What's New with Forms FDA 3542 and 3542a

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Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Agenda

I. Introduction to Forms FDA 3542a and 3542
II. Walk-through of Form 3542
III. Frequently asked questions

What are Forms FDA 3542a and 3542?

- Patent information submitted to FDA
- Form FDA 3542a:
  - Submitted with original unapproved NDA, amendment, or supplement
- Form FDA 3542:
  - Submitted within 30 days after new drug application (NDA) or supplement approval
  - Within 30 days of patent issuance as required by 21 CFR 314.53(c)(2)(ii)
- Orange Book publishes certain information provided on Form FDA 3542

Why Were the Forms Updated?

- ✓ Reduce time needed to complete and process forms
- ✓ Update certain form fields in response to common errors
- ✓ Provide technical fixes to streamline form completion

What Changes Were Made?

- Increased character limit for Active Ingredient and Strength fields
- Field 1e: Checkboxes added that specify whether U.S. Agent represents patent owner, NDA holder, or both
- Field 1h: Information regarding Method of Use changes added
- Field 4.2: Clarifying language added
- Certain date restrictions removed

FORM FDA 3542: WALK-THROUGH WITH MOCK DATA

What's new in Form FDA 3542

Form FDA 3542: Application Information

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

PATENT INFORMATION SUBMITTED UPON AND AFTER APPROVAL OF AN NDA OR SUPPLEMENT

For Each Patent That Claims a Drug Substance (Active Ingredient), Drug Product (Formulation or Composition) and/or Method of Use

Form Approved: OMB No. 0910-0513
See OMB Statement on last page.

NDA Number
876543

Name of NDA Holder
Drug Pharmaceuticals

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)
CALCIPHEROUS CHLORIDE; METHYLDEXTROSE; MAGNACIFEROUS HYDROCHLORIDE; GLUTATIONEOXIDE; PENTYLHEXADYL CHLORIDE; SODIUM BIHEXYLNATE; SODIUM HYDROCHLORIDE; SODIUM PENTYLPHOSPHATE; TRIHEXIDINE HYDROCHLORIDE

Trade Name
Lettdrug

Strength(s) *(Include applicable Product Number, if available - See instructions)*
0.255MCG/ML;0.392MCG/ML;0.42MCG/ML;0.384MCG/ML;0.378MCG/ML;23.1MCG/ML;75.14MCG/ML;1.42MCG/ML

Dosage Form(s)	Route(s) of Administration	Type of Use
Tablets	Oral	☒ Prescription ☐ Over-the-Counter

Approval Date of NDA or Supplement to which patent information relates *(Enter date, and select either NDA or Supplement.)*
07/20/2019 ☐ NDA ☒ Supplement

Form FDA 3542: Application Information, continued

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Trade Name	Strength(s) *(Include applicable Product Number, if available - See instructions)*
Lettdrug	[Product 001] 0.255MCG/ML;0.392MCG/ML;0.42MCG/ML;0.384MCG/ML;0.378MCG/ML;23.1MCG/ML;75.14MCG/ML;1.42MCG/ML

Dosage Form(s)	Route(s) of Administration	Type of Use
Tablets	Oral	☒ Prescription ☐ Over-the-Counter

Approval Date of NDA or Supplement to which patent information relates *(Enter date, and select either NDA or Supplement.)*

07/20/2019 ☐ NDA ☒ Supplement

Form FDA 3542: Fields 1a – 1d

This patent declaration form is required to be submitted to the Food and Drug Administration (FDA) within thirty (30) days after the date of approval of an NDA or supplement or within thirty (30) days of issuance of a patent as required by 21 CFR 314.53(c)(2)(ii) at the address provided in 21 CFR 314.53(d)(4). Except as provided in 21 CFR 314.53(f)(1), a patent declaration form containing an amendment to the description of the approved method(s) of use claimed by the patent is required to be submitted to FDA within thirty (30) days of patent issuance, within thirty (30) days of approval of a corresponding change to product labeling, or within thirty (30) days of a decision described in 21 CFR 314.50(i)(4)(i)(C) or 314.94(a)(12)(vi)(A)(*3*).

FDA will not list patent information if the patent declaration does not contain the information required by 21 CFR § 314.53(c)(2) or the patent declaration indicates the patent is not eligible for listing.

For each patent submitted for the approved NDA or supplement referenced above, you must submit the information described below. If you are not submitting any patents for this NDA or supplement, complete the section above and sections 5 and 6.

1. GENERAL *(Please note: If 1.a is NOT entered, then section 5 later in form must be marked as "Yes" in its check box.)*

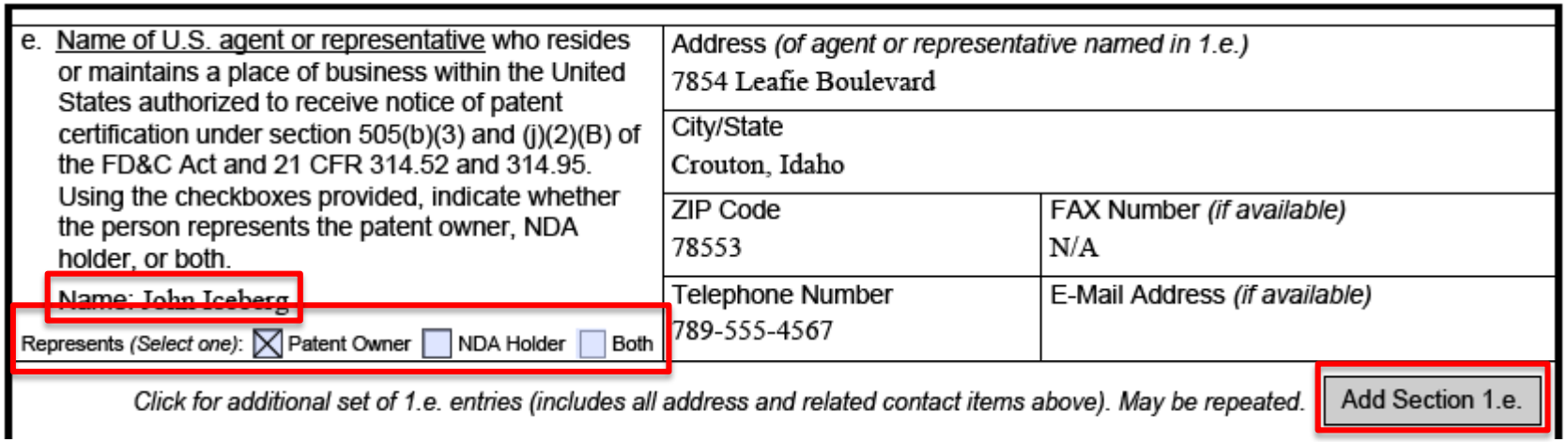
a. United States Patent Number	b. Issue Date of Patent	c. Expiration Date of Patent
27654321	07/23/2017	07/12/2032

d. Name of Patent Owner
Romaine Institute

Address *(of Patent Owner)*	City		
19000 Olive Street	Wedge		
State/Province/Region	**Country**	**ZIP or Postal Code**	
Thousand Islands	Iceland	54321	
FAX Number *(if available)*	**Telephone Number**	**E-Mail Address** *(if available)*	
N/A	354-555-7890		

Click for additional set of 1.d. entries (includes all address and related contact items above). May be repeated. Add Section 1.d.

Form FDA 3542: Field 1e



e. Name of U.S. agent or representative 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.

Name: John Iceberg

Represents *(Select one)*: ☒ Patent Owner ☐ NDA Holder ☐ Both

Address *(of agent or representative named in 1.e.)*
7854 Leafie Boulevard

City/State
Crouton, Idaho

ZIP Code
78553

FAX Number *(if available)*
N/A

Telephone Number
789-555-4567

E-Mail Address *(if available)*

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

Form FDA 3542: Field 1e, continued

e. Name of U.S. agent or representative 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. Name: John Iceberg Represents *(Select one)*: ☒ Patent Owner ☐ NDA Holder ☐ Both	Address *(of agent or representative named in 1.e.)* 7854 Leafie Boulevard	
	City/State Crouton, Idaho	
	ZIP Code 78553	FAX Number *(if available)* N/A
	Telephone Number 789-555-4567	E-Mail Address *(if available)*
e. Name of U.S. agent or representative 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. Name: Mary Roman Represents *(Select one)*: ☐ Patent Owner ☒ NDA Holder ☐ Both	Address *(of agent or representative named in 1.e.)* 4562 Cabbage Drive	
	City/State Dressing, Wisconsin	
	ZIP Code 65489	FAX Number *(if available)* N/A
	Telephone Number 544-232-5467	E-Mail Address *(if available)*

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

Form FDA 3542: Fields 1f – 1h

f. Name of NDA Holder Drug Pharmaceuticals			
Address *(of NDA Holder)* 71624 Cobb Road		City Choppin	
State/Province/Region Thousand Islands	Country Iceland		ZIP or Postal Code 54321
FAX Number *(if available)* N/A	Telephone Number 354-555-7890	E-Mail Address *(if available)*	
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).			

Form FDA 3542: Fields 2.1 – 2.6

For the patent referenced above, provide the following information on whether the patent claims the drug substance, drug product, or method of use that is the subject of the approved NDA or supplement. FDA will not list patent information if the patent declaration does not contain the information required by 21 CFR § 314.53(c)(2) or the patent declaration indicates the patent is not eligible for listing.

- ***If the patent is eligible for listing as claiming the drug substance and section 2 is completed, it is not necessary to complete section 3 even if the patent also is eligible for listing as claiming the drug product.***
- ***If the patent is eligible for listing as claiming the drug product and section 3 is completed, it is not necessary to complete section 2 even if the patent also is eligible for listing as claiming the drug substance.***

FDA will consider incomplete a patent declaration that does not include a response to all required questions contained within each section below applicable to the patent referenced above.

2. DRUG SUBSTANCE (ACTIVE INGREDIENT)		
2.1 Does the patent claim the drug substance that is the active ingredient in the drug product described in the approved NDA or supplement? If yes, skip to Question 2.5.	☒ Yes	☐ No
2.2 Does the patent claim only a drug substance that is a different polymorph of the active ingredient described in the NDA?	☐ Yes	☐ No
2.3 If the answer to question **2.2** is "Yes," do you certify that, as of the date of this declaration, you have test data demonstrating that a drug product containing the polymorph will perform the same as the drug product described in the NDA? The type of test data required is described at 21 CFR 314.53(b).	☐ Yes	☐ No
2.4 Specify the polymorphic form(s) claimed by the patent for which you have the test results described in **2.3**.		
2.5 Does the patent claim only a metabolite of the approved active ingredient? *(Complete the information in section 4 below if the patent claims an approved method of using the approved drug product to administer the metabolite.)*	☐ Yes	☒ No
2.6 Does the patent claim only an intermediate?	☐ Yes	☒ No

Form FDA 3542: Fields 2.7 – 3.3

2.7 If the patent referenced in **2.1** is a product-by-process patent, is the product claimed in the patent novel?	☒ Not Applicable	☐ Yes	☐ No
FDA will not list the patent in the Orange Book as claiming the drug substance if: • **the answers to 2.1 and 2.2 are "No," or,** • **the answer to 2.2 is "Yes" and the answer to 2.3 is "No," or,** • **the answer to 2.3 is "Yes" and there is no response to 2.4, or,** • **the answer to 2.5 or 2.6 is "Yes."** • **the answer to 2.7 is "No."**			
3. DRUG PRODUCT (COMPOSITION/FORMULATION)			
3.1 Does the patent claim the approved drug product as defined in 21 CFR 314.3?		☒ Yes	☐ No
3.2 Does the patent claim only an intermediate?		☐ Yes	☒ No
3.3 If the patent referenced in **3.1** is a product-by-process patent, is the product claimed in the patent novel?	☒ Not Applicable	☐ Yes	☐ No
FDA will not list the patent in the Orange Book as claiming the drug product if: • **the answer to question 3.1 is "No," or,** • **the answer to question 3.2 is "Yes," or,** • **the answer to 3.3 is "No."**			

Form FDA 3542: Method of Use

4. METHOD OF USE

NDA holders must submit the information in section 4 for each approved method of using the approved drug product claimed by the patent. An NDA holder may list together multiple patent claims for each approved method of use; however, each approved method of use claimed by the patent must be separately identified within this section. Continuation pages may be used to separately list method of use information within this section. For each approved method of use claimed by the patent, provide the following information:

4.1 Does the patent claim one or more approved methods of using the approved drug product? *(Select one)*

- ☐ Yes (only one approved method of use)
- ☒ Yes (more than one approved method of use)
- ☐ No

4.2 Patent Claim Number(s) *(as listed in the patent) (Please separate numbers with commas.)*

Claims 1,2,3,4, 7-14

Does (Do) the patent claim(s) referenced in **4.2** claim an approved method of use of the approved drug product?

- ☒ Yes
- ☐ No

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.)*

PLR Format: Section 1 (Indications and Usage), Subsection 1 (Treatment of lettuce aversion in patients also being treated for salad dressing aversion)

Non- PLR Format: Section: Indications and Usage, Subsection: Treatment of lettuce aversion in patients also being treated for salad dressing aversion

Nonprescription drug products: Section: Uses, Subsection: N/A

If there is no applicable subsection, insert "subsection N/A"

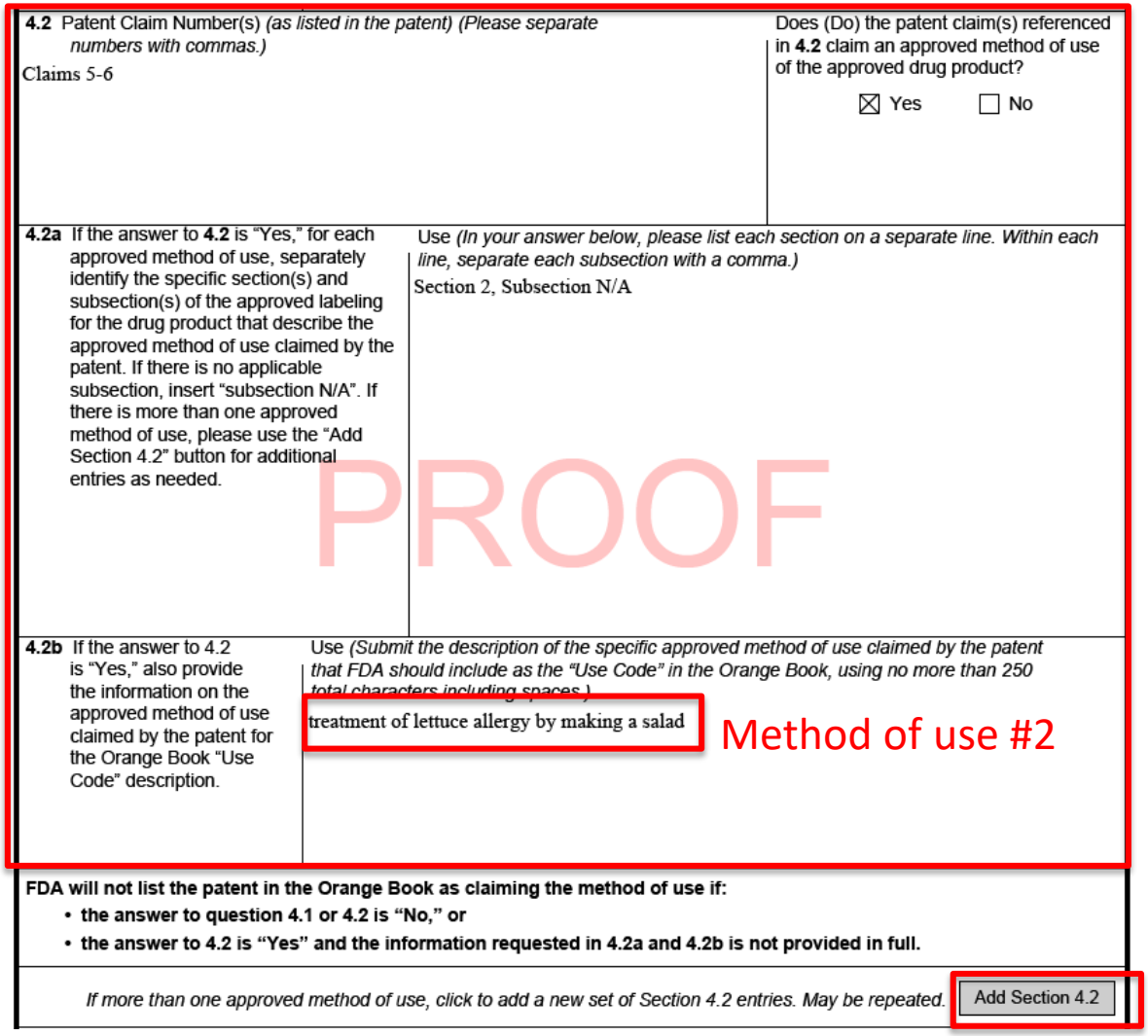
4.2b If the answer to 4.2 is "Yes," also provide the information on the approved method of use claimed by the patent for the Orange Book "Use Code" description.

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 lettuce aversion in patients also being treated for salad dressing aversion

Method of use #1

Form FDA 3542: Method of Use #2



4.2 Patent Claim Number(s) *(as listed in the patent) (Please separate numbers with commas.)*

Claims 5-6

Does (Do) the patent claim(s) referenced in **4.2** claim an approved method of use of the approved drug product?

☒ Yes ☐ No

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.)*

Section 2, Subsection N/A

4.2b If the answer to 4.2 is "Yes," also provide the information on the approved method of use claimed by the patent for the Orange Book "Use Code" description.

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 lettuce allergy by making a salad

Method of use #2

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

Form FDA 3542: Fields 6.1 – 6.3

6. DECLARATION CERTIFICATION

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.***

Warning: A willfully and knowingly false statement is a criminal offense under 18 U.S.C. 1001.

6.2 Authorized Signature of NDA Holder or Patent Owner *(Attorney, Agent, Representative or other Authorized Official) (Provide Information below)*	Date Signed
Alicia Chen -S Sign	07/23/2019
6.3 Countersignature of Authorized U.S. Agent	Date Signed
Countersign	

NOTE: Only an NDA holder may submit this declaration directly to the FDA. A patent owner who is not the NDA holder is authorized to sign the declaration but may not submit it directly to FDA. 21 CFR 314.53(c)(4) and (d)(4).

Check applicable box and provide information below.

☒ NDA Holder	☐ NDA Holder's Attorney, Agent (Representative) or Other Authorized Official
☐ Patent Owner	☐ Patent Owner's Attorney, Agent (Representative) or Other Authorized Official

Name		
Kendra Stewart		
Address		City
71624 Cobb Road		Choppin
State/Province/Region	Country	ZIP or Postal Code
Thousand Islands	Iceland	54321
FAX Number *(if available)*	Telephone Number	E-Mail Address *(if available)*
N/A	+354-555-7890 ext 1234	

FREQUENTLY ASKED QUESTIONS

Forms FDA 3542a and 3542

Which form should I use to submit a patent for Orange Book listing?

- **Form FDA 3542**
  - Used to submit patent information on a patent that claims the following:
    - An *approved* drug
    - An *approved* method of using the drug
  - Submitted upon approval of an NDA or supplement

Where can I find the updated forms?

- **FDA's Forms Webpage** http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm
  - Search: "3542"
- Separate form instructions:
  - Patent Information Submitted With the Filing of An NDA, Amendment, or Supplement-CDER [**3542** Supplement]

Who is responsible for submitting Forms FDA 3542a and 3542 to the FDA?

- NDA holder/applicant

If I have a new supplemental approval, should I resubmit already listed patents on the new forms?

- **No.** If patent information was submitted on the old versions of Forms 3542a and 3542, patent information does not need to be re-submitted on the updated forms to maintain their current Orange Book listings

Where should I submit the forms?

- 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

What if the submitted form is incomplete?

- FDA will notify the NDA holder
- NDA holder must submit acceptable Form FDA 3542 within 15 days of FDA's notification
  - If not submitted within 15 days, the Form will not be considered timely filed as of the date of the original submission of patent information

Can I submit more than one patent on the form?

- **No.** Each patent the NDA holder wants listed in the Orange Book must be submitted on separate Forms FDA 3542a and 3542.

Questions on Listed Patents

- For questions on Orange Book-listed patents, you may contact:
  - Orange Book Staff
  - E-mail: orangebook@fda.hhs.gov

Other questions?

- Contact the Division of Drug Information (DDI)
  - Phone: 855-543-3784
  - E-mail: druginfo@fda.hhs.gov

Helpful Links

- Orange Book: www.fda.gov/orangebook
- CFR Search: https://www.ecfr.gov/
- FDA Forms: https://www.fda.gov/about-fda/reports-manuals-forms/forms


FDA
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ADMINISTRATION