



NDA 20-972/S-024

NDA 21-360/S-009

GlaxoSmithKline
Attn: Crystina Cupp, Ph.D.
Manager, Global Regulatory Sciences
P.O. Box 13398
Five Moore Drive
Research Triangle Park
North Carolina 27709

Dear Dr. Cupp:

Please refer to your supplemental new drug applications dated, April 21, 2004 and received April 21, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sustiva[®] (efavirenz) tablets and capsules.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for changes in the PRECAUTIONS; Pregnancy section of the package insert.

We completed our review of these supplemental new drug applications, they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 8, 2004.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

NDA 21-003/S-006

NDA 21-004/S-007

Page 2

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 Vasavi Reddy, RPh, Regulatory Project Manager, at (301) 827-2413.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office Drug Evaluation IV
Food and Drug Administration

Attachment:

FPL

**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
10/22/04 03:10:37 PM