FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Request for CLIA Categorization	60	15	900	1	900	$46,800

[1] There are no capital costs associated with this collection of information.

The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at $52 per hour ($52 \times 900$), totaling $46,800. This includes the cost of copying and mailing copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (*e.g.,* paper).

Dated: April 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09769 Filed 4–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Office of Medical Products and Tobacco; Center for Drug Evaluation and Research; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Medical Policy has modified its structure. This new organizational structure was approved by the Secretary of Health and Human Services on December 15, 2016, and effective on April 17, 2016.

FOR FURTHER INFORMATION CONTACT: Melanie Keller, Office of Management, Center for Drug Evaluation and Research, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301–796–3291.

I. Summary

This organization will expand current activities in the Office of Medical Policy and foster efficient oversight of clinical trials conducted through policy initiatives that build quality upfront and science-based inspectional approaches. This will provide an oversight and direction for new and ongoing policy initiatives in broad-based medical and clinical policy areas, including initiatives to improve science and efficiency trials.

The Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Medical Policy has been restructured as follows:

DKKNF. ORGANIZATION. The Office of Medical Policy is headed by the Director, Office of Medical Policy and includes the following organizational units:

Office of Medical Policy
Office of Prescription Drug Promotion
Division of Advertising and Promotion Review I
Division of Advertising and Promotion Review II

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guides (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's Web site at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm.*

Authority: 44 U.S.C. 3101.

Dated: April 19, 2016.

Sylvia M. Burwell,

Secretary of Health and Human Services.

[FR Doc. 2016–09761 Filed 4–26–16; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (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 June 27, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, Parklawn Building, 5600 Fishers Lane, Rockville, MD 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 the HRSA Information Collection Clearance Officer at (301) 443–1984.

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