• The written policies and procedures established to ensure that contractors conform to the same requirements (e.g., education, training, and experience) that would apply to the applicant if it were performing the inspection or aspects of the inspection contracted. These policies and procedures should ensure that the contractor conducts inspections in accordance with the same procedures under which the applicant operates. The applicant should include assurances that it will maintain documentary evidence that the contractor has the necessary technical competence and resources to carry out contracted activities;

• Written policies and procedures documenting that the applicant will not contract the overall responsibility for reviewing the results of the inspections;

• Documentation of an agreement delineating the duties, responsibilities, and accountability of the contractor; and

• The written policies and procedures for establishing a register of qualified contractors.

AP QS

FDA will consider the following factors to determine whether the applicant has established an adequate quality system to ensure compliance with FDA policies and procedures relevant to inspections:

• The applicant should establish a documented quality system to ensure that there are processes and procedures in place to demonstrate compliance with section 704(g) of the act;

• The policies and procedures the applicant follows are adequate to maintain control of all quality system documentation and to ensure that a current version is available at all locations; and

• The policies and procedures for internal auditing to ensure the quality system is implemented effectively and that resources are available for conducting such audits.

Certification Agreement Statement

The applicant should provide a copy of a documented statement, which will be signed by the most responsible individual, certifying that:

• The AP has appropriate policies and procedures to meet FDA's conflict of interest provisions, has the appropriate staff and procedures in place to ensure technical competence for conducting inspections under section 704(g) of the act, and has the quality system in place to ensure acceptable and consistent inspections;

• Where the AP uses the services of a contractor for QS/GMP inspections, the AP should also certify that its contractor(s) meets the APs established criteria for freedom from conflicts of interest and technical competence;

• The AP consents to FDA inspection and copying of all records, correspondence, and other materials relating to any inspections conducted by the AP under this program, including records on personnel, education, training, skills, and experience and all documentation on prevention of conflicts of interest, including certification/compliance statements; and

• The AP will protect trade secret and confidential commercial or financial information, and will treat as private information about specific patient identifiers in records such as adverse event reports, except that such information may be made available to FDA.

III. The Guidance

We are issuing a revised guidance entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria,'' which repeats the AP criteria set out in section II of this document. In addition, the guidance provides other useful information such as suggestions about the format and content of the accreditation applications. The revised guidance reflects changes to the law made by the Medical Device Technical Corrections Act.

The guidance represents the agency's current thinking on the ''Implementation of the Inspection by Accredited Persons Program under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria.'' The issuance of this guidance is consistent with FDA's good guidance practices regulation (21 CFR 10.115). 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 statutes and regulations.

IV. Electronic Access

To receive ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria'' by 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 (1200) 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 by 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 Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

V. Paperwork Reduction Act of 1995

This document and the guidance entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria'' contain a proposed collection of information that requires clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under OMB control number 0910–0510.

VI. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance document at any time. Submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22211 Filed 10–1–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0443]

Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations.'' The draft guidance describes the key elements of a robust quality systems model and shows how persons implementing such a model can achieve compliance with the CGMP regulations.

DATES: Submit written or electronic comments on the draft guidance by December 3, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Monica Caphart, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–9047; or

Robert Sausville, Center for Biologics Evaluation and Research (HFM–624), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6201; or

June Liang, Center for Veterinary Medicine (HFV–12), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–8789; or

Patricia Maroney-Benassi, Office of Regulatory Affairs (HFC–240), 15800 Crabbs Branch Way, Rockville MD 20855, 240–632–6819.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations.'' The draft guidance illustrates where FDA can harmonize across agency centers and with other non-U.S. pharmaceutical quality management requirements. This draft guidance was developed by the quality systems group formed as part of the CGMP for the 21st Century initiative. The draft guidance is intended to encourage the use of modern quality management system principles by the regulated industry and foster innovation and continuous improvements in pharmaceutical manufacturing.

The Pharmaceutical CGMPs for the 21st Century: A Risk Based Approach initiative was announced in August 2002 (*http://www.fda.gov/cder/gmp/2ndProgressRept__Plan.htm*). Among the many CGMP issues identified at that time were: (1) The increase in the number of pharmaceutical products and in the role of medicines in health care; (2) the decrease in the frequency of FDA manufacturing inspections resulting from fewer available resources; (3) FDA's increasing experience with, and lessons learned from, various approaches to the regulation of product quality; (4) advances in the pharmaceutical sciences and manufacturing technologies; (5) the increasing application of biotechnology in drug discovery and manufacturing; (6) advances in the science and management of quality; and (7) the globalization of the pharmaceutical industry.

At the outset, the agency established a set of guiding principles for the initiative:

- Maintain a risk-based orientation;
- Policies and standards must be science based;
- The agency's orientation must be toward integrated quality systems;
- International cooperation is very important; and
- Protection of the public health must remain top priority.

The initiative's announcement stated that 21 CFR parts 210, 211, and parts 600 and 610 are flexible and will allow the agency to embark on a science-based risk management approach to CGMPs. This draft guidance, developed by a cross-center working group established by the initiative, is key in achieving the agency's goals. By showing how modern quality systems approaches relate to the existing CGMP regulation, the agency can help manufacturers meet the requirements of the agency's CGMP while using a robust quality systems approach to the production of human and animal medical products. Such a comprehensive approach should foster flexibility and allow for continued innovation, while maintaining the principles of the CGMP regulations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22206 Filed 9–29–04; 1:51 pm]

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