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 Annual Report**

Dear Dr. [Division Director]:

Per 21 CFR 312.33, we are submitting this annual report for the above-referenced IND XX,XXX for use of DRUG in the treatment of disease. This report summarizes the progress of our investigations during the time interval Date to Date.

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*

201X Annual Report