Suitability Petitions: A Policy Perspective

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Advancing Generic Drug Development: Translating Science to Approval
September 21, 2022

Learning Objectives

- Describe the types of changes for which a suitability petition may be submitted
- Learn of potential obstacles to using suitability petitions
- Understand the changes that will be coming to processes for reviewing suitability petitions under the Generic Drug User Fee Amendments (GDUFA III) Commitment Letter

What is a Suitability Petition?

- A request to submit an abbreviated new drug application (ANDA) that is different from the reference listed drug (RLD):
  - Route of administration
  - Dosage form
  - Strength
  - One different active ingredient in a fixed-dose combination drug product
- Petition must be submitted ***and*** approved before ANDA can be submitted

A Suitability Petition Will Be Approved Unless:

- Investigations must be conducted to show the safety and efficacy (S&E) of the drug product or proposed change from RLD
- Requested change has been approved in a new drug application (NDA)
- Requested change triggers the need for pediatric studies under Pediatric Research Equity Act (PREA) to assess S&E and FDA does not waive the requirement

A Suitability Petition Will Be Approved Unless:

- For change in active ingredient –
  - RLD is not a fixed-dose combination product
  - Drug cannot be adequately evaluated for approval without data from studies beyond scope of ANDA
  - Petition does not contain info to show that active is of same pharmacological or therapeutic class and can be expected to have the same therapeutic effect as RLD
  - Different active is not contained in a listed drug
  - Remaining actives are not identical to RLD

A Suitability Petition Will Be Approved Unless:

- Proposed change would require significant labeling changes to address newly introduced safety or effectiveness problem
- FDA has determined RLD was withdrawn from sale for safety or efficacy reasons, or RLD has been voluntarily withdrawn from sale and Agency has not made S&E determination

Suitability Petition Process

- Suitability petition is submitted to FDA
  - Reviewed per process outlined in MAPP 5240.5 ANDA Suitability Petitions
  - Approved unless FDA identifies reason under 21 CFR 314.93(e)(1) not to approve
- Once approved, an ANDA with that change can be submitted

Basis of Submission – First Petitioned ANDA

- Basis of submission is RLD + approved suitability petition
- ANDA must contain:
  - RLD which must be the same as the RLD identified in the approved suitability petition
  - Reference to petition's FDA-assigned docket number
  - Copy of correspondence approving the suitability petition
- Form FDA 356h – Identify RLD
- Basis of submission statement (1.12.11) – identify RLD, reference docket number, and include petition approval letter; RLD generally identified as reference standard

Basis of Submission – Previous Petitioned ANDA Approved

- Basis of submission is RLD + approved suitability petition
- ANDA must contain:
  - RLD which must be the same as the RLD identified in the approved suitability petition
  - Reference to petition's FDA-assigned docket number
  - Copy of correspondence approving the suitability petition
- First approved petitioned ANDA generally selected as reference standard and should be identified in appropriate sections of subsequent ANDA as the reference standard

Therapeutic Equivalence

- Petitioned ANDA is not therapeutically equivalent to RLD because of difference that makes product not pharmaceutically equivalent
- First approved petitioned ANDA does not receive a therapeutic equivalence code
- Subsequent petitioned ANDA would be designated therapeutically equivalent to first petitioned ANDA

NDA Approval for Same Change

- What if an NDA is submitted for the same change?
  - If NDA is approved before approval of an ANDA submitted pursuant to an approved suitability petition, ANDA can no longer reference the suitability petition

Venlafaxine Case Study

10/20/1997	Venlafaxine Extended-release (ER) Capsules approved via NDA
4/16/2003	Suitability petition submitted for change in dosage form to ER Tablets
3/30/2005	Suitability petition approved
12/12/2006	505(b)(2) NDA received for ER Tablets
5/20/2008	505(b)(2) NDA approved for ER Tablets

Venlafaxine Case Study - Impact

- ANDAs could no longer reference the suitability petition
  - Must reference 505(b)(2) NDA for ER Tablets as RLD
- Pending ANDAs cannot change RLD (21 CFR 314.96(c))
  - Any pending ANDAs citing suitability petition should withdraw application
- Must submit a new ANDA referencing the 505(b)(2) NDA for ER Tablets and perform testing against new RLD

GDUFA III – What's Ahead?

Under the GDUFA III Commitment Letter, in FY 2023, FDA agreed to work diligently to:

- Enhance the Agency's processes for reviewing and responding to suitability petitions, and
- Review and respond to pending suitability petitions

GDUFA III – What's Ahead?

Prior to FY 2024:

- FDA agreed to take appropriate action to determine if petitioners who submitted suitability petitions prior to FY2023 remain interested in a response

GDUFA III – What's Ahead?

FY 2024-2027:

- Conduct a completeness assessment of petitions submitted in these FYs
  - 21 days after the date of the petition submission, or
  - If an information request (IR) is issued as part of the completeness assessment, FDA agreed to finish the completeness assessment within 21 days after the date of receipt of the IR response

GDUFA III – What's Ahead?

- Suitability petitions submitted in FY 2024-2027 will receive a goal date
  - Those submitted prior to FY 2024 will not receive a goal date
  - If a petitioner wants to receive a goal date on a suitability petition submitted prior to FY 2024, may withdraw and submit a new suitability petition in FY 2024-2027

GDUFA III – What's Ahead?

Goal Dates: Review and respond to

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

*Date of submission for the purposes of determining the fiscal year of submission will be the date of FDA's completion of the completeness assessment

GDUFA III – What's Ahead?

Prioritization of suitability petitions:

Could mitigate or resolve a drug shortage and prevent future shortages

Address a public health emergency declared by the Secretary of HHS under section 319 of the PHS Act, or anticipated under the same criteria as apply to such a declaration

Is 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

Is subject to special review programs under the President's Emergency Plan for AIDS Relief (PEPFAR)

GDUFA III – What's Ahead

Missed goal dates due to increased submissions:

- Prioritize the review where goal date missed prior to reviewing newly submitted suitability petitions for the current fiscal year
  - Except for suitability petitions prioritized under criteria on previous slide

Challenge Question #1

Suitability petitions will have goal dates beginning in:

A. FY 2023

B. FY 2024

C. FY 2025

D. FY 2026

Challenge Question #2

Which of the following statements is NOT true?

A. Certain changes may be made via a 505(b)(2) NDA or a suitability petition.

B. An ANDA may not rely on a suitability petition for the change once the same change is approved in an NDA.

C. Suitability petitions can be submitted for a change in indication.

D. In GDUFA III, the review of certain suitability petitions will be prioritized.

Suitability Petition Resources

- Sections 505(j)(2)(C) and 505B of the Federal Food, Drug, and Cosmetic Act
- 21 CFR 10.20, 10.30, and 314.93
- MAPP 5240.5 ANDA Suitability Petitions
- Referencing Approved Drug Products in ANDA Submissions guidance for industry
- Determining Whether to Submit an ANDA or a 505(b)(2) Application guidance for industry
- Evaluation of Therapeutic Equivalence draft guidance for industry
- GDUFA III Commitment Letter

Summary

- Suitability petitions are a request to submit an ANDA that is different from the RLD
- Be aware of limitations and obstacles to using suitability petitions
- Changes are coming as part of GDUFA III commitments

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Questions?

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