Suitability Petition
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-2932

Dear Gene Nakagawa:

This is in reference to your petition received on June 19, 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: Rosuvastatin Orally Disintegrating Tablets, 5 mg, 10 mg, 20 mg and 40 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 8, 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}

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

Kaitlin Harves

Digitally signed by Kaitlin Harves
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