



**TRANSMITTED BY FACSIMILE**

Kenneth Palmer, M.S., Associate Director  
Drug Regulatory Affairs  
Sanofi-Synthelabo Inc.  
90 Park Avenue  
New York, New York 10016

**RE: NDA 20-839**  
Plavix (clopidogrel bisulfate) 75 mg Tablets  
MACMIS ID#: 10107

Dear Mr. Palmer:

This letter concerns Sanofi-Synthelabo Inc.'s (Sanofi) dissemination of a direct-to-consumer (DTC) television broadcast advertisement (ad) for Plavix Tablets (i.e., 60 second direct response DRTV "Grandpa"/69202885). The Division of Marketing, Advertising, and Communications (DDMAC) reviewed this ad as part of its monitoring and surveillance program and concludes that it is misleading and fails to comply with regulatory requirements. Therefore, this ad violates the Federal Food, Drug, and Cosmetic Act and applicable regulations. Our specific objections follow.

Misleading Minimization of the Role of the Physician in the Prescribing Process

The broadcast ad is misleading because it minimizes the role of the doctor in determining whether Plavix is the appropriate medication to prescribe for the patient's condition. The narrative spoken by the "patient" (an actor portraying a grandfather) lacks any clear and prominent mention of his need to talk to a doctor in deciding if Plavix is right for him (e.g., "I talked to my doctor about Plavix" or "Ask your doctor if Plavix is right for you"). The lack of this disclosure, in combination with the overall tone of the ad, undermines the prescription-only status of Plavix by implying that the patient alone, rather than in consultation with a health care professional, weighs the product's benefits and risks in deciding if Plavix is appropriate. The overall presentation suggests that the patient merely needs to call a toll-free phone number to receive product information and make arrangements for getting the drug. Furthermore, this misleading impression is not sufficiently remedied by the one-time reference to Plavix as a "prescription pill," or to the SUPER "Talk to your doctor" displayed later in the ad while risk information is being discussed.

Failure to Fulfill "Adequate Provision" Through Insufficient Presentation

The broadcast ad does not fulfill the regulatory requirement for ensuring "adequate provision" for disseminating the approved product labeling. One component of "adequate provision" is the inclusion of a disclosure that healthcare providers, such as doctors, are an additional source of drug product information. The SUPER "Talk to your doctor" appears during the description of product risk

information but lacks the needed context to communicate that the physician is a source of product information.

Sanofi should immediately cease running this broadcast ad for Plavix and cease using any other promotional materials that contain the same or similar presentations. We should receive your written response no later than June 22, 2001, and it should list any similarly violative materials, with a description of your method of discontinuation and the discontinuation date.

Your response should be directed to Andrew S.T. Haffer, Pharm.D., by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm 17-B-20, 5600 Fishers Lane, Rockville, Maryland 20857. We remind Sanofi that only written communications are official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID# 10107 in addition to the NDA number.

Sincerely,

*{See appended electronic signature page}*

Joan Hankin, J.D.  
Consumer Promotion Analyst  
Division of Drug Marketing,  
Advertising, and Communications

**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**

/s/

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Joan Hankin  
6/8/01 10:42:23 AM

# PLAVIX

"DRTV GRANDPA"  
DRTV :60 5/16/2001



**GRANDPA VO:**  
If you've had a heart attack...



...or a stroke, the last thing you need is another one...



...sneaking up on you.



In my case, I had a heart attack.



Then I heard about PLAVIX. So I called for more information...



...and learned that PLAVIX is a prescription pill that can help...



...protect you from a heart attack or stroke, if you've recently had one, or if you have...



...poor circulation in the legs causing pain.



**ANNCR VO:**  
Call now 1-888-681-1224...



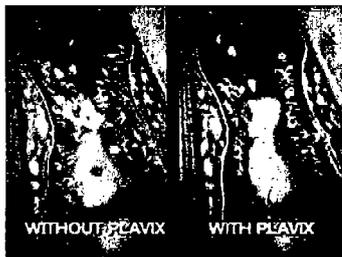
...to receive a free package of valuable information...



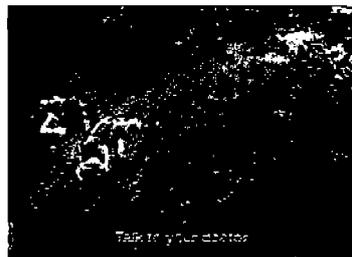
...about treatment options.



PLAVIX is proven to help keep blood platelets from sticking together...



...and forming clots, which helps keep your blood flowing. This can help protect you from...



...another heart attack or stroke. If you have a medical condition that is causing bleeding...



...such as a stomach ulcer, you should not use PLAVIX.



Side effects include itching, rash, diarrhea and bruising.



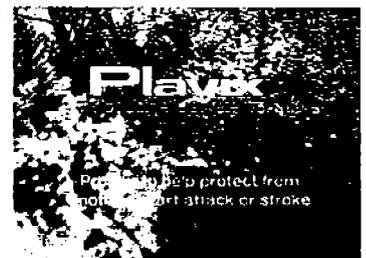
Additional rare but serious side effects could occur.



Call now to learn more.  
1888-681-1224



**GRANDPA VO:**  
Taking PLAVIX once a day helps protect me.



Plavix Story Boards  
69-202885