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APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-007/SE7-006
21-039/SE7-006

Correspondence

May 9, 2001

DESK COPY

GlaxoSmithKline

GlaxoSmithKline
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Debra Birnkrant, M.D., Acting Director
Division of Antiviral Drug Products
Attn: Document Control Room
Food and Drug Administration
Fourth Floor, HFD-530
9201 Corporate Boulevard
Rockville, MD 20850

Re: NDA 21-007/S-006; AGENERASE® (amprenavir) Capsules
NDA 21-039/S-006; AGENERASE® (amprenavir) Oral Solution
Response to FDA Request/Comment: Labeling and Phase 4 Commitment

Dear Dr. Birnkrant:

Reference is made to the supplemental new drug application for traditional approval of Agenerase submitted on July 13, 2000. Reference is also made to the most recent labeling comments received from Melissa Truffa on May 9, 2001. The purpose of this communication is to provide final draft labeling and a phase 4 commitment for Agenerase Oral Solution as requested by the Division.

Labeling was discussed with the Division through a series of communications on March 30, April 11, April 30, May 2, May 3, May 4, May 7, and in teleconferences on May 4 and May 7, 2001. The following phase 4 commitment is agreed for Agenerase Oral Solution.

GlaxoSmithKline will commit to the submission of data that will address concerns about the potential for toxicity related to the high propylene glycol content of Agenerase (amprenavir) oral solution. These data will include propylene glycol concentration data and adverse events reported from clinical trials and from post-marketing reports, as outlined in correspondence of May 8, 2000. This information will be provided within 60 days of receiving traditional approval of Agenerase.

The revised package inserts are provided as attachments to this letter, with changes indicated by revision marks on one copy. In addition clean copies of each insert are attached. The package inserts are provided as Word files via email to Melissa Truffa and on diskette with this submission.

This submission is provided in duplicate with four additional desk copies provided directly to Ms. Truffa. Please contact me at 919-483-6972 if there are any questions or concerns. We would like to thank you and the review team for their time in completing the review of this application.

Sincerely,

Robert S. Watson
Director
Regulatory Affairs