OMB Comment: OMB is required to make a decision concerning the collection of information between 30 to 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: November 30, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–32283 Filed 12–3–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–1021]

Rohm and Haas Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Rohm and Haas Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of certain styrene-acrylic copolymers as components of coatings for paper and paperboard intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4632) has been filed by Rohm and Haas Co., 100 Independence Mall West, Philadelphia, PA 19106. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of certain styrene-acrylic copolymers as components of coatings for paper and paperboard. The copolymers contain monomer units from styrene and methyl methylacrylate and may contain monomer units from butyl methacrylate, methacrylic acid, butyl acrylate, acrylic acid, and allyl methacrylate.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: November 10, 1998.

George H. Pauli,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–32250 Filed 12–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–0425]

Medical Devices; Exemptions From Premarket Notification; Surgical Lamps

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order denying a petition requesting an exemption from the premarket notification requirements for surgical lamps. FDA is publishing this notice in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: December 4, 1998.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Pub. L. 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Pub. L. 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an

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