startup nitro
by altitude lab

Pre-IND Meeting Request Template

This document is intended to serve as a template for submitting a Pre-IND Meeting request to the FDA. It is a starting point only and should be tailored to meet your specific requirements.

The FDA requires meeting requests be submitted via electronic gateway or the CDER NextGen Portal as appropriate. Meeting requests need to be addressed to the appropriate center (CDER/CBER) and review division or office.

- CDER Offices and Divisions
- CBER Offices and Divisions

Questions that are submitted within a single meeting request should be limited to what can be reasonably answered within the allotted meeting time (12 questions max for a 60 min. meeting).
You will need to submit your meeting package 30 days before the scheduled meeting. Ensure that your questions and the numbering of questions in your meeting package are identical to what was submitted in the meeting request or you may have to reschedule.

References

- FDA Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products.
- Electronic Common Technical Document (eCTD) Resources
- Portable Document Format (PDF) Specifications
- FAQ

Resources

- Consulting agencies used by past residents in FDA submissions:
    - Premier Consulting
    - PPD
    - MedPace

Helpful Tips for Template:

- Any items in italicized brackets are intended to be customized or informative.
- PIND Number Guidance
- Serial Number: IND submission should be consecutively numbered. The initial IND should be numbered “Serial number: 0000.” The next submission (e.g., amendment, report, or correspondence) should be numbered “Serial Number: 0001.” Subsequent submissions should be numbered consecutively in the order in which they are submitted.
- Use hypertext links throughout the body of the document to link to supporting annotations, related sections, references, appendices, tables or figures that are not located on the same page as the narrative text. Hypertext links in text can be designated by blue text (HEX: #0000EE). A consistent method of designating links in a document avoids confusion. Hypertext links that open a file or document should be set to open the file or document in a new window.
- The FDA can help with questions related to the initial first in human study and other questions that could affect the IND application, including those related to the nonclinical program, manufacturing and product quality for the investigational product, and regulatory considerations.

TABLE OF CONTENTS

1. PRODUCT INFORMATION

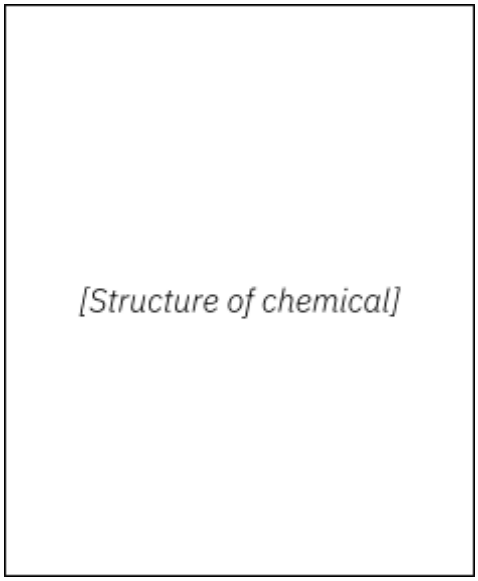
1.1. Product Name

[Name of product]

1.2. Chemical Name and Structure

Chemical Name: *[Chemical name]*
Molecular Formula: *[Molecular formula]*
Molecular Weight: *[Molecular weight]* g/mol
CAS: *[CAS RN ID]*
Source: *[Source of Figure]*

Figure 1 Structure of *[Chemical name]*



1.3. Dosage Form, Route of Administration, and Dosing Regimen

- *[Provide details on state of matter, basic dose form, release characteristics, transformation, intended site, and administration method along with dosing regimen, including concentration, amount dosed, and frequency and duration of dosing if known.]*

2. PROPOSED REGULATORY PATHWAY

[Company name] intends to submit an NDA via the *[regulatory pathway, e.g., 505(b)(1), 505(b)(2)]* regulatory pathway for its proposed *[name of product]* product.

3. PROPOSED INDICATION(S)

The proposed indication is *[describe intended indication].*

4. RATIONALE FOR THE PROPOSED PRODUCT

[Company name] has developed a novel *[brief explanation of product]* to *[outcome of product].*

[Write a summary of your product by including the following information: 1) Clearly articulate the problem statement, stressing the unmet need supported by relevant data. 2) Highlight the importance of addressing this need to patients and stakeholders, underscoring its impact on treatment outcomes and healthcare delivery. 3) Describe the unique features and intended use of the product or treatment modality being developed. 4) Provide an overview of the intended regulatory pathway for market approval, including key requirements and milestones.]

5. MEETING INFORMATION

5.1. Meeting Type Requested

Pursuant to 21 CFR §312.82(a) and *PDUFA VII: Reauthorization Performance Goals and Procedures Fiscal Years 2022 Through 2023, [company name]* requests a 60-minute Type-B, Pre-IND Meeting with the FDA.

5.2. Proposed Meeting Format

[Company name] requests a *[indicate type of meeting, i.e. in person face-to-face, virtual face-to-face, teleconference, or written response only].*

5.3. Statement of Purpose and Meeting Objectives

[Company name] intends to submit an NDA via the *[proposed regulatory pathway]* regulatory pathway for its proposed *[product name]* product.

The objectives for this Pre-IND Meeting are to discuss and secure consensus on the following:
[Summarize the general issues being raised, e.g., Obtain FDA feedback on the proposed nonclinical studies to ensure they adequately support the planned clinical development program.]

5.4. Proposed Meeting Agenda

[Customize table with the proposed agenda, include estimated time for each agenda item.]

Agenda Item	**Estimated Time**
Introductions	5 minutes
Discussion of FDA Division's comments regarding the questions submitted in the Pre-IND Meeting Package	45 minutes
Meeting Summary	10 minutes

5.5. Preliminary Sponsor Attendees

[Customize table with list of planned attendees from your organization, include consultants if applicable.]

Name	**Title**	**Affiliation**
Jane Doe	CEO	Altitude Lab
John Doe	Project Manager	Contracted Consulting

5.6. Requested FDA Attendees

[Customize table with list of requested FDA attendees and/or discipline representatives.]

	Requested Disciplines
1.	Statistics
2.	Project Manager
3.	Chemistry, Manufacturing, Controls (CMC)
4.	Pharmacology/Toxicology

5.7. Proposed Meeting Dates and Times

[List at least 4-5 dates and times –morning or afternoon- for the meeting; the dates should be scheduled to occur approximately 60 calendar days from the Agency's receipt of the written request for a meeting. Make sure you will be ready to submit your information package at least 30 calendar days prior to the first proposed meeting date.]

5.8. Meeting Package Submission Date

Supporting documentation will be sent to the Review Division by the date specified in the Meeting Granted letter.

6. LIST OF PROPOSED QUESTIONS, BY DISCIPLINE

[Customize fields with context and purpose of each question followed up by actual question. Questions need to be grouped by FDA disciplines. ***Instructions for formatting:*** *Ensure that when you add questions to each discipline, you assign the question as Heading 3 so it auto populates into your Table of Contents properly.]*

6.1. Chemistry, Manufacturing, Controls (CMC)

[Topic]

[Brief explanation of the context and purpose of the question.]

Question 1

[e.g., Does the FDA agree with the manufacturing process and control strategy?]

[Topic]

[Brief explanation of the context and purpose of the question.]

Question 2

[e.g., Is the delivery device compatibility plan sufficient?]

6.2. Clinical

[Topic]

[Brief explanation of the context and purpose of the question.]

Question 4

[e.g., • Does OTP agree with the approach used to determine the proposed starting dose and dose-escalation plan for the product in the proposed Phase 1 trial?]

[Topic]

[Brief explanation of the context and purpose of the question.]

Question 5

[Insert question]

6.3. Nonclinical

[Topic]

[Brief explanation of the context and purpose of the question.]

Question 6

[e.g., Does the FDA agree that the study design for the definitive toxicology study is adequate?]

6.4. Regulatory

[Topic]

[Brief explanation of the context and purpose of the question.]

Question 7

[Insert question]

[Topic]

[Brief explanation of the context and purpose of the question.]

Question 8

[Insert question]

[Topic]

[Brief explanation of the context and purpose of the question.]

Question 9

[Insert question]

7. REFERENCES

[List references as applicable]