DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-039/SLR017

GlaxoSmithKline
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Benson:

Please refer to your new drug application (NDA) dated June 10, 2005, received June 13, 2005 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AGENERASE® (amprenavir) Oral Solution for treatment of HIV infection.

We acknowledge receipt of your Special Supplement "Changes Being Effected, Labeling" dated June 10, 2005 submitted in response to a letter from the Division dated April 11, 2005.

This "Changes Being Effected" supplemental new drug application updates the WARNINGS and PRECAUTIONS section of the label to include information regarding immune reconstitution syndrome and drug-drug interactions with fluticasone proprionate and trazodone.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling (FPL) submitted with the supplement.

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 Kenny Shade, Regulatory Project Manager**,** at (301)796-1500.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director,
Division of Antiviral Products

Enclosure:

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

/s/

Jeffrey Murray
11/4/2005 10:58:40 AM