

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 90D-0427]

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Certifier G. Penley

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Class III Medical Devices Without Premarket Clearance; Revocation of Compliance Policy Guide 7124.30

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of a Compliance Policy Guide (CPG) entitled "Sec. 300.700 Direct Reference Authority for Class III Medical Devices Without a Premarket Notification (510(k)) or an Approved Premarket Approval Application (PMA) (CPG 7124.30)." This CPG no longer reflects current agency policy.

DATES: The revocation is effective [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written requests for single copies of the CPG 7124.30 to the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, FAX 301-827-0482. A copy of the CPG may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD, between 9 a.m. and 4 p.m., Monday through Friday. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory

Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD
20857, 301-827-0411.

SUPPLEMENTARY INFORMATION:

I. Background

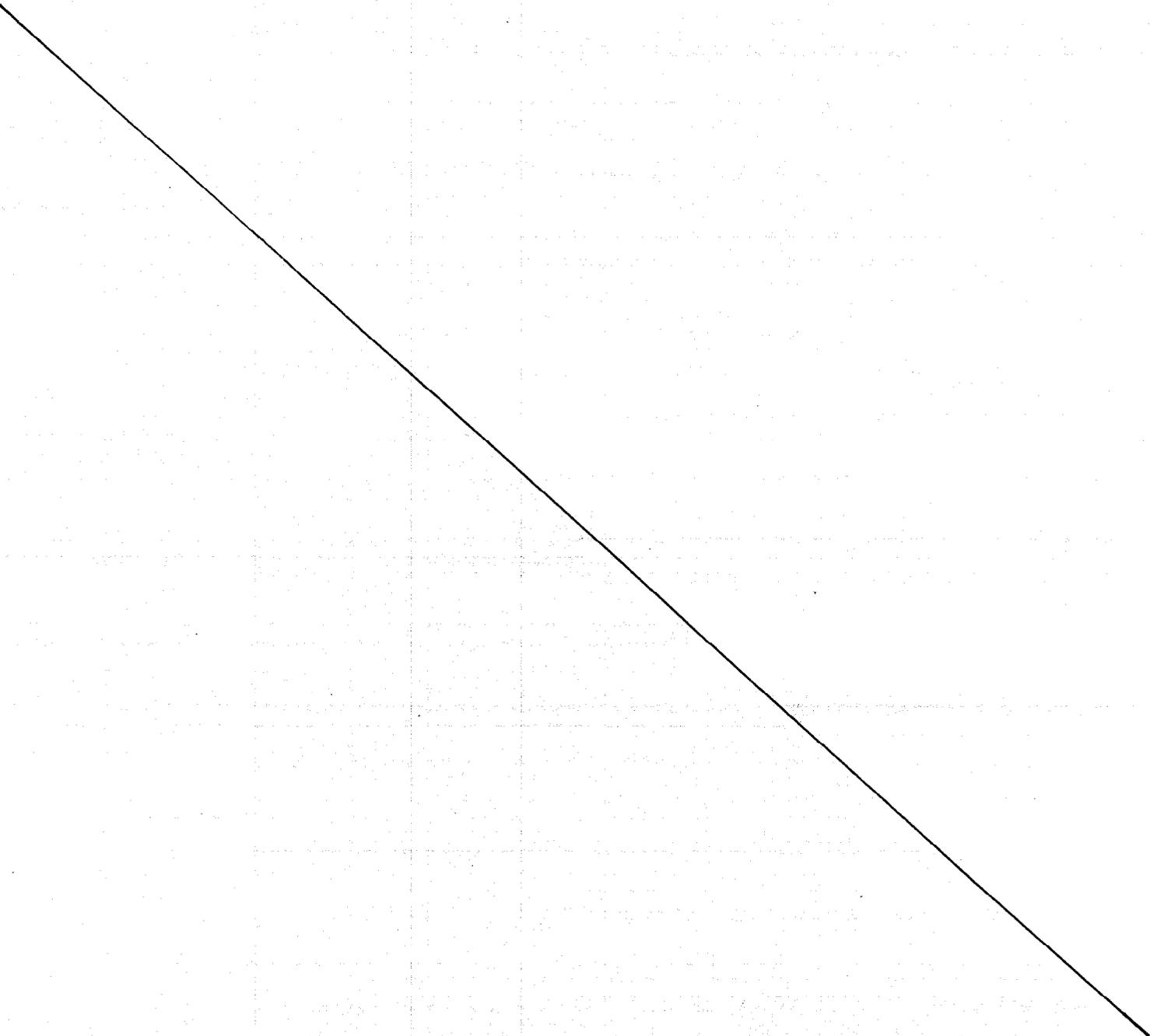
Section 513(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(a)(1)(C)) describes a class III device, in part, as represented for use in supporting or sustaining human life, in preventing impairment of human health or presenting an unreasonable risk of illness or injury. An individual or firm that commercially distributes a class III device, in interstate commerce, without an approved premarket approval application (PMA) or a substantially equivalent premarket notification (510(k)) is in violation of the act. In legal terms, the device is adulterated in accordance with section 501(f)(1) of the act (21 U.S.C. 351(f)(1)) and misbranded within the meaning of section 502(o) of the act (21 U.S.C. 352(o)).

On February 26, 1991, FDA issued the CPG entitled "Sec. 300.700 Direct Reference Authority for Class III Medical Devices Without a Premarket Notification (510(k)) or an Approved Premarket Approval Application (PMA) (CPG 7124.30)." This CPG authorizes FDA's field districts to issue a Warning Letter or recommend a seizure action, if warranted, without prior concurrence and review by FDA's Center for Devices and Radiological Health (CDRH) for the referenced violations. This procedure no longer reflects current agency policy. Field districts should forward all Warning Letter and seizure recommendations concerning device premarket clearance violations to CDRH for concurrence. The Regulatory Procedures Manual includes the latter procedure.

FDA is revoking CPG 7124.30, in its entirety, to eliminate obsolete compliance policy.

II. Electronic Access

Prior to the revocation effective date (see **DATES**), a copy of the CPG may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs home page includes the CPG that may be accessed at http://www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg300-700.html.



Dated: 8.28.02
August 28, 2002.

John Marzilli (for)
John Marzilli,
Acting Associate Commissioner for
Regulatory Affairs.

98

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**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Gloria Lesley