rm. 1–23, 12420 Parklawn Dr., 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 AMARYL® (glimepiride). AMARYL® is indicated as an adjunct to diet and exercise to lower the blood glucose in patients with noninsulin-dependent (Type II) diabetes mellitus (NIDDM) whose hyperglycemia cannot be controlled by diet and exercise alone. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for AMARYL® (U.S. Patent No. 4,379,785) from Hoechst Atiengesellschaft, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 1, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of AMARYL® 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 AMARYL® is 2,683 days. Of this time, 2,225 days occurred during the testing phase of the regulatory review period, while 458 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*: July 28, 1988. FDA has verified the applicant's claim that the date that the investigational new drug application (IND) became effective was on July 28, 1988.

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*: August 30, 1994. FDA has verified the applicant's claim that the new drug application (NDA) for AMARYL® (NDA 20–496) was initially submitted on August 30, 1994.

3. *The date the application was approved:* November 30, 1995. FDA has verified the applicant's claim that NDA 20–496 was approved on November 30, 1995.

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 1,569 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 29, 1996, 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 November 25, 1996, 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: May 13, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–13311 Filed 5–28–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–2567–A]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

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 (DHHS), has submitted to the Office of Management and Budget (OMB) the following request for Emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 C.F.R., Part 1320, in order to permit recertification of OPOs as required by statute. Failure to issue these rules in time for the 1996 redesignation process may result in the termination of OPO agreements. This means that persons in need of organs may not receive them. The Agency cannot reasonably comply with the normal clearance procedures because public harm is likely to result if normal clearance procedures are followed. Without this information, HCFA could not assure compliance with this Congressional mandate.

HCFA is requesting that OMB review this document on 5/31/96 and grant a 90-day approval. During this 90-day period HCFA will publish a separate Federal Register notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. Then HCFA will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Statement of Deficiencies and Plan of Correction; *Form No.:* HCFA–2567–A; *Use:* This Paperwork package provides information regarding deficiencies for

Organ Procurement Organizations (OPO) as well as deficiencies noted during periodic facility and laboratory certification surveys. This information is used to make decisions concerning OPO redesignation, certification/recertification of health care facilities participating in the Medicare/Medicaid Programs, and laboratories regulated by CLIA. *Frequency:* Annually and Biennially; *Affected Public:* State, Local or Tribal Governments, Business or other for-profit, Not-for-profit institutions, Federal Government; *Number of Respondents:* 49,200; *Total Annual Responses:* 98,400; *Total Annual Hours Requested:* 196,800.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent by 5/31/96 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: May 22, 1996.

Kathleen B. Larson,

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

[FR Doc. 96–13519 Filed 5–28–96; 8:45 am]

BILLING CODE 4120–03–P–M

National Institutes of Health

National Cancer Institute: Opportunity for a Cooperative Research and Development Agreement (CRADA) for the Scientific and Commercial Development of Hydroxylated Aromatic Protein Cross-Linking Compounds for the Treatment of Hyperproliferative Epithelial Lesions

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (DHHS) seeks a company that can collaboratively pursue the pre-clinical and clinical development of Hydroxylated Aromatic Protein Cross-Linking Compounds for the treatment of hyperproliferative epithelial lesions including skin neoplasia, warts and other hyperproliferative skin disorders. The National Cancer Institute, Laboratory of Cellular Carcinogenesis and Tumor Promotion (LCCTP) has established that this class of compounds (cinnamic acid derivatives) may be effective in treating hyperproliferative skin disorders. The selected sponsor will be awarded a CRADA for the co-development of this agent with the National Cancer Institute.

ADDRESS: Questions about this opportunity may be addressed to Jeremy A. Cubert, M.S., J.D., Office of Technology Development, NCI, 6120 Executive Blvd., MSC 7182, Bethesda MD 20892–7182, Phone: (301) 496–0477, Facsimile: (301) 402–2117, from whom further information may be obtained.

DATE: In view of the important priority of developing new agents for the treatment or prevention of cancer, interested parties should notify this office in writing no later than July 12, 1996. Respondents will then be provided an additional 30 days for the filing of formal proposals.

SUPPLEMENTARY INFORMATION: ''Cooperative Research Development Agreement'' or ''CRADA'' means the anticipated joint agreement to be entered into by NCI pursaunt to the Federal Technology Transfer Act of 1986 and amendments (including 104 P.L. 113) and Executive Order 12591 of October 10, 1987 to collaborate on the specific research project described below.

The Government is seeking a pharmaceutical company which, in accordance with the requirements of the regulations governing the transfer of agents in which the Government has taken an active role in developing (37 CFR 404.8), can further develop the subject compounds through Federal Food and Drug Administration approval and to a commercially available status to meet the needs of the public and with the best terms for the Government. The government has applied for a patent application directed to methods for the treatment for Hyperproliferative Epithelial Lesions by Topical Application of Hydroxylated Aromatic Protein Cross-Linking-Compounds.

Methyl 2,5-dihydroxycinnamate (MC), a cinnamic acid derivative, has been shown to both inhibit cell growth and chemically cross-link proteins. The growth inhibitory and protein cross-linking activity of MC are independent and complementary. The cross-linking effect of the compounds is rapid and leads to programmed cell death for many cell types. At lower concentrations, the compounds inhibit tyrosine kinases and cell growth. The compounds have been shown to be effective in many cell types indicating potential for topical treatment of a wide range of localized hyperproliferative epithelial disorders.

The LCCTP, Division of Basic Sciences, NCI is interested is establishing a CRADA with a company to assist in the continuing development of these compounds. The Government will provide all available expertise and information to date and will jointly pursue pre-clinical and clinical studies as required, giving the company full access to existing data and data developed pursuant to the CRADA. The successful company will provide the necessary scientific, financial and organizational support to establish clinical efficacy and possible commercial status of the subject compounds.

The expected duration of the CRADA will be two (2) to five (5) years.

The role of the National Cancer Institute, includes the following:

1. Selection of appropriate compounds for *in vitro* screening.
2. Selection of appropriate compounds for *in vivo* screening.
3. Conduct *in vitro* screening of appropriate compounds.
4. Identify chemical basis of activity for class of compounds.
5. Conduct *in vivo* testing of appropriate compounds.
6. Evaluation of test results.
7. Preparation of manuscripts for publication.
8. Relevant Government intellectual property rights are available for licensing through the Office of Technology Transfer, National Institutes of Health. For further information contact Allan Kiang, J.D., NIH Office of Technology Transfer, 6011 Executive Blvd., Suite 325, Rockville, MD 20852, Phone: (301) 496–7735 (ext. 270); Facsimile: (301) 402–0220.

The role of the collaborator company, includes the following:

1. Conduct *in vitro* screening of appropriate compounds.
2. Identify chemical basis of activity for class of compounds.
3. Conduct *in vivo* testing of appropriate compounds.
4. Evaluation of test results.
5. Develop vehicle for delivery of compounds to patients.
6. Conduct pre-clinical and clinical trials of appropriate candidate compounds.

Criteria for choosing the company include its demonstrated experience and commitment to the following:

1. Scientific expertise in and demonstraterd commitment to the treatment of skin related disorders.
2. Scientific expertise in and demonstrated commitment to the development of drug delivery systems.
3. Experience in preclinical and clinical drug development.
4. Experience and ability to produce, package, market and distribute pharmaceutical products.
5. Experience in the monitoring, evaluation and interpretation of the data from