September 25, 2019

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,

The undersigned submits this citizen petition electronically under Section 505(j) of the Federal Food Drug, and Cosmetic Act and 21 CFR 10.20, 10.30 and 314.93, to request the Food and Drug Administration to designate a suitable RLD/RS for purpose of submitting an ANDA application for Clindamycin topical solution 1% with reference to the current electronic orange book database (Approved Drug Products with Therapeutic Equivalence Evaluation).

The request is being made on following grounds;

1. Current Orange Book lists CLEOCIN T (Topical Solution) 1%, NDA # N050537 by PHARMACIA AND UPJOHN CO (a division of Pfizer). as Reference Standard as well as Reference Listed Drug. However, though not listed as discontinued in Electronic Orange Book, as per IMS (MAT) data, quantity of the current reference standard in distribution is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for development and comparison.

2. Approved generic product ANDA #064050, Clindamycin phosphate topical solution 1% of Perrigo New York Inc. listed in the Orange Book and the National Drug Code Directory is currently the market leader and hence eligible to be designated as reference standard due to limited availability of the current orange book listed Reference Listed Drug lists "CLEOCIN T (Topical Solution) 1%, NDA # N050537 by PHARMACIA AND UPJOHN CO"

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A. Action Requested

Macleods Pharmaceuticals Limited requests the Food and Drug Administration (FDA) to designate the approved ANDA #064050, Clindamycin phosphate topical solution 1% of Perrigo New York Inc. as a reference standard or designate a suitable alternative reference standard, upon which ANDA applicant can rely for purpose of in vivo bioequivalence testing.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products, which are eligible for submission as Abbreviated New Drug Applications (ANDA's) in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (The Orange Book).

FDC Act §505(j) allows the marketing of generic versions of previously approved drug products when the generic drug product is the subject of an ANDA. To obtain ANDA approval, the application sponsor must show, among other things, that with respect to a listed drug (i.e., a previously approved drug product), the generic drug product has the same active ingredient(s) in the same strength, has essentially identical labeling.

Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book) database Current through **September 2019*** is provided in following table;

Marketing status	Active ingredient	Proprietary name	Application no	Dosage form	Route of administration	Strength	Product number	Approval date	TE code	RLD	Applicant holder
Rx	Clindamycin Phosphate	CLEOCIN T	N050537	Solution	Topical	EQ 1% Base	001	Approved Prior to Jan 1, 1982	At	Yes	Pharmacia And Upjohn Co
Rx	Clindamycin Phosphate	CLINDA-DERM	A063329	Solution	Topical	EQ 1% Base	001	Sep 30, 1992	At	No	Paddock Laboratories Llc
Rx	Clindamycin Phosphate	CLINDAMYCIN PHOSPHATE	A209914	Solution	Topical	EQ 1% Base	001	Jan 28, 2019	At	No	Encube Ethicals Pvt Ltd
Rx	Clindamycin Phosphate	CLINDAMYCIN PHOSPHATE	A064159	Solution	Topical	EQ 1% Base	001	Jun 5, 1997	At	No	Fougera pharmaceuticals inc
Rx	Clindamycin Phosphate	CLINDAMYCIN PHOSPHATE	A065254	Solution	Topical	EQ 1% Base	001	Feb 14, 2006	At	No	Fougera pharmaceuticals inc

Marketing status	Active ingredient	Proprietary name	Application no	Dosage form	Route of administration	Strength	Product number	Approval date	TE code	RLD	Applicant holder
Rx	Clindamycin Phosphate	CLINDAMYCIN PHOSPHATE	A062811	Solution	Topical	EQ 1% Base	001	Sep 1, 1988	At	No	G and W Laboratories INC
Rx	Clindamycin Phosphate	CLINDAMYCIN PHOSPHATE	A209846	Solution	Topical	EQ 1% Base	001	Feb 8, 2018	At	No	Glasshouse pharmaceuticals Ltd Canada
Rx	Clindamycin Phosphate	CLINDAMYCIN PHOSPHATE	A064050	Solution	Topical	EQ 1% Base	001	Nov 30, 1995	At	No	Perrigo New York INC
Rx	Clindamycin Phosphate	CLINDAMYCIN PHOSPHATE	A065184	Solution	Topical	EQ 1% Base	001	Mar 31, 2004	At	No	Taro pharmaceutical industries ltd
Rx	Clindamycin Phosphate	CLINDAMYCIN PHOSPHATE	A206945	Solution	Topical	EQ 1% Base	001	Dec 30, 2016	At	No	Teligent pharma inc
Rx	Clindamycin Phosphate	CLINDAMYCIN PHOSPHATE	A203343	Solution	Topical	EQ 1% Base	001	May 29, 2015	At	No	Vintage pharmaceuticals
Rx	Clindamycin Phosphate	CLINDAMYCIN PHOSPHATE	A208767	Solution	Topical	EQ 1% Base	001	Jul 16, 2018	At	No	Zydus pharmaceuticals usa inc

* Data accessed on September 24, 2019.

Due to market unavailability of designated reference standard, evaluation/comparison of a Macleod's generic drug could not be executed.

As per Draft Guidance for Industry, *Referencing Approved Drug Products in ANDA Submissions, III.C.2 and 3*, "FDA also will consider selecting a new reference standard when the Agency determines that the quantity of the current reference standard in distribution is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for in vivo bioequivalence testing (even if the current reference standard is not in the Discontinued Section of the Orange Book). When selecting a new reference standard, FDA generally selects a drug product that is therapeutically equivalent to the RLD and is the market leader based on units sold. If there is a reference standard in the Active Section of the Orange Book but there are limited or no quantities of the reference standard in distribution, or a potential ANDA applicant believes a reference standard other than the one selected by FDA is appropriate, then the potential applicant may submit a citizen petition under 21 CFR 10.25(a) and 10.30 to request that FDA select that different listed drug also as a reference standard."

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The Petitioner (Macleods) therefore requests FDA to designate Approved Generic product ANDA #064050, Clindamycin phosphate topical solution 1% of Perrigo New York Inc. as a reference standard (RS), as FDC Act §505(j) allows the marketing of generic versions of previously approved drug products when the generic drug product is the subject of an ANDA.

In support of the designation of the reference standard to Approved Generic ANDA #064050, Clindamycin phosphate topical solution 1% of Perrigo New York Inc., we have included the following data;

1. Current Orange Book Search Results
2. NDC Directory Search Results
3. Drug@FDA Search Results
4. Detailed IMS, Moving annual total (MAT) data indicating Approved Generic product ANDA #064050, Clindamycin phosphate topical solution 1% of Perrigo New York Inc. as the market leader.

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.

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Sincerely,

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