

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 21-342

APPROVAL LETTER



NDA 21-342

Mova Pharmaceutical Corporation
Attention: Aracelis Ramirez
Vice President, Regulatory & Quality Affairs
Villa Blanca Industrial Park
State Street Road No. 1 Km 34.8/Jose Garrido Avenue (End)
Caquas, P.R. 00725

Dear Ms. Ramirez:

Please refer to your new drug application (NDA) dated April 30, 2001, received May 1, 2001, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Levo-T® (levothyroxine sodium tablets, USP), 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg.

We acknowledge receipt of your submissions dated May 21, September 11, October 26, November 8, and December 7, 2001, and January 24 and February 4, 6, 8, 13, and 28(2), 2002.

This new drug application provides for the use of Levo-T (levothyroxine sodium tablets, USP) for hypothyroidism and suppression of thyroid-stimulating hormone.

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

The final printed labeling (FPL) must be identical to, except for the indicated revision, the submitted draft labeling (package insert [enclosed] submitted February 28, 2002, and the immediate container label for the 25 mcg x 5000 count bottle submitted February 28, 2002.) In your February 28, 2002, letter, you agreed to revise the other 43 labels submitted on April 30, 2001, to add the word "permitted" to the end of the first storage condition sentence exactly as in the 25 mcg x 5000 bottle label submitted February 28, 2002. The revision is a term of the NDA approval. Marketing the product before making the revision, exactly as stated, in the product's labeling may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please 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 21-342." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated February 8, 2002. This commitment is listed below.

You committed to establishing an in-process specification for levothyroxine sodium assay for the _____ stage within one year of approval.

In addition we have the following comments and requests:

CHEMISTRY

The tentative expiration date for the drug product is 18 months.

BIOPHARMACEUTICS

The dissolution method and tolerance specifications should be as follows:

Apparatus Type	2 (paddles)
Media	0.01 N HCl containing 0.2% sodium lauryl sulfate
Volume	500 mL
Speed of Rotation	50 R(b)
Tolerance Specifications	NLT (4)---(Q) of the labeled amount of levothyroxine sodium is dissolved in 15 minu---

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit 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, Maryland 20857

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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 Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE

**APPEARS THIS WAY
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/s/

Mary Parks
3/1/02 02:22:11 PM
for Dr. Orloff

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