CENTER FOR DRUG EVALUATION AND RESEARCH

ADVISORY COMMITTEE: JOINT MEETING OF DERMATOLOGIC and OPHTHALMIC DRUGS ADVISORY COMMITTEE AND ENDOCRINOLOGIC and METABOLIC DRUGS ADVSORY COMMITTEE

DATE OF MEETING: 03/11/98

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AGENDA

Food and Drug Administration
Center for Drug Evaluation and Research
Joint Meeting
Ophthalmic Drugs Subcommittee of the Dermatologic and Ophthalmic Drugs Advisory Committee and the Endocrine and Metabolic Drugs Advisory Committee.
March 11, 1998
Holiday Inn, Gaithersburg, MD
AGENDA
Diabetic Retinopathy Clinical Trial Endpoints

8:00 - 8:40	Call to Order: Welcome and Information Henry G. Bone, III, M.D., Chairman
	Conflict of Interest Statement Tracy Riley, Executive Secretary
	Open Public Hearing 1 - Scientific presentations of the open session will begin once the last open hearing participant has spoken.
8:40- 8:45	Introductory Remarks Wiley Chambers, M.D.
9:45- 10:45	Lilly Research Laboratories Presentation Lloyd P. Aiello, M.D., Ph.D Matthew Davis, M.D. Frederick L. Ferris, III, M.D.
10:45 - 11:00	Break
11:00 - 11:45	FDA Presentation Wiley Chambers, M.D.
11:45 - 1:00	Lunch
1:00 - 1:30	Open Public Hearing 2
1:30 - 2:30	Open Committee Discussion & Questions
2:30 - 2:45	Break
3:00 - 5:00	Open Committee Discussion & Questions

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Diabetic Retinopathy Clinical Trial Endpoints

PARTICIPANTS

Ophthalmic Drugs Subcommittee of the Dermatologic and Ophthalmic Drugs Advisory Committee

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ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE
CENTER FOR DRUG EVALUATION AND RESEARCH

CHAIRMAN

Bone, Henry G. III, M.D. 6/30/00
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MEMBERS

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BIOSTATISTICIAN EPIDEMIOLOGIST

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Molitch, Mark E., M.D. 6/30/00
Professor of Medicine
Northwestern University Medical School
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CONSUMER REPRESENTATIVE

Davidson, Jaime A., M.D. 6/30/01
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CONSULTANT

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Diabetic Retinopathy Clinical Trial Endpoints

Name	Participant Status	Address
William S. Gilbert, M.D.	SGE/Guest Speaker	Retina Group of Washington 5454 Wisconsin Avenue, #1540 Chevy Chase, MD 20815-6948
Stephen S. Feman, M.D. Department of Ophthalmology	SGE/Guest Speaker	Vanderbilt University Medical Center 8011 Medical Center East Nashville, TN 37232-8808
Frank A. Spellman, M.D.	SGE/Guest Speaker	1712 EYE Street NW, Suite 500 Washington, DC 20006
Marcia D. Carney, M.D. Department of Ophthalmology	SGE/Guest Speaker	Medical College of Virginia Box 262 MCV Station Richmond VA 23298
William R. Freeman, M.D.	SGE/Guest Speaker	USCD, Shiley Eye Center/0946 La Jolla, CA 92093
R. Sloan Wilson, M.D.	SGE/Guest Speaker	Doctor's Building, Suite 519 500 South University Avenue Little Rock, AK 72205
Dr. Kim Birch North American Regulatory Affairs	Industry Contact	Lilly Research Laboratories Lilly Corporate Center Indianapolis, IN 46285

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Diabetic Retinopathy Clinical Trial Endpoints

PARTICIPANTS

FDA

Michael Weintraub, M.D.	Director, Office of Drug Evaluation V
James Bilstad, M.D.	Director, Office of Drug Evaluation II
Wiley Chambers, M.D.	Deputy Director, Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products
Solomon Sobel, M.D.	Director, Division of Metabolic and Endocrine Drug Products
Elizabeth M. Ludwig, M.D.	Medical Officer, Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products
Jonca Bull, M.D.	Medical Officer, Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products
Alexander Fleming, M.D.	Group Leader, Division of Metabolic and Endocrine Drug Products
Lori Gorski	Project Manager, Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products
Kathleen R. Reedy	Executive Secretary, Endocrine & Metabolic Drugs Advisory Committee

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Diabetic Retinopathy Clinical Trial Endpoints

QUESTIONS

1. Is each of the "Clinical Benefit Endpoints" considered to be a clear clinical benefit?

2. Are there additional "Clinical Benefit Endpoints?" If so, what data exists to support the clinical benefit?

3. Is each of the "Proposed Surrogate Endpoints" considered to be a recognizable surrogate endpoint?

4. Are there additional "Proposed Surrogate Endpoints?"

5. What is the best means to validate the proposed surrogate endpoints (specific trial designs, duration and ultimate outcomes)?

6. What are other acceptable means to validate the proposed surrogate endpoints?

7. Are there additional issues (not already listed) which should be considered with respect to defining diabetic retinopathy endpoints?