PURPOSE

This MAPP establishes the policies and procedures for responding to an abbreviated new drug application (ANDA) suitability petition submitted under Federal Food, Drug, and Cosmetic Act (FD&C Act) section 505(j)(2)(C), and pursuant to 21 CFR 10.20, 10.30, and 314.93.

This MAPP addresses suitability petitions assigned to OGD as the action office.

BACKGROUND

An applicant can submit a petition (commonly referred to as a suitability petition) that requests permission to submit an ANDA for a drug product that is not the same as a listed drug with respect to certain characteristics. An approved suitability petition is required for any proposed ANDA drug product that differs from the listed drug with respect to (1) route of administration, (2) dosage form, (3) strength, or (4) when one active ingredient is substituted for one of the active ingredients in a listed combination drug product.

Under 21 CFR 314.93(e), the Agency will approve or deny the petition no later than 90 days after the petition is submitted.
POLICY

OGD’s goal is to respond to suitability petitions in an efficient and effective manner. To meet this goal, a number of parties within the Center for Drug Evaluation and Research (CDER) and throughout the Agency must work in a coordinated manner. OGD, the office primarily responsible for responding to suitability petitions, has developed procedures for enhancing communication among parties involved in addressing the request(s) in the suitability petitions.

RESPONSIBILITIES

OGD Lead:

- Ensures that the appropriate Agency staff is involved in the development of the suitability petition response; serves as the lead author; and bears the ultimate responsibility for successful completion, clearance, and issuance of the suitability petition response. The OGD lead, along with the consulting expert and, when appropriate, the Office of Chief Counsel (OCC), ensures that the information in the suitability petition response is accurate and consistent with CDER and Agency regulations and policies, and relevant precedent.

Regulatory Policy Advisor (RPA):

- Assigns suitability petitions to an OGD lead and provides guidance and leadership to OGD lead throughout the development and clearance of the suitability petition response.

Director of the Division of Clinical Review (DCR):

- Provides guidance and leadership to the OGD lead and the RPA throughout the development and clearance of the suitability petition response.

OGD Director:

- Provides leadership to the OGD lead, the RPA, and the director of the DCR, and provides final clearance on all suitability petition responses.

OGD Technical Information Specialist (TIS):

- Maintains the suitability petitions database and reviews the suitability petition response for format and accuracy, and issues the final response after it has been cleared by the OGD lead, the RPA, and the DCR, and signed by the OGD Director.
Consulting Expert:

- May be located in any CDER office and is requested by the OGD lead to provide expert guidance on the development and clearance of the suitability petition response. The consulting expert, along with the OGD lead, ensures that the scientific information in the suitability petition response is accurate and consistent with CDER and Agency regulations and policies, as well as precedent cases.

Pediatric Review Committee (PeRC):

- Reviews requests under the Pediatric Research Equity Act (PREA) for waiver of pediatric studies for suitability petitions that request a change in route of administration, dosage form, or when one active ingredient is substituted for one of the active ingredients in a listed combination drug.

Office of Chief Counsel (OCC):

- Reviews suitability petition denials or suitability petitions that raise legal issues or novel or controversial issues that could possibly involve litigation, but is not ordinarily involved in the clearance of most other suitability petition responses. Requests for OCC review are triaged through the CDER Office of Regulatory Policy (CDER-ORP Requests on the DHHS Global Address List).

PROCEDURES

- The OGD TIS enters the petition into the suitability petitions database when the suitability petition is received from the Division of Dockets Management and routes the suitability petition to the OGD lead.

- The OGD lead prepares a summary of the suitability petition, considers whether the suitability petition meets the regulatory requirements regarding format and content, determines whether a listed drug has been approved for the change described in the suitability petition, generates a clearance sheet, and determines, with the support of the director of DCR, whether the suitability petition requires review by a consulting expert(s). If review by a consulting expert is necessary, then a consult request is drafted and routed to the appropriate review division(s).

- The OGD lead prepares a draft suitability petition response.

- The OGD lead forwards the complete suitability petition package, which includes any consult responses and the draft suitability petition response, for clearance by the director of DCR.

- The director of DCR edits the suitability petition response, as necessary.
The director of DCR forwards the suitability petition package to the RPA for clearance.

The RPA provides further edits or comments to the suitability petition package, if necessary, confirms that a listed drug has not been approved for the change described in the suitability petition, and determines whether the suitability petition response requires further consultation with or clearance from OCC or PeRC.

The RPA provides additional information if requested or schedules a meeting with OCC or representatives of PeRC, if needed.

The OGD TIS reviews the suitability petition response for format and accuracy, finalizes the suitability petition response, and issues the response via USPS once it has been signed by the OGD Director or Deputy Director.

REFERENCES

1. Federal Food, Drug, and Cosmetic Act section 505(j)(2)(C)
2. 21 CFR 314.93
3. 21 CFR 10.20 and 10.30

DEFINITIONS

ANDA Suitability Petition – A petition submitted under section 505(j)(2)(C) of the Act and pursuant to 21 CFR 10.20, 10.30, and 314.93, that requests permission to submit an ANDA for a drug product that differs in route of administration, dosage form, strength, or one active ingredient in a combination product from that of a listed drug.

EFFECTIVE DATE

This MAPP is effective upon date of publication.