Heart Disease and Stroke. You're the Cure.

American Heart Association® | American Stroke Association®
Learn and Live℠

February 23, 2007

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2007N-0005

Dear Sir/Madam:

On behalf of the American Heart Association (AHA), including the American Stroke Association (ASA) and over 22.5 million AHA and ASA volunteers and supporters, we appreciate the opportunity to submit our comments in response to the Food and Drug Administration's (FDA) proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA).

Since 1924, AHA has dedicated itself to reducing disability and death from cardiovascular disease and stroke – the #1 and #3 leading causes of death in the United States – through research, education, community based programs and advocacy. AHA and ASA are committed to achieving a reduction in cardiovascular disease, stroke, and associated risk by 25 percent by 2010. Innovative drugs and novel medical devices are essential to the provision of high quality health care that we promote to patients and providers through the Association's consensus guidelines and scientific statements.

Support of the FDA Mission

AHA applauds the work of the Food and Drug Administration and views the Agency as a valued partner in our fight against cardiovascular disease and stroke. The FDA is widely recognized as the standard setter for regulation of food, drugs, and medical devices. The professionalism and expertise of the Agency's dedicated staff are an important national resource in advancing the public's health.

As part of its mission, the FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of all drugs, biological products, and medical devices. The Agency is also responsible for advancing the public health by

American Heart Association Advocacy Department
1150 Connecticut Ave., NW, Suite 300, Washington, DC 20036
202-785-7900 . Fax 202-785-7950 . www.americanheart.org/yourethecure

speeding innovation – bringing drugs and devices to market in a timely fashion. This is a significant responsibility; health care providers and patients rely on the FDA for the timely approval of drugs and devices that are both safe and effective. The American public has come to expect this of the Agency and they deserve no less.

To carry out its vital mission, the Agency must have sufficient resources: scientific, technical, and financial. The need is particularly important when considering implementation of the Agency's Critical Path Initiative, the recommendations in the Institute of Medicine's (IOM) 2006 report, "The Future of Drug Safety – Promoting and Protecting the Health of the Public," or the Agency's post-marketing safety surveillance activities. Although AHA is pleased that some additional funding for the Agency has been proposed in the President's FY2008 budget, we are concerned that this increase is insufficient to meet the Agency's needs. We are also disappointed that the proposed budget continues to rely so heavily on funding obtained through user fees.

Since 1993, when FDA first began collecting user fees under the Prescription Drug User Fee Act, a portion of the Agency's funding has come from drug manufacturers. In recent years, the portion of the Agency's budget funded by user fees has continued to grow, and has now reached the point where user fees make up a larger portion of the Agency's budget than appropriated funds. AHA is troubled by this trend. Ideally appropriated funds, not user fees, would be the major source of funding for the Agency; and as part of several coalitions, AHA is working with Congress to increase federal funding of the FDA.

However, we recognize that enhanced funding by the Federal government may be difficult to achieve in the context of substantial budget deficits and numerous competing priorities. In the current budget environment, financial support from private industry such as PDUFA funds will continue to be necessary. In accepting such support, however, it is crucial that a "firewall" is maintained between the Agency and the product sponsors in order to safeguard the integrity of the pre- and post-review process. In order for the "firewall" to be effective, it must effectively insulate the process from outside influence, maintain the highest level of transparency and openness to public scrutiny, and be continually evaluated as the environment changes.

As Congress debates PDUFA reauthorization this year, AHA will continue to call on Congress to increase funding for the Agency. Demands on the Agency continue to increase. In recent years, the FDA has been required to meet increasingly stringent annual review goals, examine a rising number of drug applications, and increase its post-marketing surveillance activities. Low funding has made it difficult for the Agency to undertake all of these activities. The FDA must be fully funded to carry out is mission. Increased funding will allow the Agency to increase staffing levels and resources allocated to the pre-market drug review process without compromising other equally important components of the process, and bring drugs and devices to the market faster, which is particularly important to patients with life threatening conditions such as cardiovascular disease and stroke.

Post-Marketing Safety Surveillance

The need for increased funding is not solely limited to Agency activities involved in the pre-market review and approval of drug applications. Just as important, is the continual evaluation of the safety of these products once they are on the market such as efforts to amplify and identify weak safety signals that may require an Agency response.

AHA supports the Agency's efforts to transform the post-market safety system. We understand that the Agency's post-marketing safety demands are growing. At the same time that the FDA has experienced a significant growth in reports of adverse events over the last eight years, the Agency's surveillance and analysis operations seems to be understaffed and there is a clear need for better post-marketing tools and methods.

Beginning with PDUFA III, the FDA was allowed to use a portion of user fees to fund limited post-marketing surveillance activities for the first three years a product is marketed. AHA applauds the Agency's proposal to further expand the ability of user fees to fund post-marketing surveillance activities for the product's entire life cycle. The reality is that some problems – and benefits – of products will not be discovered in clinical trials. Contraindications or adverse events may not be identified until a product is widely used in the general population. Expanding the Agency's post-marketing surveillance activities, including enhancing the Agency's adverse event reporting system, will allow the Agency to detect and respond to potential safety signals with a product at any point during the product's lifecycle.

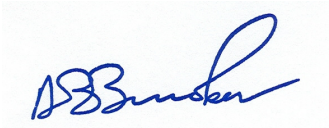
Conclusion

In closing, it is clear that the FDA requires increased funding. The financial need is well-demonstrated and substantial; current levels of funding are not adequate for the FDA to continue to meet its mission in the future. AHA will continue to call on Congress to provide the Agency with increased funding through appropriations, however, we recognize that the current budget environment makes full Federal funding of the Agency nearly impossible to obtain. Until Congress chooses or is able to fully fund the Agency, private industry user fees are one method to supply the FDA with the resources it so desperately needs.

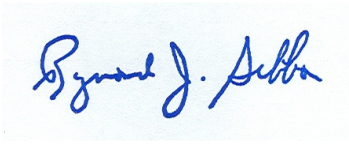
In addition, AHA reiterates our support for the Agency's efforts to modernize the drug safety system. Providing the FDA with the resources to closely monitor drug products for their entire lifecycle will allow the Agency to better collect, analyze, and respond to adverse event reports, and identify potential problems before serious patient harm can occur.

If you have any questions or need any additional information, please do not hesitate to contact Susan Bishop, MA, Regulatory Relations Manager, at 202-785-7908 or via email at susan.k.bishop@heart.org.

Sincerely,



Andrew B. Buroker, Esq.
Chairman of the Board, AHA



Raymond L. Gibbons, MD, FAHA
President, AHA