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: **Initial Investigator New Drug Application**

 **Serial Number 0000**

Dear Dr. [Division Director]:

Per 21 CFR 312.20, please find enclosed three copies of this initial application for a Sponsor-Investigator IND. We propose to evaluate [Drug generic name (Trade Name®)] under this IND for safety and efficacy for the treatment of [disease or condition].

This submission also contains the initial study protocol [*Study Number*] *Protocol* *v. 1.0* entitled, “A Multi-center, Randomized, Placebo-Controlled, Double-Blind Study of the Effects of [Drug] on [condition] in [disease].”

If you have any questions regarding this submission, please contact myself or Name of Sub-Investigator or other contact at phone number or email address. Name of Sub-Investigator or other contact can act on my behalf on any issue relating to this IND.

Sincerely,

[Sponsor Name], MD

Title

Institution

Phone number

Email address

cc: file

submitted in triplicate: *Form FDA 1571*

*Initial Investigational New Drug Application*

[*Study Number*] *Protocol* *v. 1.0*