DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0266]

International Conference on Harmonisation; Draft Guidance on Q10 Pharmaceutical Quality System; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Q10 Pharmaceutical Quality System.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance describes a model for an effective quality management system for the pharmaceutical industry, referred to as the Pharmaceutical Quality System. The draft guidance applies to drug substances and drug products, including biotechnology and biological products, throughout the product lifecycle. The draft guidance is intended to provide a comprehensive approach to an effective pharmaceutical quality system that is based on International Organization for Standardization (ISO) concepts, includes applicable good manufacturing practice (GMP) regulations, and complements the ICH guidances on ''Q8 Pharmaceutical Development'' and ''Q9 Quality Risk Management.''

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 11, 2007.

ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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*. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,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 (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the Guidance: Joseph C. Famulare, Center for Drug Evaluation and Research (HFD–300), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–8910; Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–5681; or Diana Amador-Toro, Office of Regulatory Affairs (HFR-CE350), Food and Drug Administration, 10 Waterview Blvd., Parsippany, NJ 07054, 973–331–4915.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In May 2007, the ICH Steering Committee agreed that a draft guidance entitled ''Q10 Pharmaceutical Quality System'' should be made available for public comment. The draft guidance is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

The draft guidance provides guidance on a comprehensive approach to an effective pharmaceutical quality system that is based on ISO concepts, includes applicable GMP regulations, and complements the ICH guidances on ''Q8 Pharmaceutical Development'' and ''Q9 Quality Risk Management.'' The draft guidance describes a model for a pharmaceutical quality system that can be implemented throughout the different stages of a product lifecycle.

The model demonstrates industry and regulatory authorities' support of an effective pharmaceutical quality system to enhance the quality, safety, and availability of medicines around the world in the interest of public health. Implementation of the Pharmaceutical Quality System throughout the product lifecycle should facilitate innovation and continual improvement, promote the use of scientific and risk management principles, and strengthen the link between pharmaceutical development and manufacturing activities.

The draft guidance applies to drug substances and drug products, including biotechnology and biological products, throughout the product lifecycle. Much of the content of the draft guidance applicable to manufacturing sites is currently specified by regional GMP requirements. The draft guidance is not intended to create any new expectations beyond current regulatory requirements. Consequently, content of the guidance that is additional to current GMP requirements is optional.

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. 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 *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/reading.htm*.

Dated: July 9, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Uniform Progress Reports (OMB No. 0915–0061)—Revision

The HRSA Uniform Progress Report (UPR) is used for the preparation and submission of continuation applications for Title VII and VIII health professions and nursing education and training programs. The UPR measures grantee success in meeting (1) The objectives of the grant project, and (2) the cross-cutting outcomes developed for the Bureau of Health Professions' education and training programs. Part I of the progress report is designed to collect information to determine whether sufficient progress has been made on the approved project objectives, as grantees must demonstrate satisfactory progress to warrant continuation of funding. Part II collects information on activities specific to a given program. Part III, the Comprehensive Performance Management System (CPMS), collects data on overall project performance related to the Bureau's strategic goals, objectives, outcomes, and indicators. Progress will be measured based on the objectives of the grant project, and outcome measures and indicators developed by the Bureau to meet requirements of the Government Performance and Results Act (GPRA).

The Bureau has simplified several tables in UPR II and added the ability for grantees to provide better race and ethnicity data. In addition, to respond to the requirements of GPRA, the Bureau has revised its cross-cutting goals, expected outcomes, and indicators in UPR III CPMS that provide the framework for collection of outcome data for its Title VII and VIII programs. An outcome based performance system is critical for measuring whether program support is meeting national health workforce objectives. At the core of the performance measurement system are found cross-cutting goals with respect to workforce quality, supply, diversity, and distribution of the health professions workforce.

The estimated annual burden is as follows:

Report	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Uniform progress report	1,550	1	1,550	24	37,200
Total	1,550		1,550		37,200