



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

January 9, 2004

FILE COPY



Dear Mr. 

Your petition requesting the Food and Drug Administration to review the safety of Nutropin Depot Injection, to issue direction to Genentech Inc. to add warnings regarding diabetes in their safety literature, and to consider amending 21 CFR 314.80(e) postmarketing studies was received by this office on 01/07/2004. It was assigned docket number 2004P-0013/CP 1 and it was filed on 01/09/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management

2004P-0013

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