POLICY AND PROCEDURES

Office of Generic Drugs

Receiving and Processing a Request for Voluntary Withdrawal of an Approved ANDA

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PURPOSE

This MAPP outlines the policies and procedures for receipt, review, and processing of a withdrawal request submitted by a holder of an approved abbreviated new drug application (ANDA) to the Office of Generic Drugs (OGD). This MAPP applies to the Regulatory Project Managers (RPMs) in OGD who receive and process requests for withdrawal of ANDAs pursuant to 21 CFR 314.150(c).

The scope of this MAPP is limited to the processing of a withdrawal request for an approved ANDA by the OGD RPM. If an ANDA holder requests withdrawal of an approved supplement, the OGD RPM will advise the applicant to submit a supplement requesting that change be made to the ANDA.

BACKGROUND

An ANDA holder may determine that it no longer wishes to manufacture or market a drug subject to an approved ANDA. However, until withdrawal of approval of the ANDA is made effective, the ANDA holder remains responsible for legal and regulatory requirements related to the drug product including post-approval reporting requirements and payment of any required fees.[1] An ANDA holder may request withdrawal of approval of an ANDA under 21 CFR 314.150(c) if the drug product is no longer being marketed. A voluntary withdrawal under § 314.150(c) will only be processed by OGD

[1] See, generally, 21 CFR 314.98 (requiring holders of approved ANDAs to comply with the reporting requirements of 21 CFR 314.80 and 314.81); Section 744B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j-42).

pursuant to the procedures outlined in this MAPP if none of the conditions in § 314.150(a) and (b) applies to the drug product. See the criteria identified in 21 CFR 314.150(a) and (b); see also 21 CFR 314.150(d).

POLICY

An ANDA will remain in an "approved" status in FDA's electronic regulatory tracking systems (e.g., the CDER Informatics Platform (Platform) or the Document Archiving, Reporting and Regulatory Tracking System (DARRTS)) until a notice is published in the Federal Register (FR) stating that the approval of the ANDA is withdrawn. FDA's electronic regulatory tracking systems will be updated to reflect a withdrawn status for the ANDA upon the date of the withdrawal stated in the FR notice.

Once an approved application is effectively withdrawn (i.e., the date of withdrawal as identified in the published FR notice), the ANDA holder is no longer subject to the legal and regulatory requirements for maintaining an approved ANDA.

The OGD RPM will process a voluntary request for withdrawal and any request to rescind a voluntary withdrawal that has not yet become effective.

PROCEDURES

1. Request for withdrawal under 21 CFR 314.150(c)

    a. The OGD RPM will receive a copy of the ANDA holder's request to withdraw an ANDA pursuant to 314.150(c) submitted to the ANDA File by the electronic gateway from the FDA Document Room.

    b. The OGD RPM will review the request for the following:

        i. A separate completed Form FDA 356h for each ANDA to be withdrawn.
        ii. A cover letter identifying an ANDA that has received full approval that is the subject of the withdrawal request.
        iii. A statement indicating that the ANDA holder requests withdrawal of the approved ANDA.[2]
        iv. An explicit reference to the appropriate regulation (21 CFR 314.150(c)) for voluntary withdrawal.

[2] An ANDA is defined as "the application described under [21 CFR] 314.94, including all amendments and supplements to the application." See 21 CFR 314.3(b). Accordingly, if a sponsor requests withdrawal of an approved ANDA, FDA will withdraw the approved ANDA identified including all amendments and any and all approved or pending supplements to the application.

c. If any of the information outlined in section 1. b. i-iv is not included in the request, the RPM will notify the ANDA holder that we cannot process the request.

d. The RPM will draft a letter granting the withdrawal request and ensure the letter is signed by the director of the Office of Regulatory Operations (ORO) Division of Project Management (DPM), or designee, to be issued by the document room.

e. The RPM will identify the withdrawal request in the electronic regulatory tracking system and issue a notification to the OGD Office of Generic Drug Policy (OGDP), ORO, and the CDER Office of Regulatory Policy (ORP), as appropriate, so FDA may develop the FR notice listing the withdrawal.

2. Request to rescind withdrawal request

a. If the ANDA holder requests rescission of the withdrawal request **before** the FR notice listing the ANDA as withdrawn is published, the RPM will draft a letter granting the rescission and ensure the letter is signed by the director of DPM, or designee; will issue the letter to the ANDA holder; and will notify OGDP.

b. If the ANDA holder requests rescission of the withdrawal request **after** the FR notice is published but before the withdrawal of approval is said to take place (typically 30 days after publication), as identified in the FR notice, the RPM will draft a letter granting the rescission and ensure the letter is signed by the director of DPM, or designee; will issue the letter to the ANDA holder; and will notify OGDP. FDA will issue a notice of correction in the FR.

c. If the ANDA holder requests rescission of the withdrawal request **on or after** the date approval of the ANDA is withdrawn, as identified in the FR notice, the RPM will draft a letter denying the rescission request and ensure the letter is signed by the director of DPM, or designee; will issue the letter to the ANDA holder; and will notify OGDP.

REFERENCES

1. 21 CFR 314.3(b)
2. 21 CFR 314.150

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
10/4/2017	Initial	N/A