DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

AUG 8 2003

Allen H. Heller, M.D.
Head of Global Research and Development
Bayer HealthCare LLC
36 Columbia Road
P.O. box 1910
Morristown, New Jersey 07962-1910

Re: Docket No. 77N-0094
Comment No. CP16

Dear Dr. Heller:

This is in reference to your citizen petition (CP-16) dated February 11, 2003, filed under Docket No. 77N-0094 in the Dockets Management Branch. The petition requests that the agency amend the Final Rule for Professional Labeling for Aspirin (21 CFR 343.80) to include the use of 75 to 325 milligrams aspirin for the primary prevention of myocardial infarction in those individuals at sufficient risk.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. See 21 CFR 10.30(e). This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of the existence of other priorities, the Agency is unable to provide a response to the petition at this time.

If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFD-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852

Sincerely yours,

Janet Woodcock
Director,
Center for Drug Evaluation and Research

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