For technical questions about this program, contact: Dr. Trudy Messmer, Scientific Review Administrator, 1600 Clifton Rd, MS C–19, Atlanta, GA 30333, Telephone: 404–639–3770, e-mail: *TMessmer@cdc.gov.*

Dated: March 3, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–4552 Filed 3–8–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0075]

Notice to Industry on the Development of a Web-Based System for Obtaining a User Fee Payment Identification Number and Prescription Drug User Fee Cover Sheet (FDA Form 3397); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new Web-based system to electronically obtain a user fee payment identification number and to submit your Prescription Drug User Fee (PDUFA) cover sheet (FDA Form 3397) to the Office of Financial Management. The system will enable FDA to electronically track your company's application payments and will allow your organization to obtain the user fee payment identification number over the Web. By making the user fee payment identification number and the PDUFA cover sheet available on-line, we will be able to improve service, one of PDUFA's performance goals.

DATES: Submit written or electronic comments by April 8, 2005.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. Submit electronic comments to *http://www.fda.gov/dockets.ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the new system.

FOR FURTHER INFORMATION CONTACT: Martha Louviere, Office of Financial Management (HFA–100), Food and Drug Administration, 5600 Fishers Lane, rm. 11–83, Rockville, MD 20857, 301–827–3912, e-mail: *userfees@fda.gov*.

SUPPLEMENTARY INFORMATION: Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay fees for certain new human drug applications, biologics applications, and supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee has been submitted. Form FDA 3397, the user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to help FDA track payments.

The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system to assign the user fee payment identification number. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

FDA has created an on-line user fee cover sheet which will assist FDA and pharmaceutical companies by improving service and reducing the time for applicants and their affiliates to file and comply with PDUFA through more automated channels. The new system will allow customers to obtain a user fee payment identification number, create and complete a user fee cover sheet on-line, and submit it electronically to FDA's Office of Financial Management. It will decrease the administrative burden on FDA, improve service by automating the cover sheet application process, and allow applicants to securely view their payments received by FDA on-line. This new system, which replaces the previous process, will be available on February 15, 2005.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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 brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

You can access this new system from the *http://www.fda.gov/oc/pdufa/coversheet.html* Web site. You may then select ''PDUFA User Fee Cover Sheet'' from Web site. Detailed instructions on how to use the user fee system are included at the Web site.

Dated: March 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–4635 Filed 3–8–05; 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 April 5, 2005, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, 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, e-mail: *groupec@cder.fda.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 supplemental new drug application (sNDA) S–036 to approved new drug application (NDA) 19–787, NORVASC (amlodipine besylate) Tablets (2.5 milligrams (mg), 5 mg, and 10 mg), Pfizer Inc., proposing a change in labeling for the following two additional indications of: (1) Reducing the risk of fatal coronary heart disease and nonfatal myocardial infarction and (2) reducing the risk of stroke, based on the effectiveness demonstrated in the

antihypertensive and lipid lowering treatment to prevent heart attack trial (ALLHAT).

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 by March 29, 2005. 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 before March 29, 2005, 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.

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 301–827–7001 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: March 2, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–4522 Filed 3–8–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Intravenous Immune Globulins in the 21st Century: Progress and Challenges in Efficacy, Safety, and Paths to Licensure; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: ''Intravenous Immune Globulins in the 21st Century: Progress and Challenges in Efficacy, Safety, and Paths to Licensure.'' The purpose of the workshop is to address current topics on the safety and efficacy of immune globulin products.

Date and Time: The workshop will be held on April 13, 2005, from 8 a.m. to 5:30 p.m.

Location: The workshop will be held at the Lister Hill Auditorium, Bldg. 38A, National Institutes of Health, 8600 Rockville Pike, Bethesda, MD 20894.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3514, FAX: 301–827–2843, e-mail: *dawsonr@cber.fda.gov*.

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person by April 1, 2005. There is no registration fee for the public workshop. Because seating is limited, we recommend early registration. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:15 a.m.

If you need special accommodations due to a disability, please contact Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA, in cooperation with the Primary Immune Deficiency Foundation, is announcing the following public workshop: ''Intravenous Immune Globulins in the 21st Century: Progress and Challenges in Efficacy, Safety, and Paths to Licensure.'' The 1-day workshop, consisting of three successive sessions, will discuss the following topics:

- Specific antibody levels in intravenous immune globulins (IGIVs) to common and emerging pathogens, including research questions concerning antibody levels and efficacy;
- Adverse events, including specific categories of adverse events, as well as current methods of surveillance, responses to adverse event information, and the utility of different monitoring strategies; and
- Paradigms for IGIV and subcutaneous immune globulin licensure for treatment of Primary Immune Deficiency.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/cber/minutes/workshop–min.htm*.

Dated: March 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–4634 Filed 3–8–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1993D–0394]

Draft Guideline for the Validation of Blood Establishment Computer Systems; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a guidance that was issued on September 28, 1993.

DATES: March 9, 2005.

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

SUPPLEMENTARY INFORMATION: In a notice containing a cumulative list of guidances available from the agency that published on January 5, 2005 (70 FR 824), FDA included the guidance document entitled, ''Draft Guideline for the Validation of Blood Establishment Computer Systems.'' This document is being withdrawn because it no longer reflects all of FDA's current considerations on a guidance to assist manufacturers of blood and blood components, including blood banks, plasmapheresis centers, and transfusion services in developing a computerized system validation program. FDA is revising the guidance and a draft guidance for public comment will be issued in the future.

Dated: March 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–4633 Filed 3–8–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Commission on Systemic Interoperability, March 15,