# FDA/Industry IVD Roundtable Meeting

*Sayah Nedjar, Ph.D.*

*Deputy Associate Director for Regulatory Affairs/Ombudsman*

Office of Blood Research and Review

Center for Biologics Evaluation and Research

Food and Drug Administration

December 8, 2011

# CBER Medical Devices Performance for FY -2011

The data indicate CBER has met or has the potential to meet or exceed MDUFA performance goals for the following submission types:

- 510(k)s
- PMAs
- Device BLAs

# CBER Medical Device Performance for FY2011 (Received thru 9-30-2011; Actions thru 10-31-2011)

| Submission Category | Number of Submissions Received | Number of Submissions Compl./pend. | Goal Date Reached - % Or Current Projected % Within Goal |
|---|---|---|---|
| 510(k)s | **44** (Incl. 2 Withdrawn) | **17/25** | 100% within goal so far (Avg. Review Time: 61.1 days; n=17) |
| PMA/PMAs | **14** | **8/6** | 100% within goal so far |
| BLAs (Standard) | **1** | **1/0** | 100% within goal |
| BLS (Standard Efficacy) | **1** | **0/1** | 100% within goal so far |
| BLS (Prior App Manuf) | **36** | **30/6** | 100% within goal so far |
| BLA/BLS Resubmissions | **4** | **2/2** | 100% within goal so far |
| BLS (manuf., non-MDUFMA) | **202** | **110/92** | 100% within goal so far |

# Meetings with CBER

**Purpose:**

- Provide guidance to Sponsor/Applicant
  - Product development
  - Facility design
  - Clinical study design
- Facilitate compliance with the regulations
- Gain agreements
- Resolve differences

# Meeting Types and submission Timelines

| Meeting type | Confirmation (days) | Scheduled to occur within (days) | Receipt of meeting materials |
|---|---|---|---|
| **A** | 14 | 30 | T -2 weeks |
| **B** | 21 | 60 | T-4 weeks |
| **C** | 21 | 75 | T-4 weeks |

# Meeting Types

- Type A Meeting:
  - Dispute resolution
  - Clinical holds
- Type B Meeting:
  - Pre-IND/IDE
  - Certain end-of-phase 1, and end-of-phase 2 and pre-phase 3.
  - Pre-submission (BLA, PMA and 510(K))
- Type C Meeting is any meeting other than a Type A or Type B meeting
  - Development and review of a product.

# Sponsor/Applicant Responsibilities

Before requesting a meeting:

- Sponsors/Applicants should consult other sources of regulatory/scientific/technical information applicable to their product development program, such as FDA and ICH guidance documents.
- Prepare a complete meeting request
- Prepare a comprehensive meeting packet
- Submit the request and packet to the appropriate CBER Office at the appropriate time
- Fax, email, electronic, hardcopy

# Meeting Request

- Type of Meeting being requested
- A brief statement summarizing the purpose of the meeting.
- A proposed agenda
- Product name and application number (if applicable).
- Proposed indication for use.
- List of proposed questions, grouped by discipline.
- Suggested dates and times.
- Format of meeting (face to face, teleconference)
- List of Sponsor/Applicant attendees.
- List of FDA Staff, if known, or disciplines requested.

# Meeting Request (1)

- The meeting request should include adequate information for the FDA to assess the potential utility of the meeting and to identify FDA staff .
- The objectives and agenda provide overall context for the meeting topics.
- But, it is the list of questions that is most critical to understanding the kind of input that is needed by the Sponsor/Applicant. They help to focus the discussion. Should be precise. Questions with multiple parts/subparts should be well organized and well formatted. We recommend that you do not use paragraphs that contain multiple hidden questions.

# Assessing the Meeting Request

Meeting Denied

- Based on substantive reasons – Example - meeting is premature for the stage of product development.
- Sponsor/Applicant notified with an explanation of the reason for denial.

Meeting Granted

- FDA will notify Sponsor/Applicant of the decision and schedule the meeting.
- Within timelines or as soon as possible.

# Rescheduling Meetings

- Sponsor/Applicant and FDA should try to avoid rescheduling.
- Reschedule meeting as soon as possible after original scheduled date
- Review Division determines whether meeting should be rescheduled.
- Note:
  - Internal meeting usually one week before external meeting
  - Multiple review Divisions, Offices and possible Centers.

# Rescheduling Meetings (1)

- Typical reasons for rescheduling a meeting (not all inclusive list):
  - Delay in submitting meeting package.
  - Meeting Package is inadequate, review team needs additional information.
  - Insufficient time to review the material because package is voluminous.
  - Essential attendees no longer available.
  - Sponsor/Applicant submitted new questions.
  - Attendance by additional FDA organizations not originally anticipated.

# Cancelling Meetings

- Sponsor/Applicant determines the FDA responses to their questions are sufficient for its needs and additional discussion is not necessary.
- Meeting package is not received by FDA within the specified time frames.
- Meeting package is grossly inadequate.
- Review Division determines whether meeting should be cancelled.

# Meeting Package Content

- Should provide a SUMMARY of the information relevant to the product.

- Meeting package should include the following
  - Product name and application number if applicable
  - Proposed indication for use
  - An updated list of Sponsor/Applicant attendees
  - A background section that includes the following
    - A brief history of the development program and the events leading up to the meeting.
    - The status of product development (e.g., the target indication for use).

# Meeting Package Content (1)

- A list of the final questions for discussion grouped by discipline and with a brief summary for each question to explain the need or context for the question.
- Data to support discussion organized by discipline and question

# Resolution of Dispute About Minutes

- Before the end of the meeting, FDA and Sponsor/Applicant attendees should summarize the important discussion points, agreements, clarifications, and action items.
- Official finalized minutes will be issued within 30 days of meeting.
- Sponsor/Applicant can dispute the accuracy and sufficiency of the meeting minutes. If disputing the positions taken by FDA you may go through the standard appeal procedures (see 21 CFR 10.75).

# Resolution of Dispute About Minutes

- First, ask FDA for clarification on meeting minutes only.
- If there are still significant differences in understanding, Sponsor/Applicant should notify FDA in writing.
- Review division and office director will take Sponsor/Applicant concerns under consideration.
- Two outcomes:
  - FDA determines official minutes accurately reflect meeting discussion.
  - FDA determines it is necessary to effect a change to the official minutes.
- Sponsor/Applicant notified of either outcome.

# Summary

- Do your homework – use applicable regulations and Guidance Documents.
- Hire consultants if you do not have in-house expertise- do not ask FDA to develop your program
- Pay attention to what is being said at the meeting
  - Be aware of “regulatory speak”
  - Understand and consider FDA’s perspective
- Science, not marketing, should drive your program

# Summary (1)

- If you have to ask “Can we submit the [fill in the blank] section of the application [fill in the length of time] after we submit the application?” you are not ready for a meeting

- Don’t submit your application prematurely according to corporate targets - multiple review cycles are NOT faster

# Summary (2)

- Don’t expect FDA to guess your critical issues
- Don’t present issues outside proposed agenda
- Don’t send new data and new questions just before meeting
- Don’t expect evaluation of new data presented at meeting
- Avoid voluminous packets - Full study and trial reports or detailed data generally are not appropriate at this stage

# Relevant Guidance Documents

- Draft Guidance for Industry: Standards for Clinical Trial Imaging Endpoints (August, 2011) CDER/CBER

- Guidance for Industry and FDA Staff - 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device (July 2011) CDRH/CBER

- Draft Guidance for Industry and Food and Drug Administration Staff; De Novo Classification Process (Evaluation of Automatic Class III Designation) *Federal Register Notice:* October 3, 2011) CDRH/CBER

# Relevant Guidance Documents (1)

- Draft Guidance for Industry and FDA Staff - Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (This draft guidance will supersede Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance. (May 2, 2011) CDRH/CBER

- Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle, Updated March 2011

# Relevant Guidance Documents (2)

- Draft Guidance for Industry: Pre-Storage Leukocyte Reduction of Whole Blood and Blood Components Intended for Transfusion, Jan. 2011

# We're Here to Help You!

- CBER's Office of Communication, Outreach and Development at : 301-827-2000
- Consumers, Healthcare providers: ocod@fda.hhs.gov
- Industry, Consultants: matt@fda.hhs.gov

# Resources

- CBER's webpage: http://www.fda.gov/BiologicsBloodVaccines/default.htm
- Contacting CBER: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/default.htm
- Or the CBER Contacts page: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm106001.htm