Perrigo
Pharmaceuticals

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01 October 2015

Docket No.
FDA-2006-P-0014

Food and Drug Administration
Document Management Branch, Room 1061
5630 Fishers Lane
Rockville, MD 20852

Subject: Withdrawal of Docket No. FDA-2006-P-0014

Dear Sir or Madam,

Reference is made to the unresolved Citizen Petition (Docket No. FDA-2006-P-0014) submitted by Paddock Laboratories, Inc. on 14 September 2006. In response to the correspondence received from the Agency on 30 September 2015 Paddock agrees that this petition does not raise a significant or current public health issue and does not reflect Paddock's current views and therefore, Paddock formally requests the withdrawal of Docket No. FDA-2006-P-0014.

Paddock requests that all information in this file be treated as confidential within the meaning of 21 CFR 314.430 and that no information from the file be publicly released, through FOI or any other means, without our written consent.

Any further communication concerning this docket should be sent to me at: 3940 Quebec Avenue North, Minneapolis, Minnesota 55427. I may be contacted by phone at (763) 732-0235, fax at (763) 732-0509 or email at regulatoryaffairs.USA@perrigo.com.

Best Regards,

Maureen Rath

Paddock Laboratories, LLC, a Perrigo Company
Maureen Rath
Senior Manager, Regulatory Affairs

Perrigo Pharmaceuticals
3940 Quebec Avenue N.
Minneapolis, MN 55427

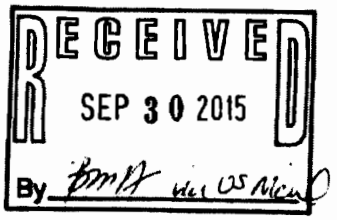
DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 8, 2015

Todd M. Delehant, Ph. D.
Paddock Laboratories, Inc.
3940 Quebec Avenue North
Minneapolis, Minnesota 55427-1237



Docket No. FDA-2006-P-0014

Dear Dr. Delehant:

According to the records of the U.S. Food and Drug Administration's (FDA or Agency) Division of Dockets Management, the petition referenced above has not been resolved.[1]

As part of the Agency's efforts to reduce the backlog of unresolved citizen petitions, the Center for Drug Evaluation and Research (CDER or Center) has reviewed the unresolved petitions assigned to it for action. One goal of this review is to identify petitions submitted more than 5 years ago that petitioners may believe are no longer timely. CDER believes that having to respond to these old petitions diminishes the Center's capacity to address in a timely fashion pressing public health issues. Therefore, these petitions have a lower priority, and it is unlikely the Center will have the resources to respond to them soon.

This petition referenced above was submitted more than 5 years ago by Paddock Laboratories, Inc. and a review of the docket shows that the petition has been inactive for many years. CDER believes that this petition does not raise a significant and current public health issue, and given the length of time since the petition was submitted, we are uncertain as to whether the views expressed in the petition reflect the current views of the petitioner.

Accordingly, we have enclosed a copy of the petition and would appreciate it if you would review it and respond to the docket number listed above if you wish to keep this petition active. Your response should reference the docket number and may be sent to the Food and Drug Administration, Dockets Management Branch, Room 1061, 5630 Fishers Lane, Rockville, MD 20852; or submitted electronically at www.regulations.gov. If we do not receive a written response from you within 30 days from the date of this letter, a copy of this letter will be filed in Docket No. FDA-2006-P-0014 with instructions that the petition be considered to have been voluntarily withdrawn without prejudice to resubmission.

If you have any questions, please contact Lauren Ciurca of my staff at 301-796-8771. Thank you

[1] This petition was originally assigned docket number 2006P-0387/CP1. The number changed to FDA-2006-P-0014 as a result of FDA's transition to its new docketing system (Regulations.gov) in January 2008.

14 September 2006

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Clobetasol Propionate Foam, 0.05%

CITIZEN PETITION

Dear Sir or Madam:

The undersigned is submitting this petition in quadruplicate, under Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) and in accordance with 21 CFR §10.20, §10.30, and §314.93 to request that the Commissioner of the Food and Drug Administration declare that the drug product Clobetasol Propionate Foam, 0.05%, is suitable for consideration in an Abbreviated New Drug Application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Clobetasol Propionate Foam, 0.05% is suitable for submission in an ANDA.

B. Statement of Grounds

The reference listed drug (RLD), upon which this petition is based, is Olux® (clobetasol propionate) Foam, 0.05%. The petitioner seeks a change in dosage form from that of the RLD. The change would be from a hydrocarbon propellant pressurized aerosol foam to a non-propellant mechanical pump-produced foam.

Under section 505(j)(2)(C) of the Act and 21 CFR §314.93(b), an ANDA suitability petition may be submitted for a change in dosage form.

The Federal Food, Drug, and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage form from that of the RLD provided the FDA has approved a petition that proposed filing such an application.

The reference listed drug, Olux® (clobetasol propionate) Foam, 0.05%, contains clobetasol propionate, USP, a synthetic corticosteroid, for topical dermatologic use. Olux® Foam is the subject of NDA 21-142, which was approved on 26 May 2000. Connetics Corporation, Palo Alto, California is the NDA holder. Each gram of Olux® Foam contains 0.5 mg clobetasol propionate, USP, in a thermolabile foam. Olux® Foam is dispensed from an aluminum can

2006P-0387 CP1

same concentration on a weight basis, administered under the same conditions of use as the RLD; see 21 CFR §314.93(d)(2).

The proposed drug product will be shown to be bioequivalent to the reference product in accordance with FDA usual criteria.

Investigations should not be necessary to show the safety and effectiveness of the proposed product, as the product only differs in dosage form from currently approved products; see 21 CFR §314.93(e)(1)(i).

In the petitioner's view, this ANDA suitability petition does not represent any new or novel issues.

Applicability of Pediatric Research Equity Act

The Pediatric Research Equity Act (PREA), which was signed into law on 02 December 2003, requires that applications for approval of a new active ingredient, indication, dosage form, dosing regimen, or route of administration contain a pediatric assessment unless the applicant has obtained a waiver or deferral under Section 505(B)(b) of the Act. If the pediatric assessment requires the conduct of clinical studies, the application will be ineligible for submission as an ANDA.

The petitioner hereby requests that a full waiver of the requirement to conduct pediatric studies be granted in respect to the proposed product that is the subject of this petition. The following information supports the request for a waiver:

1. The RLD labeling includes the statement in the Indications and Usage section "Use in children under 12 years of age is not recommended". This demonstrates that according to the labeling of the RLD, the product is not intended for use in pediatric patients.
2. The petitioner, by way of an ANDA submitted pursuant to this petition, after its approval, will seek approval for the same conditions of use as given in the approved labeling for the RLD. Thus, the proposed product will not represent any meaningful therapeutic benefit over the presently available dosage forms of clobetasol propionate.

Thus, because the requirements for the conduct of pediatric studies were waived for Connectics, Olux® Foam 505(b)(2)[2], there should be no need to conduct additional studies for the proposed product for which this petition is being submitted.

For the reasons cited above, the petitioner requests that the Commissioner find that a change in dosage form from a hydrocarbon propellant pressurized aerosol foam to a non-propellant mechanical pump-produced foam containing clobetasol propionate, 0.05%, raises no questions of safety or effectiveness. The petitioner requests that the Commissioner approve the petition accordingly.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR §25.31(a) because approval of this petition will not increase the use of the active moiety. The proposed drug product will not be

Perrigo

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Minneapolis, MN 55427

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