What's New with Forms FDA 3542a and 3542

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Agenda

Introduction to Forms FDA 3542a and 3542

Walk-through of Form 3542

Frequently asked questions

What are Forms FDA 3542a and 3542 Used For?

- Submit patent information to FDA
- Form FDA 3542a is required to be submitted to FDA with an original unapproved NDA application, amendment, or supplement
- Form FDA 3542 is required to be submitted to the NDA within 30 days after the date of approval of the NDA or supplement or within 30 days of issuance of a patent as required by 21 CFR 314.53(c)(2)(ii)
- Certain information provided on Form FDA 3542 is published in the Orange Book

Why Were the Forms Updated?

- To conform to the regulatory changes made in the final rule on "Abbreviated New Drug Applications and 505(b)(2) Applications" effective December 5, 2016, and to facilitate electronic completion of the form

What Changes Were Made?

- For patents eligible for listing in the Orange Book as claiming both the drug substance and drug product, an applicant is only required to identify one of these two bases for listing
- Information regarding polymorphs is required only if the patent claims only a drug substance that is a different polymorph
- Clarified requirements for submitting the use code and identifying the specific section(s) and subsection(s) of labeling that describe the method of use claimed by the patent

When to start using the Updated Forms?

- December 5, 2016, provided that FDA receives clearance of the revised forms under the Paperwork Reduction Act by that date
- FDA will no longer accept the previous version

Walk-through of Form FDA 3542 with Mock Data

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 Expiration Date: xx/xx/xxxx 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.

Trade Name Lettdrug	Active Ingredient(s) Lettuce Chloride
Dosage Form(s) Tablets	Strength(s) 10 mg
Route(s) of Administration Oral	Type of Use ☒ Prescription ☐ Over-the-Counter

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

11/10/2016 ☒ NDA ☐ Supplement

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.

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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
0007654321	06/11/2015	06/11/2032

d. Name of Patent Owner		
Romaine Institute		
Address *(of Patent Owner)*		City
19000 Olive Street		Wedge
State/Province/Region	Country	ZIP or Postal Code
Florida	United States	12345

FAX Number *(if available)*	Telephone Number	E-Mail Address *(if available)*
n/a	123-555-7890	

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

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e. Name of 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 Federal Food, Drug, and Cosmetic Act and 21 CFR 314.52 and 314.95 (if patent owner or NDA holder does not reside or have a place of business within the United States) Name: Iceberg Inc. (agent for NDA holder)	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.

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.

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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

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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."**

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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 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)

If there is no applicable subsection in PLR format, insert "subsection 0"

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 in non-PLR or nonprescription labeling, insert "subsection N/A"

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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.)* Use Code 001- Treatment of lettuce aversion in patients also being treated for salad dressing aversion

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

5. NO RELEVANT PATENTS

For this NDA or supplement, there are no relevant patents that claim the approved drug substance (active ingredient) or the approved drug product (formulation or composition) or approved method(s) of use with respect to 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. ☐ Yes

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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
Rinku Patel -S Digitally signed by Rinku Patel -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Rinku Patel -S, 0.9.2342.19200300.100.1.1=2000401187 Date: 2016.11.14 09:11:59 -05'00' Sign	11/14/2016
6.3 Countersignature of Authorized U.S. Agent	Date Signed
Iain Margand -S Digitally signed by Iain Margand -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Iain Margand -S, 0.9.2342.19200300.100.1.1=1300232548 Date: 2016.11.14 09:14:02 -05'00' Countersign	11/14/2016

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		
Rinku Patel		
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

How can I obtain the updated Forms FDA 3542a and 3542?

- FDA's Forms Webpage http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm
- Separate instruction sheets

  Form FDA 3542a Supplement and Form FDA 3542 Supplement

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

- NDA holder

When can I start using the revised Forms FDA 3542a and 3542?

- December 5, 2016, provided that FDA receives clearance of the revised forms under the Paperwork Reduction Act by that date

If I submitted patent information on the old versions of Forms 3542a and 3542 prior to December 5, 2016, do I need to resubmit patent information on the updated forms?

– No

Where should I submit the forms?

- Submitted to the new drug application
- Via CDER Central Document Room
- Do not submit directly to the Orange Book staff

What if the submitted form is incomplete?

- FDA will notify the NDA holder
- Must submit acceptable 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

Should I submit a copy of the patent with Forms FDA 3542a and 3542?

- No, please do not submit a copy of the patent to FDA

Can I submit more than one patent on the form?

- No, you must submit separate Forms FDA 3542a and 3542 for each patent

What if I have additional questions?

- Contact the CDER Small Business and Industry Assistance (SBIA)
- Phone: 866-405-5367

  CDERSBIA@fda.hhs.gov

Helpful Links

- **Orange Book:** http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm
- **CFR Search:** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
- **MMA Final Rule:** https://www.gpo.gov/fdsys/pkg/FR-2016-10-06/pdf/2016-22690.pdf
- **MMA 2003:** https://www.gpo.gov/fdsys/pkg/STATUTE-117/pdf/STATUTE-117-Pg2066.pdf
- **FDA Forms:** http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm
- **Division of Drug Information:** druginfo@fda.hhs.gov