Dated: August 28, 2001.

John P. Burke, III,

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

[FR Doc. 01–22177 Filed 9–4–01; 8:45 am]

BILLING CODE 4120–03–P

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.

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

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.

[FR Doc. 01–22166 Filed 9–4–01; 8:45 am]

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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.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Submitting Marketing Applications According to the ICH/CTD Format; General Considerations.'' This guidance provides general guidance on how to organize new drug applications (NDAs), abbreviated new drug applications (ANDAs) and biologics license applications (BLAs) based on the International Conference on Harmonisation (ICH) M4 guidance on organizing the Common Technical Document (CTD) for the registration of pharmaceuticals for human use.

DATES: Submit written or electronic comments on the draft guidance by November 5, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20857, 301–594–5400; or

Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Submitting Marketing Applications According to the ICH/CTD Format; General Considerations.'' This guidance is intended to supplement the ICH M4 guidances on quality, safety, and efficacy, which were signed off at step 4 of the ICH process in October 2000. Final versions of the M4 guidances on organizing the CTD will be available soon. This general considerations guidance applies to NDAs, ANDAs, and BLAs for both new molecular entities and nonnew molecular entities and all related presubmissions, supplements, and amendments.

This guidance provides some general information on the organization and format of the CTD as well as recommendations for completing module 1, which contains administrative and prescribing information specific to each regulatory authority. The content of documents in the CTD is provided in other FDA guidance documents. When finalized, this guidance will supersede the ''Guidelines on Formatting, Assembling, and Submitting of New Drug and Antibiotic Applications,'' issued in February 1987.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on general considerations for submitting marketing applications according to the ICH/CTD format. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: August 28, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–22199 Filed 9–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–64]

Notice of Submission of Proposed Information Collection to OMB; Pet Ownership in Public Housing for Elderly or Persons With Disabilities

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* October 5, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2577–0078) and should be sent to: Joseph F. Lackey, Jr., OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail Wayne__Eddins@HUD.gov; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of