above) written comments regarding this draft guidance.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 A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 28, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–21962 Filed 8–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2638]

Use of Medicated Feeds for Minor Species; Draft Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft compliance policy guide (CPG) entitled ''Use of Medicated Feeds for Minor Species.'' The purpose of the draft CPG is to provide guidance to the field concerning the agency's exercise of regulatory discretion with regard to the extra-label use of medicated feeds for minor species.

DATES: Written comments on the draft CPG may be submitted by November 23, 1999.

ADDRESSES: Submit written requests for single copies of the draft CPG entitled ''Use of Medicated Feed for Minor Species'' to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Judy A. Gushee, Center for Veterinary Medicine (HFV–232), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0150, e-mail ''jgushee@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

Prior to 1994, the Federal Food, Drug, and Cosmetic Act (the act) did not permit extra-label use of animal drugs, but FDA exercised regulatory discretion regarding extra-label use of animal drugs provided certain criteria were met. These criteria were published in CPG 7125.06 and were largely incorporated into the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA). AMDUCA amended the act to permit extra-label uses under certain conditions. The AMDUCA regulations are codified in 21 CFR part 530. AMDUCA did not permit extra-label use of medicated feeds. However, there are some minor species that cannot be practically medicated in any other way other than through the use of medicated feeds. Furthermore, minor species such as fish and game birds have very few drugs approved for their use. In such situations, a veterinarian may determine that extra-label use of medicated feeds approved for use in other species can prevent suffering and death in these minor species. Before the implementation of AMDUCA, the agency occasionally exercised regulatory discretion for extra-label use of medicated feeds for minor species based on a medical need as long as the medicated feeds were formulated and labeled in accordance with their approved application. Because AMDUCA did not permit extra-label use of medicated feeds, FDA is providing this guidance to our field personnel when such extra-label use is encountered.

This level 1 draft guidance document is being issued consistent with FDA's good guidance practices (62 FR 9061, February 27, 1997). This draft CPG represents the agency's current thinking with regard to the extra-label use of medicated feeds for minor species. It does not 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 statute, regulations, or both.

II. Request for Comments

Interested persons may, on or before November 23, 1999, submit to the Dockets Management Branch (address above) written comments on the draft CPG entitled ''Use of Medicated Feeds for Minor Species.'' 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. A copy of the draft CPG and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. The agency will review all comments, but in issuing a final CPG, need not specifically address every comment. The agency will make changes to the draft CPG in response to comments, as appropriate.

III. Electronic Access

Copies of the draft CPG may also be downloaded to a personal computer with access to the World Wide Web (www). The Office of Regulatory Affairs (ORA) and CVM home pages include the draft CPG and may be accessed at ''http://www.fda.gov/ora'' or ''http://www.fda.gov/cvm'', respectively. The draft CPG will be available on the compliance references or compliance information pages for ORA and CVM, respectively.

Dated: August 18, 1999.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 99–21961 Filed 8–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–30]

Agency Information Collection Activities: Proposed Collection; Comment Request; Notice

AGENCY: Health Care Financing Administration, HHS.

ACTION: Notice.

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: Information Collection Requirements in the Hospice Care Regulation, 42 CFR 418.22, 418.24, 418.28, 418.30, 418.56, 418.58, 418.70, 418.74, 418.83, 418.96 and 418.100;

Form No.: HCFA–R–30;

Use: These Information Collection Requirements establish standards for hospices who wish to participate in the Medicare program. The regulations establish standards for eligibility, reimbursement standards and procedures, and delineate conditions that hospices must meet to be approved for participation in Medicare.

Frequency: On occasion;

Affected Public: Business or other for-profit and Not-for-profit institutions;

Number of Respondents: 2,275;

Total Annual Responses: 2,275;

Total Annual Hours Requested: 6,042,834.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, 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, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 16, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–21974 Filed 8–24–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–137]

Agency Information Collection Activities: Submission For OMB Review; 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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. 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: Extension of a currently approved collection;

Title of Information Collection: Internal Revenue Service/Social Security Administration/Health Care Financing Administration Data Match and Supporting Regulations in 42 CFR Section 411.20–411.206;

Form No.: HCFA–R–137 (OMB# 0938–0565);

Use: The purpose of this collection is to save the Medicare program, money. MSP is essentially the same concept known in the private insurance industry as coordination of benefits, and refers to those situations where Medicare assumes a secondary payer role (private insurance being the primary payer) for covered services provided to a Medicare beneficiary. It is HCFA's responsibility to implement the various Medicare Secondary Payer (MSP) provisions.;

Frequency: Annually;

Affected Public: Federal Government, Business or other for-profit, Not-for-profit institutions, Farms, State, and Local or Tribal Government;

Number of Respondents: 327,947;

Total Annual Responses: 327,947;

Total Annual Hours: 1,096,466.

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 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 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 10, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–22070 Filed 8–24–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (''the Program''), as required by section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program generally, contact the Clerk, United States Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005, (202) 219–9657. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 8A–46, Rockville, MD 20857; (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals