

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

*Dermatologic and Ophthalmic Drugs Advisory Committee Meeting*

FOOD AND DRUG ADMINISTRATION, CENTER FOR DRUG EVALUATION AND RESEARCH  
ADVISORY COMMITTEE CONFERENCE ROOM

MAY 29, 2008

**AGENDA**

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

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| 8:00 a.m.                    | Call to Order and Opening Remarks  | <b>Marijean Miller, M.D.</b><br>Acting Chair,<br>Dermatologic and Ophthalmic Drugs Advisory Committee            |
|                              | Introduction of Committee  |  |
|                              | Conflict of Interest Statement   | <b>Yvette Waples, Pharm.D.</b><br>Designated Federal Official  |
| 8:15 a.m.                    | FDA Introductory Remarks   | <b>Wiley Chambers, M.D.</b><br>Acting Director, Division of Anti-Infective and<br>Ophthalmic Products, CDER, FDA |
| <b>INDUSTRY PRESENTATION</b> |  |  |
| 8:20 a.m.                    | Difluprednate: Efficacy and Safety Review  | <b>Roger Vogel, M.D.</b><br>Senior Vice President and<br>Chief Medical Officer, Sirion Therapeutics              |
| 9: 05 a.m.                   | Questions/Clarifications   |  |
| 9: 20 a.m.                   | <b>BREAK</b>   |  |
| <b>FDA PRESENTATION</b>      |  |  |
| 9: 35 a.m.                   | Division of Anti-Infective and<br>Ophthalmology Products Advisory<br>Committee Meeting for<br>NDA 21-212 Difluprednate | <b>Sonal Wadhwa, M.D.</b><br>Clinical Reviewer, Division of Anti-Infective and<br>Ophthalmic Products, CDER, FDA |
| 10: 20 a.m.                  | Questions/Clarifications   |  |
| 10: 35 a.m.                  | <b>BREAK</b>   |  |
| 11: 00 a.m.                  | <b>OPEN PUBLIC HEARING</b>   |  |
| 12: 00 a.m.                  | Panel Discussion/Questions   |  |
| 1:00 p.m.                    | <b>ADJOURNMENT</b>   |  |