

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 The draft guidance document is intended to provide recommendations to manufacturers, sponsors, and clinical investigators involved in the transplantation of allogeneic pancreatic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 The draft guidance is intended to provide assistance by identifying the types of data and information obtained during investigational new drug studies that may be helpful in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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by August 20, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug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 The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 The draft guidance document is intended to provide recommendations to manufacturers, sponsors, and clinical investigators involved in the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

always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss safety considerations in the development of ultrasound contrast agents, based upon the experience with the following: (1) New drug application (NDA) 21-064, perflutren lipid microsphere injectable suspension, Lantheus Medical Imaging, Inc.; (2) NDA 20-899, perflutren protein-type A microspheres injectable suspension, GE Healthcare; and (3) the investigational new drug application for sulphur hexafluoride microbubble injection, Bracco Diagnostics. Perflutren lipid microsphere injectable suspension and perflutren protein-type A microspheres injectable suspension are indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial borders.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

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 June 13, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 June 3, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public

hearing session. The contact person will notify interested persons regarding their request to speak by June 5, 2008.

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 Elaine Ferguson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

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

Dated: May 15, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-11450 Filed 5-21-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic 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: Endocrinologic and Metabolic 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 July 1, 2008, from 8 a.m. to 6 p.m. and July 2, 2008, from 8 a.m. to 4:30 p.m.

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

Contact Person: Paul Tran, 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:

paul.tran@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512536. 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 always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On both days, the committee will discuss the role of cardiovascular assessment in the preapproval and postapproval settings for drugs and biologics developed for the treatment of type 2 diabetes mellitus.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

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 June 17, 2008. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 9:45 a.m. on July 2, 2008. 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 June 9, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will