Icahn School of Medicine at Mount Sinai

Conduits
The Institutes for Translational Sciences

Pre-IND Meeting Checklist

Find out to whom you should request the pre-IND meeting, e.g. the FDA reviewer in the Division of Neurology or Gastroenterology (see FDA website below for contact information).

After you request the meeting by letter or e-mail, the FDA will respond with a date within 2 weeks. You must provide a 'Pre-IND package' at least 4 weeks prior to the scheduled meeting date.

A Pre-IND package is background information. The package should contain all the information that the FDA would need to respond to the questions proposed for the meeting. The contents of the information package vary, depending on the product, indication, phase of drug development and issues to be discussed.

The package generally includes:

- Cover Letter
- Form 1571 (the serial # would be '0000'). Subsequent correspondence to the FDA would have sequential serial #'s
- 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.

FDA Regulations and Guidance Websites

The following are web addresses for select FDA guidance websites and documents along with a link to the FDA IND regulations that may useful. For additional FDA guidance documents and regulations, please go to the FDA website, http://www.fda.gov/.

FDA Guidance Document - Formal Meetings between the FDA and Sponsors or Applicants
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM153222.pdf

FDA informational website - Industry Meeting Types
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/ucm071774.htm

FDA CDER PRE-IND Consultation Contacts
http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/Overview/UCM166356.pdf

FDA CBER SOPP 8101.1: Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants, Version #4, Effective Date: May 18, 2007
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079448.htm

FDA Website for IND Applications for Drugs
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm