

(1) patent issuance, (2) approval of a corresponding change to product labeling, or (3) a decision by the U.S. Patent and Trademark Office or a federal court that is specific to the patent and alters the construction of a method-of-use claim(s) of the patent (and the amendment contains a copy of the decision). Outside of these circumstances and except as provided in the patent listing dispute regulation (21 CFR 314.53(f)(1)), an amendment to the description of the approved method(s) of use claimed by the patent will not be considered timely filed.

If the amendment to the description of the approved method(s) of use claimed by the patent is filed within an acceptable time frame but is incomplete or shows that the patent is not eligible for listing, the NDA holder must submit an acceptable Form FDA 3542 within 15 days of the FDA's notification to be considered timely filed as of the date of the submission of amended patent information.

15. What actions must a pending ANDA or 505(b)(2) applicant take if patent information is untimely filed?

If patent information is untimely filed, generally a previously submitted ANDA or 505(b)(2) applicant is not required to submit a patent certification or statement to address the patent or patent information that is late-listed with respect to the pending ANDA or 505(b)(2) application.

16. Is there a specific format in which patent information needs to be submitted to the agency?

If the NDA applicant is submitting patent information with an original NDA, an amendment, or a supplement prior to approval, use Form FDA 3542a. If the NDA holder is submitting information on a patent that claims an approved drug or an approved method of using the drug after approval of an NDA or supplement, use Form FDA 3542. The agency will not list or publish patent information in the Orange Book if it is not provided on Form FDA 3542.

17. To which submissions does the final rule apply?

The effective date of the final rule on "Abbreviated New Drug Applications and 505(b)(2) Applications" applies to any submission received by the FDA on or made after December 5, 2016, the effective date of the rule, including any changes to the previously submitted patent information.

18. Does previously submitted patent information have to be resubmitted on the new Forms FDA 3542 and 3542a?

No. While any patent information submitted after the effective date of the final rule must be submitted in a manner consistent with the final rule, including use of the new forms, NDA holders and applicants are not required to resubmit patent information previously submitted on a prior version of the form.

19. Who do I contact with specific questions regarding what patents are eligible for listing in the Orange Book?

The FDA's patent listing role is ministerial. Generally, we will not respond to specific questions regarding the eligibility of patents for listing.