There are also an estimated 4,500 Health Care Financing Administration registered transfusion services. The recordkeeping chart reflects the estimate that 95 percent of the recordkeepers which collect 98 percent of the blood supply had developed SOP's as part of their normal business practice. Establishments may minimize burdens associated with the CGMP and related regulations by using model SOP's developed by blood organizations. These blood organizations represent almost all of the registered establishments.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
606.170(b)	42	1	42	8	336

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
606.100(b)	151	1	151	24	3,624
606.100(c)	151	3.6	550	3.6	550
606.110(a)	90	5	450	2.5	225
606.151(e)	239	12	2,868	1	239
606.160	151	3,112	470,000	1,556	234,956
606.165	151	3,112	470,000	258	38,958
606.170(a)	376	12	4,512	12	4,512

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32458 Filed 12–10–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0453]

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 January 12, 1998.

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

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Human Tissue Intended for Transplantation (OMB Control Number 0910–0302)—Reinstatement

FDA issued final regulations in the **Federal Register** of July 29, 1997 (62 FR 40429) to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B, and hepatitis C through the use of human tissue for transplantation. The final regulations closely parallel those contained in the interim rule on human tissue intended for transplantation. Both the interim and final rule provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet standards intended to ensure appropriate screening and testing of human tissue donors and ensure that records are kept documenting that the appropriate screening and testing have been completed.

There are approximately 60 tissue establishments with 300 employees that are members of the American Association of Tissue Banks. There are an additional 600 individual members of which 50 percent are performing a tissue banking activity. The Eye Bank Association of America's membership consists of 120 eye banks of which 110 are in the continental United States.

With the rare exceptions noted in the preamble of the rule, FDA believes that all respondents perform donor testing and screening for HIV and hepatitis and these regulations add no additional requirements. 21 CFR 1270.31(c) and (d) require written procedures for the designation and identification of quarantined tissue and to prevent the contamination or cross-contamination of tissue during processing. 21 CFR 1270.35(c) requires documentation of the distribution and receipt of human tissue, completing the accounting of tissue between determination of suitability, and the destruction or disposition of the tissue.

When the interim rule was issued in the **Federal Register** of December 14, 1993 (58 FR 65514), accredited members of the American Association of Tissue Banks and the Eye Bank Association of America were already in compliance with the regulations by adhering to the standards established by these organizations. The requirements in the

final rule do not impose an additional burden since the members will be complying with the current organizations' standards which are comparable to the requirements in the final rule. To account for persons or establishments that may not be a member of an industry organization and, for whom therefore, the extent of compliance with the requirements of the final rule is unknown, FDA will be using 1 percent as an estimation of the information collection burden on the tissue industry.

Industry estimates that in 1994 there were 350,000 bone transplants, 42,000 corneal transplants, 5,000 patellar tendon transplants, and the transplantation of 5,000 square feet of skin. There are approximately 300 persons and 170 tissue banks currently operating in the Untied States affected by the regulations.

The total annual estimated burden imposed by this collection of information is 32,260 hours annually.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1270.31 (b)–(d)	11	4	44	28	308
1270.35 (a)–(b)	11	420	4,620	290	3,190
1270.35 (c)	11	2,893	31,823	4,782	52,602
1270.35 (d)	11	17	187	17	187
Total	.....	.....	.....	.....	56,287

There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32459 Filed 12–10–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that published in the **Federal Register** of November 25, 1997 (62 FR 62777). The notice announced a meeting of the Orthopaedics and Rehabilitation Devices Panel of the Medical Devices Advisory Committee that is scheduled for December 11 and 12, 1997. The notice published with an error. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 25, 1997 (62 FR 62777), in FR Doc. 97–30914, FDA announced that a meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee would be held on December 11 and 12, 1997. The notice published with an error in the first sentence in the *Agenda* portion of the meeting.

Beginning on page 62777, in the 2d column, under the *Agenda* portion of the meeting, the first sentence should be corrected to read ''On December 11, 1997, the committee will discuss, make recommendations, and vote on one premarket approval application (PMA) for a spinal intervertebral fusion device and a second PMA for a spinal intervertebral fusion system.''

Dated: December 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–32584 Filed 12–9–97; 3:03 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of February 1998:

Name: National Advisory Committee on Rural Health.

Dates and Time: February 1–4, 1998.

Place: J.W. Marriott Hotel, 1331 Pennsylvania Avenue, N.W., Washington, D.C. 20004, Phone: (202) 393–2000, FAX: (202) 626–6915.

The meeting is open to the public.

Agenda: The plenary session on Monday morning, February 2, will include a national legislative update, discussion of quality issues, universal service provisions of the Telecommunications Act, definition of rural, and telemedicine payment issues.

Presentations on graduate medical education, the rural minority health project, and long-term care; assisted living housing will be the bases of discussion for the Committee of the Whole on Tuesday.

The final plenary session will be convened on Wednesday, February 4, at 8:00 a.m. During this session there will be an update of the Office of Rural Health Policy activities, a report of the Committee of the Whole regarding the discussions that took place on Tuesday, and information regarding the next agenda and future meeting dates and places will be discussed. The meeting will be adjourned at approximately 11:30 a.m.

Anyone requiring information regarding the subject Committee should contact Dena S. Puskin, Sc.D., Executive Secretary, National Advisory Committee on Rural Health, Health Resources and Services Administration, Room 9–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443–0835, FAX (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Arlene A. Granderson or Lilly Smetana, Office of Rural Health Policy, (301) 443–0835.

Agenda items change as priorities dictate.

Dated: December 4, 1997.

Jane M. Harrison,

Committee Management Office, HRSA.

[FR Doc. 97–32409 Filed 12–10–97; 8:45 am]

BILLING CODE 4160–15–P

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 the following meeting: