

danger to the health of individuals. The final regulation for Banned Devices (44 FR 29221), which issued on May 18, 1979 (part 895 (21 CFR part 895)),

contained certain reporting requirements (§§ 895.21(d) and 895.22(a)).

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22(a)	26	1	26	16	416
Total					441

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
800.55(k)	1	1	1	20	20

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the burden under the administrative detention provision is based on FDA's discussion with the last firm whose devices had been detained. Historically, FDA has had very few or no annual responses for this information collection.

Dated: June 1, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-8838 Filed 6-6-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006D-0190]

#### Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Olfactory Test Device; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Olfactory Test Device." This guidance document describes a means by which the olfactory test device may comply with the requirement of special controls for class II devices. It includes recommendations for validation of device performance and labeling. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify these device types into class II (special controls).

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Olfactory Test Device" 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 one self-addressed adhesive label 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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Eric A. Mann, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2080.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying olfactory test device into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C.

360c(f)(2)). This guidance document will serve as the special control for olfactory test device.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

##### **II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the agency's current thinking on olfactory test devices. 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

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive "Class II Special Controls Guidance Document: Olfactory Test Device," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1595 to identify the guidance you are requesting.

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 home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions [including lists of approved applications and manufacturers' addresses], small manufacturer's 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 Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

### IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910-0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910-0485.

### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that

individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 24, 2006.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. E6-8792 Filed 6-6-06; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors for Basic Sciences National Cancer Institute. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institutes, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors for Basic Sciences National Cancer Institute.

*Date:* July 10, 2006.

*Time:* 11 a.m. to 4 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31/Conference Room 6, Bethesda, MD 20892.

*Time:* 7 p.m. to 11 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.

*Place:* National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31/Conference Room 6, Bethesda, MD 20892.

*Contact Person:* Florence E. Farber, Ph.D., Executive Secretary, Office of the Director, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 2115, Bethesda, MD 20892. 301-496-7628. [ff6p@nih.gov](mailto:ff6p@nih.gov).

In the interest of security, NIH has instituted stringent procedures for entrance

onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 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, National Institutes of Health, HHS)

Dated: May 31, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-5146 Filed 6-6-06; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Board of Scientific Advisors.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* National Cancer Institute Board of Scientific Advisors.

*Date:* June 29-30, 2006.

*Time:* June 29, 2006, 8 a.m. to 6 p.m.

*Agenda:* Director's Report; Ongoing and New Business; Reports Program Review Group(s); and Budget Presentation; Reports of Special Initiatives; RFA and RFP Concept Review; and Scientific Presentations.

*Place:* National Institutes of Health, Building 31, C Wing, 6 Floor, Conference Rm. 10, 9000 Rockville Pike, Bethesda, MD 20892.

*Time:* June 30, 2006, 8:30 a.m. to 1 p.m.

*Agenda:* Ongoing and New Business; Reports of Program Review Group(s); and Budget Presentation; Reports of Special Initiatives; RFA and RFP Concept Review; and Scientific Presentations.

*Place:* National Institutes of Health, Building 31, C Wing, 6 Floor, Conference Rm. 10, 9000 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Paulette S. Gray, Ph.D., Executive Secretary, Director, Division of