Pooja Kulkarni
Assistant Vice President, Regulatory Affairs
Macleods Pharmaceuticals Limited
G-2 Mahakali Caves Road, Shanti Nagar
Andheri (East), Mumbai – 400093, India

December 12, 2024

Re: Docket No. FDA-2022-P-2768

Dear Pooja Kulkarni:

This letter responds to your citizen petition received on November 4, 2022, requesting that the Food and Drug Administration (FDA) determine whether Trandate (labetalol hydrochloride) tablets, 100 milligrams (mg), new drug application 018716, held by Alvogen Inc., was voluntarily withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Trandate (labetalol hydrochloride) tablets, 100 mg, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Trandate (labetalol hydrochloride) tablets, 100 mg, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-0110.

Sincerely,

Awo Archampong-gray -S

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Awo Archampong-Gray
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure