

Proposed Rules

Federal Register

Vol. 60, No. 141

Monday, July 24, 1995

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 162

RIN 1515-AB72

Search Warrants; Correction

AGENCY: Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: This document makes a correction to the document which was previously published in the **Federal Register** proposing to amend the Customs Regulations by removing a regulation limiting the authority of Customs officers to whom search warrants are issued.

FOR FURTHER INFORMATION CONTACT: Janet L. Johnson, Attorney, Regulations Branch, (202) 482-6930.

SUPPLEMENTARY INFORMATION:

Background

On July 12, 1995, Customs published in the **Federal Register** (60 FR 35881) a document proposing to amend the Customs Regulations by deleting section 162.14 (19 CFR 162.14) in order to make the regulations consistent with the current state of the law.

This document corrects an error contained in that document. The error concerns the statement "This document does meet the criteria for a 'significant regulatory action' as specified in Executive Order 12866." The word "not" was inadvertently omitted from the sentence. The document does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866. Accordingly, this document corrects that error.

Correction of Publication

Accordingly, the publication of July 12, 1995 of the notice of proposed rulemaking (60 FR 35881) is corrected as follows:

On page 35881, in the third column under the heading "The Regulatory

Flexibility Act and Executive Order 12866", the last paragraph is corrected to read "This document does not meet the criteria for a 'significant regulatory action' as specified in Executive Order 12866."

Dated: July 14, 1995.

Harold M. Singer,

Chief, Regulations Branch.

[FR Doc. 95-17985 Filed 7-21-95; 8:45 am]

BILLING CODE 4820-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 820

[Docket No. 90N-0172]

RIN No. 0905-AD59

Medical Devices; Working Draft of the Current Good Manufacturing Practice (CGMP) Final Rule; Notice of Availability; Request for Comments; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability and announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a working draft of a final rule on the revision of the current good manufacturing practice (CGMP) regulation for devices (quality system regulation). The quality system regulation includes requirements related to the methods used in and the facilities and controls used for: Designing, purchasing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use. The working draft contains a number of changes made in response to the many comments received on the proposal to amend the CGMP regulation, and it represents the agency's view of the necessary elements of a CGMP regulation. In this document, FDA is also announcing a public meeting to be held on the working draft. At a later time, FDA will announce a meeting of the Device Good Manufacturing Practice Advisory Committee. The publication of this document is intended to make the working draft of the quality system

regulation available to the public in order to give those who will attend the public meetings the opportunity to be informed of the agency's current thinking on the final rule and to allow interested parties an additional opportunity to comment before a final regulation is issued.

DATES: The public meeting will be held on Wednesday, August 23, 1995, from 9 a.m. to 4:30 p.m. Should more time be needed, Thursday, August 24, 1995, has been set aside for this purpose.

Interested persons, whether or not they are able to attend, may submit written comments on the issues described in this notice by October 23, 1995. Submit written notices of participation on or before August 8, 1995. Any final regulation that may issue, after a thorough review of the comments received on this working draft, will become effective 180 days following its publication in the **Federal Register**. A transcript of the meeting will be available from the Dockets Management Branch (address below).

ADDRESSES: The meeting will be held at the Parklawn Bldg, conference room D, 5600 Fishers Lane, Rockville, MD. There is no registration fee for this meeting. Submit written requests to make a presentation at the meeting to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Submit written requests for single copies of the working draft of the quality system regulation to the Division of Small Manufacturers Assistance (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request. Submit written comments on the working draft to the Dockets Management Branch (HFA-305) (address above). Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the working draft and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Copies of a facsimile of the working draft, totaling approximately 230 pages (approximately 190 pages of draft preamble and 40 pages of draft regulation), are available from CDRH

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

participation and accompanying information, FDA will schedule each appearance and notify each participant by mail or telephone of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. Each presentation will be limited in time in order to provide sufficient time for prepared presentations by the agency followed by a discussion period. The schedule of the public meeting will be available at the meeting, and later it will be placed on file in the Dockets Management Branch (address above).

Individuals and organizations that do not submit a notice of participation but would like to testify will have the opportunity, if time permits. A transcript of the proceedings of the public meeting, as well as all data and information submitted voluntarily to FDA during the public meeting to discuss the working draft, will become part of the administrative record and will be available to the public under 21 CFR 20.111 from the Dockets Management Branch (address above).

While oral presentations from specific individuals and organizations will be limited during the public meeting, the written comments submitted as part of the administrative record may contain a discussion of any issues of concern. All relevant data and documentation should be submitted with the written comments.

There will also be a public meeting with the Device GMP Advisory Committee, established under section 520(f)(1)(B) of the act, on the working draft. That meeting will be governed by part 14 (21 CFR part 14) of FDA's administrative practices and procedures regulations, which specifies the requirements for filing notices of appearance. The tentative dates for the meeting are September 13 and 14, 1995. A notice of the exact dates, time, and place for the meeting will appear in a future issue of the **Federal Register**. After considering the written comments and the views expressed at the public meeting and at the September advisory committee meeting, FDA will publish a final rule in the **Federal Register**.

IV. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday:

(1) ISO 9001:1994 "Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing."

(2) ISO working draft revision of ISO/DIS 13485 "Quality Systems—Medical Devices—Supplementary Requirements to ISO 9001."

V. Comments

Interested persons may, on or before October 23, 1995, submit to the Dockets Management Branch (address above), written comments regarding this working draft. Two copies of any 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 working draft and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-18080 Filed 7-19-95; 1:36 pm]

BILLING CODE 4160-01-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[FRL-5260-2]

Approval of Existing Federally Enforceable State and Local Operating Permit Programs To Limit Potential To Emit for Air Toxics; State of Alabama; Knox County, Tennessee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes approval of the State of Alabama's Federally enforceable state operating permits program (FESOP) under section 112(l) of the Clean Air Act as amended in 1990 (CAA). EPA proposes approval of the Knox County, Tennessee Federally enforceable local operating permit program (FELOP) under section 112(l) of the CAA. EPA is proposing approval of both of these requests under section 112(l) of the CAA for purposes of limiting potential to emit (PTE) for hazardous air pollutant (HAP) sources. In the final rules section of this **Federal Register**, EPA is approving Alabama and Knox County, Tennessee's submittals as a direct final rule without prior proposal because the EPA views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA

receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: To be considered, comments must be received by August 23, 1995.

ADDRESSES: Written comments should be addressed to Scott Miller of the EPA Regional office listed below.

Copies of the material submitted by both agencies may be examined during normal business hours at the following locations:

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.
Environmental Protection Agency, Region 4 Air Programs Branch, 345 Courtland Street NE., Atlanta, Georgia 30365.

Alabama Department of Environmental Management, Air Division, 1751 Congressman W.L. Dickinson Drive, Montgomery, Alabama 36109.

Knox County Department of Air Pollution Control, City/County Building, Suite 339, 400 West Main Street, Knoxville, Tennessee 37902.

FURTHER INFORMATION CONTACT: Scott Miller, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street NE., Atlanta, Georgia 30365. The telephone number is 404/347-2864.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this **Federal Register**.

Dated: June 23, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

[FR Doc. 95-17614 Filed 7-21-95; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 95

RIN 0970-AB46

Reduction of Reporting Requirements for the State Systems Advance Planning Document (APD) Process

AGENCY: Administration for Children and Families, HHS.