

phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* May 6, 1995. The applicant claims April 30, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 6, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* January 17, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for Zemplar (NDA 20-819) was initially submitted on January 17, 1997.

3. *The date the application was approved:* April 17, 1998. FDA has verified the applicant's claim that NDA 20-819 was approved on April 17, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 574 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before April 30, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 30, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857,

part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 16, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99-4877 Filed 2-26-99; 8:45 am]

BILLING CODE 4160-01-F

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 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, call the HRSA Reports Clearance Officer on (301) 443-1891.

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: Health Education Assistance Loan (HEAL) Program: Lender's Application for Insurance Claim Form and Request for Collection Assistance Form (OMB No. 0915-0036)—Extension

This clearance request is for a revision of two forms that are currently approved by OMB. HEAL lenders use the Lenders Application for Insurance Claim to request payment from the Federal Government for federally insured loans lost due to borrowers' death, disability, bankruptcy, or default. The Lenders Application for Insurance Claim form has been revised to reflect information necessary to approve a claim and is substantiated in supporting documentation submitted with each claim request. These revisions will facilitate the Department's efforts towards electronic claim request submissions. The Request for Collection Assistance form is used by HEAL lenders to request federal assistance with the collection of delinquent payments from HEAL borrowers. No changes are proposed for the Request for Collection Assistance form.

The estimates of annualized burden are as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Lender's Application for Insurance Claim	20	75	1,500	30 minutes	750
Request for Collection Assistance	20	1,260	25,200	10 minutes	4,208
Total Burden	20	4,958

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 23, 1999.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99-4948 Filed 2-26-99; 8:45 am]

BILLING CODE 4160-15-P

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, Public Law 104-13), the Health Resources and Services Administration

(HRSA) publishes 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 and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1891.

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: Project to Assess Ethnicity/Race and Services to Bi/Multilingual Populations in Community and Migrant Health Centers—NEW

The Office of Minority and Women's Health (OMWH) in the Bureau of

Primary Health Care (BPHC), Health Resources and Services Administration (HRSA), recognizes that full understanding of the ethnicity of clients and providers and the provision of language appropriate services are vital to guaranteeing full and effective health care. OMWH proposes to conduct a voluntary survey, the purpose of which will be two-fold: (1) To obtain detailed data on the ethnic/racial composition of health center users and providers; and (2) to collect information about the composition and provision of bi/multilingual services. This information will be collected from a sample of approximately 150 health centers.

These data will provide HRSA with information which will be used to make resource and staffing decisions related to reducing barriers to health care often faced by ethnic/racial minorities and by non- or limited-English-speaking populations.

The burden estimate for this project is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Survey	150	1	150	2	300

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 23, 1999.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99-4949 Filed 2-26-99; 8:45 am]

BILLING CODE 4160-15-U

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 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, 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: Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program Administrative Requirements (Regulations and Policy) (OMB No. 0915-0047)—Extension

The regulations for the Health Professions Student Loan (HPSL) Program and Nursing Student Loan (NSL) Program contain a number of reporting and recordkeeping requirements for schools and loan applicants. The requirements are essential for assuring that borrowers are aware of rights and responsibilities, that schools know the history and status of each loan account, that schools pursue aggressive collection efforts to reduce default rates, and that they maintain adequate records for audit and assessment purposes. Schools are free to use improved information technology to manage the information required by the regulations.

The burden estimate is as follows: