

Food and Drug Administration  
Center for Drug Evaluation and Research

8772 '99 AUG 30 P3:12  
**SUMMARY MINUTES**

**ARTHRITIS ADVISORY COMMITTEE**

**March 25, 1998**

Gaithersburg Hilton  
620 Perry Parkway, Gaithersburg, MD

**Members Present**

Michelle Petri M.D., M.P.H., Chair  
Steven B. Abramson, M.D.  
David Yocum, M.D.  
Leona Malone, MSW  
Frank Pucino, Jr., Pharm.D.  
E. Nigel Harris, M.D.  
Matthew Liang, M.D., M.P.H.  
Lee Simon, M.D.  
Barbara Tilley, Ph.D.  
Patricia McGrath, Ph.C.  
Lynn McKinley-Grant, M.D.  
Mary Ann Koda-Kimble, Pharm.D.  
Theodore Tong, Pharm.D.  
George A. Blewitt, M.D.

**FDA Participants**

Michael Weintraub, M.D.  
John Hyde, M.D., Ph.D.  
Linda Katz, M.D., M.P.H.

**Guest Experts**

Eugene Laska, Ph.D.

**Consultants**

Felix Fernandez-Madrid, M.D., Ph.D.  
Larry Moreland, M.D.  
Leigh Callahan, Ph.D.  
Kenneth Brandt, M.D.  
Mitchell B. Max, M.D.

**Members Absent**

Daniel Lovell, M.D., M.P.H.  
Harvinder Luthra, M.D.

**Executive Secretary**

Kathleen R. Reedy

These summary minutes for the March 25, 1998 meeting of the Arthritis Advisory Committee were approved on 8/26/99.

I certify that I attended the March 25, 1998 meeting of the Arthritis Advisory Committee and that these minutes accurately reflect what transpired.

  
Kathleen R. Reedy,  
Executive Secretary

  
Michelle A. Petri, M.D., M.P.H.  
Chairperson

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The Arthritis Advisory Committee with representation from the Nonprescription Drugs Advisory Committee met on March 25, 1998 at the Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD to discuss the fast onset of pain relief for prescription and nonprescription oral analgesics in the morning session and a pain claim structure for chronic and acute pain in the afternoon session. The committee had been provided a briefing document from the agency as background for the discussion of issues approximately 15 days before the meeting. There were approximately 200 people in attendance.

The meeting was called to order at 8:00 by Michelle Petri, M.D., Chair of the Arthritis Advisory Committee. The Meeting Statement was read by Kathleen Reedy, Executive Secretary of the Arthritis Advisory Committee. The members of both Committees, the consultants and guest expert introduced themselves. A welcome and introduction to the topic by Michael Weintraub, M.D., Acting Director, Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products began the discussion.

There were two speakers at the Open Public Hearing. George Ehrlich, M. D., U of Pennsylvania and William Soller, Ph.D. of the NonPrescription Drugs Manufacturing Association:

The fast onset of pain relief for prescription and nonprescription oral analgesics was the topic for the morning session. Eugene Laska, Ph.D. presented "A method of measuring fast", followed by discussion and questions. The committee's general discussion was conducted around Measurement, Study Design and Definitions.

These questions were addressed with discussion by the committee.

1. How should fast analgesic claims be labeled?
  - time in minutes or a set period of time
  - clinical improvement, pain relief defined as no more pain or an improvement in pain?
2. Should fast be measured clinically in terms of:
  - onset of any effect (perceptible pain relief)
  - meaningful or substantial relief
  - pain half gone
  - pain completely gone
3. What are some recommended study designs to establish fast analgesic claims?
4. What types of comparative product claims could be allowed?
5. What do the terms fast and relief mean to the consumer?

The issue for discussion in the afternoon was a pain claim structure for chronic and acute pain. John Hyde, M.D., Ph.D., Medical Officer and Acting Deputy Director of the Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products gave an Introduction and Overview. The committee's general discussion was conducted around Categories, Subcategories and Study Design.

These questions were addressed with discussion by the committee.

1. How should pain claims be categorized?
  - e.g., unrestricted general pain
  - acute pain
  - chronic pain
  - pain associated with specific categories (e.g. neuropathic pain)
  - Pain associated with subcategories (e.g. pain due to diabetic neuropathy, a subcategory of neuropathic pain)
2. What study designs and study details should be required in terms of number of studies, pain models, duration of study, etc., to support efficacy and safety claims for the pain indications as listed under question #1?
3. For a pain category which has subcategories, how should the subcategories be studied and replicated to support efficacy claims for the pain category? (E.g. major subcategories, a mixture of subcategories, etc.)?
4. What study designs should be required to establish the duration or pattern for short term use (acute pain), long term analgesics?

A verbatim transcript of the meeting is available for more detailed examination of the discussion issues.

The meeting was adjourned at approximately 4:00 pm.