Former name	New name
Federal Building and United States Courthouse, 315 S. McDuffie Street, Anderson, SC 29621.	G. Ross Anderson, Jr. Federal Building and United States Courthouse, 315 S. McDuffie Street, Anderson, SC 29621.
Federal Building and United States Courthouse, 550 West Fort Street, Boise, ID 83724.	James A. McClure Federal Building and United States Courthouse, 550 West Fort Street, Boise, ID 83724.

Dated: January 30, 2002.

Stephen A. Perry,

Administrator of General Services.

[FR Doc. 02–2659 Filed 2–4–02; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–02–23]

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 the CDC Reports Clearance Officer on (404) 639–7090.

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. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Use of a Reader Response Form by Workers Notified if Results of Epidemiologic Studies—NEW—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). The mission of NIOSH is to promote safety and health at work for all people through research and prevention.

NIOSH routinely notifies subjects about the results of epidemiologic studies and the implications of the results. The overall purpose of the proposed project is to gain insight into the effectiveness of NIOSH worker notification, in order to improve the quality and usefulness of the Institute's worker notification activities. Researchers from the NIOSH Division of Surveillance, Hazard Evaluations and Field Studies (DSHEFS) propose to provide notified workers with a Reader Response Form as an evaluation instrument for routinely assessing individual letter notification materials sent to them by NIOSH.

The results of this ongoing evaluation activity will be used to refine notification activities by standardizing and streamlining written notification materials, and to develop materials which are more readable, understandable, and informative to notified workers, their families, and other stakeholders. The findings from these evaluations may also allow the NIOSH worker notification program to help alleviate any negative impacts and enhance any positive impacts of risk communications.

The objective of the Reader Response Form, therefore, is to provide a structured reporting form which will capture the recipients' responses concerning the effectiveness of the NIOSH notification efforts and their impact on workers and other stakeholders.

The average number of letter-type notifications is estimated at 8,000 per year. Each form is estimated to take less than 10 minutes to complete. There are no cost to respondents other than their time to complete the Reader Response Form.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden per response (in hours)	Total burden (in hours)
Reader Response Form	8000	1	10/60	1,333

Dated: January 29, 2002.

Nancy E. Cheal,

Acting Associate Director for Program, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 02–2646 Filed 2–4–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Exploratory Developmental Grant (R21) Program, RFA OH–02–001

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Exploratory Developmental Grant (R21) Program, RFA OH–02–001.

Times and Dates: 8 a.m.-8:30 a.m., February 19, 2002 (Open), 8:40 a.m.-5 p.m., February 19, 2002 (Closed), 8 a.m.-5 p.m., February 20, 2002 (Closed).

Place: Loews L'Enfant Plaza Hotel, 480 L'Enfant SW., Washington DC 20024.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the

Determination of the Deputy Director for Program Management, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to RFA OH–02–001.

FOR FURTHER INFORMATION CONTACT: Pervis Major, Ph.D., Scientific Review Administrator, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, M/S B228, telephone (304) 285–5979.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: January 30, 2002.

Alvin Hall,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–2658 Filed 2–4–02; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E–0097]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for REFACTO 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 biological product.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (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: Claudia V. Grillo, Office of Regulatory Policy (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biological product REFACTO (novel procoagulant proteins). REFACTO is indicated for the control and prevention of hemorrhagic episodes and for short-term routine and surgical prophylaxis in patients with hemophilia A. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for REFACTO (U.S. Patent No. 4,868,112) from the Genetics Institute, 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 May 11, 2001, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of REFACTO 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 REFACTO is 1,751 days. Of this time, 987 days occurred during the testing phase of the regulatory review period, while 764 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 23, 1995. The applicant claims March 14, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 23, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* February 2, 1998. FDA has verified the applicant's claim that the product license application (PLA) for REFACTO (PLA 98–0137) was initially submitted on February 2, 1998.

3. The date the application was approved: March 6, 2000. FDA has verified the applicant's claim that PLA 98–0137 was approved on March 6, 2000.

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 1,475 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written or electronic comments and ask for a redetermination by April 8, 2002. 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 August 5, 2002. 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. Three copies of any information are to be submitted, except that individuals may submit one copy.