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

[Sponsor-Investigator or address]

[DATE]

[Recipient Address – FDA Project Manager Responsible for IND]

RE: Protocol Amendment [Insert type of amendment: New Protocol OR Change in a Protocol OR New Investigator] for IND Number [Insert ###,###], for [Insert Product Name]

Dear [Insert FDA Project Manager Name],

Please find enclosed a Protocol Amendment [Insert type of amendment: New Protocol OR Change in a Protocol OR New Investigator] for IND Number [Insert ###,###], for [Insert Product Name] .

(Note: If the amendment is not yet approved by the IRB, insert a statement explaining status of IRB review. Statement such as “This amendment has been submitted to the IRB and is scheduled to be reviewed on XX/XX/XXXXX.”)

Sincerely,

[Sponsor-Investigator Name]

[Title]

Enclosure: