Forms FDA 3542a and FDA 3542: Questions and Answers

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact Rachel Erdman at 301-651-8301.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

June 2026
Generic Drugs

Forms FDA 3542a and FDA 3542: Questions and Answers

Guidance for Industry

Additional copies are available from:

Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
Phone: 855-543-3784 or 301-796-3400
Email: druginfo@fda.hhs.gov
https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

June 2026
Generic Drugs

TABLE OF CONTENTS

Forms FDA 3542a and FDA 3542: Questions and Answers Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended to assist new drug application (NDA) applicants[2] and NDA holders[3] in submitting patent information to their NDAs using the appropriate forms, Form FDA 3542, Patent Information Submitted Upon and After Approval of an NDA or Supplement, or Form FDA 3542a, Patent Information Submitted With the Filing of an NDA, Amendment, or Supplement, under 21 CFR 314.53(d).[4] This guidance provides answers to commonly asked questions regarding Forms FDA 3542 and FDA 3542a.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. This document is intended only to provide clarity to the public regarding existing requirements under the law. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Section 505(b)(1)(A)(viii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(b)(1)(A)(viii)) requires an NDA applicant to submit, as part of its NDA, certain information for "each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the

[1] This guidance has been prepared by the Office of Generic Drugs in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.
[2] An *NDA applicant* is any person who submits an NDA (including a 505(b)(2) application) or an amendment or supplement to an NDA to obtain FDA approval of a new drug and any person who owns an approved NDA. See 21 CFR 314.3(b).
[3] An *NDA holder* is the applicant that owns an approved NDA. 21 CFR 314.3(b).
[4] Forms FDA 3542 and FDA 3542a, along with instructions for completing these forms, are available on the FDA Forms web page at https://www.fda.gov/about-fda/reports-manuals-forms/forms.

drug, and that — (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or (II) claims a method of using such drug for which approval is sought … in the application."[5]

Section 505(c)(2) of the FD&C Act (21 U.S.C. 355(c)(2)) requires an NDA holder to submit, no later than 30 days after the date of approval of the NDA, certain information "for each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that — (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or (II) claims a method of using such drug for which approval… has been granted in the application."[6] Section 505(c)(2) further requires that "a patent that is identified as claiming a method of using such drug shall be filed only if the patent claims a method of use approved in the application."[7]

NDA applicants and NDA holders must submit the required patent information via the appropriate forms.[8] Form FDA 3542a must be used when an NDA applicant submits information on a patent that claims a drug substance (active ingredient), drug product (formulation or composition), or method of using the drug that is the subject of an unapproved original NDA, amendment to an NDA, or supplement to an NDA.[9] Form FDA 3542 must be used when an NDA holder submits information on a patent that claims a drug substance (active ingredient), drug product (formulation or composition), or method of using the drug that is the subject of an approved NDA or approved supplement to an NDA.[10] The FD&C Act requires FDA to regularly revise the publication *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book)[11] to include, among other things, patent information required to be submitted under section 505(c)(2) of the FD&C Act.[12]

A. Required Patent Information

Patent information that NDA applicants and NDA holders are required to submit includes "the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that — (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or (II) claims a method of using such drug for which approval is sought or has been granted in the application."[13]

---

[5] Section 505(b)(1)(A)(viii) of the FD&C Act; see also 21 CFR 314.53(b)(1).
[6] See section 505(c)(2) of the FD&C Act (referencing section 505(b)(1)(A)(viii)); see also 21 CFR 314.53(b)(1).
[7] Section 505(c)(2) of the FD&C Act; see also 21 CFR 314.53(b)(1).
[8] 21 CFR 314.53(c).
[9] 21 CFR 314.53(c)(2)(i).
[10] 21 CFR 314.53(c)(2)(ii).
[11] Available at: https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.
[12] Section 505(c)(2) and 505(j)(7)(A)(iii) of the FD&C Act.
[13] Section 505(b)(1)(A)(viii) of the FD&C Act; see also 21 CFR 314.53.

For patents claiming a drug substance, the NDA applicant or NDA holder must submit information only on those patents that claim the drug substance that is the subject of the pending or approved NDA or that claim a drug substance that is the same as the active ingredient that is the subject of the pending or approved NDA.[14] For patents that claim only a polymorph that is the same as the active ingredient described by the NDA (i.e., patents that have no other basis for listing), the NDA applicant or NDA holder must certify in the required FDA declaration form that the NDA applicant or NDA holder has test data demonstrating that the drug product containing the polymorph will perform the same as a drug product described in the NDA.[15] For patents claiming a drug product, the NDA applicant or NDA holder must submit information only on those patents that claim the drug product that is described in the pending or approved NDA.[16] For patents claiming a method of use, the NDA applicant or NDA holder must submit information only on those patents that claim indications or other conditions of use for which approval is sought or has been granted in the NDA, and the NDA applicant or NDA holder must separately identify each pending or approved method of use and the related patent claim(s).[17] For approved NDAs, the NDA holder also must provide a description of each patented approved method of use ("use code").[18] If the method(s) of use claimed by the patent do(es) not cover an indication or other approved condition of use in its entirety, the use code must describe only the specific approved method of use claimed by the patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product.[19]

B. Timing

For Form FDA 3542 to be considered timely filed:

- The NDA holder must submit required patent information for listing in the Orange Book no later than 30 days after the date of approval of an NDA or an NDA supplement.[20]

- If a patent issues after the date of approval of the NDA, the NDA holder must submit a Form FDA 3542 no later than 30 days after the date of issuance of the patent.[21]

[14] *Drug substance* is defined in FDA regulations as "an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body but does not include intermediates used in the synthesis of such ingredient." *Active ingredient* is defined in FDA regulations as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect" (see 21 CFR 314.3(b)).
[15] Ibid.
[16] Ibid.
[17] Ibid.
[18] 21 CFR 314.53(c)(2)(ii)(P)(*3*).
[19] 21 CFR 314.53(b)(1).
[20] Section 505(c)(2) of the FD&C Act; see also 21 CFR 314.53(c)(1), (c)(2)(ii), and (d)(2).
[21] Section 505(c)(2) of the FD&C Act; see also 21 CFR 314.53(c)(1), (c)(2)(ii), and (d)(3).

- If FDA identifies errors or omissions in a timely filed Form FDA 3542 and notifies the NDA holder of these errors or omissions, the NDA holder must submit an acceptable Form FDA 3542 within 15 days of FDA notification.[22]

For an NDA holder's amendment to the description of the approved method(s) of use claimed by the patent to be considered timely filed, the NDA holder must submit such an amendment on Form FDA 3542 within 30 days of patent issuance, within 30 days of approval of a corresponding change to product labeling, or within 30 days of a decision by a court or the United States Patent and Trademark Office (USPTO) that is specific to the patent and alters the construction of a method-of-use claim(s) of the patent.[23] Except as provided by 21 CFR 314.53(f)(1), amendments to the description of the approved method(s) of use that do not comply with these requirements will not be considered timely filed.[24] Amendments must contain a copy of the USPTO or court decision, if applicable.[25]

For Form FDA 3542a to be considered timely filed, the form must be submitted with the NDA applicant's original NDA.[26] If a patent is issued after the NDA is filed with FDA but before the NDA is approved, the NDA applicant must submit the required patent information on Form FDA 3542a in an amendment to the NDA no later than 30 days after the date of issuance of the patent.[27]

NDA applicants and NDA holders should not submit Forms FDA 3542a and 3542 or USPTO and court decisions to FDA outside of the CDER Central Document Room through the Electronic Submissions Gateway. The Electronic Submissions Gateway is available at https://www.fda.gov/industry/electronic-submissions-gateway. Also, NDA applicants and NDA holders should not submit courtesy copies of these documents (such as through fax, electronic message, or physical mail) to FDA.[28]

III. QUESTIONS AND ANSWERS

A. Obtaining and Filling Out Forms FDA 3542a and FDA 3542

[22] 21 CFR 314.53(c)(2)(ii).
[23] 21 CFR 314.50(i)(4)(i) and 314.94(a)(12)(vi)(A).
[24] See 21 CFR 314.53(f)(1).
[25] 21 CFR 314.50(i)(4)(i)(C). An NDA holder should submit USPTO or court decisions with Form FDA 3542 via the CDER Central Document Room through the Electronic Submissions Gateway in the electronic format specified by FDA. See section 745A(a) of the FD&C Act (21 U.S.C. 379k-1(a)); see also 21 CFR 314.53(d)(4) and 21 CFR 314.50(l)(5)) and the guidance for industry *Providing Regulatory Submissions in Electronic Form — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (September 2024). We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.
[26] Section 505(b)(1)(B) of the FD&C Act; see also 21 CFR 314.53(d)(1).
[27] Ibid.
[28] See section 745A(a) of the FD&C Act (21 U.S.C. 379k-1(a)); see also 21 CFR 314.53(d)(4) and 21 CFR 314.50(l)(5)) and the guidance for industry *Providing Regulatory Submissions in Electronic Form — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (September 2024).

Q1. How can one obtain the most updated versions of Forms FDA 3542a and FDA 3542?

A1. FDA posts the most updated versions of Forms FDA 3542a and FDA 3542 on the FDA Forms web page at https://www.fda.gov/about-fda/reports-manuals-forms/forms?Page=5.

For step-by-step instructions for completing the forms, refer to the corresponding instruction sheets available on the FDA Forms web page titled "Instructions for Filling Out Form FDA 3542 — Patent Information Submitted Upon and After Approval of an NDA or Supplement" (Form FDA 3542 Supplement) and "Instructions for Filling Out Form 3542a — Patent Information Submitted With the Filing of An NDA, Amendment, or Supplement" (Form FDA 3542a Supplement).

Q2. What form must be used by an NDA applicant to submit required patent information as part of its unapproved NDA?

A2. NDA applicants must use Form FDA 3542a to submit information on a patent that claims a drug substance (active ingredient), drug product (formulation or composition), or a method of using the drug that is the subject of an unapproved original NDA, amendment to an NDA, or supplement to an NDA.[29]

Q3. What form must be used by an NDA holder to submit required patent information for listing in the Orange Book?

A3. NDA holders must use Form FDA 3542 to submit information on a patent that claims a drug substance (active ingredient), drug product (formulation or composition), or method of using the drug that is the subject of an approved original NDA or approved supplement to an NDA upon approval of said NDA or supplement to an NDA.[30] FDA publishes certain information from Form FDA 3542 in the Orange Book.[31]

Q4. Who is responsible for preparing and submitting Forms FDA 3542a and FDA 3542 to FDA?

A4. NDA applicants, NDA holders, or patent owners,[32] or any of their respective attorneys, agents, representatives, or other authorized officials may complete and sign Forms FDA 3542a and FDA 3542.[33] However, only an NDA applicant or NDA holder can submit these forms to FDA under its NDA.[34]

---

[29] 21 CFR 314.53(c)(2)(i).
[30] 21 CFR 314.53(c)(2)(ii).
[31] FDA will publish the patent number and expiration date of each patent that is required to be, and is, submitted to FDA by an applicant, and, for each method-of-use patent, the description of the method of use claimed by the patent (21 CFR 314.53(e)).
[32] For purposes of this guidance, the term "patent owner" refers to an entity that owns the patent for which information is being submitted for listing in the Orange Book and that is not also the NDA applicant or NDA holder, as applicable.
[33] 21 CFR 314.53(c)(4).
[34] See generally 21 CFR 314.53(c)(4) and (d)(4).

Q5. Which sections of Forms FDA 3542a and FDA 3542 can a patent owner complete?

A5. Where a patent owner is not also the NDA applicant or NDA holder and is completing the form for the NDA applicant or NDA holder to submit to its NDA, that patent owner may need to obtain information from the NDA applicant or NDA holder to complete the form.[35] If required information (including, for example, contact information for the NDA applicant or NDA holder or its attorney, agent, or representative; whether the patent has previously been submitted for listing for this drug product; and information regarding the proposed or approved drug product claimed by the patent) is not provided on the form, the patent owner will not be able to electronically sign the form, and FDA will not consider the form to be complete.[36]

Q6. Can a patent owner submit Form FDA 3542a or Form FDA 3542 directly to FDA?

A6. No. A patent owner who is not the NDA applicant or NDA holder is authorized to sign the declaration certification in Section 6 of Form FDA 3542a or Form FDA 3542 but is not permitted to submit the forms directly to FDA.[37] Only an NDA applicant or NDA holder can submit Form FDA 3542a or Form FDA 3542, respectively, directly to FDA under its NDA.[38] If a patent owner is completing the form for the NDA applicant or NDA holder, the patent owner should send the completed form to the NDA applicant or NDA holder for submission to FDA.

Q7. Can an NDA applicant or NDA holder submit information about more than one patent on a single form?

A7. No. NDA holders and NDA applicants must submit a separate Form FDA 3542a or FDA 3542, as applicable, for each patent.[39]

Q8. Does a U.S. agent need to be identified for an NDA applicant, NDA holder, or patent owner without a place of business within the United States or residing outside of the United States?

A8. Yes. If the NDA applicant, NDA holder, or patent owner does not reside or have a place of business within the United States, the required information on the name and address of each NDA applicant, NDA holder, or patent owner's agent or representative who resides or maintains a place of business within the United States who is authorized to receive notice of patent certification must be provided in field 1.f of Form FDA 3542a or Form FDA 3542.[40]

[35] See 21 CFR 314.53(c)(2)(i), (c)(2)(ii), and (c)(4).
[36] See 21 CFR 314.53(c)(1)–(2).
[37] 21 CFR 314.53(c)(4) and (d)(4).
[38] Ibid.
[39] 21 CFR 314.53(b)(1), (c)(1), (c)(2)(i), and (c)(2)(ii).
[40] 21 CFR 314.53(c)(2)(i)(I) and (c)(2)(ii)(J).

Q9. If an NDA applicant or NDA holder submitted patent information using an expired version of Form FDA 3542a or Form FDA 3542, does the NDA applicant or NDA holder need to resubmit patent information on the updated form?

A9. Generally, yes.[41] FDA will not accept expired Forms FDA 3542a and 3542 unless the forms are the most updated versions available.[42] If an NDA applicant or NDA holder submits information on an expired version of Form FDA 3542a or Form FDA 3542 when an updated version of the form is available, the NDA applicant or NDA holder must resubmit the patent information on the most recent version of the form. This principle applies even if the submission of patent information relates to drug products or patents for which information was submitted previously on an expired version of the form.

Q10. What if the most updated versions of Forms FDA 3542a or FDA 3542 available on the FDA Forms website are expired?

A10. If the most updated forms posted on the FDA Forms website have reached their expiration date, NDA applicants and NDA holders should continue using these forms until a newer form is made available on the website.[43]

Q11. How should an NDA holder submit corrections or changes to previously submitted patent information for a listed patent?

A11. If the NDA holder is submitting a correction or change to previously submitted patent information for a listed patent, the NDA holder must submit the change or correction on the most updated version of Form FDA 3542 by checking "yes" on the box in field 1.g and following the instructions in field 1.h.[44] The change or correction to previously submitted patent information for a listed patent must comply with the requirements in 21 CFR 314.53. FDA will not accept the corrections or changes unless they are submitted on the appropriate forms.[45]

Q12. What if the NDA holder is adding a use code to an existing patent listing in the Orange Book?

A12. If the NDA holder is adding a use code to an existing patent listing, the NDA holder must submit the change on the most updated version of Form FDA 3542 by checking "yes" on the box

[41] If the NDA applicant or NDA holder submits an expired version of the form requiring patent information that no longer conforms with the current rules and regulations, FDA will require the NDA applicant or NDA holder to resubmit the patent information on the most updated version of the form. See, generally, 21 CFR 314.53.
[42] 21 CFR 314.53(c)(1); see also the "What should I do if the FDA form I need to use has expired?" web page at https://www.fda.gov/industry/fda-basics-industry/what-should-i-do-if-fda-form-i-need-use-has-expired.
[43] See 21 CFR 314.53(c)(1); see also the "What should I do if the FDA form I need to use has expired?" web page at https://www.fda.gov/industry/fda-basics-industry/what-should-i-do-if-fda-form-i-need-use-has-expired.
[44] See 21 CFR 314.53(f)(2).
[45] See 21 CFR 314.53(f)(2)(iii). In addition, a withdrawal or request to remove a patent from the list may also be submitted by letter. See 21 CFR 314.53(f)(2)(iv).

in field 1.g and following the instructions in field 1.h,[46] and must comply with the requirements in 21 CFR 314.53.[47]

Q13. If the NDA holder intends to remove a use code from an existing patent listing, how should the NDA holder communicate this intent?

A13. If the NDA holder intends to remove a use code from an existing patent listing, the NDA holder should state this intent to remove the use code in field 1.h of the most updated version of Form FDA 3542.[48] The NDA holder should also inform FDA it intends to remove a use code in the cover letter.

Q14. Will FDA consider modification of an existing use code to be a removal if field 1.h of the form does not include a statement of intent to remove the use code?

A14. No. Modifying an existing use code will not result in its removal if field 1.h does not include a statement of intent to remove the existing use code.[49] If an NDA holder intends to remove a use code from an existing patent listing, the NDA holder should state that intent in field 1.h of the most updated version of FDA Form 3542 and in the cover letter to FDA.

Q15. If an NDA applicant or NDA holder is submitting patent information for listing that is for a method-of-use patent only, does the NDA applicant or NDA holder need to check the "No" boxes in the drug substance and drug product sections?

A15. No. If the patent for which information is submitted for listing only claims a method of use and does not claim the drug substance or drug product, the NDA applicant or NDA holder should not check any boxes in section 2 (drug substance) or section 3 (drug product) of the forms.

B. Section 6 – Declaration Certification

Q16. Is the form automatically submitted to FDA after the form is signed electronically?

A16. No. After electronically signing a Form FDA 3542a or Form FDA 3542, the NDA applicant or NDA holder must save the form as a portable document format (PDF) file and submit the form to its NDA accompanied by a Form FDA 356h, Application to Market a New or

[46] See 21 CFR 314.53(f)(2).
[47] See the final rule, "Abbreviated New Drug Applications and 505(b)(2) Applications," published October 6, 2016 (81 FR 69580 at 69607-08), with effective date of December 5, 2016; see also 21 CFR 314.53(f)(2)(iii).
[48] See 21 CFR 314.53(f)(2)(i) and (iii). In addition, patent information, including use codes, will remain listed in the Orange Book until FDA has determined that no first applicant is eligible for 180-day exclusivity based on a paragraph IV certification to that patent or after the 180-day exclusivity period of a first applicant based on that patent has expired or has been extinguished. See 21 CFR 314.53(f)(2)(i).
[49] See 21 CFR 314.53(f)(2)(i) and (iii).

Abbreviated New Drug or Biologic for Human Use.[50] FDA recommends that NDA holders and NDA applicants include either the term *3542a* or *3542* in the file name, as appropriate.

Q17. Can the form be signed manually and submitted as a hard copy?

A17. No. Forms FDA 3542a and FDA 3542 and other submissions under sections 505(b), (i), and (j) of the FD&C Act must be signed electronically and submitted in the electronic format specified by FDA.[51]

Q18. If an attorney, agent, representative, or other authorized official who resides or maintains a place of business in the United States signs the form in field 6.2 on behalf of an NDA applicant, NDA holder, or patent owner, does that person need to provide a countersignature in field 6.3 if the NDA applicant, NDA holder, or patent owner does not reside or maintain a place of business in the United States?

A18. No. An attorney, agent, representative, or other authorized official who resides or maintains a place of business in the United States and is signing the form on behalf of the NDA applicant, NDA holder, or patent owner only needs to sign the form once. In this scenario, the attorney, agent, representative, or other authorized official can sign the form in field 6.2, check the applicable box for the NDA Applicant's, NDA Holder's, or Patent Owner's Attorney, Agent (Representative) or Other Authorized Official, and provide the contact information at the end of Section 6.[52]

Q19. Whose contact information should be provided at the end of Section 6, and how does it relate to the person(s) signing the form in fields 6.2 and 6.3?

A19. The contact information at the end of Section 6 must be provided for the person signing the form in field 6.2.[53] If the person signing the form in field 6.2, including an NDA applicant or NDA holder from outside of the United States, does not provide contact information at the end of Section 6, FDA will consider the form to be incomplete.[54]

C. Submitting Patent Information to FDA

Q20. Should an NDA applicant or NDA holder submit a copy of the patent to FDA along with Form FDA 3542a or Form FDA 3542?

A20. No. The NDA applicant or NDA holder does not need to submit a copy of the patent to FDA.

---

[50] See 21 CFR 314.50(h) and 21 CFR 314.53(d)(4). See also section 745A(a) of the FD&C Act; see also the guidance for industry *Providing Regulatory Submissions in Electronic Form — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (September 2024).
[51] 21 CFR 314.53(d)(4). See section 745A(a) of the FD&C Act; see also the guidance for industry *Providing Regulatory Submissions in Electronic Form — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (September 2024).
[52] See 21 CFR 314.53(c)(1), (c)(2)(i)(I), (c)(2)(ii)(J), and (c)(4).
[53] See 21 CFR 314.53(c)(1)–(2).
[54] Ibid.

Q21. Where are NDA holders and NDA applicants required to submit Forms FDA 3542a and FDA 3542?

A21. NDA holders and NDA applicants must submit Forms FDA 3542a and FDA 3542 to FDA under their NDA via the Center for Drug Evaluation and Research (CDER) Central Document Room through the Electronic Submissions Gateway in the electronic format specified by FDA.[55] NDA holders and NDA applicants should not submit either form directly to other divisions within FDA, including the Division of Orange Book Publication and Regulatory Assessment (DOBPRA) in the Office of Generic Drugs.[56]

Q22. To ensure patent information is timely filed and listed in the Orange Book, can an NDA holder send a courtesy copy of the patent information submission to the Orange Book staff?

A22. No. Courtesy copies should not be submitted (such as through fax, electronic message, or physical mail) to FDA, including DOBPRA. DOBPRA intends to rely only on submissions of Form FDA 3542 that are received from the CDER Central Document Room through the Electronic Submissions Gateway and to disregard any duplicative copies or courtesy copies of Form FDA 3542 that are submitted through other channels.[57] For purposes of determining whether patent information has been timely filed, patent information is considered submitted to FDA on the earlier of the date that the form is date-stamped by the Central Document Room, or officially received by FDA in an electronic format submission that complies with § 314.50(l)(5).[58]

Q23. What if the submitted Form FDA 3542 is incomplete?

A23. If the NDA holder timely submits the required information on Form FDA 3542, but FDA notifies the NDA holder that its Form FDA 3542 is incomplete or shows that the patent is not eligible for listing, the NDA holder must submit an acceptable (i.e., a complete form that shows that the patent is eligible for listing) Form FDA 3542 within 15 days of FDA's notification to be considered timely filed as of the date of the original submission of patent information.[59]

Q24. Is the 15-day period to submit an acceptable (i.e., complete) Form FDA 3542 based on business or calendar days?

---

[55] 21 CFR 314.53(d)(4). The Electronic Submissions Gateway is available at https://www.fda.gov/industry/electronic-submissions-gateway. Questions related to electronic submissions should be emailed to the CDER Electronic Submission Team at esub@fda.hhs.gov. For additional information, see the guidance for industry *Providing Regulatory Submissions in Electronic Form — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (September 2024).

[56] 21 CFR 314.53(d)(4).

[57] The Electronic Submissions Gateway is available at https://www.fda.gov/industry/electronic-submissions-gateway. Questions related to electronic submissions should be emailed to the CDER Electronic Submission Team at esub@fda.hhs.gov. See also 21 CFR 314.53(d)(4).

[58] 21 CFR 314.53(d)(5).

[59] 21 CFR 314.53(c)(2)(ii).

A24. It is 15 calendar days.[60]

Q25. Should an NDA applicant or NDA holder submit information on a patent before it has been issued by the USPTO?

A25. No. NDA applicants and NDA holders should not submit any information on patents that have not yet been issued. Only information about patents that have been issued by the USPTO should be submitted with Forms FDA 3542a and FDA 3542.[61] NDA holders must submit information on patents within 30 days of the date of issuance of the patent or within 30 days after NDA approval.[62]

Q26. If the USPTO has reissued a patent, can information on the reissued patent and the original patent both be listed in the Orange Book?

A26. If the NDA holder determines that a patent or patent claim no longer meets the statutory requirements for listing in section 505(b)(1) or (c)(2) of the FD&C Act (e.g., because the original patent has been surrendered upon reissuance), the NDA holder must promptly notify FDA to amend or withdraw the patent information and request that the patent information be removed from the Orange Book.[63]

If the Orange Book patent list reflects that an NDA holder has requested that information on a patent be removed from the Orange Book, and one or more first applicants[64] are eligible for 180-day exclusivity based on a paragraph IV certification to that patent, the patent information will remain listed in the Orange Book until any 180-day exclusivity based on that patent has expired or has been extinguished.[65] Accordingly, there may be circumstances in which information on both the original patent and the reissued patent are listed in the Orange Book.[66]

Q27. If an NDA holder has discontinued marketing a drug product for business reasons but has not requested that FDA withdraw approval of the NDA, is the NDA holder

---

[60] Ibid.
[61] 21 CFR 314.53(b).
[62] 21 CFR 314.53(c)(2)(ii) and (d); see also 21 CFR 314.50(i)(4).
[63] 21 CFR 314.53(f)(2)(i); see also the final rule, "Abbreviated New Drug Applications and 505(b)(2) Applications," published October 6, 2016 (81 FR 69580 at 69601).
[64] *First applicant* is defined in FDA regulations as "an ANDA applicant that, on the first day on which a substantially complete application containing a paragraph IV certification is submitted for approval of a drug, submits a substantially complete application that contains, and for which the applicant lawfully maintains, a paragraph IV certification for the drug" (see 21 CFR 314.3(b)).
[65] 21 CFR 314.53(f)(2)(i); 21 CFR 314.94(a)(12)(viii)(B).
[66] See the final rule and the preamble to the final rule, "Abbreviated New Drug Applications and 505(b)(2) Applications," published October 6, 2016 (81 FR 69580 at 69601). ("Upon patent reissuance, the original patent is surrendered and ceases to have legal effect (see 37 CFR 1.178(a)). Thus, an NDA holder is required to withdraw the original patent and request that the original patent be removed from listing in the Orange Book after patent reissuance (see [21 CFR] 314.53(f)(2)). Consistent with [FDA's] policy for any request to remove a patent from listing in the Orange Book, an original patent that has been reissued would remain listed in the Orange Book until FDA determined that no first applicant is eligible for 180-day exclusivity based on a paragraph IV certification to that patent or after the 180-day exclusivity period of a first applicant based on that patent has expired or has been extinguished.").

required to submit information on a newly issued patent that claims the discontinued drug product?

A27. Yes. NDA holders must continue to comply with the statutory requirements for patent listing for approved drug products that have been discontinued from marketing.[67]

Q28. Has FDA identified common deficiencies in Form FDA 3542 submissions?

A28. Yes. Below is a nonexhaustive list of common deficiencies in submitted Form FDA 3542:

- Field 1: Failure to identify any applicable U.S. agent[68] for either the patent owner or NDA holder when either the patent owner or NDA holder reside outside of the United States. If the same U.S. agent identified in 1.f represents both the patent owner and NDA holder, field 1.f should name the U.S. agent and have checked the "Both" box to specify that the agent represents both parties. If the patent owner and NDA holder have different U.S. agents, field 1.f should list both agents by using the "Add Section 1.f." button and have checked the appropriate box to specify whether that agent represents the patent owner or the NDA holder.

- Field 1.h: Failure to describe and clearly explain all changes made by the NDA holder to a use code listed for its drug product in the Orange Book.[69] For example, this may occur when an NDA holder submits a modification of a currently listed use code and intends to remove the currently listed use code. The currently listed use code will not be removed if the NDA holder did not provide a statement of the intent to remove this patent information. If intending to remove a currently listed use code, the NDA holder should explicitly state this intent in the cover letter and in field 1.h.[70]

- Field 4.2a: Failure to identify the specific subsections of the approved product labeling that describe the approved method of use claimed by the patent submitted.[71] If there are no applicable subsections, NDA holders should insert "subsection N/A."

- Field 4.2b: Where an NDA holder submits patent information pursuant to 21 CFR 314.53(d)(2)(i) upon approval of a supplement and intends to use an existing use code, failure to submit a use code identical to the use code published in the Orange Book. If intending to list a patent with an existing use code, and no changes are sought to the use

[67] 21 CFR 314.53(a) ("This section applies to any applicant who submits to FDA an NDA or an amendment to it . . . or a supplement to an approved NDA . . . ."); 21 CFR 314.53(d)(3) ("If a patent is issued for a drug substance, drug product, or method of use after an NDA is approved, the applicant must submit to FDA, as described in paragraph (d)(4) of this section, the required patent information within 30 days of the date of issuance of the patent"); see also, e.g., 21 CFR 314.150, 314.80, and 314.81.
[68] See 21 CFR 314.53(c)(2)(i)(I) and (ii)(J). For more information on U.S. agents, see the U.S. Agents web page at https://www.fda.gov/medical-devices/device-registration-and-listing/us-agents.
[69] 21 CFR 314.53(d)(2)(ii).
[70] 21 CFR 314.53(f)(2)(iii).
[71] 21 CFR 314.53(c)(2)(i)(O)(*2*) and (c)(2)(ii)(P)(*2*).

code, the NDA applicant or NDA holder should ensure the use code description matches the corresponding use code description in the Orange Book.

To avoid common mistakes, FDA encourages NDA applicants and NDA holders to review the current instructions for filling out Forms FDA 3542a and FDA 3542. The latest versions of these instructions are located on the FDA Forms web page at https://www.fda.gov/about-fda/reports-manuals-forms/forms.

Q29. How can FDA staff be reached to answer additional questions regarding Forms FDA 3542a and FDA 3542?

A29. For answers to additional questions regarding Forms FDA 3542a and FDA 3542, or for follow-up questions regarding an electronic submission, contact DOBPRA at OrangeBook@fda.hhs.gov.