



NATIONAL  
OSTEOPOROSIS  
FOUNDATION

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August 14, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

To Whom It May Concern:

Regarding Docket No.00D-1307, CDER 67, Guidance for Industry: "Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis", the National Osteoporosis Foundation is concerned with the overly restrictive definition of osteoporosis for those who would be permitted to participate in clinical trials regarding this treatment. As defined, only those with a lumbar spine or hip T-score of  $\leq -2.5$  and the presence of at least one clinically manifest, radiographically documented osteoporotic fracture at the baseline could participate. We recommend that bone loss or fracture be the criteria for the trials.

In addition, the restrictive guidelines for the clinical trials would likely be carried over into labeling of the Parathyroid Hormone, meaning that this would be approved for limited use and thousands of patients would be denied a highly effective therapy for osteoporosis.

The National Osteoporosis Foundation appreciates the opportunity to provide comments on this important issue.

Sincerely,

*Sandra C. Raymond*  
Sandra C. Raymond  
Executive Director

00D-1307

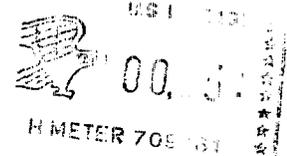
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