DEPARTMENT OF HEALTH AND HUMAN SERVICES

Program Support Center; Senior Executive Service; Performance Review Board Members

Title 5, U.S. Code, Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that appointment of Performance Review Board members be published in the Federal Register.

Dated: September 30, 1996.

Lynnda M. Regan,

Director, Program Support Center.

The following persons will serve on the Performance Review Board which oversees the evaluation of performance appraisals of Senior Executive Service members of the Department of Health and Human Services in the Program Support Center:

John C. West, Chairperson
Lawrence S. Cohan
Luana Reyes
William A. Robinson, M.D.

[FR Doc. 96–25727 Filed 10–7–96; 8:45 am]
BILLING CODE 4160–17–M

Food and Drug Administration

[Docket No. 95D–0377]

Advertising and Promotion; Guidances

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The agency is publishing two guidances entitled ''Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data'' and ''Guidance for Industry Funded Dissemination of Reference Texts.'' These guidances relate to the dissemination, by sponsors of human and animal drugs, medical devices, and biological products of certain reprints of journal articles and reference texts (medical textbooks and compendia), which contain information concerning FDA-approved products that may not be consistent with the approved labeling for the products. These guidances describe the circumstances under which the agency intends to allow the dissemination of these reprints and reference texts to health care professionals. These guidances are intended to assist the agency in fulfilling its mission to help ensure the safety and effectiveness of human and animal drugs, medical devices, and biological products. The full texts of these guidances are published in this document.

FOR FURTHER INFORMATION CONTACT:
Regarding general questions: Ilisa B. G. Bernstein, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, rm. 15–74, Rockville, MD 20857, 301–827–3380, or via Internet at IBERNSTE@BANGATE.FDA.GOV;
Regarding human drugs: Patrick O'Brien, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, rm. 17B–17, Rockville, MD 20857, 301–827–3901, or via Internet at OBRIENP@CDER.FDA.GOV;
Regarding animal drugs: Edward L. Spenser, Division of Surveillance (HFV–210), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1722, or via Internet at ESPENSER@BANGATE.FDA.GOV;
Regarding medical devices: Byron L. Tart, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20879, 301–594–4639, or via Internet at BXT@FDADR.CDER.FDA.GOV;
Regarding biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–202), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3028, or via Internet at STIFANO@CBER.FDA.GOV

SUPPLEMENTARY INFORMATION: In the Federal Register of December 8, 1995 (60 FR 63384), FDA published and sought public comment on two draft guidances entitled ''Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data'' and ''Guidance for Industry Funded Dissemination of Reference Texts.'' These guidances relate to the dissemination, by sponsors of human and animal drugs, medical devices, and biological products, of certain reprints of journal articles and reference texts (medical textbooks and compendia), which contain information concerning FDA-approved products that may not be consistent with the approved labeling for the products.

The agency received over 57 comments in response to the request for comments on the draft guidances. The comments came from drug and device manufacturers, professional health organizations, industry trade organizations, patient advocacy organizations, health communications specialists, attorneys, and health professionals. The agency has reviewed and considered these comments in its analysis of whether and what changes should be made in finalizing these guidances. As a result of this analysis, the agency has determined that no changes need to be made to the ''Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data.'' The ''Guidance for Industry Funded Dissemination of Reference Texts'' remains essentially unchanged; except in the discussion of circumstances for dissemination of reference texts, FDA added an additional circumstance concerning product promotion, as noted below.

The agency received several comments claiming that the guidance on dissemination of certain reprints does not go far enough, arguing that companies should be permitted to disseminate any article they choose, regardless of what information is discussed in the article or whether the information is consistent with the approved product labeling. The agency also received several comments that gave specific suggestions of the types of articles that should be permitted under a policy with a broader scope (e.g., all peer-reviewed articles, technical reports). FDA believes that the guidances that are the subject of this notice strike the proper balance between the need for an exchange of reliable scientific data and information within the health care community, and the statutory requirements that prohibit companies from promoting products for unapproved uses. However, the agency will continue to evaluate its policies related to the advertising and promotion of FDA-regulated products, and these guidances are just one part of its policy in this area.

The agency also received comments seeking clarification of certain aspects of the guidances. Although these comments were considered in determining the final version of these guidances, they are not individually addressed in this notice. The agency welcomes questions from interested parties regarding the practical application of these guidances. Specific questions should be directed to the appropriate persons within the agency who address advertising and promotion issues for the particular regulated product. (See contact persons above.)

One comment suggested that sponsors should not be allowed to use reprints or reference texts as a tool to promote unapproved uses of their products. The agency does not intend for these materials to be used in this way. Upon consideration, the agency has determined that an additional ''circumstance'' should be added to the

guidance on reference texts making it clear that company representatives should not refer to, or otherwise promote, information in the reference text that is not consistent with the approved labeling for a product.

The texts of the final guidance documents follow:

Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data [1]

I. Purpose of Guidance

Sponsors frequently want to disseminate reprints of articles reporting the results of the effectiveness trials that have been relied on by FDA in its approval or clearance of a drug, device, or biologic product. However, such articles may contain effectiveness rates, data, analyses, uses, regimens, or other information that is different from the approved labeling, and might, if disseminated by the sponsor, be considered violative promotional activities.

Nonetheless, the agency intends to allow sponsors to disseminate reprints of articles that represent the peer-reviewed, published version of original efficacy trials, under the circumstances described in section II., below.

II. Circumstances for Dissemination of Certain Journal Articles Discussing FDA-Approved Products

1. The principal subject of the article should be the use(s) or indication(s) that has been approved by FDA. The article should be published in accordance with the regular peer-review procedure of the journal in which it is published, and the article should report the original study that was represented by the sponsor, submitted to FDA, and accepted by the agency as one of the adequate and well-controlled studies providing evidence of effectiveness. In the case of a medical device, this guidance also applies to studies that were otherwise represented by the sponsor, submitted to the agency, and accepted by the agency as valid and material evidence of safety or effectiveness in lieu of adequate and well-controlled studies;

2. The reprint should be from a bona fide peer-reviewed journal. A bona fide peer-reviewed journal is a journal that uses experts to objectively review and select, reject, or provide comments about proposed articles. Such experts should have demonstrated expertise in the subject of the article under review, and be independent from the journal;

3. If the article contains effectiveness rates, data, analyses, uses, regimens, or other information that is different from approved labeling, the reprint should prominently state the difference(s), with specificity, on the face of the reprint. One acceptable means of achieving the appropriate prominence for this statement is to permanently affix to the reprint a sticker stating the differences; and

4. The reprint should disclose all material facts and should not be false or misleading.

Guidance for Industry Funded Dissemination of Reference Texts [2]

I. Purpose of Guidance

Sponsors have expressed a desire to disseminate reference texts, i.e., medical textbooks and compendia, to health care professionals. These texts typically discuss a wide range of medical diagnoses and treatments, including drug product utilization, surgical techniques, and other medical topics, and are often useful to clinicians in the practice of medicine.

Reference texts often contain information about the use of drugs, devices, or biologic products in the treatment, diagnosis, or prevention of disease that may not be consistent with the FDA-approved labeling for the products (e.g., discussion of unapproved uses). While many textbooks do not necessarily highlight a particular drug or device manufacturer's products, the dissemination of these reference texts by regulated industry may still be in conflict with the Federal Food, Drug, and Cosmetic Act (the act) and implementing regulations. [3]

Nonetheless, FDA intends to permit the distribution of sound, authoritative materials that are written, published, and disseminated independent of the commercial interest of a sponsoring company and are not false or misleading. FDA, therefore, intends to allow sponsors to disseminate reference texts that discuss human or animal drug, device, or biologic products, under the circumstances described in section II., below.

II. Circumstances for Dissemination of Reference Texts

1. The reference text should not have been written, edited, excerpted, or published specifically for, or at the request of, a drug, device, or biologic firm, unless the text was prepared in a manner that results in a balanced presentation of the subject matter (see III. below);

2. The content of the reference text should not have been reviewed, edited, or significantly influenced by a drug, device, or biologic firm, or agent thereof, unless the text was prepared in a manner that results in a balanced presentation of the subject matter (see III. below);

3. The reference text should not be distributed only or primarily through drug, device, or biologic firms (e.g., it should be generally available for sale in bookstores or other distribution channels where similar books are normally available);

4. The reference text should not focus primarily on any particular drug(s), device(s), or biologic(s) of the disseminating company, nor should it have a significant focus on unapproved uses of the drug(s), device(s), or biologic(s) marketed or under investigation by the firm supporting the dissemination of the text;

5. Specific product information (other than the approved package insert) should not be physically appended to the reference text; and

6. A drug, device, or biological product company representative should not refer to, or otherwise promote, in any manner or at any time, information in the reference text that is not consistent with the approved labeling for a product.

III. Exception

The agency recognizes that there are some useful reference texts that are written, edited, or published by a sponsor or agent of a sponsor. In those instances, where the authorship, editing, and publishing of the reference text results in a balanced presentation of the subject matter, FDA intends to allow the distribution of a reference text under the circumstances described in paragraphs 3 through 6 above. Typically, evidence of a balanced presentation of the subject matter would consist of an authorship and editorial process that fosters input from a relatively wide spectrum of sources and allows for consideration of information from all sources.

Dated: October 1, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

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[1] This guidance does not apply to reprints of articles that discuss the specific prohibited uses of animal drugs listed in FDA's Center for Veterinary Medicine's Compliance Policy Guide 7125.06 or the Animal Medicinal Drug Use Clarification Act implementing regulations. Although this guidance does not create or confer any rights on any person and does not operate to bind FDA in any way, it does represent the agency's current thinking on the dissemination of reprints of certain published, original data. The agency will consider individual circumstances on a case-by-case basis.

[2] Although this guidance does not create or confer any rights, on any person, and does not operate to bind FDA in any way, it does represent the agency's current thinking on industry funded dissemination of reference texts. Although FDA believes that this guidance encompasses the vast majority of reference texts, the agency will consider, on a case-by-case basis, reference texts that do not fall within the parameters of this guidance document. This guidance does not apply to textbooks or compendia that discuss the specific prohibited uses or animal drugs listed in the Center for Veterinary Medicine's Compliance Policy Guide 7125.06 or the Animal Medicinal Drug Use Clarification Act implementing regulations.

[3] Printed materials, such as medical textbooks and compendia, which supplement, explain, or are textually related to a regulated product are considered labeling for that product when disseminated by or on behalf of the manufacturer, packer, or distributor of the product. See section 201(m) of the act (21 U.S.C. 321(m)) and *Kordel* v. *United States*, 338 U.S. 345, 350 (1948).

[Docket No. 96M–0357]

Medtronic, Inc.; Premarket Approval of the CapSureFix® Pacing Lead, Model 4068

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Medtronic, Inc., Minneapolis, MN, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the CapSureFix® Pacing Lead, Model