



F
/





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-210/S-003

Jerome Stevens Pharmaceuticals, Inc.
Attention: Ronald J. Steinlauf
Vice President
Sixty DaVinci Drive
Bohemia, NY 11716

Dear Mr. Steinlauf:

Please refer to your March 26, 2003 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Unithroid (levothyroxine sodium tablets, USP).

After a preliminary review, we find your application is not sufficiently complete to permit a substantive review. Therefore, we are refusing to file this application under 21 CFR 314.101(d) for the following reason:

In this supplement, you propose to establish that Unithroid is comparable (i.e., therapeutically equivalent) to Synthroid (levothyroxine sodium tablets, USP) manufactured by Abbott Laboratories and request an "AB" rating in FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (referred to as the "Orange Book".)

To support this claim, you compared Unithroid to Synthroid (Lot # 0000339726) in a comparative bioavailability study (P1CK02001) in which the reference material, Synthroid tablets, used in your study was not the subject of an approved new drug application.

The Code of Federal Regulations requires that the "reference material should be taken from a current batch of a drug product that is the subject of an approved new drug application and that contains the same active drug ingredient or therapeutic moiety, if the new formulation . . . is intended to be comparable to or to meet any comparative labeling claims made in relation to the drug product that is the subject of an approved new drug application" (21 CFR 320.25(e)(3)).

Within 30 days of the date of this letter, you may request in writing an informal conference about our refusal to file the application. To file this application over FDA's protest, you must avail yourself of this informal conference.

NDA 21-210/S-003

Page 2

If, after the informal conference, you still do not agree with our conclusions, you may request that the application be filed over protest. In that case, the filing date will be 60 days after the date you requested the informal conference. The application will be considered a new original application for user fee purposes.

If you have any questions, call Enid Galliers, Chief, Project Management Staff, at (301) 827-6429.

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