**Meeting Request**

**Instructions for Meeting Requests with the FDA**

**All IND Meeting Requests must be submitted to the IIS team for shipment to the FDA. Please provide the IIS team with the original and one copy of the meeting request.** Upon receiving the submission, the IIS team will send to the FDA. The IIS team should be copied on all correspondence with the FDA.

**Types of Meeting Requests**

1. **Type A Meeting**

**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*.
* 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.**

1. **Type B Meeting**

Type B meetings include the following:

* 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.**

1. **Type C Meeting**

* 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.**

**TEMPLATE COVER LETTER ON FOLLOWING PAGE**

Food and Drug Administration

Center for Drug Evaluation and Research

Central Document Room

5901-B Ammendale Road

Beltsville, MD 20705-1266

Date

Re: Request for a Type *[A, B, or C*] Meeting (*include the pre-IND number if received*)

Dear Division Director:

Enclosed please find a request for a Type *[A, B, or C]* meeting. We plan to investigate [*product name*] with the chemical structure outlined below for the proposed indication of [*insert proposed indication for use*].

Chemical structure

[*Insert chemical structure*]

Respectfully, we request a [*written response only, teleconference, or face-to-face meeting*] and suggest the following dates and times [*Suggested date needs to be within the timeframe requirements for each specific type of meeting.]*

The purpose and objectives of this meeting are to [*include a brief statement of the purpose and objectives of the meeting. 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.]*

Additionally, we have enclosed the following for the request.

* A proposed agenda
* A list of proposed questions [*to be grouped by discipline (e.g., Clinical, CMC, Pharm Tox). For each question there should be a brief explanation of the context and purpose of the question.*]
* A list of all individuals with their titles and affiliations who will attend the requested meeting from the sponsor’s or applicant’s organization and consultants.
* [*A list of FDA staff, if known, or disciplines asked to participate in the requested meeting*.]

Please contact me at [email] or [phone] with any questions. Thank you for your consideration of this application.

Sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Sponsor-Investigator Printed Name of Sponsor-Investigator