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: **IND XX,XXX, Serial Number 000X**

DRUG Trade Name® (generic name)

**IND Protocol Amendment: i.e.: [New Protocol] [Change in protocol]**

Dear Dr. [Division Director]:

Per 21 CFR 312.3 we are submitting this protocol amendment for the above-referenced IND XX,XXX for use of DRUG in the treatment of disease. [This submission contains a new protocol entitled, Protocol Number and Name.] [This submission contains v. 2.0 of the protocol entitled, Protocol Number and Name.]

*Include a high level summary of the protocol, one to two paragraphs in length, from the study synopsis. Ask for comments, if required.*

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*

Protocol Number and Name