

# Meetings with FDA

Martha A. Feldman, RAC  
Drug & Device Development Co., Inc.

UW Bioen 599

# Topics for this Session

- FDA's views on meetings
- Kinds of Meetings
- Make request for a meeting
- Prepare for Meeting
- Participate in Meeting
- Follow-up to Meeting
- Miscellaneous

# FDA's View of Meetings

- FDA is committed to communicating and interacting with sponsors
- FDA believes face-to-face meetings benefit both sponsor and agency
- FDA believes meetings are cost-effective in the long run for both sponsor and agency
- This slide and several of the following slides are abstracted from Elisa D. Harvey, "Understanding the Pre-IDE Program: FDA Perspective", 25 May 2005
- [http://www.fda.gov/cdrh/present/advamed-052505-harvey/index\\_files/index.html](http://www.fda.gov/cdrh/present/advamed-052505-harvey/index_files/index.html)

# Kinds of Meetings: Medical Devices

- Scientific Meeting/Prior to proof of concept animal studies
- Early Collaboration Meetings (Agreement and/or Determination)
- Pre-IDE Meeting/Post-feasibility/Pre-Pivotal Study Meeting
- Informal Pre-IDE Meetings
- Other Device Meetings
  - Pre-PMA Meeting
  - 100-Day PMA Meetings
  - Post-deficiency letter for 510(k) or PMA
  - Appeal of final decision on PMA, 510(k), IDE disapproval
  - Advisory Committee Meeting

# Scientific/Pre-proof of Concept Testing

- Discuss concepts, broad outline of test plans, including need for certain bench studies, need for animal studies and need for clinical studies (no test results needed, just plans, at this meeting)
- Discuss regulatory options, possible pathways
- Discuss primary mode of action issues of a possible combination product; jurisdictional issues

# Early Collaboration Meetings

<http://www.fda.gov/cdrh/ode/guidance/310.html>

- Present early prototype evaluation in preliminary animal models
- Discuss proposed clinical application, indication for use
- Get FDA feedback on bench and animal study plans; feasibility study plans.
- Start asking specific questions (e.g., patient population; acceptable endpoints)
- Discuss probable regulatory pathway (non-binding discussion), including Risk Determination for device (SR/NSR) <http://www.fda.gov/cdrh/d861.html>

# Pre-IDE Meeting/Post-feasibility/Pre-Pivotal Study Meeting

- Sponsor presents results of animal and feasibility study; describe finalized device design
- Sponsor discusses pivotal trial protocol (1° and 2° endpoints, duration, statistical analysis and evaluation methods), including Indication for Use and patient population
- FDA gives feedback on above and on proposed regulatory pathway, and nonbinding feedback on expedited status, need for Advisory Panel meeting
- FDA gives feedback on focused questions

# Pre-IDE Meetings

## ■ Are

- To provide feedback on preclinical test plan
- To provide feedback on clinical plans
- Determine what is Exempt/NSR investigation
- To discuss international (OUS) studies

## ■ Are Not

- A tool for negotiation
- For modular review
- To preview data
- For an in depth IDE review
- Legally binding
- For dispute resolution
- To hold FDA to years-old informal feedback
- To be part of a series of such meetings

# Informal Pre-IDE Meetings

- Not determination or agreement meetings
- Nothing binding
- May not have full review team present
- Individual divisions may have their own checklists about what to submit prior to the meeting – ascertain prior to sending package

# Other Device Meetings

- Pre-PMA Meeting
- 100-Day PMA Meeting
- Post-deficiency letter for 510(k) or PMA
- Appeal of final decision on PMA, 510(k), IDE disapproval

# Advisory Panel Meeting

- Requirements (Section 513(b)(6)(B))
  - Must have adequate time for initial presentation
  - Must have adequate time provided for response to any differing views by persons whose devices are the subject of a classification panel
  - Must encourage free and open participation by all interested persons

# Advisory Panel

- Sponsor sends FDA material on Panel presentation
- FDA sends to the Sponsor the list of items it will include in package to members of the Panel
- FDA sends package of materials to Panel members; no new data provided within last 2 weeks prior to meeting
- Time lines for presentation to the Panel are provided in guidance document  
<http://www.fda.gov/cdrh/modact/amendpan.html>

# FDA Does Not Have to Accept Recommendations from the Panel

# Requesting a Meeting with FDA

# Whom to Meet With

- Check Center's organizational chart to determine to which group to send meeting request
- Call the division and give a brief overview of why a meeting is being requested, i.e., the purpose and scope of the meeting; give regulatory status of the product (e.g., new, re-vamped in some way, new indication for previously approved product)
- Get a name of the person to whom the package should be addressed, usually the Branch Chief
- The package must be received before a meeting is scheduled, usually about 2-3 weeks in advance.

# Setting a date

- Be flexible as to dates – give several possible dates and times.
- NOTE: If significant additional information is submitted after the package has been sent and after the meeting has been scheduled, the meeting might be cancelled or postponed.
- If you have to cancel, do it at least 48 hours ahead.

# The Device “Package” Includes:

- Proposed agenda (and time allotment) and list of attendees and each person’s affiliation
- Background of clinical condition or disease
- Currently available products, balanced view of pros and cons of each
- Product description and rationale for use in this condition or disease
  - intended use and indication for us
- Test plans: bench, animal, clinical
- List of questions to be addressed at meeting

# What FDA does when it Receives the Package

- Branch Chief (BC) receives package
- BC determines who will be on Review Team
- BC assigns project to a lead reviewer
- Copies prepared (or requested of Sponsor) and distributed
- Internal pre-meeting and sponsor meetings are scheduled
- Team members review package and prepare memos prior to pre-meeting
- Internal pre-meeting held to discuss issues, reach consensus, get further information from Team/management

# Preparing for a Meeting with FDA

# Planning the Presentation-1

- Use the time optimally.
  - Presentation of the agenda and list of attendees should take no more than 2 minutes
  - Assume the FDA has read all of the material; do not waste time in your presentation reviewing material sent in the package.
- Call a week ahead of meeting to see if the Lead Reviewer can send you a list of the questions generated at their internal meeting.

# Planning the Presentation - 2

- The preliminary questions from the reviewing team may cover deficiencies and/or other issues
- Compare your list of questions with the preliminary questions from the review team. Ensure your presentation will cover them and, if possible, without presenting significant new information.
- Focus your presentation to elicit as much information, comments, suggestions from the agency.
- Manage the time by rehearsing presenters so that they keep to their time allotment.
- Limit the number of presenters – too much time can be lost during change of speakers.

# Preparing for the Meeting

- Do a mock rehearsal with two groups of people:
  - Those that know a lot about the product and research - to ensure you have not omitted critical information and have included all possible issues
  - Those that do not know anything about the product and have read only the “package” - to ensure your presentation is comprehensible and flows smoothly

# Participating in a Meeting with FDA

# The Meeting - 1

- Get to the building early as there is a lengthy sign-in and inspection procedure.
- Meetings are usually one hour long. They will start and end on time.
- **TURN OFF CELL PHONES AND PAGERS!**
- There will be a sign-in sheet circulated during the meeting, which will be copied for the sponsor.
- Stick to the agenda.

# The Meeting - 2

- Manage the time well. Leave small talk to the end, if there is time.
- Be brief and stay focused on scope of meeting.
- No side conversations.
- No open-ended questions.
- If the group gets bogged down on one issue, suggest that the one issue be handled off-line and continue with the other topics.
- Ensure that at least one person from your company is taking notes during the meeting.

# The Meeting - 3

- While taking notes, mark the items that are action items,
  - commitments for providing follow-up information to the company
  - commitments for providing follow-up information to the FDA,
  - arranging for off-line discussions
- Make sure there is about 10 minutes at the end of the meeting to review the Action Item list.
- Get a copy of the attendees list.

# Follow-Up After a Meeting with the FDA

# Debrief

- As soon as possible after the meeting, gather the company representatives to debrief
- As part of the debriefing, get people's perceptions of the reaction to the presentation of each member of the FDA's Team
  - Assess if there may be any misunderstandings or mistaken impressions by anyone – can expand upon some things in the minutes or add an addendum with clarification
  - See if you may have "supporters"

# Minutes of the Meeting

- Have one person take everyone's notes and draft the minutes, including a section for the action items
- Distribute to the other attendees for review in order to ensure full capture of information, commitments, etc.
- Issue minutes to management
- Send to FDA with a cover letter asking for comments

# References

- Early Collaboration Meetings under FDAMA  
- Meeting guidance  
<http://www.fda.gov/cdrh/ode/guidance/310.html>
- Advisory Panel Meetings  
<http://www.fda.gov/modact/amendpan.html>
- Advisory Panel/Committee Information Contact  
<http://fda.gov/cdrh/commline.html>