

techniques, when appropriate, and other forms of information technology.

1. Evaluation of Proposed OTC Label Formats and OTC Label Format Preference

Under sections 201(n) and 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C 321(n) and 352), FDA has the authority to ensure that approved drugs are properly labeled. Section 201(n) of the act defines a drug as misbranded if its labeling or advertising is misleading; this includes the failure to reveal material facts. Under section 903 of the act (21 U.S.C. 393), FDA may conduct research related to drugs and conduct educational and public information programs relating to the responsibilities of the FDA. FDA will evaluate proposed OTC label formats and study the effect of various label formats on consumers' preference. The agency will conduct two studies:

In study A (Evaluation of Proposed OTC Label Formats), consumers will be shown the label of an OTC drug using either the proposed or the traditional format. Based on the different labels and different reading conditions, consumers' knowledge, attitudes, and decisions about proper drug use will be investigated.

In study B (OTC Label Format Preference), consumers will be asked to view examples and variations of current OTC label designs. Respondents will be asked to indicate their preference for various designs, as well as demonstrate memory retention of labeling information. Also, consumers will be asked to evaluate labeling terminology and graphics to investigate how they interpret various ways of communicating drug safety and effectiveness.

2. Evaluation of Statement of Identity Comprehension and of Alcohol Warning Statement Comprehension

Under sections 201(n) and 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C 321(n) and 352), FDA has the authority to ensure that approved drugs are properly labeled. Section 201(n) of the act defines a drug as misbranded if its labeling or advertising is misleading; this includes the failure to reveal material facts. Under section 903 of the act (21 U.S.C. 393), FDA may conduct research related to drugs and conduct educational and public information programs relating to the responsibilities of the FDA. FDA will study the comprehension of the statement of identity and warning

information on labeling for OTC drug products. FDA will conduct two studies:

In study C (Statement of Identity Comprehension), consumers will be asked to view examples and variations of the placement of OTC statement of identity information. Respondents will be asked to demonstrate their perceptions and reactions to placement of active ingredient(s), pharmacologic category, and/or intended action information on the front and/or back portion of the product package.

In study D (Alcohol Warning Statement Comprehension), consumers will be asked to rate the clarity or understandability of the warning message. Respondents will be asked to rate various methods of conveying the alcohol warning that systematically vary the specificity, permissiveness, frequency, and quantity descriptors in the alcohol warning messages.

In each of the four studies, participants will examine materials varied by one or more format or content variables. Central location intercept sites that are geographically dispersed will be used to recruit and question respondents.

FDA estimates the burden of these collections of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
A & B	2,100	1	2,100	.5	1,050
C & D	480	1	480	.5	240

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

Dated: May 19, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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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 35, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and

Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to 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, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (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: The Health Education Assistance Loan (HEAL) Program: Forms—0915-0043—Extension, No Change

This clearance request is for extension of approval for 3 HEAL forms: the Repayment Schedule is used by lenders to inform the borrower of the cost of a HEAL loan, the number and amount of payments, and the Truth-in-Lending requirements; the Promissory Note is used by the lender to provide the borrower with the legally binding terms of the loan; and the Lender's Report (also known as the Call Report) is used by the lender to provide the Department with information on the status of all loans outstanding. The forms are needed to provide borrowers with information on their responsibilities and to determine which lenders may have

excessive delinquencies and defaulted

loans. The estimate of burden for the forms are as follows:

Form and No.	Number of respondents	Responses per respondent	Number of responses	Burden per response (hrs.)	Total burden hours
Disclosure:					
Repayment Schedule HRSA 501-1,2	11	1,090	12,000	.5	6,000
Promissory Note, HRSA 500-1,2, & 3	11	1,384	15,227	.5	7,614
Disclosure Subtotal	11	2,474	27,227	.5	13,614
Reporting:					
Call Report HRSA 512	32	4	128	.75	96
Reporting Subtotal	32	4	128	.75	96
Total	32	855	27,355	.5	13,710

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 14, 1997.

J. Henry Montes,

Director, Office of Policy and Information Coordination.

[FR Doc. 97-13610 Filed 5-22-97; 8:45 am]

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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 35, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub.L. 104-13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to 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, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (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: Progress Reports for Continuation Training Grants—0915-0061—Extension and Revision (Former Title “HRSA Noncompeting Training Grant Application”)

The HRSA Noncompeting Training Grant Application (HRSA Form 6025-2) has been used in the past for the preparation and submission of continuation applications for Titles VII and VIII health professions and nursing education and training programs. These continuation applications included general grantee information, a detailed budget and justification for the current budget year, a progress report, and other related information.

The HRSA Bureau of Health Professions has recently done a comprehensive review of grants management processes and made changes to streamline the processes for both grantees and Bureau staff. One of the changes resulted in replacing the requirement for submission of the continuation application with submission of a focused progress report with measurable objectives and outcome measures. Other information that was included in the application is either repetitious of information already contained in grants files or is not needed.

The progress report is needed to determine whether progress has been sufficient under the original project objectives to warrant continuation support. Grantees must demonstrate satisfactory progress or continuation awards cannot be made. Progress will be measured based on the objectives of the grant project, and outcome measures and indicators developed by the Bureau

to meet requirements of the Government Performance and Results Act (GPRA).

The new progress report is in development and will be completely automated allowing the grantees to obtain, complete and submit the report electronically.

The estimate of burden for the progress reports for continuation training grants is as follows:

Number of respondents	Responses per respondent	Hours per response	Total burden hours
927	1	20	18,540

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: May 14, 1997.

J. Henry Montes,

Director, Office of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Project Grants for Renovation or Construction of Non-Acute Health Care Facilities

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of limited competition for grant funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that approximately \$725,000 is available for project grants to renovate or construct outpatient clinics. Funds were appropriated by Public Law 104-