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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 99 D-0972]

Policy on the Disposition of Publications That Constitute Labeling; Draft Revised Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice,

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revised Compliance Policy Guide (CPG 7153.13) entitled “Regulatory Policy on the Disposition of Publications that Constitute Labeling.” We are revising the current CPG to provide clarification and further guidance to our field employees about when publications may constitute labeling for regulated products and to stress our policy with regard to the disposition of these materials when they cause a product to be in violation of the Federal Food, Drug, and Cosmetic Act.

DATES: You may submit written comments on the draft revised CPG by *(insert date 90 days after date of publication in the Federal Register)*.

ADDRESSES: You may submit written requests for single copies of the draft revised CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0420. Please send two self-addressed adhesive labels to assist us in processing your requests, or you may fax your request to 301-827-0482.

Please see the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft revised CPG to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane rm., 1061, Rockville, MD 20852.

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FOR FURTHER INFORMATION CONTACT: JoAnne C. Marrone, Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.301-827-1242.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has had a longstanding policy related to the seizure of books that constitute labeling for a product. We articulated this policy in a Compliance Policy Guide (CPG 7153.13) in December 1982, which we revised on August 31, 1989. In recent years, questions have arisen concerning when published materials may constitute labeling for regulated products, as well as our position and policy on the disposition of these materials. We intend this draft revised CPG to clarify these issues and to improve guidance to our field employees.

This draft Level 1 guidance document is being issued consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on the disposition of publications that constitute labeling for a product that renders a product violative. 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 if such approach satisfies the requirements of the applicable statute, regulations, or both.

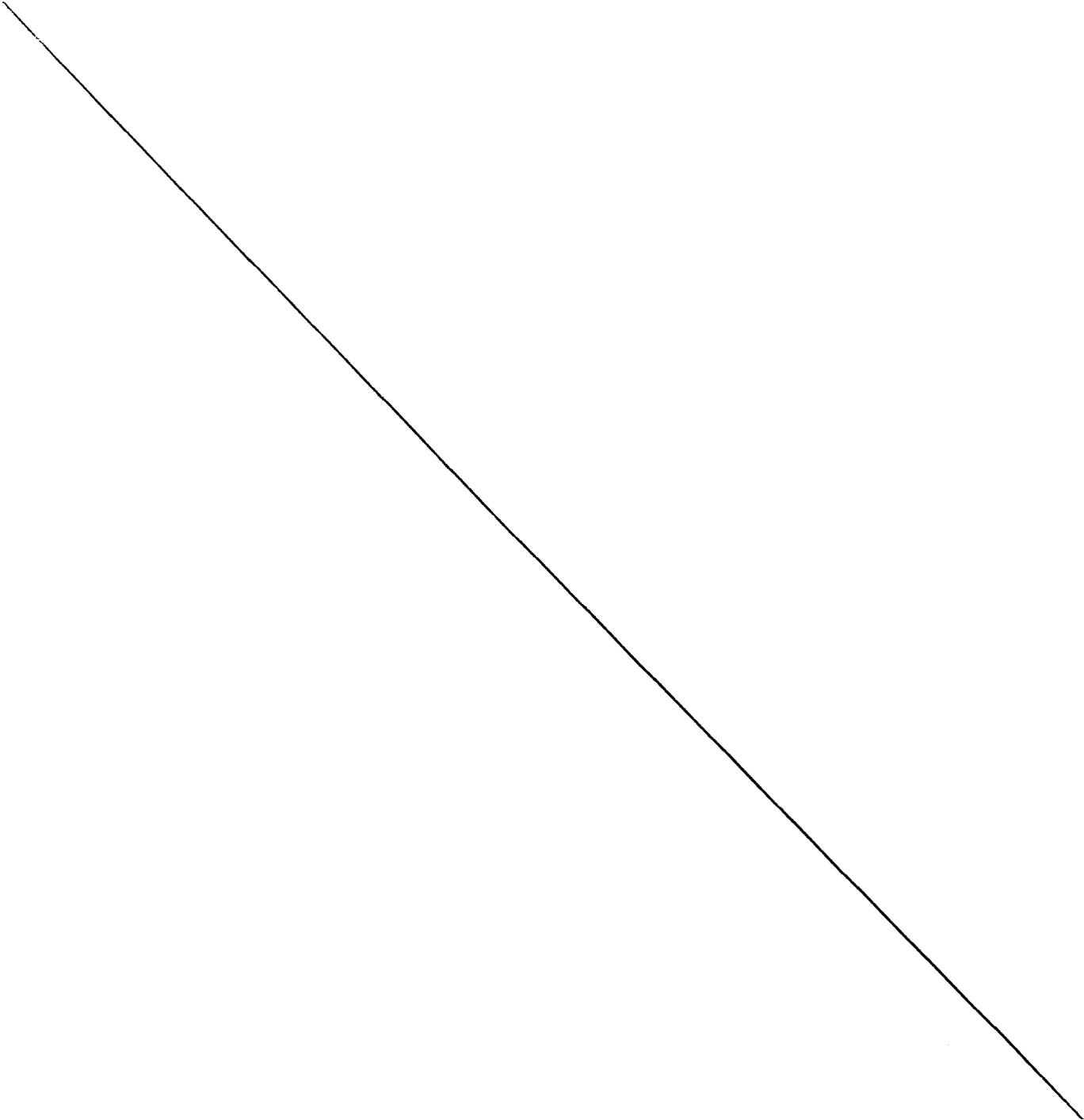
II. Request for Comments

You may submit to the Dockets Management Branch (address above) written comments on the draft revised CPG entitled "Regulatory Policy on the Disposition of Publications that Constitute Labeling." You must submit two copies of any comments, except that you may submit one copy if you are an individual. You must identify your comments with the docket number found in brackets in the heading of this document. The agency will review all comments, but in issuing a final CPG, need not specifically address every comment. We will make changes to the CPG

in response to comments, as appropriate. You may see a copy of the draft revised CPG and comments received in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

You also may download copies of the draft revised CPG to a personal computer with access



to the World Wide Web (WWW). The Office of Regulatory Affairs' (ORA) home page entitled "compliance references" includes this draft revised CPG, and you may access it at 'http://www.fda.gov/ora/compliance_ref/default.htm'.

Dated: 4-20-99
April 20, 1999



Dennis E. Baker
Associate Commissioner for Regulatory Affairs

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