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 emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0342. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

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.

Substances Generally Recognized as Safe (GRAS): Notification Procedure—21 CFR Part 170, Subpart E and 21 CFR Part 570, Subpart E

OMB Control Number 0910–0342—Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that all food additives (as defined by section 201(s) (21 U.S.C. 321(s)) be approved by FDA before they are marketed. Section 409 of the FD&C Act (21 U.S.C. 349) establishes a premarket approval requirement for ''food additives.'' Section 201(s) of the FD&C Act provides an exclusion to the definition of food additive and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. The GRAS provision of section 201(s) of the FD&C Act is implemented in (part 170) 21 CFR part 170 and (part 570) 21 CFR part 570 for human food and animal food, respectively. Part 170, subpart E and part 570, subpart E provide a standard format for the submission of a notice. This collection utilizes a voluntary administrative procedure for notifying FDA about a conclusion that a substance is GRAS under the conditions of its intended use in human food or animal food. The information submitted to us in a GRAS notice is necessary to allow us to administer efficiently the FD&C Act's various provisions that apply to the use of substances added to food, specifically with regard to whether a substance is GRAS under the conditions of its intended use or is a food additive subject to premarket review. We use the information collected through the GRAS notification procedures to complete our evaluation within specific timelines.

Description of Respondents: The respondents to this collection of information are manufacturers of substances used in human food and animal food and feed.

In the **Federal Register** of March 12, 2019 (84 FR 8876), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
GRAS notification procedure for human food; 170.210–170.280 (part 170, subpart E)	100	1	100	170	17,000
GRAS notification procedure for animal food and animal feed; 570.210–570.280 (part 570, subpart E)	25	1	25	170	4,250
Total			75		21,250

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

Our estimated burden reflects an overall increase of 8,500 hours, which corresponds to an increase in GRAS submissions for human food from 50 to 100 we have received over the last 2 years.

Dated: June 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13220 Filed 6–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Small Rural Hospital Transition Project (SRHT), OMB No. 0906–0026—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than August 20, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the

information request collection title for reference.

Information Collection Request Title: Small Rural Hospital Transition Project (SRHT), OMB No. 0906–0026—Extension.

Abstract: Under Section 330A of the Public Health Service Act (42 U.S.C. 254c), the Federal Office of Rural Health Policy (FORHP) funds grant programs supporting expanding access to, coordinating, restraining the cost of, and improving the quality of essential health care services in rural and frontier communities. Small rural hospitals are facing many challenges in the new health care environment including the concurrent need to better measure and account for quality of care in all settings, improve transitions of care as patients move from one care setting to another, the evolution of new payment approaches such as value-based purchasing, and new approaches to care delivery such as accountable care organizations (ACO) and patient-centered medical homes. Success in this new environment will require bridging the gaps between the current system and the newly emerging system of healthcare delivery and payment. Because little is known about how these new models might impact rural communities, there is a need to help hospitals understand and consider those factors that would make them logical participants in health care systems that focus on quality, rather than the quantity of care provided to patients. The Small Rural Hospital Transition (SRHT), also funded by Section 330A, assists small rural hospitals facing these challenges. The purpose of the project is to provide on-site technical assistance to nine small rural hospitals residing in persistent poverty counties. Technical assistance is provided in the areas of: (1) Conducting financial assessments, (2) creating a quality-focused environment, (3) aligning services to community need, and (4) to the extent that financial and quality core areas have been stabilized, providing assistance to help recipients of technical assistance consider factors that would make them logical participants in health care systems that focus on value (*e.g.,* ACOs, shared savings programs, and primary care medical homes).

Need and Proposed Use of the Information: This information collection request consists of two forms: The SRHT Online Application and the Assessment. The application form is designed to solicit information that will be scored and ranked to aid in the selection of nine small rural hospitals to receive on-site technical assistance. The assessment determines applicant capacity in specific key areas leading to performance excellence across the organization (*e.g.,* leadership, strategic planning, operations, and processes).

Likely Respondents: The likely respondents are small rural hospitals located in a rural community. Hospitals must be (1) rural, as defined by FORHP and reside in a persistent poverty county or (2) reside in the rural census tract of a metro county (non-rural county) that is also a persistent poverty county and have 49 staffed beds or less as reported on the hospital's most recently filed Medicare Cost Report. Hospitals may be for-profit or not-for-profit.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total
SRHT Online Application	30	1	30	.50	15.0
Assessment: Performance Excellence for Rural Hospitals	30	1	30	.25	7.5
Total	*30		60		22.5

*The same individuals complete the SRHT Online Application and the Assessment for a total of 30 respondents.

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–13195 Filed 6–20–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates to be considered for appointment as members of the Advisory Committee on Organ Transplantation (ACOT). ACOT shall: (1) Advise the Secretary, acting through the HRSA Administrator, on all aspects of organ donation, procurement, allocation, and transplantation, and on such other matters that the Secretary determines; (2) advise the Secretary on federal efforts to maximize the number of deceased donor organs made available for transplantation and to support the safety of living organ donation; (3) at the request of the Secretary, review significant proposed Organ Procurement and Transplantation Network (OPTN) policies submitted for the Secretary's approval to recommend whether they should be made enforceable; and (4) provide expert input to the Secretary on the latest advances in the science of