Advisory Committee Meetings: Improving FDA and Industry Collaboration

FDA/CDER-CHPA Seminar Series

Fall Seminar
September 27, 2006

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Co-Sponsorship Agreement

- Consumer Healthcare Products Association (CHPA)
- Food and Drug Administration (FDA)
- Renewed this year; extended to 2009

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Purpose

To promote a better FDA and industry understanding of the unique challenges in the present and future OTC healthcare environment.

Past Seminars

- Challenges of Change: OTC Label Implementation
- OTC Monographs: Challenges for the Future
- Over-the-Counter and On-the-Air: The Advertising of OTC Drug Products
- OTC Squares
- Management of Post-Marketing Surveillance Data for OTC Products

Steering Committee

FDA

Bob Eshelman
Michelle Jackson
Mike Koenig
Amy Mason
Keith Olin
Mitch Weitzman

CHPA

Greg Collier (Procter & Gamble)
Doreen Frank (Schering-Plough)
Sue James (GlaxoSmith Kline)
Lorna Totman (CHPA)

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Planning Committee

FDA

Igor Cerny
Mike Koenig
Darrell Lyons
Steve Osborne
Neel Patel
Colleen Rogers
Dornette Spell-Lesane

CHPA/Industry

Doug Bierer
Kevin McLaughlin
Lauren Quinn
David Schifkovitz
Lorna Totman

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Today's Seminar

Advisory Committee Meetings: Improving FDA and Industry Collaboration

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Key Milestones in Rx-to-OTC Switch

- Decision to pursue switch
- Access to product (within Pharma side of organization or license agreement with outside company)
- Development discussions with FDA under IND
- Conduct studies → decision to go forward
- Compile and submit NDA
- Advisory Committee Meeting
- FDA Action Letter
- Product Launch

FDA CHPA celebrating 125 years

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Agenda

- Introduction
- Background on FDA Advisory Committees
- Non NDA Specific NDAC Meetings
- FDA/Industry Timelines to NDAC Meetings
- FDA Questions for the NDAC
- Panel Discussion

Background on FDA Advisory Committees

FDA/CHPA Meeting
September 27, 2006

Igor Cerny, Pharm.D.
Director, Advisors and Consultants Staff

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Federal Advisory Committee

- Definition: Any committee, board, commission, council, conference, panel, task force, initial review group, special emphasis panel, working or other similar group which is not composed entirely of full-time officers or employees of the Federal Government. It is established or utilized by a department or agency to advise or make recommendations on matters relating to programs, responsibilities or activities of the department or agency.

Federal Advisory Committee Act (FACA)

- FDA Advisory Committees operate within the legal framework of the Federal Advisory Committee Act, Public Law 92-463 (FACA)
- Congress passed FACA Oct. 6, 1972
- Executive Branch has many advisory committees

Federal Advisory Committees

- Government in Sunshine Act, Public Law 94-409, Amendment to FACA - rights of citizens to participate/obtain information on the decision-making process of the Federal Government is balanced with protecting the rights of the individual.

FDA Controlling Regulations: 21 CFR Part 14

- Policies and procedures for FDA Advisory Committees were codified in late 1970's
- "Part 14 - Public Hearing Before a Public Advisory Committee"
- Subpart A through Subpart I

Food and Drug Modernization Act (FDAMA) Highlights

- Representative of consumer, patient, and *industry* interests on Committees
- Two or more specialists in the disease or condition should be on the Committee
- FDA should notify the "affected persons" of the final decision 90 days after the meeting

Composition of the NDAC

- Chair and Members Selected by ONP then Appointed By Commissioner to serve up to Four Years
- Members are pre-eminent scientists in their field, specialties as specified in the charter
- Consumer Reps (voting) appointed by FDA; and Industry Reps (non-voting) nominated by Industry– all represent broader interests
- Committees are usually supplemented with additional Consultants such as Patient Representatives

Who Can Recommend a Prospective Member?

- **Referrals come from:**
  - Former/Current Advisory Committee Members
  - ONP Scientists
  - Professional Societies and Journals
  - Academic Institutions
  - Consumer Groups
  - Self Nominations
  - Congressional Staff
  - Industry

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Member Selection *Continued*

- Résumés Reviewed by ONP to:
  - *Screen for Needed Expertise*
  - *Preliminary Screen for Conflicts of Interest*
- ONP Selects the New Member; ACS Does the Administrative Paperwork to Get Member Appointed to the NDAC
- ACS Reminds ONP that Consideration is Made for Committee Balance: Race, Gender, Geography, Institution, e.g.

Who's involved in AC meetings on the CDER side?

- ONP
- Advisors & Consultants Staff (ACS/CDER)
- Division of Information Disclosure Policy (DIDP) aka "FOI" (CDER)
- Dockets (OC/FDA)
- FDA Ethics, ACOMS, Associate Commissioner for Policy & Planning (OC), HHS's OGC (Conflict of Interest "COI")

Depending on the Meeting, these entities can also be involved:

- Office of New Drugs (OND)
- Center Director
- Office of the Commissioner (OC)
- Office of Surveillance & Epi (OSE)
- One or more Review Divisions in CDER (consult or joint meeting – Rx to OTC switch primarily)

CDER ACS

- ACS Makes Sure That the Meeting Process Satisfies FACA, FDAMA, CFRs, and FDA Policies / Memos
- Organizes/Coordinates Administrative Meeting Logistics: Backgrounder, Hotel, AV, Transcriber, Travel for Members/Consultants
- The ACS Executive Secretary = Project Manager of the Meeting on the Admin End

CDER ACS, *continued*

- Exec Sec is a Conduit for Information Between ONP, Sponsor, AC Members, Public
- ACS is Intermediary between the ONP and NDAC – Communications between Those Two Must Flow through ACS
- ACS Conducts Training for New Members at least Once a Year

How Does ONP Determine the Need for the AC Meeting?

- Typically Rx to OTC switch or monograph issues – ONP usually Decides
- Typical Triggers Include:
  - Safety, Efficacy, Risk/Benefit Questions
  - Dosing Concerns
  - Target Population
  - Labeling Issues
  - Appeals of FDA Decisions

Background document

- Both ONP and the sponsor prepare a document ("backgrounder") that summarizes the data as they see it.
- Prepared for the NDAC members, keep in mind that both will post onto the web 1 day before the meeting
- NDAC members get both 18 business days before the meeting (up to them to read it!)

Background document – sponsor considerations

- Draft Disclosability Guidance requires sponsor to submit backgrounder with "material exempt from disclosure" no later than 48 business days prior to AC.
- Fully releasable package due 22 business days prior.
- Fully releasable backgrounder should state that the information contained within is "AVAILABLE FOR PUBLIC DISCLOSURE WITHOUT REDACTION" or "fully releasable" – NOT "confidential"!

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Background document – sponsor considerations, *continued*

- Sponsors should provide 30+ hard copies of their backgrounder
- Backgrounder should also be provided in PDF format
- We have begun providing electronic formats to committee members ; you may be asked to provide 30 copies of the electronic format.
- Published articles can not be posted, therefore a reference list must be included for posting

When Will You Get to See the Questions?

- In the Backgrounder(?)
- If not, hopefully Contact Between Sponsor & ONP Has Been Frequent & Meaningful so That Surprises Are Minimal (?)
- ACS Has Been Encouraging all Divisions to Include Either “Points to Consider” and / or a Cover Memo for the Backgrounder
- ACS Has Also Encouraged all Divisions to Avoid “Regulatory Conclusions”

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Important Factoids

- Backgrounder timelines are not very flexible: work With the Exec Sec
- Errata Sheets Allowed for Sponsor & ONP
- Actual Data Amendments Are Discouraged
- ACS Applies the Disclosability Guidance to Non-NDA Meetings for Consistency
- ACS Doesn't Release SGE Names, Specialties Only
- MAPP 6001.1: SGEs Appearing Before FDA
- Other Feds Can't Represent You Before FDA

FY ’06 Appropriations Bill

- *“none of the funds made available in this Act may be used to…grant a waiver of a financial conflict of interest…*
- *[this] shall not apply to a waiver…if – (1) not later than 15 days prior to a meeting of an advisory committee , the Secretary of HHS discloses on the Internet website of the FDA…the nature and basis of such waiver…..”*
- Any SGE Who Needs a Waiver MUST Have This Waiver Posted on the Web 15 Calendar Days Before the Meeting – Your First Chance to See Some of the Added Consultants Who Will Be There!

Criminal Conflict of Interest Statute Title 18 U.S.C. 208

- Prior to every meeting each SGE is re-evaluated for conflict of interest relative to the meeting topic as well as “competing products”
- Competing products are anticipated to “significantly” gain or lose market share depending upon FDA decision on subject product
- CPs are used for same indication or in the same therapeutic category/class?

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What Are the Types of Interests Are Screened?

- Stocks and Investments
- Primary Employment
- Consultant Work
- Contracts / Grants / CRADAS
- Patent / Royalties / Trademarks
- Expert Witness Activities
- Teaching / Speaking / Writing
- Department Heads / Administrative Duties
- Exceptions for Institutional Directors

Conflict of Interest *Continued*

- Interests Are Also Imputed to the Spouse, Minor Child, and Employer.
- There are Provisions for on excludable interests – WAIVERS
- FDA May NOT Grant a Waiver for an Advisory Committee Member to Review Their Own Work
- Current FDA Criteria Used for COI Screening Are Found on the Web

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COI Clearance Workflow

CDER ACS (Working w/ Review Division)
- Assesses of Matter at Issue, IDs All Entities With Financial Interest
- Reviews SGE's Reported Interests Against Waiver Criteria Document
- Prepares Waivers for Ethics & Integrity Staff Review
- Forwards Waivers to FOI for Redaction

Associate Commissioner
Approves or Denies Waiver

FDA's Ethics & Integrity Staff
- Reviews Waiver, Recommends to ACOMS

ACOMS
- Reviews Waiver in Consult w/EIS
- Makes Recommendation to the Associate Commissioner

ACOMS
- Notifies Center of Reason for Waiver Denial

CDER ACS
- Forwards Approved Redacted Waivers and Consent for Disclosure Documents to Dockets
- Notifies Review Div. of Denied Waiver

Division of Documents Management
- Posts Approved Waivers & Consent For Disclosure for Advisory Meetings on FDA's Internet

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Conflict of Interest Dilemma

- Congress, Consumer Watchdog Groups, the Public Want AC Members With "Minimal Conflicts" – Who Doesn't? Is That Possible?
- Ideal AC Member Has Practitioner + Clinical Trials Experience
- Where Does One Get Clinical Trials Experience?

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Conflict of Interest Dilemma *Continued*

- Since Drug Development Is Primarily Funded by Private Sector, Most Clinical Trial Experience Is Gained by Working With Industry-Sponsored Trials
- FDA Doesn't Want AC Members Who Lack Clinical Trial Experience – Can't Properly Advise FDA, Can Potentially Hurt the Company, Hurt the Public (95% of Time, FDA Agrees With AC)
- FDA will continue to refine how it determines and discloses the Balance Between Experience and "Conflict"

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DOs for the Sponsor

- Keep Up the GREAT Work Regarding Rehearsals – Presentations are Excellent
- Keep Up the GREAT Work Regarding Back-up Slides – Some Are Amazing – Because:
- Keep Up the GREAT Work in "Knowing the Committee"

DON'Ts for the Sponsor

- Don't Forget: ACS Doesn't Release SGE Names – Other Centers Do – We Release Specialties (SGE Clearance Hard to Predict)
- Don't Forget About MAPP 6001.1: SGEs Representing You in Front of FDA
- Ex-FDAers Have a Lifetime If Worked on That Issue; 1-Year Cooling-off Otherwise
- Other Feds Can't Represent You Before FDA
- Don't Forget: Sponsor Package Goes to FOI
- Don't Spring New Data or B.S. Committee
- Don't Lose Your Cool!

Websites of Interest

- Where to find backgrounders & waivers on the Web: http://www.fda.gov/ohrms/dockets/ac/acmenu.htm
- Disclosability Guidance at: http://www.fda.gov/cder/guidance/3479dft.htm
- Conflict of Interest Criteria at: http://www.fda.gov/oc/advisory/conflictofinterest/intro.html
- MAPP 6001.1 at http://www.fda.gov/cder/mapp/6001-1.pdf

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Non NDA Specific
NDAC Meetings
CHPA/Industry Activities

David Schifkovitz
GlaxoSmithKline Consumer Healthcare

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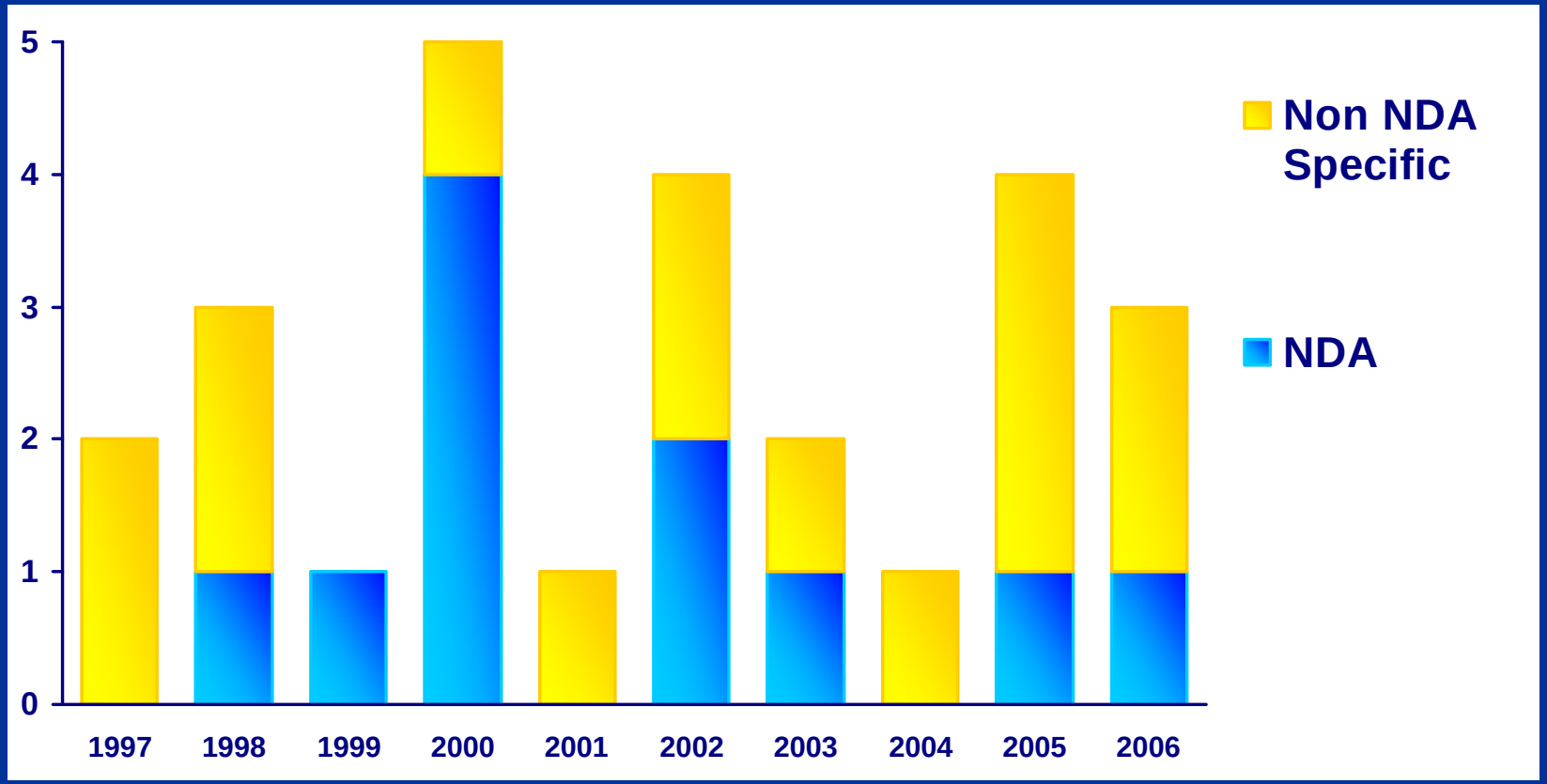
NDA vs Non NDA NDAC Meetings

Since 1997

- Rx to OTC Switch = 11
- OTC Monograph = 14

NDAC Meetings



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NDAC Topics

- Class Labeling
- Safety – Testing and Evaluation
- Efficacy – Testing and Evaluation

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NDAC Meetings

- Same requirements as per 21 CFR Part 14
  - Federal Register notice at least 15 days prior to meeting (usual 30 - 60 day notice)
  - Date, Time, Location, Contact, Agenda, Open/Closed
  - Background materials no later than 24 hours prior to the meeting
  - Public Process – prior notification of meeting limited to Federal Register notification

CHPA/Industry Activities

- CHPA member notification for Monograph or NDA products that may be impacted by NDAC
- Alert Industry Representative to NDAC
- Coordinates Industry interest in formation of Task Group to consider NDAC issue and development of common position based on scientific review

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CHPA/Industry Activities

- Task Group activities can include:
  - evaluation of public information and individual company data to address issue
  - evaluation of need to conduct studies to generate additional data
  - assessment of industry impact and timing

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CHPA/Industry Activities

- Task Group determines need for outside experts
- CHPA request meeting with FDA to discuss:
  - Need for Industry Presentation at NDAC
  - Time allocation for Industry Presentation
- Monitor FDA website for background materials

CHPA/Industry Activities

- Finalize Industry positions/presentation
- Brief Industry Representative on Task Group Perspectives
- Development of stand-by press statement based on potential outcomes of NDAC

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NDAC Non NDA Meetings

- Unique Issues
  - Very short time period for preparation
  - Unlike NDA products where FDA and sponsor have access to all data; data may be limited
  - Individual companies may opt out of Task Group participation due to product specific issues or general disagreement with Task Group positions

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FDA Review Division and ACS Timelines for Advisory Committee Meetings

FDA/CHPA Meeting
September 27, 2006

LCDR Dornette Spell-LeSane, NP-C, MHA
Office of Advisors and Consultants Staff, FDA

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NDA Sponsor Timelines for Advisory Committee Meetings

FDA/CHPA Meeting
September 27, 2006

Douglas Ws. Bierer, Ph.D.
Douglas Bierer Consulting, LLC

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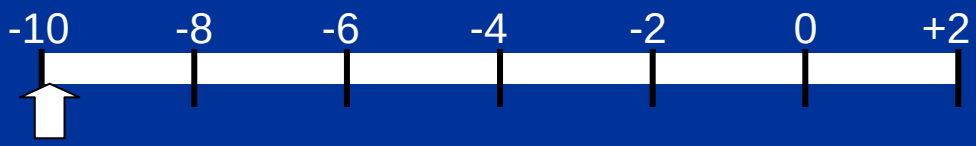
Terms

AC	Advisory Committee
ACS	Advisors and Consultants Staff
ACOMS	Advisory Committee Oversight and Management Staff
DFO	Designated Federal Officer
FR	Federal Register
KOL	Key Opinion Leaders
SGE	Special Government Employees

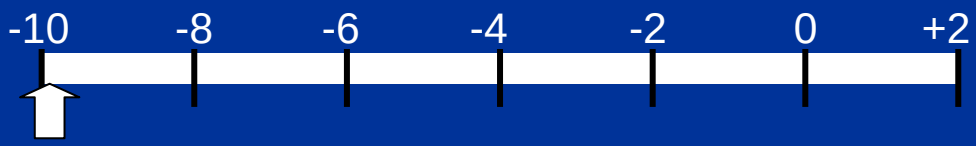
Before the NDA Is Filed . . .

- Sponsor assessment – Is this application product a candidate for Advisory Committee?
  - First in Class Switch
  - New Indication for existing OTC Class
  - Product has unique characteristics impacting
    - Safety
    - Efficacy
    - Misuse/Abuse



Before the NDA Is Filed . . .

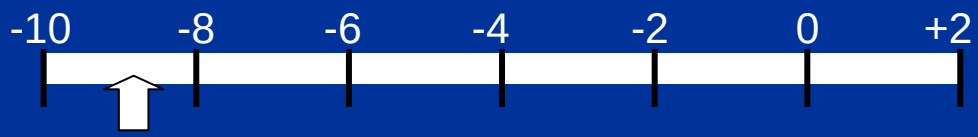
- If Yes – Start Developing R&D + Commercial Plans for Advisory Committee
  - Assign AC Coordinator
  - ID responsible team members
  - ID potential company speakers
  - ID potential external presenters
  - Determine need for additional external support
    - Speaker training, AV support



We're On?
9 Months Before AC

Review Division

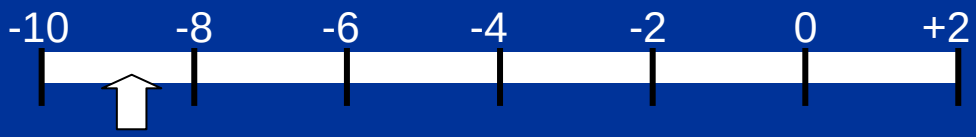
- Begins review of application and collection of data
- Includes discipline review (medical, safety, statistical, chemistry etc.)
- Identifies potential topic(s) and or issue
- Begins to make the decision for an advisory committee meeting



We're On?
9 Months Before AC

Advisors and Consultant Staff (ACS)

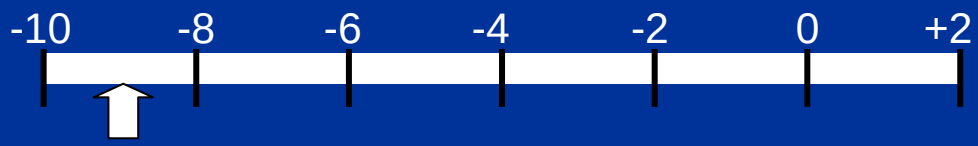
- Polls committee for available dates
- Develops meeting calendar
- Reviews committee status



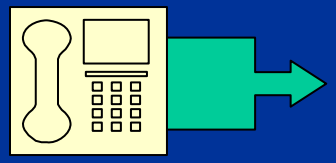
We're On!
9 Months Before AC

Development of the Overall Strategy

- What information should be included in the briefing document?
- What key messages must the Sponsor get across to the panel members?
- What questions will the panel members ask?
- Data and support from original Rx NDA
- How should outside experts be used?



4 Months Before AC

Review Division  **ACS**

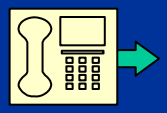
- Draft Federal Register (FR) notice
- Determine Meeting topic(s)/issues for discussion
- Draft competing/affected products list to determine conflict of interest for meeting attendees
- Provide names and contact information for individuals who need special Government Employee (SGE) status

4 Months Before AC

ACS

- ACS timelines begin +76 business days (approximately 4 months) prior to the meeting.
- Timelines are based on business days.

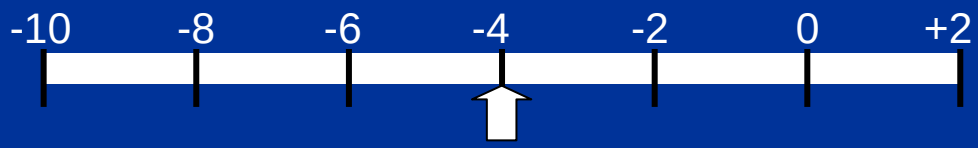
4 Months Before AC

ACS  Sponsor

- Date, time, and location of AC
- ACS contact names and numbers
- Dates background materials are due to the DFO (Designated Federal Officer)
- Request for Sponsor presenters and topics
- List of AC members or SGEs who will be attending
- Copy of Investigators and marketing information
- Address for FedEx shipment of backgrounders

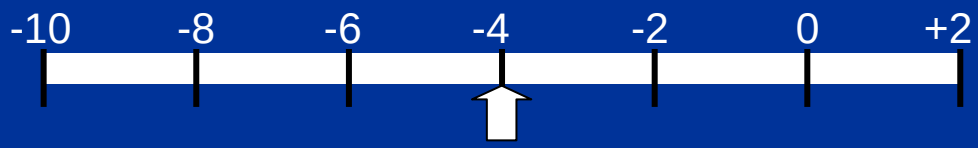
4 Months Before AC

- Creation of Sponsor Teams
  - NDA Review Response Team
  - Core Presentation Team
  - Administrative Working Group



4 Months Before AC

- **NDA Review Response Team**
  - Address any questions raised by FDA during their review of the NDA
  - Keep presentation team aware of issues raised by FDA
  - Provide content/review for presentation team
- **Composition:**
  - Multidisciplinary: Biostatistics, Clinical, Medical, Toxicology, Epidemiology, etc.

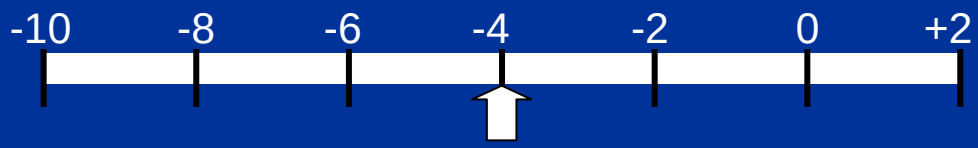


4 Months Before AC

- **Core Presentation Team**
  - Prepare briefing document
  - Develop and prepare presentation
  - Interaction with external presenters
  - Prepare for questions and answers
  - Review background of advisory committee members
  - Speaker training
  - Conduct rehearsals

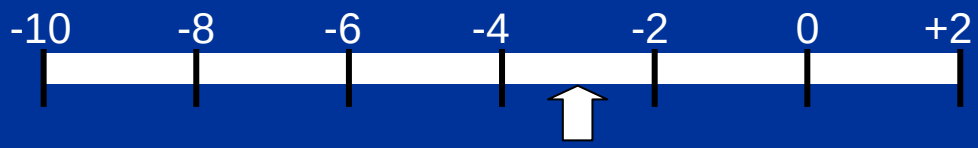
4 Months Before AC

- **Administrative Working Group**
  - Manage team's logistical needs
  - Support for external speakers if needed
  - Prepare and organize slides
  - Meeting planning and logistics
  - Interaction with audio/visual specialists
  - IT specialists



3 Months Before AC

- **Review Division**
  - Writes reviews of data
  - Drafts agenda
  - Identifies speakers
- **ACS finalizes:**
  - FR notice
  - Attendee list
  - Competing/affected product list



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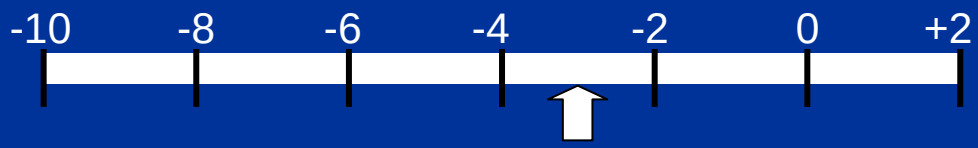
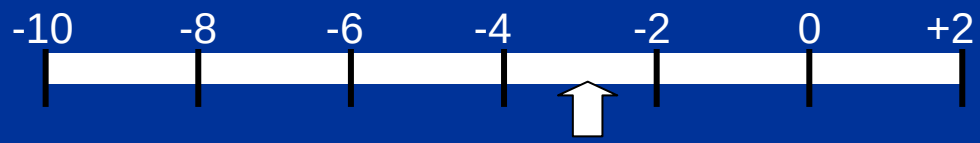


FR Notice

ACS → ACOMS → Regulations Editorial Staff → Associate Commissioner for Policy and Planning

Submitted to the Federal Register for final publication. (The Federal Advisory Committee Act requires that a meeting announcement be published no less than 15 calendar days before a meeting)	The Center is notified immediately, either by phone or email, that the meeting can be announced on the Advisory Committee Information Line making the announcement **Public**

There is approximately A 3-5 day delay between the announcement on the information line and posting of the official Federal Register Notice on the internet website of the Division of Dockets Management.



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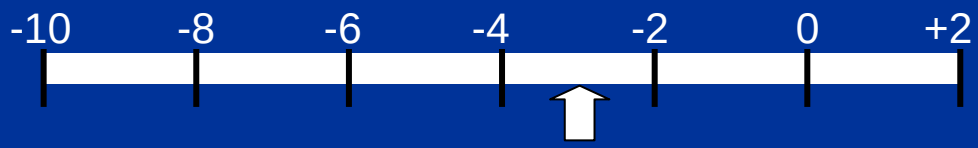


Attendee List

Member - Appointed to the Committee, serving a term

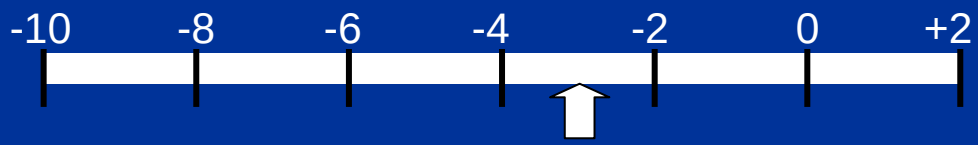
Consultant - Provides technical expertise in the specialty area, supplements the committee

Consumer - Represents the consumer perspective (member)

Industry - Represents industry's global position (member)

Patient - Represents the patient or caregivers

Guest speakers - Experts



3 Months Before AC

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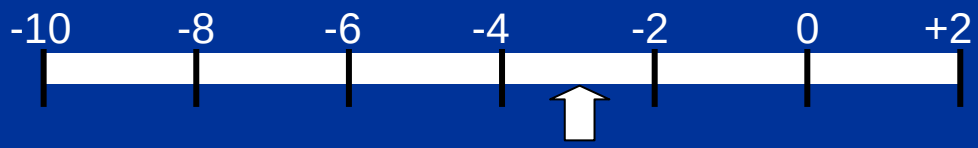
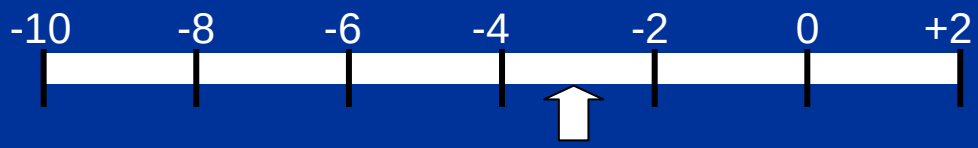


Competing Product

Competing product (affected product)

- Critical list for an advisory committee meeting (prepared by ACS and the division)
- Based upon medical, scientific, and economic considerations
- Determines conflict of Interest for meeting participants



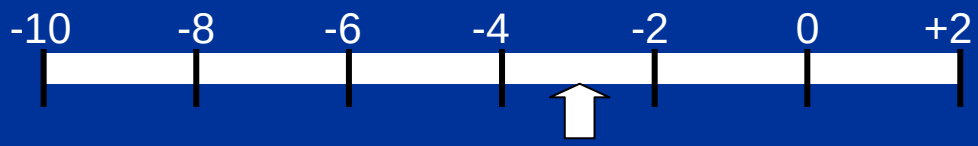
3 Months Before AC

Mock Advisory Committee Meeting

Make-up

- Consultants/experts
- Former advisory committee members

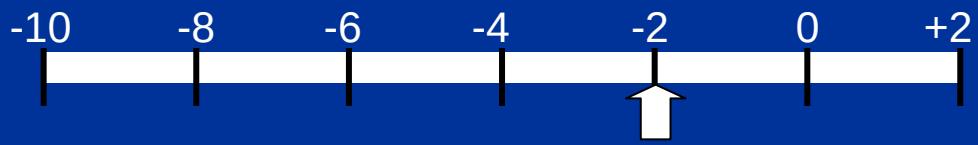
- **Purpose**
  - Simulate as best as possible the advisory committee meeting
  - Refine presentation
  - Practice Q & A



Countdown 2 months

Review Division

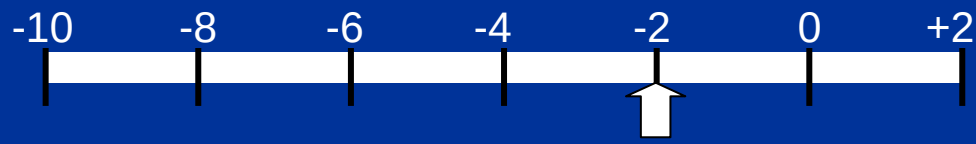
- Review ACS changes, if any, to affected products list
- Outline presentations
- Discuss any new data/request(s) with sponsor



Countdown 2 months

ACS

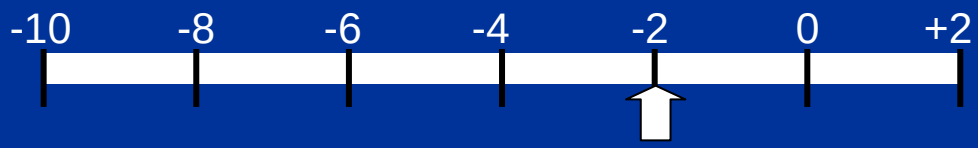
- Conflict of Interest Screening begins
- No SGE's are added to the attendee list
- Sponsor Consultantant list is due
- ACS Schedules Team meetings (occurs 1/wk)
- Finalize Hotel, transcriber, AV company



Countdown 2 months

Sponsor

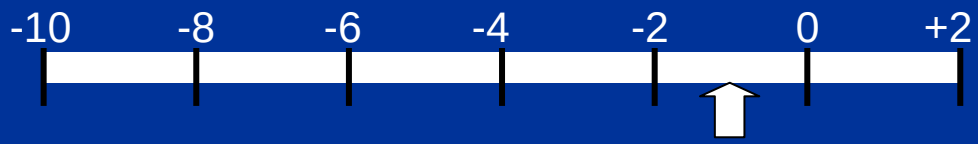
- Submit outline of briefing document to FDA
- Briefing document refinement continues
- Contact AC Executive Secretary regarding number of copies and timing of briefing document
- Presentation preparation and practice continues
- Back-up slides for Q&A continues



Countdown 1 month

Review Division

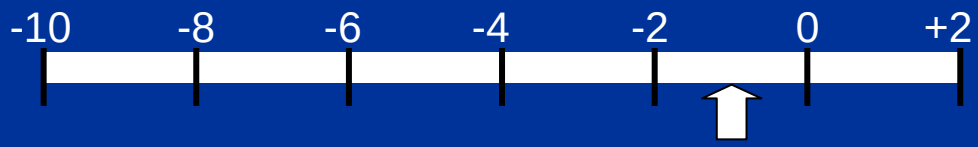
- Finalize reviews
- Write executive summaries
- Draft questions for AC
- Submit background package to ACS
- Complete and practice presentations



Countdown 1 month

ACS

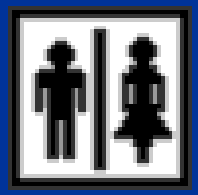
- FDA Backgrounders
- Sponsor Backgrounders
- Agenda

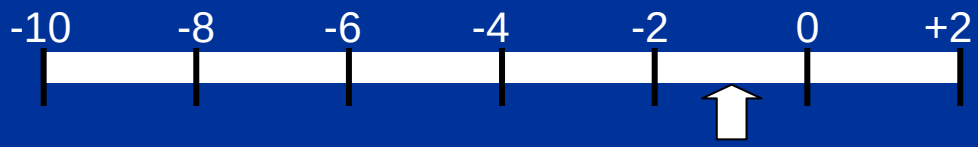


Agenda

Three important pieces to the Agenda

- **OPH (Open Public Hearing)**
- **Sponsor presentation**
- **FDA presentation**

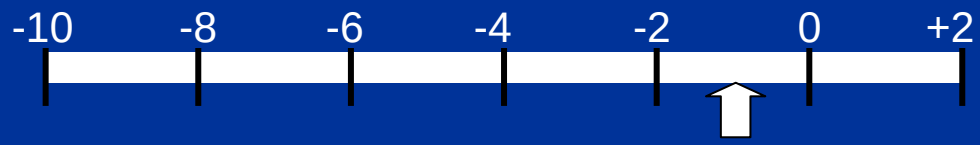




Agenda

Open Public Hearing

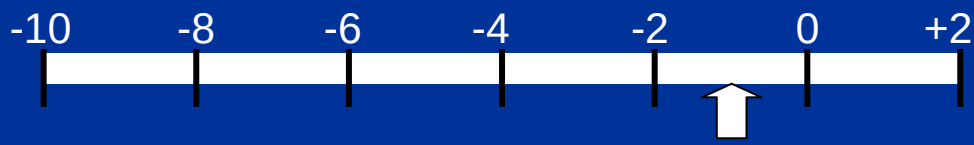
- At least one hour of time must be allocated to the open public hearing per meeting (One meeting = 1 FR notice). In all cases, the OPH must be completed before the committee votes.
- Time allocation is decided at the time of the writing of the FR notice.
- An announcement is placed in the FR notice of the deadline for requests to speak.



Agenda

Open Public Hearing

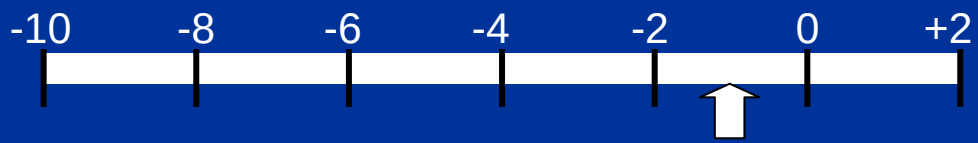
- Requests are submitted 10 days before the meeting with time and subject
- Each speaker is assigned the same time, unless there are group speakers, who may receive additional time
- Confidentiality maintained



Agenda

Open Public Hearing

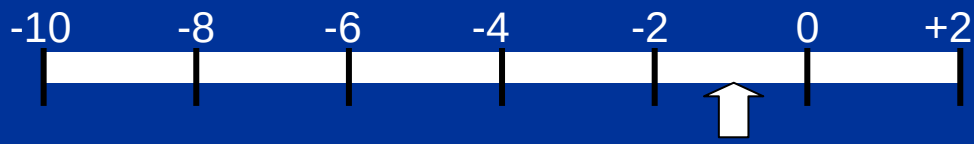
- Chair's discretion to grant additional time or to grant time to OPH speakers if they have not previously registered
- A timer is used to control time
- Special Accommodations (seating, video)



Agenda

Sponsor Presentation

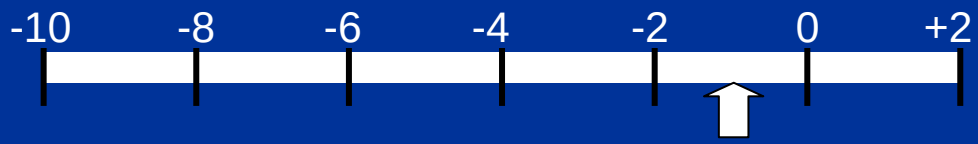
- Discussions occur between the Division and Sponsor
- The sponsor is typically provided 60-90 minutes for presentation
- Sponsor supplies own AV support
- Sponsor should communicate with ACS regarding logistics



Agenda

FDA Presentation

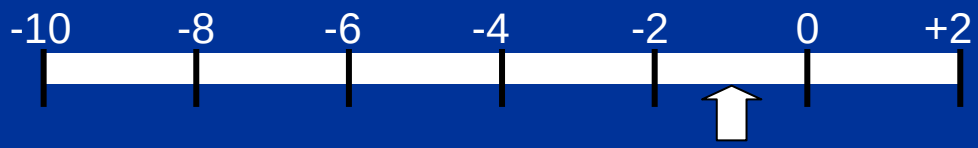
- **FDA may or may not make a presentation**
- **Typically, FDA will follow sponsor presentation**



Countdown 1 Month

Sponsor

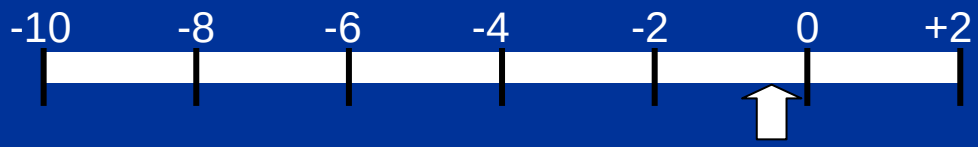
- **Briefing Document:**
  - **FDA comments incorporated**
  - **Document finalized and sent to FDA**
- **Meeting with FDA to discuss advisory committee meeting process**
- **Final Mock Advisory Committee Meeting**
- **Receive FDA Briefing Document**
  - **Review and incorporate any issues into presentation**



Countdown 2 Weeks

Review Division

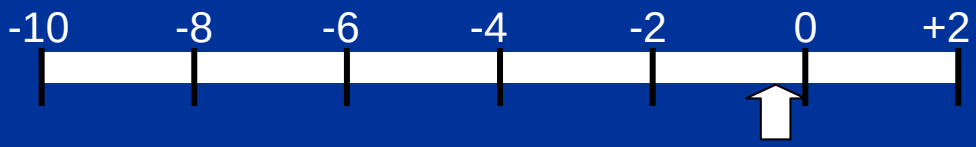
- Refine questions
- Speak with SGEs (guest speakers) about presentations
- Practice/coordinate presentations

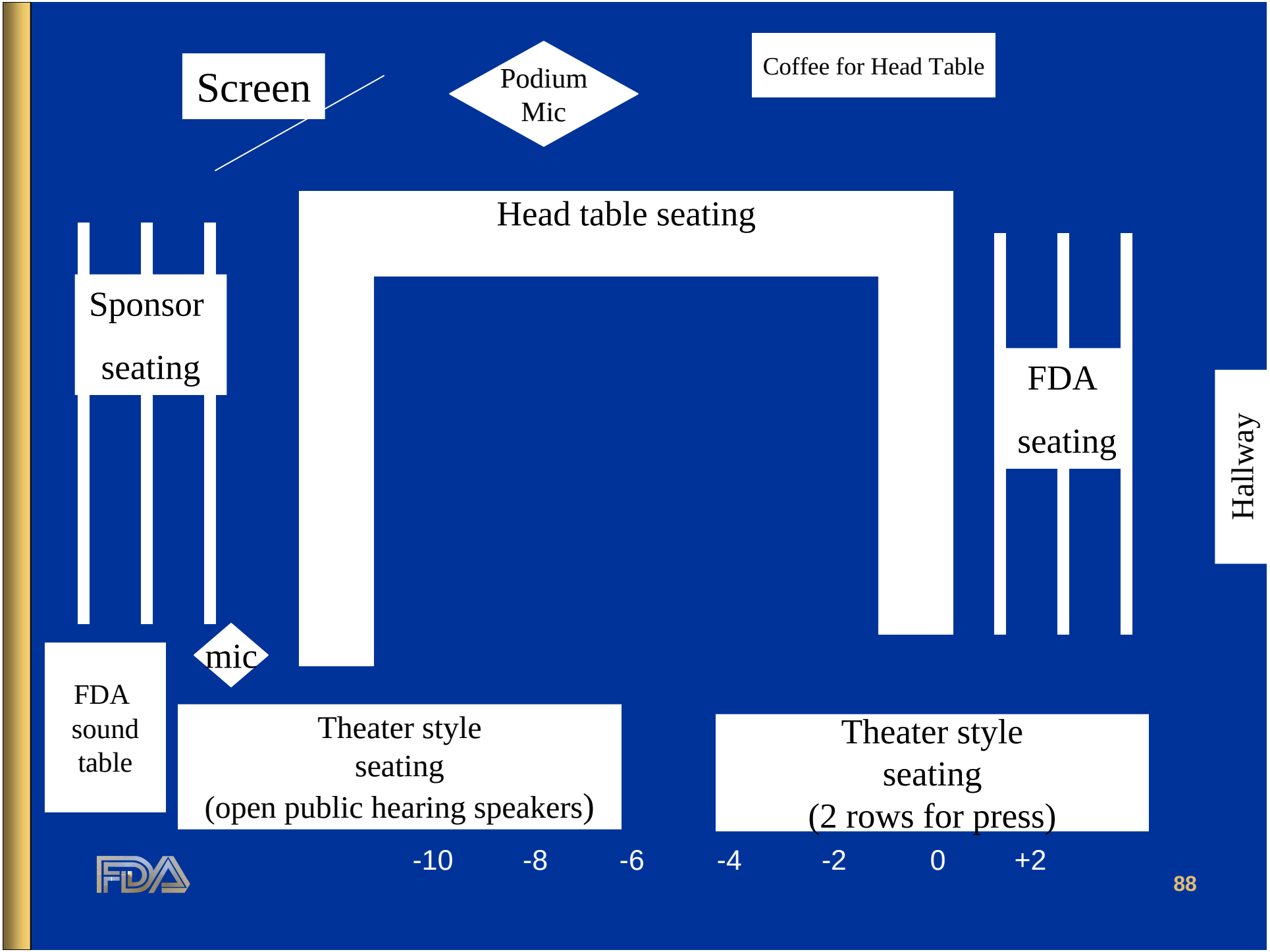


Countdown 2 Weeks

ACS

- Schedule teleconference with Chair and Division
- Review list of those who may be recused or have limited participation
- Prepare attendee list for handout
- Finalize list for Open Public Hearing
- Review logistics with sponsor and site

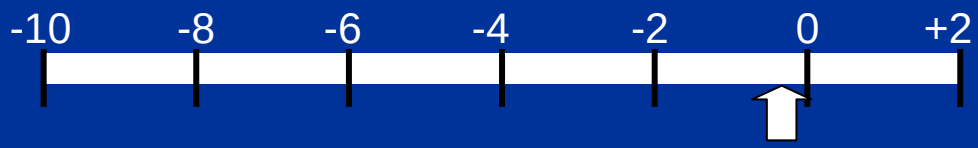



Screen
Podium
Mic
Coffee for Head Table
Head table seating
Sponsor
seating
FDA
seating
Hallway
mic
FDA
sound
table
Theater style
seating
(open public hearing speakers)
Theater style
seating
(2 rows for press)
-10
-8
-6
-4
-2
0
+2

Countdown 2 Weeks

Sponsor

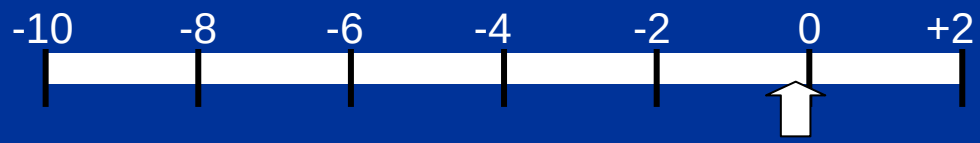
- Optional meeting with Industry Liaison Representative (ILR)
  - Review presentation and key messages
    - Identify key potential issues and Sponsor's position
- Practice Q & A
  - Review old and new issues
  - Identify who will handle what questions
- Practice presentation – senior management



Countdown 1 Week

Review Division

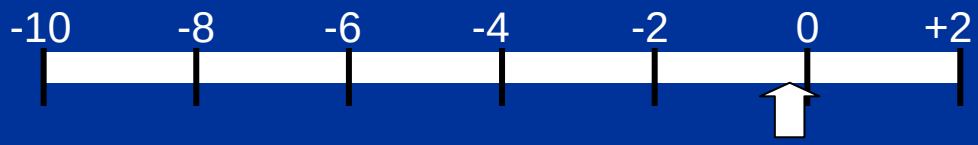
- Practice with other division
- Final revisions
  - Questions
  - Slides



Countdown 1 Week

ACS

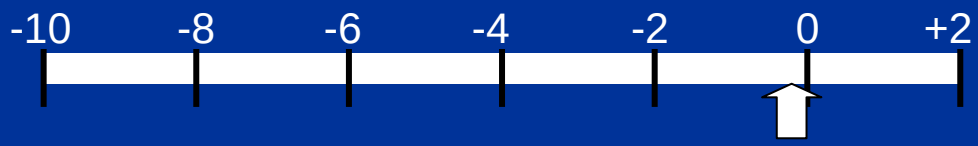
- Document preparation for web posting to dockets (posted the day before the meeting)
- Copying of handouts
- Finalizing meeting logistics and materials



Countdown 1 Week

Sponsor

- Move operations to hotel
  - Final rehearsals
  - Last minute slide changes
- IT makes certain process for communications back to company to address questions during AC meeting
- Discuss with FDA on public access to Sponsor's information in FDA's briefing document



For a September 27, 2006 meeting:

# Business Days prior to first day of AC meeting	Approximate Due Dates**	ACTIONS
-76	6/9/06	**Review Division:** * *notifies sponsor and ACS of need for AC meeting;* * *begins identifying and notifying current and prospective SGEs for the AC meeting;* * *identifies topic, space needed and begins preparing competing product list*
-71	6/16/06	**Review Division** submits to ACS: **names & contact info (form 2725) for individuals who need to be appointed as SGEs;* * *proposed FR including indication/topics for agenda section;* * *draft competing/affected products list;* * *meeting topics/issues for discussion.*
-61	6/30/06	**ACS** receives complete SGE appointment paperwork from prospective SGEs. If paperwork not received in ACS by this date, prospective SGE will not be able to attend meeting
-55	7/11/06	**Review Division/ACS** meet to discuss: **ACS's changes (if any) in the division's draft competing/affected products list;* * *draft agenda;* * *draft questions.* **if there's a need to open a docket*
-50	7/18/06	**Review Division/ACS:** * *finalize/sign-off on the FR Notice;* * *finalize competing/affected products;* * *finalize attendee list;* * *Review Division submits last of the names of current SGEs and guest speakers needed*

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Meeting Calendar Cont.

-46	7/24/06	**ACS** begins screening current SGEs and those just appointed as SGEs (can begin screening only after appointed as SGEs)
-36	8/7/06	**ACS** receives complete answers to COI questions from SGEs & begins to finalize waivers
-26	8/21/06	**ACS** completes waivers and forwards to Ethics/OC/Dockets and concurrently to DIDP
-22	8/25/06	**Sponsor submits backgrounder to ACS** (*disclosability guidance*)
-19	8/30/06	**Review Division** submits Background Package to ACS
-18	8/31/06	*Backgrounders are sent to committee members
-14	9/7/06	**ACS overnights redacted backgrounder to Sponsor**
-11	9/12/06	**FDA Dockets** posts waivers onto the web.
-1	9/26/06	**24 hours prior to the meeting, FDA posts on backgrounders on the website**
0	9/27/06	AC Meeting takes place.

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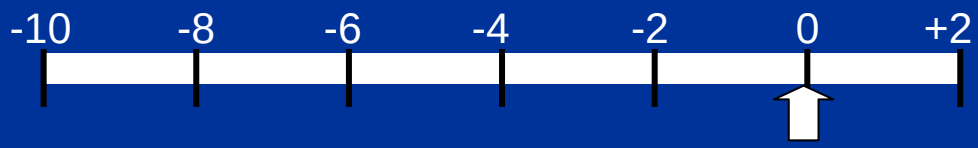
Countdown 24-48 Hours

Sponsor

- Receive FDA questions for Advisory Committee
  - Major presentation changes are virtually impossible at this time
- Copies of presentation slides provided to Advisory Committee Executive Secretary for making copes for Advisory Committee members



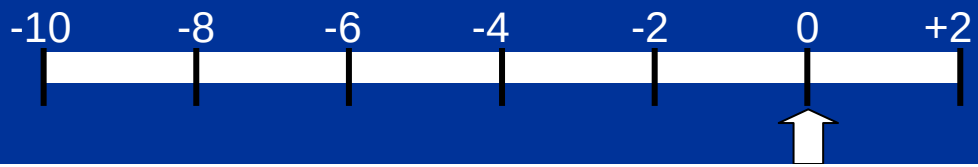
The Meeting Day

ACS

- Arrive at hotel 6:30 a.m.
- Survey Meeting room for changes
- Review meeting Agenda with Transcriber
- Distribute Meeting Materials
- Meet with Hotel staff, Industry, Audiovisual company and Press

Division

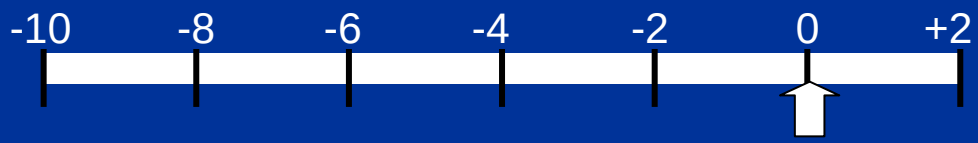
- Arrives at hotel 30 minutes before the meeting
- Reviews slides



The Meeting Day

Sponsor

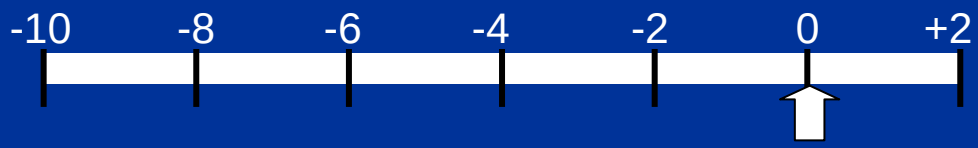
- Presentation Team Leader
  - Introduces him/herself to AC chair
  - Discusses format of Sponsor's presentation
- Ensure presentation and back-up slides are operational
  - At least one back up computer present.
- Identify note takers and back-up slide counters
  - Ensure technical experts (Biostat, Tox, Medical) are in place to address questions, if needed
- Have external relations person identified who can address questions from press/media



The Meeting Day

Sponsor

- Presentation Team Leader will answer questions or direct question to designated individual
  - Listen
  - Think
  - Speak - direct response to question
- Lunch Hour
  - Important to have the ability to retrieve data and create new slides in response to specific questions

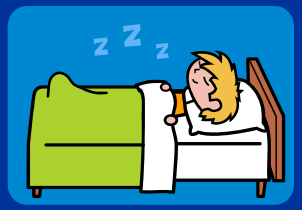


Immediately After AC

Sponsor

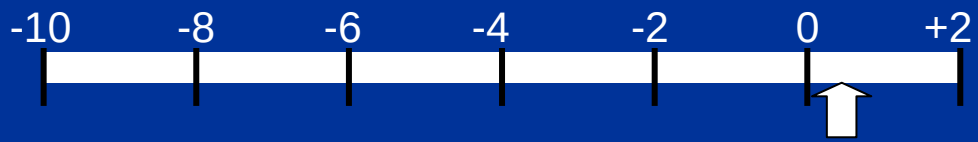
- **Audio/Visual controller identifies what slides used as back-up and makes a CD for FDA**
- **External relations responds to media on outcome of meeting**

Post AC



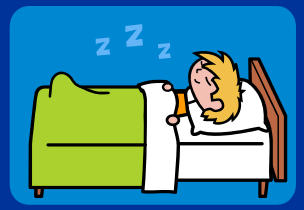
Review Division(s)

- Meeting debrief
- Evaluation of committee answers to questions
- NDA: complete review
- Monograph: prepare proposed/final rule

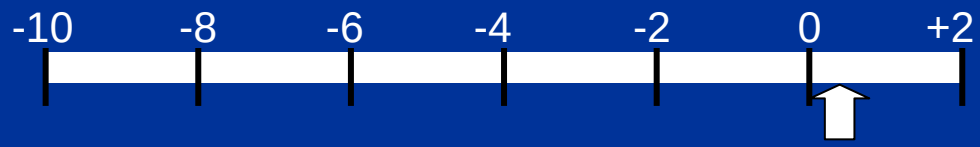


Post AC

ACS



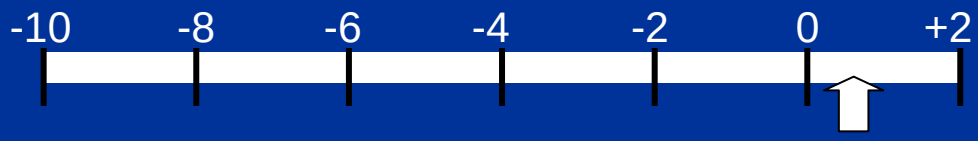
- Slides presented at the meeting are posted 2-5 days after the meeting
- Meeting minutes (quick minutes) are drafted and finalized by the chair
- Transcripts are posted 7-10 days after the meeting
- Final minutes are posted on the web 10-20 days after the meeting



Post AC

Sponsor

- Meeting debrief
- Evaluate need for additional media response
- Key Opinion Leader debrief on AC issues/discussion
- Review transcript
- Evaluate need for additional data to address AC issues
- Continued dialogue with FDA regarding AC outcome
- Best Practice Evaluation – share what worked well and what could be improved at next meeting



On to the next meeting

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Agenda

- Introduction
- Background on FDA Advisory Committees
- Non NDA Specific NDAC Meetings
- FDA/Industry Timelines to NDAC Meetings
- FDA Questions for the NDAC
- Panel Discussion

FDA Questions for the NDAC

Charles J. Ganley, M.D.
Office of Nonprescription Products

Agenda

- General Concepts
- Deciding what goes to an NDAC
- Considerations in Question Development
- Process

General Concepts

- The purpose of the AC meeting is to provide advice to FDA
- Time is limited so questions should help focus the discussion on important issues.
- The wording of the FDA questions may not be to the liking of all committee members
  - Discourage committee members from rewriting the questions during the meeting
    - Committee members are free to ask questions of the company or FDA

General Concepts (2)

- The questions from FDA are not the only important questions
  - The FDA or sponsor's responses to questions from committee members are going to influence how the committee responds to FDA questions
- The background information should provide sufficient information to allow a member to answer a question…..unless there is a need to emphasize that there is insufficient data for a specific issue
- We do not try to be unfair
- The discussion or justification of a response to a voting question is as important as the vote

What will go to an advisory committee?

- NDA
  - Decided early in the review cycle
    - Have to have some sense of the issues in the application and what generic questions may be asked
    - FDA disagreement with the interpretation data by the sponsor is not a prerequisite
  - First in class, new category of ingredient, new indication
  - Safety issues
  - Efficacy
  - Behavior in the OTC setting

What will go to an advisory committee? (2)

- Monograph
  - Safety or efficacy
  - Testing procedures
  - Category with important health or policy implication
  - FDA position differs from comment(s)

Considerations in Question Development

- The question should try to mean the same thing to many people.
  - Rewriting questions during the meeting will lead to confusion….will not get the discussion we are looking for
- Logical progression
  - Group like topics (safety, efficacy, consumer behavior)
  - Understanding the relationship between questions
- Question at the beginning should not be such that a negative answer would preclude consideration for OTC marketing
  - Example: Are there significant safety concerns ***that would preclude the marketing*** of Drug X for OTC marketing?

Considerations in Question Development (2)

- Complex versus simple question
  - Does the question need a preamble to help explain what it is we are after
- General verses Focused question
  - Are there any significant safety concerns with the use of drug X? (General)
  - Does the data suggest that Drug X causes significant liver toxicity? (Focused)

Considerations in Question Development (3)

- Questions should not result in advice that is not helpful
  - Consider possible answers
    - This exercise helps to fine tune the questions
    - Helps avoid questions where the answers lead down a blind alley (path of discussion that is not helpful to the decision process)
- Approvability Question
  - This is a separate question!!!
    - Ask it after all data related safety and efficacy questions have been asked
    - Avoid: Does the data suggest that Drug X causes significant liver toxicity that would preclude the marketing of the drug?

Process Questions

- How are the issues identified?
- Who writes the initial draft questions?
- How are the questions vetted?
- When two divisions/offices are involved, who has final signoff of the questions?
- What is the involvement of the NDAC chair?

Process Answers

- Questions will address issues that are raised by the scientific reviews
  - These are limited to the important issues because of time constraints
- There are no set procedures for writing questions
- The writing of initial draft questions can be assigned to anyone.
- Questions are generally vetted through the disciplines that have applicable issues for consideration.
- Multiple rewrites.

Process Answers (2)

- NDAC chair provides input after there is a version that we think is close to what we want…….provides input and leads to final version.
- Ultimately, a division or office director determine the final version.

Agenda

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- Background on FDA Advisory Committees
- Non NDA Specific NDAC Meetings
- FDA/Industry Timelines to NDAC Meetings
- FDA Questions for the NDAC
- Panel Discussion

Panel Members

- Louis R. Cantilena, MD, PhD, Former Chair, NDAC
- Igor Cerny, PharmD., Director, CDER ACS
- Edwin Hemwall, PhD, Vice President of Global Scientific and Regulatory Affairs, J&J-Merck Consumer Pharmaceuticals
- Andrea Leonard-Segal, MD, Director, Division of Nonprescription Clinical Evaluation

CLOSING REMARKS

W. Greg Collier, PhD
Procter & Gamble Oral Care

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THANK YOU!

- **SPEAKERS:**
  - Mike Koenig
  - Dave Schifkovitz
  - Igor Cerny
  - Doug Bierer
  - Dornette Spell-Lesane
  - Charles Ganley
- **PANEL:**
  - Igor Cerny
  - Andrea Leonard-Segal
  - Lou Cantilena
  - Ed Hemwall
- **LOGISTICS:**
  - Amy Mason
  - Lorna Totman

NEXT SEMINAR

- Early Spring 2007
- White Oak Campus
- Seminar Topic Ideas Welcome!