POLICY AND PROCEDURES

OFFICE OF GENERIC DRUGS

Transfer of Ownership

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PURPOSE

This Manual of Policies and Procedures (MAPP) details how the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") staff in the Office of Generic Drugs (OGD) will process the requests submitted by former and new owners of drug applications to transfer drug application ownership.

BACKGROUND

The Orange Book is an FDA publication mandated under section 505(j)(7)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) which provides a listing of drugs approved as safe and effective. The Orange Book also serves as the regulatory resource for information on drug marketing availability, bioequivalence, therapeutic equivalence, and patent and exclusivity data. The information included in the Orange Book is relied upon by applicants for information required to be included in an abbreviated new drug application (ANDA). OGD is responsible for updating the Orange Book with information relating to drug applications including: (1) change in ownership submissions; (2) corporate merger and acquisition submissions; and (3) changes to marketing status.[1]

[1] For more information regarding changes to marketing status, see FDA's draft guidance for industry *Marketing Status Notifications under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format* https://www.fda.gov/media/120095/download.

POLICY

An applicant may transfer ownership of its application under 21 CFR 314.72. At the time of transfer, the new and former owners are required to submit information to the Food and Drug Administration (FDA).

An applicant may also submit changes in application information relating to corporate mergers and acquisitions.

A. Transfer of Ownership Requests[2]

Orange Book project managers and pharmacists in OGD will ensure that both the new and former application owners have submitted the required information to FDA at the time of transfer in accordance with 21 CFR 314.72.

- Orange Book project managers and pharmacists will confirm that the former application owner has submitted a letter or document that states all rights have been transferred to the new owner. Orange Book project managers and pharmacists will confirm that the former application owner has submitted a change of ownership request (generally a stand-alone submission identified as a "Transfer of Ownership"), and a consolidated list of applications to be transferred.

- Orange Book project managers and pharmacists will confirm that the new application owner has submitted an application form signed by the new owner accompanied by a letter (also referred to as an acceptance letter) or other document containing the following:

    1. The new owner's commitment to agreements, promises, and conditions made by the former owner and contained in the application.

    2. The date the change in ownership is effective.[3]

    3. Either a statement that the new owner has a complete copy of the approved application, including supplements and records that are required to be kept under §314.81, or a request for a copy of the application from FDA's files.[4]

- Orange Book project managers and pharmacists will determine if the new application owner has submitted documents to FDA regarding any change in the conditions in the

[2] For purposes of this MAPP, a change in ownership submission refers to a request to transfer ownership of a drug application from a current application owner to a separate, unrelated entity.
[3] A change in ownership becomes effective once both the former and the new application owner submit all required documents. Any delay in the submission of required documents will delay the change in ownership from becoming effective.
[4] FDA will provide a copy of the application to the new owner under the fee schedule in FDA's public information regulations (see 21 CFR 20.45).

approved application under 21 CFR 314.70 and 21 CFR 314.97.[5] Orange Book project managers and pharmacists will confirm that the new application owner has submitted an acceptance letter for newly acquired applications, which is generally identified as an "Acceptance of Ownership."

B. Changes due to Corporate Mergers and Acquisitions[6]

FDA will not consider changes to drug applications resulting from corporate mergers and acquisitions a transfer of ownership.

Generally, changes to drug applications resulting from corporate mergers and acquisitions are effectuated by the applicant making a request for one or more of the following:

- Corporate Name Change
- Change in Address
- Change in Contact Information

Applicant requests for the above are submitted with a Form FDA 356h accompanied by a cover letter that generally:

- Prominently identifies the submission (e.g., Corporate Name Change)
- Identifies the date of the corporate merger and/or acquisition
- Identifies the new name, address, or contact information[7]
- If applicable, contains a consolidated list of applications affected by the change

RESPONSIBILITIES

- Orange Book project managers, or their designee, perform all initial reviews of requests for changes in ownership and requests for changes in application information relating to corporate mergers and acquisitions. In the event that a request for change in ownership or a request for changes in application information relating to corporate mergers and acquisitions has omitted required information, the Orange Book project manager notifies the application's new owner that OGD cannot process their request until the omitted information is provided. Following verification by an Orange Book pharmacist, Orange Book project managers process requests for changes in ownership and requests for changes in application information relating to corporate mergers and acquisitions by updating the Orange Book database.

[5] The new owner may advise FDA in the next annual report about a change in the drug product's label or labeling to change the product's brand or the name of its manufacturer, packer, or distributor.
[6] For purposes of this MAPP, transfers of drug applications resulting from corporate mergers and acquisitions refers to transfers between two entities that are related to each other (i.e., application transfers between companies operating under the same parent company).
[7] Applicants located outside the United States must provide the name and address of a U.S. Agent (see 21 CFR 314.94(a)(1) and 314.50(a)(5)).

- Orange Book pharmacists, or their designee, verify required documentation for changes in ownership and requests for changes in application information relating to corporate mergers and acquisitions has been submitted.

PROCEDURES

1. Request for change in ownership under 21 CFR 314.72.

    a. An Orange Book project manager will receive a copy of the request for a change in ownership pursuant to 21 CFR 314.72 submitted to the application file by the electronic gateway from the FDA Document Room.

    b. The Orange Book project manager will review the request for the following:

        i. The former application owner has submitted a letter or document that states all rights have been transferred to the new owner.

        ii. The new application owner has submitted an application form signed by the new owner and accompanied by a letter (also referred to as an acceptance letter) or other document containing the following:

            1. The new owner's commitment to agreements, promises, and conditions made by the former owner and contained in the application.

            2. The date the change in ownership is effective.

            3. Either a statement that the new owner has a complete copy of the approved application, including supplements and records that are required to be kept under 21 CFR 314.81, or a request for a copy of the application from FDA's files.

        iii. The new application owner has submitted documents to FDA regarding any change in the conditions in the approved application under 21 CFR 314.70 and 21 CFR 314.97.

    c. If any of the information outlined in section 1. b. i-ii is not included in the request, an Orange Book project manager will notify the application's new owner that OGD cannot process the request until the omitted information is provided.

    d. Once an Orange Book project manager completes their review of the change in ownership request, a pharmacist on the Orange Book staff will verify the required documentation under 314.72 has been submitted.

e. Upon verification by an Orange Book pharmacist, an Orange Book project manager will process the request for change in ownership by updating the Orange Book database.[8]

2. Requests for changes in application information relating to corporate mergers and acquisitions.

   a. An Orange Book project manager will receive a copy of a request for corporate name change, change in address, and/or change in contact information submitted to the application file by the electronic gateway from the FDA Document Room.

   b. An Orange Book project manager will review the request to ensure the application owner has submitted a Form FDA 356h and a cover letter that includes the following:

      1. The date of the corporate merger and/or acquisition.

      2. The new name, address, and/or contact information.

      3. If applicable, a consolidated list of applications affected by the change.

   c. If any of the information outlined in section 2. b. is not included in the request, an Orange Book project manager will notify the application holder that OGD cannot process the request until the omitted information is provided.

   d. Once the Orange Book project manager completes their review of the request regarding changes to an application resulting from corporate mergers and acquisitions, a pharmacist on the Orange Book staff will verify that the information outlined in section 2. b. has been submitted.

   e. After the Orange Book pharmacist has verified that the appropriate information has been submitted, an Orange Book project manager will process requests regarding changes to applications resulting from corporate mergers and acquisitions by updating the Orange Book database.

REFERENCES

1. 21 CFR 314.72
2. 21 CFR 314.70
3. 21 CFR 314.97
4. 21 CFR 314.81
5. 21 CFR 20.45

[8] Revisions to drug product listings are generally published in the next monthly cumulative supplement of the Orange Book.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
8/26/2020	N/A	Initial