DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

**TRANSMITTED VIA FACSIMILE**

JUL 16 1999

Ellen F. Wallace, Ph.D.
Manager, Regulatory Affairs
Gilead Sciences
333 Lakeside Drive
Foster City, CA 94403

Re: adefovir dipivoxil
Macmis # 8117

Dear Dr. Wallace:

The Division of Drug Marketing, Advertising, and Communications ("DDMAC") has reviewed a press release disseminated by Gilead Sciences ("Gilead") in support of its drug adefovir dipivoxil. After reviewing the press release we have determined that Gilead is promoting adefovir dipivoxil prior to its approval for marketing. Such conduct violates the Federal Food, Drug, and Cosmetic Act, and applicable regulations.

Adefovir dipivoxil has investigational new drug status with the Food and Drug Administration. The regulations at 21 C.F.R. 312.7(a) include that a "sponsor or investigator, . . . shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug." The intent of this regulation is not to inhibit the exchange of scientific findings. "Rather [the intent] is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation, and to preclude commercialization of the drug before it is approved for commercial distribution."

On June 29, 1999, Gilead issued a press release that made conclusions that promote the effectiveness of adefovir dipivoxil. Specifically, Gilead concluded (not all inclusive) the following: " . . . data suggest that therapy with adefovir dipivoxil results in antiviral activity in treatment-experienced patients who have developed resistance to commonly used antiretroviral medications." Furthermore, the press release was promotional in tone.

Gilead should immediately discontinue the dissemination of all materials that make claims of effectiveness or safety for adefovir dipivoxil. In addition, you should acknowledge receipt of this letter by July 30, 1999. Further, you should describe plans to discontinue the use of the above referenced press release and any similar violative promotional activities, and indicate the date on which Gilead has ceased all promotion of adefovir dipivoxil.

Please direct your response to 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 # 8117 . As a reminder, only written communications are considered official.

Sincerely,

/S/

Sherrie Shade, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications