

[Your Name]  
[Your Title]  
[Your Company Name]  
[Your Company Address]  
[City, State, Zip Code]  
[Email Address]  
[Phone Number]  
[Date]

[Recipient Name]  
[Recipient Title]  
[Food and Drug Administration]  
[Office/Division Name]  
[FDA Address]  
[City, State, Zip Code]

Subject: Submission of [Type of Submission, e.g., New Drug Application, IND, etc.]

Dear [Recipient Name],

I am writing to formally submit the [type of submission, e.g., New Drug Application for [Drug Name]] to the FDA for your review and consideration.

**\*\*1. Overview of Submission\*\***

Provide a brief overview of the submission, including its purpose and any relevant background information.

**\*\*2. Summary of Data\*\***

Summarize the key data and findings that support the submission, including clinical trial results, safety data, and efficacy evidence.

**\*\*3. Enclosures\*\***

List the documents and materials included with the submission.

- [Document 1]
- [Document 2]
- [Document 3]

**\*\*4. Contact Information\*\***

For any questions or further correspondence, please contact me at [your phone number] or [your email address].

Thank you for your attention to this submission. We look forward to your review and feedback.

Sincerely,

[Your Name]  
[Your Title]  
[Your Company Name]