

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., Phoenix, AZ 85040-4705.
ANDA 89-994 .....	Oxycodone Hydrochloride and Acetaminophen Capsules, 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in the hearing for failure to file a notice of participation, and the holder of NDA's 8-072 and 11-983 has formally withdrawn its appeal of the initial decision of the ALJ.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of the applications listed in the table in this document, and all amendments and supplements thereto, is hereby withdrawn, effective July 25, 1997.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](mailto: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.

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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