



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-342/S-008 and S-014

Alara Pharmaceuticals
Attention: Claribel Velez
U.S. Regulatory Agent
P.O. Box 7439
Caguas, PR 00726

Dear Ms. Velez:

Please refer to your supplemental new drug applications dated January 24, 2005, received January 26, 2005 (S-008) and dated December 10, 2007, received December 12, 2007 (S-014), 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 December 6, 2007, and May 23, 2008, to S-008 and dated May 23, 2008, to S-014.

Your submission of December 6, 2007, constituted a complete response to our July 26, 2005, action letter for S-008.

These "Changes Being Effected" supplemental new drug applications provide for the following:

S-008: Revisions to the PRECAUTIONS and DOSAGE AND ADMINISTRATION sections of the package insert to indicate that Levo-T should be taken with a full glass of water.

S-014: Revisions to the PRECAUTIONS section of the package insert regarding interaction with orlistat, in response to our supplement request letter dated September 28, 2007.

In addition, the revised package insert includes revisions that were made in response to our supplement request letter dated June 10, 2005. This supplement request letter requested changes to the PRECAUTIONS and DESCRIPTIONS sections of the package insert.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 and Container Labels

**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
6/10/2008 12:33:27 PM