DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 21 1999

TRANSMITTED VIA FACSIMILE

Sydney A. Gilman
Director, Regulatory Affairs
Amylin Pharmaceuticals, Inc.
9373 Towne Center Drive
San Diego, California 92121

RE:
Pramlintide
MACMIS ID #7518

Dear Mr. Gilman:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a press release for pramlintide, disseminated by Amylin Pharmaceuticals, Inc. (Amylin), 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 January 11, 1999, announcing Amylin's filing strategy for pramlintide and new clinical data from phase 3 trials. This press release is considered promotional labeling for pramlintide 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. The press release in question is considered to be violative because it promotes the safety and efficacy of pramlintide, an investigational new drug. These claims include statements about the drug's intended use in the treatment of type 1 and type 2 diabetes and other claims, such as:

> "...patients who derived substantial benefit in terms of glucose control from pramlintide can be identified by their glucose response at four weeks of therapy."
>
> "...Amylin released data demonstrating pramlintide's durability of effect over a two-year study period."

"These patients...continued to realize clinically important benefits from pramlintide therapy..."

"...patients who respond to pramlintide may achieve the benefit of long term improved glucose control."

"New information has also been gleaned from the data...indicating a potential effect of pramlintide on bone metabolism in post-menopausal women with type 1 diabetes."

"...the addition of pramlintide to patients' insulin regimen may lead to positive effects on bone metabolism. This finding is potentially important in view of the...observation that female patients with type 1 diabetes have decreased bone mass referred to as 'diabetic osteopenia.'"

"The company has pioneered research of the hormone amylin, which is believed to play an important role in metabolic control and is missing or deficient in millions of people with diabetes."

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

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

2. Provide to DDMAC, in writing, Amylin's intent to comply with #1 above. Your response should be received by February 4, 1999.

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

If Amylin 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 Amylin that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #7518 in addition to the IND number.

Sincerely,

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