DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-342/S-001

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

Dear Ms. Garcia:

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

We acknowledge receipt of your submission dated February 4, 2003.

Your submission of August 25, 2003 constituted a complete response to our August 5, 2003 Approvable letter.

This supplemental new drug application provides for a new strength, 137 mcg, round tablets.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 25, 2003.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Oluchi Elekwachi, Regulatory Project Manager, at (301) 301-827-6381.

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

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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