will consider Part 11 deviations to be more significant if a firm has a history of Part 11 violations or of inadequate or unreliable recordkeeping. Until firms attain full compliance with Part 11, FDA investigators will exercise greater vigilance to detect inconsistencies, unauthorized modifications, poor attributability, and any other problems associated with failure to comply with Part 11.

Regulatory Action Guidance:

Program monitors and center compliance offices should be consulted prior to recommending regulatory action. FDA will consider regulatory action with respect to Part 11 when the electronic records or electronic signatures are unacceptable substitutes for paper records or handwritten signatures, and that therefore, requirements of the applicable regulations (e.g., CGMP and GLP regulations) are not met. Regulatory citations should reference such predicate regulations in addition to Part 11. The following is an example of a regulatory citation for a violation of the device quality system regulations.

Failure to establish and maintain procedures to control all documents that are required by 21 CFR 820.40, and failure to use authority checks to ensure that only authorized individuals can use the system and alter records, as required by 21 CFR 11.10(g). For example, engineering drawings for manufacturing equipment and devices are stored in AutoCAD form on a desktop computer. The storage device was not protected from unauthorized access and modification of the drawings.

Dated: July 23,1999.

William K. Hubbard.

Senior Associate Commissioner for Policy, Planning and Coordination

[FR Doc. 99–19477 Filed 7–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1817]

Home Uterine Activity Monitors Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications.'' Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of the panel recommendation to reclassify home uterine activity monitors (HUAM's) into class II (special controls) and FDA's tentative findings. FDA agrees that these monitors should be reclassified in class II, and the guidance that is the subject of this notice of availability is one of the special controls that FDA believes will provide reasonable assurance of the safety and effectiveness of these devices.

DATES: Submit written comments by October 28, 1999.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance entitled ''Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the ''Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications'' to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kathy Daws-Kopp, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180, ext. 132.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document describes a means by which HUAM's may comply with the requirement of special controls for class II devices. Designation of this guidance document 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; preclinical data including electrical safety testing, electromagnetic compatibility, software, material safety, and bench validation testing; clinical data; cleaning and disinfection; and labeling.

In addition to this guidance document, FDA is also proposing that patient registries be a special control for HUAM's.

II. Significance of Guidance

This guidance 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), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (820) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Home Uterine Activity Monitors; Guidance for the Submission of 510(k) Premarket Notifications,'' 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, on or before October 28, 1999, submit to the Dockets Management Branch (address above) written comments regarding this draft 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. The guidance

document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 30, 1999.

Linda S. Kahan,

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

[FR Doc. 99–19531 Filed 7–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–0377/0378/R–0054]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

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:* Request for Certification, HCFA–377 and the Ambulatory Surgical Center Survey Report Form, HCFA–378 and HCFA-R–0054 Supporting Regulations Contained in 42 CFR 416.1 thru 416.49; *Form No.*: HCFA–0377/0378/R–0054 (OMB# 0938–0200); *Use:* The ASC request for certification form is utilized as an application for facilities wishing to participate in the Medicare program as an ASC. This form initiates the process of obtaining a decision as to whether the conditions of coverage are met. It also promotes data retrieval from the Online Data Input Edit (ODIE system, a subsystem of the Online Survey Certification and Report (OSCAR) system by the Health Care Financing Administration's (HCFA) Regional Offices (RO)). The ASC report form is an instrument used by the State survey agency to record data collection in order to determine supplier compliance with individual conditions of coverage and to report it to the Federal government. The form is primarily a coding worksheet designed to facilitate data reduction and retrieval into the ODIE/OSCAR system at the HCFA ROs. This form includes basic information on compliance (i.e., met, not met and explanatory statements) and does not require any descriptive information regarding the survey activity itself.; *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 2,798; *Total Annual Responses:* 2,798; *Total Annual Hours:* 2,100.

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: Louis Blank, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: July 22, 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. 99–19482 Filed 7–29–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0106 and HCFA–R–0284]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration.

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.

1. *Type of Information Collection Request:* Reinstatement, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Criteria for Medicare Coverage of Heart Transplants; *Form No.:* HCFA–R–106 (OMB No 0938–0490); *Use:* Medicare participating hospitals must file an application to be approved for coverage and payment of heart transplants performed on Medicare beneficiaries. The application must include the following data: patient selection, patient management, commitment, facility plans, experience and survival rates, maintenance of data, organ procurement, laboratory procedures, and billing. *Frequency:* Annually; *Affected Public:* Business or other for-profit; *Number of Respondents:* 5; *Total Annual Responses:* 5; *Total Annual Hours Requested:* 500.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Statistical Information System (MSIS); *Form No.:* HCFA–R–0284 (OMB# 0938–0345); *Use:* State data are reported by a Federally mandated process known as MSIS. These data are the basis for: Medicaid actuarial forecasts for service utilization and costs; Medicaid legislative analysis and cost savings estimates; and responding to requests for information from HCFA components, the Department, Congress, and other customers. The national MSIS database will contain details that will allow constructive or predictive analysis of today's Medicaid issues (e.g., pregnant women, and infants).; *Frequency:* Quarterly and Annually; *Affected Public:* State, Local, or Tribal