Dated: July 15, 2005.

Joan F. Karr,

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

[FR Doc. 05–14370 Filed 7–20–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–05–05CN]

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 404–371–5983 and send comments to Seleda Perryman, CDC Assistant 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

2005 Business Responds to AIDS (BRTA) Survey—New—National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Business Responds to AIDS (BRTA) program is a partnership among CDC, business, labor, and the public health sector that began in 1992. The purpose of the program is to encourage businesses to implement HIV/AIDS policies and education programs in the workplace. CDC is requesting a 3-year approval from OMB to administer a survey to business owners or human resource directors to assess business practices and policies relating to HIV/AIDS in the workplace. This proposed data collection will incorporate some questions, but will be a shorter version, from a previously approved data collection, ''Business Responds to AIDS Benchmark Study,'' OMB No. 0920–0359, which expired on January 31, 1996.

The target population for the 2005 survey will be private-sector worksites employing 15 or more individuals and operating in the United States at the time of the survey. Selected worksites will be able to respond to the survey by telephone or electronically through the internet. An introductory letter describing the BRTA program and the survey will be mailed to each selected worksite two weeks prior to implementation of the actual survey. The initial point of contact at the worksites is expected to be the business owner for smaller sites and the human resources director for larger sites. This individual will be asked to either complete the interview or provide an appropriate referral within the company. CDC anticipates that information from the survey will allow the agency to revise and strengthen the objectives and strategies of the BRTA program in an effort to support business practices and policies related to HIV/AIDS.

There is no cost to respondents participate in the survey other than their time.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)	Total burden hours
Business Owners or Human Resources Directors	2,200	1	20/60	733

Dated: July 15, 2005.

Joan F. Karr,

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

[FR Doc. 05–14371 Filed 7–20–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health Advisory Board on Radiation and Worker Health

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 committee meeting:

Name: Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH) and Subcommittee for Dose Reconstruction and Site Profile Reviews.

Working Group Meeting Time and Date: 11 a.m.–1 p.m., EDT, Tuesday, July 26, 2005.

Place: Teleconference call via FTS Conferencing. The USA toll free dial in number is 1–800–988–9740 with a pass code of 56001.

Status: Open to the public, but without a public comment period.

Background: The ABRWH was established under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 to advise the President, delegated to the Secretary of Health and Human Services (HHS), on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by HHS as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, and renewed on August 3, 2003.

Purpose: This board is charged with (a) providing advice to the Secretary, HHS on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c)

upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Discussed: Agenda for this meeting will focus on priority issues related to the Mallinckrodt Site Profile Review. Specifically, the identification and clarification of specific issues to be included in the review; finalization of a timeline to complete the review; setting a time and location for future meetings and interactions; and initiating discussions of technical issues as appropriate.

The agenda is subject to change as priorities dictate.

In the event a member of the working group cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

Contact Person for More Information: Dr. Lewis V. Wade, Executive Secretary, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533–6825, fax (513) 533–6826.

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: July 15, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–14380 Filed 7–20–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0083]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, and Forms FDA 356h and 2567

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 22, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, and Forms FDA 356h and 2567—(OMB Control Number 0910–0338)—Extension

Under Section 351 of the Public Health Services Act (the PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to insure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601).

Section 601.2(a) requires manufacturers of a biological product to submit an application with accompanying information, including labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under part 610 (21 CFR part 610) §§ 610.60, 610.61, and 610.62. The estimate for these regulations is included in the estimate under § 601.2(a) in table 1 of this document.

Section 601.5(a) requires licensees to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires licensees to notify selling agents and distributors upon suspension of its license, and provide FDA with records of such notification.

Section 601.12(a)(2) requires, generally, that the holder of an approved biologics license application must assess the effects of a manufacturing change before distributing a biological product made with the change. Section 601.12(a)(4) requires applicants to promptly revise all promotional labeling and advertising to make it consistent with certain labeling changes implemented. Section 601.12(a)(5) requires applicants to include a list of all changes contained in the supplement or annual report; for supplements, this list must be provided in the cover letter. The burden estimates for § 601.12(a)(2) are included in the estimates for supplements (§ 601.12(b) and (c)) and annual reports (§ 601.12(d)). The burden estimates for § 601.12(a)(4) are included in the estimates under § 601.12(f)(4) in table 1 of this document or OMB control number 0910–0001 (expires May 31, 2008) because the required information is submitted with Forms FDA 2567 or 2253.

Section 601.12(b)(1) and (b)(3), (c)(1) and (c)(3), (c)(5), and (d)(1) and (d)(3) require applicants to follow specific procedures to inform FDA of each change, in the product, production process, quality controls, equipment, facilities, responsible personnel or labeling established in an approved license application. The appropriate procedure depends on the potential for the change to have a substantial, moderate, or minimal adverse effect on the identity, strength, quality, purity, or potency of the products as they may relate to the safety or effectiveness of the product. Under § 601.12(b)(4), applicants may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship on the applicant. The burden estimate for § 601.12(b)(4) is minimal and included in the estimate under § 601.12(b)(1) and (b)(3) in table 1 of this document.

Section 601.12(e) requires applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval before distributing the product. Section 601.12(f)(1), (f)(2), and (f)(3) requires applicants to follow specific procedures to report labeling changes to FDA. The appropriate procedure depends on the potential for the change to have a substantial, moderate, or minimal adverse effect on the safety or effectiveness of the product. Section 601.12(f)(4) requires