



Document Management Branch  
U.S. Food and Drug Administration  
Department of Health and Human Services  
Room 1061, HFA-305  
5630 Fishers Lane  
Rockville, MD 20857

Re: National Stroke Association final comments to  
Docket #2005P-0048/CPI  
Professional Labeling for Aspirin Dosing for  
Secondary Cerebrovascular Prevention

To Whom It May Concern:

Since our initial letter dated May 23, 2005, the National Stroke Association has followed with great interest the subsequent comments and data presented regarding the need to change professional labeling for aspirin dosing.

As a result, we invited all members of our prevention advisory board, recognized thought leaders in the field of cerebrovascular prevention, to review and comment on all data presented to date, and all known data currently available. The consensus of the group is that the numerous interpretations of the data presented is largely due to the variety of trials from which the data was derived, and that until data becomes available from a trial designed to measure the efficacy of distinct, specific low doses of ASA, it is not clear which low dose is the optimal for patients in general. We believe that low doses of aspirin have the potential to offer stroke prevention and decrease risk of unwanted bleeding. We similarly believe that the decision of which dose aspirin is best for an individual patient's needs is best made by each individual patient after full physician consultation.

Accordingly, we support the concept of low dose aspirin as one of the methods of stroke prevention available to Americans today. However, until definitive data becomes available to the contrary, we believe that the agency ruling in 1998 for a dosage of 50 to 325 mg continues to best serve the physician and patient communities. Lastly, we support the FDA's interest in providing the optimal labeling information for aspirin dosing for secondary cerebrovascular prevention.

Respectfully,

James Baranski  
CEO/Executive Director

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