U.S. FOOD & DRUG ADMINISTRATION

Suitability Petitions

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Learning Objectives

- Understand the use and purpose of a Suitability Petition
- Know the proper format and content of a suitability petition and learn how to submit
- List the reasons for denial of a suitability petition
- Provide progress update on GDUFA III Suitability Petitions
- Understand Suitability Petition assessment approach and Case Studies

What is a Suitability Petition?

A request to submit an abbreviated new drug application (ANDA) that is different from the reference listed drug (RLD) in one or more of the following:

- Strength
- Route of administration
- Dosage form
- Change in one active ingredient in a fixed-combination drug product (i.e., a drug product with multiple active ingredients)

Submitting a Suitability Petition

- Suitability petitions are a type of citizen petition. Follow the format as outlined in 21 CFR 10.30

- Suitability petitions are submitted to Dockets Management Staff (DMS).

  – Submissions, supplemental material, and amendments (i.e., responses to information requests) **related to a specific docket ID** should be uploaded using **FDA's Electronic Method for Specific Electronic Submissions** via docket ID FDA-2013-S-0610.

  – All supplemental or supported related material (SRMs) and amendments **must reference** the previously **assigned docket ID** (ex. Subject: Amendment to FDA-2024-P-XXXX) for DMS to process it in compliance with the Code of Federal Regulations (CFR).

  – For additional information, refer to **Instructions on "how to upload"**: Electronic Method for Specific Electronic Submissions to FDA's Division of Dockets Management Staff.

Submitting a Suitability Petition

Format and Content

- Five Sections of a Citizen Petition (21 CFR 10.30):
  A. Action Requested
  B. Statement of Grounds
  C. Environmental Impact
  D. Economic Impact
  E. Certification

- Additional content specifically for Suitability Petitions (21 CFR 314.93(d)):
  – Identify a reference listed drug (RLD)
  – Copy of the currently approved RLD labeling
  – Copy of the proposed labeling

- Pediatric Research Equity Act (PREA) Requirements Waiver Request[1]

[1] PREA Waiver Request warranted for petitions proposing any type of change that triggers PREA.

Suitability Petitions and PREA

- Suitability petitions proposing a change in **dosage form**, **route of administration**, **or** for **a change in active ingredient in a fixed-combination drug** trigger the requirement for pediatric assessments or molecularly targeted pediatric cancer investigations under PREA.
- These requirements may be waived by the Pediatric Review Committee (PeRC). Petitioners must submit a waiver request to waive these requirements.
- PREA authorizes FDA to waive the requirement to submit a pediatric assessment, based on established criteria, for some or all pediatric age groups.
- For information on PREA requirements and requesting a waiver, refer to Draft Guidance for Industry: 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

Requesting a PREA Waiver

To request a waiver, petitioners should provide the following:

- Petitioner name, drug name, and indication.
- The age group(s) included in the waiver request.
- The statutory reason(s) for requesting a waiver, including reference to the applicable statutory authority.[1]
- Evidence that the request meets the statutory reason(s) for waiver. All relevant scientific/clinical justifications for the waiver request should be included.

[1] See section 505B(a)(5) of the FD&C Act (21 U.S.C. 355c(a)(5))

Common Reasons for Denial of a Suitability Petition

FDA will approve a suitability petition unless, among other reasons, one of the following is applicable (see 21 CFR 314.93(e)(1)(i)-(vi)):

- Investigations must be conducted
- A drug product is approved in an NDA for the change described in the petition
- Triggers the need for pediatric studies under the Pediatric Research Equity Act (PREA) and the waiver request has been denied
- The proposed change from the RLD is not one of the permitted types of changes outlined in 21 CFR 314.93(b)
- Significant labeling changes are necessary
- RLD has been withdrawn from sale for safety or effectiveness (S/E) reasons or RLD has been voluntarily withdrawn from sale and the Agency has not made an S/E determination

Suitability Petition Best Practices

- Check the Orange Book!
  - Has an NDA already been approved for the drug product proposed in your petition?
    - Regardless of whether a petition has been approved for the proposed drug product
    - If the drug product is approved in an NDA for the change described in the petition, the petition and the listed drug identified in the petition can no longer be the basis for ANDA submission. (see 21 CFR 314.93(f)(2)).
  - Has the RLD cited as the basis of your submission been discontinued?
    - Ensure a determination has been made that the product was not discontinued or withdrawn for safety or effectiveness reasons.
    - If a determination has not been made, submit a separate citizen petition under 21 CFR 10.25(a) and 10.30 seeking a determination whether the listed drug has been withdrawn from sale for safety or effectiveness reasons. This determination must be made prior to approving a suitability petition relying on a discontinued NDA.

- Wait for approval of your suitability petition!
  - FDA will refuse to receive an ANDA citing a *pending* suitability petition (or a suitability petition that was denied) as that ANDA would lack a legal basis of submission. (see 21 CFR 314.94(a)(3)(i)/(iii))

GDUFA III UPDATES

SUITABILITY PETITIONS IN GDUFA III

GDUFA III Commitment	Outcome
In FY 2024, 50 percent of submissions within 6 months after completeness assessment, up to a maximum of 50 suitability petitions completed	99/103 on time (96%)
In FY 2025, 70 percent of submissions within 6 months after completeness assessment, up to a maximum of 70 suitability petitions completed	94/94 on time (100%)
In FY 2026, 80 percent of submissions within 6 months after completeness assessment, up to a maximum of 80 suitability petitions completed	N/A
In FY 2027, 90 percent of submissions within 6 months after completeness assessment, up to a maximum of 90 suitability petitions completed	N/A

GDUFA III Petitions

Total petitions received to date: 263

	FY '24	FY '25	FY '26
# of petitions filed (10/1/xx - 9/30/xx)	109	94	60
# of completeness assessments completed	103	94	52
Substantive responses issued	103	94	8
Answered on time	99	94	8
Missed goal dates	4	0	-
Percentage answered on time	96%	100%	-

GDUFA III Petitions (continued)

Changes Proposed in Suitability Petitions

Type of Change	Petitions Submitted (FY24 and FY25)
Strength	128 (63%)
Dosage Form	47 (23%)
Strength & Dosage Form	24 (12%)
Route of Administration	2 (1%)
Other (Non-petitionable Changes)	2 (1%)
Total	203

GDUFA III Petitions (continued)

Final determinations:

	FY '24	FY '25	FY '26
Substantive responses issued	103	94	8
Approved	48	55	6
Denied	52	36	2
• Already approved NDA product	8	2	0
• Non-petitionable change proposed	2	1	0
• No S/E determination for discontinued RLD	2	2	0
• PREA waiver denied*	17	9	0
• Other (clinical trials or significant labeling changes necessary)	23	22	2
Partial Grant/Partial Denial	3	3	-
Withdrawn (by petitioner or administratively by OGD)	3	2	1

*37% of all dosage form/route of administration changes denied by PERC

SUITABILITY PETITION ASSESSMENT

Assessment Approach and Resources

- Suitability Petition
  - Proposed change, petitioner rationale
- RLD Labeling
  - Dosage & Administration, Special Populations, Warnings/Precautions, Clinical Pharmacology
- Proposed Labeling
  - How does labeling differ from RLD labeling?

Does it fail any criteria established in 21 CFR 314.93(e)(1)(i)-(vi))?

Assessment Approach

- Strength Changes
  - Review of all RLD indications and dosing
  - 75% of GDUFA III petitions
- Dosage Form Changes
  - Past precedent for allowing change
  - Highlight Orally disintegrating tablets (>50% of dosage form change)

RLD Labeling Assessment: Strength Change

- How explicit is RLD dosing?
  - Weight based?
  - Dosing range?
  - Fixed dose titration?
- Does RLD labeling mention proposed strength?
  - Dosage & Administration
  - Special Populations
- Does the change need new dosage and administration instructions?
  - Should be limited labeling changes for RLD
  - How Supplied should only be impacted

Assessment Approach: Strength Change

Approval Criteria

- Strength explicitly mentioned in dosing instructions, often with fixed increments
- Intermediate strength (between approved strengths) supported by RLD dosage labeling
- Strength falls within the explicit dosing range or via weight-based dosing.
- Strength(s) implied by titrated and/or individualized dosing instructions in RLD labeling
- Strength included in the RLD labeling for a special population (e.g., reduced dose with hepatic or renal impairment)

Denial Criteria

- Lower strength below approved dosing range
- Intermediate strength without specific dosing information
- Higher strength outside dosing range
- RLD labeling does not permit individualized dosing

Assessment Approach Case Study: Strength Change

- FDA-2025-P-2077 Fluoxetine Capsules, 15 mg and 30 mg
- RLD Prozac (Fluoxetine) Capsules, **10 mg, 20 mg, 40 mg**
- 30 mg (Approve): “A dose range of 20 **to** 60 mg/day is recommended; however, doses up to 80 mg/day have been well tolerated”
- 15 mg (Deny): “Panic Disorder: Initiate treatment with PROZAC 10 mg/day. After one week, increase the dose to 20 mg/day”
- Final Recommendation: **Partial Grant**

Orally Disintegrating Tablet (ODT) Changes

- Most common dosage form change under GDUFA III
- Precedent for ODT petition approvals
- Precedent for ANDA approval citing approved petition
  - Carbidopa/Levodopa 10mg/100mg, 25mg/100mg, 25mg/250mg (RLD Sinemet N017555)
  - Petition for ODT change approved 8/29/2002 (#02P-0033/CP1)
  - 4 approved ODT Carbidopa/Levodopa products in Orange Book.
- Approved ODTs under 505(b)(2) have relied only on BE testing
- ODTs not intended to be split, potential concern if RLD tablet scored with split tablet dosing

Case Study: ODT Changes

- FDA-2023-P-4293 Glycopyrrolate ODT, 1 mg, 2 mg
- RLD: Robinul and Robinul Forte (Glycopyrrolate) **Tablets**, 1 mg and 2 mg
- Assessment consideration
  - NDA 215019, Dartisla (Glycopyrrolate ODT), 0.85 mg and 1.7 mg, approved as 505(b)(2) application referencing Robinul Forte. The strength of the API was adjusted from 2 mg to 1.7 mg glycopyrrolate after an initial BE pilot study demonstrated a Cmax ~25% greater for the ODT.
  - No grounds for denial:
    - Differences in bioavailability would be evaluated during the ANDA review process
    - Aligns with existing dosing instructions in labeling
- Final Recommendation: **Approve**

Assessment Approach: Proposed Labeling

- How does proposed change(s) affect current RLD labeling?
  - **How Supplied** or **Dosage Forms and Strengths** changes only?
  - New **administration** or **preparation** instructions, including Instructions for Use (IFU)?
  - New **dosing information** or instructions
  - New **warning** to safely use product needed?
- Must consider if changes to labeling will be needed, compared to RLD, and if such changes are allowable under a future ANDA.
- Note: This is NOT a thorough labeling assessment.
- Labeling changes to **How Supplied** or **Dosage Forms and Strengths** generally permissible
- Labeling changes in ANDAs **are generally permissible** for additional administration instructions to describe how to use the proposed product

Assessment Approach: Proposed Labeling

- Changes that generally are NOT permissible and may be grounds for denial
  - New dosing instructions/indications
  - New warnings to safely use this product
- Any of the proposed changes from the listed drug would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem per [21 CFR 314.93(e)(1)(**iv**)]
  - Requiring new safety warnings for how to use (or not use) the proposed change are grounds for denial.
    - Proposed strength is below dosing range and must take multiple tablets to equal approved dose.
    - Proposed product can only be used for specific indications, strengths, or patient populations.

Reminders about future ANDAs

<u>All petitioned ANDAs</u>

- Adequate BE testing required
- If approved, will not be therapeutically equivalent to RLD

<u>Dosage form changes</u>

- ANDA labeling should describe administration instructions (if applicable)
- Appropriate BE testing corresponds to specific administration instructions

Approved petition does not guarantee future ANDA approval