CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20089/S2

APPROVAL LETTER

NDA 19-909/S-003
NDA 18-828/S-010
NDA 20-089/S-002

FEB 26 1992

Mr. Donald A. Knight
Burroughs Wellcome Co.
3030 Cornwallis Road
Research Triangle Park, NC 27709

Dear Mr. Knight:

Please refer to your supplemental New Drug Applications (NDAs) dated October 18, 1990 (19-909/S-003 and 18-828/S-010) and February 11, 1992 (20-089/S-002), submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zovirax (acyclovir) Suspension, Capsules and Tablets, respectively.

In addition, please refer to your letter dated February 11, 1992 in which you agree to do additional post-marketing studies of acyclovir suspension, capsules and tablets in the treatment of chickenpox in normal children as outlined in Appendix C of this submission.

We also acknowledge receipt of your additional communication dated February 24, 1992, in which you further define and reaffirm your commitment to conduct the postmarketing studies referred to in your February 11, 1992 letter. In this communication you also agree to revise Attachment E of the draft labeling submitted in your February 21, 1992 communication as follows:

> **Treatment of Chickenpox:** 20 mg/kg (not to exceed 800mg) orally, 4 times daily for 5 days. "Therapy should be initiated at the earliest sign or symptom."

These supplemental applications provide for the use of Zovirax suspension, capsules and tablets in the treatment of primary varicella infections.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the draft labeling dated February 21, 1992 as revised. Accordingly, these applications, with the labeling revisions above, are approved, effective as of the date of this letter.

These revisions are terms of the supplemental NDA approval. Marketing these products before making the revisions, exactly as requested, in the product's final printed labeling (FPL) may render the products misbranded and an unapproved new drug.

Please submit twelve (12) copies of the FPL when it is available. This submission should be designated for administrative purposes an "FPL Supplement" to the approved NDAs. Approval of the supplement by FDA is not required before the labeling is used.

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

Sincerely yours,

/S/ 2/26/92

David W. Feigal, Jr., M.D., M.P.H.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research