

OARSI FDA INITIATIVE: PUBLIC MEETING

December 15, 2009

Washington, DC



OARSI FDA Initiative

- Federal register notice posted 14 August 2007 seeking proposals to lead a centralized effort of conducting & managing the coordination of a critical appraisal related to the design of clinical development programs for drugs, biological products & medical devices for the treatment/prevention of OA
- OARSI submitted a proposal in response to the FDA notice 11 October 2007
- February 2008: OARSI proposal approved by FDA Commissioner's office

**FEDERAL REGISTER NOTICE
14 AUGUST 2007**

- FDA seeks additional information on issues related to clinical development programs for human drugs, biological products, and medical devices for the treatment and prevention of osteoarthritis
- Information will be taken into account as the FDA works to finalize the draft OA guidance issued in July 1999. The finalized guidance will aid sponsors and other interested parties in developing new products to treat OA

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- Specifically, the agency is inviting any interested group ... to conduct and manage the coordination of a critical appraisal of certain fundamentals of the science related to OA.
- To provide a starting point for discussion, FDA has developed a list of some key concepts that the interested parties may want to consider for discussion at the meeting.

KEY CONCEPTS 1

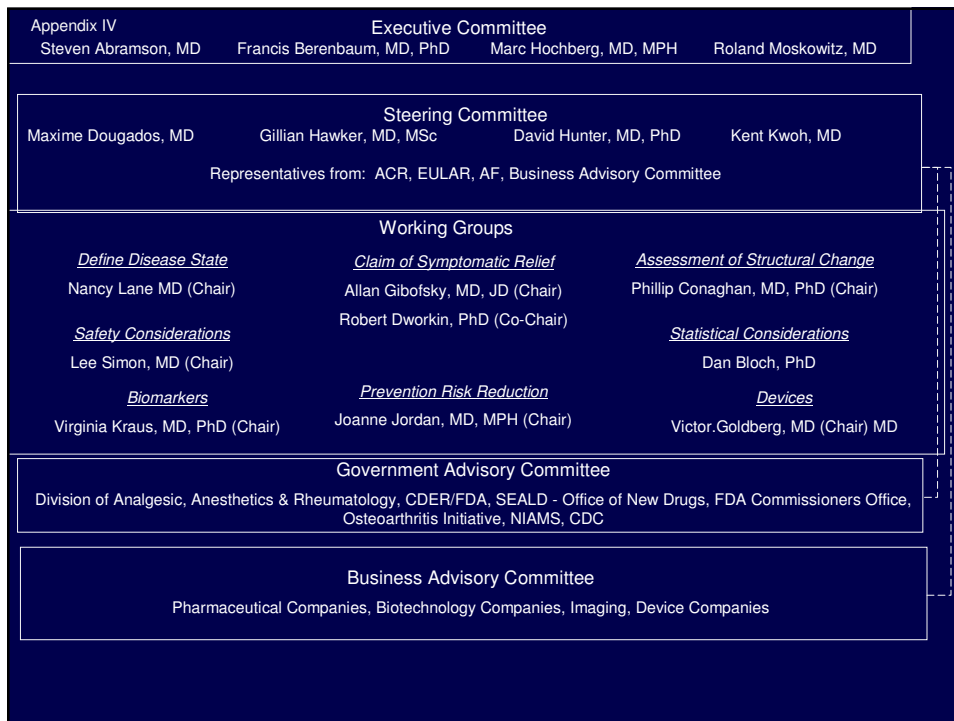
- Should the scope of the guidance apply to OA alone? Are there particular clinical subgroups of OA that need to be explicitly considered and addressed?
- For a *claim of symptomatic relief* in OA, what are the optimal outcomes measures and trial designs?
 - If withdrawal and flare designs are not optimal, what alternative designs could be used?
 - What should the size & duration of exposure of the safety database be for symptomatic relief?
- Is a *claim of decreased rate of progression* useful and, if so, what would be the appropriate outcome measures to establish the claim?

KEY CONCEPTS 2

- For a *claim of prevention or risk reduction* for the development of OA, what are potential outcome measures? If biomarkers are used, what is their state of qualification?
- Are there *additional claims* that should be considered? What outcome measures and trial designs should be used?
- In any *long term studies*, what are the best statistical comparisons for inference testing? Since longer trials have substantial dropouts, what imputation methods for dropouts are most appropriate or should trial results be based on a survival analysis or a time to event analysis?

OARSI FDA OA Initiative: Meetings/Timeline

- June 2008: Executive/Steering Committee Meeting



OARSI FDA OA Initiative: Meetings/Timeline

- June 2008: Executive/Steering Committee
- September 2008: Executive/Steering Committee
- November 2008: Executive/Steering/Working Groups
- December 2008: Executive/Steering Committee
- December 2008: Public Meeting; Attended by governmental agencies and pharmaceutical & device companies
- April 2009: Executive/Steering Committee
- September 2009: Executive/Steering Committee
- October 2009: Executive/Steering Committee/Working Groups
- December 2009: Executive/Steering Committee
- December 2009: Second public meeting
- First quarter 2010: Submission of Initiative report to OARSI BOD; submission of recommendations to FDA
- Second quarter 2010: Submission of manuscripts to O&C

Supporters: FDA OA Initiative

- American College of Rheumatology
- Amgen
- ArthroVision
- Astra Zeneca
- Bayer HealthCare
- Chondrometrics
- CombinatoRx
- Cypress BioScience
- DePuy Mitek
- Expanscience
- Genzyme
- 4QImaging
- IBSA-Genévrier
- King (Alpharma)
- Merck
- Merck Serono
- NicOx
- Novartis
- Pfizer
- Rottapharm
- Smith & Nephew
- Wyeth

Agenda

7:30 AM – 7:45 AM	Welcome	Marc Hochberg, MD, MPH
7:45 AM – 8:05 AM 8:05 AM – 8:30 AM	Definition of Disease State Discussion	Marc Hochberg, MD, MPH
8:30 AM - 8:50 AM 8:50 AM – 9:15 AM	Claim of Symptomatic Relief Discussion	Robert Dworkin, PhD
9:15 AM – 9:35 AM 9:35 AM – 10:00 AM	Safety Considerations Discussion	Lee Simon, MD
10:00 AM – 10:15 AM	BREAK	
10:15 AM – 10:35 AM 10:35 AM – 11:00 AM	Assessment of Structural Change Discussion	Philip Conaghan, MBBS, PhD
11:00 AM – 11:20 AM 11:20 AM – 11:45 AM	Prevention/Risk Reduction Discussion	Joanne Jordan, MD, MPH
11:45 AM – 12:30 PM	LUNCH	
12:30 PM – 12:50 PM 12:50 PM – 1:15 PM	Biomarkers Discussion	Virginia Kraus, MD, PhD
1:15 PM – 1:35 PM 1:35 PM – 2:00 PM	Devices Discussion	Victor Goldberg, MD
2:00 PM	Closing Comments	

THANK YOU FOR ATTENDING!

