Facts on Demand (1-800-899-0381). Copies of the revision may also be obtained from the electronic docket administered by the Division of Small Manufacturers Assistance and are available to anyone with a video terminal or personal computer (1-800-252-1366).

FOR FURTHER INFORMATION CONTACT: Kimberly A. Trautman, Office of Compliance, Center for Devices and Radiological Health (HFZ–341), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4648.

SUPPLEMENTARY INFORMATION:

I. Background

Manufacturers establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA regulated products (food, drugs, biologics, and devices) are known as CGMP's. CGMP requirements for devices (part 820 (21 CFR part 820)) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)), which was among the authorities added to the act by the Medical Device Amendments of 1976 (Pub. L. 94–295). The Safe Medical Devices Act (the SMDA) of 1990 (Pub. L. 101–629), enacted on November 28, 1990, amended section 520(f) of the act, providing FDA with the explicit authority to add preproduction design validation controls to the CGMP regulation. The SMDA also added a new section 803 to the act (21 U.S.C. 383) which, among other things, encourages FDA to work with foreign countries toward mutual recognition of CGMP requirements. –

FDA undertook the revision of the CGMP regulation in part to add the design controls authorized by the SMDA to the CGMP regulation, and in part because the agency believes that it would be beneficial to the public, as well as the medical device industry, for the CGMP regulation to be consistent, to the extent possible, with the requirements for quality systems contained in applicable international standards, namely, the International Organization for Standards (ISO) 9001:1994 ''Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing'' (Ref. 1), and the ISO working draft revision of ISO/DIS 13485 ''Quality Systems—Medical Devices—Supplementary Requirements to ISO 9001'' (Ref. 2), among others. The preamble to the November 23, 1993, proposal contained a detailed discussion of the history of the device CGMP regulation, from the agency's initial issuance of the regulation through FDA's decision to propose revising the regulation.–

The agency's working draft embraces the same ''umbrella'' approach to CGMP regulation that is the underpinning of the existing CGMP regulation. Thus, because this regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation lays the framework that all manufacturers must follow, requiring that the manufacturer develop and follow procedures, and fill in the details, that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device. FDA has made further changes to the proposed regulation, as the working draft evidences, to provide manufacturers with even greater flexibility in achieving the quality requirements.

II. Decision to Make a Working Draft Available for Comment

On November 23, 1993 (58 FR 61952), the agency issued the proposed revisions to the CGMP regulation, entitled ''Medical Devices; Current Good Manufacturing Practice (CGMP) Regulations; Proposed Revisions; Request for Comments,'' and public comment was solicited. After the proposal issued, FDA met with the Global Harmonization Task Force (GHTF) Study Group in early March 1994, in Brussels, to compare the provisions of the proposal with the provisions of ISO 9001:1994 and European National (EN) standard EN 46001 ''Quality Systems—Medical Devices—Particular Requirements for the Application of EN 29001.'' The GHTF includes: Representatives of the Canadian Ministry of Health and Welfare; the Japanese Ministry of Health and Welfare; FDA; and industry members from the European Union, Australia, Canada, Japan, and the United States. The participants at the GHTF meeting favorably regarded FDA's effort toward harmonization with international standards. The GHTF submitted comments, however, noting where FDA could more closely harmonize to achieve consistency with quality system requirements worldwide. Since the proposal published, FDA has also attended numerous industry and professional association seminars and workshops, including ISO Technical Committee 210 ''Quality Management and Corresponding General Aspects for Medical Devices'' meetings, where the proposed revisions were discussed.

The original period for comment on the proposal closed on February 22, 1994, and was extended until April 4, 1994. Because of the heavy volume of comments and the desire to increase public participation in the development of the quality system regulation, FDA decided to publish this notice of availability in the **Federal Register** to allow comment on the working draft, to be followed by two public meetings, as described below, before issuing a final regulation.

This working draft represents the agency's current views on how it would respond to the many comments received, and on how the agency believes a final rule should be framed. FDA solicits public comment on this working draft to determine if the agency has adequately addressed the many comments received and whether the agency has framed a final rule that achieves the public health goals to be gained from implementation of quality systems in the most efficient manner.

III. Opportunity for Public Meeting

FDA intends to hold two public meetings on the revision of the quality system regulation. One meeting, which will be held pursuant to 21 CFR part 10.65(b), is scheduled for August 23, 1995. Interested persons who wish to participate in the public meeting may, on or before August 8, 1995 submit a written notice of participation to the Dockets Management Branch (address above). All notices submitted should be identified with the docket number found in brackets in the heading of this document and should be clearly marked ''Notice of Participation.'' The notice should also contain the name, address, telephone number, business affiliation of the person requesting to make a presentation, a brief summary of the presentation, and the approximate time requested for the presentation.

Individuals or groups having similar interests are requested to consolidate their comments and present them through a single representative. FDA may require joint presentations by persons with common interests. FDA will allocate the time available for the meeting among the persons who properly submit a written notice of participation. The meeting is informal, and the rules of evidence do not apply.

Because of the complexity of the issues to be discussed at the public meeting, FDA has concluded that it would not be beneficial to the meeting participants or the agency to devote the entire meeting to public presentations. Therefore, after reviewing the notices of