{{submission\_date}}

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

Subject: **Initial Investigational New Drug Application (IND)**  
Drug: {{drug\_name}}  
Indication: {{indication}}  
Sponsor: {{sponsor\_name}}  
Serial Number: {{serial\_number}}

Dear Sir or Madam:

{{sponsor\_name}} is pleased to submit this Initial Investigational New Drug Application for {{drug\_name}} for the treatment of {{indication}}. This application is being submitted in accordance with 21 CFR Part 312.

This submission contains the following:

• FDA Form 1571  
• FDA Form 1572  
• FDA Form 3674  
• Investigator's Brochure  
• Clinical Protocol: {{protocol\_number}} - {{protocol\_title}}  
• Chemistry, Manufacturing, and Controls Information  
• Pharmacology and Toxicology Information  
• Previous Human Experience Information

If you have any questions or require additional information regarding this submission, please contact:

{{contact\_name}}  
{{contact\_title}}  
Phone: {{contact\_phone}}  
Email: {{contact\_email}}

Sincerely,

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

{{authorizer\_name}}  
{{authorizer\_title}}  
{{sponsor\_name}}