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Phone 317 276 2000

August 14, 2000

Mr. John Gomez  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20852

**Docket No. 00D-1307, CDER 67. Guidance for Industry: "Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis" published on June 14, 2000**

Dear Mr. Gomez:

Per your conversation with Dr. Greg Enas, director of U.S. Regulatory Affairs, we are providing the following letter. We clarify that Lilly's response signed by Dr. Tim Franson, dated August 4, 2000, will be available to the public through the Freedom of Information and is not confidential as erroneously noted on the stationary.

Lilly appreciates the contact by the Agency to correct the note in the upper right-hand corner stating that the information is confidential. The response from Lilly was on the draft guidance document that was published in the Federal Register on June 14, 2000.

Sincerely,

ELI LILLY AND COMPANY



Gregory G. Enas, Ph.D.  
Director, U.S. Regulatory Affairs

GGE:pb

00D-1307

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Answers That Matter.

**Fax**

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**US Regulatory Affairs**

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**TO: Mr. John Gomez**  
**Fax number: 301/827-6870**

**FROM: Greg Enas**

**DATE: 8/14/00**

**2 pages including cover**  
**If problems receiving please call 317-276-5185, Peggy Basham**  
**Thank you.**