Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 31, 2001.

Linda S. Kahan,

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

[FR Doc. 01–5814 Filed 3–8–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0107]

Guidance for Industry: Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#121) entitled ''Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims.'' The guidance provides advice to industry about the process that the Center for Veterinary Medicine (CVM) plans to use to grant expedited review status (ERS) for applications for new animal drugs intended to reduce human pathogens in food-producing animals.

DATES: Submit written comments on the guidance at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7580, e-mail: svaughn@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Expedited Review for New Animal Drug Applications for Human Pathogen Reduction Claims.'' The guidance advises industry about the process that CVM intends to use to grant expedited review status for applications for new animal drugs designed to reduce human pathogens in food-producing animals and to thereby potentially decrease the incidence of human illness. Specifically, it provides procedures for requesting and criteria for granting expedited review status for new animal drug applications and investigational new animal drug applications for new animal drugs that will have human pathogen reduction claims on their labels. The guidance reflects the agency's current thinking on these procedures and criteria.

This Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). FDA has determined that obtaining public participation prior to issuance of this guidance is not appropriate. The goal of this guidance is to allow products to be approved more quickly if they potentially offer important advances in reducing human pathogens in food animals, and thereby may result in a decrease of the incidence of human illness, and are supported by appropriate data. Implementing the guidance immediately, prior to receiving public comment, will further advance this goal. The concern for public health is supported by Congress. The committee reports for the fiscal year 2001 agriculture appropriations bills (H. Rept. 106–619 and S. Rept. 106–288) state that: ''In view of the significant public health benefits of competitive exclusion products, the FDA should review new animal drug applications for these products on an expedited basis.''

While FDA will immediately implement this guidance, the agency is inviting public comment and will revise the document as appropriate. The guidance represents the agency's current thinking on the procedures for requesting and criteria for granting ERS for applications for new animal drugs designed to reduce human pathogens in food-producing animals. 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 statute and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the guidance at any time. 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 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

Copies of this guidance document may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm/.

Dated: March 6, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–5952 Filed 3–6–01; 4:25 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–2728]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, 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:* End Stage Renal

Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration and Supporting Regulations in 42 CFR, Section 405.2133; *Form No.:* HCFA–2728 (0938–0046); *Use:* This form captures the necessary medical information required to determine Medicare eligibility of an end stage renal disease claimant. It also captures the specific medical data required for research and policy decisions on this population as required by law. *Frequency:* Weekly, Monthly, Quarterly, Semi-annually, and Annually; *Affected Public:* Individuals or households, Business or other for-profit, Not-for-profit institutions; *Number of Respondents:* 60,000; *Total Annual Responses:* 60,000; *Total Annual Hours Requested:* 25,000.

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: Melissa Musotto, Room: N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 14, 2001.

John P. Burke III,

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

[FR Doc. 01–5784 Filed 3–8–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10016]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, 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: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Oxygen Consumer Survey: Medical Equipment and Supplies Consumer Survey; *Form No.:* HCFA–10016 (OMB# 0938–0807); *Use:* The Oxygen Consumer Survey and Medical Equipment and Supplies Consumer Survey will be used to collect information from Medicare beneficiaries who use oxygen equipment, hospital beds, wheelchairs, orthotics, and inhalation drugs used with a nebulizer. This information will be used to evaluate the Health Care Financing Administration's (HCFA's) Competitive Bidding Demonstration for Durable Medicare Equipment (DME) and Prosthetics, Orthotics, and Supplies (POS). In the demonstration, HCFA will use competitive bidding to set Medicare Part B fees for selected types of DME and POS.

The purpose of the evaluation is to determine whether the demonstration affects Medicare expenditures, access to care, quality of care, diversity of product selection, and industry competitiveness. The evaluation will also examine any problems associated with implementing competitive bidding for Part B services. Results of the evaluation will be used by HCFA and Congress to determine whether it is feasible to expand competitive bidding.

The research questions to be addressed by the surveys focus on access, quality, and product selection. Our information collection process will include fielding a survey for oxygen users and a survey for other medical equipment and supplies users before the demonstration begins and again after the new demonstration prices have been put into effect. Beneficiaries within the demonstration area will be surveyed; we will also survey beneficiaries within a control site that is similar to the demonstration site in terms of population, managed care penetration, volume of services, and number of beneficiaries. We will also control the socioeconomic factors when analyzing the date. This design will allow us to separate the effects of the demonstration from beneficiary-or site-specific effects.

This evaluation was expanded to a second site, San Antonio, Texas as of March 2000. The Balanced Budget Act of 1997 allowed for the demonstration to be conducted in up to three different regions. The demonstration has been ongoing in the first site, Polk County, Florida, since 1999. The baseline Polk County beneficiary surveys were conducted between March and June of 1999. The follow-up Polk County beneficiary surveys were conducted during the fall of 2000.

We are seeking approval for the new beneficiary surveys (Baseline and Follow-up) for the San Antonio demonstration and comparison site and any subsequent demonstration and comparison sites that include the same DME and POS products. The surveys for the second site, San Antonio, are almost identical to the surveys used in the first site, Polk County, Florida; *Frequency:* Annually; *Affected Public:* Individuals and Households; *Number of Respondents:* 2,500; *Total Annual Responses:* 725; *Total Annual Hours:* 725.

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: Melissa Musotto, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 22, 2001.

John P. Burke III,

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

[FR Doc. 01–5785 Filed 3–8–01; 8:45 am]

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