DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR - 1 1999

TRANSMITTED VIA FACSIMILE

Katrina Garcia
Regulatory Affairs
Amgen, Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789

RE:
Abarelix-Depot
MACMIS ID #7776

Dear Ms. Garcia:

As part of its routine monitoring and surveillance activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of a press release for Aberelix, disseminated by Amgen, Inc. (Amgen), that is in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and its implementing regulations. DDMAC specifically refers to the press release issued on March 10, 1999, entitled "Amgen and Praecis Form Collaboration to Develop and Commercialize Phase 3 Drug for Prostate Cancer and Other Disorders." *This press* release is considered promotional labeling for Aberelix and is in violation of the Act for the following reasons.

Pre-Approval Promotion

Section 21 CFR 312.7 states, among other things, that an investigational new drug may not be promoted as being safe or effective for the uses under investigation. Amgen's March 10, 1999, press release is considered to be violative because it promotes the safety and efficacy of Aberelix, an investigational new drug. These claims include statements about the Aberelix's intended use in the treatment of prostate cancer and other conclusions about the safety and efficacy of the drug such as:

"Aberelix is the first of a new class of drugs that more rapidly reduces the levels of testosterone and estrogen and represents a potential advance for patients because it acts more quickly and may eliminate some of the adverse events of existing drugs."

"Aberelix has been shown in clinical trials to halt the production of hormones quickly and without the surge and resulting clinical flare associated with hormonal superagonists."

In order to address these objections, DDMAC recommends that Amgen take the following actions:

1. Immediately discontinue the use of this, and all other promotional materials for Aberelix that contain the same or similar violations.

2. Provide to DDMAC, in writing, Amgen's intent to comply with #1 above. Your response should be received by April 15, 1999.

3. This response should include a list of all similarly violative promotional materials and Amgen's method for discontinuing their use.

If Amgen has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Amgen that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #7776 in addition to the IND number.

Sincerely,

Mark W. Askine, R.Ph.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications