DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-007/S-014, S-015
NDA 21-039/S-013, S-014

GlaxoSmithKline
Attention: Mr. Robert S. Watson
P.O. Box 13398
Five Moore Drive
Research Triangle Park
North Carolina, 27709

Dear Mr. Watson:

Please refer to your supplemental new drug applications dated February 11, 2002, received February 12, 2002 and dated April 24, 2002, received April 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AGENERASE® CAPSULES and AGENERASE® Oral Solution.

We acknowledge receipt of your submission dated August 20, 2002.

The supplemental new drug applications NDA 21-007/S-014, NDA 21-039/S-013 provide for a change in the Carcinogenesis and Mutagenesis section of the AGENERASE® (amprenavir) product labeling based on the results of a two-year carcinogenicity studies in mice and rats.

The supplemental new drug applications NDA 21-007/S-015, NDA 21-039/S-014 provide for the inclusion of information in the AGENERASE® (amprenavir) product labeling regarding co-administration of AGENERASE® (amprenavir) with delavirdine (NDA 21-007/S-015, NDA 21-039/S-014).

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 agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted August 20, 2002, patient package insert submitted August 20, 2002).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 21-007/S-014, NDA 21-039/S-013 and NDA 21-

007/S-015, NDA 21-039/S-014." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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, please contact Destry M. Sillivan, M.S., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
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/

Debra Birnkrant
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NDA 21-039, 21-007