

# Attachment #7

Subj: **Genentech's Nutropin Depot**  
Date: 5/16/2003 12:13:05 PM Eastern Daylight Time  
Fr: KRUEGERC@cder.fda.gov (Krueger, Carol L)  
To: [ ]  
CC: DOBBSD@cder.fda.gov (Dobbs, Donald), SCHMID@cder.fda.gov (Schmid, Ralph J)

Dear Mr. [ ]

Please let me explain why I informed Mr. Dobbs that I concluded that Genentech has been compliant in their reporting of your daughter's adverse event. I have re-examined the documents concerning the data submitted by Genentech and the information that I have received in your emails.

Genentech received notification in November 2000 from the clinical investigator about your daughter's adverse event during the study. When initially reported to Genentech, the investigator did not find the adverse event related to the drug. In March of this year, the investigator changed his assessment, notified Genentech of the change, and Genentech submitted a report.

Under 21 CFR 314.80, for adverse events that occur during postmarketing studies, the only reports that need to be submitted are 15-day Alert reports (serious and unlabeled events) when the applicant concludes that there is a reasonable possibility that the drug caused the adverse experience.

If an adverse event is not required to be submitted as a 15-day Alert report, a firm may be exempted from submitting the event in their periodic report under 314.80(c)(2)- specifically 314.80(c)(2)(iii) - "Periodic reporting, except for information regarding 15-day Alert reports, does not apply to adverse drug experience information obtained from postmarketing studies (whether or not conducted under an investigational new drug application), from reports in the scientific literature, and from foreign marketing experience."

Since the study event was initially reported to Genentech as not related to the use of the drug, it would not need to be submitted as a 15-day Alert report, and since the event occurred during a study, it would not need to be submitted in a periodic report.

Genentech submitted a report about the event after the study investigator notified them this year that he had changed his assessment of causality, which made the event reportable to FDA.

I understand that the regulations can be confusing. Please contact me if you have any further questions.

Carol Krueger

—Original Message—

From: [ ]  
Sent: Thursday, May 15, 2003 9:01 AM  
To: kruegerc@cder.fda.gov  
Cc: [ ]  
Subject: Genentech's Nutropin Depot [ ]