DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 10 1998

TRANSMITTED VIA FACSIMILE

Nicholas L. Teti
President
DuPont Pharmaceuticals Company
Chestnut Run Plaza, Maple Run
974 Centre Road
Wilmington, DE 19805

Re: NDA 20-972 Sustiva (efavirenz) capsules
Macmis # 7375

Dear Mr. Teti:

The Division of Drug Marketing, Advertising, and Communications ("DDMAC") is seriously concerned about DuPont Pharmaceuticals Company's ("DuPont") promotion of Sustiva (efavirenz) capsules, in violation of the Federal Food, Drug, and Cosmetic Act, and regulations promulgated thereunder. DuPont has repeatedly violated 21 C.F.R. Part 314, Subpart H-Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses, in its promotion of Sustiva. Sustiva received accelerated approval from the Food and Drug Administration on September 17, 1998. Drugs approved pursuant to Subpart H are subject to certain requirements, such as that stated in section 314.550, regarding promotional materials. Pursuant to section 314.550, sponsors must submit promotional materials to DDMAC prior to the time of expected dissemination. Compliance with section 314.550 is not optional.

Notwithstanding these regulatory requirements, on September 24, 1998, DuPont disseminated promotional materials for Sustiva prior to submitting such materials to DDMAC. In a letter dated October 2, 1998, DDMAC stated its concern with DuPont's apparent lack of compliance with regulations for promoting drugs that were approved under accelerated approval. On November 30, 1998, and December 1, 1998, in promotion of Sustiva, and contrary to section 314.550, DuPont, again, disseminated materials prior to submission of such to DDMAC.

DDMAC is seriously concerned about DuPont's flagrant disregard of section 314.550. Such actions may raise serious public health and safety issues, and denigrate the safeguards associated with drugs subject to conditions of accelerated approval. Furthermore, DuPont's failure to respond to DDMAC's concerns illustrates DuPont's lack of a good faith effort towards compliance with the law.

Consequently, DuPont should respond to this letter on or before December 18, 1998. Should DuPont have any questions, please contact the undersigned by facsimile at (301) 594-6771, or by mail at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857. In all future correspondence regarding this matter, please refer to MACMIS ID # 7375 and the NDA number. As a reminder, only written communications are considered official.

Sincerely,

Norman Drezin, R.Ph., J.D.
Deputy Director
Division of Drug Marketing,
Advertising and Communications

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