DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 808, 812, and 820

[Docket No. 90N–0172]

RIN 0910–AA09

Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the current good manufacturing practice (CGMP) requirements for medical devices and incorporating them into a quality system regulation. The quality system regulation includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use. This action is necessary to add preproduction design controls and to achieve consistency with quality system requirements worldwide. This regulation sets forth the framework for device manufacturers to follow and gives them greater flexibility in achieving quality requirements.

DATES: The regulation is effective June 1, 1997. For more information on compliance with 21 CFR 820.30 see section IV. of this document.

Written comments on the information collection requirements should be submitted by December 6, 1996.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kimberly A. Trautman, 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 in 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).

Under section 520(f) of the act, FDA issued a final rule in the **Federal Register** of July 21, 1978 (43 FR 31 508), prescribing CGMP requirements for the methods used in, and the facilities and controls used for the manufacture, packing, storage, and installation of medical devices. This regulation became effective on December 18, 1978, and is codified under part 820. Except for editorial changes to update organizational references in the regulation and revisions to the list of critical devices that was included in the preamble to the final regulation, the device CGMP requirements have not been revised since 1978. This final rule is the result of an extensive effort begun in 1990 to revise this regulation.

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), enacted on November 28, 1990, amended section 520(f) of the act, providing FDA with the authority to add preproduction design controls to the CGMP regulation. This change in law was based on findings that a significant proportion of device recalls were attributed to faulty design of product. Specifically, in January 1990, FDA published the results of an evaluation of device recalls that occurred from October 1983 through September 1989, in a report entitled ''Device Recalls: A Study of Quality Problems'' (Ref. 1). (See 55 FR 21108, May 22, 1990, where FDA announced the availability of the report.) FDA found that approximately 44 percent of the quality problems that led to voluntary recall actions during this 6-year period were attributed to errors or deficiencies that were designed into particular devices and may have been prevented by adequate design controls. These design-related defects involved both noncritical devices (e.g., patient chair lifts, in vitro diagnostics, and administration sets) and critical devices (e.g., pacemakers and ventilators). Also in 1990, the Department of Health and Human Services' Inspector General conducted a study entitled ''FDA Medical Device Regulation From Premarket Review to Recall'' (Ref. 2), which reached similar conclusions. With respect to software used to operate medical devices, the data were even more striking. A subsequent study of software-related recalls for the period of fiscal year (FY) 1983 through FY 1991 indicated that over 90 percent of all software-related device failures were due to design-related errors, generally, the failure to validate software prior to routine production (Ref. 3).

The SMDA also added 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 to add the design controls authorized by the SMDA to the CGMP regulation, as well as because the agency believed that it would be beneficial to the public and 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, primarily, the International Organization for Standards (ISO) 9001:1994 ''Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing'' (Ref. 4), and the ISO committee draft (CD) revision of ISO/CD 13485 ''Quality Systems—Medical Devices—Supplementary Requirements to ISO 9001'' (Ref. 5).

This action is being taken under those provisions of the SMDA and in response to the following: (1) Notices that appeared in the **Federal Register** of April 25, 1990 (55 FR 17502), and in the **Federal Register** of April 17, 1991 (56 FR 15626), that announced meetings of the agency's Device Good Manufacturing Practice Advisory Committee (GMP Advisory Committee), at which the need for revisions to the CGMP regulation was explored; (2) an advance notice of proposed rulemaking (ANPRM) that appeared in the **Federal Register** of June 15, 1990 (55 FR 24544), that announced the agency's intent to revise the CGMP regulation; (3) a notice of availability of a document that appeared in the **Federal Register** of November 30, 1990 (55 FR 49644), entitled ''Medical Devices; Current Good Manufacturing Practices (CGMP) Regulations Document; Suggested Changes; Availability'' (Ref. 6) and comments solicited from the public about the document; (4) a proposed rule in the **Federal Register** of November 23, 1993 (58 FR 61952), (Ref. 7) and comments solicited from the public about the proposal; (5) a notice of availability that appeared in the **Federal Register** of July 24, 1995 (60 FR 37856), announcing the availability of the ''Working Draft of the Current Good Manufacturing Practice (CGMP) Final Rule'' (hereinafter referred to as the Working Draft) (Ref. 8) and comments

solicited from the public about the Working Draft; (6) testimony at an August 23, 1995, open public meeting announced in the **Federal Register** (60 FR 37856); (7) and testimony and advisory committee recommendations from the September 13 and 14, 1995, meeting of the GMP Advisory Committee announced in the **Federal Register** of August 24, 1995 (60 FR 44036). Thus, FDA's decision to revise the CGMP regulation is based on changes in the law made by the SMDA, the agency's discussions with others including its GMP Advisory Committee, responses to the **Federal Register** notices on this matter, FDA's analysis of recall data, its experience with the regulatory application of the original CGMP regulation, and its assessment of international quality standards.

The agency's final rule embraces the same ''umbrella'' approach to the CGMP regulation that is the underpinning of the original CGMP regulation. 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 provides the framework that all manufacturers must follow by requiring that manufacturers 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 changes to the proposed regulation and the Working Draft, as the final rule evidences, to provide manufacturers with even greater flexibility in achieving the quality requirements.

The Supreme Court recently addressed the preemptive effect, under section 521 of the act (21 U.S.C. 360k), of the original CGMP regulation and other FDA requirements for medical devices on State tort actions. In *Medtronic, Inc.* v. *Lohr,* 116 S. Ct. 2240 (1996), the Supreme Court gave substantial deference to the agency's interpretation of section 521 of the act found at § 808.1 (21 CFR 808.1). The Court noted that CGMP requirements are general rather than ''specific requirements applicable to a particular device,'' and that State common law remedies are similarly general, and do not establish a ''substantive requirement for a specific device.'' (*Lohr* at 2257; see also § 808.1(d) and (d)(6)(ii).) Moreover, the Court drew a distinction between remedies and requirements, noting that while common law tort actions may provide remedies different from those available under the act, no preemption occurs unless the substantive requirements of the State law are ''different from, or in addition to,'' those imposed by the act. (See *Lohr* at 2255.) Under the Supreme Court's analysis in *Lohr,* the requirements imposed by the original CGMP regulation would rarely have preemptive effect.

FDA believes that the reasoning of *Medtronic* v. *Lohr* applies equally to the new quality system regulation, which, as does the original CGMP regulation, prescribes requirements that apply to medical devices in general, rather than to any particular medical device. Therefore, FDA has concurrently amended part 808 (21 CFR part 808) to make clear the new quality system regulation does not preempt State tort and common law remedies.

II. Decision to Make a Working Draft Available for Comment

In the **Federal Register** of November 23, 1993, 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 (the 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 Standard (EN) 46001 ''Quality Systems—Medical Devices—Particular Requirements for the Application of EN 29001'' (Ref. 9). ISO 9001:1994 and EN 46001:1994 are written as voluntary standards, but when used to fulfill the requirements of the European Medical Device Directives, or other national regulations, these standards are mandatory requirements similar to the CGMP requirements. 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 (EU), 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 (TC) 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 the notice of availability in the **Federal Register** to allow comment on the Working Draft before issuing a final regulation.

The Working Draft represented the agency's views at the time on how it would respond to the many comments received, and on how the agency believed a final rule should be framed. FDA solicited public comment on the Working Draft until October 23, 1995, to determine if the agency had adequately addressed the many comments received and whether the agency had framed a final rule that achieved the public health goals to be gained from implementation of quality systems in the most efficient manner.

III. Open Public Meeting and GMP Advisory Committee Meeting

FDA held an open public meeting on the quality system regulation on August 23, 1995. The public meeting consisted of prepared presentations followed by an open discussion period. Both the agency and the participants found the meeting to be very productive in focusing attention on the few main areas of concern in the Working Draft. The main issues were: The application of the regulation to component manufacturers; the application of the regulation to third party servicers and refurbishers; and the implementation timeframe of the final rule. A transcript of the proceedings of the public meeting, as well as data and information submitted to FDA during the public meeting, are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

There also was a meeting of the GMP Advisory Committee on the Working Draft on September 13 and 14, 1995. A notice of the meeting was published in the **Federal Register** of August 24, 1995. FDA made a brief presentation to the committee on the changes from the 1993 proposal to the 1995 Working Draft and discussed some changes that FDA was recommending as a result of the August 1995 meeting. Two consultants also made presentations to the committee, one a representative from ISO TC 176 (the TC that authored the ISO 9000 series) and the other a representative from the European Committee for Standardization (CEN). The remainder of the meeting consisted of prepared

presentations from the public and the committee's discussion on the main issues.

The overwhelming majority of the committee members believed that the Working Draft met the public health needs, gave manufacturers sufficient flexibility to comply with the regulation, and met the agency's goal of harmonizing the quality system requirements with those of other countries. The GMP Advisory Committee strongly supported FDA's recommendation, in response to the August 1995 public meeting, to not include component manufacturers under this final rule. However, the GMP Advisory Committee was clearly divided on several issues related to the proposed regulation of third party servicers and refurbishers. A transcript of the proceedings of the GMP Advisory Committee meeting, as well as data and information submitted to FDA during the meeting, are available from the Dockets Management Branch (address above).

After considering the written comments and the views expressed at meetings with the GHTF, at the August 1995 public meeting, and at the September 1995 GMP Advisory Committee meeting, FDA is publishing this final rule. A summary of changes from the July 1995 Working Draft to the final rule is contained at the end of this preamble.

IV. Implementation of the Final Rule

FDA has decided, in response to the many comments and concerns expressed about the need for more time to implement design controls, to implement the final rule in two stages. Under stage one, on June 1, 1997, approximately 1 year after this rule is published in the **Federal Register**, all elements of the final rule become effective. However, with respect to the design control requirements in § 820.30, as long as manufacturers are taking reasonable steps to come into compliance, FDA will implement a special 1-year transition program, with a midcourse review, during which official agency action will not be initiated, including FDA Form 483 observations, warning letters, or enforcement cases, based on failure to comply with § 820.30. Under stage two, beginning June 1, 1998, FDA will treat noncompliance with design control requirements in § 820.30 the same as noncompliance with other provisions of the CGMP regulation.

To prepare for stage one of this implementation plan, FDA intends to develop, by April of 1997, a strategy for inspecting the design control requirements. Both industry and FDA field investigators will then be trained on this inspectional strategy for design controls during April and May 1997. Starting June 1, 1997, manufacturers will be inspected for compliance with all the new quality system requirements, including design controls, in the manner described in the inspectional strategy. However, as part of the transition program, from June 1, 1997, for a period of 1 year, although FDA will inspect firms for compliance with the design control requirements, the field will issue any observations to the manufacturer on a separate design control inspectional strategy report, not on FDA Form 483. The design control inspectional strategy report will be made a part of the manufacturer's establishment inspection report (EIR), but the observations relating to § 820.30 will not be included in any warning letters or regulatory actions during this initial 1-year period. FDA notes that it can, at any time, take action against unsafe or adulterated medical devices under different regulatory or statutory authorities. FDA wants to emphasize that *manufacturers are required to take reasonable steps to come into compliance with the design control requirements during the June 1, 1997, to June 1, 1998, period.*

FDA also emphasizes that this transition period relates only to the design control requirements of § 820.30, and that beginning June 1, 1997, the agency will issue observations on FDA Form 483's, issue warning letters, and take any necessary regulatory action for violations of all other provisions of the CGMP final rule. The time period from June 1, 1997, to June 1, 1998, is intended to allow both the industry and FDA field investigators time to become familiar with the design control requirements and the enforcement aspects of this new area.

Finally, as described elsewhere in this preamble, FDA intends to conduct a midcourse review of the new design control requirements during the transition year (June 1997 to June 1998). Specifically, the results of the first several months of design control inspections will be reviewed by early 1998. FDA will review all of the completed design control inspectional strategy reports that were given to manufacturers from between June 1, 1997, through December 1, 1997. The completed strategy reports will be reviewed with particular attention paid to clarity of information obtained, the appropriateness of the information collected with respect to the design control requirements, the appropriateness of the questions on the inspectional strategy, the manner in which the investigators are writing out their observations, and any requirements that seem to be giving manufacturers a problem or where there might be misunderstandings as to what the regulation requires. FDA will then hold an open public meeting in early 1998 to discuss with industry these findings and to further explore any concerns industry might be having in implementing the new design control requirements. As a result of the midcourse review and open public meeting, FDA might hold additional workshops, meetings, and/or training sessions.

Any midcourse adjustments to the inspectional strategy will be instituted and made public by the spring of 1998. Also during this midcourse review, FDA will evaluate the information gathered at that point and determine if the design control requirements as written in this final rule are appropriate to obtain the goals expressed in this preamble. FDA will consider minor or even major changes, based on experience to date. Any necessary adjustments or proposed revisions will be published in the **Federal Register** and comments will be solicited as necessary during the spring of 1998. This implementation strategy is responsive to requests by industry for FDA to harmonize the quality system regulation's implementation with the mandatory date for implementation of the EU's Medical Device Directive, which is June 1998. However, if during the midcourse review of stage one it is determined that the industry and/or FDA needs more time to fully implement the design control requirements, FDA will publish an extension of the regulatory implementation date for design control requirements prior to June 1, 1998.

V. Response to Comments and Rationale for Changes

Approximately 280 separate individuals or groups commented on the proposal published in the **Federal Register** of November 23, 1993, and approximately 175 separate individuals or groups commented on the Working Draft that was announced in a notice of availability published in the **Federal Register** on July 24, 1995. FDA made many changes in response to the comments. Most of the changes were made in response to specific comments, in response to comments for clarity, understanding, and readability, or to further harmonize FDA requirements with international standards, as many comments requested.

Numerous comments stated that industry was very pleased with FDA's

Working Draft and the effort that was made to harmonize with ISO, as well as to engage industry in commenting on the Working Draft through the open public meeting and the GMP Advisory Committee meeting that were held in August and September 1995, respectively.

FDA's responses to the comments received on the proposal and the Working Draft, as well as explanations for the changes made, follow.

A. General Provisions (Subpart A)

i. Scope (§ 820.1)

1. The title of the regulation, as reflected in this section, has been changed from the ''Current Good Manufacturing Practices (CGMP)'' regulation to the ''Quality System'' regulation. This revision follows the suggestion underlying many comments on specific provisions that FDA generally harmonize the CGMP requirements and terminology with international standards. ISO 9001:1994, ISO/CD 13485, and EN 46001 employ this terminology to describe the CGMP requirements. In addition, this title accurately describes the sum of the requirements, which now include the CGMP requirements for design, purchasing, and servicing controls. CGMP requirements now cover a full quality system.

FDA notes that the principles embodied in this quality system regulation have been accepted worldwide as a means of ensuring that acceptable products are produced. While the regulation has been harmonized with the medical device requirements in Europe, Australia, and Japan, as well as the requirements proposed by Canada, it is anticipated that other countries will adopt similar requirements in the near future.

FDA, however, did not adopt ISO 9001:1994 verbatim for two reasons. First, there were complications in dealing with the issue of copyrights and, second, FDA along with health agencies of other governments does not believe that for medical devices ISO 9001:1994 alone is sufficient to adequately protect the public health. Therefore, FDA has worked closely with the GHTF and TC 210 to develop a regulation which is consistent with both ISO 9001:1994 and ISO/CD 13485. FDA made several suggestions to TC 210 on the drafts of the ISO/CD 13485 document in order to minimize differences and move closer to harmonization. In some cases, FDA has explicitly stated requirements that many experts believe are inherent in ISO 9001:1994. Through the many years of experience enforcing and evaluating compliance with the original CGMP regulation, FDA has found that it is necessary to clearly spell out its expectations. This difference in approach does not represent any fundamentally different requirements that would hinder global harmonization. In fact, numerous comments expressed their approval and satisfaction with FDA's effort to harmonize the quality system requirements with those of ISO 9001:1994 and ISO/CD 13485.

2. One comment suggested that the term ''purchasing'' in the scope be deleted because it could be interpreted to mean the purchase of finished medical devices by health care institutions and medical professionals, instead of the purchase of components and manufacturing materials as intended.

FDA agrees and has deleted the term ''purchasing'' throughout the regulation when used in this context.

3. Several comments suggested that § 820.1(a)(1) should not state that the regulation establishes the ''minimum'' requirements because it implies that compliance with the stated requirements may be insufficient. They asked that FDA delete the word ''minimum,'' to avoid having auditors search for additional requirements.

FDA does not believe that the provision would have required that manufacturers meet additional requirements not mandated by the regulation but has modified the section to clarify its intent by stating that the regulation establishes the ''basic'' requirements for manufacturing devices. The quality system regulation provides a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements. The regulation provides the flexibility necessary to allow manufacturers to adopt advances in technology, as well as new manufacturing and quality system procedures, as they become available.

During inspections, FDA will assess whether a manufacturer has established procedures and followed requirements that are appropriate to a given device under the current state-of-the-art manufacturing for that specific device. FDA investigators receive extensive training to ensure uniform interpretation and application of the regulation to the medical device industry. Thus, the agency does not believe that FDA investigators will cite deviations from requirements not contained in this part. However, as noted above, FDA has altered the language of the scope to make clear that additional, unstated requirements do not exist.

4. A few comments suggested eliminating the distinction between critical and noncritical devices, thus eliminating the need for distinct requirements for critical devices. Other comments disagreed, asserting that eliminating the distinction would increase the cost of production of low-risk devices without improving their safety and effectiveness.

FDA agrees in part with the comments that suggest eliminating the distinction between critical and noncritical devices and has eliminated the term ''critical device'' from the scope, definitions, and regulation in §§ 820.65 *Critical devices, traceability* and 820.165 *Critical devices, labeling.* However, FDA has retained the concept of distinguishing between devices for the traceability requirements in § 820.65. As addressed in the discussion under that section, FDA believes that it is imperative that manufacturers be able to trace, by control number, any device, or where appropriate component of a device, that is intended for surgical implant into the body or to support or sustain life whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user.

The deletion of the terminology will bring the regulation in closer harmony with ISO 9001:1994 and the quality system standards or requirements of other countries.

Finally, FDA notes that eliminating the term ''critical device'' and the list of critical devices does not result in the imposition of new requirements. In fact the new regulation is less prescriptive and gives the manufacturer the flexibility to determine the controls that are necessary commensurate with risk. The burden is on the manufacturer, however, to describe the types and degree of controls and how those controls were decided upon. Such determinations are made in accordance with standard operating procedures (SOP's) established by the manufacturer.

5. In response to numerous comments, FDA has added the sentence ''If a person engages in only some operations subject to the requirements in this part, and not in others, that person need only comply with those requirements applicable to the operations in which he or she is engaged.'' This sentence was added to clarify the scope of the regulation and

the responsibility of those who fall under this regulation. The wording is the same as that used in the drug CGMP.

6. Several comments recommended that the short list of class I devices subject to design control requirements be deleted from the regulation and be placed in the preamble, to allow additions or deletions without requiring a change to the entire regulation. Others commented that the list of class I devices should be entirely eliminated to harmonize with Europe and Japan.

FDA disagrees that the list of devices subject to design control requirements should be deleted from the regulation. FDA has experienced problems or has concerns with the class I devices listed and has determined that design controls are needed for the listed devices. Further, placing the list in the regulation establishes the requirements related to those devices, and is convenient for use by persons who are not familiar with, or who do not have access to, the preamble. Further, FDA notes that individual sections of a regulation may be revised independent of the remainder of the regulation.

7. Numerous written comments and persons who testified at the August and September 1995 meetings stated that application of the regulation to component manufacturers would increase product cost, with questionable value added to device safety and effectiveness, and that many component suppliers would refuse to supply components or services to the medical device industry. This would be especially likely to occur, it was suggested, where medical device manufacturers account for a small fraction of the supplier's sales.

FDA believes that because of the complexity of many components used in medical devices, their adequacy cannot always be assured through inspection and testing at the finished device manufacturer. This is especially true of software and software-related components, such as microprocessors and microcircuits. Quality must be designed and built into components through the application of proper quality systems.

However, FDA notes that the quality system regulation now explicitly requires that the finished device manufacturer assess the capability of suppliers, contractors, and consultants to provide quality products pursuant to § 820.50 *Purchasing controls.* These requirements supplement the acceptance requirements under § 820.80. Manufacturers must comply with both sections for any incoming component or subassembly or service, regardless of the finished device manufacturer's financial or business affiliation with the person providing such products or services. FDA believes that these purchasing controls are sufficient to provide the needed assurance that suppliers, contractors, and consultants have adequate controls to produce acceptable components.

Therefore, balancing the many concerns of the medical device industry and the agency's public health and safety concerns, FDA has decided to remove the provision making the CGMP regulation applicable to component manufacturers and return to the language in the original CGMP regulation. This approach was unanimously endorsed by the members of the GMP Advisory Committee at the September 1995 meeting. FDA will continue to focus its inspections on finished device manufacturers and expects that such manufacturers will properly ensure that the components they purchase are safe and effective. Finished device manufacturers who fail to comply with §§ 820.50 and 820.80 will be subject to enforcement action. FDA notes that the legal authority exists to cover component manufacturers under the CGMP regulation should the need arise.

8. One comment stated that proposed § 820.1(a)(2) should be revised to include the District of Columbia and the Commonwealth of Puerto Rico, as in the original CGMP regulation.

FDA agrees with the comment. These localities were inadvertently omitted and have been added to the regulation.

9. FDA added § 820.1(a)(3) on how to interpret the phrase ''where appropriate'' in the regulation, as recommended by the GMP Advisory Committee. This section is consistent with the statement in ISO/CD 13485.

10. Some comments on proposed § 820.1(c) recommended that the section be deleted as it already appears in the act. Others stated that the provision implies that FDA will subject devices or persons to legal action, regardless of the level of noncompliance. Still others suggested that only intentional violations of the regulation should give rise to regulatory action.

FDA disagrees with these comments. The consequences of the failure to comply, and the legal authority under which regulatory action may be taken, are included in the regulation so that the public may be fully apprised of the possible consequences of noncompliance and understand the importance of compliance. FDA notes that the agency exercises discretion when deciding whether to pursue a regulatory action and does not take enforcement action for every violation it encounters. Further, FDA generally provides manufacturers with warning prior to initiating regulatory action and encourages voluntary compliance. The agency also notes, however, that violations of this regulation need not be intentional to place the public at serious risk or for FDA to take regulatory action for such violations.

In response to the concerns regarding the tone of the section, however, the title has been changed. FDA has also deleted the specific provisions referenced in the proposed section with which the failure to comply would render the devices adulterated. The term ''part'' includes all of the regulation's requirements.

11. A few comments on proposed § 820.1(c)(2), now § 820.1(d), requested that the agency clarify what is meant by requiring that foreign manufacturers ''schedule'' an inspection. A few comments stated that FDA was adding new requirements for foreign manufacturers in this section. Others stated that the proposed language would prohibit global harmonization because it would limit third party audits in place of FDA inspections.

FDA has moved the provision related to foreign manufacturers into a separate section and has modified the language. The language in the regulation reflects the language in section 801(a) of the act (21 U.S.C. 381(a)). FDA disagrees that it is adding new requirements for foreign manufacturers in § 820.1(d) because the section recites the current requirement and standard used, and is consistent with current agency policy. The agency believes that it is imperative that foreign facilities be inspected for compliance with this regulation and that they be held to the same high standards to which U.S. manufacturers are held. Otherwise, the U.S. public will not be sufficiently protected from potentially dangerous devices, and the U.S. medical device industry will be at a competitive disadvantage.

FDA intends to continue scheduling inspections of foreign manufacturers in advance to assure their availability and avoid conflicts with holidays and shut down periods. However, the language pertaining to the ''scheduling'' of such inspections has been deleted to allow flexibility in scheduling methods.

FDA disagrees that, as written, the language would prohibit inspections by third parties. FDA may use third party inspections, as it uses other compliance information, in setting its priorities and utilizing its resources related to foreign inspections. In this regard, FDA looks forward to entering into agreements with foreign countries related to CGMP

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