

CENTER FOR DRUG EVALUATION AND RESEARCH

**ADVISORY COMMITTEE: Dermatologic and Ophthalmic Drugs Advisory
Committee**

DATE OF MEETING: 07/14-15/97

AGENDA

Food and Drug Administration
Center for Drug Evaluation and Research
DERMATOLOGIC AND OPHTHALMIC DRUGS
ADVISORY COMMITTEE MEETING # 46
July 14 & 15, 1997
Holiday Inn, Bethesda, MD

AGENDA
July 14

BLA 96-1408, Regranex®
for treatment of chronic diabetic ulcers

8:30 - 9:10 Call to Order: Welcome and Information
Joseph McGuire, Jr., M.D., Chairman

Conflict of Interest Statement
Tracy Riley, Executive Secretary

Open Public Hearing Session 1

Scientific presentations of the open session begin once last open hearing participant has spoken.

9:10 - 9:40 Introductory Remarks- David S. Finbloom, M.D.

Growth Factors in Wound Healing - Thomas A. Mustoe, M.D., Ph.D.

Standard Care of Diabetic Ulcers - O. Fred Miller, M.D.

9:40 - 10:00 Break

10:00 - 11:15 *Sponsor Presentation*

Introductory Remarks - Jacqueline A. Coelln, R.Ph.

Disease Overview - David L. Steed, M.D.

Clinical Efficacy and Safety Results - Janice M. Smiell, M.D.

Gel Product Characteristics - Basant Sharma, , Ph.D.

Labeling and Conclusions - Jacqueline A. Coelln, R.Ph.

**DERMATOLOGIC AND OPHTHALMIC DRUGS
ADVISORY COMMITTEE MEETING # 46
BLA 96-1408, Regranex®
OMJ Pharmaceuticals**

- 11:15 - 12:30 *FDA/CBER Evaluation*
- Drug Substance, Bioavailability and Low Bioburden
Kurt Stromberg, M.D.
- Clinical Efficacy and Clinical Safety
Libero Marzella, M.D., Ph.D.
- 12:30 - 1:30 Lunch
- 1:30 - 2:00 Open Public Hearing Session 2
- 2:00 - 5:00 Open Committee Discussion

**AGENDA
Wound Healing Discussion
July 15, 1997**

- 8:30 - 8:45 Call to Order: Welcome and Introductory Remarks
Joseph McGuire, Jr., M.D., Chairman
- Conflict of Interest Statement
Tracy Riley, Executive Secretary
- 8:45 - 9:15 Open Public Hearing Session 1

Scientific presentations of the open session begin once last open hearing participant has spoken.

- 9:15 - 10:30 Topic 1 -- Standard of Care
- 10:30 - 10:45 Break
- 10:45 - 12:00 Topic 2 -- Discontinuation of Study Treatment for Adverse Events; Study
Masking; and Vehicle Controls
- 12:00 - 1:00 Lunch
- 1:00 - 2:15 Topic 3 -- Entry Criteria: Indications

**DERMATOLOGIC AND OPHTHALMIC DRUGS
ADVISORY COMMITTEE MEETING # 46
Wound Healing Discussion**

2:15 - 2:45 Open Public Hearing Session 1

Scientific presentations of the open session begin once last open hearing participant has spoken.

2:45 - 3:30 Topic 4 -- Wound Assessment

3:30 - 3:45 Break

3:45 - 4:45 Topic 5 -- Endpoints

4:45 - 5:15 Topic 6 - Sterility of Product

PARTICIPANTS

FDA

Center for Drug Evaluation and Research

Michael Weintraub, M.D.	Director, Office of Drug Evaluation V
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July 9, 1997

DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE

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July 9, 1997

**DERMATOLOGIC AND OPHTHALMIC DRUGS
ADVISORY COMMITTEE MEETING # 46**

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**DERMATOLOGIC AND OPHTHALMIC DRUGS
ADVISORY COMMITTEE MEETING # 46**

Sponsor Participants

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Open Public Hearing Participants

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Statement