reviewed. A sponsor who submits a deficient submission should not resubmit the submission until the submission has been reviewed rigorously for accuracy and completeness.

Refusing to review deficient submissions is only part of CVM's strategy to facilitate the timely approval of safe and effective new animal drugs. CVM intends to continue issuing guidance that will clarify approval requirements and the procedures and formats for various types of submissions. CVM intends to balance the need for guidance with the need to complete pending review work. CVM encourages sponsors to request presubmission conferences to reach agreement on investigational and approval requirements for specific new animal drugs. In addition, CVM continues to encourage sponsors to submit protocols for studies that are key to approval to CVM for review well in advance of beginning the studies. Finally, CVM is committed to continuing to work to improve its processes and approve safe and effective new animal drugs in a timely manner.

This level 1 final guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on its handling of deficient submissions filed during the investigation of a new animal drug. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used as long as it satisfies the requirements of applicable statutes and regulations.

II. Comments

As with all of FDA's guidance, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The public will be notified of any such amendments through a notice in the **Federal Register**.

III. Electronic Access

Persons with access to the Internet may obtain a copy of the final guidance document entitled ''Guidance for Industry and Reviewers: ''How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During Investigation of a New Animal Drug'' from the CVM home page at *http://www.fda.gov/cvm*.

Dated: August 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–22566 Filed 9–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 90D–0427]

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 October 7, 2002.

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: August 28, 2002.

John Marzilli,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 02–22638 Filed 9–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Single Source Cooperative Agreement Supplemental Award to the District of Columbia State Incentive Grant to Fund Best Friends Foundation Youth Development Program and ''Marriage is Manly'' Media Campaign

AGENCY: Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services