

prescription or veterinary feed directive antimicrobial drugs.

The PFL concept has been a topic of discussion for many years. Recent workshops on PFL were held in April and December 1995 under the cosponsorship of the Center for Veterinary Medicine, the American Academy of Veterinary Pharmacology and Therapeutics, the Animal Health Institute, and the American Veterinary Medical Association.

A summary of the discussions and opinions expressed in the April, 1995 workshop were published in the *Journal of the American Veterinary Medical Association (JAVMA)*, October 1, 1995. At the conclusion of the December, 1995 workshop, a task force prepared a report on the PFL concept. The task force report, which included a model drug label, was published in the *JAVMA* on July 1, 1996.

This draft guidance is intended to describe how the PFL concept can be applied to prescription antimicrobial products to enable veterinary practitioners to apply their expertise to appropriately, effectively, and safely use antimicrobials for specific clinical cases. The draft document provides specific guidance for drug sponsors on the development of PFL labeling for therapeutic veterinary prescription antimicrobial drugs. Ultimately, the labeling of products such as described in this draft guidance will better accommodate the needs of veterinary practitioners in utilizing animal drugs to treat animals in the course of their professional practices.

Approaches to PFL may not be equally applicable to all classes of therapeutic prescription products (e.g., antimicrobials, antiparasitics, physiologics). Therefore, CVM intends to develop PFL guidances that are specific to the various classes of drugs. This draft guidance document specifically addresses the application of the PFL concept to prescription therapeutic antimicrobial products.

A sponsor may follow the guidance provided in this draft document, or a sponsor may choose to follow alternate procedures or practices. If a sponsor elects to use alternate procedures or practices, that sponsor may wish to discuss the matter *a priori* with the agency to prevent an expenditure of money and effort on activities that may later be determined to be unacceptable to FDA.

This draft document represents current FDA thinking on PFL for antimicrobial drugs. This draft guidance document does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An

alternate approach may be used if such an approach satisfies the requirements of the applicable statute, regulations, or both. FDA may amend this draft guidance document based upon comments submitted by interested persons.

Request for Comments

Interested persons may, on or before April 22, 1998, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. 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, and with the full title of the guidance document.

The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guidance is available on the Internet at <http://www.fda.gov>. After review of these comments, FDA will finalize the guidance document with any appropriate changes. Thereafter, interested persons may submit written comment on the guidance document directly to the CVM Communications Staff (address above).

Dated: January 14, 1998.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 98-1417 Filed 1-15-98; 3:51 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-226]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 the 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: New Collection; *Title of Information Collection:* Evaluation of Medicare Choices Demonstration; *Form No.:* HCFA-R-226; *Use:* The objective of the evaluation of the Medicare Choices Demonstration is to determine whether the newer types of managed care delivery systems in the demonstration are effective at attracting and retaining Medicare enrollees and providing a high quality, cost-effective care. The key research questions HCFA will ask Medicare enrollees include: (A) Beneficiary choice, knowledge, and biased selection. Why do beneficiaries enroll (or not enroll) in plans? What proportion of enrollees disenroll, and why? What is the nature and extent of biased selection in the demonstration, and does it vary across plans? How well do enrollees understand their plans and the rules and procedures for obtaining care? (B) Effects on service use. What are the effects of the plans on the use of Medicare-covered services? Are some plans more effective at controlling service use than others? (C) Effects on Medicare costs. What are the effects of the various payment methods being tested in the demonstration on Medicare costs? (D) Effects on satisfaction, access, and quality. What are the effects of the plans on enrollee satisfaction, access to care, and quality of care? How does this vary across plans? *Frequency:* one time; *Affected Public:* Individuals or Households; *Number of Respondents:* 10,000; *Total Annual Responses:* 10,000; *Total Annual Hours:* 3,880.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.hcfa.gov/regs/prdact95.htm>, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: John Rudolph, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 8, 1998

John P. Burke III,

*HCFA Reports Clearance Officer, Division of
HCFA Enterprise Standards, Health Care
Financing Administration.*

[FR Doc. 98-1516 Filed 1-21-98; 8:45 am]

BILLING CODE 4120-03-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting and Correction of Meeting Notice

Pursuant to Public Law 92-463, notice is hereby given of a correction of a notice of meeting of the SAMHSA National Advisory Council and of the meeting of the Center for Substance Abuse Treatment (CSAT) National Advisory Council to be held in January 1998.

Public notice was given in the **Federal Register** on January 8, 1998 (Volume 63, Number 5, page 1120) that the SAMHSA National Advisory Council would be meeting on January 21, 1998, at the Parklawn Building, Room 17-89. The date of this meeting has subsequently changed to January 22, 1998. The agenda of the meeting and the contact for additional information remain as announced.

With regard to the CSAT National Advisory Council meeting, a portion of the meeting will be open and include discussion of the Center's policy issues and current administrative, legislative, and program developments. If anyone needs special accommodations for persons with disabilities please notify the Contact listed below.

The meeting will include the discussion of information about the Center for Substance Abuse Treatment's procurement plans. Therefore a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(3) and 5 U.S.C. App. 2, section 10(d).

A summary of the meeting and roster of council members may be obtained from: Mrs. Marjorie Cashion, CSAT, National Advisory Council, Rockwall II Building, Suite 619, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-8923.

Substantive program information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: Center for Substance Abuse Treatment, National Advisory Council.

Meeting Date: January 27, 1998—8:30 a.m.—5:00 p.m.; January 28, 1998—9:00 a.m.—2:00 p.m.

Place: Omni Shoreham Hotel, Hampton Room, 2500 Calvert Street, N.W., Washington, D.C. 20008.

Type: Closed: January 27, 1998—8:30 a.m.—9:00 a.m. Open: January 27, 1998—9:00 a.m.—5:00 p.m.; January 28, 1998—9:00 a.m.—2:00 p.m.

Contact: Marjorie M. Cashion, Executive Secretary, Telephone: (301) 443-8923, and FAX: (301) 480-6077.

This notice is being published with less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

Dated: January 20, 1998.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 98-1611 Filed 1-20-98; 12:12 pm]

BILLING CODE 4162-20-U

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4263-N-72]

Submission for OMB Review: Comment Request

AGENCY: Office of Administration, 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: February 23, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within thirty (30) days from the date of this Notice. Comments should refer to the proposal by name and/or OMB approval number 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, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708-1305. 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 an information collection requirement; and (10) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: January 15, 1998.

David S. Cristy,

Director, Information Resources, Management Policy and Management Division.

Notice of Submission of Proposed Information Collection to OMB

Title of Proposal: Survey Instructions and Certificate.

Office: Housing.

OMB Approval Number: 2502-0010.

Description of the Need for the Information and its Proposed Use: A land survey and related information are necessary to secure a marketable title and title insurance for the property that provides security for project mortgage insurance furnished under the FHA multifamily programs. Form HUD-2457 provides a uniform method for acceptably meeting program criteria to minimize risk to the insurance fund and the U.S. Treasury that might arise from inadequate project land surveys and related data.

Form Number: HUD-2457.

Respondents: Business or Other For-Profit and Not-For-Profit Institutions.

Frequency of Submission: On Occasion.

Reporting Burden: