

**Summary Minutes of the
Anti-Infective Drugs Advisory Committee
June 2, 2009**

Location: Hilton DC Ballroom, 8727 Colesville Road, Silver Spring, MD

All external requests for the meeting transcripts should be submitted to the CDER, Freedom of Information office.

These summary minutes for the June 2, 2009, Meeting of the Anti-Infective Drugs Advisory Committee of the Food and Drug Administration were approved on July 8, 2009.

I certify that I attended the June 2, 2009, meeting of the Anti-Infective Drugs Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

_____/s/_____
Janie Kim, Pharm.D.
Designated Federal Official, AIDAC

_____/s/_____
Thomas A. Moore, M.D.
Committee Chair

Minutes of the Anti-Infective Drugs Advisory Committee June 2, 2009

The Anti-Infective Drugs Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research met on June 2, 2009, at the Hilton/Washington DC Ballroom, 8727 Colesville Road, Silver Spring, Maryland. Prior to the meeting, members and invited consultants were provided copies of the background material from the FDA and the sponsor. The meeting was called to order by Thomas A. Moore, M.D. (Committee Chair); the conflict of interest statement was read into the record by Janie Kim, Pharm.D. (Designated Federal Official). There were approximately 100 persons in attendance. There was one (1) speaker for the Open Public Hearing session.

Issue: The committees discussed new drug application (NDA) 22-398, cethromycin oral tablets, sponsored by Advanced Life Sciences, for the proposed indication of outpatient treatment of adults with mild to moderate community-acquired pneumonia.

Attendance:

Anti-Infective Drug Advisory Committee Members Present (Voting):

W. Kemper Alston, M.D., Dean Follmann, Ph.D., Matthew Goetz, M.D., Sheldon Kaplan, M.D., Peter Katona, M.D., Carol Kauffman, M.D., Thomas A. Moore, M.D., Kent Sepkowitz, M.D., Margo Smith, M.D., Melvin Weinstein, M.D., Annie Wong-Beringer, Pharm.D. (Consumer Representative)

Anti-Infective Drug Advisory Committee Member Present (Non-Voting):

John Rex, M.D. (Industry Representative)

Special Government Employee Consultants Present (Voting):

William Calhoun, M.D., Thomas Fleming, Ph.D., Gregory Townsend, M.D.

Guest Speaker Present (Non-Voting): None.

Anti-Infective Drugs Advisory Committee Members Not Present:

Archana Chatterjee, M.D., Susan Rehm, M.D.

FDA Participants (Non-Voting): Edward Cox, M.D., M.P.H., Kathleen Laessig, M.D., Nasim Moledina, M.D., John Alexander, M.D., M.P.H., Christopher Kadoorie, Ph.D., Thamban Valappil, Ph.D.

Designated Federal Official:

Janie Kim, Pharm.D.

Open Public Hearing Speaker: James Floyd, M.D., Public Citizen

The agenda was as follows:

Call to Order and Introductions	Thomas A. Moore, M.D. (Committee Chair)
Conflict of Interest Statement	Janie Kim, Pharm.D. Designated Federal Official

Introduction/Background

Kathleen Laessig, M.D.
Deputy Director, Division of Anti-infective and Ophthalmology Products
Office of Antimicrobial Products (OAP)

Sponsor Presentation

Advanced Life Sciences

Questions to the Presenters

FDA Presentations

Discussion of Efficacy

Christopher Kadoorie, Ph.D.
Biometrics Reviewer

Discussion of Safety

Nasim Moledina, MD
Medical Officer, DAIOP, OAP

Questions to the Presenters

Open Public Hearing

Charge and Questions
to the Committee

Edward Cox, M.D.
Director, Office of Antimicrobial Products

Adjourn

Questions to the committee:

1. Do the data presented demonstrate the safety of cethromycin for the treatment of community-acquired pneumonia?

(vote yes or no)

Vote : Yes= 11 No = 3 Abstain = 1

If your answer is yes, are there any particular issues that warrant specific mention in product labeling?

The committee discussed mentioning the following in the product label

- Possible renal and hepatic toxicities
- Possible exacerbations of myasthenia gravis
- Possible drug-drug and food-drug interactions due to cethromycin's metabolism through the cytochrome P450 3A4 dependent pathway.

If your answer is no, what additional data/studies are needed?

The committee discussed additional studies in

- geriatric patients
- patients with renal impairments
- patients with co-morbid conditions (e.g., hepatitis, HIV co-infections)
- drug interaction studies with antiretroviral drugs (e.g., protease inhibitors), certain antihistamines, HMG Co-A reductase inhibitors, also known as ("statins"),
- patients with Pneumonia Outcome Research Team (PORT) Scores of III-IV.

2. Do the data presented demonstrate the efficacy of cethromycin for the treatment of community-acquired pneumonia?

Vote : Yes= 3 No = 11 Abstain = 1

- If your answer is no, what additional data/studies are needed?

The committee discussed additional studies using a superiority trial design, mortality and symptom based measures of efficacy, and a macrolide-resistant patient population. They also discussed the relative merits of using non-inferiority trial design for outpatient treatment of mild to moderate respiratory diseases.

Please see the transcript for detailed discussion.

The session adjourned @ approximately 2 p.m.