

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 | 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 |
| 8:15 a.m. | FDA Introductory Remarks | Wiley Chambers, M.D.
Acting Director, Division of Anti-Infective and
Ophthalmic Products, CDER, FDA |
| INDUSTRY PRESENTATION | | |
| 8:20 a.m. | Difluprednate: Efficacy and Safety Review | Roger Vogel, M.D.
Senior Vice President and
Chief Medical Officer, Sirion Therapeutics |
| 9: 05 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 21-212 Difluprednate | Sonal Wadhwa, M.D.
Clinical Reviewer, Division of Anti-Infective and
Ophthalmic Products, CDER, FDA |
| 10: 20 a.m. | Questions/Clarifications | |
| 10: 35 a.m. | BREAK | |
| 11: 00 a.m. | OPEN PUBLIC HEARING | |
| 12: 00 a.m. | Panel Discussion/Questions | |
| 1:00 p.m. | ADJOURNMENT | |