DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL - 2 1997

TRANSMITTED VIA FACSIMILE

Dawn Watson, R.Ph.
DRA Manager
Drug Regulatory Affairs
Boehringer Ingelheim Pharmaceuticals Inc.
900 Ridgebury Road, P.O. Box 368
Ridgefield, Connecticut 06877

RE: NDA 20-636
Viramune (nevirapine)
MACMIS ID #5389

Dear Ms. Watson:

Reference is made to Boehringer Ingelheim Pharmaceuticals, Inc.'s (BIPI) May 2, 1997, submission of a press release discussing the results of a study in HIV-infected infants and children for Viramune. This press release was distributed on May 7, 1997, by BIPI. The Division of Drug Marketing, Advertising and Communications (DDMAC) find this press release to be in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations for the following reasons:

- The press release is misleading because it overstates the efficacy of Viramune by claiming that this study confirms the efficacy and sustained tolerability of a triple combination in vertically-HIV-infected infants and children. Further, the press release fails to present that the safety and efficacy of Viramune in pediatric patients have not been established, as contained in Viramune's approved product labeling. It also fails to present the indication and warnings about Viramune's use.

- The press release is misleading because it implies that the combination of Viramune with AZT and ddI is effective in treating HIV infection in the central nervous system. However, there are no adequate clinical efficacy data to support this claim.

- The press release fails to provide Viramune's WARNING about rash and Steven-Johnson syndrome and that these reactions have occurred in pediatric patients.

- The press release was disseminated prior to the 30 day period for the Agency to comment, as required by 21 CFR §314.550.

The Division of Drug Marketing, Advertising and Communications (DDMAC), has reviewed BIPI's May 29, 1997, letter explaining the circumstances surrounding the dissemination of this press release and the corrective measures taken by BIPI. Since BIPI stopped the distribution of the press release on May 9, 1997, DDMAC considers this matter closed. However, DDMAC will continue to evaluate BIPI's compliance with the regulations and may determine that remedial measures will be necessary to fully correct the false and/or misleading messages resulting from BIPI's violative conduct.

If BIPI has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all correspondence related to this matter, please refer to MACMIS ID #5389, in addition to the NDA number.

Sincerely,

Leah Palmer, Pharm.D.
Branch Chief
Division of Drug Marketing,
Advertising and Communications