

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier L. CLAWSON
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Food and Drug Administration

[Docket No. 2007D-0493]

**International Conference on Harmonisation; Draft Guidance on Q8(R1)
Pharmaceutical Development; 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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Q8(R1) Pharmaceutical Development Revision 1.” The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use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 The draft guidance is an annex to the parent ICH guidance entitled “Q8 Pharmaceutical Development” (71 FR 29344, May 22, 2006) (ICH Q8). It provides further clarification of key concepts outlined in ICH Q8 and describes the principles of quality by design (QbD). The draft guidance is intended to show how concepts and tools (e.g., design space) outlined in ICH Q8 could be put into practice by the applicant for all dosage forms.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

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2007D-0493

NAD 1

ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,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, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800.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 and other guidances mentioned in this document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Moheb Nasr, Center for Drug Evaluation and Research (HFD-800), Food and Drug Administration, 10903 New Hampshire Ave., bldg. 21, rm. 2630, Silver Spring, MD 20993-0002, 301-796-1900; or Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-20), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-435-5681.

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 November 2007, the ICH steering committee agreed that a draft guidance entitled “Q8(R1) Pharmaceutical Development Revision 1” 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 is an annex to the parent guidance ICH Q8. It provides further clarification of key concepts outlined in ICH Q8 and describes the principles of QbD. The annex is not intended to establish new standards or increase regulatory expectations. It is intended to show how concepts and tools (e.g., design space) outlined in ICH Q8 could be put into practice by the applicant for all dosage forms. Where a company chooses to apply QbD and quality risk management (see ICH “Q9 Quality Risk Management”), linked to an appropriate pharmaceutical quality system (see ICH “Q10 Pharmaceutical Quality Systems”), then opportunities arise to enhance science- and risk-based regulatory approaches.

The draft guidance outlines the elements that should be included in pharmaceutical development and additional elements when QbD principles are applied. It elaborates, by means of description and example, possible approaches to gaining a more systematic, enhanced understanding of the product and process under development. The draft guidance also provides recommendations on the placement of pharmaceutical development and other related information in module 3 of a regulatory submission in the common technical document format.

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

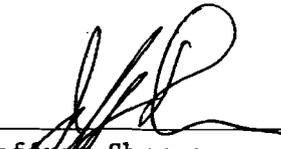
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

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/publications.htm>.

Dated: 1/2/08
January 2, 2008



Jeffrey Shuren,
Assistant Commissioner for Policy.

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