FDA U.S. FOOD & DRUG ADMINISTRATION

Patent Information Dispute Process

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Celebrating 40 Years: An In-Depth Examination of the FDA Orange Book
October 27, 2020

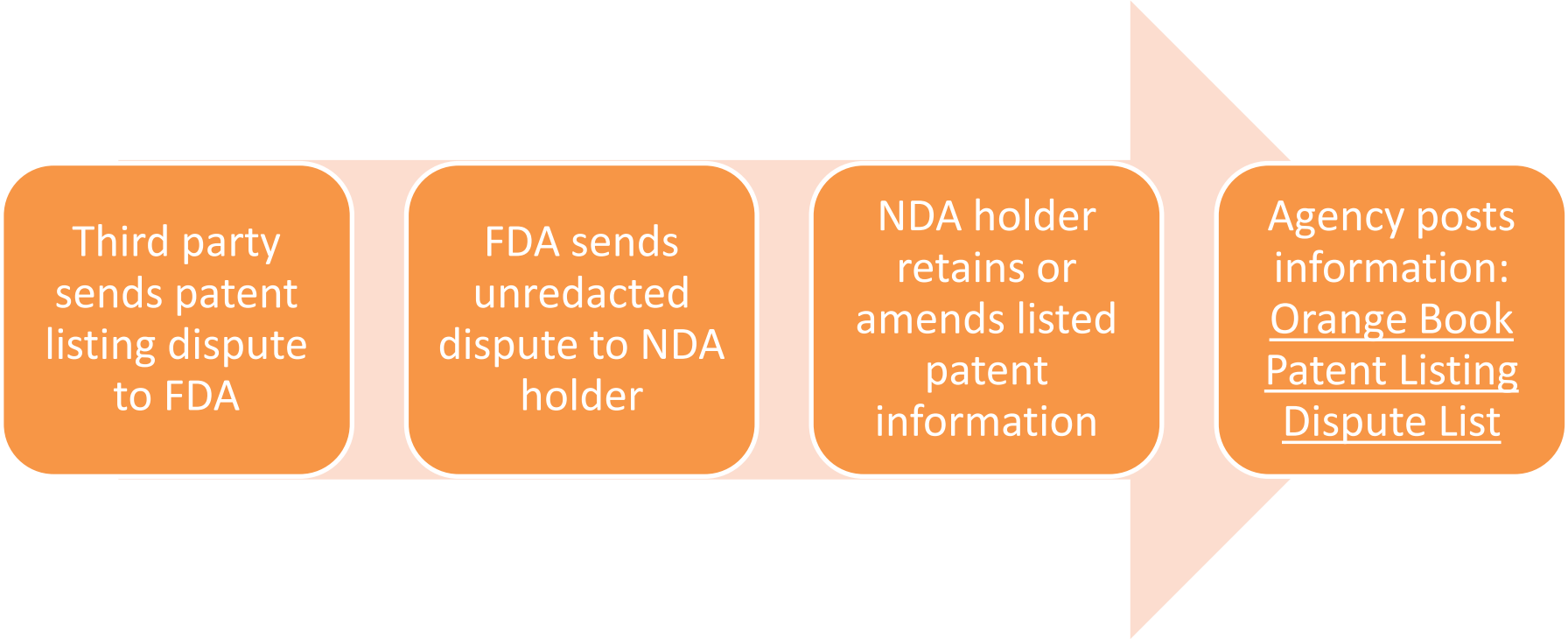
Learning Objectives

1. Explain the patent information dispute process
2. Describe FDA's patent listing dispute list
3. Discuss the timeline for corrections to Form FDA 3542

Patent Information Disputes

- FDA's role in patent listings is ministerial
- Orange Book lists patents based on information provided by NDA applicants in Form FDA 3542
- May be disputed by third party (*See 21 CFR 314.53(f)(1)*)

Patent Dispute Process



Dispute Submission Requirements

- Communication titled 314.53(f) Patent Listing Dispute
- Statement of Dispute **attached** or clearly identified
- *Method of use disputes*: narrative (maximum 250 words) describing interpretation of patent scope
- Include only information for which you consent to disclosure

Patent Dispute Processing

- FDA forwards statement of dispute without review or redaction
- E-mailed to NDA holder on most recent Form FDA 356h submitted to the NDA
- Patent listing dispute information publicly posted

NDA Holder Response Requirements

- 30 days to substantively respond
- Options for response: confirm or withdraw or amend
- *Method of use disputes:* Narrative description (no more than 250 words) explaining appropriateness of existing or amended use code
- Must include signed verification

See § 314.53(c)(2)(ii)(R) and § 314.53(f)(2)

NDA Holder Response Processing

- Have requirements been met?
  - Is the response timely?
  - Does NDA holder response include narrative description (for MOU patents) and signed verification?
- Confirmation of correctness vs. request for revised patent information or withdrawal of patent information
- FDA forwards narrative description without review or redaction to the person who submitted the dispute

Challenge Question #1

Patent listing disputes submitted to the Agency must cite which regulation?

a. 21 CFR 320.22(b)(1)

b. 21 CFR 314.53(f)

c. 21 CFR 314.53(f)(2)

d. 21 CFR 314.108

Patent Listing Dispute List

Patent Listing Dispute List

- List of patent listing disputes
- Advises prospective and pending 505(b)(2) or ANDA applicants of disputes that have been submitted
- Information regarding timeliness of NDA holder response

Orange Book Patent Listing Dispute List

- Published monthly in parallel with Orange Book Cumulative Supplement
- Lists information for relevant patent and corresponding drug product

Patent Listing Dispute List

Established Drug Product Name	NDA Number	NDA Holder	Strength(s)	Relevant U.S. Patent Number(s)	Type of Patent Claim
cangrelor	204958	Chiesi	50 mg/vial	8,680,052	Method of Use
fingolimod hydrochloride	022527	Novartis	EQ 0.5mg Base	9,187,405	Method of Use
paliperidone palmitate	022264	Janssen Pharms	39 mg/0.25 mL, 78 mg/0.5 mL, 117 mg/0.75 mL, 156 mg/mL	9,439,906	Method of Use
paliperidone palmitate	022264	Janssen Pharms	39 mg/0.25 mL, 78 mg/0.5 mL, 117 mg/0.75 mL, 156 mg/mL	9,439,906	Method of Use
		Teva Pharms		8,232,250, 8,399,413, 8,969,302	Disputes Not Related to

Patent Listing Dispute List, continued

Original Use Code (if applicable)	Revised Use Code (if applicable)	Due Date for NDA Holder Response	NDA Holder Response Date	Dispute Outcome
U-1715: P2Y12 Platelet Inhibitor for use as adjunct to percutaneous coronary intervention to reduce risk of various diseases/conditions in patients not treated with a P2Y12 platelet inhibitor and not given a glycoprotein IIb/IIIA inhibitor	U-2869: IV Administration of cangrelor before PCI and continuous infusion for at least 2 hours or the duration of the PCI and, during or after the continuous infusion, administration of a loading dose of ticagrelor or an equivalent therapy (per labeling)	8/9/2020	8/7/2020	Patent Listing Updated
U-2613: Treatment of Relapsing-Remitting Sclerosis (MS)	N/A	6/15/2020	6/10/2020	No Orange Book Changes
U-543: Treatment of Schizophrenia	U-2757: Dosing regimen for the treatment of schizophrenia in adults by administering two loading doses of paliperidone palmitate followed by maintenance dose(s)	3/21/2020	3/20/2020	Patent Listing Updated
U-1901: Treatment of Schizoaffective Disorder as a Monotherapy and as an adjunct to mood stabilizers or antidepressants	U-2758: Dosing regimen for the treatment of schizoaffective disorder in adults as a monotherapy and as an adjunct to mood stabilizers or antidepressants by administering two loading doses of paliperidone palmitate followed by maintenance dose(s)	3/21/2020	3/20/2020	Patent Listing Updated

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 on last page.

NDA Number

Name of NDA Holder

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)

Trade Name

Strength(s) *(Include applicable Product Number, if available - See instructions)*

Corrections to Form FDA 3542

Orange Book Patent Processing

- Daily review of patent submissions
- Deficiency letters sent for incomplete forms
  - Description of specific error(s)
- Review of re-submitted forms

Corrections to Form 3542

- NDA holders have a single 15-day period to re-submit with corrections
- Orange Book Questions and Answers: Guidance for Industry (May 2020)
  - Question #13: Timely filing of patent information

See § 314.53(c)(2)(ii))

Challenge Question #2

- **Question [True/False]:** When the FDA identifies deficiencies in an NDA Holder's Form FDA 3542 form, the NDA holder has a single 15-day period to make corrections.

Summary

- Patent information can be disputed by third parties as outlined under 314.53(f)(1)
- FDA maintains a publicly available Patent Listing Dispute List
- NDA holders have a single 15-day period to adequately make corrections to Form FDA 3542

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Questions?

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Closing Thought

NDA holders are responsible for accurate submissions of patent information, and challenges can be made via the patent listing dispute process.


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