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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 97 N-0477]

**Medical Devices; Reconditioners, Rebuilder of Medical Devices; Revocation of Compliance Policy Guide; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is revoking Compliance Policy Guide (CPG) 7124.28 because application of current good manufacturing practice (CGMP) requirements to ‘reconditioners/rebuilders’ of used medical devices does not comport with definitions in the quality system (QS) regulation or guidance in the final rule that applies CGMP requirements to “manufacturers” and “remanufacturers.” Because ‘reconditioners/rebuilders’ are specifically excluded from the definition of “manufacturer” or “remanufacture” in the QS regulation, guidance in the CPG on the applicability of registration, listing, and other statutory and regulatory requirements to ‘reconditioners/rebuilders’ does not represent current agency thinking. In the advance notice of proposed rulemaking (ANPRM), published in the December 23, 1997, **Federal Register**, FDA announced its intention to consider identifying the used device market, for regulatory purposes, in terms of “refurbishers,” “as-is remarketers,” and “servicers” whose activities do not significantly change the safety, performance, or use of a device, and to examine alternative approaches for regulating these firms. Pending the issuance of a rule or guidance setting forth FDA’s current position, CPG 7124.28 is being revoked to eliminate obsolete guidance and reduce industry burdens.

**EFFECTIVE DATE:** *(Insert date 30 days after date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:** Walter W. Morgenstern, Center for Devices and Radiological Health (HFZ-305), 2094 Gaither Rd., Rockville, MD 20850.301594-4699. ext.102.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA issued CPG 7124.28, Reconditioners/Rebuilders of Medical Devices, on December 29, 1987. As revised in March 1995, it is currently found in Section 300.200 of the Compliance Policy Guides Manual. CPG 7124.28 identifies a “reconditioner/ rebuilder” as a person or firm that acquires ownership of a used device and, for purposes of resale or commercial distribution, “restores” or “refurbishes” the device to the manufacturer’s original or current specifications, or new specifications.

CPG 7124.28 provides that “reconditioners” or “rebuilder” must register under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) and 21 CFR 807.20(a), and they are subject to the premarket notification requirements of 21 CFR 807.81. The CPG specifies label statements that must be displayed on restored or refurbished devices in accordance with 21 CFR 801.1 and, if appropriate, 21 CFR 801.109 or 809.10. The CPG also states that “reconditioners” or “rebuilder” are subject to biennial inspection requirements under the act, if they manufacture class II or class III devices, and to the medical device reporting (MDR) requirements in 21 CFR 803. The CPG further cautions that the resale of devices restored by “reconditioners” and “rebuilder” who do not comply with requirements cited in the CPG renders the restored devices adulterated under section 501 (h) of the act (21 U.S.C. 351(h)), or misbranded under sections 502(a) or (f), or 510 of the act (21 U.S.C. 352(a) or (f), or 360), as appropriate.

The guidance in CPG 7124.28 represented the agency’s current thinking, until publication of the CGMP/QS final rule in the **Federal Register** of October 7, 1996 (61 FR 52602), which codified the QS at 21 CFR 820. The guidance did not create or confer any rights for or on any person and did not operate to bind FDA or the public. An alternative approach may have been used if such approach had satisfied the applicable statute, regulations, or both.

## II. Basis for Revoking CPG 7124.28

### *A. Guidance Concerning the Applicability of CGMP Requirements*

CPG **7124.28** applies CGMP requirements to “reconditioners/rebuilders” who “restore” or “refurbish” used devices. The definition that the guidance provides for these entities is now considered obsolete and the application of CGMP’s in the guidance is contrary to current agency thinking, as discussed in section II.A and II.B of this document.

The July 1995 “Working Draft of the Current Good Manufacturing Practice (CGMP) Final Rule” contained definitions for the terms “refurbisher” and “servicing.” It also included “refurbishers” and “servicers” within the definition of “manufacturer.” This “working draft” was made available for public comment (60 FR 37856, July 15, 1996), and it was discussed extensively in written comments, in public and industry testimony, and in recommendations of FDA’s GMP Advisory Committee during meetings in August and September 1995. Comments on the “working draft” claimed that using the “end-of-life” characteristic of a device to distinguish a “refurbisher’s” activities from “servicing” activities was confusing, unnecessary, and raised legal and liability issues (see CGMP/QS final rule (61 FR 52609, October 7, 1996)). The concerns of cost, equity, and competitive concerns were also raised regarding the regulation of “refurbishers,” “servicers,” and “third-party” service organizations (61 FR 52604 and 52640). Under these concerns, the terms “refurbisher,” “servicer,” and “servicing” were not included in the final CGMP/QS regulation, as they relate to entities outside the control of the original device manufacturer, even though FDA believes that “persons who perform such functions meet the definition of manufacturer” (61 FR 52610). FDA elected to address the application of CGMP requirements to “refurbishers” and “servicers” in a separate rulemaking (61 FR 52610 and 52611).

The agency focused, instead, on used-device processors making significant modifications to finished devices. The new term “remanufacture” was added to the final regulation, included within the meaning of “manufacturer,” and defined in 21 CFR 820.3(w) to mean “any person who

processes, conditions, renovates, repackages, restores, or Jots any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." As a result of this rulemaking, the guidance in CPG 7124.28 has become obsolete because its terminology and application of CGMP requirements do not conform with the terms and applicability of the current CGMP/QS regulation. The CPG applies CGMP requirements to "reconditioners" or "rebuilder" who acquire ownership of used devices and "restore" and/or "refurbish" the devices to meet the device manufacturer's original or current specifications, or new specifications, prior to reselling or remarketing the used devices. The only term used in this guidance that is used in the current regulation is "restore." By virtue of acquiring ownership of the devices which they "restore" or "refurbish," the "reconditioners" or "rebuilders" identified in CPG 7124.28 would consist almost exclusively of entities who operate outside the control of the original device manufacturer. As noted previously, the terms "refurbisher" and "servicer," as they relate to such entities, are not found in the current regulation and their CGMP responsibilities are to be addressed by FDA in a separate rulemaking.

Thus, the guidance in CPG 7124.28 applies CGMP requirements to entities, i.e., "reconditioners/rebuilders," whose definition is obsolete and whose definition contains a term, "refurbishes," which the agency intends to consider defining in another context. Consequently, guidance in CPG 7124.28 applies CGMP'S in a manner contrary to current agency thinking. For these reasons, then, and in conjunction with other used-device remarketing issues discussed in section II.B of this document, FDA is revoking rather than revising CPG 7124.28 in order to eliminate obsolete CGMP guidance, minimize confusion, and reduce attendant industry burdens.

#### *B. Guidance Concerning the Applicability of Other Statutory and Regulatory Requirements*

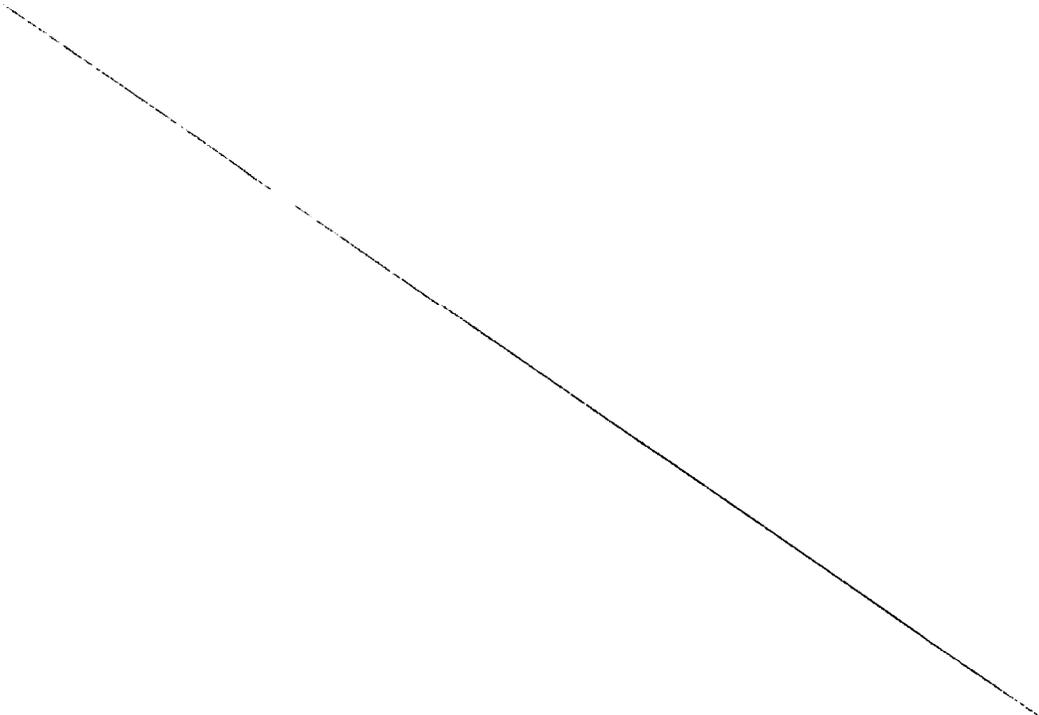
CPG 7124.28 applies registration, listing, premarket notification, labeling, and MDR reporting requirements to "reconditioners" or "rebuilder" of used devices. This portion of the guidance is likewise obsolete in applying statutory and regulatory requirements to a group of entities whose

common definition is no longer considered relevant. Such guidance also does not represent current agency thinking, as discussed in section II.B of this document.

On the basis of industry concerns raised during CGMP rulemaking, FDA's knowledge of changes in the used-device market, and information on used-device "remarketer" and "servicers" obtained through the International Association of Medical Equipment Remarketer, FDA no longer believes that the processing, remarketing, or servicing of used devices should be characterized in terms of whether or not the processor acquires ownership of the device for purposes of resale or remarketing. FDA now believes that it may be more appropriate to identify and distinguish between the types of processing conducted on used devices on the basis of whether or not significant changes occur, or are made, in the performance or safety specifications or intended use of the finished device, as a result of the processing.

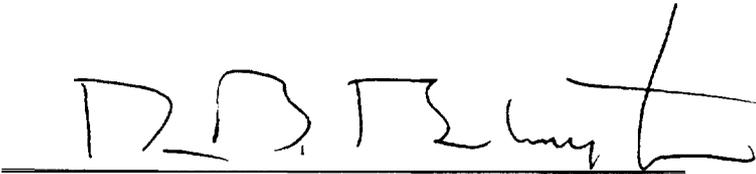
FDA has already incorporated its current thinking in the definition of "remanufacture" that it added to the CGMP/QS regulation. The processing activities of a "remanufacture" significantly change the safety, performance, or use of a finished device. In the ANPRM published in the December 23, 1997, **Federal Register** (62 FR 67011), FDA announced, and solicited public comment upon, its intention to further distinguish the used-device market, for regulatory purposes, in terms of processors whose activities do not significantly change the performance or safety specifications, or intended use of a finished device, in contrast to the activities of "remanufactures." FDA preliminarily identified the activities of certain such processors, and solicited public comment and input on the tentative definitions it drafted and presented in the ANPRM, identifying the activities of "refurbishers," "as-is remarketers," and "servicers" of used devices. Public comment was also solicited concerning whether FDA should define such processors, or other types of processors identified following public comment, through rulemaking or the issuance of guidance, under the agency's "Good Guidance Practices" (GGP) policy (62 FR 8961, February 27, 1997).

FDA also announced in the December 23, 1997, ANPRM its intention to reexamine its options in regulating remarketers and servicers of used devices. FDA currently believes that it may be appropriate for the agency to apply certain regulatory controls to certain used-device processors, using alternative regulatory approaches, if their processing activities do not result in significant changes in the used device's safety or performance specifications, or intended use. Public comment and input were solicited concerning alternative regulatory approaches the agency might consider in applying regulatory controls upon the activities of "refurbishers," "as-is remarketer," and "servicers," or other types of used-device processors identified following comments. As a consequence of these agency actions, the guidance in CPG 7124.28 concerning the applicability of registration, listing, and other statutory and regulatory requirements to "reconditioners/rebuilder" of used devices is obsolete and no longer represents current agency thinking. Pending



FDA's issuance of a rule or guidance setting forth the agency's current position on these matters. FDA is revoking, rather than revising CPG 7124.28 in its entirety in order to eliminate obsolete guidance, minimize confusion, and reduce attendant industry burdens.

Dated: 10-23-98  
October 23, 1998



D.B. Burlington  
Director  
Center for Devices and Radiological Health

[FR Dec. 98-'????' Filed '?'-'?'-98; 8:45am]

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