



Corporate Regulatory and Quality Science

2370 04 MAY 10 19:10

April Veoukas
Corporate Regulatory Affairs
D-3QC, AP6C-1
Telephone: (847) 937-8197

100 Abbott Park Road
Abbott Park, Illinois 60064-6091
Facsimile: (847) 938-4422
E-mail: april.veoukas@abbott.com

May 7, 2004

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

RE: Draft Guidances for Industry on Improving Information About
Medical Products and Health Conditions [Docket 2004D-0042]

Dear Sir or Madam:

Abbott Laboratories submits the following comments regarding FDA draft guidance document "Consumer-Directed Broadcast Advertising of Restricted Devices" published in the Federal Register on February 10, 2004 at 69 FR 6308.

Thank you for the opportunity to provide these comments. Our comments pertain to the "adequate provision" section of the guidance document, as well as a couple general items in which we recommend clarification.

Adequate provision, as used in this guidance document, means allowing most of a potentially diverse audience to have reasonably convenient access to the advertised device's labeling. We note the term adequate provision stems from the drug regulations.¹ Unlike pharmaceuticals, there are no regulations governing the advertising of restricted medical devices. The statutory provision, however, provides that restricted device advertising is to include a brief statement of intended uses of the device and relevant warnings, precautions, side effects, and contraindications.² Thus, it is not necessary for guidance on restricted device advertising to mirror that for pharmaceuticals. Rather such guidance should reflect what is appropriate for the medical device industry and restricted medical devices.

It appears from the guidance document that to satisfy the adequate provision requirement, it is necessary to engage in all of the following activities: (1) maintain a toll-free telephone number for consumers to call for the approved package labeling, (2) reference a print advertisement or make brochures available, (3) disclose an Internet web page address, and (4) disclose in the advertisement that practitioners may provide additional device information. Multiple provisions for disseminating package labeling

¹ 21 C.F.R. § 202.1(e)(1).

² 21 U.S.C. § 352(r)(2).

2004D-0042

011



appears predicated on the conclusion that the Internet is sophisticated technology, and presumably not reasonably convenient to a potentially diverse audience. Further, this conclusion appears to mirror that found in the guidance for the pharmaceutical industry on broadcast advertising, which was issued as a draft in 1997 and finalized in 1999.

Internet technology and accessibility have changed in the last five years.³ Further, in accordance with recent statutory amendments, electronic medical device labeling is now permissible.⁴ The guidance document, however, does not appear to recognize such advances, specifically as it relates to the adequate provision. Due to these advances, it would be more appropriate to permit firms to use one of the first three mechanisms to disseminate device labeling, rather than all three. Accordingly, the first three items, toll-free telephone number, reference a print advertisement or make brochures available, and Internet address, should be presented as options, rather than additive activities.

In addition to the above comments, there are two additional areas of comment. First, clarification of expectations regarding package labeling is needed. Footnote three acknowledges the highly technical nature and, often, extensive length of device package labeling (e.g., instrument manuals), and recommends the use of patient labeling or an abbreviated version of package labeling. Section B references "full package labeling," while other sections simply reference package labeling. It appears the references to package labeling, full or otherwise, are intended to mean the abbreviated version of the package labeling discussed in footnote three. However, due to the impracticality of supplying items, such as manuals, and the questionable usefulness to the consumer, clarity of this item is sought.

Second, we recommend including as part of footnote two the information contained in footnote one of the FDA draft guidance, "'Help Seeking' and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms." Footnote one of the Help Seeking guidance states, "[t]he agency's authority over device advertising only extends to restricted devices. Other device advertising is regulated by the Federal Trade Commission (FTC)." Inclusion of this additional information provides some guidance for devices that are not restricted and greater consistency between the two guidances.

Should you have any questions, please contact me at (847) 937-8197 or by facsimile at (847) 938-4422.

Sincerely,

A handwritten signature in cursive script that reads "April Veoukas".

April Veoukas, J.D.
Associate Director, Regulatory Affairs
Corporate Regulatory Affairs, Abbott Laboratories

³ See Economics and Statistics Administration and National Telecommunications and Information Administration, U.S. Department of Commerce, *A Nation Online: How Americans Are Expanding Their Use of the Internet*, (2002). The report states, as of September 2001, more than half the nation is online, at 1. In September 2001, 143 million Americans (about 54 percent of the population) were using the Internet – an increase of 26 million in 13 months, at 1. It is reported that this is a 44.5 percent increase from August 2000, at 4. Further, Internet use has grown at a rate of 20 percent a year since 1998, at 10.

⁴ Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, § 206, 116 STAT. 1613.