

Food and Drug Administration
Center for Drug Evaluation and Research

SUMMARY MINUTES
ENDOCRINOLOGIC AND METABOLIC DRUGS ADVISORY COMMITTEE #65

February 20, 1997
Bethesda Holiday Inn
8120 Wisconsin Avenue, Bethesda MD

Members Present

Cathy Critchlow, Ph.D., Acting Chair
Jules Hirsch, M.D.
Robert Marcus, M.D.
Colleen A. Colley, Pharm.D.
Mark Molitch, M.D.
D. Roger Illingworth, M.D., Ph.D.
Robert A. Kreisberg, M.D.
Maria I. New, M.D.

FDA Participants

James M. Bilstad, M.D.
Solomon Sobel, M.D.
Gloria Troendle, M.D.
Samarendra Dutta, M.D.
Dan Marticello

Consultants

Guest Experts

Members Absent

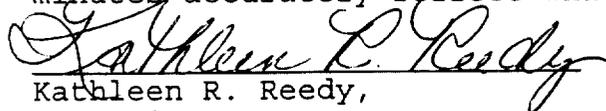
Jose Francisco Cara, M.D.
Robert S. Sherwin, M.D.
Henry G. Bone III, M.D.

Executive Secretary

Kathleen R. Reedy

These summary minutes for the February 20, 1997 meeting of the Endocrinologic and Metabolic Drugs Advisory Committee were approved on 8/24/99.

I certify that I attended the February 20, 1997 meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and that these minutes accurately reflect what transpired.


Kathleen R. Reedy,
Executive Secretary


Cathy W. Critchlow, Ph.D.
Acting Chairperson

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d) Should alendronate be recommended for women who are candidates for hormone replacement therapy?

Offered as a choice

e) Are there other criteria that should be used to determine who should receive alendronate for the prevention of osteoporosis?

No - 6

1 - 2 subsequent BMD showing accelerated loss

3. Do the BMD data on 2.5 and 5 mg of alendronate per day demonstrate that the 2.5 mg dose is an acceptable minimum dose for the prevention of osteoporosis?

No - 7

Alternatively, is the 5 mg dose proposed by the sponsor the most appropriate choice for preventive therapy?

Yes - 7

4. Taking into consideration the overall benefits and risks, do you recommend that alendronate be approved for prevention of osteoporosis in postmenopausal women?

Yes - 7

5. Do results of the vertebral fracture study (FIT) and those of the U.S./Multinational postmenopausal osteoporosis treatment studies provide substantial evidence that alendronate is effective for prevention of vertebral (compression), hip and wrist fractures?

Yes - 7

6. Taking into consideration the overall benefits and risks, do you recommend that alendronate be approved for prevention of fractures of the spine (compression), hip and wrist in postmenopausal women with pre-existing vertebral fractures?

Yes - 7

7. Do you recommend changes in the material proposed by the sponsor for incorporation into the Indications and Usage section? Is there any need to incorporate further safety information based on the submitted studies?

No - 3

3 - relationship to estrogen

The meeting was adjourned at 3:30.

Kathleen Reedy, Executive Secretary
Endocrinologic and Metabolic Drugs Advisory Committee