

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.

[FR Doc. E6-12307 Filed 7-31-06; 8:45 am]

BILLING CODE 4163-18-P

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

year 2006 and scroll down to the above named committee meeting.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 13, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants and an indication of the approximate time requested to make their presentation on or before September 13, 2006.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact John Lauttman at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 18, 2006.

Randall W. Lutter,
Associate Commissioner for Policy and Planning.

[FR Doc. E6-12269 Filed 7-31-06; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0312]

Meeting to Present Work-In-Progress on a Method for Ranking Feed Contaminants According to the Relative Risks They Pose to Animal and Public Health; Part 1: Health Consequence Scoring for Feed Contaminants

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting it will hold to present work-in-progress on a method for

ranking animal feed contaminants by their relative risks to animal and human health. The relative risk posed by feed contaminants to animal and human health consists of two components, namely health consequence scoring and exposure scoring. At this meeting the agency will describe the methods it plans to use to develop animal and human health consequence scoring for chemical, physical, and biological feed contaminants. At one or more subsequent public meetings, FDA will present information about how the health consequence scoring will be combined with information about the exposure of animals and humans to feed contaminants to determine the relative risks of such contaminants in feed.

Date and Time: The public meeting will be held on September 12, 2006, from 9 a.m. to 4:30 p.m.

Location: The meeting will be held at the Center for Drug Evaluation and Research Conference Room, third floor, 7519 Standish Pl., Rockville, MD 20855.

ADDRESSES: You may submit written comments 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.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments.

FOR FURTHER INFORMATION CONTACT: Zoe Gill, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6867, FAX 240-453-6882, e-mail: zoe.gill@fda.hhs.gov.

Registration: You may register by telephone, fax, or e-mail by contacting Nanette Milton, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6840, FAX 240-453-6880, e-mail: nanette.milton@fda.hhs.gov. Send registration information (including name, title, firm name, address, telephone, and fax number to Nanette Milton. To obtain the registration form via the Internet go to <http://www.fda.gov/cvm/AFSS.htm#Meetings>. Due to limited meeting space, registration will be required. We strongly encourage early registration.

SUPPLEMENTARY INFORMATION:

I. Background

The Animal Feed Safety System (AFSS) is FDA's program for animal feed aimed at protecting human and animal health by ensuring animal feed is safe. It covers the entire spectrum of agency activities from preapproval of

food additives and drugs for use in feed, to establishing limits for feed contaminants, providing education and training, and conducting inspections and taking enforcement actions for ensuring compliance with agency regulations. AFSS includes oversight of all feed ingredients and mixed feed at all stages of manufacture, production, distribution, and use, whether at commercial or non-commercial establishments.

During the past several years, FDA has been considering changes that need to be made to AFSS to ensure that it is comprehensive, preventive, and risk-based. As part of this effort, the agency is developing a model for ranking the relative risks to human and animal health of contaminants in animal feed. An effective model will permit the agency to systematically distinguish among feed hazards based on the relative risks they pose to animals or humans. Such a model will consider the risks of hazards present in incoming materials or feed ingredients and will also consider how activities at feed manufacturing, storage, distribution, and transportation facilities may modify such risks. For the purpose of AFSS, FDA defines a feed hazard as a biological, chemical, or physical agent in, or condition of, feed with the potential to cause an adverse health effect in animals or humans.

Previously, FDA held two public meetings to discuss AFSS, including discussions of the agency's plan to develop a risk ranking model for determining the relative risks to animal or human health of feed hazards. The first meeting was held on September 23 and 24, 2003, in Herndon, VA, and the second meeting was held on April 5 and 6, 2005, in Omaha, NE. The public meetings included active participation by consumers, animal feed processors, animal producers, and State and other Federal Government agencies. Following the meetings, we placed a number of documents in FDA's docket for the AFSS project (found in brackets in the heading of this document). These documents included transcripts of the meetings, summaries of break-out discussion groups, presentations of invited speakers, and meeting summaries. We also placed in the docket a number of other documents relating to AFSS, including a framework for AFSS that lists the principal components of AFSS and the gaps the agency has identified which are being addressed by the agency team working on the AFSS project. These documents provide excellent, general background material on AFSS for the public meeting that will be held on September 12, 2006.