DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

SEP 17 1998

Shannon Williams, Ph.D.
Associate Director, Regulatory Affairs
Otsuka America Pharmaceutical, Inc.
Regulatory Affairs Department
2440 Research Boulevard
Rockville, MD 20850

RE:

Pletal (cilostazol) Tablets
MACMIS ID# 7072

Dear Dr. Williams:

As part of its routine monitoring activities, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a journal advertisement (ID 5023) for Pletal, submitted by Otsuka America Pharmaceutical, Inc. (Otsuka) under cover of Form FDA 2253. DDMAC has determined that this advertisement is in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Specifically, this journal advertisement promotes an unapproved new drug.

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. Therefore, DDMAC usually considers pre-approval promotion of drug products to be violative. However, DDMAC has traditionally recognized two methods in which sponsors may discuss products under FDA review, without making promotional claims of safety or efficacy that are prohibited by the Act.

The first method of permissible pre-approval promotion is "institutional promotion." Institutional advertisements state that a particular drug company is conducting research in a certain therapeutic area. The advertisement may not suggest any particular drug by name (proprietary or established) or otherwise suggest that a particular drug will soon be approved for use in the therapeutic area under discussion.

The second method of permissible pre-approval promotion is "coming soon" advertisements. Coming soon advertisements announce the name of a new product that will be available soon, but do not make written, verbal, or graphic representations or suggestions concerning the safety, efficacy, or intended use of the product.

This advertisement is not considered an institutional advertisement because it makes claims or representations concerning the efficacy of a specific new product, including its intended use. The ad states that a new therapy, developed by Otsuka, will be used for the treatment of patients with intermittent claudication and implies a beneficial clinical effect for this new therapy in patients' ambulatory capability. Although the ad does not mention Pletal by name, there is a clear association with Pletal by Otsuka's dissemination of the journal ad, and Otsuka's description of the intended use and implications for clinical benefit for the product. Specifically, the journal ad makes the following statements:

- How far will Sadie go in her new shoes? Only as far as her legs will carry her.
- A new therapy for intermittent claudication is coming soon from Otsuka America Pharmaceutical, Inc.
- ...for life's important steps.

Otsuka should immediately discontinue use of this journal ad and other promotional materials that are similarly violative. Please respond in writing by October 1, 1998, with your intent to comply with the above. Address your response to the undersigned 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 Otsuka that only written communications are considered official.

In all future correspondence regarding the issues raised in this letter, please refer to MACMIS ID # 7072 in addition to the NDA numbers.

Sincerely,

Janet Norden, MSN, RN
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications