DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-941/S-009

GlaxoSmithKline Consumer Healthcare
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 8, 2007, received August 8, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abreva® (10% docosanol) cream.

We acknowledge receipt of your submission dated September 21, 2007.

This "Changes Being Effected in 30 days" supplemental new drug application proposes an alternate manufacturing site for the drug product packaged in the 2 g non-metered pump package configuration and labeling changes. The proposed labeling changes include removing the coupon from the consumer information insert, removing the blank panels from the Principal Display Panel – Drug Facts fold-out and the consumer information insert, and changing the country of origin on the outer carton label (Principal Display Panel – Drug Facts fold-out) and the immediate container label.

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 outer carton label (Principal Display Panel – Drug Facts fold-out with consumer information insert) and the immediate container label submitted September 21, 2007, and must be formatted in accordance with the applicable requirements of 21 CFR 201, including 21 CFR 201.66.

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-009**." Approval of this submission by FDA is not required before the labeling is used.

As stated in our May 23, 2007 approval letter for the 2 g non-metered pump package configuration, you must remove the statement "NEW PUMP" from the label 6 months after the labeling bearing this statement was originally introduced to 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, contact Geri Smith, Regulatory Project Manager, at geri.smith@fda.hhs.gov or (301) 796-2204.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Andrea Segal

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