Month XY, 20XY

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center – WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Attn: *Jane Doe*, MD

Director, Division of *Something*

**RE: Pre-Submission Meeting Request for an IDE (or 510(k))**

Dear *Dr. Doe*,

Please find enclosed an electronic copy, on CD, of this Pre-Submission Meeting request.

We are requesting a Pre-Submission Meeting to discuss the development and regulatory path of *“X Device”* for the treatment of *“ZW Syndrome”*.

The details of the requested meeting are below:

**Proposed Agenda:** *Describe the topics to be presented and the estimated time for each agenda item. You should propose the duration of the meeting you are requesting, one (1) hour is adequate for most meetings.*

We request a one hour meeting to discuss the following topics:

1. Introductions(5 minutes)
2. *Topic A* (20 minutes)
3. *Topic B* (15 minutes)
4. *Topic C* (20 minutes)

**Meeting Format:** *i.e. Teleconference or in-person. If requesting an in person meeting, include a list of any audiovisual equipment you will need, such as conference phone or LCD projector.*

**Preferred Meeting Dates:** *Include three or more preferred dates and times when you are available to meet*

1. Month XY, 20XY- Between X and Y EST
2. Month XY, 20XY- Between X and Y EST
3. Month XY, 20XY- Between X and Y EST

**Planned Attendees:** *Include the planned attendees, including each attendee’s position or title, and affiliation. If you have not yet identified all of your attendees, you should indicate the type of subject matter experts you plan to invite. Identify any appropriate FDA staff that are requested to attend the meeting if specific expertise may be needed (e.g. staff from other Centers).*

1. *John Doe*, MD, *Professor of Something*, Duke University School of Medicine

If there are any questions regarding this submission, please contact myself or *Jacob Durham,* at (919) 668-xxxx or xxxx@duke.edu. *Mr. Durham* is authorized to communicate with the FDA on any issue relating to this Pre-Submission Meeting request.

Sincerely,

*John Doe*, MD

*Professor*, Department of *Something*

Duke University

*Address*

Phone: 919-684-XXXX

Fax: 919-684-XXXX

Email: *john.doe*@duke.edu