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*Pharmaceuticals for Medicine, Pharmacy and Science*

April 24, 2008

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



*Pharmaceuticals for Medicine, Pharmacy and Science*

**Mary Lou Freathy, J.D.**  
Vice President

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## 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

Dr. Julie Beitz  
Office of New Drugs  
April 24, 2008  
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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

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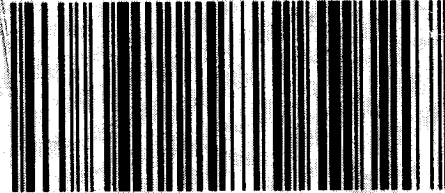
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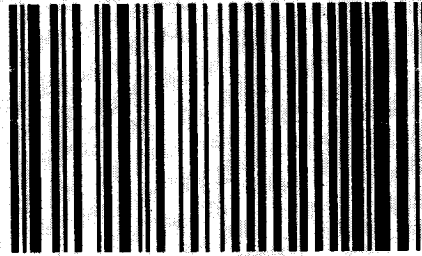
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