



Susan Alpert, Ph.D., M.D.
Vice President
Chief Quality and Regulatory Officer

August 10, 2004

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

Via Electronic Submission

Re: Docket Number 2004D-0042: Draft Guidances for Industry on Improving Information About Medical Products and Health Conditions

Dear Sir or Madam:

Medtronic, Inc. appreciates the opportunity to provide comments to FDA's proposed guidance documents. We are writing in support of the comments submitted by the Advanced Medical Technology Association (AdvaMed) in response to FDA's February 10, 2004 *Federal Register Notice*, as they relate to the *Brief Summary: Disclosing Risk Information in Consumer Direct Print Ads, Help-Seeking, and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms Consumer Directed Broadcast Advertising of Restricted Devices* draft guidance documents.

In particular, we believe it is imperative that differences in the way devices and drugs are advertised be recognized by the regulatory scheme and that convening an open public meeting on device advertising would allow the issues that are unique to devices to be presented and considered. We believe that such a forum will allow FDA an opportunity to ensure that any guidance document it issues will address the unique interactions between the device industry and customers and patients.

Respectfully submitted,

Susan Alpert
Vice President, Chief Quality and Regulatory Officer
Medtronic, Inc.