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Draft Guidance on Professional Flexible Labeling of Antimicrobial Drugs; Availability; Request for Comments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 This draft guidance is intended to provide specific guidance on the development of Professional Flexible Labeling (PFL) for therapeutic veterinary prescription antimicrobial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 The agency is requesting comments on this draft guidance.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ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.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