



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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JUL 13 2005

Ms. Claudia Louis
Manager, Government Relations
American Heart Association
1150 Connecticut Avenue NW #300
Washington, DC 20036

Re: Docket No. 199N-0418

We have received your letter dated January 26, 2004, commenting on the reclassification of Automatic External Defibrillators. In order for FDA to make a decision regarding reclassification, we request additional information from you.

1. You identify post-market surveillance as a method of obtaining data on these devices. The FDA has a number of different ways to follow device performance in the post-market period, including Medical Device Reporting and post-market studies. Please suggest what kinds of basic questions you would want to see answered in post-market surveillance studies. Please also comment on the types of questions you would ask for an over-the-counter device.
2. You stated that postmarket surveillance could be facilitated by designating sudden death as a reportable disease through collaboration with CDC. The FDA is interested in the progress of these discussions. Please provide us with an update.

To respond to this request, please refer to the Docket Number, above, and submit your comments within 30 days from the date on this letter, to:

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

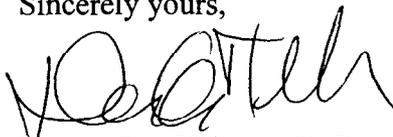
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If you have additional questions, please contact Oscar Tovar, MD, (301) 443-8609, extension 156.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna-Bea Tillman". The signature is fluid and cursive, with the first name being the most prominent.

Donna-Bea Tillman, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health