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