

TABLE 2.—ESTIMATED REPORTING BURDENS FOR LABELING REVISIONS TO ALREADY-APPROVED DRUG PRODUCTS¹—
Continued

Category (21 CFR Section)	Year(s) In Which Burdens Occur After June 30, 2006	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours	Total Capital Costs
Burden associated with revised labeling for efficacy supplements for generic drug products (§ 201.57)	Beginning year 3, continuing annually thereafter	42	8	336 (for years 1–10)	27	9,072	\$2.5 million
Total						112,952	Up to \$8.3 million

¹ There are no operating and maintenance costs associated with this collection of information.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: September 17, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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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 (42 U.S.C. 3501 *et seq.*). To request a copy

of the clearance requests submitted to OMB for review, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Office at (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: Data Collection Tool for State Offices of Rural Health Grant Program: (New)

The mission of the Office of Rural Health Policy (ORHP) is to sustain and improve access to quality care services for rural communities. In its authorizing language (Sec. 711 of the Social Security Act [42 U.S.C. 912]), Congress charged ORHP with “administer[ing] grants, cooperative agreements, and contracts to provide technical assistance and other activities as necessary to support activities related to improving health care in rural areas.”

The State Offices of Rural Health Grant Program (SORH) is authorized by Section 338J of the Public Health Service Act (42 U.S.C. 254r). The purpose of SORH is to assist States in strengthening their rural health care delivery systems by helping to support a focal point for rural health within each State. The program provides funding for an institutional framework that links rural hospitals, providers and

communities with State and Federal resources to help develop long term solutions to rural health problems. The average annual award for each State based grantee is \$150,000. The law provides for a Federal-State partnership, requiring a State funding match of \$3 for each \$1 of Federal funding. Over the past 16 years, this program has leveraged in excess of \$200 million in State matching funds for rural health.

For SORH, program performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. ORHP seeks to collect information from grantees on their efforts to provide technical assistance to clients within their State. SORH grantees would be required to submit a Technical Assistance Report that includes: 1) The total number of technical assistance encounters provided directly by the grantee; and, 2) the total number of clients that received direct technical assistance from the grantee. Submission of the Technical Assistance Report would be done via e-mail to ORHP no later than 30 days after the end of each twelve month budget period.

The estimated average annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Technical Assistance Report	50	1	50	12.5	625
Total	50	625

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: September 22, 2008

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

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