

Dated: August 28, 2001.

John P. Burke, III,

Reports Clearance Officer, Security and Standards Group, Division of CMS Enterprise Standards.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-10037]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Real Choice Systems Change Grants; Nursing Facility Transition/Access Housing Grants; Community Personal Assistance Service and Supports Grants, National Technical Assistance and Learning Collaborative Grants to Support Systems Change for Community Living; *Form No.:* CMS-10037 (OMB# 0938-0836); *Use:* Information sought by CMSO/DEHPG is needed to award competitive grants to States and other eligible entities for the purposes of designing and implementing effective and enduring improvements in consumer-directed long term service and support systems; *Frequency:* Annually; *Affected Public:* State, local or tribal gov.; *Number of Respondents:* 76; *Total*

Annual Responses: 76; *Total Annual Hours:* 7600.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office at (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Attention: Julie Brown Attn.: CMS-10037, Room N2-14-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antiviral 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: Antiviral 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 October 3 and 4, 2001, from 8:30 a.m. to 5 p.m.

Location: The Town Center Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Contact: Tara P. Turner, 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: TurnerT@cder.fda.gov, or FDA Advisory

Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12531. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 3, 2001, the committee will discuss new drug application (NDA) 21-356, Viread™ (tenofovir disoproxil fumarate) Tablets, Gilead Sciences, Inc., proposed for the treatment of human immunodeficiency virus (HIV) infection. On October 4, 2001, the committee will discuss NDA 21-266, Vfend™ (voriconazole) Tablets and NDA 21-267, Vfend™ I.V. (voriconazole) for infusion, Pfizer Global Research and Development, proposed for the treatment of invasive aspergillosis, serious Candida infections, infections caused by *Scedosporium* spp. and *Fusarium* spp., rare and refractory infections, and empirical treatment of febrile neutropenia.

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 September 26, 2001. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 26, 2001, 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.

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

Dated: August 28, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0368]

Draft Guidance for Industry on Submitting Marketing Applications According to the ICH/CTD Format; General Considerations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.