POLICY AND PROCEDURES

OFFICE OF GENERIC DRUGS

ANDA Suitability Petitions

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PURPOSE

- This Manual of Policies and Procedures (MAPP) describes how the Office of Generic Drugs (OGD) will respond to suitability petitions submitted to it by or on behalf of prospective abbreviated new drug application (ANDA) applicants.

- This MAPP includes procedures to which FDA committed, and industry agreed, as part of the reauthorization of the Generic Drug User Fee Amendments (GDUFA III).[1]

BACKGROUND

- The Generic Drug User Fee Amendments of 2012 (GDUFA I)[2] amended the FD&C Act to authorize FDA to assess and collect user fees to provide the Agency with resources to help ensure patients have access to quality, affordable, safe, and effective generic drugs. GDUFA fee resources[3] bring greater predictability and timeliness to the review of generic drug applications. GDUFA has been reauthorized every 5 years to continue FDA's

[1] The GDUFA III commitment letter is available at https://www.fda.gov/media/153631/download.
[2] Title III of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144.
[3] User fees are available for obligation in accordance with appropriations acts.

ability to assess and collect GDUFA fees, and this user fee program has been reauthorized two times since GDUFA I, most recently in Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023.[4] As described in the GDUFA III commitment letter applicable to this latest reauthorization,[5] FDA has agreed to performance goals and program enhancements regarding aspects of the generic drug assessment program that build on previous authorizations of GDUFA. New enhancements to the program are designed to maximize the efficiency and utility of each assessment cycle, with the intent of reducing the number of assessment cycles for ANDAs and facilitating timely access to generic medicines for American patients.

- Consistent with the GDUFA III Commitment Letter, OGD is issuing this MAPP to note that we will take certain actions to enhance the tracking and performance for responding to suitability petitions.

POLICY

- A prospective applicant may submit a petition to the Food and Drug Administration (FDA) to request 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).[6]

- FDA will refuse to receive an ANDA citing a pending suitability petition (or a suitability petition that was denied) because that ANDA would lack a legal basis for submission.[7]

- FDA will approve a suitability petition unless, among other reasons, one of the following occurs:[8]

    - 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.

[4] See Division F, Title III of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180).
[5] See footnote 1.
[6] Section 505(j)(2)(C) of the 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.
[7] See section 505(j)(2)(A)(ii) -(iv) of the FD&C Act (21 U.S.C. 355(j)(2)(A)(ii)-(iv); See 21 CFR 314.101(d)(3).
[8] See section 505(j)(2)(C) of the FD&C Act (21 U.S.C. 355(j)(2)(C)); see also 21 CFR 314.93(e).

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

- FDA has determined that the reference listed drug has been withdrawn from sale for safety or effectiveness reasons under 21 CFR 314.161 or the reference listed drug has been voluntarily withdrawn from sale and the agency has not determined whether the withdrawal was for safety or effectiveness reasons.

- The suitability petition requests a change to a drug product that triggers 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; such studies render the proposed product ineligible for approval in an ANDA.[9]

The GDUFA III states:[10]

- FDA will work in fiscal year (FY) 2023 to enhance the Agency's processes for reviewing and responding to suitability petitions.

- FDA will contact petitioners who submitted suitability petitions prior to FY 2023 to determine if they remain interested in receiving a response.

- FDA will conduct a completeness assessment within 21 days of the date of receipt of a petition, or within 21 days of the date of receipt of an Information Request (IR) response, if issued as part of a completeness assessment, for petitions submitted[11] in FYs 2024-2027.

- FDA will prioritize review of certain suitability petitions for drug products that:

    - Could mitigate or resolve a drug shortage and prevent future shortages
    - Address a public health emergency declared by the Secretary of the U.S. Department of Health and Human Services under section 319 of the Public Health Service Act (PHS Act), or are anticipated under the

[9]See section 505(j)(2)(A) of the FD&C Act. See 21 CFR 314.93(e)(1)(i). See also draft guidance, *Pediatric Drug Development: Regulatory Considerations — Complying with the Pediatric Research Equity Act and Qualifying for Pediatric Exclusivity Under the Best Pharmaceuticals for Children Act* (May 2023) at 9, which when final will represent the agency's current thinking on this topic.

[10] GDUFA III Commitment Letter at 21-22. These commitments represent the product of the FDA's discussions with the regulated industry and public stakeholders, as mandated by Congress. Id. at 4. They are not binding on the agency.

[11] The date of submission for the purposes of determining the fiscal year of submission is the date of FDA's completion of the completeness assessment.

same criteria as apply to such a declaration
- Are for a new strength of a parenteral product that could aid in eliminating pharmaceutical waste or mitigating the number of vials needed per dose by addressing differences in patient weight, body size, or age
- May be subject to special review programs under the President's Emergency Plan for AIDS Relief (PEPFAR)[12]

- Beginning in FY 2024, FDA will review and respond to suitability petitions that have been assigned a goal date as follows:

  - In FY 2024, 50 percent of submissions within 6 months after completeness assessment, up to a maximum of 50 suitability petitions completed
  - In FY 2025, 70 percent of submissions within 6 months after completeness assessment, up to a maximum 70 suitability petitions completed
  - In FY 2026, 80 percent of submissions within 6 months after completeness assessment, up to a maximum of 80 suitability petitions completed
  - In FY 2027, 90 percent of submissions within 6 months after completeness assessment, up to a maximum of 90 suitability petitions completed

- As a general matter, if FDA misses an assigned goal date, FDA will prioritize the review of suitability petitions for which a goal date was missed prior to reviewing newly submitted suitability petitions for the current fiscal year, except for those suitability petitions that are otherwise prioritized, as noted above.[13]

RESPONSIBILITIES

- **Division of Legal and Regulatory Support (DLRS) Project Manager (PM)**

[12] An ANDA for single-entity (SE) antiretroviral (ARV) and fixed-combination (FC) ARV drug products for the treatment or prevention of human immunodeficiency virus-one (HIV-1) infection that are intended for distribution outside of the United States under the President's Emergency Plan for AIDS Relief (PEPFAR) may be subject to special review provisions. See FDA's draft guidance for industry, *Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of Prevention of HIV-1 Under PEPFAR* (August 2023) which when final will represent the agency's current thinking on this topic; See also MAPP 5240.3 Rev. 6 *Prioritization of the Review of Original ANDAs, Amendments, and Supplements*.

[13] See Appendix: Prioritization of Suitability Petitions in the GDUFA III commitment letter for further information on how FDA will operationalize review of petitions.

- Receives the suitability petition from the Dockets Management Staff and routes the suitability petition to the Division of Filing Review (DFR) PM.

- Contacts Dockets Management Staff to upload completeness assessment related correspondence and petition response to the docket for the suitability petition

- Assigns the petition to a primary DLRS policy reviewer

- Maintains draft and final versions of all documents within internal OGDP document repositories

- **Division of Filing Review (DFR) PM**

  - Assigns the suitability petition to a DFR primary and secondary reviewer

  - If DFR primary reviewer determines information and/or clarification from the petitioner is needed to review the petition, an Information Request (IR) will be issued by the DFR PM.

  - Issues correspondence to petitioner following an acceptable completeness assessment which indicates the assigned goal date for review of the petition. Notifies DLRS PM to send a copy of the correspondence to Dockets Management Staff to upload to the docket for the suitability petition.

  - Sends any consult requests that were prepared by and received from the DFR primary reviewer. Consult requests will be issued within 30 days after the completeness assessment is finalized.

  - Issues to the petitioner any IR identified as necessary to provide a response on a consult request by a consulted Office or Division. If, after a consult request is issued, an Office or Division determines additional information is necessary to provide a consult response, they will prepare an IR and coordinate to issue it to the petitioner with the DFR PM.

  - Receives, from the consulting expert(s), responses to consult requests.

  - If there is a differing opinion among the consulted disciplines related to the proposed response to the suitability petition, DFR, DLRS, and the Division of Clinical Review (DCR)[14] will discuss to reach a resolution. The DFR PM will coordinate any meetings, as necessary.

[14] DCR is in OGD's Office of Safety and Clinical Evaluation.

- Sends the suitability petition package to the DLRS PM to be assigned to a DLRS primary policy reviewer.

- **DFR Primary Reviewer**

  - Conducts a completeness assessment and considers whether the format and content of the suitability petition meet the regulatory requirements.

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

  - Determines whether a duplicate suitability petition was already approved or denied for the same change.

  - Determines if additional information is needed from the petitioner and drafts IR for the DFR PM to issue to petitioner.

  - Prioritizes petitions, as appropriate, based on goal dates and/or other factors.

  - Prepares the following:

    - Consult requests for the Office of New Drugs' (OND's) appropriate review discipline for the RLD, Divisions of Medication Error Prevention and Analysis (DMEPA),[15] Pediatric Review Committee (PeRC), and DCR

    - A written summary of the suitability petition ("staff work") that addresses all the foregoing DFR primary reviewer considerations

    - A draft response to the petitioner.

  - Forwards the staff work to the DFR secondary reviewer.

  - Receives the staff work back from the DFR secondary reviewer and, if no edits or revisions are needed, then sends the consults to the DFR PM to issue to the appropriate office(s).

  - If revisions are needed, edits staff work 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 to the appropriate office.

[15] DMEPA is in the Office of Surveillance and Epidemiology's Office of Medication Error Prevention and Risk Management.

- **DFR Secondary Reviewer**

    - Reviews the completeness assessment, staff work, consult requests, consult responses and draft response to the petitioner that were prepared by and received from the DFR primary reviewer. Makes any necessary edits or suggestions for revision to the documents and sends these to the DFR primary reviewer for incorporation. If no edits or revisions are necessary, the DFR secondary reviewer notifies the DFR primary reviewer.

- **DLRS Primary Reviewer**

    - Reviews, as soon as practicable upon assignment, 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 request to address the comment(s) and/or forwarding comments to the appropriate office for review).

    - 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 withdrawn,[16] 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 (i.e., summary of the suitability petition, draft response to petition, consult responses, etc.) to a DLRS secondary policy reviewer for review.

    - Following review by the DLRS secondary reviewer, the DLRS primary policy reviewer issues a consult request to FDA's Office of Chief Counsel (OCC) if the suitability petition raises a novel or controversial issue. DLRS and OCC will coordinate action on the

[16] An approval is withdrawn as of the date of withdrawal identified in the published Federal Register notice. See 21 CFR 314.152; see also 21 CFR 314.150(d).

consult request in individual cases in an effort to issue a response by the goal date.

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

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

- **DLRS Secondary Reviewer**

  - The DLRS secondary policy reviewer edits the response to the suitability petition as necessary.

- **OCC**

  - Reviews and replies to consult requests from DLRS primary reviewer that are issued if the suitability petition raises a novel or controversial issue. DLRS and OCC will coordinate action on the consult request in individual cases to issue a response by the goal date.

- **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 primary policy reviewer.

- **OND Review Division**

  - Reviews and replies to consult requests from DFR primary reviewer

- **PERC**

  - Reviews and replies to consult requests from DLRS primary reviewer

- **DCR**

  - Reviews and replies to consult requests from DFR primary reviewer

- **DMEPA**
    - Reviews and replies to consult requests from DFR primary reviewer

PROCEDURES

- A PM in DLRS[17] receives the suitability petition from the Dockets Management Staff[18] and routes the suitability petition to the DFR PM.[19]
- The DFR PM assigns the suitability petition to a DFR primary and secondary reviewer.
- The DFR primary reviewer:
    - Conducts a completeness assessment and considers whether the format and content of the suitability petition meet the regulatory requirements and includes the information necessary for FDA to act on the petition. For example, 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[20]
        - Suitability petition follows 21 CFR 10.30
        - Suitability petition identifies a valid RLD as the basis for their submission[21] (FDA identifies listed drugs that have been designated as RLDs in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (Orange Book)[22])
        - Proposed labeling and RLD labeling are provided[23]
        - Suitability petition contains a Pediatric Research Equity Act (PREA) waiver request, if applicable, accompanied by supportive information and data
    - Determines whether a listed drug has been approved for the change

[17] DLRS is in OGD's Office of Generic Drug Policy.
[18] The Dockets Management Staff is in FDA's Office of the Commissioner.
[19] DFR is in OGD's Office of Regulatory Operations.
[20] Section 505(j)(2)(C) of the FD&C Act (21 U.S.C. 355(j)(2)(C)); 21 CFR 314.93.
[21] 21 CFR 314.93(d).
[22] The Orange Book is available at https://www.accessdata.fda.gov/scripts/cder/ob/. See also FDA's guidance for industry, *Referencing Approved Drug Products in ANDA Submissions* (October 2020) which describes general considerations on how to identify a reference listed drug and the basis of submission in an ANDA.
[23] 21 C.F.R. 314.93(d).

described in the suitability petition.

- Determines whether a duplicate suitability petition was already approved or denied for the same change. If a petition for the same change has been denied, consideration should be given to whether there are any differences between the denied petition and the new petition that would allow the new petition to move forward.

- Determines if additional information is needed from the petitioner and drafts IR for the DFR PM to issue to petitioner.

- Prioritizes petitions, as appropriate, based on goal dates and/or other factors.[24]

- Prepares the following:

  - Consults for OND's appropriate review discipline for the RLD, DMEPA, PeRC, and DCR

  - A written summary of the suitability petition ("staff work") that addresses all the foregoing DFR primary reviewer considerations

  - A draft response to the petitioner.

- Forwards the staff work to the DFR secondary reviewer.

- Receives the staff work back from the DFR secondary reviewer and, if no edits or revisions are needed, then sends the consults to the DFR PM to issue to the appropriate offices.

  - If revisions are needed, edits staff work 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 to the appropriate office.

- The DFR secondary reviewer:

  - Reviews the completeness assessment, staff work, consult requests, consult responses and draft response to the petitioner that were prepared by and received from the DFR primary reviewer. Makes any necessary edits or suggestions for revision to the documents and sends these to the DFR primary reviewer for incorporation. If no edits or revisions are necessary, the DFR secondary reviewer notifies the DFR primary reviewer.

[24] See footnote 9.

- The DFR PM:

    - If DFR primary reviewer determines information and/or clarification from the petitioner is needed to review the petition, an IR will be issued. If an IR is issued, the 21-day period for the completeness assessment will be adjusted to begin upon receipt of the response. If an IR is issued during review of the petition, after the completeness assessment is finalized, a response from petitioners will be requested within 10 calendar days.

    - Issues correspondence to petitioner following an acceptable completeness assessment which indicates the assigned goal date for review of the petition. Notifies DLRS PM to send a copy of the correspondence to Dockets Management Staff to upload to the docket for the suitability petition.

    - Sends any consult requests that were prepared by and received from the DFR primary reviewer. Consult requests will be issued within 30 days after the completeness assessment is finalized.

    - Issues to the petitioner any IR identified as necessary to provide a response on a consult request by a consulted Office or Division. If, after a consult request is issued, an Office or Division determines additional information is necessary to provide a consult response, they will prepare an IR and coordinate to issue it to the petitioner with the DFR PM.

    - Receives, from the consulting expert(s), consult request responses.

    - If there is a differing opinion among the consulted disciplines related to the proposed response to the suitability petition, DFR, DLRS, and DCR will discuss to reach a resolution.[25] The DFR PM will coordinate any meetings, as necessary.

- Once all necessary consults are complete, the DFR primary reviewer prepares a draft response to the petitioner and compiles a suitability petition response package (i.e., summary of the suitability petition, draft response to petition, consult responses, etc.) and sends it to the DFR secondary reviewer. The DFR secondary reviewer will revise/edit accordingly. Once all revisions/edits are accepted, if any, the DFR PM sends the suitability petition package to the DLRS PM to be assigned to a primary policy reviewer.

[25] See MAPP 4151.8, Rev. 1, *Equal Voice: Collaboration and Regulatory and Policy Decision-Making in CDER*, available at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/cder-manual-policies-procedures-mapp.

- The DLRS primary policy reviewer:

    - Reviews, as soon as practicable upon assignment and again before final review, 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 request to address the comment(s) and/or forwarding comments to the appropriate office for review).

    - 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 withdrawn, 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 policy reviewer issues a consult request to OCC if the suitability petition raises a novel or controversial issue. DLRS and OCC will coordinate action on the consult request in individual cases in an effort to issue a response by the goal date.

- After review by the DLRS secondary policy reviewer and OCC, as appropriate, the DLRS primary policy 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 primary policy reviewer.

- The DLRS primary policy reviewer sends the signed petition response and the complete suitability petition response package to the DLRS PM. The DLRS PM maintains draft and final versions of all documents within internal OGDP document repositories. Final versions of responses and internal reviews are also maintained within FDA's Records Management Client.

- The DLRS PM ensures a copy of the response is sent to the Dockets Management Staff so that it 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
08/21/13	Initial	N/A
08/10/18	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.
10/09/20	2	Revised for clarification and minor updates to the process and organization.
9/29/23	3	Revised to account for changes made by the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027 (GDUFA III commitment letter) and certain other updates to process and organization.

ATTACHMENT – COMPLETENESS ASSESSMENT

Petition Number:	FDA-20XX-P-XXXX
Petitioner:	Applicant
Attention:	Point of Contact
Address Line 1:	Address Line 1
Address Line 2:	Address Line 2
Proposed Drug Product:	Drug product name, strength(s), dosage form
Reference Listed Drug (RLD):	RLD Name NDA number Sponsor
Requested Type of Change:	Select requested change or click to type if multiple changes proposed
Date of Petition:	Date in Suitability Petition
Received Date:	Received date
Filing Date:	Filing date
Information Request (IR) needed:	Yes or No Date IR issued, if applicable
IR Due Date:	Date IR due, if applicable
GDUFA Goal Date:	GDUFA Goal Date
Pediatric Waiver Requested:	Choose an item
Waiver Justification:	Choose an item
Priority:	Choose an item
Priority Designation:	Choose an item

Reasons for Denial	
Already an approved product listed in the Orange Book?	Yes or No Enter approved Drug Product information, if applicable Primary Reviewer Check: Reviewer name and date checked Secondary Reviewer Check: Reviewer name and date checked
Is the proposed change a non-petitionable change?	Yes or No Explain
Has the RLD been withdrawn from sale for safety or effectiveness reasons?	Yes or No

Has the RLD been voluntarily withdrawn from sale and the agency has **not** made a safety/effectiveness (S/E) determination?	Yes or No

Related Suitability Petitions	
Already an approved Suitability Petition (SP) requesting the same change?	Yes or No Enter approved Suitability Petition information, if applicable
Any pending SPs requesting the same change?	Yes or No Enter pending Suitability Petition information, if applicable

Is an Information Request needed?		Comments
All Sections of Petition Provided?	Yes or No	
Appropriate Basis of Submission (BOS) Identified?	Yes or No	
RLD Labeling Provided?	Yes or No	
Proposed Labeling Provided?	Yes or No	
Is PREA Triggered?	Yes, No, N/A	
PREA Waiver Justification Provided?	Yes, No, N/A	

Recommendation	☐**Acceptable for Review** ☐**Denied for Review**
Primary Reviewer/Date:	Enter Primary Reviewer and Date
Secondary Reviewer/Date:	Enter Secondary Reviewer and Date
IR Issued:	☐Yes Click to enter date IR issued ☐N/A
Date Response Received:	Click to enter date IR Response received
PeRC Consult Needed:	☐Yes ☐No