

regarding how the agency can best meet these six objectives of its modernization plan address seven questions. An information packet, available on the FDA webpage or from the designated contact person listed in this document, provides substantive background information; it is highly recommended that those individuals or groups who wish to make a presentation or submit written comments obtain this packet. Specific questions relate to each objective as follows:

1. What can FDA do to improve its explanation of the agency's submission review processes, and make explanations more available to product sponsors and other interested parties?
2. How can the agency maximize the availability and clarity of information concerning new products?
3. How can FDA work with its partners to ensure that products—both domestic and foreign—produced and marketed by the regulated industry are of high quality and provide necessary consumer protection; and how can FDA best establish and sustain an effective, timely, and science-based postmarketing surveillance system for reporting, monitoring, evaluating, and correcting problems associated with use/consumption of FDA-regulated products?
4. What approach should FDA use to assure an appropriate scientific infrastructure, with continued access to the scientific and technical expertise needed to meet its statutory obligations and strengthen its science-based decisionmaking process?
5. What do you believe FDA should do to adequately meet the demands that are beginning to burden the application review process, especially for non-user fee products, so that it can meet its statutory obligations to achieve timely product reviews?
6. What suggestions do you have for the agency to eliminate backlogs in the review process?
7. What other objectives related to the agency's statutory obligations or public expectations—beyond the six objectives—should be included in the FDA plan?

II. Comments

Written comments should be identified with the docket number found in brackets in the heading of this document and should be submitted by September 11, 1998, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments can be sent to the Dockets Management Branch at the following e-mail address

"FDADockets@bangate.fda.gov" or via the FDA website "http://www.fda.gov".

III. Additional Meetings

This meeting is related to a series of other public meetings held that were announced in the **Federal Register** of July 24, 1998. A separate FDAMA section on the FDA website is available for information about these public meetings.

An additional public meeting is being planned for September 14, 1998, to obtain stakeholder views on potential recurring themes and the best approach for consolidating these themes agencywide. A separate notice of this meeting will be published in the **Federal Register**.

IV. Transcripts

Transcripts of these meetings may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript of the meeting will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA website "http://www.fda.gov".

Dated: August 13, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-22393 Filed 8-19-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-8003 and HCFA-R-185]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed

information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection

Request: Revision of a currently approved collection; **Title of Information Collection:** Home and Community-Based Services Waiver Requests and Supporting Regulations in 42 CFR 440.180-.185, and 441.301-441.310; **Form No.:** HCFA-8003 (OMB# 0938-0449); **Use:** Under a Secretarial waiver, States may offer a wide array of home and community-based services to individuals who would otherwise require institutionalization. States requesting a waiver must provide certain assurances, documentation and cost & utilization estimates which are reviewed, approved and maintained for the purpose of identifying/verifying States' compliance with such statutory and regulatory requirements. The purpose of this request is to provide authority for the State to furnish such individuals with services in the home and community-based setting; **Frequency:** When a State requests a waiver or amendment to a waiver; **Affected Public:** State, Local or Tribal Government; **Number of Respondents:** 50; **Total Annual Responses:** 140; **Total Annual Hours:** 8,220.

Type of Information Collection

Request: Extension of a currently approved collection; **Title of Information Collection:** Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and of CLIA Exemption Under State Laboratory Programs and Supporting Regulations in 42 CFR 493.501, 493.506, 493.513, and 493.515; **Form No.:** HCFA-R-185 (OMB# 0938-0686); **Use:** The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation/licensure process is equal to or more stringent than those of CLIA. This information also provides a CLIA exemption of laboratories in a State that applies licensure requirements that are equal to or more stringent than those of CLIA; **Frequency:** Initial Application/as needed; **Affected Public:** Not-for-profit institutions, and State, Local, or Tribal Government; **Number of Respondents:** 22; **Total Annual Responses:** 11; **Total Annual Hours:** 2,112.

To obtain copies of the supporting statement and any related forms for the

proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Louis Blank, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: August 12, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 98-22356 Filed 8-19-98; 8:45 am]

BILLING CODE 4120-03-P

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 the following meeting.

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

Name of Committee: National Cancer Institute Special Emphasis Panel, Preclinical Evaluation of Intermediate Endpoints and their Modulation by Chemopreventive Agents.

Date: September 14, 1998.

Time: 3:00 PM to 5:30 PM.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Blvd. 6th Floor, Rockville, MD 20852.

Contact Person: Lalita D. Palekar, Scientific Review Administrator, Special Review,

Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard EPN-622B, Rockville, MD 20892-7405, 301/496-7575.

(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: August 14, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98-22410 Filed 8-19-98; 8:45 am]

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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 the following meeting.

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

Name of Committee: National Cancer Institute Special Emphasis Panel, Role of ETS Genes in Transformation and Differentiation.

Date: August 19, 1998.

Time: 2:00 PM to 5:00 PM.

Agenda: To review and evaluate grant applications.

Place: 6130 Executive Blvd. 6th Floor, Rockville, MD 20852.

Contact Person: David Irwin, PHD, Research Programs Review Section Chief, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institute of Health, 6130 Executive Boulevard, EPN-Room 635E, MSC 7405, Rockville, MD 20892-7405, (301) 402-0371, dj4k@nih.gov.

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

(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: August 14, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98-22411 Filed 8-19-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research 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 Board of Scientific Counselors, National Human Genome Research Institute.

The meeting will be open to the public as indicated below, 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.

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 Human Genome Research Institute, 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, National Human Genome Research Institute.

Date: September 16-18, 1998.

Closed: September 16, 1998, 5:30 PM to Recess.

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

Place: Airlie Center, 6809 Airlie Road, Warrenton, VA 20187.

Open: September 17, 1998, 8:30 AM to adjournment on September 18.

Agenda: Reports on the status of NHGRI, the status of the Division of Intramural Research, and updates on the branches.

Place: Airlie Center, 6809 Airlie Road, Warrenton, VA 20187.