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E L E C T R O N I C M A I L M E S S A G E

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Date: 02-Jan-2001 04:31pm EST
From: Gary Buehler
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TO: Donald Hare

(HARE)

CC: Robert West

(WESTR)

CC: Christine Rogers

(ROGERSC)

Subject: Re: levothyroxine

Don

I discussed this issue at Bio DDs and Dale suggested the same plan. Since there were no clinical trials required for this application, the feeling was that there may be some statement made that they have been marketing this same formulation for __ years etc.

I + me know hat you find out.

>links
>Gary

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>Gary:

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>I called Chris Rogers, the attorney who has the lead on the levothyroxin issue.

>She provide a lot of valuable information which may forestall the contacting of

>JS.

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>She suggested that I contact David Lewis, the chemist with the responsibility

>for the 505(b) levothyroxin applications. Chris seem to think that historical

>data was also submitted with JS NDA which may answer our question of whether the

>Mylan ANDA used the correct formulation in their BE study.

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> have tried calling David a couple of times but only get the answering

>machine.

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>Stayed tuned.