POLICY AND PROCEDURES

OFFICE OF GENERIC DRUGS

ANDA Suitability Petitions

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PURPOSE

This MAPP establishes the policies and procedures of the Office of Generic Drugs (OGD) for responding to suitability petitions submitted to it by or on behalf of prospective abbreviated new drug application (ANDA) applicants.

POLICY

A prospective applicant may submit a suitability petition to the Food and Drug Administration (FDA) under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)(2)(C)), as well as under 21 CFR 10.20, 10.30, and 314.93, requesting permission to submit an ANDA for a generic drug product that differs from a reference listed drug (RLD) in its route of administration, dosage form, or strength or that has one different active ingredient in a fixed-combination drug product (i.e., a drug product with multiple active ingredients).

The Food and Drug Administration (FDA) will approve a suitability petition unless, among other reasons, one of the following occurs:

- FDA determines that the safety and effectiveness of the proposed change from the reference listed drug (RLD) cannot be adequately evaluated without data from investigations that would be beyond the scope of what may be required for an ANDA.

- A drug product is approved in a new drug application for the change requested in the suitability petition.

- The suitability petition requests changes to a drug product that trigger the need for pediatric studies under the Pediatric Research Equity Act (Public Law 108-155) to assess the safety and efficacy of that drug product in a relevant pediatric subpopulation that would not be waived by FDA, which renders the proposed product ineligible for approval in an ANDA.[1]

FDA will refuse to receive an ANDA citing to a pending suitability petition (or to a suitability petition that was denied) because that ANDA would lack a legal basis for submission.

RESPONSIBILITIES AND PROCEDURES

- A project manager (PM) in the Division of Legal and Regulatory Support (DLRS)[2] receives the suitability petition from the Dockets Management Staff[3] and routes the suitability petition to the Division of Filing Review (DFR).[4]

- The DFR primary reviewer:

  - Prepares a written summary of the suitability petition, which:

    - Considers whether the format and content of the suitability petition meet the regulatory requirements for approval (e.g., whether the suitability petition is requesting permission to submit an ANDA for a generic drug product that differs from its RLD in its route of administration, dosage form, strength, and/or, for fixed-combination drug products, one of its active ingredients; whether the suitability petition follows 21 CFR 10.30; whether the suitability petition identifies the RLD (typically by including pages from the *Approved Drug Products With Therapeutic Equivalence Evaluations* (Orange Book)),[5] and includes copies of the proposed labeling and the RLD labeling; and whether the suitability petition contains a Pediatric Research Equity Act waiver request, if applicable, accompanied by supportive information and data)

    - Determines whether a listed drug has been approved for the change described in the suitability petition

    - Determines whether a duplicate suitability petition was already filed for the same change

[1] See section 505(j)(2)(A) of the FD&C Act.

[2] DLRS is in OGD's Office of Generic Drug Policy.

[3] The Dockets Management Staff is in FDA's Office of the Commissioner.

[4] DFR is in OGD's Office of Regulatory Operations.

[5] The Orange Books is available at https://www.accessdata.fda.gov/scripts/cder/ob/.

- Determines if additional information is needed from the petitioner and, if so forwards that determination to the DFR PM to contact the petitioner for a response

- Generates a clearance sheet

- Determines whether the suitability petition requires review by a consulting expert or experts outside of OGD and, if so:

  - Prepares any consult request that may be necessary

  - Forwards the consult requests to the DFR secondary reviewer and the DFR PM

- Forwards the written summary to the DFR secondary reviewer

- The DFR secondary reviewer reviews the summary of the suitability petition and any consult requests that were prepared by and received from the DFR primary reviewer, and sends the consult package to the DFR PM for distribution, as described below.

- The DFR PM:

  - Sends any consult requests that were prepared by and received from the DFR primary reviewer

  - Receives, from the consulting experts, consult request responses

  - Requests additional information from the petitioner if the DFR primary reviewer determined that this information is needed

  - Issues a consult request to the Division of Clinical Review (DCR)[6] (via a DCR PM) if there is a disagreement or differing opinion related to the proposed response to the suitability petition (e.g., between DFR and a consulting office or between different consulting offices) or the proposed response is a denial of the suitability petition

- If the DCR PM receives a consult request from the DFR PM, the DCR PM forwards that request to the DCR review team (which contains a medical officer (MO) and a secondary reviewer)

[6] DCR is in OGD's Office of Bioequivalence.

- If the DCR review team receives a consult request from the DCR PM, the DCR review team:

  - Reviews the suitability petition, the consult response recommendation, and other clinical information relevant to the petition

  - Concludes whether the petition should be approved or denied

    - If the DCR review team disagrees with the recommendation of a consulting expert or experts about the approvability or deniability of the suitability petition, the DCR MO contacts that expert or those experts and attempts to resolve the disagreement

    - If the DCR MO determines additional expertise is needed, the DCR MO drafts a consult request and distributes that request, via the DCR PM, to the consulting expert(s) and meets with the expert(s) as necessary to resolve any additional disagreements

    - If new consult requests have been distributed, the DCR MO reviews the responses and incorporates them into the approval or denial recommendation

- Once all necessary consults are complete, the DFR primary reviewer prepares a draft response to the petitioner and compiles a suitability petition response package that is sent to a DLRS primary policy reviewer.

- The DLRS primary policy reviewer:

  - Reviews the public docket associated with the suitability petition to determine if any comments were submitted and ensures that any adverse comments are addressed in FDA's response to the petitioner (which may include issuing a new consult to address the comment(s))

  - Reviews the Orange Book to determine whether a listed drug has been approved for the change described in the suitability petition

  - Determines whether the RLD has been discontinued from sale or whether approval has been effectively withdrawn,[7] and if so, confirms whether a determination that the RLD has not been discontinued from sale or effectively withdrawn for reasons of safety and/or effectiveness has been made

[7] For purposes of this MAPP, an approval is "effectively withdrawn" as of the date of withdrawal identified in the published Federal Register notice.

- Issues a consult request to FDA's Office of Chief Counsel if the suitability petition raises a novel or controversial issue or if FDA's proposed response to the suitability petition is a denial

- Revises the response to the suitability petition, to incorporate responses from consults requests, and notifies the OGD Deputy Director (or his or her designee) that a suitability petition response will be forthcoming for signature

- Sends the suitability petition response package to a DLRS secondary policy reviewer for review

- The DLRS secondary policy reviewer reviews the response to the suitability petition and sends that response to the OGD Deputy Director (or his or her designee) for clearance and signature.

- The OGD Deputy Director (or his or her designee):

  - Provides final review and clearance of the response to the suitability petition and signs the response to the petitioner

  - Returns the signed suitability petition response to the DLRS secondary policy reviewer

- The DLRS secondary policy reviewer sends the signed petition response and the complete suitability petition response package to the DLRS PM.

- The DLRS PM ensures that the signed response is mailed to the petitioner and a copy is sent to the Dockets Management Staff so that the copy may be added to the docket for the suitability petition.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
8/21/13	Initial	N/A
8/10/18	1	Revised to reflect the new policies and procedures of OGD, which commenced after it reorganized in 2014, for responding to suitability petitions submitted to it.