Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hrs.)	Total burden (in hrs.)
Manual Entry Registration Form	500	1	0.083	41.5
Scantron Registration Form	500	1	0.083	41.5

Dated: May 29, 1997.

Wilma G. Johnson,

Acting Associate Director for Policy Planning And Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–14531 Filed 6–3–97; 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): Cooperative Agreements for Community-Based Primary Prevention Programs to Prevent Intimate Partner Violence for a Safe America, Program Announcement 727: Meeting

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: Disease, Disability, and Injury Prevention and Control SEP: Cooperative Agreements for Community-Based Primary Prevention Programs to Prevent Intimate Partner Violence for a Safe America, Program Announcement 727.

Time and Date: 8:30 a.m.–5 p.m., June 24–25, 1997.

Place: Ramada Plaza Hotel, 4001 Presidential Parkway, Atlanta, Georgia 30341.

Status: Closed.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 727.

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 Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Contact Person for More Information: James S. Belloni, Associate Director, State and Community Activities, National Center for Injury Prevention and Control, CDC, M/S K02, 4770 Buford Highway, NE, Atlanta, Georgia 30341–3724, telephone 770/488–4538.

Dated: May 28, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–14524 Filed 6–3–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) Announces the Following Meeting

Name: Determination of Optimal Frequency and Minimum Power Requirements for a New Radio-Frequency-Controlled Electrical Injury Protection System study protocol peer review.

Time and Date: 8:30–11:30 a.m., June 24, 1997.

Location: Suncrest Facility, Large Conference Room, NIOSH, CDC, 3040 University Avenue, Morgantown, West Virginia 26505.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: Participants will provide NIOSH with their individual advice and comments regarding technical and scientific aspects of the NIOSH protocol Determination of Optimal Frequency and Minimum Power Requirements for a New Radio-Frequency-Controlled Electrical Injury Protection System. Peer review panelists will review the study protocol and provide individual advice on the conduct of the study. Viewpoints and suggestions from industry, labor, academia, other governmental agencies, and the public are invited.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Shengke Zeng, NIOSH, CDC, M/S 119, 1095 Willowdale Road, Morgantown, West Virginia 26505, telephone (304) 285–5971.

Dated: May 29, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–14523 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0180]

Agency Information Collection Activities: Proposed Collection; Comment Request; Reinstatement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements relating to the preapproved or emergency shipment of a blood product for manufacturing prior to completion of hepatitis B surface antigen (HBsAg) testing and shipment of a blood product for manufacturing when the donor is known to be reactive for HBsAg.

DATES: Submit written comments on the collection of information by August 4, 1997.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600

Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Shipment of a Blood Product Prior to Completion of Testing for Hepatitis B Surface Antigen (HbsAg)—21 CFR 610.40(b); and Shipment of Blood Products Known Reactive for HbsAg—21 CFR 610.40(d)—(OMB Control Number 0910–0168)—Reinstatement

Under Sections 351 and 361 of the Public Health Service Act (42 U.S.C. 262 and 264), FDA prescribes standards designed to ensure the safety, purity, potency, and effectiveness of biological products including blood and blood components and to prevent the transmission of communicable diseases. To accomplish this, FDA requires, among other things, that each unit of Whole Blood or Source Plasma be tested by a licensed serologic test for HbsAg. Section 610.40(b)(4) (21 CFR 610.40(b)(4)) permits preapproved or emergency shipments of blood products for further manufacturing before the test for HBsAg is completed. To obtain approval for such shipments, the collection facility must submit a description of the control procedures to be used by the collection facility and manufacturer. Proper control procedures are essential to ensure the safe shipment, handling, quarantine of untested or incompletely tested blood products, communication of test results, and appropriate use or disposal of the blood products based on the test results. Section 610.40(d)(1) and (d)(2) requires that a collection facility notify FDA of each shipment of HBsAg reactive source blood, plasma, or serum for manufacturing into hepatitis B vaccine and licensed or unlicensed in vitro diagnostic biological products, including clinical chemistry control reagents. The reporting requirements inform FDA of the shipment of potentially infectious biological products that may be capable of transmitting disease. The respondents for this information collection are the blood collection facilities that are shipping hepatitis B reactive products. FDA's monitoring of such activity is essential in the event that any deviations occur that may require immediate corrective action to protect public safety. The labeling helps ensure that product is safely and appropriately handled and used by the collection facility, shipper, and manufacturer.

Only a few firms are actually engaged in shipping hepatitis B reactive products and making the reports required by § 610.40. Further, there are very few to no emergency shipments per year related to further manufacturing and the only product currently shipped prior to completion of hepatitis B testing is a licensed product, Source Leukocytes. Shipments of Source Leukocytes are preapproved under the product license applications and do not require notification for each shipment. Currently, there have been no respondents reporting emergency or preapproved shipments (§ 610.40(b)). However, FDA is currently listing one report per year for emergency or preapproved shipments to account for the possibility of future emergency shipments.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.40(b)[1]	1	1	1	0.5	0.5
610.40(d)[2]	6	8.5	51	0.5	25.5

There are no capital costs or operating and maintenance costs associated with this information collection.

[1] This notice involves a brief letter and an enclosure. The letter identifies who is making the shipment, to whom the product was shipped, the nature of the emergency, the kind and quantity shipped, and the date of shipment. The enclosure is a copy of the shippers written standard operating procedures for handling, labeling storage, and shipment of contaminated (contagious) product. The burden for development and maintenance of standard operating procedures is approved under OMB No. 0910–0116. Preparation of the notice and duplication of standard operating procedure documents is estimated at one half hour per notice.

[2] The notice of reactive product shipment is limited to information on: the identity of the kind and amount of source material shipped; the name and address of the consignee; the date of shipment; and the manner in which the source material is labeled.

FDA has calculated no additional burden in this information collection package for the labeling requirements in § 610.40(d) because the information and statements on the label necessary for public disclosure and safety are provided by FDA in these regulations. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: May 28, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–14601 Filed 6–3–97; 8:45 am]

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