*IND Information Amendment: Cover Letter Template – On Sponsor-Investigator letterhead*

[Sponsor-Investigator or address]

[DATE]

[Insert FDA Project Manager and CDER Office/Division]

Central Document Room

Center for Drug Evaluation and Research

Food and Drug Administration

5901-B Ammendale Rd.

Beltsville, MD 20705-1266

RE: Information Amendment [Insert description of amendment] for IND Number [Insert IND###,###]

Dear [Insert FDA Project Manager Name],

Enclosed please find an Information Amendment for IND Number [Insert IND ###,###], for [Insert Product Name].

[Instructions: if the sponsor-investigator wishes to request FDA comment on the amendment, include a statement asking for a comment here.]

Sincerely,

[Insert Sponsor-Investigator Name]

[Insert Title]

[Insert Affiliation]

Enclosure: