

Orange Book: Regulatory Considerations for Changes in Application Ownership

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Presentation Objectives

At the end of this presentation, participants will:

- Recognize the relevant information to be included in a submission when requesting updates to application ownership
- Apply best practices for submitting a change in ownership request to the FDA

Orange Book's Role: Change in Ownership

- Update the Orange Book with the new owner's name
- Ensure appropriate data entry is performed in tracking databases
- Relevant contact information provided for notice of patent certifications (*See 21 CFR 314.95(a)(2)*)

Change in Ownership Submission

- ***Administrative Change/Applicant***
 - Form FDA 356h
 - Both** new and former owners are required to submit information to the FDA
 - Change in ownership is made effective once former owner indicates all rights have been transferred to the new owner and the new owner files the acceptance letter for the relevant application(s)

Change in Ownership Submission

- **Former Owner Responsibilities**
 - Shall submit correspondence that states that all rights to the application have been transferred to the new owner

‡ See 21 CFR 314.72 for full reference

Change in Ownership Submission

- **New Owner Responsibilities**
 - Commitment to agreements, promises, and conditions made by the former owner and contained in the application
 - Date that the change in ownership is effective
 - A statement that the new owner has a complete copy of the approved application or a request for a copy of the application from FDA's files

‡ See 21 CFR 314.72 for full reference

Change in Ownership Submission



SUBMISSION BEST PRACTICES

FORMER OWNER

- Submit a consolidated list of applications to be transferred
- Submit change in ownership request as a stand-alone submission to the FDA
- Prominently identify submission as “Transfer of Ownership”

NEW OWNER

- Timely submit acceptance letter for newly acquired applications
- Prominently identify submission as “Acceptance of Ownership”

Corporate Mergers/Acquisitions

- Corporate mergers and acquisitions are not processed as a change of ownership
- Generally effectuated by the applicant requesting one or more of the following:
 - Corporate Name Change
 - Change in Address
 - Change in Contact information

Corporate Mergers/Acquisitions

- Form FDA 356h
- Cover letter:
 - Prominently identify the submission (i.e., “Corporate Name Change”)
 - Identify the new name and/or address
 - If applicable, identify any updated contact information
 - Applicants located outside the U.S. (i.e., in foreign countries) must provide a U.S. Agent name and address
 - Identify the date the change occurred
- Submit a consolidated list of applications affected

Orange Book: Change in Applicant Holder Name



- When looking at the Orange Book, how can I tell when an application has either changed ownership or updated its company name?
 - CAHN: Change code appearing in the monthly cumulative supplement to the Orange Book on drug products with a Change in Applicant Holder Name (CAHN)

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>A>	AA	!	LGM PHARMA	300MG;50MG	A090956	001	Aug 23, 2011	Aug	CAHN
>D>	AA	!	NEXGEN PHARMA	300MG;50MG	A090956	001	Aug 23, 2011	Aug	CAHN

Orange Book Update - Timing?

The following are published in the monthly updates to the Orange Book

- Applicant Holder Name Changes
 - Change in ownership
 - Note: Requests are processed once the FDA has received the relevant information from both the old owner and the new owner
 - Corporate Mergers/Acquisitions
- Market status changes (e.g., movement of a drug product from the discontinued list to the prescription list of the Orange Book)

Challenge Question

- **When is a change in ownership made effective?**
 - A. As soon as the former owner submits a transfer of ownership to the FDA
 - B. Once the former owner indicates all rights have been transferred to the new owner
 - C. When the new owner submits the acceptance letter to the former owner
 - D. When the new owner files the acceptance letter for the relevant application
 - E. Both B. and D.

Summary

- OGD is responsible for updating the Orange Book with information relating to drug applications including: (1) changes in application ownership; and (2) changes as a result of corporate mergers and acquisitions
- When an applicant transfers ownership of its application both the new and former owners are required to submit information to the Food and Drug Administration (FDA)
- Members of the Orange Book staff are responsible for ensuring that complete information is submitted to the Agency prior to updating relevant databases

Reference

- MAPP 5242.1 *Transfer of Ownership*,
<https://www.fda.gov/media/141551/download>

