

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 This draft guidance is part of this initiative and is intended to facilitate progress to this desired state.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic.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The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time.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may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance.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 A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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Persons with access to the Internet may obtain the draft guidance at either 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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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Draft Guidance for Industry on "Sterile Drug Products Produced by Aseptic Processing"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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Sterile Drug Products Produced by Aseptic Processing."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