applicant for extension acted with due diligence during the regulatory review period by September 5, 2001. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information 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. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 16, 2001.

Jane A. Axlerad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 01–5812 Filed 3–8–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1817]

Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors.'' This guidance describes the special controls FDA believes will provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying the home uterine activity monitors (HUAM's) from class III to class II.

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5 diskette of the guidance document entitled ''Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning this guidance 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 docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document describes a means by which manufacturers of HUAM's may comply with the requirements of special controls for class II devices. Designation of this guidance as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate HUAM should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

The guidance document addresses such areas as: Intended use and indications for use; labeling; design controls; clinical data; patient registry; preclinical data including electrical safety testing, electromagnetic compatibility, software, device accuracy, material safety, and cleaning and disinfection.

This guidance document was issued for public comment in the **Federal Register** of July 30, 1999 (64 FR 41443), as a draft guidance entitled ''Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications.'' The document has been modified from the original draft version for purposes of clarity and adding detail regarding the device description, bench testing, and design controls.

II. Significance of Guidance

This guidance document represents the agency's current thinking on premarket notifications for HUAM's. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), and published the final rule which set forth the agency's regulations for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This guidance document is issued as a Level 1 final guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors'' via your fax machine, call the CDRH Facts-on-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (820) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''Final Guidance for Industry and FDA Reviewers: Class II Special Controls Guidance for Home Uterine Activity Monitors,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, at any time, submit written comments regarding the guidance to the Dockets Management Branch (address above). Such comments will be considered when determining whether to amend the current guidance. 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.

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]

BILLING CODE 4160–01–F

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