DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0443]

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 guidance for industry entitled ''Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations.'' This guidance explains FDA's current thinking regarding advances that have been made in the quality and manufacturing sciences since the current good manufacturing practice (CGMP) regulations were issued in 1978. The 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 agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the 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, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the 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*.

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;

Robert Sausville, Center for Biologics Evaluation and Research (HFM–610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6205;

June Liang, Center for Veterinary Medicine (HFV–143), 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 guidance for industry entitled ''Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations.'' This guidance was developed by the quality systems working group formed as part of the Pharmaceutical CGMPs for the 21st Century: A Risk Based Approach initiative (the initiative) now the Council on Pharmaceutical Quality. The 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 initiative was announced in August 2002 (*http://www.fda.gov/cder/gmp/2ndprogressrept_plan.htm*). Among the many 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 resources available for pharmaceutical manufacturing inspections; (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 the top priority.

The initiative's announcement stated that 21 CFR parts 210, 211, 600, and 610 are flexible and will allow the agency to embark on a science-based risk management approach to CGMPs. This 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 regulations, the agency can help manufacturers meet the requirements of the agency's CGMPs 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.

On October 4, 2004, FDA issued a draft of this guidance (69 FR 59256). Comments were received and considered carefully as the agency finalized the guidance. No substantive changes were made to the final guidance, although a number of clarifying edits were made throughout the guidance based on the comments received. In addition, the reference list and the graphic depicting a quality management systems approach were updated.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on a quality systems approach to pharmaceutical CGMP regulations. 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 regarding this document. Submit a single copy of electronic comments or 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. Received comments may be seen 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 7, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notification of a Class Deviation of Grants Policy Directive Part 2.04

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: In accordance with the Grants Policy Directive Part 1.03, the Office of Health Information Technology (OHIT) has been granted a class deviation from the competition requirements contained in the Grants Policy Directive Part 2.04 to provide an additional year of funding without competition for Health Center Controlled Network (HCCN) Initiatives funded under Section 330 of the Public Health Service Act, as amended.

FOR FURTHER INFORMATION CONTACT: Susan Lumsden, Director, Division of Health Information Technology State and Community Assistance, Office of Health Information Technology, Health Resources and Services Administration, 5600 Fishers Lane, 7C–22, Rockville, Maryland 20857; telephone number: 301–594–4472; fax number: 301–443–1330.

SUPPLEMENTARY INFORMATION: In accordance with Public Health Service Act, Title III, Section 330(e)(1)(C), 42 U.S.C.254b (as amended).

Background

OHIT serves as the HRSA Administrator's principal advisor for promoting the adoption of and implementing health care information technology for the medically uninsured, underserved and other vulnerable populations, ensuring that key issues affecting the public and private adoption of health information technology are addressed (*e.g.*, privacy and security issues, standardization, and interoperability). The HCCNs are key partners in enabling HRSA to help adopt and implement the President's Health Information Technology Initiative in the safety net community. The HCCNs support the creation, development, and operation of networks of safety net providers to ensure access to health care for the medically underserved populations through the enhancement of health center operations. The HCCNs routinely perform core business functions for their safety net members across their marketplace, State, or region. The core business functions range from electronic health records, credentialing and privileging programs, utilization review and management, and clinical quality improvement. They provide these functions at or below marketplace cost to their members to increase efficiencies, reduce costs, and improve health care quality for underserved and uninsured populations. As such, the HCCNs are key to achieving the President's goal of assuring that every American in the Nation will have an electronic health record by 2014.

Justification for the Exception to Competition

The creation of OHIT was part of HRSA's new priorities related to HIT and it is necessary that HRSA have an opportunity to ensure that its new HIT strategy and resources are reflected in its grant programs. Because OHIT was just established on December 27, 2005, and only became fully staffed in May 2006, there has been inadequate time to develop a new strategy to promote HIT in the safety net community and to establish funding priorities that are in line with the new office's goals.

The OHIT has granted 18 HCCN grants a one-time 12-month extension (with funds) of the current budget period, which expires August 31, 2006. This will avoid disruption of the HCCNs infrastructure and any impairment to the accomplishment of their work plans that would likely result from a competitive reallocation of funds without careful planning and advanced notice. All future funding for these activities will be based on a full and open competition that will focus on the most effective utilization of available resources in support of the Administration's new HIT objectives.

Grantee name	State	12 month extension
South Cove CHC, Inc.	MA	$86,788
SW Virginia Community Health System	VA	57,859
Keystone Rural Health Center	PA	70,611
Aaron E. Henry CHC	MS	57,859
Cook Area Health Services	MN	62,487
Horizon Health Care, Inc.	SD	86,788
Mariposa Community Health Center	AZ	57,859
Asian Health Services	CA	86,788
Southwest Virginia Community Health	VA	167,742
Health Choice Network	FL	173,576
Neighborhood Health Care Network	MN	173,576
Central Oklahoma Integrated Network System	OK	88,900
Colorado Community Managed Care Network	CO	128,646
Community Health Center Network	CA	173,576
Klamath Health Partnership	OR	173,576
Collier Health Services, Inc.	FL	82,237
Wasatch Homeless Health Care, Inc.	UT	159,111
Oregon Primary Care Association	OR	162,022
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