



NDA 21-137

Vintage Pharmaceuticals, Inc.  
Attention: Christopher J. Nascone  
Regulatory Affairs  
3241 Woodpark Boulevard  
Charlotte, NC 28206

Dear Mr. Nascone:

Please refer to your new drug application (NDA) dated April 30, 1999, received May 11, 1999, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Levolet (levothyroxine sodium tablets, USP), 0.025, 0.05, 0.075, 0.088, 0.1, 0.112, 0.125, 0.137, 0.15, 0.175, 0.2, and 0.3 mg.

We acknowledge receipt of your submission dated April 7, 2003 containing final printed labeling.

The April 7, 2003, submission constituted a complete response to our June 12, 2002, action letter.

This new drug application provides for the use of Levolet for the following indications:

***Hypothyroidism*** – As replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology, except transient hypothyroidism during the recovery phase of subacute thyroiditis. Specific indications include: primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) hypothyroidism and subclinical hypothyroidism. Primary hypothyroidism may result from functional deficiency, primary atrophy, partial or total congenital absence of the thyroid gland, or from the effects of surgery, radiation, or drugs, with or without the presence of goiter.

***Pituitary TSH Suppression*** – In the treatment or prevention of various types of euthyroid goiters (see **WARNINGS** and **PRECAUTIONS**), including thyroid nodules (see **WARNINGS** and **PRECAUTIONS**), subacute or chronic lymphocytic thyroiditis (Hashimoto's thyroiditis), multinodular goiter (see **WARNINGS** and **PRECAUTIONS**), and as an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling (package insert and carton labels submitted April 7, 2003).

Submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send 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, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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 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, HFD-510  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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/s/

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David Orloff  
6/6/03 11:15:00 AM