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ELECTRONIC MAIL MESSAGE

Sensitivity: COMPANY CONFIDENTIAL

Date: 29-Dec-2000 01:51pm EST  
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CC: Robert West ( WESTR )  
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CC: Dale Conner ( CONNERD )  
CC: Lizzie Sanchez ( SANCHEZL )  
CC: Rita Hassall ( HASSALLR )

Subject: RE: levothyroxine

Gary:

I agree with your concern regarding the formulation of the JS levothyroxin (LT) tablets that were approved and the formulation of the JS LT tablets that were marketed without an approved application possibly not being the same. Although the formulation of the two LT tablets are probably the same I think that it will have to be checked out.

A similar situation occurred when a firm did a verapamil ER tablet BE study and used Searle's Calan SR, a distributor of the RLD, as the RLD rather than Isoptin SR. Jason had to check it out to make sure that the Calan SR that was being distributed by Searle was manufactured by Knoll and was the same formulation.

As an aside even though the initial decision has been made based upon the new BA/BE guidance to only have one RLD, i.e. the 0.3 mg tablet, for 11 strengths of a medically important drug, it may be reconsidered. Mylan was wise in doing three BE studies but you have to wonder why they did not use the same lot.

Don