

Pre-IND Package

A Pre-IND package is information provided by a sponsor to the FDA as background information for a pre-IND meeting. The package should contain all the information that the FDA would need to respond to the questions proposed for the meeting. The Pre-IND Information Package must be received at the FDA at least four weeks prior to the scheduled meeting date.

Although the contents of the information package will vary, depending on the product, indication, phase of drug development and issues to be discussed, information packages generally include the following items.

- Cover Letter
- Form 1571
- Product name and application number
- Chemical name and structure
- Proposed indication(s)
- Dosage form, route of administration and dosing regimen (frequency and duration)
- A brief statement of the purpose of the meeting
- A list of specific objectives/outcomes expected from the meeting
- A proposed agenda
- A list of specific questions grouped by discipline
- Clinical protocol and/or data summary
- Nonclinical protocol and/or data
- Chemistry, Manufacturing, and Controls information

The information in the Pre-IND package should be the most current and accurate information available to the sponsor. The sponsor should coordinate the agenda and the contents of the package to expedite the review process and discussion at the meeting. The FDA will have already reviewed the material before the meeting and will prefer to address those questions raised by the applicant rather than hearing a presentation of the information package.

The following site provides more information about the Pre-IND process:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/ucm077546.htm>