11,919. (For policy questions regarding this collection contact Marla Rothouse at 410–786–8063. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *November 2, 2009.*

OMB, Office of Information and Regulatory Affairs,

Attention: CMS Desk Officer.

Fax Number: (202) 395–6974.

E-mail: OIRA_submission@omb.eop.gov.

Dated: September 24, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–23707 Filed 9–30–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–09–08AU]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Assessing Problem Areas in Referrals for Chronic Hematologic Malignancies and Developing Interventions to Address Them—New—Division of Cancer Prevention and Control (DCPC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Despite the advent of new diagnostics and therapeutics for patients with chronic hematological malignancies, data from the United States, Europe and Canada allude to a problem of timely referral and diagnosis for patients with cancer. Improving the timeliness of care and referral to appropriate specialists are key health care quality objectives.

CDC proposes to conduct a one-time study to collect qualitative and quantitative information on optimal and suboptimal referral patterns for patients with confirmed or suspected chronic hematologic malignancies. Information will be collected to identify specific factors related to delays in diagnosis and/or referral to appropriate medical specialists. Information will be collected through in-depth interviews with hematologic cancer patients, in-depth interviews and focus groups with primary care providers, interviews with specialists in hematology and oncology, and a one-time postal survey to a sample of primary care providers (PCP). The PCP survey may be completed in paper form or via the Web.

The ultimate goal is to develop tools that will improve the awareness, diagnosis, and referral of persons with chronic hematological cancers by primary care providers.

There are no costs to respondents other than their time. The total estimated annualized burden hours are 198.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	No. of respondents	No. of responses per respondent	Average burden per response (in hours)
Community Hematologists/Oncologists	Community Hematologists and Oncologists Interview Phone Recruitment Script.	100	1	2/60
	Community Hematologists and Oncologists Interview Guide.	18	1	1.5
Patients	Patient Interview Phone Recruitment Script	50	1	2/60
	Patient Interview Guide	18	1	1.5
Primary Care Providers (PCP)	PCP Survey Cover Letter	250	1	2/60
	PCP Survey	150	1	20/60
	PCP Opt-Out Card	100	1	2/60
	PCP Survey Reminder Letter	200	1	2/60
	PCP Interview Phone Recruitment Script	100	1	3/60
	PCP Interview Guide	18	1	1.5
	PCP Focus Group Phone Recruitment Script	50	1	3/60
	PCP Focus Group Guide	18	1	2

Dated: September 20, 2009.

Maryam I. Daneshvar,

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

[FR Doc. E9–23681 Filed 9–30–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–E–0017 and FDA–2009–E–0019]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for CLEVIPREX 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

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 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 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 CLEVIPREX (clevidipine butyrate). CLEVIPREX is indicated for the reduction of blood pressure when oral therapy is not feasible or not desirable. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for CLEVIPREX (U.S. Patent Nos. 5,739,152 and 5,856,346) from AstraZeneca AB, and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibilities for patent term restoration. In a letter dated February 18, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of CLEVIPREX 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 CLEVIPREX is 4,475 days. Of this time, 4,078 days occurred during the testing phase of the regulatory review period, while 397 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 CosmeticAct (the act) (21 U.S.C. 355(i)) became effective*: May 3, 1996. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 3, 1996.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* July 2, 2007. FDA has verified the applicant's claim that the new drug application (NDA) 22–156 was submitted on July 2, 2007.

3. *The date the application was approved*: August 1, 2008. FDA has verified the applicant's claim that NDA 22–156 was approved on August 1, 2008.

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 1,314 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 November 30, 2009. 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 March 30, 2010. 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 Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 23, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–23650 Filed 9–30–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0461]

Draft Guidance for Industry on Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications; Availability

AGENCY: Food and Drug Administration, HHS.