

1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

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April 2, 2004

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

Re: Request for Extension of Comment Period; Docket Number 2004D-0042

Dear Sir or Madam:

I am writing on behalf of the Advanced Medical technology Association (AdvaMed). AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,100 members and subsidiaries manufacture nearly 90 percent of the \$75 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.

The purpose of this letter is to request a 60-day extension of the comment period for three draft guidance documents addressing improving medical information about medical products and health conditions: Disclosing Risk Information in Consumer-Directed Print Advertisements, Help-Seeking and Other Disease Awareness communication by or on Behalf of Drug and Device Firms and Consumer-Directed Broadcast Advertising of Restricted Devices. Our member companies manufacture a variety of medical devices that will be impacted by these guidance documents.

We believe that we have critical information to contribute to the development of these guidance documents. However, as we are a consensus-driven organization, it takes time to advise our members and collect and organize their input.

Additionally, the February 10, 2004 *Federal Register Notice* indicated that the guidance documents were prepared in part based on discussions and presentations at a September 3, 2003 open public meeting on consumer-directed advertising. The meeting announcement indicated that the focus of the meeting would be consumer-directed drug advertising. As consumer-

2004D-0042

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EXT 1

Division of Dockets Management
Request for Extension of Comment Period
April 2, 2004
Page two

directed device advertising issues did not appear to be the focus of the meeting, the device industry did not benefit from the discussions at the September 2003 meeting and has not had an opportunity in an open public forum to raise their issues.

Because of the reasons stated above, we asked that the extra time be provided so that we can provide FDA the type of high quality comments we would prefer to submit.

We appreciate your consideration in this matter. You may contact me directly at (202) 434-7267 or cjones@advamed.com.

Sincerely ,



Carolyn D. Jones
Associate Vice President
Technology and Regulatory Affairs

cc: David Feigal
Beverly Rothstein