

Best Practices for Submitting a Suitability Petition

*SBIA 2022: Advancing Generic Drug Development:
Translating Science to Approval*

Day 2, Session 8: Enabling Generics: Changes to Suitability Petitions in GDUFA III

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Learning Objectives

- Provide a general background on suitability petitions
- Describe the proper format and content of a suitability petition
- Review the requirements for submitting suitability petitions that trigger the Pediatric Research Equity Act (PREA)
- List the reasons for denial of a suitability petition
- Identify best practices and tips for submitting a quality suitability petition

Suitability Petition - Background



- Prospective applicants 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) and in accordance with 21 CFR 10.20, 10.30, and 314.93 requesting permission to submit an Abbreviated New Drug Application (ANDA) for a generic drug product that differs from a reference listed drug (RLD) in one or more of the following:
 - Route of administration
 - Dosage form
 - Strength
 - Change in one active ingredient in a fixed-combination drug product (i.e., a drug product with multiple active ingredients)

Format and Content

- Suitability petitions are a type of citizen petition. Sponsors must follow the format as outlined in 21 CFR 10.30
- Suitability petitions are submitted to Dockets Management Staff (DMS)
- The request and the FDA's response are publicly disclosed
- Five sections:
 - A. Action Requested
 - B. Statement of Grounds
 - C. Environmental Impact
 - D. Economic Impact
 - E. Certification

Format and Content (continued)



A. Action Requested

- Identification of the proposed generic product and a description of the permissible change(s) being requested
- Identification of the RLD, including dosage form; strength and active ingredient(s)

B. Statement of Grounds

- Comprehensive justification for the proposed change from the RLD being requested

Format and Content (continued)



C. Environmental Impact

- May request a categorical exclusion under 21 CFR 25.30 from the requirement to prepare an environmental assessment or may provide an environmental assessment under 21 CFR 25.40

D. Economic Impact

- Must provide an economic impact statement if requested by the Commissioner following review of the petition. The petitioner must indicate that such an analysis will be provided upon request.

Format and Content (continued)



E. Certification

- Certification that the petition includes, to the best knowledge and belief of the petitioner, all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition

Additional Content to Include When Submitting a Suitability Petition



- Labeling (21 CFR 314.93(d)):
 - Copy of the currently approved RLD labeling
 - Copy of the proposed labeling
- Recommended supplemental information:
 - Annotated proposed labeling identifying all differences in prescribing information from the RLD
 - If there is a proposed change in strength, provide a description of the proposed product, e.g., tablet color, shape, size, identifying imprint code(s)
 - Proposed carton labeling and container labels, if available

Additional Content to Include When Submitting a Suitability Petition (continued)



- Recommended supplemental information:
 - For petitions requesting a different active ingredient in a fixed-combination drug product:
 - Provide a description of any differences in clinical safety or efficacy that may be seen with the newly proposed active ingredient compared to the active ingredient in the RLD (e.g., if the new active ingredient has a narrow therapeutic index or may give rise to different adverse events).
 - Verify whether dosing (or presentation of strength) of the overall product will change as a result of the substitution of one of the active ingredients

Additional Content to Include When Submitting a Suitability Petition (continued)



- Recommended supplemental information:
 - For petitions requesting a different route of administration or dosage form:
 - Verify whether dosing of the drug product will change
 - Submit information on whether a different route of administration or dosage form gives rise to a potentially different adverse event profile (e.g., going from a tablet to an injection may lead to injection site reactions that do not otherwise exist for the tablet formulation). Include details of what the clinical outcome/impact is if a user were to administer the proposed product through the RLD's intended route of administration.
 - Indicate any changes in administration technique or instructions for use (e.g., changes from a tablet to an orally disintegrating tablet)

Suitability Petitions and PREA

- ANDAs submitted under an approved suitability petition for changes in dosage form, route of administration, or new active ingredient in fixed-combination products are subject to the pediatric assessment requirements that PREA imposes.
- PREA authorizes FDA to waive the requirement to submit a pediatric assessment, based on established criteria, for some, or all, pediatric age groups.
 - Thus, for any suitability petition requesting a change in dosage form, route of administration, or new ingredient in fixed-combination products, an applicant must provide a request to waive the requirements triggered by PREA.
 - If clinical studies are required under PREA for a proposed product submitted under a suitability petition and a waiver is not granted, the suitability petition will be denied.

What to Include in a PREA Waiver Request



- State the reason(s) for waiving pediatric assessment requirements with reference to applicable statutory authority:
 - a) Necessary studies are impossible or highly impracticable (because, for example, the number of pediatric patients is so small or geographically dispersed). (section 505B(a)(4)(B)(i) of the Act)
 - b) The product would be ineffective or unsafe in one or more of the pediatric age group(s) for which a waiver is being requested. (section 505B(a)(4)(B)(ii) of the Act)
 - c) The product fails to represent a meaningful therapeutic benefit over existing therapies for pediatric patients **and** is unlikely to be used in a substantial number of all pediatric age groups or the pediatric age group(s) for which a waiver is being requested. 505B(a)(4)(B)(iii) of the Act)
 - d) Reasonable attempts to produce a pediatric formulation for one or more of the pediatric age group(s) for which the waiver is being requested have failed. (section 505B(a)(4)(B)(iv) of the Act)
- Provide evidence that the statutory basis(es) for waiver of pediatric studies have been met
- Provide a certification to the information provided in the PREA waiver

Reasons for Denial of a Suitability Petition



- 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 PREA to assess the safety and efficacy of the drug product in a relevant pediatric subpopulation that would not be waived by the FDA, which renders the proposed product ineligible for approval in an ANDA
 - The suitability petition requests a type of change(s) to a drug product that is/are not permitted under 21 CFR 314.93(b)

Best Practices for Submitting a Suitability Petition and Associated ANDA



- Check for already approved drug products in the Orange Book
 - A suitability petition will be denied if the proposed drug product has already been approved
 - This includes drug products approved through the 505(b)(2) pathway
- Check for approved suitability petitions or duplicate petitions on [regulations.gov](https://www.fda.gov/regulations)
- 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 for submission

Challenge Question #1



Which of the following is **NOT** a permissible type of change from an RLD to request in a suitability petition?

- A. Change in dosage form
- B. Change in route of administration
- C. Change in salt form of the active pharmaceutical ingredient (API)
- D. Change in strength

Challenge Question #2



Which of the following is **NOT** a valid justification for requesting a waiver for pediatric studies for a suitability petition with a proposed change(s) that triggers PREA?

- A. The product would be ineffective or unsafe in one or more of the pediatric age group(s) for which a waiver is being requested
- B. Necessary studies are impossible or highly impracticable (because, for example, the number of pediatric patients is so small or geographically dispersed).
- C. The product fails to represent a meaningful therapeutic benefit over existing therapies for pediatric patients **and** is unlikely to be used in a substantial number of all pediatric age groups or the pediatric age group(s) for which a waiver is being requested.
- D. The sponsor does not have the resources or funding to perform pediatric studies to assess the safety and efficacy of the drug product in a relevant pediatric subpopulation.

Resources



- 21 CFR 10.20, 10.30, and 314.93
- [Regulations.gov](https://www.fda.gov/regulatory-information/federal-regulations)
- [Manual of Policies and Procedures – Center for Drug Evaluation and Research – Office of Generic Drugs – Suitability Petitions 5240.5 Rev. 2 Suitability Petitions](#)
- [Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations](#)
- [How to Comply with the Pediatric Research Equity Act | FDA](#)

Summary



- Follow the format and content for petitions as set forth in 21 CFR 10.30
- Provide a waiver request for suitability petitions proposing a change to a drug product that triggers the need for clinical pediatric studies under PREA
- Applicants are strongly encouraged to provide the recommended supplemental information
- Remember the best practices for submitting a quality suitability petition
- Submit your ANDA after the applicable suitability petition is approved

Questions?

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