Dated: January 7, 1998.

Donald Sykes,

Director, Office of Community Services.

[FR Doc. 98–1526 Filed 1–21–98; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0192]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Quality Mammography Standards'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 28, 1997 (62 FR 55851), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0309. The approval expires on December 31, 2000.

Dated: January 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1419 Filed 1–21–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0016]

Draft Guidance on Professional Flexible Labeling of Antimicrobial Drugs; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft level 1 Guidance for Industry entitled ''Professional Flexible Labeling of Antimicrobial Drugs (#66).'' This draft guidance is intended to provide specific guidance on the development of Professional Flexible Labeling (PFL) for therapeutic veterinary prescription antimicrobial drugs. The agency is requesting comments on this draft guidance.

DATES: Submit written comments by April 22, 1998.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

Submit written requests for single copies of this draft guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests.

Copies of this draft guidance document may also be obtained from the CVM Home Page (http://www.cvm.fda.gov) on the Internet.

FOR FURTHER INFORMATION CONTACT: John D. Baker, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0130. E-mail: jbaker@bangate.fda.gov.

SUPPLEMENTARY INFORMATION:

Background

For many years, CVM has approved veterinary prescription antimicrobial products labeled with single fixed dosages for a narrow range of specific diseases and organisms. The very narrow label indications often failed to address the fact that, while some specific bacteria produce repeatable, recognized disease, many organisms are either opportunistic or are known to produce a variety of clinical manifestations. In addition, with the approval of single fixed dosages, the efficacy of some products could become suboptimal as bacterial susceptibility patterns change with time.

The basic concept of Professional Flexible Labeling (PFL) is to provide prescription veterinary products that carry useful prescribing information for the range of clinical situations included within their approved conditions of use. Implementation of PFL is based on the recognition that, as a function of their medical training, veterinarians possess the knowledge, skills, and abilities to interpret medical diagnostic and prescribing information. Accordingly, they are able to develop these data into appropriate therapeutic regimens. In the course of their professional studies, veterinarians are trained in microbiology, the interpretation of bacterial culture and sensitivity determinative procedures, and pharmacokinetics. This knowledge gives them the ability to determine the appropriateness of a particular drug for use in a specific case.

Under section 502 (f)(1) of the Federal Food, Drug, and Cosmetic Act (the act), a drug is deemed to be misbranded unless its labeling bears adequate directions for use (21 U.S.C. 352(f)(1)). The regulations regarding veterinary drugs at 21 CFR 201.105 exempt a drug from this provision of the act if it is in the possession of a licensed veterinarian for use in the course of professional practice, is dispensed in accordance with section 503(f) of the act (21 U.S.C. 353(f)), and its label bears certain stipulated information. Section 504 of the act (21 U.S.C. 354) stipulates that a veterinary feed directive drug, a drug intended for use in or on animal feed which is limited to use under the supervision of a licensed veterinarian, is exempt from section 502(f) when labeled, distributed, held, and used in accordance with the conditions set forth in section 504.

Drugs labeled in accordance with the PFL concept require the training of licensed veterinarians to help ensure appropriate clinical usage. Such labels would not provide adequate directions for use by the lay person. Therefore, use of PFL on nonprescription or nonveterinary feed directive drugs would cause the drugs to be misbranded under section 502 (f)(1) of the act, PFL-labeled drugs must be classified as prescription animal drugs or veterinary feed directive drugs. Accordingly, the PFL concept discussed in this document may apply to either veterinary

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]

BILLING CODE 4160–01–F

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.