U.S. FOOD & DRUG ADMINISTRATION

Ask us about Pre- ANDA Communication Pathways!

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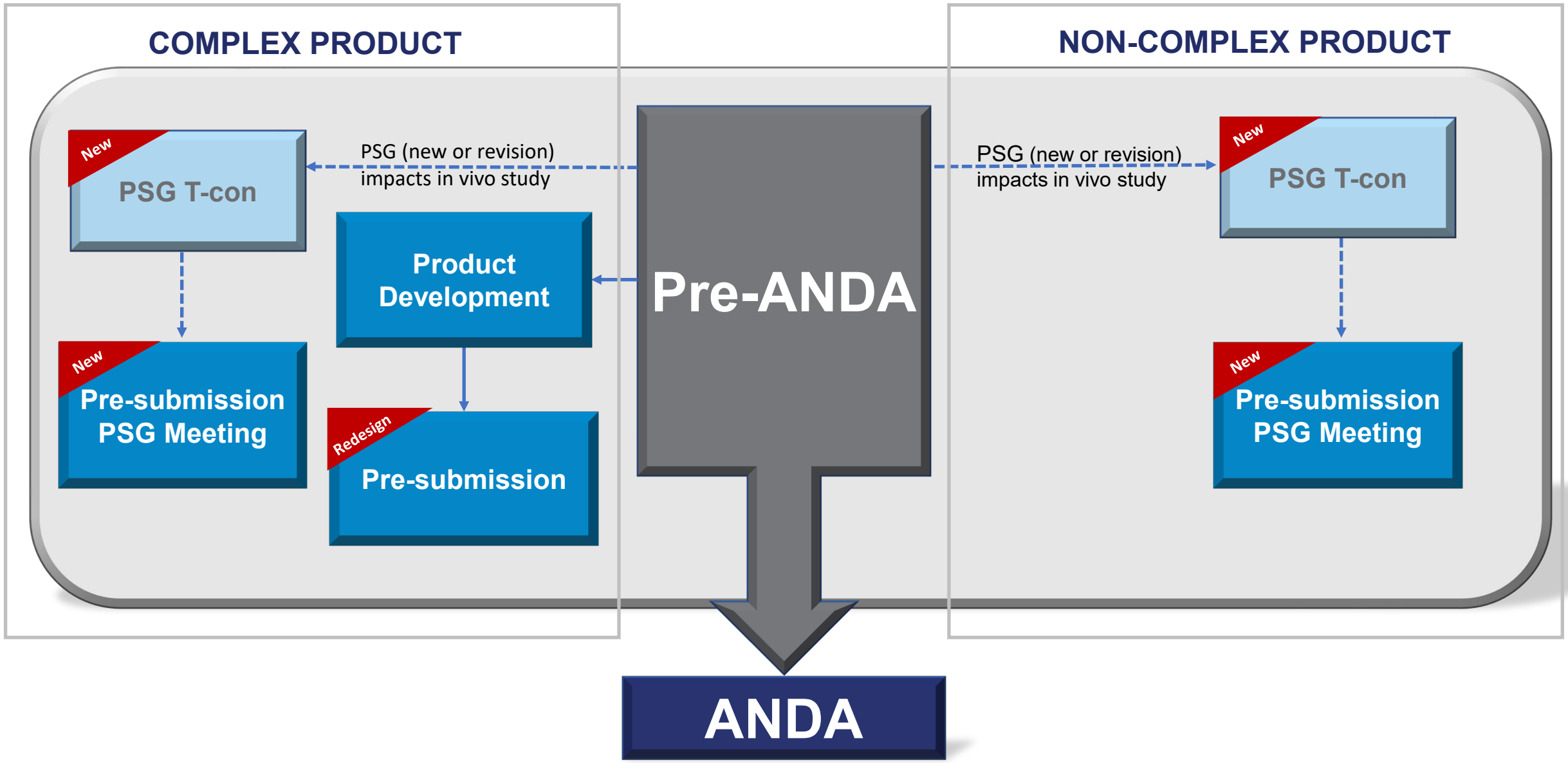
GDUFA III Pre- ANDA Scientific Meetings



GDUFA III Pre- ANDA Scientific Meetings:

Product Development and Pre- Submission Meetings

Facilitate communications between FDA and prospective applicants related to complex products and/or complicated drug development questions

Product Development (PDEV) Meetings
Pre-submission (PSUB) Meetings

GDUFA III Pre- ANDA Scientific Meetings:
Product- Specific Guidance Teleconferences and Meetings

Can be requested when FDA publishes a new or revised guidance that introduces or revises a recommendation and:

- **Recommendation is related to an in vivo bioequivalence (BE) study**
- **ANDA applicant has already commenced an in vivo BE study that may be different from product-specific guidance (PSG) recommendations as of the published date for the new or revised PSG**

PSG Teleconference
Pre-submission PSG Meeting[1]

[1] Following a PSG T-con, a PSG meeting can be requested to discuss scientific rationale for an approach other than the approach recommended in the PSG

Additional Pre- ANDA Scientific Meetings

Additional Pre-ANDA Scientific Meetings available not covered under GDUFA III that may be more suitable for your program needs.

Parallel Scientific Advice (PSA) Pilot Program for Complex/Hybrid Products

Model-Integrated Evidence (MIE) Industry Meeting Pilot

Refer to

- FDA-EMA Parallel Scientific Advice Pilot Program for Complex Generic/Hybrid Products Webpage
- Expanding Generic Drug Access Through International Engagements Webinar
- Model-Integrated Evidence (MIE) Industry Meeting Pilot Between FDA and Generic Drug Applicants Webpage
- A Deep Dive: FDA's Model-Integrated Evidence (MIE) Industry Meeting Pilot Program for Generic Drugs Webinar

Controlled Correspondence or PDEV Meeting?

Controlled correspondence (CC)

- Single or small group of closely related questions
- Questions outside of PDEV scope
- Response within 60 days (Level 1) or 120 days (Level 2)

PDEV Meeting

- Falls under will or may grant situation
- Multiple or multi- disciplinary questions
- New information, data, or questions not suitable for a CC
- Response within 120 days of PDEV being granted

Do not submit the same questions through a CC and PDEV meeting around a similar timeframe

Product- Specific Guidance

Reflects FDA's current thinking and expectations on how to develop a generic drug product therapeutically equivalent to a specific reference listed drug (RLD)

Upcoming Product-Specific Guidances for Generic Drug Product Development

Guidances | Drugs

Product-Specific Guidances for Generic Drug Development

Guidance Snapshot Pilot

Introduction

This web page provides information related to upcoming new and revised product-specific guidances (PSGs) to support the development and approval of safe and effective generic drug products, including the projected date of PSG publication, as a commitment under the Generic Drug User Fee Amendments of 2022 (GDUFA III). Upcoming PSGs for both complex and non-complex products that are planned to be published in the next 12 months are listed (these may be subject to change).

How often does FDA publish new and revised PSGs?

To support generic drug development and generic drug approval, FDA issues new and revised PSGs on a quarterly and as needed basis. These PSGs, including PSGs for both complex and non-complex generic drug products, when finalized, describe the agency's current thinking and expectations on how to develop generic drug products to specific reference listed drugs and are intended to assist the generic pharmaceutical industry with identifying the most appropriate methodology and evidence needed to support a specific generic drug's approval. The published PSGs are announced in the Federal Register and made available to the public on FDA's website.

Content current as of:

09/13/2024

Regulated Product(s)

Drugs
Generic Drugs


We care about enhancing access to generic drugs
WE ARE THE GENERIC DRUG PROGRAM