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.

[FR Doc. 96–25728 Filed 10–7–96; 8:45 am]

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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

4068. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of March 29, 1996, of the approval of the application.

DATES: Petitions for administrative review by November 7, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Tara A. Ryan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8243.

SUPPLEMENTARY INFORMATION: On November 1, 1993, Medtronic, Inc., Minneapolis, MN 55432–3576, submitted to CDRH an application for premarket approval of the CapSureFix® Pacing Lead, Model 4068. The device is a permanent implantable cardiac pacemaker electrode (lead) and is designed to be used with a pulse generator as part of a cardiac pacing system. The lead has application where implantable atrial or ventricular, single chamber or dual chamber pacing systems are indicated.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On March 29, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before November 7, 1996 file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: September 20, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–25812 Filed 10–7–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given to the meetings of the National Cancer Institute Special Emphasis Panel (SEP):

Name of SEP: Development of Dosage Forms & Delivery Systems for Antitumor and Anti-AIDS Agents.

Date: October 4, 1996.

Time: October 4—8:30 am.

Place: Executive Plaza North, Conference Room G, 6130 Executive Boulevard, Rockville, MD 20852.

Contact Person: Dr. Courtney Michael Kerwin, Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 601, 6130 Executive Boulevard MSC 7405, Bethesda, MD 20892–7405, Telephone: 301/496–7421.

Purpose/Agenda: This meeting will be devoted to the review, discussion, and evaluation of a grant application.

Name of SEP: Modulation of Apoptosis to Improve Cancer Therapy.

Date: October 6–7, 1996.

Time: October 6—8 pm, October 7—8 am.

Place: Holiday Inn—Georgetown, 2101 Wisconsin Avenue, NW, Washington, DC 20007.

Contact Person: Dr. David Irwin, Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 635E, 6130 Executive Boulevard MSC 7405, Bethesda, MD 20892–7405, Telephone: 301/406–0371.

Purpose/Agenda: This meeting will be devoted to the review, discussion, and evaluation of a grant application.

Name of SEP: Evaluation of Chemopreventive Agents by In Vitro Techniques.

Date: October 7, 1996.

Time: October 7—2 pm.

Place: Executive Plaza North, 6130 Executive Boulevard, Rockville, MD 20852.

Contact Person: Dr. Lalita D. Palekar, Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 601, 6130 Executive Boulevard MSC 7405, Bethesda, MD 20892–7405, Telephone: 301/496–7575.

Purpose/Agenda: This meeting will be devoted to the review, discussion, and evaluation of a grant application.

The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being submitted less than 15 days prior to the above meetings due to the urgent need to meet timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: October 3, 1996.

Paula N. Hayes,

Acting Management Officer, NIH.

[FR Doc. 96–25861 Filed 10–3–96; 4:51 pm]

BILLING CODE 4140–01–M