

[Your Name]  
[Your Position]  
[Your Company]  
[Your Company Address]  
[City, State, Zip Code]  
[Email Address]  
[Phone Number]  
[Date]  
[Recipient Name]  
[Recipient Title]  
[Food and Drug Administration]  
[Office Address]  
[City, State, Zip Code]

Dear [Recipient Name],

Subject: Letter of Intent for FDA Approval

I am writing on behalf of [Your Company] to express our intent to submit a request for FDA approval for [specific product/therapy name]. We are committed to ensuring that our product meets all regulatory requirements and provide safe, effective options for [target market/indication].

Overview of Product:

- Product Name: [Product Name]
- Description: [Brief description of the product and its intended use]
- Target Indication: [Specific medical condition or purpose]

Our team has conducted extensive preclinical and clinical evaluations to gather data supporting the safety and efficacy of [Product Name]. We are preparing our submission and anticipate submitting the [type of submission, e.g., IND, NDA, 510(k)] by [anticipated submission date].

We would like to request a pre-submission meeting to discuss our plans and ensure alignment on the submission process. Please let us know your availability for this meeting at your earliest convenience.

Thank you for your attention to this matter. We look forward to working closely with the FDA to advance [Product Name] and contribute to public health.

Sincerely,

[Your Name]  
[Your Position]  
[Your Company]  
[Your Contact Information]