POLICY AND PROCEDURES

OFFICE OF GENERIC DRUGS

ANDA Suitability Petitions

Table of Contents

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 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).

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 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 (NDA) 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 to assess the safety and efficacy of the 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.

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:

  - Considers whether the format and content of the suitability petition meet the regulatory requirements (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 (e.g., by including relevant pages from the *Approved Drug Products With Therapeutic Equivalence Evaluations* (Orange Book)[5]), 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.

  - Determines if additional information is needed from the petitioner and forwards that determination to the DFR PM.

[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 Book is available at https://www.accessdata.fda.gov/scripts/cder/ob/.

- Determines whether the suitability petition requires review by a consulting expert(s) outside of OGD and, if so:
  - Prepares any consult requests that may be necessary.
  - Forwards the consult requests to the DFR secondary reviewer and the DFR PM.
- Prepares a written summary of the suitability petition that adresses all of the foregoing DFR primary reviewer considerations and forwards the summary to the DFR secondary reviewer.
- Receives the suitability petition summary back from the DFR secondary reviewer and if no edits or revisions are needed, then sends the consults to the DFR PM to issue.
  - If revisions are needed, edits suitability petition summary accordingly and sends it to the DFR secondary reviewer. Once revisions are agreed upon by the DFR secondary reviewer, forwards the consults to the DFR PM to issue.

- 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, makes any necessary edits or suggestions for revision to the summary and/or consult request(s), and sends these to the DFR primary reviewer for incorporation. If no edits or revisions are necessary, the DFR secondary reviewer sends clean copies to the DFR primary reviewer.

- The DFR PM:
  - Sends any consult requests that were prepared by and received from the DFR primary reviewer.
  - Receives, from the consulting expert(s), consult request responses.
  - Requests any information and/or clarification from the petitioner that the DFR primary reviewer determines is needed for the review of the petition.
  - Issues a consult request to the Division of Clinical Review (DCR)[6] (via a DCR PM) if there is a differing opinion among the disciplines related to the

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

proposed response to the suitability petition (e.g., DFR recommends approval and a consulting office recommends denial) or if the proposed response is a denial of the suitability petition.

- When the DCR PM receives a consult request from the DFR PM, the DCR PM forwards that request to the DCR review team with a physician as the primary reviewer and a secondary reviewer.

- After receipt of a consult request from the DCR PM, the DCR review team:

  - Reviews the suitability petition, the consult response recommendation(s), and other clinical information relevant to the petition.

  - Assesses whether the petition should be approved or denied.

    - If the DCR review team disagrees with the recommendation of a consulting expert(s) about the approvability or deniability of the suitability petition, the DCR primary reviewer contacts the expert(s) and attempts to resolve the disagreement.

    - If the DCR primary reviewer and the consulting expert(s) cannot agree on the approvability or deniability of the petition, the DCR primary reviewer will schedule a meeting with the consulting expert(s) and management as necessary to resolve the disagreement.

    - If necessary, the DCR primary reviewer drafts a new consult request and distributes that request, via the DCR PM, to the consulting expert(s).

    - If new consult requests have been distributed, the DCR primary reviewer 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 and sends it 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 (this may include issuing a new consult to address the comment(s)).

  - Reviews the Orange Book and Drugs@FDA 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 approval has been effectively withdrawn,[7] and if so, confirms that there is a determination that the RLD has not been discontinued from sale or effectively withdrawn for reasons of safety or effectiveness.

- Edits the response to the suitability petition, as needed, and notifies the OGD Deputy Director for Clinical and Regulatory Affairs (or 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 edits the response to the suitability petition as necessary.

- Following review by the DLRS secondary reviewer, the DLRS primary reviewer 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 for a reason other than that a drug product is approved in an NDA for the change requested in the suitability petition.

- After review by the DLRS secondary policy reviewer and OCC, as appropriate, the DLRS primary reviewer will send the response to the OGD Deputy Director for Clinical and Regulatory Affairs (or designee).

- The OGD Deputy Director for Clinical and Regulatory Affairs (or designee):

  - Provides a 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.

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

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.
10/9/2020	2	Revised for clarification and minor updates to the process and organization.