

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
76067

ADMINISTRATIVE DOCUMENTS

**REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH**

ANDA Number: 76-067

Date of Submission: Dec. 21, 2000

Applicant's Name: Clay-Park Labs Inc.

Established Name: Mometasone Furoate Ointment USP, 0.1%


Labeling Deficiencies:

1. CONTAINER – 15 g and 45 g
You may delete the period following "Rx only".
2. CARTON 15 g and 45 g
 - a. Please include the lot number and expiration date.
 - b. The product name and strength should also appear on the flap.
 - c. See comment under CONTAINER.
3. INSERT – Include the revision date.

Please revise your labels and labeling, as instructed above, and submit 12 final printed labels and labeling

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes - http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.



Wm. Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

RECORD OF TELEPHONE CONVERSATION

<p>On this date, we contacted Clay-Park Labs, Inc. (CPL) and made reference to their amendment dated November 28, 2001 for ANDA 76-067.</p> <p>We requested that CPL tighten the unknown impurity stability specification of the drug product and the total impurity specification, accordingly, based on the 3 month accelerated and 6 month room temperature data.</p> <p><i>12</i></p> <p>Ms. Edwards will submit the requested information as a telephone amendment, to be faxed with a hard copy to follow in the mail.</p>	<p style="text-align: center;">DATE: 12/13/01</p> <hr/> <p style="text-align: center;">ANDA NUMBER 76-067</p> <hr/> <p style="text-align: center;">TELECON INITIATED BY AGENT</p> <hr/> <p style="text-align: center;">PRODUCT NAME: Mometasone Furoate Ointment USP, 0.1 %</p> <hr/> <p style="text-align: center;">FIRM NAME: Clay-Park Labs, Inc.</p> <hr/> <p style="text-align: center;">FIRM REPRESENTATIVES: Candis Edwards, Director of Regulatory Affairs Munira Rampersand, Project Manager Ala Rupleuge, Manager of Regulatory Affair Vijaya Ramesh, Analytical R & D Manager</p> <hr/> <p style="text-align: center;">TELEPHONE NUMBER: 718-960-9976</p> <hr/> <p style="text-align: center;">FDA REPRESENTATIVES Gil Kang <i>GK 12/18/01</i> James Fan Sarah Ho</p> <hr/> <p style="text-align: center;">SIGNATURES: G.Kang J.Fan <i>JF 12/21/01</i> S.Ho <i>SH 12/21/01</i></p>
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Orig: ANDA 76-067
 Cc: Division File
 Chem. I Telecon Binder