



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUL 2 2004

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Mr. Edward Odland  
103 Downing Street  
Plymouth, PA 18651

Re: Docket No. 2004P-0013/CP1

Dear Mr. Odland:

I am writing to inform you that the Food and Drug Administration has not yet completed a response to your citizen petition submitted on January 7, 2004. Your petition requests that the Agency (1) review AERS for safety signals related to Nutropin Depot or other human growth hormones, (2) require Genentech to include warning information in their patient guides, and (3) amend reporting requirements at 21 CFR 314.80(e).

FDA has been unable to complete a response to your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

2004P-0013

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