and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Survey to Evaluate FDA's Food Defense Awareness Initiative ALERT

In July 2006, FDA announced its Food Defense Awareness Initiative, called ALERT (the letters stand for the five key components of the initiative: (assure, look, employees, report, and threat). The ALERT initiative is intended to raise the awareness of State and local government agencies and the food industry regarding food defense issues. ALERT identifies five key points that industry and businesses can use to decrease the risk of intentional food contamination at their facility. The ALERT Web-based training module and more information on ALERT are available at *www.cfsan.fda.gov/~dms/defterr.html*.

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393 (b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. Under this authority, FDA is planning to conduct a survey of first line supervisors working in a range of capacities in the food industry about their awareness and perceptions of the agency's ALERT initiative and the ALERT initiative informational materials. The purpose of the survey is to help FDA evaluate ALERT informational materials and to gauge whether the materials succeed in informing food industry supervisory employees about the risk of intentional food contamination and in motivating them to engage in protective behaviors. The survey results will be used to assess how knowledge and awareness, threat perceptions, attitudes, norms, benefits and barriers affect the implementation of the ALERT initiative.

The data will be collected using a Web-based questionnaire. The survey will employ a stratified, cluster sampling design. Using industry networks and listings, we will randomly sample from databases of eight industry groups (regulators, growers, packers, processors, warehousers, transporters, retailers, and food service operators). We will stratify within groups by organization size (small, medium, and large) based on number of employees on the payroll, for a total random sample of 200 organizations. Participation in the survey is voluntary. Cognitive interviews and a pre-test will be conducted prior to fielding the survey.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
Cognitive Interviews	10	10	10	1	10
Pre-tests	10	1	10	.4	4
Survey	200	1	200	.4	80
Total					94

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on prior experience with consumer surveys similar to this proposed survey.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: May 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–11514 Filed 5–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0293]

Draft Guidance for Industry: Considerations for Allogeneic Pancreatic Islet Cell Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the

availability of a draft document entitled ''Guidance for Industry: Considerations for Allogeneic Pancreatic Islet Cell Products'' dated May 2008. The draft guidance document is intended to provide recommendations to manufacturers, sponsors, and clinical investigators involved in the transplantation of allogeneic pancreatic islet cell products for clinical investigations of the treatment of type 1 diabetes mellitus. The draft guidance is intended to provide assistance by identifying the types of data and information obtained during investigational new drug studies that may be helpful in establishing the safety, purity, and potency of a biological product in a biologics license application (BLA).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by August 20, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Considerations for Allogeneic Pancreatic Islet Cell Products'' dated May 2008. The draft guidance document is intended to provide recommendations to manufacturers, sponsors, and clinical investigators involved in the transplantation of allogeneic pancreatic islet cell products for clinical investigations of the treatment of type 1 diabetes mellitus. The draft guidance is intended to provide assistance with the types of data and information that may be obtained during investigational new drug studies to assist in establishing the safety, purity, and potency of a biological product in a BLA. However, the guidance is not intended to identify all of the product, preclinical, and clinical data that may be needed to successfully support a BLA.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 211 has been approved under 0910–0139; the collections of information in 21 CFR part 312 has been approved under 0910–0014; the collections of information in 21 CFR parts 601 and 610 have been approved under 0910–0338; and the collections of information in 21 CFR part 1271 has been approved under 0910–0543 and 0910–0559.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: May 13, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–11516 Filed 5–21–08; 8:45 am]

BILLING CODE 4160–01–S

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 June 24, 2008, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD, 301–589–5200.

Contact Person: Elaine Ferguson, 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: 301–827–6776, e-mail: *elaine.ferguson@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. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot