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ELECTRONIC MAIL MESSAGE

Date: 04-Jan-2001 03:29pm EST
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TO: Gary Buehler (BUEHLER)
CC: Robert West (WESTR)
CC: Rita Hassall (HASSALLR)
CC: Cecelia Parise (PARISEC)
CC: Dale Conner (CONNERD)
CC: Frank Holcombe (HOLCOMBE)

Subject: levothyroxin.

Gary:

I met with David Lewis this afternoon and he was extremely helpful. He reviewed the JS NDA and could not find any reference to a pre-approval formulation. David then called his contact at JS with a number of questions to ask so as to be able to answer our question as to whether JS was marketing levothyroxin tablets before JS NDA was approved and if they were marketing before approval was the formulation the same as what was approved.

JS indicated that they had been marketing levothyroxin tablets for about 10 years and the approved formulation had not changed from the formulation that was marketed before approval. With this information David did not have to ask additional questions to confirm what we hope to be true i.e. Mylan had used JS approved formulation in their BE study.

Therefore based upon this JS answer to David's question any other ANDA applicant using a marketed JS levothyroxin tablet as the reference listed drug will be using the same formulation as Mylan and when approved the two ANDAs can be rated as therapeutic equivalent.

David also indicated that he would share the experience he gain in reviewing the levothyroxin NDAs with any of our chemists that are assigned to review the levothyroxin tablet ANDAs. [He indicated that acceptable stability data was extremely difficult to obtain on the lower strengths.] *

Don

THIS IS A FALSE STATEMENT

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