



Food and Drug
Administration
Rockville MD 20857

NDA 21-292

Genpharm, Inc.
Attention: Eugene M. Pfeifer
U.S. Agent for Genpharm, Inc.
King and Spalding
1730 Pennsylvania Ave., NW
Washington, DC 20006-4706

Dear Mr. Pfeifer:

Please refer to your new drug application (NDA) dated June 27, 2000, received July 6, 2000, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Novothyrox (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 May 11, July 17, and November 9 and 29, 2001; and February 25, March 13, and May 27, 2002. Your submission of November 29, 2001, constituted a complete response to our May 4, 2001, action letter.

This new drug application provides for the use of Novothyrox (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 the submitted draft labeling (package insert submitted May 27, 2002, [enclosed], and blister, bottle, and carton labels submitted May 27, 2002.) Marketing the product with FPL that is not identical to the approved labeling text 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 21-292." Approval of this submission by FDA is not required before the labeling is used.

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

The Office of Clinical Pharmacology and Biopharmaceutics has reviewed your data and has set the dissolution method and tolerance specifications as follows:

Revised Genpharm Dissolution Method- Levothyroxine sodium		
	25 mcg – 175 mcg	200 mcg – 300 mcg
(b)(4))----- ----	----- ----
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We note that your data support a 24 month expiry for all presentations and all strengths of this product.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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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

**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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