practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on ''Part 11, Electronic Records; Electronic Signatures—Scope and Application.'' 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 guidance at any time. Two paper copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch 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: August 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–22574 Filed 9–03–03; 10:00 am]

BILLING CODE 4160–01–S

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Draft Guidance for Industry: Process Analytical Technology — A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: PAT — A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance.'' The draft guidance explains a science-based, risk-based framework, ''Process Analytical Technology, or PAT,'' for developing and implementing innovative manufacturing technology.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DATES: Submit written or electronic comments on this draft guidance on paper or electronically, by November 4, 2003. 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 Divison 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.

[FR Doc. 03–22578 Filed 9–3–03; 10:00 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0382]

Draft Guidance for Industry on ''Sterile Drug Products Produced by Aseptic Processing''

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Sterile Drug Products Produced by Aseptic Processing.'' FDA expects that enhanced compliance in the area of sterile drug manufacture will lead to a higher assurance of process consistency and minimize supply problems with therapeutically necessary drugs.

DATES: Submit written or electronic comments on the draft guidance by November 4, 2003. 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. 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:

Richard Friedman, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9041; or

Robert Sausville, Center for Biologics Evaluations and Research (HFM–624), Food and Drug Administration,1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6201; or

Bob Coleman, Office of Regulatory Affairs (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 404–253–4295.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2002, FDA released a ''concept paper'' regarding aseptic processing (*www.fda.gov/cder/dmpq*) to solicit early input prior to formal issuance of a draft guidance for public comment. We are now issuing the draft guidance, which when finalized will revise the 1987 industry guidance ''Sterile Drug Products Produced by Aseptic Processing.'' FDA's objective in revising the 1987 guidance is to issue a document that meets the following goals: (1) Provides greater clarity by including updated information regarding current good manufacturing practice (CGMP) expectations for aseptic processing facilities, and (2) reflects the latest scientific developments in this area of sterile drug quality. The 1987 guidance is being revised as part of the agency's broad effort ''Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach,'' announced in August 2002.

In preparation for issuing this draft guidance, we presented our CGMP concept for aseptic processing at the Advisory Committee for Pharmaceutical Science on October 22, 2002. At this meeting, the concept paper was discussed in a public forum and critiqued by the advisory committee's members as well as a panel of invited aseptic processing experts. The advisory committee meeting yielded a number of issues that provided impetus for further discussion. In December 2002, a working group under the Product Quality Research Institute (PQRI) was formed to address these issues. The PQRI working group, comprising 41 aseptic processing experts from industry, academia, and FDA, recommended 8 specific text clarifications on the concept paper and 10 detailed recommendations on various issues of aseptic processing. The PQRI Steering Committee forwarded the working group's final report to FDA on March 19, 2003, and it was subsequently posted on PQRI's Web site *www.pqri.org*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) We have taken comments from the Advisory Committee and PQRI Working Group into consideration in converting the Concept Paper into this draft guidance.

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 manufacturing of sterile drugs produced by aseptic processing. It does