

issued a notice proposing changes to the methodology currently used to determine cigarette ratings for tar, nicotine, and carbon monoxide. See 62 FR 48,158 (Sept. 12, 1997). The proposed methodology would produce tar, nicotine, and carbon monoxide yields using both the current testing parameters and more intensive smoking conditions, thus producing a range of potential yields for each cigarette. The Commission requested comment on those proposed changes to the testing methodology, and on the feasibility of generating the upper tier of tar, nicotine, and carbon monoxide ratings through mathematical formulas, rather than actual testing on a smoking machine. The Commission also placed on the public record two different legends that could be used in advertising to disclose the ratings and sought comment on the usefulness and feasibility of these potential disclosure formats. Finally, comment was requested on alternative approaches that were considered but not proposed by the Commission. The deadline for submission of the requested comments was November 17, 1997.

The Commission has received requests for extension of this deadline from the Food and Drug Administration, the four largest cigarette manufacturers (Brown & Williamson Tobacco Corporation, Lorillard Tobacco Company, Philip Morris Incorporated and R.J. Reynolds Tobacco Company), the American Lung Association, the Commonwealth of Massachusetts and the American Society of Addiction Medicine.

In light of the importance and complexity of the issues addressed by

the Commission's **Federal Register** notice, and the number of issues on which comment is being requested, the Commission has decided to extend the filing deadline until January 20, 1998.

By direction of the Commission.

**Donald S. Clark,**  
*Secretary.*

[FR Doc. 97-28913 Filed 10-30-97; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 93N-0195]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Submit written comments on the collection of information by December 1, 1997.

**ADDRESSES:** Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Margaret R. Wolff, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

In a final rule entitled "Procedures for the Safe Processing and Importing of Fish and Fishery Products" (60 FR 65096, December 18, 1995), FDA issued regulations in part 123 (21 CFR part 123) mandating the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control designed to help ensure the safety of foods.

The regulations were issued under FDA's statutory authority to regulate food safety, including section 402(a)(1) and (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and (a)(4)), and will become affective on December 18, 1997.

Certain provisions in the regulations require that processors and importers of seafood collect and record information. In the final rule (60 FR 65096 at 65177 and 65178), the agency requested comments on the information collection provisions of the new regulations. No comments were received in response to this request.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1, 5</sup>

21 CFR Section	No. of Record-keepers	Annual Frequency of Recordkeeping <sup>2</sup>	Total Annual Records	Hours per Record-keeper <sup>3</sup>	Total Hours
123.6(a),(b),(c) .....	4,850	1	4,850	16	77,600 <sup>4</sup>
123.6(c)(5) .....	4,850	4	19,400	0.30	5,820
123.8(a)(1),(c) .....	4,850	1	4,850	4	19,400
123.12(a)(2)(ii) .....	1,000	80	80,000	0.20	16,000
123.6(c)(7) .....	4,850	280	1,358,000	0.30	407,400
123.7(d) .....	1,940	4	7,760	0.10	1,940
123.8(d) .....	4,850	47	227,950	0.10	22,795
123.11(c) .....	4,850	280	1,358,000	0.10	135,800
123.12(c) .....	1,000	80	80,000	0.10	8,000
123.12(a)(2) .....	1,000	1	1,000	4	4,000 <sup>4</sup>
123.10 .....	4,850	1	24	24	116,400 <sup>4</sup>
First year total burden hours .....					815,155
Annual recurring burden hours .....					617,155

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

<sup>2</sup> Based on an estimated of 280 working days per year.

<sup>3</sup> Estimated average time per 8 hour workday unless one time response.

<sup>4</sup> Nonrecurring burdens.

<sup>5</sup> The above estimates include the information collection requirements in the following sections:—

- 123.16 Smoked Fish—process controls (see 123.6(b))
- 123.28(a) Source Controls—Molluscan Shellfish (see 123.6(b))
- 123.28(c),(d) Records—molluscan shellfish (see 123.6(c)(7))
- 123.9 Records control—general (see recording and records)

The time and costs of these activities will vary considerably among processors and importers of fish and fishery products, depending on the type and number of products involved, and the nature of the equipment or instruments required to monitor critical control points. The burdens have been estimated using typical small seafood processing firms as a model because these firms represent a significant proportion of the industry.

The burden estimate in Table 1 includes only those collections of information under the seafood HACCP regulations that are not already required under other statutes and regulations. For example, the current food manufacturing practices provisions in 21 CFR part 110 already require that all food processors ensure good sanitary practices and conditions, monitor the quality of incoming materials, monitor and control food temperatures to prevent bacterial growth, and perform certain corrective actions and verification procedures. Furthermore, the estimate does not include collections of information that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (21 CFR 1240.60) is a customary and usual practice among seafood processors. Consequently the estimates in Table 1 account only for new information collection and recording requirements attributable to part 123.

There were some inadvertent errors in the total burden hours column of the estimates for § 123.6(c)(5) and (c)(7) in the final rule. These errors have been corrected in this document, and the totals for part 123 as a whole have been adjusted accordingly.

Dated: October 27, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97-28940 Filed 10-30-97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Research Resources; 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 the following National Center for Research Resources Special Emphasis Panel (SEP) meeting:

*Name of SEP:* General Clinical Research Centers.

*Date:* December 18-19, 1997.

*Time:* 8:00 a.m.

*Place:* Georgetown University Conference Center, 800 Reservoir Road, N.W., Washington, DC 20057, (202) 687-3200.

*Contact Person:* Dr. Jill Carrington, Scientific Review Administrator, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892-7965, (301) 435-0822.

*Purpose/Agenda:* To evaluate and review grant applications.

This meeting 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.

(Catalog of Federal Domestic Assistance Program No. 93.306, Laboratory Animal Science and Primate Research, National Institutes of Health, HHS)

Dated: October 24, 1997.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 97-28847 Filed 10-30-97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; 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 of the following National Institute on Drug Abuse (NIDA) Special Emphasis Panel meetings.

*Purpose/agenda:* To review and evaluate grant applications.

*Name of Committee:* NIDA Special Emphasis Panel (Training Grants).

*Date:* November 4, 1997.

*Time:* 10:00 a.m.

*Place:* National Institutes of Health, The Natcher Building, Conference Rm. H, 45 Center Drive, Bethesda, MD 20982.

*Contact Person:* Mark Swieter, Ph.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10-42, Telephone (301) 443-2620.

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

*Name of Committee:* NIDA Special Emphasis Panel (Clinic Neuroscience and Imaging).

*Date:* November 18, 1997.

*Time:* 1:00 p.m.

*Place:* Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Mark Swieter, Ph.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10-42, Telephone (301) 443-2620.

*Name of Committee:* NIDA Special Emphasis Panel (AIDS Biomedical and Clinical).

*Date:* November 19, 1997.

*Time:* 11:00 a.m.

*Place:* Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20818.

*Contact Person:* Khursheed Asghar, Ph.D., Scientific Review Administrator, Office of Extramural Program Review, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10-22, Telephone (301) 443-2620.

The meetings will be closed in accordance with provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. The 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, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.277, Drug Abuse Research Scientist Development and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs)

Dated: October 28, 1997.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

[FR Doc. 97-28922 Filed 10-30-97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Dental Research; 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 the following National Institute of Dental Research Special Emphasis Panel (SEP) meetings:

*Name of SEP:* National Institute of Dental Research Special Emphasis Panel—Review of F32 grant (98-11).

*Dates:* November 18, 1997.

*Time:* 1:00 p.m.

*Place:* Natcher Building, Rm. 4AN-44F, National Institutes of Health, Bethesda, MD 20892, (teleconference).