November 4, 2022

To,

Division of Dockets Management (HFA-305)

Food and Drug Administration

Department of Health and Human Services

5630 Fishers Lane, Room 1061

Rockville, MD 20852

CITIZEN PETITION

Dear Sir / Madam,

Pursuant to 21 CFR 10.25 (a) and 21 CFR 10.30, Macleods pharmaceuticals limited is submitting this citizen petition request to the Commissioner of Food and Drug Administration for determination of whether the reference listed drug product Trandate, (Labetalol hydrochloride) tablets, 100 mg strength was withdrawn from commercial distribution for reason of safety or effectiveness.

A. Action Requested

The Macleods pharmaceuticals limited requests to the Food and Drug Administration to declare that the drug product Trandate, (Labetalol hydrochloride) tablets, 100 mg strength listed below was withdrawn from the market for reasons other than safety and efficacy.

This drug product strength is listed in the Discontinued Section and no indication is given as to agency determination for the reason of withdrawal from commercial distribution. The drug product strength is as follows:

Labetalol Hydrochloride Tablet, 100 mg

Application Number: N018716

Applicant: County Line Pharmaceuticals LLC (Currently marketed by Alvogen Inc.).

Trade name: Trandate

MACLEODS PHARMACEUTICALS LIMITED

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B. Statement of Grounds

In accordance with 21 CFR 314.61(a)(1)(3) a determination whether a listed drug that has been voluntarily withdrawn from sale was withdrawn for safety or effectiveness reasons may be made by the agency at any time after the drug has been voluntarily withdrawn from sale, but must be made when a person petitions for such a determination under 21CFR 10.25(a) and 21 CFR10.30.

Thus, with the filing of this Citizens Petition and in accordance with 21CFR 10.25(a) and 21CFR 10.30 we request a prompt review and determination for the reason(s) of withdrawal for this drug product tablet strength.

C. Environmental Impact

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR § 25.31(a) and 25.15(d).

D. Economic Impact Statement

Information on the economic impact of the action requested by this Citizen Petition will be submitted if requested by FDA.

E. Certification

Macleods Pharmaceuticals Limited certifies, that to the best of knowledge and belief, this petition includes all information upon which this petition relies, and that it includes representative data and information known to the Petitioner which is unfavorable to this petition.

References:

- Orange book, patent information provided overleaf

Sincerely,

Pooja Kulkarni,

Assistant Vice President, Regulatory Affairs

Macleods Pharmaceuticals Limited,

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Contact details of US agent

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Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Home (index.cfm?resetfields=1) | Modify Search (index.cfm?panel=0&drugname=trandate)

Search Results for Proprietary Name, Active Ingredient or Application Number: *trandate*

RX OTC DISCN

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Display 50 records per page

Showing 1 to 4 of 4 entries (filtered from 9 total records)

18716

Mkt. Status	Active Ingredient	Proprietary Name	Appl. No.	Dosage Form	Route	Strength	TE Code (https://www.fda.gov/Drugs/DevelopmentApprovalProce
RX	LABETALOL HYDROCHLORIDE	TRANDATE	N018716 (results_product.cfm?Appl_Type=N&Appl_No=018716#20433)	TABLET	ORAL	200MG	AB
RX	LABETALOL HYDROCHLORIDE	TRANDATE	N018716 (results_product.cfm?Appl_Type=N&Appl_No=018716#20434)	TABLET	ORAL	300MG	AB
DISCN	LABETALOL HYDROCHLORIDE	TRANDATE	N018716 (results_product.cfm?Appl_Type=N&Appl_No=018716#2532)	TABLET	ORAL	100MG	
DISCN	LABETALOL HYDROCHLORIDE	TRANDATE	N018716 (results_product.cfm?Appl_Type=N&Appl_No=018716#2533)	TABLET	ORAL	400MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**	
Mkt. Status	**Active Ingredient**	**Proprietary Name**	**Appl. No.**	**Dosage Form**	**Route**	**Strength**	**TE Code (https://www.fda.gov/Drugs/DevelopmentApprovalProce**

Showing 1 to 4 of 4 entries (filtered from 9 total records)

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TRANDATE (LABETALOL HYDROCHLORIDE)
100MG
Marketing Status: Discontinued

Active Ingredient: LABETALOL HYDROCHLORIDE
Proprietary Name: TRANDATE
Dosage Form; Route of Administration: TABLET; ORAL
Strength: 100MG
Reference Listed Drug: Yes
Reference Standard: No
TE Code:
Application Number: N018716
Product Number: 001
Approval Date: May 24, 1985
Applicant Holder Full Name: ALVOGEN INC
Marketing Status: Discontinued
Patent and Exclusivity Information