

An Overview of FDA's Patent Listing Process

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Division of Legal and Regulatory Support (DLRS)

Office of Generic Drugs Policy (OGDP)

CDER | U.S. FDA

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Learning Objectives

- Provide an overview of patent listing requirements
- Explain patent information submission process
- Explain key aspects of Form FDA 3542

Statutory and Regulatory Background



- Patents are granted by U.S. Patent and Trademark Office (USPTO)
- New Drug Application (NDA) applicants are required to file patent information for each patent that claims the drug or a method of using their drug:
 - Drug Substance (active ingredient) patents
 - Drug Product (formulation and composition) patents
 - Method of Use (MOU) patents
- The FD&C Act establishes requirements for FDA to list patent information in the Orange Book

Statutory and Regulatory Background



- FDA has a ministerial role with regard to the listing of patent information
- Patent information must be submitted on the appropriate form, Form FDA 3542 or 3542a

Patent Submission Requirement



- Patent information must be included with all original NDAs and certain supplemental NDAs
 - Must use FORM FDA 3542a
 - Form FDA 3542a should not be submitted to the Orange Book Staff (submit to the NDA file)

Patent Submission Requirement



- Patent information for listing in the Orange Book must be on Form FDA 3542, and must be submitted:
 - Within 30 days following approval of an NDA or sNDA
 - Within 30 days of the issuance of the patent, for patents issued after approval
- Incomplete Form FDA 3542
 - must submit an acceptable Form FDA 3542 within 15 days of FDA's notification that the form is incomplete



Challenge Question #1

To make sure your patent information is appropriately listed in the Orange Book, the FDA is required to

- A. Verify the accuracy of your patent(s) with USPTO
- B. Verify the accuracy of your patent(s) with court filing
- C. Verify the accuracy of your patent(s) with OGD's Patent and Exclusivity Team (PET)
- D. FDA's role is ministerial only

Request to Amend Patent Listing Info



- If the NDA holder determines that a patent or patent claim no longer meets the requirements for listing in the Orange Book, the NDA holder must promptly notify FDA to amend the patent information or withdraw the patent or patent information.

Form FDA 3542 Information



Forms expire after 3 years

Last update was in 2019

Current form expiration date:
10/31/2022



**Current forms and information can
be found**

[Forms webpage](#)

[SBIA webinar](#)

Highlight of New Form FDA 3542

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration PATENT INFORMATION SUBMITTED UPON AND AFTER APPROVAL OF AN NDA OR SUPPLEMENT <i>For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation or Composition) and/or Method of Use</i>		Form Approved: OMB No. 0910-0513 Expiration Date: 10/31/2022 See OMB Statement on last page.
		NDA Number 1536453
		Name of NDA Holder Drug Industries
Refer to instruction sheet (FORM FDA 3542 SUPPLEMENT) for more information.		
The following is provided in accordance with Section 505(b) and (c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).		
Active Ingredient(s) BETAMETHASONE VALERATE; CLINDAMYCIN PHOSPHATE; DEXAMETHASONE SODIUM PHOSPHATE; HYDROCORTISON ACETATE; NYSTATIN; MOMETASONE FUROATE; MUPIROCIIN CALCIUM; CLOTRIMAZOLE; MECLIZINE SULFOSALICYLATE		
Trade Name G	Strength(s) (Include applicable Product Number, if available - See instructions) PRODUCT 001: 3 GM/ML; 10%	
Dosage Form(s) OINTMENT	Route(s) of Administration TOPICAL	Type of Use <input checked="" type="checkbox"/> Prescription <input type="checkbox"/> Over-the-Counter
Approval Date of NDA or Supplement to which patent information relates (Enter date, and select either NDA or Supplement.) 09/24/2020 <input checked="" type="checkbox"/> NDA <input type="checkbox"/> Supplement		

Version

More characters

Product number

Highlight of New Form FDA 3542

<p>e. <u>Name of U.S. agent or representative</u> who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the FD&C Act and 21 CFR 314.52 and 314.95. Using the checkboxes provided, indicate whether the person represents the patent owner, NDA holder, or both.</p> <p>Name: <u>John Smith</u></p> <p>Represents (Select one): <input checked="" type="checkbox"/> Patent Owner <input type="checkbox"/> NDA Holder <input type="checkbox"/> Both</p>		<p>Address (of agent or representative named in 1.e.)</p> <p>City/State</p> <p>ZIP Code FAX Number (if available)</p> <p>Telephone Number E-Mail Address (if available)</p>	
<p>e. <u>Name of U.S. agent or representative</u> who resides or maintains a place of business within the United States authorized to receive notice of patent certification under section 505(b)(3) and (j)(2)(B) of the FD&C Act and 21 CFR 314.52 and 314.95. Using the checkboxes provided, indicate whether the person represents the patent owner, NDA holder, or both.</p> <p>Name: <u>Jane Doe</u></p> <p>Represents (Select one): <input type="checkbox"/> Patent Owner <input checked="" type="checkbox"/> NDA Holder <input type="checkbox"/> Both</p>		<p>Address (of agent or representative named in 1.e.)</p> <p>City/State</p> <p>ZIP Code FAX Number (if available)</p> <p>Telephone Number E-Mail Address (if available)</p>	

Click for additional set of 1.e. entries (including all address and related contact items above). May be repeated.

Add Section 1.e.

New checkboxes

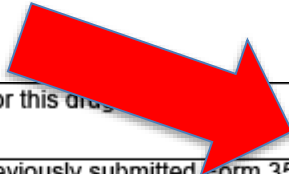
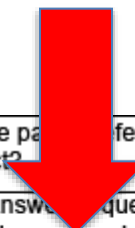
Click to create new section

New checkboxes

Highlight of New Form FDA 3542

- Identify all changes, e.g., addition of new MOU, patent date extension, etc.

New Instruction for Information regarding MOU changes



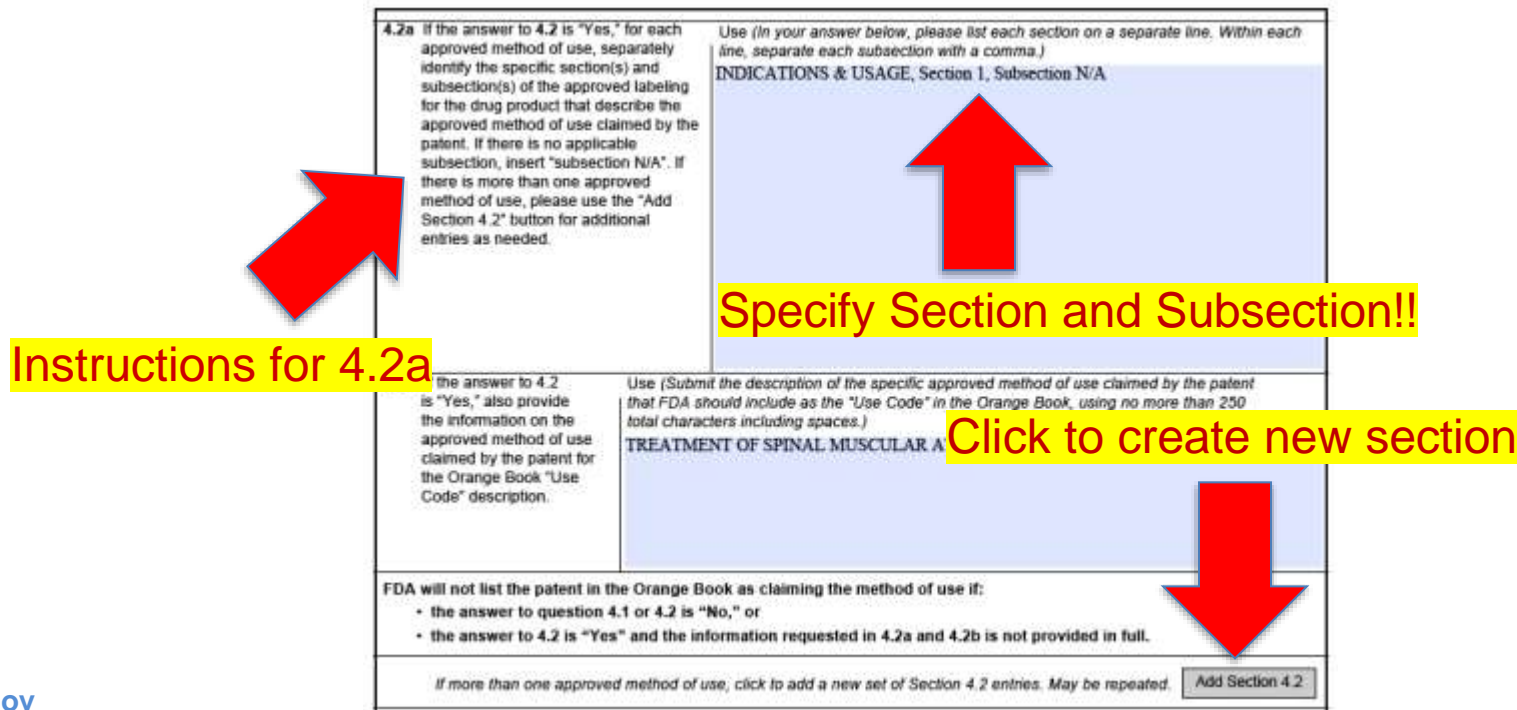
g. Has the patent referenced above been submitted previously for listing for this drug product? ☒ Yes ☐ No

h. If the answer to question 1.g. is "Yes," identify all change(s) from the previously submitted Form 3542 and specify whether each change is related to the patent or related to an FDA action or procedure. (See FORM FDA 3542 SUPPLEMENT – FORM INSTRUCTIONS for additional information regarding changes to the method(s) of use listed for the patent).

Relates to FDA Action: NDAXxx was initially approved for the treatment of COPD with a single strength product; this sNDA adds a new indication (asthma) using the initial approved strength, as well as a second strength product; This 3542 recites additional MOT patent claims for indications. Claims of 1234567 cover both strengths

Highlight of New Form FDA 3542

- Identify Section and subsection in 4.2a



The image shows a screenshot of Form FDA 3542 with several annotations. A red arrow points from the 'Instructions for 4.2a' text box to the 4.2a instruction area. Another red arrow points from the 'Specify Section and Subsection!!' text box to the 'INDICATIONS & USAGE, Section 1, Subsection N/A' area. A third red arrow points from the 'Click to create new section' text box to the 'Add Section 4.2' button.

Instructions for 4.2a

4.2a If the answer to 4.2 is "Yes," for each approved method of use, separately identify the specific section(s) and subsection(s) of the approved labeling for the drug product that describe the approved method of use claimed by the patent. If there is no applicable subsection, insert "subsection N/A". If there is more than one approved method of use, please use the "Add Section 4.2" button for additional entries as needed.

Use (In your answer below, please list each section on a separate line. Within each line, separate each subsection with a comma.)
INDICATIONS & USAGE, Section 1, Subsection N/A

Specify Section and Subsection!!

Use (Submit the description of the specific approved method of use claimed by the patent that FDA should include as the "Use Code" in the Orange Book, using no more than 250 total characters including spaces.)
TREATMENT OF SPINAL MUSCULAR A

Click to create new section

FDA will not list the patent in the Orange Book as claiming the method of use if:

- the answer to question 4.1 or 4.2 is "No," or
- the answer to 4.2 is "Yes" and the information requested in 4.2a and 4.2b is not provided in full.

If more than one approved method of use, click to add a new set of Section 4.2 entries. May be repeated.

Add Section 4.2

Highlight of New Form FDA 3542

<p>6.1 The undersigned declares that this is an accurate and complete submission of patent information for the NDA or supplement approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This time-sensitive patent information or response to a request under 21 CFR 314.53(f)(1) is submitted pursuant to 21 CFR 314.53. I attest that I am familiar with 21 CFR 314.53 and this submission complies with the requirements of the regulation. I verify under penalty of perjury that the foregoing is true and correct.</p> <p>Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.</p>	
<p>6.2 Authorized Signature of NDA Holder or Patent Owner (Attorney, Agent, Representative or other Authorized Official) (Provide Information below)</p> <p style="text-align: right;">Sign</p>	<p>Date Signed</p>
<p>6.3 Signature of Authorized U.S. Agent</p> <p style="text-align: right;">Countersign</p>	<p>Date Signed</p>

Don't forget to sign the form

Declaration directly to the FDA. A patent owner who is not the NDA holder is submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

<input type="checkbox"/> NDA Holder	<input type="checkbox"/> NDA Holder's Attorney, Agent (Representative) or Other Authorized Official
<input type="checkbox"/> Patent Owner	<input type="checkbox"/> Patent Owner's Attorney, Agent (Representative) or Other Authorized Official
<p>Name</p>	

Submitting Form FDA 3542



- Electronically to the NDA via CDER Central Document Room
- Do **not** submit directly to the Orange Book staff
- Do **not** submit a **copy** of the patent to FDA



Challenge Question #2

After receiving FDA's notification that your Form FDA 3542 is incomplete, you must submit an acceptable Form FDA 3542 to the Agency within

- A. 10 days
- B. 15 days
- C. 30 days
- D. 45 days

Resources

- [FDA regulations to submission of patent information \(21 CFR 314.53\)](#)
- [Form FDA 3542](#)
- [Electronic Orange Book](#)
- [FDA Introduces patent submission date update to the Orange Book](#)
- [Frequently Asked Questions on Patents and Exclusivity](#)

Summary



- FDA has a ministerial role with regard to the listing of patent information
- Know the differences between Form FDA 3542 and Form FDA 3542a and when each should be submitted
- Submit within the required timeframes for the patent information to be considered timely filed

Questions?

Orangebook@fda.hhs.gov



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ADMINISTRATION