



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CONFIDENTIAL

IND 62,720

Abbott Laboratories
Attention: Douglas Sporn
Divisional Vice President, Corporate Regulatory Affairs
D-387, AP6C-1
100 Abbott Park Road
Abbott Park, IL 60064-6091

Dear Mr. Sporn:

We received your October 10, 2002, correspondence on October 11, 2002 requesting a meeting to discuss the suitability of the current bioequivalence requirements for levothyroxine sodium tablets. We apologize for the delay in responding to your request. We considered your request and concluded the meeting is unnecessary.

We have carefully evaluated your data and the issues you raised based on the results of Study M02-417, which were included in your meeting request. We agree that a baseline correction method should be used when evaluating levothyroxine sodium tablet products for an AB rating. We concluded that the Agency will recommend to sponsors seeking to obtain an AB rating of their product with respect to a reference listed levothyroxine sodium tablet product the following: It will be necessary to conduct a two-way crossover study in healthy subjects under fasting conditions using a three pre-dose baseline subtraction method to evaluate total thyroxine.

If you disagree with our decision regarding your meeting request, you may discuss the matter with Enid Galliers, Chief, Project Management Staff, at (301) 827-6429. If the issue cannot be resolved at the division level, you may formally request reconsideration according to our guidance for industry titled *Formal Dispute Resolution: Appeals Above the Division Level* (February 2000). The guidance can be found at <http://www.fda.gov/cder/guidance/2740fn1.htm>.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

David Orloff
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