# MEETINGS WITH THE OFFICE OF SCIENCE


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# GOALS/OBJECTIVES

- History
- May 2012 Meetings Guidance
- Meetings Process
- Factors for Granting Meetings
- Formal vs. Informal Meeting
- Important Considerations

# HISTORY

# HISTORY: MEETINGS WITH THE CENTER FOR TOBACCO PRODUCTS

- Since 2010 the Center for Tobacco Products (CTP) has received multiple meeting requests. Typically meetings have been held with:
  - Office of the Center Director:
    - Listening sessions
    - 21 CFR 10.75 related
  - Office of Science:
    - Product development
    - Application development
  - Office of Compliance and Enforcement

# HISTORY: MEETINGS WITH THE OFFICE OF SCIENCE

- Since 2011, the Office of Science (OS) has received close to 100 formal meeting requests
  - Of these, OS has held over 65 meetings
  - Meeting content has focused on:
    - Pre-submission
    - General protocol development
    - General scientific and regulatory questions

# MAY 2012 MEETINGS GUIDANCE

# MAY 2012 MEETINGS GUIDANCE

May 24, 2012, CTP published a guidance entitled, “Meetings with Industry and Investigators on the Research and Development of Tobacco Products”

- Intended to assist tobacco manufacturers, importers, researchers, and/or investigators who seek meetings with CTP staff, relating to their plans to conduct research to inform the regulation of tobacco products or support the development or marketing of tobacco products.

# MAY 2012 MEETINGS GUIDANCE: CONTENT

Requesting a meeting:

- When – generally, prior to submission of an application
- How:
  - Submit a written meeting request to the Document Control Center, attention: Director, Office of Science, CTP, at FDA
  - Request should be prominently identified as “OS Meeting Request”
- What to include:
  - Product information
  - Contact information
  - Draft questions, purpose, expectations
  - Logistical information

# MAY 2012 MEETINGS GUIDANCE: CONTENT 2

- In general, FDA intends to respond in writing within 21 calendar days of receipt of the request with two possible outcomes:
  - Denial
  - Granted
- If granted, FDA recommends submitting a meeting information package at least 45 days prior to the scheduled meeting
  - FDA may decide to postpone or cancel a meeting if we do not receive adequate supporting documentation for a productive meeting within this timeframe
  - Your meeting information package should include summary information relevant to your product(s) and the proposed agenda

# MEETING PROCESS

# MEETING PROCESS: DECISION ON MEETING

- Receipt, processing, and decision:
  - Meeting requests are officially received through CTP Document Control Center
  - After receipt FDA intends to issue decision within 21 days via letter:
    - Granted:
      - Type of meeting (face-to-face, teleconference, or letter) listed
      - Logistical information
    - Denied:
      - Clear explanation should be provided
      - Note: a subsequent meeting request is a new request

# MEETING PROCESS: IF GRANTED, NEXT STEPS

- Meeting information packages should be received by FDA at least 45 days prior to scheduled meeting
- FDA reviews the meeting information package
- FDA will try to provide preliminary responses to the posed questions 2 days in advance of the meeting (if face-to-face or teleconference)
  - Allows the meeting requestor the opportunity to cancel meeting
  - Focuses meeting discussion on those topics that still require clarification

# MEETING PROCESS: MEETING HELD

- Discussion is limited to the scope of the questions and the material in the information meeting package:
  - If questions or data are out of scope, FDA likely will not comment
- Prior to the end of the meeting, attendees should summarize the important discussion points, agreements, clarifications, and action items
  - Attendees' summary ensures that there is mutual understanding
  - FDA staff should add or further clarify any important points not covered in the summary.

# MEETING PROCESS: MINUTES

- Official minutes are prepared by FDA:
  - Issued via letter
  - Goal: issue within 45 days of meeting
- Question or Concern with Official Minutes:
  - Send your comments and suggested changes, including your recommendations and rationale, to your point of contact for our consideration
  - If FDA deems it appropriate to change the official minutes, the Agency intends to document this change in an addendum to the official minutes

# CONSIDERATIONS FOR GRANTING MEETINGS

# CONSIDERATIONS FOR GRANTING MEETINGS: 3 QUESTIONS

Question 1:

- Does the meeting request include the information recommended in the May 2012 guidance?

Question 2:

- Is the meeting necessary or appropriate?

Question 3:

- Is the meeting request timely?

# CONSIDERATIONS FOR GRANTING MEETINGS: QUESTION 1

Does the meeting request include the information in the May 2012 guidance?

- Does it contain, for example, the product identification, meeting purpose and objectives, and draft questions?
- Does it contain a proposed list of attendees, proposed dates for a meeting, contact information, and approximate arrival date for supporting information?

Note: if missing any of the above, FDA may deny the meeting

# CONSIDERATIONS FOR GRANTING MEETINGS: QUESTION 1 (CONT)

- OS has denied meeting requests that do not contain the recommended information described in the May 2012 guidance. For example, meeting requests have been denied for lacking the following:
  - Purpose or objective
  - Agenda or scope
  - Draft questions
  - Approximate date additional background material will arrive at FDA
  - Suggested date for the meeting
  - Suggested format of meeting (e.g., teleconference)

# CONSIDERATIONS FOR GRANTING MEETINGS: QUESTION 2

Is the meeting necessary or appropriate?

- Does the meeting request seek general feedback on research plans or request comprehensive consultation and review?
- Is the information sought already available to the requestor?
- Is the purpose of the meeting to support research or product development, or contest and seek to overturn a previous decision?

# CONSIDERATIONS FOR GRANTING MEETINGS: QUESTION 2 (CONT)

- Will the meeting improve a future submission and facilitate FDA review?
- Is the meeting request not in line with the FDA review process?
- Will the meeting duplicate ongoing FDA efforts?
- Will the meeting delay FDA decisions?

NOTE: FDA does not intend to grant a meeting to discuss deficiencies for an application that is currently under review

# CONSIDERATIONS FOR GRANTING MEETINGS: QUESTION 2 (CONT)

OS has previously denied meetings that are not necessary or appropriate. Examples of past meeting request denials include:

- Meetings which sought to overturn a decision (may be more appropriate under 21 CFR 10.75)
- Meetings to discuss tobacco products that are the subject of applications under review and the meeting's scope, purpose, and questions focused on deficiency language received, disagreement with FDA's assessment, and potential ways to rectify the situation
- A second meeting request on the same purpose and topic

# CONSIDERATIONS FOR GRANTING MEETINGS: QUESTION 3

Is the meeting request timely?

- Is the meeting request premature?

- Is the purpose of the meeting to discuss deficiencies prior to final action?

# CONSIDERATIONS FOR GRANTING MEETINGS: QUESTION 3 (CONT)

Examples of meetings that may be denied under this question include but are not limited to:

- if an applicant submitted a meeting request to discuss postmarket studies for a modified risk tobacco product but they have not yet submitted a modified risk application
- a meeting to discuss deficiencies in an application currently under review

# FORMAL VERSUS INFORMAL MEETING

# FORMAL MEETING

- A formal meeting is what is described in the May 2012 Meetings Guidance
- Formal meetings have performance measures

| Category | Performance Measure | Submission Cohort |
|---|---|---|
| **Meeting Management** | Respond to meeting requests within 21 calendar days. | FY15: 80%, FY16: 80%, FY17: 90%, FY18: 90% |

- A formal meeting request may have the proposed questions answered through a face-to-face meeting, a teleconference, or by written response.

# INFORMAL MEETING

- An informal meeting is one where a person (e.g., manufacturer):
  - Seeks clarification on a request or a deficiency from FDA
  - Notes a potential discrepancy or error in FDA correspondence
  - Requests an update on its application status

- An informal meeting may be requested by FDA or an applicant
- An informal meeting is generally a short teleconference scheduled via phone or email

# INFORMAL MEETING (CONT)

An informal meeting is NOT:

- to seek advice on how to resolve a particular deficiency
- to discuss a difference of opinion with FDA on the deficiency
- an occasion that alters the timing or process of the review of an application
- formally tracked with performance measures
- a decision
- a process that typically results in letters (e.g., grant, deny, meeting minutes)

# IMPORTANT CONSIDERATIONS

# IMPORTANT NOTES TO CONSIDER

- A specific scientific question might be adequately addressed in numerous ways.

- To help ensure an application will be complete at the time of submission and likely to provide the data and information required for FDA to make a final authorization decision, it is recommended that a meeting be held well in advance of the planned premarket submission so that the applicant has the opportunity to consider CTP feedback prior to preparing the application.

# IMPORTANT NOTES TO CONSIDER (CONT)

- The applicant is responsible for fully developing their programs and submissions
  - Applicants may benefit by consulting with experts outside FDA prior to meeting with FDA. These consultants may advise and/or assist applicants in developing the plan to address the regulatory requirements and preparing well-organized submissions.
- CTP is a regulatory agency, performs scientific review of product applications, and provides response to the sufficiency of the scientific evidence developed by applicants, but does not furnish scientific expertise to companies as they develop their research plans and study designs or perform data analysis *in place of* the applicant's own responsibility.

# IMPORTANT NOTES TO CONSIDER (CONT)

- Pre-submission meetings are not intended as a substitute for a full application review nor to provide the level of detail that FDA would consider during the course of scientific review.
- Meetings, whether formal or informal, are beneficial to share information; however, the advice provided is not decisional.
- Formal meetings can be a good tool for applicants to receive FDA's feedback on approaches to answering scientific questions and discussing significant challenges.

# IMPORTANT NOTES TO CONSIDER (CONT)

- FDA intends to grant meetings for product development if:
  - the meeting request includes the information recommended in the May 2012 guidance
  - the meeting is necessary and appropriate
  - the meeting is timely

- FDA does not intend to grant meetings if it:
  - Is not in line with the FDA review process
  - Duplicates ongoing FDA efforts
  - Delays FDA decisions

TO HELP INFORM FDA'S EDUCATIONAL EFFORTS AND GENERAL QUESTIONS RELATED TO POTENTIAL FUTURE SUBMISSIONS, WE ARE SOLICITING QUESTIONS. PLEASE SUBMIT YOUR QUESTIONS TO ASKCTP@FDA.HHS.GOV.

THE END