of, or restrict, physicians in contracting with payors outside of the arrangement.

As defined in the proposed order, a ''qualified risk-sharing joint arrangement'' possesses two key characteristics. First, all physician participants must share substantial financial risk through the arrangement, such that the arrangement creates incentives for the physician participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

A ''qualified clinically-integrated joint arrangement,'' on the other hand, need not involve any sharing of financial risk. Instead, as defined in the proposed order, physician participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns in order to control costs and ensure the quality of services provided, and the arrangement must create a high degree of interdependence and cooperation among physicians. As with qualified risk-sharing arrangements, any agreement concerning price or other terms of dealing must be reasonably necessary to achieve the efficiency goals of the joint arrangement.

Paragraph III, for three years, requires Preferred Health to notify the Commission before participating in contracting with health plans on behalf of a qualified risk-sharing joint arrangement or qualified clinically-integrated joint arrangement. Paragraph III sets out the information necessary to make the notification complete.

Paragraph IV, for three years after the bar on messengering ends, requires Preferred Health to notify the Commission before entering into any arrangement to act as a messenger, or as an agent on behalf of any physicians, with payors regarding contracts. Paragraph IV also sets out the information necessary to make the notification complete.

Paragraph V requires Preferred Health to distribute the complaint and order to all physicians who have participated in Preferred Health, and to payors that negotiated contracts with Preferred Health or indicated an interest in contracting with Preferred Health. Paragraph V.C requires Preferred Health, at any payor's request and without penalty, or within one year after the Order is made final, to terminate its current contracts with respect to providing physician services. Paragraph V.D requires Preferred Health to distribute payor requests for contract termination to all physicians who participate in Preferred Health. Paragraph V.E.1.b requires Preferred Health to distribute the complaint and order to any payors that negotiate contracts with Preferred Health in the next three years.

Paragraphs VI and VII of the proposed order impose various obligations on Respondent to report or provide access to information to the Commission to facilitate monitoring Respondent's compliance with the order.

The proposed order will expire in 20 years.

By direction of the Commission, Chairman Majoras not participating.

Donald S. Clark,

Secretary.

[FR Doc. 05–4594 Filed 3–8–05; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Comparisons of Community with Facility Management of Malaria and Pneumonia in Rural Tanzania; Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2005 funds for a cooperative agreement program to establish the effectiveness of combination antimalarial therapy policies within the context of intense malaria transmission and to develop an evidence-based comparison between two approaches to managing febrile illness in rural sub-Sahara Africa. Specifically, the two approaches of interest are an enhanced facility-based management approach and a community- or household-based approach. The aim is to generate detailed data enabling international public health organizations to make recommendations to national governments based on quality scientific evidence. The Catalog of Federal Domestic Assistance number for this program is 93.283.

B. Eligible Applicant

Assistance will be provided only to the Ifakara Health Research and Development Centre, Ifakara, Tanzania. No other applications are solicited.

The Ifakara Health Research and Development Centre (IHRDC) is the only institution located in Tanzania that possesses the requisite scientific and technical expertise, the infrastructure capacity and experience in conducting the described research topics and which has collaborative relationships with the Ministry of Health to ensure that all aspects of this agreement can be fulfilled. Because of its work in malaria for more than 15 years, the IHDRC is an internationally respected research institution.

Investigators at IHDRC have a detailed understanding of the epidemiologic patterns and geographic distribution of malaria infection and transmission in their area, are actively engaged in using state-of-the-art techniques for evaluating antimicrobial drug resistance, and have needed and proven expertise in socio-behavioral and economic research related to febrile illness. In addition, the IHDRC has the following required experience and capabilities:

- Maintains a DSS covering over 100,000 individuals, allowing for measurement of public health impact of malaria treatment policies.
- Proven experience in carrying out large-scale community-based public health interventions, to conduct malaria research, and to correctly diagnose drug resistant malaria infections in its laboratories and field activities.
- Located in an area of very intense malaria transmission in a country that is has adopted a national malaria treatment policy of ACT while remaining actively engaged in investigating future treatment options.
- Maintains a close relationship with the National Malaria Control Program of the Ministry of Health and as well as close relationship with other relevant research and public health entities in the country and region.
- Actively engaged in research activities that are directly related to the objectives of this RFA with proven experience and capacity.

C. Funding

Approximately $1,000,000 is available in FY 2004 to fund this award. It is expected that the award will begin on or before September 1, 2005, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

D. Where to Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

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