II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any nonelectronic comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ora/compliance_ref/part11/default.htm*.

Dated: August 27, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–22634 Filed 9–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0146]

Final Guidance for Industry and Reviewers on How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry and reviewers (#119) entitled ''How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug.'' This final guidance announces the Center for Veterinary Medicine's (CVM's) policy regarding the circumstances under which CVM intends to not accept for review submissions filed during the investigation of a new animal drug and notify the sponsor that CVM intends not to review the submission.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments on this final guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. All comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

Submit written requests for single copies of the final guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the final guidance document.

FOR FURTHER INFORMATION CONTACT: Gail Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–1796, e-mail: *gschmer1@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 4, 2001 (66 FR 17914), FDA published a notice of availability for a draft guidance entitled ''How the Center for Veterinary Medicine Intends to Handle Deficient Submissions Filed During the Investigation of a New Animal Drug,'' giving interested persons until July 3, 2001, to submit comments.

CVM determined that there was a need for such a guidance for two reasons: (1) Having reviewers attempt to review submissions that have significant deficiencies is an inefficient use of CVM's limited resources, and (2) its practice of keeping submissions requiring significant additional information or rehabilitation ''active,'' (i.e., in the review queue), has contributed to a backlog in the review of pending submissions. This final guidance for industry and reviewers announces CVM's policy regarding the circumstances under which CVM intends to not accept for review submissions filed during the investigation of a new animal drug, notify the sponsor that the submission will not be reviewed, and remove the submission from the review queue.

CVM's primary goal is to approve safe and effective new animal drugs in a timely manner. To further this goal, CVM's responsibility is to ensure the quality of the review process. On the other hand, it is the sponsor's responsibility to ensure the quality of its submissions.

The quality of a submission can prevent or severely hinder its review. Poor quality submissions can be impossible or difficult to review. FDA received comments to the draft guidance suggesting that the problem CVM attributes to poor quality submissions is in part the variation in format and content of submissions as required by individual reviewers. However, an informal survey of reviewers in the Office of New Animal Drug Evaluation (ONADE) revealed that submissions were deficient because, among other things: They contained data discrepancies, incorrect statistical analyses, final reports that did not reflect actual data, electronic copies of data that did not match paper copies of raw data, or no documentation of drug source. ONADE has also received supplemental applications in which sponsors submitted the same data or information for the supplement that they submitted for the original application, i.e., without changing the relevant indications or conditions of use for which the supplement was submitted.

CVM has determined that it can no longer expend time and resources attempting to review submissions that have significant deficiencies. Poor quality submissions decrease the efficiency of the new animal drug application review and approval process by diverting limited resources from the review of submissions that are complete. Furthermore, as one comment to the draft guidance noted, a sponsor who submits a quality submission should not have its submission wait in the queue while a reviewer spends an inordinate amount of time reviewing a poor quality submission.

The final guidance clarifies that ONADE should use criteria and procedures similar to those found in 21 CFR 514.110 to determine whether it will not accept a submission for review, i.e., refuse to review the submission further. ONADE should, among other reasons, not review a submission if on its face the information is so inadequate that the submission is clearly not reviewable. ONADE should consider a submission to be inadequate if the numbers or types of errors in the submission or flaws in the development plan, call into question the quality of the entire submission to the extent it is deemed by ONADE that the submission cannot reasonably be reviewed.

ONADE should notify the sponsor by letter within 60 days of the receipt of the submission of its decision not to accept the submission for review. The letter notifying the sponsor that ONADE will not accept the submission for review should summarize in detail commensurate with the quality of the submission the reasons it cannot be

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]

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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