interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the World Wide Web on the CDRH home page at ''http://www.fda.gov/cdrh'' or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. Petitions

On June 17, 1998, FDA received a petition requesting an exemption from premarket notification for surgical lamps from Getinge/Castle, Inc. On September 30, 1998 (63 FR 52275), FDA published a notice announcing that it had received three petitions, including the one from Getinge/Castle, Inc., requesting exemption from premarket notification for class II devices and providing an opportunity for interested persons to submit comments on the petitions by October 30, 1998. FDA received no comments. FDA has reviewed these petitions and, for the following reasons, has determined that surgical lamps do not meet the criteria for exemption described previously and is, therefore, issuing this order denying the petition to exempt these devices from the requirements of premarket notification. The other two petitions will be addressed separately in another issue of the **Federal Register**.

FDA has determined from its medical devices reporting (MDR) database that there is a risk of over-exposure to ultraviolet (UV) light from surgical lamps and there is a risk of surgical lamps falling on surgical personnel during use. FDA has recently completed a guidance document for surgical lamps entitled ''Guidance Document for Surgical Lamp 510(k)s.'' FDA is also aware of a draft standard from the International Electrotechnical Commission (IEC), IEC–60601–2–41, that would be applicable. FDA believes that the guidance and the draft standard would address the risks to health presented by surgical lamps. At some time in the future, FDA may adopt the guidance document and the IEC standard as special controls for surgical lamps. Without the guidance and the IEC standard as special controls, FDA believes that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of sunlamps.

Dated: November 23, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–32248 Filed 12–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0477]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 ''remanufacturer'' 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: January 4, 1999.

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 ''rebuilders'' 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 ''rebuilders'' 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 ''rebuilders'' 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 ''remanufacturer'' 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 does 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 ''rebuilders'' 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 ''rebuilders'' 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 ''remarketers'' and ''servicers'' obtained through the International Association of Medical Equipment Remarketers, 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 ''remanufacturer'' that it added to the CGMP/QS regulation. The processing activities of a ''remanufacturer'' 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 ''remanufacturers.'' 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 remarketers,'' 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/rebuilders'' 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: October 23, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–32249 Filed 12–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2025–N]

RIN 0938–AJ07

Medicare Program; Recognition of NAIC Model Standards for Regulation of Medicare Supplemental Insurance

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice describes changes made by the Balanced Budget Act of 1997 to section 1882 of the Social Security Act, which governs Medicare supplemental insurance. It also recognizes that the Model Regulation adopted by the National Association of Insurance Commissioners (NAIC) on April 29, 1998, as corrected and clarified by HCFA, is considered to be the applicable NAIC Model Regulation for purposes of section 1882 of the Social Security Act. The changes made by HCFA (1) correct a drafting error in section 12.B(2) of the Model that is inconsistent with Federal law, and (2) add a clarification that copayments for hospital outpatient department services under Part B of Medicare must be covered under the ''core benefits'' of a Medicare supplemental insurance policy in the same manner as coinsurance for those services. Finally, this notice prints as an addendum the full text of the NAIC Model Regulation, as corrected and clarified by HCFA.

DATES: Medicare supplemental insurance policies issued in any State must conform to the requirements of section 1882(s)(3) of the Social Security Act as of July 1, 1998, and to the standards contained in the revised NAIC Model Regulation as of the date the State adopts the revised standards, which generally must be no later than April 29, 1999.

FOR FURTHER INFORMATION CONTACT: Terese Klitenic (410) 786–1565.

SUPPLEMENTARY INFORMATION:

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I. Background

A. The Medicare Program

The Medicare program was established by Congress in 1965 with the enactment of title XVIII of the Social Security Act (the Act). The program provides payment for certain medical services for persons 65 years of age or older, disabled beneficiaries, and persons with end-stage renal disease. The Medicare program consists of two separate but complementary insurance programs, a hospital insurance program (Part A), which covers services furnished by hospitals, skilled nursing facilities, home health agencies and hospices; and a supplementary medical insurance program (Part B), which covers a wide range of medical services and supplies, including physicians' services, outpatient hospital services, outpatient physical and occupational therapy services, and home health services. Part B also covers certain drugs and biologicals that cannot be self-administered, diagnostic x-ray and laboratory tests, purchase or rental of durable medical equipment, ambulance services, prosthetic devices, and certain medical supplies.

While the Medicare program provides extensive hospital insurance benefits and supplementary medical insurance, it was not designed to cover the total cost of medical care for Medicare beneficiaries. Amounts payable under both Parts A and B are reduced by certain deductible and coinsurance amounts for which the beneficiary is responsible.

In 1998, the Part A inpatient hospital deductible is $764 ($768 for 1999) for each ''benefit period'' (the period beginning on the first day of hospitalization and extending until the beneficiary is no longer an inpatient of a hospital or skilled nursing facility for 60 consecutive days).

The Part B deductible is $100 for calendar years 1998 and 1999. Beneficiaries are also responsible for paying certain coinsurance amounts for covered items and services. For example, the coinsurance applicable to physicians' services under Part B is generally 20 percent of the Medicare-approved amount for the service. When beneficiaries receive covered services from physicians who do not accept assignment of their Medicare claims, the beneficiaries may also be required to pay amounts in excess of the Medicare approved amount (''excess charges''), up to a limit established under the Act.

There are a number of items and services that are not covered under either Part A or Part B; for example, custodial nursing home care, most dental care, eyeglasses, and most prescription drugs are not covered. Beneficiaries must pay the full cost of these items and services out-of-pocket or may purchase additional private insurance to help pay the costs.

Because Medicare does not cover the total cost of providing medical care, a