*[Letterhead]*

**FDA Address for a Drug:**

Food and Drug Administration  
Center for Drug Evaluation and Research  
Central Document Room  
5901-B Ammendale Rd.  
Beltsville, Md. 20705-1266

**OR**

**FDA Address for a Therapeutic Biological Product:**

Food and Drug Administration  
Center for Drug Evaluation and Research  
Therapeutic Biological Products Document Room  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

*[Date]*

**RE: IND \_\_\_**

This letter is in reference to IND \_\_\_ and is an amendment request submitted to perform a new protocol entitled “\_\_\_\_\_\_\_\_\_\_”. \_\_\_\_\_\_\_\_ will be the sponsor and \_\_\_\_\_\_ will be the investigator. The most clinically significant differences between the new protocol and the previous protocols are \_\_\_\_\_\_\_.

Attached with this cover letter are the original and two photocopies of the protocol, Forms 1571 & 1572, CV & medical license of the investigator. Form 3674 is also attached.

For any clinical or technical questions regarding this submission, please contact me directly at \_\_\_\_\_ or by email: \_\_\_\_\_\_\_\_ Questions of an administrative nature should be addressed to \_\_\_\_\_\_\_\_ at \_\_\_\_\_\_\_ or by email\_\_\_\_\_\_\_\_\_\_\_.

Thank you very much for your consideration.

Yours sincerely

Name & Title