DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1458]

Enforcement Policy: Electronic Records; Electronic Signatures—Compliance Policy Guide; Guidance for FDA Personnel

Note: On July 21, 1999 (64 FR 39146), this document was published with some inadvertent errors. For the convenience of the reader, the document is being republished in its entirety.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new Compliance Policy Guide (CPG) section 160.850 entitled ''Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures.'' This CPG is intended to represent the agency's current thinking on how to comply with the regulations for electronic records and electronic signatures. It also provides that agency decisions on whether or not to pursue regulatory actions will be based on a case-by-case evaluation. The text of the CPG is included in this document.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of CPG section 160.850 entitled ''Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures'' to the Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852. Send two self-addressed adhesive labels to assist that office in processing your requests. Written comments should be identified with the docket number found in brackets in the heading of this document and should be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A copy of the CPG is available on FDA's website at ''http://www.fda.gov/ora/compliance_ref/cpg/cpggenl/default.htm''. Scroll down the CPG page to locate section 160.850.

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, 301–827–0425.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a new CPG section 160.850 entitled ''Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures.'' The CPG is an update to the Compliance Policy Guides Manual (August 1996 ed.). It is a new CPG and will be included in the next printing of the Compliance Policy Guides Manual. The CPG is intended for FDA personnel and is available electronically to the public. See the **ADDRESSES** section for electronic access to the CPG. The CPG is a level 2 guidance which is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). 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, regulation, or both.

The text of the CPG follows:

Section 160.850

Title: Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures (CPG 7153.17)

Background:

This compliance guidance document is an update to the Compliance Policy Guides Manual (August 1996 edition). This is a new Compliance Policy Guide (CPG) and will be included in the next printing of the Compliance Policy Guides Manual. The CPG is intended for Food and Drug Administration (FDA) personnel and is available electronically to the public. This guidance document represents the agency's current thinking on what is required to be fully compliant with 21 CFR Part 11, ''Electronic Records; Electronic Signatures'' and provides that agency decisions on whether or not to pursue regulatory actions will be based on a case by case evaluation. The CPG 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, regulation, or both.

In the **Federal Register** of March 20, 1997 at 62 FR 13429, FDA issued a notice of final rulemaking for 21 CFR, Part 11, Electronic Records; Electronic Signatures. The rule went into effect on August 20, 1997. Part 11 is intended to create criteria for electronic recordkeeping technologies while preserving the agency's ability to protect and promote the public health (e.g., by facilitating timely review and approval of safe and effective new medical products, conducting efficient audits of required records, and when necessary pursuing regulatory actions). Part 11 applies to all FDA program areas, but does not mandate electronic recordkeeping. Part 11 describes the technical and procedural requirements that must be met if a person chooses to maintain records electronically and use electronic signatures. Part 11 applies to those records required by an FDA predicate rule and to signatures required by an FDA predicate rule, as well as signatures that are not required, but appear in required records.

Part 11 was developed in concert with industry over a period of six years. Virtually all of the rule's requirements had been suggested by industry comments to a July 21, 1992 Advance Notice of Proposed Rulemaking (at 57 FR 32185). In response to comments to an August 31, 1994 Proposed Rule (at 59 FR 45160), the agency refined and reduced many of the proposed requirements in order to minimize the burden of compliance. The final rule's provisions are consistent with an emerging body of federal and state law as well as commercial standards and practices.

Certain older electronic systems may not have been in full compliance with Part 11 by August 20, 1997, and modification to these so called ''legacy systems'' may take more time. As explained in the preamble to the final rule, Part 11 does not grandfather legacy systems and FDA expects that firms using legacy systems will begin taking steps to achieve full compliance.

Policy:

When persons are not fully compliant with Part 11, decisions on whether or not to pursue regulatory actions will be based on a case by case evaluation, which may include the following:

Nature and extent of Part 11 deviation(s). FDA will consider Part 11 deviations to be more significant if those deviations are numerous, if the deviations make it difficult for the agency to audit or interpret data, or if the deviations undermine the integrity of the data or the electronic system. For example, FDA expects that firms will use file formats that permit the agency to make accurate and complete copies in both human readable and electronic form of audited electronic records. Similarly, FDA would have little confidence in data from firms that do not hold their employees accountable and responsible for actions taken under their electronic signatures.

Effect on product quality and data integrity. For example, FDA would consider the absence of an audit trail to be highly significant when there are data discrepancies and when individuals deny responsibility for record entries. Similarly, lack of operational system checks to enforce event sequencing would be significant if an operator's ability to deviate from the prescribed order of manufacturing steps results in an adulterated or misbranded product.

Adequacy and timeliness of planned corrective measures. Firms should have a reasonable timetable for promptly modifying any systems not in compliance (including legacy systems) to make them Part 11 compliant, and should be able to demonstrate progress in implementing their timetable. FDA expects that Part 11 requirements for procedural controls will already be in place. FDA recognizes that technology based controls may take longer to install in older systems.

Compliance history of the establishment, especially with respect to data integrity. FDA

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