Month XX, 202X

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

[Regulatory program manager email address]

RE: **IND XXXXX, Serial Number 000X**

DRUG Trade Name® (generic name)

 **IND Annual Report**

Dear [Regulatory Program Manager]:

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

We appreciate your time and consideration. Per FDA guidance, this annual report has been submitted to the CDER NextGen portal and an email courtesy copy has been sent to FDA Regulatory Program Manager name of program manager.

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

Attachments:

1. Form FDA 1571 Serial Number 000X Dated XX/XX/202X
2. 202X Annual Report Dated XX/XX/202X