

Attachment #4

Subj: Re: [redacted]
Date: 4/29/2003 3:29:40 PM Eastern Daylight Time
[redacted] MD)
To: [redacted]

The most recent check was last month, and turned up the two cases I told you about [redacted] plus the other girl on a different preparation). It took several phone calls and asking for a personal favor to get the right answers to the right questions but we finally got it. I'm not going to ask everyone to redo it a month later in case another case has been reported.

We did it to find out if there had been enough cases to warrant concern about a higher risk. The overall rates of type 1 diabetes reported with GH use continue to be monitored as part of the yearly safety review. Several new cases would warrant action or relabelling, but 1 or 2 cases out of 66 or more girls treated do not warrant a change in current use. It does warrant continued surveillance of the numbers as it continues to be used.

>>> [redacted] 04/29/03 01:04PM >>>
Dear Dr [redacted]

CDER has indicated that they will be forwarding me the data printout for all adverse events reported to them regarding Nutropin Depot by Friday. If the printout does identify a second case of insulin-dependent diabetes as the ally I received did, could I ask you to generate a new request? The indication may be more recent than your former requests. Thank You [redacted]

----- Headers -----