Food and Drug Administration

[Docket No. 96N–0222]

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.

DATES: Submit written comments on the collection of information by October 10, 1996.

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

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1686.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance: §§ 70.25 *Labeling requirements for color additives (other than hair dyes)* (21 CFR 70.25) and 71.1 *Petitions* (21 CFR 71.1) (OMB Control Number 0910–0185—Reinstatement).

Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379e) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or unless the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Color additive petitions are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is approved already. Section 71.1 specifies the information that a petitioner must submit in order to establish the safety of a color additive and to secure the issuance of a regulation permitting its use.

FDA scientific personnel review color additive petitions to ensure that the intended use of the color additive in or on food, drugs, cosmetics, and medical devices is suitable and safe. Color additive petitions were specifically provided for by Congress when it enacted the Color Additive Amendments of 1960 (Pub. L. 94–295). If FDA stopped accepting color additive petitions or stopped requiring them to contain the information specified in § 71.1, the number of new color additives approved would decrease.

FDA's color additive labeling requirements in § 70.25 require that color additives that are to be used in foods, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

FDA estimates the burden of complying with the information collection provisions of the agency's color additive regulations as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
70.25	2	1	2			
71.1	2	1	2	1,700	3,415	$6,000
Total	2				3,415	$6,000

There are no capital costs associated with this collection.

This estimate is based on the number of new color additive petitions received in 1994. Although the burden varies with the type of petition submitted, a color additive petition involves analytical work and appropriate toxicology studies, as well as the work of drafting the petition itself. Because labeling requirements under § 70.25 for a particular color additive involve information required as part of the color additive petition safety review process, the estimate for number respondents is the same for § 70.25 as for § 71.1, and the burden hours for labeling are included in the estimate for § 71.1.

Dated: September 3, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–23098 Filed 9–9–96; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Alternative Medicine Program Advisory Council; Notice of Meeting

Pursuant to sec. 10(d) of the Federal Advisory Committee Act (FACA), as amended (Title 5, U.S.C. Appendix 2), notice is hereby given of the meeting of the Alternative Medicine Program Advisory Council on September 16, 1996 from 8:30 am to 5 pm and on September 17 from 8:30 am to 1 pm in the Versailles II Room of the Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland.

The entire meeting will be open to the public. The purpose of the meeting will be to update the Council on the progress of the Office of Alternative Medicine and obtain Council's advice on strategic planning for complementary and alternative medicine research. There will also be a scientific presentation, ''Shifting Paradigms in Growth Factor/Cytokine Biotechnology: The Science, the Paradigm, the Interface,'' by Barbara Brewitt, M.Div., Ph.D., Chief Scientist, Biomed Comm, Inc. and Leana Standish, N.D., Ph.D., Research Director, CAM Research Center, Bastyr University. Attendance by the public will be limited to space available.

Ms. Elizabeth Clay, Committee Management Officer, Office of Alternative Medicine, NIH, 9000 Rockville Pike, Building 31, Room 5B37, MSC 2182 Bethesda, MD 20892, phone (301) 594–1990, fax (301) 402–4741, E-Mail: bethclay@helix.nih.gov, will furnish the meeting agenda, roster of committee members, and substantive program information upon request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Clay at the above location no later than September 11, 1996.

This notice is being published less than 15 days prior to the meeting due

to the urgent need to proceed with the meeting as scheduled in order to address these issues in a timely manner.

Dated: August 30, 1996.

Margery G. Grubb,

Senior Committee Management Specialist, NIH.

[FR Doc. 96–22996 Filed 9–9–96; 8:45 am]

BILLING CODE 4140–01–M

Genetic Testing Task Force; Notice of Meeting

Notice is hereby given of the fourth meeting of the Task Force on Genetic Testing of the National Institutes of Health-Department of Energy Joint Working Group on the Ethical, Legal, and Social Implications of Human Genome Research (ELSI Working Group) on Tuesday, September 24, 1996, 1:00 pm to recess; Wednesday, September 25, 1996, 7:30 am to adjournment, at the Clarion Hotel at Mount Vernon Square, 612 Cathedral Street, Baltimore, Maryland, (410) 727–7101.

CONTACT PERSON: Neil Holtzman, M.D., M.P.H., Genetics and Public Policy Studies, The Johns Hopkins Medical Institutions, 550 North Broadway, Suite 511, Baltimore, Maryland 21205, (410) 955–7894.

The Task Force has developed Interim Principles primarily regarding scientific validation of new tests; laboratory quality; and education, counseling, and delivery. At this meeting, the Task Force will continue its consideration of recommendations to implement the Interim Principles, as well as revisions to the Interim Principles. The Interim Principles are available on the World Wide Web at: http://infonet.welch.jhu.edu/policy/genetics/

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Holtzman in advance of the meeting.

Dated: September 4, 1996.

Margery G. Grubb,

Senior Committee Management Specialist, NIH.

[FR Doc. 96–23012 Filed 9–9–96; 8:45 am]

BILLING CODE 4140–01–M

Notice of Meeting

Notice is hereby given of the open, public hearing of the National Institutes of Health-Department of Energy Joint Working Group on the Ethical, Legal, and Social Implications of Human Genome Research (ELSI Working Group) Evaluation Committee, on Wednesday, October 23, 1996, 9:00 am to noon at Hotel Sofitel Chicago, 5550 N. River Road, Rosemont, Illinois 60018–5194; TEL: (847) 678–4488.

Contact Person: Bettie Graham, Ph.D., NIH/NCHGR Bldg. 38A, Rm. 614, Bethesda, MD 20892; (301) 496–7531.

The ELSI Working Group Evaluation Committee has been charged with evaluation of the ELSO activities and role of external advisors in the ELSO program. The Committee will assess how, in the near term, it would be best to structure input on ELSI issues raised by and as a consequence of the Human Genome Project. The Committee will also assess how, in the longer term, it would be best to structure input on ELSI issues raised more generally by research involving human genetics. The Committee is seeking public comments on the following questions:

1. What role should external advisors (currently the ELSI Working Group) play in the ELSI program?
2. How should the external ELSI advisors relate to other government and private groups studying these issues?
3. How should the external ELSI advisors relate to other institutes, programs, and entities at the National Institutes of Health (NIH) and Department of Energy (DOE) with a shared research interest?
4. To whom at the NIH and the DOE should the external advisors report?
5. What procedures should be established for appointment of members, priority setting, budget, staffing, and policy development?
6. What changes, if any, will be necessary in the ELSI program as the focus of research shifts away from genomics?

Individuals or representatives of organizations wishing to make an oral presentation, of no more than five minutes, to the ELSI Working Group Evaluation Committee, on Wednesday, October 23, should submit their name, affiliation, address, telephone number, and summary of their remarks to Dr. Graham at the above address by October 14. Those making oral comments to the Committee will be accommodated to the extent possible during the time allotted for oral public comments. Written comments will be accepted up to October 14.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Dr. Graham two weeks in advance of the meeting.

Individuals who are unable to attend the public meeting, but who would like to submit comments may do so by writing to Mark A. Rothstein, Co-Chair, ELSI Working Group Evaluation Committee, Health Law and Policy Institute, University of Houston, Houston, TX 77204–6381 or to the Committee by e-mail at: elsiwg@net,bio.net.

Dated: September 4, 1996.

Margery G. Grubb,

Senior Committee Management Specialsit, NIH.

[FR Doc. 96–23008 Filed 9–9–96; 8:45 am]

BILLING CODE 4140–01–M

Notice of Meeting of the National Bioethics Advisory Commission (NBAC)

SUMMARY: Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), this notice is hereby given to announce an open meeting of the National Bioethics Advisory Commission (NBAC). The purpose of the meeting is to address: (i) the protections of the rights and welfare of human research subjects and (ii) the management and use of genetic information.

DATES: October 4, 1996, 8:30 a.m.–4:30 p.m.

PLACE: Conference Room 10, Building 31, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892.

SUPPLEMENTARY INFORMATION: The President established the National Bioethics Advisory Commission (NBAC) by Executive Order 12975, October 3, 1995. The purpose of the NBAC is to provide advice and make recommendations to the National Science and Technology Council, and other appropriate entities on bioethical issues arising from research on human biology and behavior and the applications, including the clinical applications, of that research.

Tentative Agenda

Friday, October 4, 1995

8:30 a.m. Call to order, opening remarks, and introductions
8:45 a.m. Presentations by spokespersons for members of the U.S. Senate and U.S. House of Representatives and discussion with and among NBAC members
10:30 a.m. Break
10:50 a.m. Morning presentations and discussions continue
11:45 a.m. Lunch
1:00 p.m. Presentations by Administration spokespersons and discussion with and among NBAC members