DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-807/S-025

Forest Laboratories, Inc.
Attention: Amy Rubin
Director, Regulatory Affairs
Harborside Financial Center
Plaza Three, Suite 602
Jersey City, New Jersey 07311

Dear Ms. Rubin:

Please refer to your supplemental new drug application dated April 3, 2002, received April 4, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thyrolar Tablets (liotrix, USP).

This supplement provides for changes to the storage statements on the bottle label and to the package insert to emphasize the requirement to store the tablets under refrigeration. The package insert now has the following BOLDED statement in both the HOW SUPPLIED and PRECAUTIONS sections**: "Tablets should be stored at cold temperature, between 36° and 46°F (2° and 8°C) in a tight, light-resistant container."** A similar, bolded statement was enlarged and moved to the main panel on the bottle label.

We completed our review of this supplemental application and have concluded that adequate information has been presented to demonstrate the drug is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted April 3, 2002, immediate container bottle label (for 1/4 grain tablets submitted April 4, 2002.) The bottle labels for the other strengths must duplicate the changes approved for the sample label. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs.* Alternatively, you may submit 20 copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 16-807/S-025." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Endocrine and
Metabolic Drug Products,.HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Orloff

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