

Formal FDA Meeting Request: Guidance and Template

ICTR Navigators

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The Johns Hopkins Institute for
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**ICTR—Where Science and
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2.0 Abbreviations

IND	Investigational New Drug
CFR	Code of Federal Regulations
FDA	U.S. Food and Drug Administration
CDER	Center for Drug Evaluation and Research
CDER	Center for Biologics Evaluation and Research
CDRH	Center for Devices and Radiological Health
CMC	Chemistry, Manufacturing, and Controls
GCP	Good Clinical Practices
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
BLA	Biologic License Application
NDA	New Drug Application
PMA	Pre-Market Application
IDE	Investigational Device Exemption

3.0 FDA Regulations and Guidance Websites

Below are web addresses for select FDA guidance websites and documents along with a link to the FDA IND regulations that may be useful. For additional FDA guidance documents and regulations, please go to the FDA website, <http://www.fda.gov/>.

FDA Guidance Document - Formal Meetings between the FDA and Sponsors or Applicants

- <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf>

FDA informational website - Industry Meeting Types

- <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071774.htm>

FDA CDER PRE-IND Consultation Contacts

- <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/UCM166356.pdf>

FDA CBER SOPP 8101.1: Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants, Version #4, Effective Date: May 18, 2007

- <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079448.htm>

FDA CDER – End-of-Phase 2A Meetings, Guidance for Industry

- <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079690>

FDA CDER MaPP 4151.4- Multi-Disciplinary Procedures for Managing End-of-Phase 2A Meetings, Effective Date 05/04/2010

- <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM210686.pdf>

FDA Title 21 Regulations Search Engine (e.g., 21CFR312 for IND regulations)

- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>

FDA Website for IND Applications for Drugs

- <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>

4.0 Introduction

The enclosed information is intended to provide an overview of the process for requesting a formal meeting (e.g., pre-IND meeting) with the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) and/or the Center for Biologics Evaluation and Research (CBER). Also included are template documents for the meeting request submissions. The information and templates presented here are based on the May 2009 FDA guidance document entitled, 'Guidance for

Industry Formal Meetings Between the FDA and Sponsors or Applicants', which is a nonbinding recommendation document. (Note, this guidance and template document does not address formal meetings with Center for Devices and Radiological Health (CDRH) because the above referenced FDA guidance only pertains to CDER and CBER.) A nonbinding recommendation document is one written by the FDA that presents their current thinking on the topic but does not bind (e.g., legally require) the FDA or the public to comply with the contents of the document. Alternative approaches to requesting a meeting with the FDA can be used, as long as the approach complies with current laws and regulations, but should be discussed with the FDA prior to use.

The enclosed instructional templates can be modified as needed and are only intended as a suggested format based on the above referenced guidance document and previous experience. Within each template you will find italicized text inside of brackets. If the text is not bolded, then text is instructional information. If the text is bolded, the requested information should be inserted there. In some instances, a choice is provided and in others you must provide the appropriate information. Since these are general templates, use your best judgment concerning the information provided as your particular situation may be unique. An editable version of the templates are available on the DDRS website, <http://ictr.johnshopkins.edu/DDRS>.

If you have any questions regarding the information presented below or in the templates included, please contact the ICTR Research Navigators at ICTR_Navigators@jhmi.edu or via telephone at 410-955-8120 or 410-614-5383.

5.0 Formal Meeting Request between Sponsor and FDA

5.1 Overview

To make the most efficient use of FDA resources, before seeking a meeting with CBER or CDER, sponsors or applicants should consider other sources of input applicable to their product development program, such as FDA and International Conference on Harmonization (ICH) guidances. If a meeting is still needed, written correspondence to request such a meeting should be submitted to the sponsor's or applicant's application (e.g., IND, NDA, BLA) through the controlled document system. If there is no application, the request should be submitted to either the appropriate CDER division director with a copy sent to the division's chief of the project management staff or to the appropriate office contact within CBER. Before submitting any meeting request by fax or e-mail when there is no application, the sponsor or applicant should contact the appropriate review division to determine to whom the request should be directed, how the request should be submitted, the appropriate format for the request, and to arrange for confirmation of receipt of the request. This prevents the possibility that faxed or e-mailed requests will be overlooked because of the volume of e-mails received daily by FDA staff. Faxed or e-mailed requests should be sent during official business hours (8:00 a.m. to 4:30 p.m. EST/EDT) Monday through Friday (except Federal government holidays). Processing and receipt may be delayed for requests where confirmation of receipt has not been pre-arranged.

The meeting request, regardless of the method of submission, should include adequate information for the FDA to assess the potential utility of the meeting and to identify FDA staff necessary to discuss proposed agenda items.

The sponsor or applicant, when writing a meeting request that contains the requested meeting components, should define the specific areas of input needed from CBER or CDER. A well-written meeting request that uses the requested meeting components as a guide can help the FDA understand and assess the utility and timing of the meeting related to product development or review. Although CBER or CDER will determine the final meeting type (i.e., Type A, Type B, or Type C), the sponsor or applicant should provide its meeting type assessment as it relates to the product's development. The list of sponsor or applicant attendees and the list of requested FDA attendees can be useful in providing or preparing for the input needed at the meeting. However, during the time between the request and the meeting, the projected attendees can change. Therefore, an updated list of attendees with their titles and affiliations should be included in the meeting package and a final list provided to the appropriate FDA contact before the meeting.

The objectives and agenda provide overall context for the meeting topics. The list of questions are the provided in the packets are critical for the FDA to understanding the kind of information or input needed by the sponsor or applicant and to focus the discussion, should the meeting be granted. Each question should be precise and include a brief explanation of the context and purpose of the question.

5.2 Meeting Types:

There are three types of formal meetings a sponsor can request with the FDA. The three types of meetings are a Type A, Type B, and a Type C. Below are the descriptions of each meeting as stated in the May 2009 '*FDA Formal Meetings Between the FDA and Sponsors or Applicants*' guidance document.

5.2.1 Type A Meetings

"A Type A meeting is a meeting needed to help an otherwise stalled product development program proceed. Examples of a Type A meeting include:

- Dispute resolution meetings as described in 21 CFR 10.75, 312.48, and 314.103 and in the guidance for industry *Formal Dispute Resolution: Appeals Above the Division Level 3*
- Meetings to discuss clinical holds in which a response to hold issues has been submitted, but the FDA and the sponsor or applicant agree that the development is stalled and a new path forward should be discussed
- Special protocol assessment meetings that are requested by sponsors or applicants after receipt of FDA evaluation of protocols under the special protocol assessment procedures as described in the guidance for industry Special Protocol Assessment

If sponsors or applicants are considering a request for a Type A meeting, before submitting the request they should contact the review division in either CBER or CDER to discuss the appropriateness of the request. Type A meetings should be scheduled to occur within 30 days of FDA receipt of a written meeting request. If a sponsor or applicant requests a meeting date that is beyond 30 days from the date of the request receipt, we will work with the sponsor or applicant to determine the earliest agreeable date."

5.2.2 Type B Meetings

“Type B meetings are as follows:

- Pre-investigational new drug application (pre-IND) meetings (21 CFR 312.82)
- Certain end-of-phase 1 meetings (21 CFR 312.82)
- End-of-phase 2 and pre-phase 3 meetings (21 CFR 312.47)
- Pre-new drug application/biologics license application meetings (21 CFR 312.47)

Type B meetings should be scheduled to occur within 60 days of FDA receipt of the written meeting request. If a sponsor or applicant requests a meeting date that is beyond 60 days from the date of request receipt, we will work with the sponsor or applicant to determine the earliest agreeable date.

To promote efficient management of formal meetings, the requestor should try to anticipate future needs and, to the extent practical, combine product development issues into the fewest possible meetings. Generally, we will not grant more than one of each of the Type B meetings for each potential application (e.g., investigational new drug application (IND), new drug application (NDA), biologics license application (BLA)) or combination of closely related products developed by the same sponsor or applicant (e.g., same active ingredient but different dosage forms being developed concurrently), but we can do so when it would be beneficial to hold separate meetings to discuss unrelated issues. It also may be appropriate to conduct more than one of some of the Type B meetings for concurrent development of a product for unrelated claims.”

5.2.3 Type C Meetings

“A Type C meeting is any meeting other than a Type A or Type B meeting between CBER or CDER and a sponsor or applicant regarding the development and review of a product.

Type C meetings should be scheduled to occur within 75 days of FDA receipt of the written meeting request. If a sponsor or applicant requests a meeting date that is beyond 75 days from the date of the request receipt, we will work with the sponsor or applicant to determine the earliest agreeable date.”

5.3 Additional Information for FDA Meetings

5.3.1 Pre-IND Type B Meetings

5.3.1.1 CDER Pre-IND Consultation Contact List

The ‘*CDER Pre-IND Consultation Contact List*’ can be found at the following website:

- <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/UCM166356.pdf>.

The consultation list provides the names, phone numbers, and fax numbers for the different divisional contacts for each Office of Drug Evaluation (I-IV), the Office of Antimicrobial Products, and Office of Oncology Drug Products. It is advised that if you know which division will review your pre-

IND meeting request, you should contact the person listed to discuss your submission prior to sending the paperwork.

If you are unable to reach the person by phone, you can look up their email address in the Health and Human Services (HHS) employee directory located at the following website:

- <http://directory.psc.gov/employee.htm>.

There are no specific pre-IND meeting resources for CBER, but CBER does have a SOPP that provides information concerning all formal meeting requests. See section 5.3.3 below for this information.

5.3.1.2 CDER Office of Antimicrobial Products (OAP) Pre-IND Consultation Program

The Office of Antimicrobial Products Consultation Program is designed to facilitate and foster early communications between the divisions of OAP and potential sponsors of new therapeutics under the office's purview.

The website for the OAP Pre-IND Consultation Program is:

- <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/default.htm>

5.3.1.3 FDA CDER - Small Business Assistance: FAQs on the Pre-IND Meeting

The FDA Small Business Assistance program maintains a Frequently Asked Questions (FAQ) website that provides valuable information about pre-IND meetings. If you are planning to request a pre-IND with CDER, you should review this information prior to submitting a request. The address for the website is:

- <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069906.htm>.

5.3.2 CDER End-of-Phase 2A Meetings (Type C Meeting)

An end-of-phase 2A meeting is one in which the FDA and sponsor or sponsor-investigator discuss the use of quantitative drug development methods such as trial simulations and modeling to estimate doses for a phase 2B or 3 clinical trial. Please see the FDA guidance document entitled '*End-of-Phase 2A Meetings*', website address listed below, for additional information concerning this Type C meeting. CDER also maintains MAPP document (internal procedural document) entitled '*MAPP 4151.4 Multi-disciplinary Procedures for Managing End-Of-Phase 2A Meetings*', website address listed below, that may also be a useful resource when requesting this type of meeting.

FDA Guidance document - End-of-Phase 2A Meetings

- <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079690.pdf>

MAPP 4151.4 - Multi-Disciplinary Procedures for Managing End-of-Phase 2A Meetings

- <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM210686.pdf>

5.3.3 CBER Meeting Formal Meeting Requests (Types A, B, and C)

CBER maintains a biological procedure (SOPP 8101.1) document that describes the process FDA staff needs to follow for Formal FDA meetings with Sponsors. If you are scheduling a meeting with a CBER, it may be helpful to review the SOPP to understand the expectations of CBER staff when reviewing formal meeting requests. SOPP 8101.1 can be found at the following web address:

- <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079448.htm>

5.4 FDA Mailing Addresses:

5.4.1 CDER Mailing Address:

When submitting meeting requests to CDER please contact the assigned FDA Project Coordinator/Manager to verify the address submissions should be sent to, or in the case of Type B pre-IND meetings, contact the representative listed on the pre-IND consultation list (see 5.3.1 above).

Otherwise, the following addresses can be used:

For Drug Products:

Central Document Room
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

OR

For Therapeutic Biological products managed by CDER:

Therapeutic Biological Products Document Room
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

5.4.2 CBER Mailing Address:

When submitting documents to CBER, you need to address the submissions to the attention of the CBER Office (see below) that regulates the product along with the below mailing address. If you are not sure which office is responsible for reviewing the product, then call “CBER’s Questions about biologics phone number” (listed below) to ask for assistance with determining the reviewing office.

- CBER’s Questions about biologics phone number:

301-827-2000

- Mailing Address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center,
HFM-99, Suite 200N
1401 Rockville Pike
Rockville, MD 20852-1448

- CBER Offices:

- Office of Blood Research and Review
Division Director for Blood Applications
- Office of Compliance and Biologics Quality
Division Director for Manufacturing and Product Quality
- Office of Therapeutics Research and Review
Division Director for Application Review and Policy
- Office of Vaccines Research and Review
Division Director for Vaccines and Related Products Applications
- Office of Cellular, Tissue, and Gene Therapies
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/ucm094338.htm>

6.0 Meeting Request Template

The meeting request template consists of a cover letter template and an instructional meeting request information pack template.

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6.1 Cover Letter Template

[Date of letter]

Recipient Address

[INSTRUCTIONS: If there is no application number, the request should be submitted to either the appropriate CDER Division Director with a copy sent to the Division's Chief of Project Management staff or to the appropriate office contact within CBER.]

RE: Request for ***[INSERT: Description of meeting request based on Type A, B, or C descriptions]***
Meeting, Type ***[INSERT: A, B, or C – chose based on above description]***, for ***[INSERT: Product name]***
in ***[INSERT: describe proposed indication]***.

Dear :

I am writing to request a formal meeting with the FDA to discuss a proposed investigator-sponsored IND application for developing ***[INSERT: PRODUCT NAME]*** for use in ***[INSERT: describe proposed indication or population]***.

[COMBINATION PRODUCTS INSTRUCTIONS: If this is a combination product, indicate whether or not a Request for Designation, either formal or informal, has been submitted or obtained. If formal, indicate when it was submitted to whom the request was sent. If an outcome is available, please include here. If an informal request for designation was sought, indicate when and from whom it was requested. If an outcome is available, please include here.]

Please find enclosed the Meeting Request information.

Thank you for considering this ***[INSERT: Describe meeting request based on Type A, B, or C descriptions]*** meeting request. Please do not hesitate to contact me at ***[INSERT: supply investigator-sponsor's phone number and email]*** to discuss meeting dates or any additional information. ***{[INSTRUCTIONS: ADD FOLLOWING IF YOU HAVE DESIGNEE- "Additionally, you may also contact my designee, [INSERT: DESIGNEE NAME] at [INSERT: designee's phone number and email]."} }***

Sincerely,

[INSERT: Supply investigator-sponsor's name, title and affiliation]

Enclosure: Meeting Request Packet

6.2 Meeting Request Information Packet Template

Formal Meeting Request

Type **[INSERT: A, B, or C]**,

[INSERT: Indicate the type of meeting being requested based on Type A, B, or C descriptions]

[INSERT: application or pre-IND number if assigned.]

[INSERT: Sponsor –investigator name]

1. Product name

[INSTRUCTIONS: If there is more than one name associated with the product, supply them all. However, you should designate if known, the name that will be used in all documents submitted to the FDA. Note if this is a combination product indicate each component stating if it is a drug, biologic, or device.]

2. Application number.

[INSTRUCTIONS: Include current IND number, pre-IND number (PIND), or state that a number has not been assigned. Note, if the meeting request is for a pre-IND meeting, when the FDA responds to request, they will assign a pre-IND number that should be used on all documents submitted after the request until such time that the actual IND number is assigned, e.g., Acknowledgement of receipt of IND application.]

3. Chemical name and structure.

[INSTRUCTIONS: Provide chemical name and structure. Note if this is a combination product, provide chemical physical, or biological composition of each component product.]

4. Proposed indication(s) or context of product development.

[INSTRUCTIONS: Provide enough detail so the Agency will understand the intended use, while being as brief as possible. In the background package you will be able to expand on this if necessary.]

5. Meeting Type.

[INSTRUCTIONS: The type of meeting being requested (i.e., Type A, Type B, or Type C). If a Type A meeting is requested, the rationale should be included.]

6. Statement of the purpose and objectives of the meeting.

[INSTRUCTIONS: This statement should include a brief background of the issues underlying the agenda. It also can include a brief summary of completed or planned studies and clinical trials or data that the sponsor or applicant intends to discuss at the meeting, the general nature of the critical questions to be asked, and where the meeting fits in overall development plans. Although the statement should not provide detailed documentation of trial designs or completed studies and clinical trials, it should provide enough information to facilitate understanding of the issues, such as a small table that summarizes major results.]

- a. Purpose
- b. Objectives

7. Proposed Agenda

[INSTRUCTIONS: A preliminary proposed agenda, including estimated amounts of time needed for each agenda item and designated speaker(s). You can use the below table to provide the agenda or whatever format you prefer.]

Agenda Item	Designated Speaker	Estimated Time
I. Introduction/Background		[##] minutes
II. Discussion of Submitted Questions		
(A) CMC Issues	<i>[INSERT: All participants and/or designated individuals]</i>	[##] minutes
(B) Nonclinical Issues	<i>[INSERT: All participants and/or designated individuals]</i>	[##] minutes
(C) Clinical Trial Design	<i>[INSERT: All participants and/or designated individuals]</i>	[##] minutes
(D) Specify other	<i>[INSERT: All participants and/or designated individuals]</i>	[##] minutes
Estimated Total Time:		[##] minutes

8. List of proposed questions, grouped by discipline.

[INSTRUCTIONS: For each question, there should be a brief explanation of the context and purpose of the question. Below are examples of how you group the questions by discipline. Please format this section so the information is presented clearly. Try to make questions as specific as possible and present them in the same order in which the material appears/will appear in the IND.))]

- a. Clinical Trial Design
- b. CMC
- c. Nonclinical Pharmacology
- d. Nonclinical Toxicology
- e. Specify Other

9. List of attendees invited by the sponsor for the ***[INSERT: Describe meeting request based on Type A, B, or C descriptions]*** meeting for development of ***[INSERT: Product]*** for use in ***[INSERT: describe proposed indication or population]***.

[INSTRUCTIONS: List all individuals who will attend the requested meeting from the sponsor or applicant's organization and consultants with their titles and affiliations.]

Name	Title	Affiliation

10. Requested FDA discipline areas and/or FDA staff to participate in the meeting.

[INSTRUCTIONS: List FDA staff including specific names of individuals, if known, or request that an individual with an expertise in a particular discipline participate in the requested meeting.]

11. Suggested dates and times for the meeting.

[INSTRUCTIONS: Suggested dates and times (e.g., morning or afternoon) for the meeting that are within or beyond the appropriate time frame of the meeting type being requested. The dates and times should be listed in order of preference. Note the FDA's official business hours are 8:00 a.m. to 4:30 p.m. so the times should be within that timeframe with the estimated end time before 4:30 p.m. Also, be cognizant of federal holidays when suggesting dates for the meeting. Type A meetings should be scheduled to occur within 30 days of FDA receipt of a written meeting request. Type B meetings should be scheduled to occur within 60 days of FDA receipt of the written meeting request. Type C meetings should be scheduled to occur within 75 days of FDA receipt of the written meeting request.]

12. Meeting format.

[INSTRUCTIONS: Describe the format of the meeting (i.e. face-to-face, teleconference, or videoconference). Verify that you have access to necessary teleconference or videoconference equipment prior to suggesting this format.]

7.0 FDA Meeting Briefing Packet Content and Submission

7.1 FDA Meeting Briefing Packet Contents and Submission Overview

Pre-meeting preparation is critical for achieving a productive discussion or exchange of information. Preparing the meeting briefing packet should help the sponsor or applicant focus on describing its principal areas of interest. The meeting briefing packet should provide information relevant to the discussion topics and enable the FDA to prepare adequately for the meeting. In addition, the timely submission of the meeting package is important for ensuring that there is sufficient time for meeting preparation, accommodating adjustments to the meeting agenda, and accommodating appropriate pre-meeting communications.

- Meeting briefing packets should be submitted to the appropriate review division.
- The meeting briefing packet should identify the date, time, and subject of the meeting. An archival copy should be submitted to the relevant application (e.g., IND, NDA, or BLA); if there is no established application (e.g., for a pre-IND meeting), the responsible point of contact in the review division will provide instructions on how to submit the meeting briefing packets.
- Sponsors or applicants are encouraged to submit the archival meeting briefing packet electronically according to the electronic submission formatting recommendations.
 - See the draft guidance for industry: *'Providing Regulatory Submissions in Electronic Format General Considerations'*
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm124737.htm>.
 - The FDA CDER also maintains an Electronic Submission website that we suggest be reviewed prior to submitting documents electronically. The website address is <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/default.htm>
 - Prior to submitting document electronically, the responsible point of contact in the review division should be informed and made aware of the intended submission date.
- The number of copies of a meeting briefing packet will vary based on the meeting.
- The responsible point of contact in the review division will advise on the number of copies needed for the meeting attendees.
- **To facilitate the meeting process, it is suggested that copies of meeting briefing packets provided in electronic format also be provided in paper.**

Timing of Submission

A meeting briefing packet should be submitted to the appropriate review division so that it is received in accordance with the following time frames:

- Type A meeting — At least 2 weeks before the formal meeting.
- Type B meeting — At least 4 weeks before the formal meeting.
- Type C meeting — At least 4 weeks before the formal meeting.

Meeting Briefing Packet:

To facilitate FDA review, the meeting briefing packet content should be organized according to the proposed agenda. The meeting briefing packet should be a sequentially paginated document (individual sections can be numbered separately, as long as there is an overall pagination covering the whole submission) with a table of contents, appropriate indices, appendices, cross references, and tabs differentiating sections. Meeting packets generally should include the following information:

1. Product name and application number (if applicable).
2. Chemical name and structure
3. Proposed indication
4. Dosage form, route of administration, and dosing regimen (frequency and duration).
5. An updated list of sponsor or applicant attendees, affiliations, and titles.
6. A background section that includes the following:
 - a. A brief history of the development program and the events leading up to the meeting.
 - b. The status of product development (e.g., the target indication for use).
7. A brief statement summarizing the purpose of the meeting.
8. A proposed agenda.
9. A list of the final questions for discussion grouped by discipline and with a brief summary for each question to explain the need or context for the question.
10. Data to support discussion organized by discipline and question. For example, for an end-of-phase 2 meeting, this section should include the following, if not already provided in the background section (refer to item #6 above): description and results of controlled trials conducted to determine dose-response information; adequately detailed descriptors of planned phase 3 trials identifying major trial features such as trial population, critical exclusions, trial design (e.g., randomization, blinding, choice of control group, with explanation of the basis for any non-inferiority margin if a non-inferiority trial is used), choice of dose, primary and secondary trial endpoints; and major analyses (including planned interim analyses and adaptive features, and major safety concerns).

7.2 FDA Meeting Briefing Packet Template

The following is a suggested format for the briefing packet to be submitted to the FDA once the meeting request is accepted and the date, time, and the meeting format that has been agreed upon by the Sponsor and the FDA. You may also include appendices as required.

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7.2.1 Cover Letter Template

[INSERT: Date of letter]

[INSERT: Recipient Address: Recipient address is the address of the responsible point of contact in the review division that contacted you to set up the meeting.]

RE: ***[INSERT: Describe meeting request based on Type A, B, or C descriptions]*** Meeting, Type ***[INSERT: A, B, or C – chose based on above description]***, Meeting Briefing packet for ***[INSERT: PIND or IND]*** ***[INSERT: ###,###]***

Dear ***[INSERT: Responsible point of contact in the review division that contacted you to set up meeting]:***

Please find enclosed the Meeting Briefing Packet for the ***[INSERT: Describe meeting request based on Type A, B, or C descriptions]*** Meeting, Type ***[INSERT: A, B, or C – chose based on above description]***, for ***[INSERT: product name]***, ***[Chose: PIND or IND]*** ***[INSERT: ###,###]***, ***[INSERT: insert brief description of product indication]***.

The purpose of the meeting scheduled for ***[INSERT: date of meeting]*** at ***[INSERT: Time of meeting]*** is to discuss ***[INSERT: reason for meeting]*** ***[INSERT: PRODUCT NAME]***.

Sincerely,

[INSERT: Supply investigator-sponsor's name, title and affiliation]

Enclosure: Meeting Briefing Package

7.2.2 Cover Page

[INSERT: Type of Meeting Name] Meeting Briefing Packet

[INSERT: PIND or IND]: [INSERT ###, ###]

Drug Name: *[INSERT PRODUCT NAME]*

Meeting Date: *[INSERT DATE]*

Meeting Time: *[INSERT TIME]*

Meeting Venue: *[INSERT Venue – tele/video conference, in person, etc..]*

[INSERT: Sponsor-Investigator]: [INSERT NAME]

7.2.3 Table of Contents

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2	Chemical name and structure	##
3	Proposed indication(s)	##
4	Dosage form, route of administration, and dosing regimen (frequency and duration)	##
5	A brief statement of the purpose of the meeting	##
6	A list of the specific objectives/outcomes expected from the meeting	##
7	Proposed agenda, including estimated amounts of time needed for each agenda item and designated speaker(s)	##
8	A list of specific questions, grouped by discipline	##
9	Clinical Data Summary	##
10	Data to support discussion organized by discipline and question.	##
Appendices		

7.2.4 Briefing Packet Template

1. Product name and application number.

a. Product Name

[INSTRUCTIONS: If there is more than one name associated with the product, supply them all. However, you should designate, if known, the name that will be used in all documents submitted to the FDA. Note: if this is a combination product, include requested information for each component stating whether it is a drug, biologic, or device.]

b. Application Number

[INSTRUCTIONS: Include current IND number, pre-IND number (PIND), or state that a number has not yet been assigned.]

2. Chemical name and structure

[INSTRUCTIONS: Provide chemical name and structure. Note if this is a combination product, provide chemical physical, or biological composition of each component product.]

a. Chemical name

b. Chemical structure

3. Proposed indication

[INSTRUCTIONS: Description of indication]

4. Dosage form, route of administration, and dosing regimen.

[INSTRUCTIONS: Provide information on the dosage form, route of administration, and dosing regimen under the appropriate header. If this is a combination product, provide sufficient information to describe all components under form and/or route, if applicable.]

a. Dosage form

b. Route of administration

c. Dosing regimen

[INSTRUCTIONS: Describe frequency and duration]

5. List of sponsor or applicant attendees, affiliations, and titles.

[INSTRUCTIONS: If the list has been updated since the time of the initial request, explain the change either with a sentence after the heading or revise the heading to state "Updated List".]

Name	Title	Affiliation

6. A background section:

- a. Brief history of the development program and events leading up to the meeting.

[INSTRUCTIONS: Self-explanatory]

- b. The status of product development.

[INSTRUCTIONS: e.g., the target indication for use]

7. A brief statement summarizing the purpose of the meeting.

[INSTRUCTIONS: Self-explanatory]

8. A proposed agenda.

[INSTRUCTIONS: If there have been any changes to the agenda since the initial meeting request was submitted, note the change and include a brief explanation.]

9. A list of the final questions for discussion grouped by discipline and with a brief summary for each question to explain the need or context for the question.

[INSTRUCTIONS: Note that Section 10 must be organized in the same order as this section. Please indicate whether or not any of the questions refer to more than one section of supporting data listed in section 10, e.g., cross reference as needed.]

10. Support data organized by discipline and question.

[INSTRUCTIONS: For example, for an end-of-phase 2 meeting, this section should include the following, if not already provided in the background section (refer to item #6 above): description and results of controlled trials conducted to determine dose-response information; adequately detailed descriptors of planned phase 3 trials identifying major trial features such as trial population, critical exclusions, trial design (e.g., randomization, blinding, choice of control group, with explanation of the basis for any non-inferiority margin if a non-inferiority trial is used), choice of dose, primary and secondary trial endpoints; and major analyses (including planned interim analyses and adaptive features, and major safety concerns).]

11. Appendices