NDA 021137/S-005

SUPPLEMENT APPROVAL

Genus Lifesciences Inc.
Attention: William Reightler
Vice President of Regulatory Affairs
514 N. 12th Street
Allentown, PA 18102

Dear Mr. Reightler:

Please refer to your supplemental new drug application (sNDA) dated February 18, 2021, and received February 19, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Levolet (levothyroxine sodium) tablets.

We acknowledge receipt of your amendment dated February 10, 2022, which constituted a complete response to our December 17, 2021, action letter.

This sNDA proposes to demonstrate bioequivalence between Levolet and Synthroid (b) (4)

We have determined your Levolet (levothyroxine sodium) tablets to be bioequivalent and therapeutically equivalent to Synthroid (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}

Naomi Lowy, M.D.
Deputy 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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