Month XX, 201X

Food and Drug Administration

Center for Drug Evaluation and Research

Division of [Therapeutic Area]

Central Document Room

5901-B Ammendale Rd.

Beltsville, MD 20705-1266

RE: **Request for Pre-IND Meeting**

Dear Dr. [Division Director]:

In response to our conversation on DATE, I am formally requesting a meeting to determine whether the proposed study of DRUG in DISEASE OR CONDITION patients qualifies for exemption from an IND (21 CFR Part 312.2). A proposed outline for discussion is provided below:

1. **Product Name**
2. **Chemical Name and Structure**
3. **Proposed Indication(s)**

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1. **Type of Meeting Requested**Pre-IND

Teleconference is acceptable alternative to a face-to-face meeting

1. **Statement of Purpose**To discuss the clinical study design, adequacy of manufacturing standards, the intended product formulation, and safety profile of DRUG.
2. **Specific Objectives of Meeting**Obtain answers to submitted questions
3. **Proposed Agenda**General Introductions
Brief Review of Protocol
Discussion of FDA Responses to Questions (FDA)
4. **Participants from Name of Institution**
5. **Proposed Date and Time for Teleconference**

We would ask that the meeting be held at any time other than Monday or Thursday mornings (PST) as the members of our research group have administrative responsibilities during those times. We propose the following dates in 201X:

Month DD, DD, DD, DD

Following Month D, D, D, D

1. **The approximate date on which supporting documentation will be sent to the review division**

Supporting documents will be submitted to FDA 30-days prior to the meeting date.

**PRELIMINARY LIST OF QUESTIONS FOR FDA**

**Regulatory:**

**Preclinical:**

**Chemistry, Manufacturing and Control:**

**Clinical Questions:**

If you require additional information, please contact me at the phone number or email address provided below.

Sincerely,

[Sponsor Name], MD

Title

Institution

Phone number

Email address

Attachements: