

Expanded Access Template Document

Non-Emergency Individual Patient Expanded Access IND Cover Letter

This template should be used as the cover letter in support of a non-emergency individual patient expanded access submission to the FDA.



Note: This page should be sent on University or Department letterhead.

[Date]

Food and Drug Administration
Center for Drug Evaluation and Research
[Specify applicable CDER Review Division]
Central Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: **Expanded Access Submission**
[Type of expanded access submission ie. Single Patient Expanded Access IND Request]
Investigational Agent: [name of drug]

To Whom It May Concern:

Please accept the enclosed [type of request] expanded access use request for [name of drug] for a patient with [name of disease and brief description of condition].

The patient, [initials], is a [age]-year-old [gender] who [relevant medical history, previous treatments, current status].

This is being filed in a non-emergency setting as the patient is now stable, but we are concerned that the patient may deteriorate. [Here is where you may fill in any extenuating circumstances or critical timing needs.]

I believe that [name of drug] represents the best chance of successful treatment for [patient initials]. [provide the rationale for the treatment].

My intention is to treat the patient [summarize treatment plan].

To monitor safety, [summarize safety monitoring]

As per 21 CFR 312.310 (d) (2), the following documents are included:

- FDA form 3926
- This letter, including patient history, treatment justification, and proposed treatment protocol
- Informed Consent Form
- Curriculum Vitae for prescribing physician ([physician name])
- [manufacturer] letter of authorization

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We appreciate your time in the review of this submission and look forward to your further guidance. Please include my *[insert additional contact name if needed]* in all future correspondence with me regarding this.

Sincerely,

[Physician name]

[Relevant title]

[Relevant department]

[Clinic or institution physical address]

[Physician phone number]

[Physician e-mail address]

Cc: *[if you have listed anyone above as an additional contact, include full contact information here]*

DRAFT