comments and suggestions submitted within 60 days of this publication.

Dated: May 25, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–12877 Filed 5–27–10; 8:45 am]

BILLING CODE 4184–01–P

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 the Office of Management and Budget (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, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (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 and Scientific Registry of Transplant Recipients Data System (OMB No. 0915–0157)—Extension

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 system 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 indicate the disease severity of transplant candidates, 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 to develop transplant, donation and allocation policies, to determine if institutional members are complying with policy, to determine member specific performance, to ensure patient safety and to fulfill the requirements of the OPTN Final Rule. The practical utility of the data collection is further enhanced by requirements that the OPTN data must be made available, consistent with applicable laws, 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.

No revisions of the 26 data collection forms are proposed at this time; however, the OPTN is currently undergoing a review of the forms and expects to submit proposed revisions within the next year.

The annual estimate of burden is as follows:

Form	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
Deceased Donor Registration	58	216	12,528	0.7500	9,396.00
Death referral data	58	12	696	10.0000	6,960.00
Death Notification Referral—Eligible	58	161	9338	0.2000	1,867.60
Death Notification Referral—Imminent	58	168	9744	0.5000	4,872.00
Living Donor Registration	308	39	12,012	0.6500	7,807.80
Living Donor Follow-up	308	50	15,400	0.5000	7,700.00
Donor Histocompatibility	156	131	20,436	0.1000	2,043.60
Recipient Histocompatibility	156	196	30,576	0.2000	6,115.20
Heart Candidate Registration	127	35	4,445	0.5000	2,222.50
Lung Candidate Registration	68	42	2,856	0.5000	1,428.00
Heart/Lung Candidate Registration	51	2	102	0.5000	51.00
Thoracic Registration	127	36	4,572	0.7500	3,429.00
Thoracic Follow-up	127	320	40,640	0.6500	26,416.00
Kidney Candidate Registration	241	183	44,103	0.5000	22,051.50
Kidney Registration	241	83	20,003	0.7500	15,002.25
Kidney Follow-up*	241	742	178,822	0.5500	98,352.10
Liver Candidate Registration	129	109	14,061	0.5000	7,030.50
Liver Registration	129	58	7,482	0.6500	4,863.30
Liver Follow-up	129	519	66,951	0.5000	33,475.50
Kidney/Pancreas Candidate Registration	143	14	2,002	0.5000	1,001.00
Kidney/Pancreas Registration	143	7	1,001	0.9000	900.90
Kidney/Pancreas Follow-up	143	85	12,155	0.8500	10,331.75
Pancreas Candidate Registration	143	7	1,001	0.5000	500.50
Pancreas Registration	143	3	429	0.7500	321.75
Pancreas Follow-up	143	20	2,860	0.6500	1,859.00
Intestine Candidate Registration	44	7	308	0.5000	154.00
Intestine Registration	44	5	220	0.9000	198.00
Intestine Follow-up	44	28	1,232	0.8500	1,047.20
Post Transplant Malignancy	684	10	6,840	0.2000	1,368.00

Form	Number of respondents	Responses per respondents	Total responses	Hours per response	Total burden hours
Total	463		522,815		278,765.95

* Includes an estimated 2,500 kidney transplant patients transplanted prior to the initiation of the data system.

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 25, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–12964 Filed 5–27–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0119]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 28, 2010.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0502. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002— (OMB Control Number 0910–0502)—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 415 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350d), which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. Sections 1.230 through 1.235 of FDA's regulations (21 CFR 1.230 through 1.235) set forth the procedures for registration of food facilities. Information provided to FDA under these regulations will help the agency to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply.

Description of Respondents: The respondents to this information collection include owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States. Domestic facilities are required to register whether or not food from the facility enters interstate commerce. Foreign facilities that manufacture/process, pack, or hold food also are required to register unless food from that facility undergoes further processing (including packaging) by another foreign facility before the food is exported to the United States. However, if the subsequent foreign facility performs only a minimal activity, such as putting on a label, both facilities are required to register.

FDA's regulations require that each facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States register with FDA using Form FDA 3537 (§ 1.231). The term "Form FDA 3537" refers to both the paper version of the form and the electronic system known as the Food Facility Registration Module, which is available at *http://www.access.fda.gov*. The agency strongly encourages electronic registration because it is faster and more convenient. The system the agency has developed can accept electronic registrations from anywhere in the world 24 hours a day, 7 days a week. A registering facility will receive confirmation of electronic registration and its registration number instantaneously once all the required fields on the registration screen are filled in. However, paper registrations will be accepted. Form FDA 3537 is available for download for registration by mail, fax, or CD–ROM. Registration by mail may take several weeks to several months, depending on the speed of the mail system and the number of paper registrations that FDA will have to enter manually.

Information FDA requires on the registration form includes the name and full address of the facility; emergency contact information; all trade names the facility uses; applicable food product categories identified in § 170.3 (21 CFR 170.3), unless "most/all" human food categories "or none of the above mandatory categories" is selected as a response; and a certification statement that includes the name of the individual authorized to submit the registration form. Additionally, facilities are encouraged to submit their preferred mailing address; type of activity conducted at the facility; food categories not included under § 170.3, but which are helpful to FDA for responding to an incident; type of storage, if the facility is primarily a holding facility; and approximate dates of operation if the facility's business is seasonal.

In addition to registering, a facility is required to submit timely updates within 60 days of a change to any required information on its registration form, using Form FDA 3537 (§ 1.234), and to cancel its registration when the facility ceases to operate or is sold to new owners or ceases to manufacture/process, pack, or hold food for consumption in the United States, using Form FDA 3537a (§ 1.235).

In the **Federal Register** of March 16, 2010 (75 FR 12547), FDA published a 60-day notice requesting public comment on the proposed collection of