

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day-06-0008]

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 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

Emergency Epidemic Investigations—Extension—(0920-0008), Office of Workforce and Career Development (OWCD), Centers for Disease Control and Prevention (CDC).

Background & Brief Description

The purpose of the Emergency Epidemic Investigation surveillance is to collect data on the conditions surrounding and preceding the onset of a problem. The data must be collected in a timely fashion so that information can be used to develop prevention and control techniques, to interrupt disease transmission and to help identify the cause of an outbreak. The EPI-AID mechanism is a means for Epidemic

Intelligence Service (EIS) officers of the Centers for Disease Control and Prevention (CDC), along with other CDC staff, to provide technical support to state health agencies requesting assistance for epidemiologic field investigations. This mechanism allows CDC to respond rapidly to public health problems in need of urgent attention, thereby providing an important service to state and other public health agencies; and to provide supervised training opportunities for EIS officers (and, sometimes, other CDC trainees) to actively participate in epidemiologic investigations.

Epi Trip Reports are delivered to the state health agency official requesting assistance shortly after completion of the EPI-AID investigation. This official can comment on both the timeliness and the practical utility of the recommendations from the investigation. Upon completion of the EPI-AID investigation, requesting officials at the state or local health department will be asked to complete a brief questionnaire to assess the promptness of the investigation and the usefulness of the recommendations. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	No. of respondents	No. of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Requestors of EPI-AIDs	~ 100 per year	1	15/60	25 hours per year

Dated: July 26, 2006.

Joan F. Karr,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 21, 2006, from 8 a.m. to 5 p.m.

Location: Food and Drug Administration, CDER Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Cathy Groupe, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 301-827-7001, FAX: 301-827-6778, e-mail:

Cathy.Groupe@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512533. Please call the information

line for up-to-date information on this meeting.

Agenda: The committee will discuss clinical data for aprotinin injection (trade name, TRASYOL), an approved product, new drug application (NDA) 020-304, Bayer Pharmaceuticals) with the indication for prophylactic use to reduce perioperative blood loss and the need for blood transfusion in patients undergoing cardiopulmonary bypass in the course of coronary artery bypass graft surgery. This discussion follows a February 8, 2006, FDA Public Health Advisory for the use of apportioning injection (www.fda.gov/cder/drug/advisory/aprotinin.htm). The background material for this meeting will be posted 1 business day before the meeting on FDA's Website at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> under the heading "Cardiovascular and Renal Drugs Advisory Committee." (Click on the