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November 14, 2019

BY ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned ("Petitioner") submits this petition on behalf of our client under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 C.F.R. §§ 10.20 and 10.30(b)(3), to request the Commissioner of the Food and Drug Administration (FDA) to amend the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") to designate Abbreviated New Drug Application (ANDA) No. 065049 (Clindamycin Phosphate Topical Solution USP, 1% (Pledgets)) as a Reference Standard (RS) drug.

The current Reference Listed Drug (RLD) for Clindamycin Phosphate Topical Solution USP, 1% (Pledgets) listed in the Orange Book is New Drug Application (NDA) No. 050537 Cleocin® (Clindamycin Phosphate Topical Solution USP, 1% (Pledgets)), owned by Pharmacia and Upjohn Co. Although the RLD is not listed in the discontinued section of the Orange Book, it has not been available on the market since October 2018 and therefore, ANDA applicants are not able to obtain samples for development and comparison in conducting a bioequivalence study.

A. ACTION REQUESTED

Petitioner requests the FDA to designate ANDA No. 065049 (Clindamycin Phosphate Topical Solution USP, 1% (Pledgets)) as the RS drug for the purpose of FDA evaluation of ANDAs for Clindamycin Phosphate Topical Solution USP, 1% (Pledgets).

B. STATEMENT OF GROUNDS

FDA identifies drug products that have been approved in the Orange Book. To obtain ANDA approval, an applicant must show, among other things, that with respect to a previously approved drug product listed in the Orange Book (i.e., a listed drug), the generic drug product

has the same active ingredient(s) in the same strength, dosage form and route of administration, has essentially identical labeling, and is bioequivalent.

An RLD is the listed drug identified by FDA as the drug product on which an ANDA applicant should rely in seeking approval of an application. A RS is the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an *in vivo* bioequivalence study required for approval of the ANDA. However, when there are "limited or no quantities of the reference standard in distribution," a potential ANDA applicant may request designation of a new RS through the submission of a citizen petition. See FDA Draft Guidance for Industry, Referencing Approved Drug Products in ANDA Submissions (Jan. 2017).

The Orange Book lists NDA No. 050537 Cleocin® (Clindamycin Phosphate Topical Solution USP, 1% (Pledgets)), owned by Pharmacia and Upjohn Co. as the RLD for Clindamycin Phosphate Topical Solution USP, 1% (Pledgets). There is no separate RS designated. There are currently four drug products listed for Clindamycin Phosphate 1% with a swab dosage form (i.e., pledget). See Attachment 1 (Current Orange Book Listing for Clindamycin Phosphate Topical 1% (Pledgets)).

Our client has been unable to obtain Cleocin® samples for the last several months because they are unavailable on the market with no anticipated availability date. Our client, therefore, is unable to obtain a sufficient quantity of RLD from the marketplace to establish bioequivalence . Our client is not aware of information to suggest that the RLD has been removed for reasons of safety or effectiveness.

The petitioner requests FDA to designate ANDA No. 065049 Clindamycin Phosphate Topical Solution USP, 1% (Pledgets) by Perrigo New York, Inc. as a RS drug. ANDA No. 065049 is identified by FDA as a therapeutic equivalent to the RLD. See Attachment 1 (Current Orange Book Listing for Clindamycin Phosphate Topical 1% (Pledgets)). It is also the market leader for Clindamycin Phosphate Topical 1% (Pledgets), based on units sold. See Attachment 2 (IMS data indicating units sold of Clindamycin Phosphate Topical 1% (Pledgets)).

Petitioner is aware of a citizen petition submitted by Macleod's Pharmaceuticals Limited on September 25, 2019 seeking designation of NDA #064050, Clindamycin phosphate topical solution 1% of Perrigo New York Inc., as a reference standard. The petition concerns a topical solution dosage form, however, and not a swab (pledget) dosage form. FDA has published separate guidance documents on requirements for *in vivo* bioequivalence studies for clindamycin phosphate in the swab dosage form and in a solution dosage form. See FDA Draft Guidance, Clindamycin Phosphate (Swab/Topical) (Apr. 2011) (Attachment 3) and FDA Draft Guidance, Clindamycin Phosphate (Solution/Topical) (Apr. 2011) (Attachment 4).

For these reasons, the Petitioner requests that FDA designate in the Orange Book Clindamycin Phosphate Topical Solution USP, 1% (Pledgets) approved under ANDA No. 065049 as a RS.

C. ENVIRONMENTAL IMPACT

The actions requested in this petition are subject to categorical exclusion under 21 C.F.R. § 25.31 to submit an environmental assessment under § 25.40.

D. ECONOMIC IMPACT

According to 21 C.F.R. § 10.30(b)(3), the petitioner will, upon request by the Commissioner, submit economic impact information.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Very truly yours,

HUSCH BLACKWELL LLP

By: _____
Seth A. Mailhot
Partner

Attachments:
Attachment 1 – Current Orange Book listing for Clindamycin Phosphate Topical 1% (Pledgets)
Attachment 2 – IMS data showing units sold of Clindamycin Phosphate Topical 1% (Pledgets)
Attachment 3 – FDA Draft Guidance, Clindamycin Phosphate (Swab/Topical) (Apr. 2011)
Attachment 4 – FDA Draft Guidance, Clindamycin Phosphate (Solution/Topical) (Apr. 2011)