JUL 25 2000

NDA 20-941

Avanir Pharmaceuticals
Attention: James E. Berg
Vice President of Clinical Affairs and Product Development
9393 Towne Centre Drive
Suite 200
San Diego, CA. 92121

Dear Mr. Berg:

Please refer to your new drug application (NDA) dated December 19, 1997, received December 22, 1997, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Abreva (docosanol) Cream, 10% .

We acknowledge receipt of your submissions dated June 6, 12, July 21, and 25, 2000. Your submission of June 6, 2000 constituted a complete response to our May 30, 2000 action letter.

This new drug application provides for the use of Abreva Cream, 10% (docosanol) for cold sore/fever blister treatment.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (immediate container and carton labels submitted July 21, 2000 and amended by your July 25 fax) and must be formatted in accordance with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please 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 ten of the copies on heavy-weight paper or similar material. Alternately, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 20-941." Approval of this submission by FDA is not required before the labeling is used.

You are cautioned not to promote the product as an antiviral or as providing symptomatic relief of cold sores. Promotion of symptomatic benefit should be limited to the information provided in labeling, that the product shortens healing time and duration of symptoms.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Babette Merritt, Project Manager, at (301) 827-2222.

Sincerely,

/S/ 7/25/00

Robert J. DeLap, M.D., Ph.D.
Director Office of Drug Evaluation V
Center for Drug Evaluation and Research