CEREBYX® is 3,748 days. Of this time, 3,218 days occurred during the testing phase of the regulatory review period, while 530 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: May 4, 1986. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on May 4, 1986.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: February 23, 1995. The applicant claims July 14, 1994, as the date the new drug application (NDA) for CEREBYX® (NDA 20–450) was initially submitted. However, FDA records indicate that NDA 20–450, received by the agency on July 15, 1994, was incomplete. FDA refused this application and notified the applicant of this fact by letter dated September 12, 1994. The completed NDA was then received on February 23, 1995, which is considered to be the NDA initially submitted date.

3. *The date the application was approved*: August 5, 1996. FDA has verified the applicant's claim that NDA 20–450 was approved on August 5, 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 1,826 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. 97–6976 Filed 3–19–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96E–0440]

Determination of Regulatory Review Period for Purposes of Patent Extension; HYCAMTIN™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for HYCAMTIN™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product HYCAMTIN™ (topotecan hydrochloride). HYCAMTIN™ is indicated for the treatment of patients with metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for HYCAMTIN™ (U.S. Patent No. 5,004,758) from SmithKline Beecham Corp. and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 13, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of HYCAMTIN™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for HYCAMTIN™ is 2,644 days. Of this time, 2,485 days occurred during the testing phase of the regulatory review period, while 159 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: March 4, 1989. The applicant claims January 30, 1989, as the date the investigational new drug application (IND) for HYCAMTIN™ (IND 32,693) became effective. However, FDA records indicate that IND 32,693 was received at FDA on February 2, 1989, and became effective 30 days later on March 4, 1989.

2. *The date the application was initially submitted with respect to the human drug product under section*

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;