



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 8 2005

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Rita F. Redberg, M.D., M.Sc., F.A.C.C.
Director, Women's Cardiovascular Services
UCSF National Center of Excellence in Women's Health
505 Parnassus Avenue, Suite M-1180
School of Medicine, Division of Cardiology
San Francisco, CA 94143-0124

Re: Docket No. 2005P-0107/CP1

Dear Dr. Redberg:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition filed on March 17, 2005. Your petition requests that the Agency revise the labeling on glycoprotein IIb/IIIa inhibitors to reflect the adverse event risk in women when these drugs are used for acute coronary syndrome in women not routinely scheduled to undergo early coronary revascularization. The petition also asks the Agency to hold an advisory committee meeting on this subject.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2005P-0107

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