



NDA 20-941/S-006

GlaxoSmithKline Consumer Healthcare, L.P.
Attention: Larry S. Alphas
Manager, US Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054

Dear Mr. Alphas:

Please refer to your supplemental new drug application dated August 22, 2006, received August 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abreva (10% docosanol) topical cream.

We acknowledge receipt of your submission dated January 23, 2007.

Your submission of January 23, 2007 constituted a complete response to our December 21, 2006 action letter.

This supplemental new drug application provided for a new 2 g non-metered pump container-closure system and associated labeling, primary and secondary packaging sites for the new pump, and a change in the benzyl alcohol acceptance criteria for drug product in the new pump.

We have completed our review of this application, as amended. 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 enclosed labeling (immediate container label submitted on August 22, 2006, and the outer carton with Drug Facts and consumer information leaflet label submitted on December 20, 2006), and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-941/S-006.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the flag "New Pump" from the principal display panel six months after introduction into the OTC marketplace.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

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

/s/

Joel Schiffenbauer
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