Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information related to the content and format of labeling have been approved under OMB control no. 0910–0572; the collections of information related to pharmacogenomic data have been approved under OMB control no. 0910–0557.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.regulations.gov*.

Dated: February 20, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–4372 Filed 3–2–09; 8:45 am]

BILLING CODE 4160–01–S

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 on (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: HRSA Office of Performance Review (OPR) Leading Practices Data Collection Initiative—NEW

HRSA conducts performance reviews to assure that HRSA-funded grantees are successfully accomplishing their program purposes. While the Office of Performance Review's (OPR) primary function is to conduct performance reviews, another core function is to identify leading practices through the performance review process. The purpose of this submission is to collect qualitative information from diverse grantees across HRSA and identify a program component (activity, strategy, process, or intervention) that has been shown to work effectively, and produce successful outcomes, supported by objective and/or subjective data sources. Some characteristics of the program components that grantees will be asked to describe are their ability to be replicable and adaptable, ability to be documented, and ability to lead to successful program outcomes.

In order to document and evaluate leading practices, grantees with potential leading practices will be asked to complete both the Data Collection Tool and the Narrative. The information collected through these documents will be submitted to OPR. The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Data Collection Tool	40	1	40	3	120
Narrative	40	1	40	3	120
Total					240

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: February 24, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9–4459 Filed 3–2–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Health Centers Patient Survey—New.

The Health Center program supports Community Health Centers (CHCs), Migrant Health Centers (MHCs), Health Care for the Homeless (HCH) projects, and Public Housing Primary Care (PHPC) programs. Health Centers receive grants from HRSA to provide primary and preventive health care services to medically underserved populations.

The proposed Patient Survey will collect in-depth information about health center patients, their health

status, the reasons they seek care at health centers, their diagnoses, the services they utilize at health centers and elsewhere, the quality of those services, and their satisfaction with the care they receive, through personal interviews of a stratified random sample of health center patients. Interviews are planned to take approximately 1 hour and six minutes each.

The Patient Survey builds on previous periodic User-Visit Surveys which were conducted to learn about the process and outcomes of care in CHCs and HCH projects. The original survey questions were derived from the National Health Interview Survey (NHIS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) conducted by the National Center for Health Statistics (NCHS). Conformance with the NHIS and NHAMCS allowed comparisons between these NCHS surveys and the previous CHC and HCH User-Visit Surveys. The new Patient Survey was developed using a questionnaire methodology similar to that used in the past, and will also allow some longitudinal comparisons for CHCs and HCH projects with the previous User-Visit survey data, including monitoring of process outcomes over time. In addition, this survey will include interviews of patients drawn from migrant populations and from residents of public housing; these populations were not included in the previous surveys.

The annual estimate of burden is as follows:

The estimated response burden for the survey is as follows:

SURVEY

Type of respondent; activity involved	Number of respondents	Responses per respondent	Total number of responses	Burden per response (hours)	Total hour burden
Grantee/Site Recruitment and Site Training	115	3	345	3.75	1,294
Patient Recruitment	5,658	1	5,658	.167	945
Patient Survey	4,526	1	4,526	1.1	4,979
Total	5,773	.....	10,529	.....	7,218

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. Please direct all correspondence to the ''attention of the desk officer for HRSA.''

Dated: February 24, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9–4460 Filed 3–2–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Prevention of Head and Neck Cancer Using Rapamycin and Its Analogs

Description of Technology: It is frequently observed in head and neck squamous cell carcinoma (HNSCC), a cancer occurring mostly in the mouth, that the Akt/mTOR pathway is abnormally activated. Therefore, inhibiting this signaling pathway may help in treating this disease. Rapamycin and its analogs are known to inhibit the activity of mTOR so in principle they could serve as therapeutics for treating HNSCC.

Researchers at the NIH have developed a method of potentially preventing or treating HNSCC through the inhibition of mTOR activity. The proof of this principle was demonstrated by rapid regression of mouth tumors in mice afflicted with Cowden syndrome with the administration of rapamycin. Like HNSCC, development of this disease is linked to over activation of the Akt/mTOR pathway. Furthermore, the therapeutic potential of rapamycin was demonstrated using mice in experiments that model chronic exposure to tobacco, which promotes the development of HNSCC. Therefore, inhibitors of mTOR have considerable potential in the prevention and treatment of HNSCC.

Applications: Preventing the development of oral cancer using mTOR inhibitors to halt progression of pre-cancerous lesions.

Market: Approximately 500,000 new cases of squamous cell carcinomas of the head and neck arise every year making it the 6th most common cancer in the world.

Frequently, prognosis is poor due to late detection of cancer.

Development Status: Pre-clinical proof of principle.

Inventors: J. Silvio Gutkind *et al.* (NIDCR).

Publications: 1. CH Squarize, RM Castilho, JS Gutkind. Chemoprevention and treatment of experimental Cowden's disease by mTOR inhibition with rapamycin. Cancer Res. 2008 Sep 1;68(17):7066–7072.

2. R Czerninski, P Amornphimoltham, V Patel, AA Molinolo, JS Gutkind. Targeting mTOR by rapamycin prevents tumor progression in an oral-specific chemical carcinogenesis model. Cancer Prevention Res. 2009 Jan;2(1):27–36.

Patent Status: U.S. Patent Application No. 61/090/414 filed 20 Aug 2008 (HHS Reference No. E–302–2008/0-US–01).

Licensing Status: Available for licensing.

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Dental and