

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

Draft Guidance for Industry on Process Validation: General Principles and Practices; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Process Validation: General Principles and Practices." FDA is revising its guidance for industry entitled "Guideline on General Principles of Process Validation," which issued in May 1987 (the 1987 guidance). The revised draft guidance promotes a "lifecycle" approach to process validation that includes scientifically sound design practices, robust qualification, and process verification. When finalized, this draft guidance will replace the 1987 guidance.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or to 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; or to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Brian Hasselbalch, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4364, Silver Spring, MD 20993-0002, 301-796-3279;

Grace McNally, Center for Drug Evaluation and Research (HFD-320), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4374, Silver Spring, MD 20993-0002, 301-301-796-3286;

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM-1), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-0373; or

Dennis Bensley, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Process Validation: General Principles and Practices.” This guidance outlines the general principles and approaches that FDA considers to be appropriate elements of process validation for the manufacture of human and animal drug and biological products, including active pharmaceutical ingredients (API or drug substance). This guidance incorporates principles and approaches that all manufacturers can use in validating a manufacturing process.

In the **Federal Register** of May 11, 1987 (52 FR 17638), FDA issued a notice announcing the availability of a guidance entitled “Guideline on General Principles of Process Validation” (the 1987 guidance). Since then, we have obtained additional experience through our regulatory oversight that allows us to update our recommendations to industry on this topic. The draft guidance conveys FDA’s current thinking on process validation and is consistent with basic principles first introduced in the 1987 guidance. The draft guidance also provides recommendations that reflect some of the goals of FDA’s initiative entitled “Pharmaceutical CGMPs for the 21st Century—A Risk-Based Approach,” particularly with regard to the use of technological advances in pharmaceutical manufacturing, as well as implementation of modern risk management and quality system tools and concepts. When finalized, this guidance will replace the 1987 guidance.

FDA’s current good manufacturing practice (CGMP) regulations for validating pharmaceutical (drug) manufacturing require that drug products be produced with a high degree of assurance that they meet all the attributes they are intended to possess (21 CFR 211.100(a) and 211.110(a)). Effective process validation contributes significantly to the assurance of drug quality. FDA has

the authority and responsibility to inspect and evaluate process validation performed by manufacturers.

This guidance aligns process validation activities with the product lifecycle concept and with existing FDA guidance, including International Conference on Harmonisation (ICH) guidance documents, “Q8 Pharmaceutical Development,” “Q9 Quality Risk Management,” and when it is finalized, “Q10 Pharmaceutical Quality System” (a notice of availability for the May 2007 ICH Q10 draft guidance published in the **Federal Register** on July 13, 2007 (72 FR 38604)) (the guidances are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>). The lifecycle concept links product and process development, qualification of the commercial manufacturing process, and maintenance of the process in a state of control during routine commercial production. This guidance promotes modern manufacturing principles, process improvement innovation, and sound science.

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 the general principles and practices of process validation. 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. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of

information requested in the draft guidance is covered under FDA regulations at 21 CFR part 211, and is approved under OMB Control Number 0910-0139.

III. 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, <http://www.fda.gov/cvm/guidance/published.htm>, or <http://www.regulations.gov>.

Dated: 11-10-08
November 10, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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