DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–1269]

Medical Devices; Draft Guidance on Quality Systems Inspections Technique; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Draft Guidance on Quality Systems Inspections Technique.'' This draft guidance is intended to provide FDA's field staff with a new inspectional method to assess medical device manufacturer's compliance with the quality system regulation (QSR), which became effective June 1, 1997. This draft guidance is also intended to represent the agency's current thinking on using a new inspectional technique, and it is neither final nor is it in effect at this time.

DATES: Written comments concerning this draft guidance must be submitted by August 26, 1999.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5'' diskette of the draft guidance entitled ''Draft Guidance on Quality Systems Inspections Technique'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and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 one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tim R. Wells, Center for Devices and Radiological Health (HFZ–332), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4616.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Draft Guidance on Quality Systems Inspections Technique.'' This draft guidance is intended to provide guidance to the FDA field staff for the use of a new inspectional method to assess medical device manufacturer's compliance with the QSR (21 CFR part 820). This draft guidance is also intended to provide information about an inspectional method that uses the seven subsystems of the QSR, which include: (1) Corrective and preventive actions, (2) design controls, (3) production and process controls, (4) management controls, (5) records/document/change controls, (6) material controls, and (7) facility/equipment controls. The Quality Systems Inspections Technique focuses on the first four subsystems as primary indicators of compliance with the QSR.

This draft guidance represents the agency's current thinking on a new method of inspecting medical device manufacturers to assess their compliance with QSR. 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 draft guidance is issued as a Level 1 guidance consistent with GGP's.

II. Electronic Access

In order to receive the ''Draft Guidance on Quality Systems Inspections Technique'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch tone telephone. At the first voice prompt press 1 to access DMSA Facts, at the second voice prompt press 2, and then enter the document number (1196) 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 Web. Updated on a regular basis, the CDRH home page includes the ''Draft Guidance on Quality Systems Inspections Technique,'' 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''. The ''Draft Guidance on Quality Systems Inspections Technique'' will be available at ''http://www.fda.gov/cdrh/gmp/qsitbook.html''.

III. Comments

Interested persons may submit to the Dockets Management Branch (address 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: May 17, 1999.

Linda S. Kahan,

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

[FR Doc. 99–13558 Filed 5–27–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–0029/0030, R–0106, and R–0284]

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.