

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Draft Guidance for Industry on Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations." The draft guidance describes the key elements of a robust quality systems model and shows how persons implementing such a model can achieve compliance with the CGMP regulations.

DATES: Submit written or electronic comments on the draft guidance by December 3, 2004.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857;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 (HFMA-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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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 (HFMA-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FDA is announcing the availability of a draft guidance for industry entitled "Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations."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.

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