Food and Drug Administration
Center for Drug Evaluation and Research

Summary Minutes of the Dermatologic and Ophthalmic Drugs Advisory Committee Meeting
May 29, 2008

Topic: The committee discussed new drug application (NDA) 22-212, difluprednate ophthalmic emulsion, Sirion Therapeutics, Inc., proposed for the treatment of inflammation and pain following ocular surgery.

These summary minutes for the May 29, 2008 Dermatologic and Ophthalmic Drugs Advisory Committee meeting were approved on June 2 , 2008.

I certify that I attended the May 29, 2008 Dermatologic and Ophthalmic Drugs Advisory Committee meeting and that these minutes accurately reflect what transpired.

_____-s-_____
Yvette Waples, Pharm.D.
(Designated Federal Official)

_____-s-_____
Marijean M. Miller, M.D.
(Acting Chair)

Summary Minutes of the Dermatologic and Ophthalmic Drugs Advisory Committee Meeting
May 29, 2008

The following is the final report of the Dermatologic and Ophthalmic Drugs Advisory Committee meeting held on May 29, 2008. A verbatim transcript will be available in approximately two weeks, sent to the Division and posted on the FDA website at http://www.fda.gov/ohrms/dockets/ac/cder08.html#DermatologicOphthalmicDrugs

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

The Dermatologic and Ophthalmic Drugs Advisory Committee of the Food and Drug Administration met on May 29, 2008 at the Food and Drug Administration, Center for Drug Evaluation and Research, Advisory Committee Conference Room, 5630 Fishers Lane, Rockville, Maryland. Marijean M. Miller, M.D., chaired the meeting. There were approximately 65 in attendance.

Attendance:

Dermatologic and Ophthalmic Drugs Advisory Committee Members present (voting):
Marijean M. Miller, M.D.;

Dermatologic and Ophthalmic Drugs Advisory Committee Members absent:
Michael E. Bigby, M.D. (Chair); Mary A. Majumder, Ph.D.; Bruce H. Thiers, M.D.; Robert Skinner, M.D.

Temporary Voting Members:
Joel Mindel, M.D., PhD.; Scott M. Steidl, M.D.; Paula Cofer (Patient Representative)

Industry Representative (non-voting):
Ellen Strahlman, M.D., M.H.Sc

FDA Participants (non-voting):
Edward M. Cox, M.D., MPH; Wiley Chambers, M.D.; Sonal Wadhwa, M.D.

Open Public Hearing Speaker:
None

On May 29, 2008, the committee met to discuss new drug application (NDA) 22-212, difluprednate ophthalmic emulsion, Sirion Therapeutics, Inc., proposed for the treatment of inflammation and pain following ocular surgery.

Marijean M. Miller, M.D., (Acting Chair) called the meeting to order at 8:00 a.m. The Committee members and the FDA participants introduced themselves. The conflict of interest statement was read into the record by Yvette Waples, Pharm.D., Designated Federal Official (DFO). The agenda for the meeting was as follows:

8:00 a.m.	Call to Order and Opening Remarks	**Marijean Miller, M.D.** Acting Chair, Dermatologic and Ophthalmic Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	**Yvette Waples, Pharm.D.** Designated Federal Official
8:10 a.m.	FDA Introductory Remarks	**Wiley Chambers, M.D.** Acting Director, Division of Anti-Infective and Ophthalmic Products, CDER, FDA
INDUSTRY PRESENTATION		
8:15 a.m.	Difluprednate: Efficacy and Safety Review	**Roger Vogel, M.D.** Senior Vice President and Chief Medical Officer, Sirion Therapeutics
8:50 a.m.	Questions/Clarifications	
9: 20 a.m.	**BREAK**	
FDA PRESENTATION		
9: 35 a.m.	Division of Anti-Infective and Ophthalmology Products Advisory Committee Meeting for NDA 22-212 Difluprednate	**Sonal Wadhwa, M.D.** Clinical Reviewer, Division of Anti-Infective and Ophthalmic Products, CDER, FDA
10: 00 a.m.	Questions/Clarifications	
10: 15 a.m.	**BREAK**	
10: 30 a.m.	**OPEN PUBLIC HEARING**	
10: 35 a.m.	Panel Discussion/Questions	
11:30 a.m.	**ADJOURNMENT**	

Questions to the Committee:

1. Do you think difluprednate ophthalmic emulsion should be approved for the treatment of ocular inflammation and pain following cataract surgery?

   Committee Discussion:
   (See Transcript for Complete Discussion)

   Yes: 3 No: 0 Abstain: 1

2. If no, what additional studies should be performed (Discuss and Comment)?

   Committee Discussion:
   No discussion or comments

3. If yes, any additional Phase 4 studies should be performed?

   Committee Discussion:
   The committee did not discuss the question at length but made the following recommendations for Phase 4 studies:

   - *intra-ocular pressure (IOP) screening in post-operative cataract surgery patients*
   - *subgroup studies of rate of response in steroid responders*
   - *pediatric studies*

   (See Transcript for Complete Discussion)

4. Do you have any suggestions concerning the labeling of the product?

   Committee Discussion:
   The committee agreed that efficacy was demonstrated by data presented for both twice-a-day (BID) and four times-a-day (QID) dosing for treatment of pain and inflammation. The committee recommended the labeling include the following: inclusion criteria from the Sirion Therapeutics studies, and language for use in patients with a family history of steroid response.

   (See Transcript for Complete Discussion)

The meeting was adjourned at approximately 11: 30 a.m. on May 29, 2008.