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 This draft guidance is part of this initiative and is intended to facilitate progress to this desired state.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic.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The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time.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may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance.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 A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.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### Draft Guidance for Industry on ''Sterile Drug Products Produced by Aseptic Processing''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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Sterile Drug Products Produced by Aseptic Processing.''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

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 to *http://www.fda.gov/dockets/ecomments* or two copies of any mailed comments, except that individuals may submit one copy. The draft guidance and the comments submitted to the docket may be seen 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 *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. 03–22576 Filed 9–3–03; 10:00 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### Solicitation of Information and Recommendations for Developing Compliance Program Guidance for Recipients of NIH Research Grants

**AGENCY:** Office of Inspector General (OIG), HHS.

**ACTION:** Notice.

**SUMMARY:** This **Federal Register** notice seeks the input and recommendations of interested parties as the OIG develops compliance program guidance (CPG) for recipients of extramural research grant and cooperative agreement (grant) awards from the National Institutes of Health (NIH). The OIG is soliciting comments, recommendations and other suggestions from interested parties and organizations on the value and fundamental principles of compliance programs for colleges, universities, and other recipients of NIH grants, along with the specific elements that these grant recipients should consider when developing and implementing an effective compliance program.

**DATES:** To assure consideration, comments must be delivered to the address provided below by no later than 5 p.m. on November 4, 2003.

**ADDRESSES:** Please mail or deliver your written comments, recommendations and suggestions to the following address: Department of Health and Human Services, Office of Inspector General, Attention: OIG–13–CPG, Room 5527, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to the file code OIG–13–CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5527 of the Cohen Building at 330 Independence Avenue, SW., Washington, DC 20201 on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

**FOR FURTHER INFORMATION CONTACT:** Richard Stern, Office of Counsel to the Inspector General, (202) 619–0335; or Joel Schaer, Office of Counsel to the Inspector General, (202) 619–0089.

**SUPPLEMENTARY INFORMATION:**

**1. Past CPGs**

The development of compliance program guidances is a major initiative of the OIG in its effort to assist participants in Department programs in preventing and reducing fraud and abuse and in complying with Federal program requirements. Over the past several years, the OIG has developed and issued 11 compliance program guidances. The suggestions contained in the guidances are not mandatory, nor do they represent an exclusive discussion of the advisable elements of a compliance program.

**2. Developing Draft CPG for NIH Research Grant Recipients**

Through this **Federal Register** notice, the OIG is seeking input from interested parties as the OIG considers the development of a CPG for recipients of extramural research grant awards from NIH. Under its governing statute, the OIG's oversight responsibility extends to all programs and operations of the Department, and the OIG promotes compliance efforts by all recipients of Department funds. One community of paramount importance to the Government's public health efforts is the colleges, universities, and other recipients of public funds committed to furthering biomedical research. These organizations are largely non-profit and educational, with over 50 percent of recipients of NIH research grant awards in the last several years being medical schools. Many of these organizations have instituted health care compliance programs in their hospitals, and an increasing number have begun developing compliance programs for sponsored research.

As with OIG's earlier CPGs, the purpose of this guidance will be to assist organizations in preventing fraud and abuse and in better complying with Federal requirements. We anticipate that the guidance for recipients of NIH research grants will contain seven elements that we consider necessary for a comprehensive compliance program. These seven elements include:

- Implementing written policies and procedures that foster an institutional commitment to stewardship and compliance;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and
- Responding promptly to detected problems, undertaking corrective action, and reporting to the appropriate Federal agency.

We are also considering an eighth element, ''Defining roles and responsibilities and assigning oversight responsibility,'' that would include a discussion of the importance of effectively delegating oversight authority.

We would appreciate specific comments, recommendations and suggestions on aspects of these elements.

We are also interested in comments on (a) the scope of the guidance, and particularly the types of activities, such as grant administration, that should be subject to the CPG; and (b) the risk areas for recipients of NIH research grants. Based on our fraud investigations at research institutions, we have identified internal control deficiencies that may warrant attention in a CPG. OIG would also appreciate suggestions from the public on risk areas. Risk areas we have tentatively identified include: (i) The proper allocation of charges to grant projects; (ii) ''time and effort'' reporting, including an accurate reporting of the commitment of effort by researchers; and (iii) use of program income. We would also be interested in comments on each of these areas.

We will consider all comments, recommendations and suggestions received within the time frame