***Please use UA letterhead issued by your own department.***

Month DD, YYYY

Food and Drug Administration

Center for Drug Evaluation and Research

Division of Therapeutic Area

Central Document Room

5901 – B Ammendale Road

Beltsville, MD 20705-1266

RE: IND [XX,XXX], Serial Number [000X]

[Drug Trade Name (generic name)

IND Final Report

Dear Dr. [Division Director]:

Enclosed please find three copies (the original and 2 photocopies) of the final IND closeout report for the above-referenced IND [XX,XXX] for use of [DRUG] in the treatment of [disease or condition]. This report summarizes the progress and results of our investigations during the time interval [Date] to [Date].

If you have any questions regarding this submission, please contact me 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.

Thank you for incorporating this Final Report into the respective IND file.

Sincerely,

Sponsor Name, MD

Title

Institution

Phone number

Email address

cc: file

submitted in triplicate: *Form FDA 1571*

[YYYY] Final Report