An Overview of FDA's Patent Listing Process

Kun Shen, PharmD, MS, BCPS
CDR, U.S. Public Health Service
Division of Legal and Regulatory Support (DLRS)
Office of Generic Drugs Policy (OGDP)
CDER | U.S. FDA

Orange Book Conference, October 27& 28, 2020

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 From 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

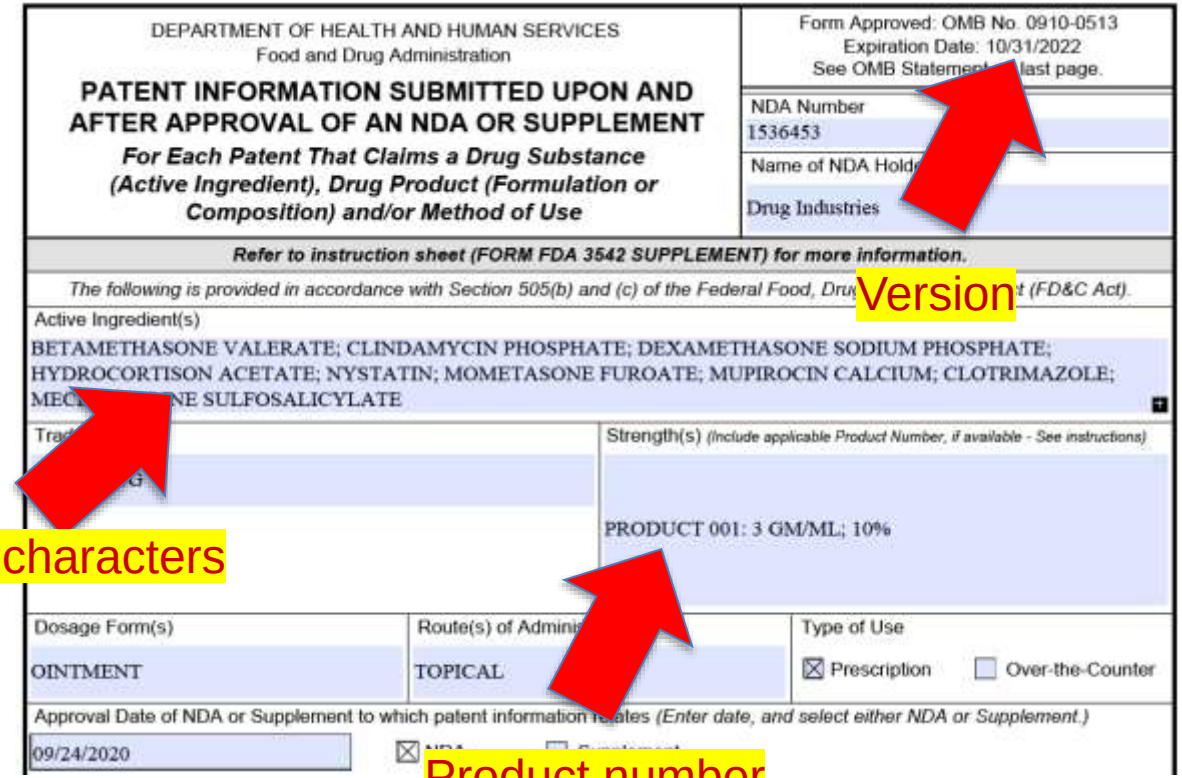
Current form expiration date: 10/31/2022

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

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: 10/31/2022
See OMB Statement [illegible] last page.

NDA Number
1536453

Name of NDA Hold[illegible]
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, Dru[illegible] (FD&C Act).

Version

Active Ingredient(s)
BETAMETHASONE VALERATE; CLINDAMYCIN PHOSPHATE; DEXAMETHASONE SODIUM PHOSPHATE; HYDROCORTISON ACETATE; NYSTATIN; MOMETASONE FUROATE; MUPIROCIN CALCIUM; CLOTRIMAZOLE; MEC[illegible]NE SULFOSALICYLATE

Tra[illegible]
G

More characters

Strength(s) *(Include applicable Product Number, if available - See instructions)*
PRODUCT 001: 3 GM/ML; 10%

Dosage Form(s)
OINTMENT

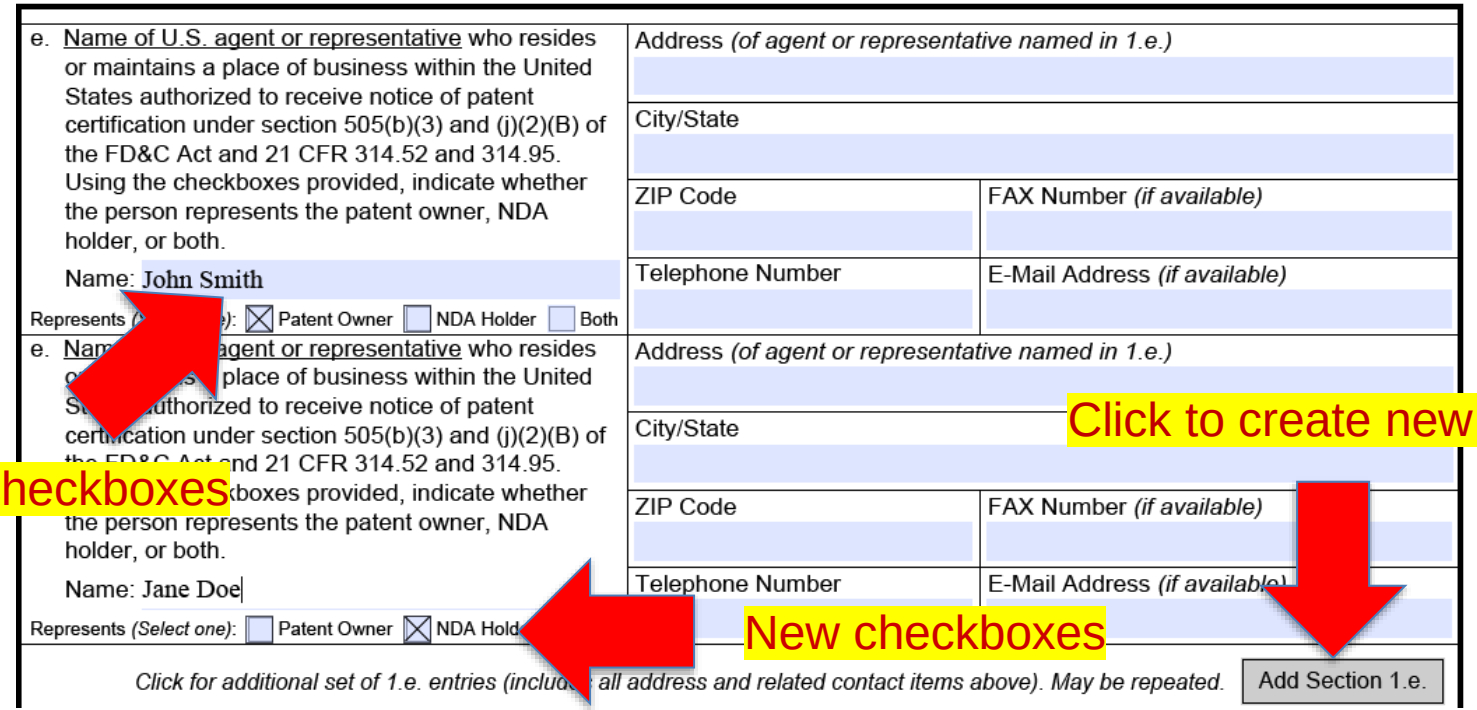
Route(s) of Admini[illegible]
TOPICAL

Type of Use
☒ Prescription ☐ Over-the-Counter

Approval Date of NDA or Supplement to which patent information re[illegible]ates *(Enter date, and select either NDA or Supplement.)*
09/24/2020 ☒ NDA ☐ Supplement

Product number

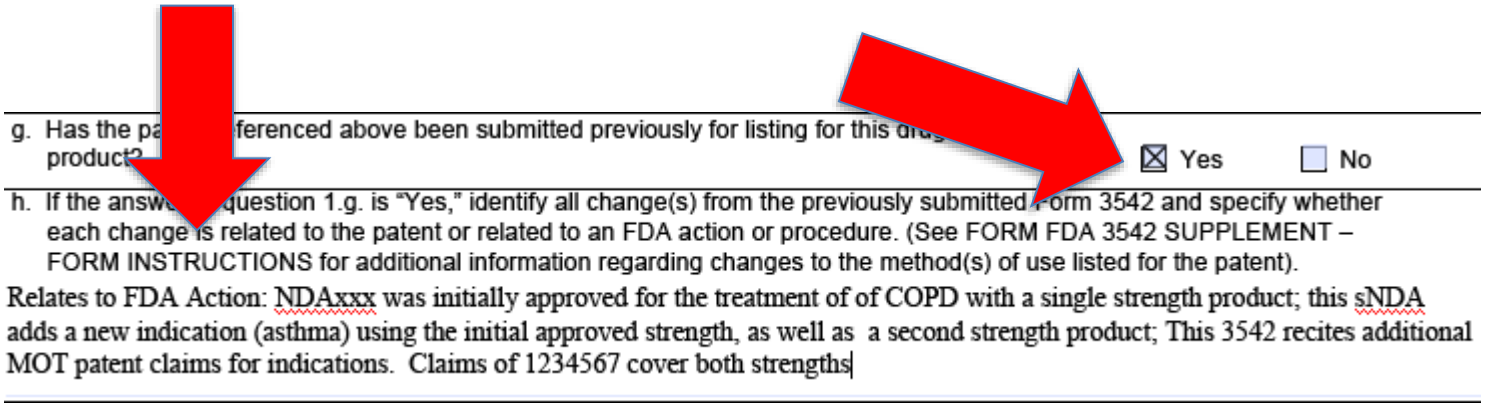
Highlight of New Form FDA 3542



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



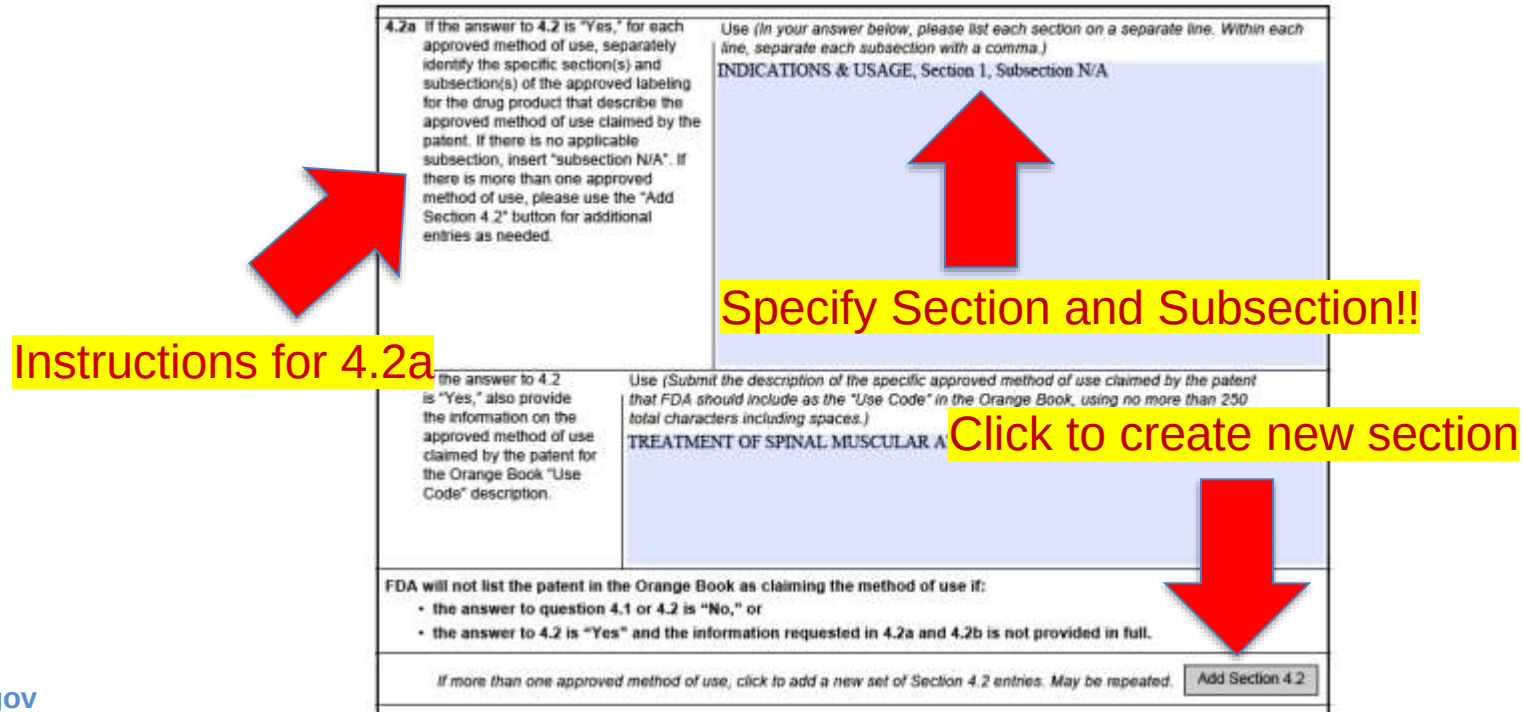
g. Has the pa[illegible]ferenced above been submitted previously for listing for this dr[illegible] product? ☒ Yes ☐ No

h. If the answ[illegible]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).

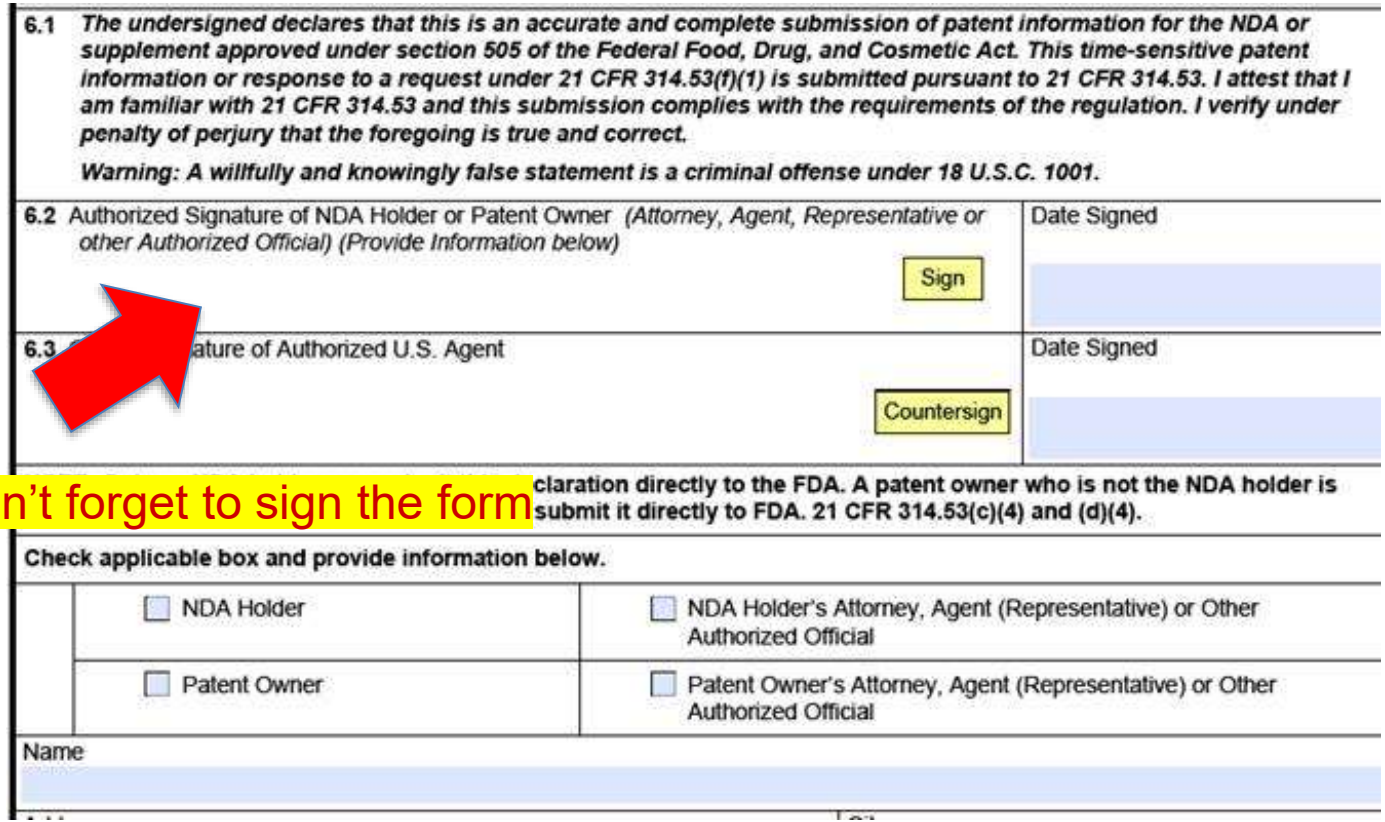
Relates to FDA Action: NDAxxx was initially approved for the treatment of of COPD with a single strength product; this sNDA adds a new indication (asthma) using the initial approved strength, as well as a second strength product; This 3542 recites additional MOT patent claims for indications. Claims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

Highlight of New Form FDA 3542

- Identify Section and subsection in 4.2a



Highlight of New Form FDA 3542



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)* Sign	Date Signed
6.3 ature of Authorized U.S. Agent Countersign	Date Signed

Don't forget to sign the form claration 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.

☐ 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

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

U.S. FOOD & DRUG ADMINISTRATION

Questions?

Orangebook@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION