ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden response (in hours)	Total burden (in hours)
Reader Response Card	8,000	1	10/60	1,333

Dated: May 18, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–10030 Filed 5–23–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–07–0658]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

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. Written comments should be received within 60 days of this notice.

Proposed Project

Capacity Building Assistance (CBA) Information, Collection, Reporting, and Monitoring (OMB# 0920–0658)—three year extension of the currently approved collection—National Center for HIV and AIDS, Viral Hepatitis, Sexually Transmitted Disease, Tuberculosis Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this request is to obtain OMB clearance to extend the 3-year clearance for information collection to monitor the HIV prevention activities of CBA provider grantees funded by CDC to provide HIV prevention CBA from April, 1 2004 through March 31, 2009. Capacity building is a key strategy for the promotion and sustainability of health prevention programs. Capacity building generally refers to the skills, infrastructure, and resources of organizations and communities that are necessary to effect and maintain behavior change, thus reducing the level of risk for disease, disability, and injury. CDC is responsible for monitoring and evaluating HIV prevention activities conducted under these cooperative agreement numbers 04019, 05015, and 06608. Reporting and monitoring forms have been used to collect information that assists in enhancing and assuring quality programming. CDC requires current information regarding CBA activities and services supported through these cooperative agreements. Therefore, forms such as the Trimester Interim Progress Report, CBA Notification Form, CBA Completion Form, and the CBA Training Events Report are considered a critical component of the monitoring/evaluation process. Because this program encompasses approximately 32 CBA provider organizations, there is a continued need for a standardized system for reporting individual episodes of CBA delivered by all CBA provider grantees. The information collected from the Trimester Progress Report, CBA Notification, CBA Completion Form, and the CBA Training Events Report, will allow CDC to further identify problems and technical assistance needs of community-based organization CBO, or CBA grantees in a timely fashion and subsequently improve the effectiveness of CBA program activities and to ensure that they are aligned with national goals. The data collected using the CBA Notification and Completion Forms, and the Training Events Report are now being collected via a Web portal (*http://www.cdc.gov/hiv/cba*) that has gone through a Certification and Accreditation process. Continued collection of this data in addition to the Trimester Progress Report will assist CDC, to aggregate data, and to discern and refine national goals and objectives for HIV prevention capacity building. This information collection process is also valuable for grantees as a management tool to routinely examining CBA program performance by assessing strengths and weaknesses in line with the CBA program, performance indicators, and national objectives.

It is estimated that form A (will require 4 hours of preparation by the respondent, form B will require 15 minutes of preparation by the respondent, and form C will require 30 minutes of preparation by the respondent, and Form D will require 2 hours of preparation by the respondent. In aggregate, report preparation requires approximately 1952 burden hours by each respondent. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden hours per response	Response burden (in hours)
Form A: CBA Trimester Report	32 Grantees	3	4	384
Form B: CBA Notification Form	32 CBA Provider Grantees	50	15/60	400
Form C: CBA Completion Form	32 CBA Provider Grantees	25	30/60	400

ESTIMATE OF ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Average burden hours per response	Response burden (in hours)
Form D: CBA Training Events Report	32 CBA Provider Grantees	12	2	768
Total				1952

Dated: May 18, 2007.

Maryam Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0457]

Determination of Regulatory Review Period for Purposes of Patent Extension; SOMAVERT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SOMAVERT 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 Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 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 human drug product 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 Director 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 SOMAVERT (pegvisomant). SOMAVERT is indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiation therapy and/or other medical therapies, or for whom these therapies are not appropriate. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SOMAVERT (U.S. Patent No. 5,849,535) from Genentech, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 6, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SOMAVERT represented the first permitted commercial marketing or use of the product. 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 SOMAVERT is 2,169 days. Of this time, 1,349 days occurred during the testing phase of the regulatory review period, while 820 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 (the act) (21 U.S.C. 355(i)) became effective*: April 18, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on April 18, 1997.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: December 26, 2000. The applicant claims December 22, 2000, as the date the new drug application (NDA) for SOMAVERT (NDA 21–106) was initially submitted. However, FDA records indicate that NDA 21–106 was submitted on December 26, 2000.

3. *The date the application was approved*: March 25, 2003. FDA has verified the applicant's claim that NDA 21–106 was approved on March 25, 2003.

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 466 days of patent term extension. Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 23, 2007. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 20, 2007. 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.