Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the recommendations to change the list by March 14, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft recommendations and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the Q3C documents at http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/guidelines.htm. Information on the Q3C maintenance process as well as proposals, data analysis, and draft and final recommendations for revisions to the tables and list are being made available at http://www.fda.gov/cder/audiences/iact/iachome.htm. The electronic address for submitting comments to Dockets Management Branch is http://www.fda.gov/dockets/ecomments.

Dated: February 5, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–3388 Filed 2–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee Meeting; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is cancelling the meeting of the Peripheral and Central Nervous System Drugs Advisory Committee scheduled for February 15, 2002. The meeting was announced in the **Federal Register** of January 22, 2002 (67 FR 2891 to 2892).

FOR FURTHER INFORMATION CONTACT: Sandra Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12543.

Dated: February 6, 2002.

Bonnie H. Malkin,

Acting Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–3372 Filed 2–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0577]

Medical Devices; Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Draft Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Draft Guidance for Industry and FDA.'' This draft guidance will serve as a special control for cutaneous carbon dioxide ($PcCO_2$) and cutaneous oxygen (PcO_2) monitor devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify these device types. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this guidance by May 13, 2002.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Draft Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: William A. Noe, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 174.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document describes a means by which cutaneous carbon dioxide ($PcCO_2$) and cutaneous oxygen (PcO_2) monitor devices may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate carbon dioxide ($PcCO_2$) or oxygen (PcO_2) monitor device must demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO2) Monitors; Draft Guidance for Industry and FDA.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Draft Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800 –899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1335) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access.

Updated on a regular basis, the CDRH Web site includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at http://www.fda.gov/cdrh. A search capability for all CDRH guidance documents is available at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written or electronic comments on the draft guidance by May 13, 2002. Submit two copies of any comments, except individuals may submit one copy. Identify comments with the docket number found in brackets in the heading of this document. The guidance document and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 29, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–3280 Filed 2–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0049]

Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees.'' This draft document is intended to provide guidance for industry, FDA staff (including special Government employees (SGEs), and other interested stakeholders concerning disclosure of financial interests for which FDA advisory committee SGEs have received conflict of interest waivers. This draft guidance describes a new policy of disclosing specific information concerning the financial interests that give rise to the waiver of a conflict of interest.

DATES: Submit written or electronic comments by March 14, 2002, to ensure adequate consideration in preparation of the final guidance document. Comments on this guidance may be submitted at any time.

ADDRESSES: Submit written comments or requests for copies of the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Linda Ann Sherman, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION:

I. Background

Two separate statutes govern whether FDA advisory committee SGEs are prohibited from participating in a particular meeting because of a conflict of interest with the work the committee is to perform: (1) Section 505(n)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(n)(4)), which is applicable to FDA SGEs working on advisory committees concerning a clinical investigation of a drug or approval for marketing of a drug or biologic; and (2) 18 U.S.C. 208, which is applicable to all Federal Government employees, including SGEs. Both statutes provide for waivers of conflicts of interest under certain conditions. Both statutes also provide for public disclosure of any conflict of interest for which a waiver has been granted. The regulation in 18 U.S.C. 208 provides for disclosure of waiver information upon request but permits agencies to redact any information that would be exempt under the Freedom of Information Act, 5 U.S.C. 552. In addition, section 505(n)(4) of the act requires SGEs to publicly disclose all conflicts of interest.

The Office of Government Ethics (OGE) has concluded that 18 U.S.C. 208 grants agencies discretion in disclosing information under 18 U.S.C. 208 where there is no foreseeable harm that will be caused by the disclosure. Similarly, the Office of Legal Counsel (OLC), Department of Justice, has concluded that FDA has discretion under section 505(n)(4) of the act to tailor the scope of the disclosure to achieve the statute's goal. FDA may weigh the competing public interests at stake. For example, the statute does not intend that the disclosure be so intrusive or onerous as to make many individuals unwilling to serve on advisory committees.

In making a decision concerning how much information to disclose in any given case, FDA has always had to balance the following competing public interests: (1) Providing as much information to the public as possible about the qualifications and abilities of the SGEs involved in the advisory committee process so that individuals may weigh the advice, (2) protecting the reasonable privacy expectations of the SGEs in their personal financial affairs, and (3) protecting FDA's interest in being able to attract sufficient expertise to the committee to provide the most reliable advice.

In the past, FDA has struck a balance between these interests by disclosing the names of individual SGEs who had received waivers and whether the waiver was granted under 18 U.S.C. 208 or section 505(n)(4) of the act, without disclosing any details about the actual financial interest at stake. In the interest of increasing transparency, FDA is now proposing to strike a different balance by disclosing more details. This disclosure, of course, will provide the public with more information concerning the financial interests of the SGEs participating, but it will also entail additional exposure of what may be private financial interests of the SGEs.

II. The Proposed New Procedures

FDA is proposing that, for advisory committee meetings to consider particular matters relating to particular products, additional disclosure of certain details concerning conflicts of interest that have been waived is warranted. In the interest of uniformity, FDA is further proposing to provide for the same degree of disclosure for waivers granted under either 18 U.S.C. 208 or section 505(n)(4) of the act for all centers and will follow similar procedures for both. With regard to committees considering general matters, see the discussion in section III of this document.

The reasons why FDA is proposing this change are twofold. First, FDA recently surveyed SGEs as to whether they were willing to provide greater public disclosure of financial interests giving rise to conflicts of interest for which waivers are received. FDA sent a detailed questionnaire to all SGEs asking for their opinion on whether