Paddock Laboratories, Inc.

0583 8 APR 25 P12:57

Pharmaceuticals for Medicine, Pharmacy and Science

April 24, 2008

Paddock Laboratories, Inc.
Pharmaceuticals for Medicine, Pharmacy and Science

Mary Lou Freathy, J.D.
Vice President
Quality Services, Regulatory Affairs & Compliance

3940 Quebec Avenue North
Minneapolis, MN 55427 U.S.A.
mlfreathy@paddocklabs.com
www.paddocklabs.com

Direct: 763.732.0479
800.328.5113 ext 479
Cell: 612.801.0073
Fax: 763.546.4842

Jane Axelrad
Associate Director
FDA/CDER
Office of Regulatory Policy
Documents Management
5630 Fishers Lane, Room 1061
Rockville, MD 20852

DESK COPY

Re: PIND 101,370: Clobetasol Propionate Foam, 0.05%
Meeting Request for Resolution of Filing Strategy

Dear Dr. Beitz:

Reference is made to Paddock Laboratories, Inc.'s (Paddock) PIND 101,370 for the above referenced drug product. Reference is also made to the telephone communication with Margo Owens, Lead Regulatory Project Manager, on April 7, 2008. In the telephone communication, Paddock was informed that the April 8, 2008 teleconference was being postponed because the Division was requesting additional information from Paddock as to why an ANDA was not being submitted for this product, even without a pending suitability petition. On April 8, 2008 Paddock submitted the additional information to the Agency. Several follow-up phone calls have been made to Ms. Owens requesting a status update and to date, Paddock's phone calls have not been returned nor has the teleconference been rescheduled.

As additional background, it should be noted that Paddock submitted a suitability petition (Docket no. 2006P-0387) on September 14, 2006, based on the Office of Generic Drugs' (OGD) May 18, 2006 recommendation, seeking the Agency's acceptance that Paddock's Clobetasol Propionate Foam, 0.05% was suitable for submission as an ANDA. Several phone calls were made to OGD requesting a status update; these status calls were not returned. Paddock amended the petition on February 5, 2008 for clarification purposes and to provide the Agency with appropriate examples.

FDA-2006-P-0014

At this time, Paddock is requesting a meeting with the Agency to determine the appropriate filing strategy for the above referenced drug product. Paddock has already missed a first to file opportunity as an ANDA and development of Paddock's product is nearing completion. Paddock believes that enough time has passed and that it is critical that Paddock receive guidance from the Agency as to what application type is appropriate for this product.

This correspondence is also being sent to Jane Axelrad, Elizabeth Dickinson, John K. Jenkins, Helen Winkle and Gary Buehler as a desk copy in order to help facilitate the filing determination.

Should you have any questions or comments regarding this correspondence, please contact me at (763) 732-0479 (telephone) or (763) 546-4842 (fax). I look forward to the Agency's response.

Sincerely,

PADDOCK LABORATORIES, INC.

Mary Lou Freathy
Vice President, Quality, Regulatory Affairs, and Compliance

Desk Copy: Jane Axelrad, Director, Office of Regulatory Policy
Elizabeth Dickinson, Attorney, Office of Chief Counsel
John K. Jenkins, Director, Office of New Drugs
Helen Winkle, Director, Office of Pharmaceutical Science
Gary Buehler, Director, Office of Generic Drugs

Extremely Urgent

This envelope is for use with the following services:

UPS Next Day Air®
UPS Worldwide Express℠
UPS 2nd Day Air®

UPS Worldwide Expedited℠
UPS 3 Da
UPS Sta
UPS Gr
Do
for:

nts on

-5877) or visit UPS.com®.

it limit for
ocuments,
r service
tems other
responding

velope may
alue. There
u can enclose.

tters weighing

FDA/CDER
5630 FISHERS LN
RM 1061
ROCKVILLE MD 20852-1750

P:5 S:BBLUE I:554

554-7000 X

1Z5642361301006078 1500

OMD2PVK MDBUR151 Apr 25 07:27:21 2008
TB 2089 HIP 7.0.6 INT4420

Call

- For
envy
and
is s
tha
rate
- For
be
is n
- Do
ove
UP
to 1
- Do

Order : 1 Customer : JANEAXELRAD

SSCC-18: (00) 0 000057417

BILLING: P/P

MLV 3.06.21 UR078.4V

TRACKING #: 1Z 564 236 13 0100 6078

UPS NEXT DAY AIR SAVER

MD 207 9-78

LTR 1 OF 1

SHIPPING MANAGER
(763) 546-4676
PADDOCK LABS
3940 QUEBEC AVE NORTH
MINNEAPOLIS MN 55427

SHIP JANE AXELRAD
TO: FDA/CDER
OFFICE OF REGU Y POLICY
5630 FISHERS RM 1061
ROCKVILLE MD 2

International Shipping Notice — Carriage hereunder may be subject to the rules relating to liability and other terms and/or conditions established by the Convention for the Unification of Certain Rules Relating to International Carriage by Air (the "Warsaw Convention") and/or the Convention Contract for the International Carriage of Goods by Road (the "CMR Convention"). These commodities, technology or software were exported from the U.S. in accordance with the Export Administration Regulations. Diversion contrary to U.S. law prohibited

100% Recycled fiber
80% Post-Consumer