
















1.2 Cover Letter

<<Insert Date>>

<<Insert Division Director's Name>>, M.D., Director

<<Insert Division's Name>>

Center for Drug Evaluation and Research

Attn: Document Control Room

5901-B Ammendale Road

Beltsville, MD 20705-1266

Re: NDA No. {NDA No.}

{Drug Name}

Original New Drug Application

1.2 Cover Letter

Dear Dr. <<Insert Director's Last Name>>:

In accordance with Section 505(b) of the Federal Food Drug and Cosmetic Act and Section 314.50 of the United States Code of Federal Regulation, {Sponsor Name} is submitting an Initial New Drug Application for {Drug Name} for the indication of {Indication}.

This IND is organized in accordance with the Agency's Guidance for Industry, "Providing Regulatory Documents in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using eCTD Specifications (June 2008)." Attached, please find the electronic submission information.

The confidentiality of this submission, and all information contained herein, is claimed by {Sponsor Name} under all applicable laws and regulations. Disclosure of any such information is not authorized without the prior written authorization of {Sponsor Name}.

Any questions concerning this submission can be addressed to me at the following address <<insert address>>, or please contact me directly at <<insert phone number>> or alternatively via email at <<insert email address>>.

Sincerely,

<<Insert Name>>

<<Insert Title>>

Electronic Submission Specifications

All files were checked and verified to be free of viruses prior to transmission through the electronic submission gateway.

-or-

All electronic files included in this submission are provided on a <<insert number>> CD-ROM or DVD and the electronic submission is approximately <<XX>> MB. All files were checked and verified to be free of viruses.

Anti-Virus Program	
Program Version	
Scan Engine Version	
Virus Definition Date	
Submission Size	

The IT point of contact for this submission is:

Name	
Phone Number	
Email Address	