



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

JUL 28 2005

William L. McComb  
President  
McNeil Consumer & Specialty Pharmaceuticals  
7050 Camp Hill Road  
Fort Washington, PA 19034

Re: Docket No. 2005P-0048/CP1

Dear Mr. McComb:

This letter is in reference to your citizen petition (CP1) dated January 31, 2005, filed under Docket No. 2005P-0048 in the Division of Dockets Management. The petition requests that the agency change the professional labeling for aspirin dosing under 21 CFR 343.80 to 75-150 mg/day for secondary cardiovascular prevention, and 50-150 mg/day for secondary cerebrovascular prevention.

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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

Steven Galson, M.D.

Acting Director

Center for Drug Evaluation and Research