



Medtronic

August 5, 2004

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

Re: Docket Number 2004D-0042: Draft Guidance for Industry on Improving Information About Medical Products and Health Conditions [69 FR 6308, February 10, 2004]

Dear Sir or Madam:

Medtronic Neurological appreciates the opportunity to provide comments to the above *Draft Guidance*. Medtronic Neurological develops, manufactures and markets innovative restorative neurological products and therapies for physicians and patients. Among our product portfolio, we have developed and commercialized an Orphan Drug Product (Lioresal® Intrathecal for severe intractable spasticity) and a Humanitarian Use Device (Activa® Therapy for chronic, intractable [drug refractory] primary Dystonia). Unfortunately, even years after approval, a large portion of health care practitioners and eligible patients remain unaware of these treatment options.

We would like to offer specific comments on Section III.A. of the *Draft Guidance* – “Characteristics of Disease Awareness Communications” (lines 118 to 125). We propose that communications regarding medical products, which are the only products in their class, are not treated by the FDA as labeling or advertising for the following reasons:

- Manufacturers may be discouraged from sponsoring these types of communications because of the costs associated with the additional regulatory requirements, if a disease awareness communication relates that a one-of-a-kind medical product is regulated as “labeling” or “advertising”. Consequently, the public, especially patients with rare disorders, may remain unaware of important health information and potential innovative therapies and, therefore, remain under-diagnosed or under-treated for their conditions.
- The FDA’s approach to regulating these communications may serve as a disincentive for companies to develop innovative products. The agency’s position is contrary to the intent of the Guidance and the FDA’s strategic intent to advance public health by accelerating innovations, and by helping the public to seek accurate, science-based information.¹ Industry, of course, bears the responsibility to provide non-misleading and accurate disease information to the public.

Thank you for considering these comments. Please contact me if you have any questions.

Sincerely,

Winifred C. Wu, RPh, MBA
Senior Regulatory Director
Medtronic Neurological

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¹ Strategic Action Plan – FDA, “Protecting and Advancing America’s Health”, <http://www.fda.gov/oc/mcclellan/FDAstrategicPlan.pdf>