

Application No.	Drug	Applicant
ANDA 88-765	Two-Dyne (Butalbital, Acetaminophen, and Caffeine Capsules USP, 50 mg/325 mg/40 mg.	Do.
ANDA 89-067	Margesic (Butalbital, Acetaminophen, and Caffeine Capsules USP, 50 mg/325 mg/40 mg.	Do.
ANDA 89-605	Prochlorperazine Edisylate Injection USP, 5 mg/mL	Steris Laboratories, Inc., 620 North 51st Ave., Pheonix, AZ 85040-4705.
ANDA 89-994	Oxycodone Hydrochloride and Acetaminophen Capulsles, 5 mg/500 mg.	Halsey Drug Co., Inc.

NDA's 8-072, 11-983, 12-311, and 16-457 were the subject of a hearing (Docket No. 87N-0262 (52 FR 32170, August 26, 1987)). The initial decision of the Administrative Law Judge (ALJ) was that the drug products covered by the NDA's lacked substantial evidence of effectiveness. The holder of NDA's 12-311 and 16-457 was stricken as a party participant in the hearing for failure to file a notice of participation, and the holder of NDA's 8-072 and 11-983 has formally withdrawn its appeal of the initial decision of the ALJ. This notice, therefore, constitutes final agency action on Docket No. 87N-0262 insofar as these four NDA's.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) approval of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective July 25, 1997.

Dated: June 17, 1997.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 97-16609 Filed 6-24-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA-R-54 and HCFA-250]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The

necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Ambulatory Surgical Center Conditions of Coverage and Supporting Regulations in 42 CFR 416.43 and 416.47; *Document No.:* HCFA-R-54; *Use:* Regulation standards are designed to ensure that each Ambulatory Surgical Center has a properly trained staff and adequate physical environment to provide an appropriate type and level of care. *Frequency:* Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 2,341; *Total Annual Hours:* 23,410.

2. *Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Medicare Secondary Payer Initial Enrollment Questionnaire; *Form No.:* HCFA 250; *Use:* This request will be mailed to all newly enrolled Medicare Beneficiaries approximately 1 to 3 months prior to his/her entitlement date. The information requested will determine if Medicare is the proper primary payer, or if the beneficiary is covered under an employer group health plan through continuation of employment after age 65, or through coverage of a currently employed spouse. This centralizes and standardizes the collection of information under one contract. *Frequency:* Other—Monthly for New Beneficiaries Only; *Affected Public:* Individual or Households; *Number of Respondents:* 2,600,000; *Total Annual Hours:* 650,000.

To obtain copies of the supporting statement for the proposed paperwork

collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.hcfa.gov/regs/prdact95.htm>, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Analysis and Planning Staff, Attention: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: June 16, 1997.

Edwin J. Glatzel,
Director, Management Analysis and Planning
Staff, Office of Financial and Human
Resources.

[FR Doc. 97-16602 Filed 6-24-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[416]

Submitted for Collection of Public Comment: Submission for OMB Review

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of

the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Request: Extension of a currently approved collection; *Title of Information Collection:* Medicaid, EPSDT, Maternal and Child Health; *Form No.:* HCFA-416; *Use:* States are required to submit annual EPSDT program reports to HCFA pursuant to Section 1902(a) (43) of the Social Security Act. These reports provide HCFA with data necessary to assess the effectiveness of State EPSDT programs, to develop trend patterns and projections nationally, and respond to inquiries. Respondents are State Medicaid agencies; *Frequency:* Annually; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,568.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: June 16, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97-16597 Filed 6-24-97; 8:45 am]

BILLING CODE 4120-03-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, 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 National Health Service Corps (NHSC) Loan Repayment Program (LRP) Application and Regulations, and NHSC State Loan Repayment Program Regulations (OMB No. 0915-0127)—

Revision and Extension—The NHSC LRP was established to assure an adequate supply of trained primary care health professionals to the neediest communities in the Health Professional Shortage Areas (HPSAs) of the United States. Under this program, the Department of Health and Human Services agrees to repay the educational

loans of the primary care health professionals. In return, the health professionals agree to serve for a specified period of time in a federally-designated HPSA approved by the Secretary for LRP participants. The State Loan Repayment Program (SLRP) is a similar program administered by the States, with matching funds provided by the Federal Government.

This request for extension of OMB approval will include the NHSC LRP application and loan verification form, as well as two minor regulatory requirements, one for the NHSC LRP and the other for the SLRP (described in footnotes to the burden table).

In an effort to improve the procedure for recruiting NHSC LRP applicants and to alleviate some of the burden and delay in the application process, three minor changes are being proposed:

(1) Instead of submitting a copy of the signed employment contract with the application, the applicant will submit a "Site Information Form," which requires information from the applicant about the proposed employment site, and requires only a signature and date from the Site Administrator/Executive Officer. This change will allow HRSA to begin consideration of the application at an earlier stage, since a signed employment contract generally takes more time to negotiate.

(2) A new one-page form, "The Request for Method of Advanced Loan Repayment" form, will be included with the application. It provides a description of three methods of payment (quarterly, annually and biennially), and asks applicants to select the method they prefer.

(3) Applicants now obtain a self-report from the National Practitioner Data Bank (NPDB) which they submit with the application form. To obtain that report, the applicant must submit a written request to the NPDB. To expedite that process, HRSA proposes to send the NPDB request form with the LRP application.

Estimates of Annualized Hour Burden: The changes to the application process are not expected to have a significant impact on applicant burden. Burden estimates are as follows:

Form/regulatory requirement	Number of respondents	Responses per respondent	Hours per response	Total burden hours
NHSC LRP Application	800	1	1.5	1,200
Loan Verification Form	*400	1	.25	100
Regulatory Requirements**	1	1	1	1
Total	1,201	1	1.08	1,301

* The remainder of the loans are verified through credit reports.