



November 4, 2022

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

Sent via email to: poojak@macleodspharma.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug to declare that the drug product Trandate, (Labetalol hydrochloride) tablets, 100 mg strength, was withdrawn from the market for reasons other than safety and efficacy was received and processed under CFR 10.30 by this office on 11/04/2022.

It was assigned docket number FDA-2022-P-2768. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)