



NDA 50-741/S-004

Ms. Mary Jane Carr
Assistant Director, Regulatory Affairs
Stiefel Laboratories
Route 145
Oak Hill, NY 12460

Dear Ms. Carr:

Please refer to your supplemental new drug application dated May 19, 2003, received May 19, 2003, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Duac (clindamycin phosphate, 1% / benzoyl peroxide, 5%) Gel.

This CBE- 30 supplemental new drug application provides for the use of tubes produced with an (b)(4)-----Duac Topical Gel. This supplement also provides for an additional package size of 20 grams and revised labeling to reflect this change.

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.

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 for the
Division of Dermatologic & Dental Drug Products,
(HFD-540)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Wilson H. DeCamp
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approved