DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 21-342/S-016

ALARA Pharmaceutical Corporation
Attention: Claribel Velez
Vice President, Regulatory Affairs & Compliance
P.O. Box 7439
Caguas, Puerto Rico 00726

Dear Ms. Velez:

Please refer to your supplemental new drug application dated January 8, 2009, received January 9, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levo-T (levothyroxine sodium) Tablets.

We acknowledge receipt of your submissions dated April 30, and May 22, 2009.

This supplemental new drug application provides for:

(1) changing the color of the 75 mcg tablet from dark blue to violet,
(2) revising the package insert to reflect the change in color of the 75 mcg tablet, and
(3) revising the format of the container labels for all dosage strengths.

We have 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (container labels submitted on May 22, 2009).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-342/S-016**." Approval of this submission by FDA is not required before the labeling is used.

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
Food and Drug Administration
Suite 12B05
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 Julie Marchick, Regulatory Project Manager, at (301) 796-1280.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures: Package Insert,
Container Labels (25 mcg – 100 tablets, 25 mcg – 1000 tablets, 50 mcg – 100 tablets, 50 mcg – 1000 tablets, 75 mcg – 100 tablets, 75 mcg - 1000 tablets, 88 mcg – 100 tablets, 88 mcg – 1000 tablets, 100 mcg – 100 tablets, 100 mcg – 1000 tablets, 112 mcg – 100 tablets, 112 mcg – 1000 tablets, 125 mcg – 100 tablets, 125 mcg – 1000 tablets, 137 mcg – 100 tablets, 137 mcg – 1000 tablets, 150 mcg – 100 tablets, 150 mcg – 1000 tablets, 175 mcg – 100 tablets, 175 mcg – 1000 tablets, 200 mcg – 100 tablets, 200 mcg – 1000 tablets, 300 mcg – 100 tablets, 300 mcg – 1000 tablets)

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

/s/

Mary Parks

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