maintenance costs in table 1 of this document are, therefore, $1,781,400.

When determining the annual recordkeeping burden (table 2 of this document), we estimated that the number of firms that would maintain records to substantiate labeling that their products were not developed using bioengineering is the same as the number of respondents with the reporting burden minus the number of firms marketing organic products (i.e., 68). We did not include products that are labeled ''organic'' in the estimated annual recordkeeeping burden because according to a proposal in the **Federal Register** of March 13, 2000 (65 FR 13512), issued by the Agriculture Marketing Service of the U.S. Department of Agriculture, a food labeled as ''organic'' would not be permitted to contain bioengineered materials. Therefore, the 16,985 organic products available today would be able to bear a voluntary labeling statement that the food was not developed using bioengineering. Thus, there is no additional paperwork burden to substantiate a claim that a product is not developed using bioengineering for these products. Because most of the non-organic products whose producers have stated they will not use bioengineered ingredients are made by large firms for whom the verification process is not likely to impose a significant burden relative to the size of their operation, we assume that the paperwork processing time associated with testing or source verification for these products is approximately 1 hour for a total of 1,768 hours per year. Therefore, FDA estimated that the total recordkeeping burden would be 1,768 hours per year. Based on our experience, we have estimated that the overhead and maintenance cost are $30 per hour. The estimated total operating and maintenance cost in table 2 of this document are, therefore, $53,040 total.

III. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by March 19, 2001, to ensure adequate consideration in the preparation of a revised guidance, if warranted. However, interested persons may submit written comments at any time. 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. Submit to the Dockets Management Branch written comments concerning this collection of information by March 19, 2001. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

An electronic version of the draft guidance also is available on the Internet at http://www.cfsan.fda.gov/dms/.

Dated: November 15, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–1047 Filed 1–17–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Organ Procurement and Transplantation Network (42 CFR Part 121, OMB No. 0915–0184): Extension

The operation of the Organ Procurement and Transplantation Network (OPTN) necessitates certain recordkeeping and reporting requirements in order to perform the functions related to organ transplantation under contract to HHS. This is a request for an extension of the current recordkeeping and reporting requirements associated with the OPTN. These data will be used by HRSA in monitoring the contracts for the OPTN and the Scientific Registry and in carrying out other statutory responsibilities. Information is needed to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, and to ensure that all qualified entities are accepted for membership in the OPTN.

The estimated annual response burden is as follows:

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

Section and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
121.3(b)(2)—OPTN membership and application requirements for OPOs, hospitals, histocompatibility laboratories	30	1	30	40	1,200
121.6(c)—Submitting criteria for organ acceptance	900	1	900	0.1	90
121.6(c)—Sending criteria to OPOs	900	1	900	0.1	90
121.7(b)(4)—Reasons for Refusal	900	0.5	34,200	0.1	3,420
121.7(e)—Transplant to prevent organ wastage	900	0.5	420	0.1	42
121.9(b)—Designated Transplant Program Requirements	10	1	10	2	20

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN—Continued

Section and activity	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Total	940	38.8	36,460	.1	4,862

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: January 10, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–1390 Filed 1–17–01; 8:45 am]

BILLING CODE 4160–15–P

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 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 Center for Research Resources, Special Emphasis Panel, Research Centers in Minority Institutions.

Date: February 22, 2001.

Time: 6 p.m. to 7 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: C. William Angus, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6705 Rockledge Drive, MSC 7965, Room 6018, Bethesda, MD 20892—7965, 301–435–0812.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333; 93.371, Biomedical Technology; 93.389, Research Infrastructure, National Institutes of Health, HHS)

Dated: January 9, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1459 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(b) 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 Institute of General Medical Sciences Special Emphasis Panel.

Date: January 10, 2001.

Time: 3 PM to 4:30 PM.

Agenda: To review and evaluate grant applications.

Place: Natcher Building, Room 1AS–13, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Laura Moen, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 1AS–13H, Bethesda, MD 20892, 301–594–3998.

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. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: January 8, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1451 Filed 1–17–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; 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 personnel information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee.

Date: February 20, 2001.

Time: 8:30 AM to 3:30 PM.

Agenda: To review and evaluate grant applications.

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

Contact Person: John R. Lymangrover, PhD, Scientific Review Administrator, National Institutes of Health, NIAMS, Natcher Bldg., Room 5As25N, Bethesda, MD 20892, 301–594–4952.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 9, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–1452 Filed 1–12–01; 8:45 am]

BILLING CODE 4140–01–M