August 12, 2019

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

CITIZEN PETITION

Dear Sir or Madam:

The undersigned, Lachman Consultant Services, Inc. (Lachman Consultants), submits this petition pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDC Act), and 21 CFR 10.20 and 10.30 to request that the Commissioner of the Food and Drug Administration (FDA) amend the *Approved Drug Products with Therapeutic Equivalence Evaluation* (the Orange Book), along with Drugs@FDA, to designate **either** Permethrin Cream 5% ANDA 074806 held by Actavis Laboratories, Inc. **or** Permethrin Cream 5% ANDA 076369 held by Perrigo Israel Pharmaceuticals, Ltd. as a new Reference Standard (RS) product. The product currently designated as the RS is the Reference Listed Drug (RLD) ELIMITE™ (permethrin) Cream 5% held by Mylan Pharmaceuticals, Inc. under NDA 019855.

A. Action requested

Lachman Consultants requests that the FDA designate **either** Permethrin Cream 5% ANDA 074806 held by Actavis Laboratories, Inc. **or** Permethrin Cream 5% ANDA 076369 held by Perrigo Israel Pharmaceuticals, Ltd. as the Reference Standard product.

Statement of Grounds

The FDA maintains a list of drug products, referred to as the Orange Book, containing all FDA- approved drug products. The FDA has decided through the comment and rule-making process that it will designate all Reference Listed Drug and Reference Standard products. The designated RLD and/or RS selected by the FDA is the reference product upon which an applicant relies in seeking approval of its generic equivalent.

Currently, the electronic Orange Book identifies ELIMITE™ (permethrin) Cream 5% NDA 019855 held by Mylan Pharmaceuticals, Inc. (Mylan) as the RLD and RS. Based on information available in the marketplace, Mylan is not currently distributing its ELIMITE™ (permethrin) Cream 5% under NDA 019855. As a result, any applicant seeking to submit a generic equivalent that identifies Mylan's drug product as the Reference Standard is precluded from doing so because the Mylan product is not available or is in distribution so limited that a potential applicant is unable to obtain a sufficient quantity for in vivo bioequivalence testing. This lack of drug product availability provides a sound basis for designating **either** Permethrin Cream 5% ANDA 074806 held by Actavis Laboratories, Inc. **or** Permethrin Cream 5% ANDA 076369 held by Perrigo Israel Pharmaceuticals, Ltd. as the Reference Standard product. Both

of these drug products are available on the market and are identified as therapeutic equivalents to the RLD in the Orange Book.

The lack of available RS product prevents the filing of generic equivalents. For this reason, the Petitioner, Lachman Consultants, respectfully requests FDA to designate **either** Permethrin Cream 5% ANDA 074806 held by Actavis Laboratories, Inc. **or** Permethrin Cream 5% ANDA 076369 held by Perrigo Israel Pharmaceuticals, Ltd. as the Reference Standard product.

B. Environmental Impact

Lachman Consultants claims a categorical exclusion under 21 CFR 25.31(a) from the requirements to submit an environmental assessment.

C. Economic Impact Statement

Lachman Consultants will, upon request by the commissioner, submit economic impact information, in accordance with 21 CFR 10.30(b).

D. 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.

If there are any questions concerning this citizen petition, please contact undersigned by telephone at (516) 972-8664 or via email at a.schutte@lachmanconsultants.com.

Sincerely,

Amy Schutte

Digitally signed by Amy Schutte
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