

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0380]

Draft Guidance for Industry: Process Analytical Technology — A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Guidance for Industry: PAT — A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance.” The draft guidance explains a science-based, risk-based framework, “Process Analytical Technology, or PAT,” for developing and implementing innovative manufacturing technology. The guidance is intended to encourage innovative pharmaceutical manufacturing and quality assurance. Working with existing regulations, this guidance also describes a regulatory approach that will enable the agency and the pharmaceutical industry to address technical and regulatory issues and questions anticipated during introduction of new manufacturing and quality assurance technologies.

DATES: Submit written or electronic comments on this draft guidance on paper or electronically, by *[insert date 60 days after date of publication in the **Federal Register**]*. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,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 to the Office of Communication, Training, and Manufacturers Assistance (HFM–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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:

Rajendra Uppoor, Center For Drug Evaluation and Research (HFD–003),
5600 Fishers Lane, Rockville, MD 20857, 301–594–5615, or

Dennis Bensley, Center for Veterinary Medicine (HFV–143), Food and
Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–
6956, or

Robert Coleman, Office of Regulatory Affairs, Food and Drug
Administration, 60 8th Street North East, Atlanta, GA 30309, 404–253–
1200, ext. 1295.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled “Guidance for Industry: PAT — A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance.” The draft guidance explains a science-based, risk-based framework, “Process Analytical Technology, or PAT,” for developing and implementing innovative

manufacturing technology. The guidance is intended to encourage innovative pharmaceutical manufacturing and quality assurance.

I. Background

Conventional pharmaceutical manufacturing is generally accomplished using batch processing with testing conducted on collected samples to ensure quality. This conventional approach has been successful in providing quality pharmaceuticals to the public. However, significant opportunities now exist for improving the efficiency of pharmaceutical manufacturing and quality assurance through the innovative application of modern process development and control technologies, including modern PAT. Unfortunately, the pharmaceutical industry generally has been hesitant to introduce new technologies and innovative systems into the manufacturing sector for a number of reasons. For example, one reason often cited is regulatory uncertainty, which may result from the perception that our existing regulatory system is unfavorable to the introduction of new technologies.

In August 2002, recognizing the need to free industry from its hesitant perspective, FDA launched a new initiative entitled “Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach.”

Pharmaceutical development and manufacturing is evolving with increased emphasis on science and engineering principles. Effective use of pharmaceutical science and engineering principles and knowledge, throughout the life cycle of a product, can improve the efficiencies of both manufacturing and regulatory processes. FDA’s initiative is designed to do just that using an integrated systems approach to regulating pharmaceutical product quality. This approach is based on science and engineering principles for assessing and mitigating risks related to poor product and process quality. The desired future

state of pharmaceutical manufacturing may be characterized as: (1) Product quality and performance achieved and ensured through the design of effective and efficient manufacturing processes, (2) product and process specifications based on a mechanistic understanding of how formulation and process factors affect product performance, (3) continuous real time quality assurance, (4) regulatory policies and procedures tailored to recognize the level of scientific knowledge supporting products and processes, (5) risk-based regulatory approaches that recognize the level of scientific understanding of how formulation and manufacturing process factors affect product quality and performance and the capability of process control strategies to prevent or mitigate the risk of producing a poor quality product. This draft guidance is part of this initiative and is intended to facilitate progress to this desired state.

The 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. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final 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 the brackets in the heading of this document. A copy of 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 draft guidance at either *<http://www.fda.gov/cder/guidance/index.htm>* or *<http://www.fda.gov/ohrms/dockets/default.htm>*.

Dated: August 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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