

*Cover Letter Template for Initial IND Submission*

*[Insert Supply Sponsor-Investigator's Name & Address]*

*[Insert Date of letter]*

*[Insert Name and address of FDA center responsible for reviewing the application]*

Re: *Initial Investigational New Drug Application*

To Whom it May Concern *or* *[Insert Name of FDA Project Manager (if known)]*:

Enclosed, please find three copies (the original and 2 photocopies) of an initial Investigator IND application.

The clinical study associated with this application will not be initiated until this IND has become effective and Investigational Review Board (IRB) approval has been received.

Thank you for your consideration of this application. Please contact me at *[telephone number of Sponsor-Investigator during normal working hours]* or *[email address of Sponsor-Investigator]* if you have any questions regarding this submission.

Sincerely,

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Signature of Sponsor-Investigator (Name, title and affiliation)