



November 2, 2005

Steven H. Chasin, Ph.D.  
Deputy, Division of Postmarket Surveillance  
Office of Surveillance and Biometrics  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Drive  
Rockville, MD 20850

Dear Dr. Chasin,

I am writing to you on behalf of AdvaMed, the Advanced Medical Technology Association, to bring to your attention an inconsistency between the “Draft Guidance for Industry and Staff, Procedures for Handling Post-Approval Studies imposed by PMA Order” and the Federal Register Notice which announced the availability of the Draft Guidance on September 15, 2005.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the \$80 billion of health care technology products purchased annually in the United States, and more than 50 percent of the \$175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. More than 70 percent of our members have less than \$30 million in domestic sales annually.

The cover page of the Draft Guidance states, “Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance.” The Federal Register announcement, in fact, states that comments and suggestions should be submitted within 60 days of publication in the Federal Register (i.e. November 14, 2005). While we understand that FDA will likely review comments sent to the docket after the close of the formal comment period, we are requesting that FDA correct the formal comment period to agree with the 90 day period (ending December 14, 2005) stated in the actual Draft Guidance document.

*November 2, 2005*

We appreciate your attention to this matter. For further information or clarification please contact me at 202-434-7224 or [jsecunda@advamed.org](mailto:jsecunda@advamed.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Jeff Secunda". The signature is written in a cursive style with a large initial "J".

Jeffrey Secunda  
Associate Vice President  
Technology and Regulatory Affairs

cc: Docket No.2005D-0348