Information Amendment: [Insert Description of Amendment]

IND Number: [Instructions: Insert IND number ###,###]

Serial Number: [Instructions: Insert serial number of 1571 being submitted with this amendment]

Drug Product Name: [Instructions: Insert name of drug product]

Date: [Instructions: Insert date of submission]

Sponsor-Investigator: [Instructions: Insert sponsor-investigator name]

Information Amendment Nature and Purpose:

[Instructions: Describe with as much detail as needed the nature and purpose of the amendment.]

Information Amendment Supporting Documents:

[Instructions: Briefly describe the documents being submitted with the amendment for the FDA to review. If a large set is being submitted as part of the supporting documents, the sponsor-investigator should include succinct summary of the data here. Each document should be listed in the table of contents.]

Request for FDA Comment:

[Instructions: Include a statement requesting that the FDA comment on the information being submitted in the amendment. If the sponsor-investigator does not wish to request FDA comment on the amendment, omit this section.]