

Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations for premarket approval applications (21 CFR part 814, OMB control number 0910–0231) and the regulations for premarket notification submissions (21 CFR part 807, OMB control number 0910–0120).

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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: Data System for Organ Procurement and Transplantation Network and Associated Forms (OMB No. 0915–0157): Revision

Section 372 of the Public Health Service (PHS) Act requires that the

Secretary, by contract, provide for the establishment and operation of an Organ Procurement and Transplantation Network (OPTN). The OPTN, among other responsibilities, operates and maintains a national waiting list of individuals requiring organ transplants, maintains a computerized system for matching donor organs with transplant candidates on the waiting list, and operates a 24-hour telephone service to facilitate matching organs with individuals included in the list.

Data for the OPTN data system are collected from transplant hospitals, organ procurement organizations, and tissue-typing laboratories. The information is used to match donor organs with recipients, to monitor compliance of member organizations with OPTN rules and requirements, and to report periodically on the clinical and scientific status of organ donation and transplantation in this country. Data are used in the development and revision of OPTN rules and requirements, operating procedures, and standards of quality for organ acquisition and preservation, some of which have provided the foundation for development of Federal regulations. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available without restriction for use by OPTN members, the Scientific Registry of Transplant Recipients, the Department of Health and Human Services, and others for evaluation, research, patient information, and other important purposes.

Revisions in the 28 data collection forms and addition of 2 survey instruments are intended to clarify existing questions, to provide additional detail and categories to avoid confusion and be more inclusive, to remove obsolete data, and to comply with requests for more complete and precise data.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Deceased Donor Registration	59	173	10,207	0.3	3,062.10
Death referral data	59	12	708	10	7,080.00
Living Donor Registration	692	10	6,920	0.2	1,384.00
Living Donor Followup	692	19	13,148	0.1	1,314.80
Donor Histocompatibility	152	87	13,224	0.1	1,322.40
Recipient Histocompatibility	152	163	24,776	0.1	2,477.60
Heart Candidate Registration	139	23	3,197	0.3	959.10
Lung Candidate Registration	70	28	1,960	0.3	588.00
Heart/Lung Candidate Registration	72	1	72	0.3	21.60
Thoracic Registration	139	24	3,336	0.3	1,000.80
Thoracic Followup	139	174	24,186	0.2	4,837.20
Kidney Candidate Registration	247	109	26,923	0.2	5,384.60
Kidney Registration	247	65	16,055	0.3	4,816.50
Kidney Followup *	247	493	121,771	0.2	24,354.20