



NDA 21-342/S-002

Alara Pharmaceutical Corporation
Attention: Mayra Garcia
Senior Regulatory Affairs Associate
P.O. Box 7439
Caguas, Puerto Rico 00726

Dear Ms. Garcia:

Please refer to your supplemental new drug application dated February 20, 2003, received February 21, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levo-TTM (levothyroxine sodium tablets, USP), 25, 50, 75, 88, 100, 112, 125, 137, 150, 175, 200, and 300 mcg.

We acknowledge receipt of your submissions dated March 19, July 9, and August 19, 2003.

This “Changes Being Effected in 30 days” supplemental new drug application provides for the addition of a new capsule-shaped tablet for all 12 strengths.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

The statement (b)(4)-----
(b)(4)-----in the label should be revised to reposition (or add for 137 mcg tablet label) the word “permitted” as follows: **“Store at controlled room temperature 20° to 25°C (68° to 77°F) with excursions permitted between 15° and 30°C (59° and 86°F).”**

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the bottle labels (submitted March 19, 2003, and to the enclosed labeling (text for the package insert submitted August 19, 2003). These revisions are terms of the approval of this application.

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDAs*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-342/S-002." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 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

Enclosure:
Package Insert

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

/s/

Eric Colman
8/21/03 03:31:59 PM
Eric Colman for David Orloff