

Food and Drug Administration
Center for Drug Evaluation and Research

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SUMMARY MINUTES
ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE #67

May 14, 1997

Bethesda Holiday Inn
8120 Wisconsin Avenue, Bethesda MD

Members Present

Robert Sherwin, M.D., Acting Chair
Jose Francisco Cara, M.D.
D. Roger Illingworth, M.D., Ph.D.
Jules Hirsch, M.D.
Mark Molitch, M.D.
Cathy Critchlow, Ph.D.
Colleen A. Colley, Pharm.D.
Henry G. Bone III, M.D.

FDA Participants

James M. Bilstad, M.D.
Solomon Sobel, M.D.
Gloria Troendle, M.D.
Hugo Gallo-Torres, M.D., Ph.D.
Eric Colman, M.D.
Bruce V. Stadel, M.D., M.P.H.

Consultants

Guest Experts

Members Absent

Robert A. Kreisberg, M.D.
Robert Marcus, M.D.
Maria I. New, M.D.

Executive Secretary

Kathleen R. Reedy

These summary minutes for the May 14, 1997 meeting of the
Endocrinologic and Metabolic Drugs Advisory Committee were approved on

8/24/99.

I certify that I attended the May 14, 1997 meeting of the
Endocrinologic and Metabolic Drugs Advisory Committee and that these
minutes accurately reflect what transpired.


Kathleen R. Reedy,
Executive Secretary


Robert S. Sherwin, M.D.
Acting Chairperson

The 67th meeting of the Endocrinologic and Metabolic Drugs Advisory Committee of the Food and Drug Administration Center for Drug Evaluation and Research was held at the Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD on May 14, 1997 was attended by approximately 300 persons. The meeting was held to discuss the efficacy and safety of NDA 20-766, Xenical™, orlistat tetrahydrolipstatin, sponsored by Hoffman-LaRoche for the long term treatment of obesity. The Committee had been provided a briefing document from the sponsor and the agency approximately twenty one days before the meeting.

Following the Call to order, introduction of members and opening Comments by Robert S. Sherwin, M.D., Acting Chair, the Meeting Statement was read by Kathleen Reedy, Executive Secretary.

The Open Public Hearing had 10 speakers.

1. Richard L. Atkinson, M.D., President, American Obesity Association
2. Lynn McAfee, Council on Size and Weight Discrimination
3. Larry Sasich, Pharm.D., Research Analyst, Public Citizen Health Research Group
4. Joyce A. Ritchey
5. Barbara J. Moore, Ph.D., President, Shape Up America!
6. Charles P. Lucas, M.D., Clinical Investigator, Division of Preventive and Nutritional Medicine
William Beaumont Hospital, Birmingham MI
7. Jerry M. Earll, M.D., Professor of Medicine, Georgetown University Medical Center
8. M. Patricia Solbach, Ph.D., Director, Menninger Center for Clinical Research
9. Diane Schaller
10. Michael A. Hamilton, M.D., Director, Duke University Diet and Fitness Center
North American Association for the Study of Obesity

The Hoffman-LaRoche Presentation consisted of:

Efficacy: Jonathan B. Hauptman, M.D.

Safety: Jonathan B. Hauptman, M.D.

William Cannovatchel, M.D.

Roberto Guerciolini, M.D.

The FDA Presentation consisted of

Medical Review: Eric C. Colman, M.D., Medical Officer

Division of Metabolic and Endocrine Drug Products

Discussion and Questions resulted in the following:

1. Is Orlistat, when dosed at 120 mg t.i.d., an effective weight loss drug?
Yes: 8 No: 0
2. Do the data indicate a need to provide vitamin supplements to all patients taking Orlistat?
Yes: 8 No: 0
3. Taking into consideration the overall benefits and risks of Orlistat, do you recommend that the drug be approved for marketing for the management of obesity?
Yes: 8 No: 0

Committee Recommendations for further study:

breast neoplasms
animal studies, particularly carcinoma effect
long term studies, 4-5 year focusing on
 breast cancer incidence
 vitamin D, and other fat soluble vitamin stasis
 bone proteins
 bone turnover, osteoporosis vulnerability
 vitamin K (other vitamin stasis)
 children at puberty and adolescence

Committee Labeling Recommendations:

use with controlled diet
limit use to two year (duration of study)
use of vitamin supplements
 frequency
 timing of ingestion
 specific vitamins and minerals need supplementation
monitor gallstone, kidney stone, breast neoplasm
no information, no trials with children
not recommended for those with intestinal disorders
effectiveness wanes over time

The meeting was adjourned at 3:00 pm.

Kathleen Reedy, Executive Secretary
Endocrinologic and Metabolic Drugs Advisory Committee