CENTER FOR DRUG EVALUATION AND RESEARCH

ADVISORY COMMITTEE: DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE

DATE OF MEETING: 03/19/98

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AGENDA

Food and Drug Administration
Center for Drug Evaluation and Research

DERMATOLOGIC AND OPHTHALMIC DRUGS
ADVISORY COMMITTEE MEETING # 49

Bioequivalence of Topical Dermatological Drug Products &
Questions Regarding Clinical Trials for Stable Plaque Psoriasis

March 19 and 20. 1998

Holiday Inn, Gaithersburg, MD

AGENDA

March 19

Bioequivalence of Topical Dermatological Drug Products

Open Session

8:30	Call to Order & Welcome Joseph McGuire, Jr., M.D., Chairman
	Conflict of Interest Statement Tracy Riley, Executive Secretary
8:40	Overview of the Issues & CDER/OPS Perspectives Roger Williams, M.D.
9:00	Approaches for BA/BE: Dermatopharmacokinetics Vinod P. Shah, Ph.D.
9:15	Division of Dermatologic and Dental Drugs Perspectives Jonathan Wilkin, M.D.
9:30	DPK and Follicular Pathways Hans Schaefer, Ph.D.
9:45	Principles of Topical Drugs Gordon Flynn, Ph.D.
10:00	Break
10:30	Open Public Hearing
12:15	Comments - Jonathan Wilkin, M.D.
	Closing Remarks - Roger Williams, M.D.

1:00 - 5:30 **Closed Session**

The Committee will discuss trade secret and/or confidential commercial information relevant to pending new drug applications and investigational new drugs. This portion of the meeting will be closed to permit discussion of this information as per 5 U.S.C. 522b(c)(4).

DERMATOLOGIC AND OPHTHALMIC DRUGS
ADVISORY COMMITTEE MEETING # 49
March 20, 1998

Questions Regarding Clinical Trials for
Stable Plaque Psoriasis

Open Session

8:30 - 8:40	Call to Order: Welcome and Information Joseph McGuire, Jr., M.D., Chairman	
	Conflict of Interest Statement Tracy Riley, Executive Secretary	
8:40 - 9:00	Open Public Hearing - Scientific presentation of the open session will begin once last open hearing participant has spoken.	
9:00 - 9:15	FDA Introductory Remarks: Objectives of the Discussion	
9:15 - 10:30	Presentations	
	Robert Stern, MD	An Overview of Psoriasis
	Mark Lebwohl, MD	An Overview of Methods for Assessment of Psoriasis Severity
	Hon-Sum Ko, MD FDA Presentation R. Srinivasan, Ph.D.	
10:30- 11:00	Break	
11:00 - 12:00	FDA Presentation	
12:00 - 1:00	Lunch	
1:00 - 1:30	Open Public Hearing 2	
1:30 - 3:30	Committee Discussion	
3:30 - 3:50	Break	
3:50 - 5:15	FDA Update for the Advisory Committee	
5:15 - 5:30	Concluding Remarks	

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March 19 & 20, 1998

Bioequivalence of Topical Dermatological Drug Products &
Questions Regarding Clinical Trials for Stable Plaque Psoriasis

FDA PARTICIPANTS

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DERMATOLOGIC AND OPHTHALMIC DRUGS
ADVISORY COMMITTEE MEETING # 49
March 19 & 20, 1998

Bioequivalence of Topical Dermatological Drug Products &
Questions Regarding Clinical Trials for Stable Plaque Psoriasis.

Special Government Employees, Consultants and Guest Speakers

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February 10, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH

ADVISORY COMMITTEE: DERMATOLOGIC AND OPHTHALMIC DRUGS ADVISORY COMMITTEE

DATE OF MEETING: 03/19/98

QUESTIONS

DERMATOLOGIC AND OPHTHALMIC DRUGS
ADVISORY COMMITTEE MEETING # 49
March 19, 1998

Bioequivalence of Topical Dermatological Drug Products.

Questions Regarding Bioequivalence of
Topical Dermatological Drug Products.

1. Can dermatopharmacokinetic (DPK) methodology be used for bioequivalence (BE) determination of dermatological drug products such as:

   (A) antibacterial;

   (B) antifungal;

   © antiviral;

   (D) glucocorticoid; and

   (E) retinoid?

2. Can in-vitro drug release be used for granting bio-waiver for lower strength of a generic topical product after the higher strength is approved as bioequivalent, and the only change is the amount of the active ingredient?

DERMATOLOGIC AND OPHTHALMIC DRUGS
ADVISORY COMMITTEE MEETING # 49
March 20, 1998

Questions Regarding Clinical Trials for
Stable Plaque Psoriasis

1. *Entry Criteria*

1.1 Should entry criteria require some minimal severity of the clinical signs?

1.2 Should entry criteria require some minimal surface area of involvement?

2. *Endpoints*

2.1 Would a dichotomous outcome for global evaluation be preferable to an all-category comparison ("edge up") as the other coprimary endpoint?

2.2 If the answer is yes to question 2.1, what should the successful outcome be in a dichotomous global evaluation? (Please describe.)

2.3 Should the three cardinal signs, plaque elevation, scaling and erythema carry equal or different weights?

How should their scores be combined for one of the coprimary endpoints?

2.4 Should area of involvement be included in the analysis of outcomes?

If so, how?

2.5 Should there be stratification for certain lesions, e.g., over bony prominences?

2.6 To what extent can quality of life assessment be used in the evaluation of success in the treatment of psoriasis?