NDA 021116/S-021

SUPPLEMENT APPROVAL

Alvogen, Inc.
Attention: Jyoti Sachdeva, PhD
Executive Director, Regulatory Affairs
44 Whippany Road, Suite 300
Morristown, NJ 07960

Dear Dr. Sachdeva:

Please refer to your supplemental new drug application (sNDA) dated and received January 26, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Thyro-Tabs (levothyroxine sodium) tablets.

We acknowledge receipt of your amendment dated June 14, 2021, which constituted a complete response to our November 15, 2018, action letter.

This sNDA proposes to demonstrate bioequivalence between Thyro-Tabs and Unithroid (b) (4)

We have determined your Thyro-Tabs (levothyroxine sodium) tablets to be bioequivalent and therapeutically equivalent to Unithroid (levothyroxine sodium) tablets.

Our review concludes that the data establish bioequivalence between these products, and this supplement as amended is approved. (b) (4)

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[1]

[1] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[2] Information and Instructions for completing the form can be found at FDA.gov.[3]

REPORTING REQUIREMENTS

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 Linda Galgay, Senior Regulatory Project Manager, at (301) 796-5383.

Sincerely,

{See appended electronic signature page}

Theresa E. Kehoe, M.D.
Director
Division of General Endocrinology
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Center for Drug Evaluation and Research

[2] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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/s/

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