Suitability Petition
***Revised* Completeness Assessment Correspondence**

Newcastle Bioscience LLC
999 Vanderbilt Beach Road, Suite 200
Naples, FL 34108
Attn: Gene Nakagawa

Sent via email to: gene@newcastlebio.com

Docket No. FDA-2024-P-3293

Dear Gene Nakagawa:

This is in reference to your petition received on July 9, 2024, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission, in accordance with 21 C.F.R. §314.93(b), to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Lacosamide Orally Disintegrating Tablets (ODT), 25 mg, 37.5 mg, 75 mg, 112.5 mg, and 175 mg. The petition was examined for initial completeness (i.e. Completeness Assessment) under CFR 10.30 and the Agency has made a threshold determination that the petition is complete.

This petition is subject to the provisions of the Generic Drugs User Fee Amendments of 2022 (GDUFA III) whereby any suitability petitions submitted in FY 2024-2027 will receive a goal date of 6 months after the completeness assessment. The GDUFA goal date for review of this petition is January 30, 2025.

Reference is made to the information request dated July 31, 2024 and to any amendments thereafter.

Reference is made to the Completeness Assessment Correspondence Letter dated July 30, 2024. A corrected letter is hereby issued that supersedes the previous letter. This letter is identical to the July 30, 2024 letter except for the proposed strengths which have been revised to accurately reflect the strengths proposed by the petitioner. The GDUFA goal date remains unchanged as January 30, 2025.

If you have any questions, contact ANDAFiling@fda.hhs.gov.

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

{See appended electronic signature page}

Rosanne Pagaduan, Pharm.D.
Supervisory Pharmacist
Division of Filing Review
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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Rosanne Pagaduan

Digitally signed by Rosanne Pagaduan
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