505(b) of the Federal Food, Drug, and Cosmetic Act: December 22, 1995. The applicant claims December 21, 1995, as the date the new drug application (NDA) for HYCAMTIN™ (NDA 20–671) was initially submitted. However, FDA records indicate that NDA 20–671 was submitted on December 22, 1995.

3. *The date the application was approved*: May 28, 1996. FDA has verified the applicant's claim that NDA 20–671 was approved on May 28, 1996.

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 572 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 20, 1997, 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 September 22, 1997, 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: March 12, 1997.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 97–6977 Filed 3–19–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA 1728 and HCFA 9049]

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 summary 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:* Home Health Agency Cost Report; *Form No.:* HCFA–1728; *Use:* The HCFA 1728 is the form used by Home Health Agencies to report their health care costs to determine the amount reimbursable for services furnished to Medicare beneficiaries. *Frequency:* Annually; *Affected Public:* Business or other for profit, Not for profit institutions, and State, Local or Tribal Gov.; *Number of Respondents:* 8,950; *Total Annual Hours:* 1,575,200.

2. *Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Information on Provider Refunds—HCFA 9049, 42 CFR 489.40–41; *Form No.:* HCFA–9049; *Use:* When a Medicare claim is denied and then paid as a result of a reconsideration, there is a possibility that the provider has already been paid by the beneficiary. These questions on provider refunds will be used on intermediary forms to verify that the provider has refunded the beneficiary's money. *Frequency:* On occasion; *Affected Public:* Business or other for profit; *Number of Respondents:* 4,236; *Total Annual Hours:* 1,059.

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: March 13, 1997.

Edwin J. Glatzel,

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

[FR Doc. 97–7085 Filed 3–19–97; 8:45 am]

BILLING CODE 4120–03–P

Public Health Service

Centers for Disease Control and Prevention; Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 61 FR 49785–49787, dated September 23, 1996) is amended to retitle the Office of Health Communication (OHC), National Center for Injury Prevention and Control (NCIPC), to the Office of Communication Resources, and revise the functional statement.

Delete the title and functional statement for the *Office of Health Communication (CE14)* and insert the following:

Office of Communication Resources (EC14). (1) Plans, develops, coordinates, and evaluates NCIPC's, publications, graphics, and technical information activities for intentional injury, unintentional injury, and acute care and rehabilitation; (2) disseminates injury control information to public and professional audiences; (3) in conjunction with the CDC Office of Public Affairs, interacts with the news media to ensure that injury topics are covered accurately and remain high on the public agenda; (4) provides expert consultation on the effective use and design of graphic materials for presentations, publications, and exhibits; (5) designs and produces professional quality graphic materials for use in NCIPC presentations and publications and designs and electronically typesets publications; (6) develops, maintains, and manages a graphics information retrieval system that allows ready access to slides and graphic presentations on injury topics;