture”); or (4) FDA determined that 180-day exclusivity has been extinguished, for example, if all first applicants have forfeited or voluntarily relinquished eligibility for 180-day exclusivity (“extinguished”).

There may be instances in which the 180-Day Decision Status reflects that FDA made a non-forfeiture decision at one point in time, e.g., non-forfeiture under the statutory provision related to obtaining approval or tentative approval within 30 months of submission (failure-to-obtain-TA in 30 months provision), and then subsequently determined based on new events that the first applicant forfeited its eligibility for exclusivity, e.g., forfeiture under the “failure to market” statutory provision. If FDA has not made any of the above determinations, this column will be blank. This column will be cumulative, with the most recent decision reflected first.

For certain 180-day exclusivity decisions that require analysis by FDA, including those under the failure-to-obtain-TA in 30 months and failure-to-market provisions, it is FDA’s practice to make these decisions in the context of specific ANDAs that are otherwise eligible for approval (i.e., when a first applicant’s ANDA or a subsequent applicant’s ANDA is ready for approval). Many factors may influence eligibility for exclusivity up to the time an application is ready for approval (e.g., patent expiration, failure to obtain a tentative or final approval within 30 months, withdrawal of ANDA) and thus could render a premature eligibility determination incorrect.

180-day exclusivity decisions under the withdrawal-of-application, amendment-of-certification, and expiration-of-all-patents forfeiture provisions generally are made once all first applicants have forfeited eligibility for 180-day exclusivity under these forfeiture provisions and the Agency confirms the forfeiture(s), unless there are complicating factors that would require analysis. In such cases, FDA generally would make a decision in the context of specific ANDAs that are otherwise eligible for approval, and any updates to this column would be posted after the Agency’s decision had been made.

- **180-Day Decision Posting Date**

This column reflects the month and year that FDA updated the PIV Certification List to reflect the corresponding 180-day decision status. This column will be cumulative, with the most recent decision date reflected first.

- **Date of First Approval of “First Applicant” ANDA**

This column indicates the first date on which a first applicant’s ANDA received final approval. If there are multiple first applicants, only the date of the first approval is posted.

- **Date of First Commercial Marketing**

This column reflects the date of first commercial marketing by any first applicant. This column, in conjunction with the Date of First Approval of “First Applicant” ANDA, provides the time frame between the dates a first applicant’s ANDA was approved and the date when a first applicant began commercial marketing. To note, if an ANDA is

determined to be eligible for 180-day exclusivity, the Orange Book posts a Patent Challenge (PC) code in the “Exclusivity Data” section of the Orange Book to only the approved ANDA(s) eligible for 180-day exclusivity upon any first applicant’s commercial marketing, indicating the date the 180-day exclusivity will expire. If the agency deferred in making a decision as to whether or not an approved ANDA(s) is eligible for 180-day exclusivity, a PC code will not be entered for this ANDA(s) in the Orange Book. The approval letters for first applicant ANDA(s) are posted on the Drugs@FDA website (<https://www.fda.gov/drugs/drug-approvals-and-databases/about-drugsfda>).

- **Expiration Date of Last Qualifying Patent**

This column lists the last expiration date of any patent(s) that qualifies any first applicant for 180-day exclusivity for a given drug product. This column indicates when 180-day exclusivity will no longer be available due to patent expiry. If there are multiple applications submitted on the first day, the patents that have at least one PIV certification amongst all the submissions will be posted. For example, if applicant 1 has PIV certifications to patents A, B, C and PIII certifications to patents D, E and F, but applicant 2 has PIV certifications to patents A, B, D and E, and PIII certifications to patents C and F, then the expiration date that is last-in-time for patents A, B, C, D and E would be posted on the PIV Certification List since there is a PIV certification for each of the patents; only one expiration date will be posted. The expiration date for patent F would not be considered because both applicants have a PIII certification to this patent. This column does not reflect any pediatric exclusivity for the RLD associated with the last qualifying patent.

Paragraph IV Certifications

- Paragraph IV Patent Certifications (PPIV) (</media/82686/download>) as of September 23, 2019 (PDF - 1 MB)

Product Name	Dosage Form	Strength	RLD/NDA	Date of Submission
Brexiprazole	Tablets	0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg	Rexulti 205422	7/10/2019
Sacubitril and Valsartan	Tablets	24 mg/26 mg, 49 mg/51 mg 97 mg/103 mg	Entresto 207620	7/8/2019

Product Name	Dosage Form	Strength	RLD/NDA	Date of Submission
Epinephrine	Injection	30 mg/30 mL	Adrenalin 204640	8/20/2018
Dolutegravir Sodium and Lamivudine	Tablets	50 mg/300 mg	Dovato 211994	7/30/2019
Cabozantinib	Tablets	20 mg, 40 mg and 60 mg	Cabometyx 208692	8/16/2019
Levothyroxine Sodium	Capsules	88 mcg, 100 mcg and 125 mcg	Tirosint 21924	8/1/2019

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](https://www.fda.gov/regulations.gov).

- [OGD Suitability Tracking Report Sorted by Drug Name \(/media/93090/download\)](/media/93090/download) (PDF – 1.3 MB) (updated August 2015)
- [OGD Suitability Tracking Report Sorted by Petition Number \(/media/93097/download\)](/media/93097/download) (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 \(/about-fda/about-center-drug-evaluation-and-research/office-generic-drugs\)](/about-fda/about-center-drug-evaluation-and-research/office-generic-drugs)
- [Approved Drug Products with Therapeutic Equivalence Evaluations \(Orange Book\) \(/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book\)](/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book)
- [First Generic Drug Approvals \(/anda-approval-reports\)](/anda-approval-reports)
- [Generic Drugs Program \(/generic-drugs\)](/generic-drugs)
- [Industry Resources \(/drugs/generic-drugs/industry-resources\)](/drugs/generic-drugs/industry-resources)

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