



NDA 50-741/S-003

Stiefel Laboratories, Inc.  
Attn: Mary Jane Carr, Assistant Director, Regulatory Affairs  
Route 145  
Oak Hill, New York 12460

Dear Ms. Carr:

Please refer to your supplemental new drug application dated April 21, 2003, received April 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Duac™ (clindamycin, 1% - benzoyl peroxide, 5%) Topical Gel.

We acknowledge receipt of your submission dated May 14, 2003.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change in labeling specific to the individual carton for the 45 gram trade size unit in accordance with the provisions of 21CFR§314.70(c). Specifically, the supplement provides for the incorporation of additional text 'Attention Pharmacist' and a change to the background color surrounding the storage statement. This includes the addition of the text "To the Pharmacist" preceding the long-term storage statement and the expanded text "Dispensing Instruction for the Pharmacist" preceding the pharmacist dispensing information. In addition, an amendment was submitted to the supplement dated May 14, 2003, which provides for minor editorial changes to reflect the changes in the storage conditions statement to be incorporated into associated labels and labeling. The associated labeling includes a revised package insert, labeling for the 45 gram trade size tube, as well as labeling for the 5 gram professional sample tube and sample packer/carton.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (carton label submitted April 21, 2003, and the package insert, container labels and carton submitted May 14, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-741/S-003." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter

as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>. To expedite review of this patent declaration form, we request you submit an additional copy of the form to this application and to the Center for Drug Evaluation and Research "Orange Book" staff at

Food and Drug Administration  
Office of Generic Drugs, HFD-610  
Orange Book Staff  
7500 Standish Place  
Metro Park North II  
Rockville, MD 20855-2773

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Margo Owens, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

*{See appended electronic signature page}*

Wilson H. DeCamp, Ph.D.  
Chemistry Team Leader  
Division of New Drug Chemistry III  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Wilson H. DeCamp  
10/20/03 10:31:08 AM  
approved