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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-4956]

Guidance for Industry: Alternative to Certain Prescription Device Labeling Requirements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Alternative to Certain Prescription Device Labeling Requirements." The FDA Modernization Act of 1997 (FDAMA) amended the Federal Food, Drug, and Cosmetic Act (the act) to require, at a minimum, that before dispensing, the labels of prescription drug products contain the symbol "Rx only" instead of the textual prohibition "Caution: Federal law prohibits dispensing without prescription." Through this guidance, the Center for Devices and Radiological Health (CDRH) announces that, in its enforcement discretion, it will apply a similar amended standard for labeling of prescription devices.

DATES: Submit written comments concerning the guidance document at any time.

ADDRESSES: Submit written comments on the guidance document to the contact person listed below. Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Alternative to Certain Prescription Device Labeling Requirements" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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FOR FURTHER INFORMATION CONTACT: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ-300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301-594-4692.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the guidance “Alternative to Certain Prescription Device Labeling Requirements.” Section 126 of Title I of FDAMA (Public Law 105-115), signed into law by President Clinton on November 21, 1997, amends prescription drug labeling requirements required by section 503(b)(4) of the act (21 U.S.C. 353(b)(4)) to require, at a minimum, that prior to dispensing, the label of prescription products contain the symbol “Rx only.” The agency announced this change for prescription drugs in the **Federal Register** of March 13, 1998 (63 FR 12473).

FDAMA did not direct the agency to amend the prescription device labeling regulation, found in the Code of Federal Regulations (CFR) at § 801.109(b)(1) (21 CFR 801.109 (b)(1)); however, CDRH believes manufacturers, repackers, relabelers, and distributors of prescription devices may wish to use the same symbol statement, “Rx only,” as an alternative to the text required by regulation. This alternative simplifies the labeling and still conveys, by custom and practice, essentially the same meaning. CDRH would like to minimize the burden on manufacturers, repackers, relabelers, and distributors that face many labeling requirements. Therefore, the agency will not object to the use of the statement “Rx only” as an alternative to the prescription device statement required by § 801.109(b)(1). This means that FDA will not view the use of the alternative symbol statement “Rx only” as a violation of the labeling requirements for prescription devices that would cause the device to be considered misbranded under section 502(f)(1) of the act (21 U.S.C. 352(f)(1)).

The alternative labeling may be implemented at the discretion of the firm responsible for labeling. Devices already in commercial distribution may immediately implement the labeling

change. Devices undergoing premarket review may implement the change once the firm is notified the product may be marketed. In vitro diagnostic devices also fall within the scope of this guidance.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the use of alternative labeling to prescription device labeling requirements. 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 applicable statute, regulations, or both.

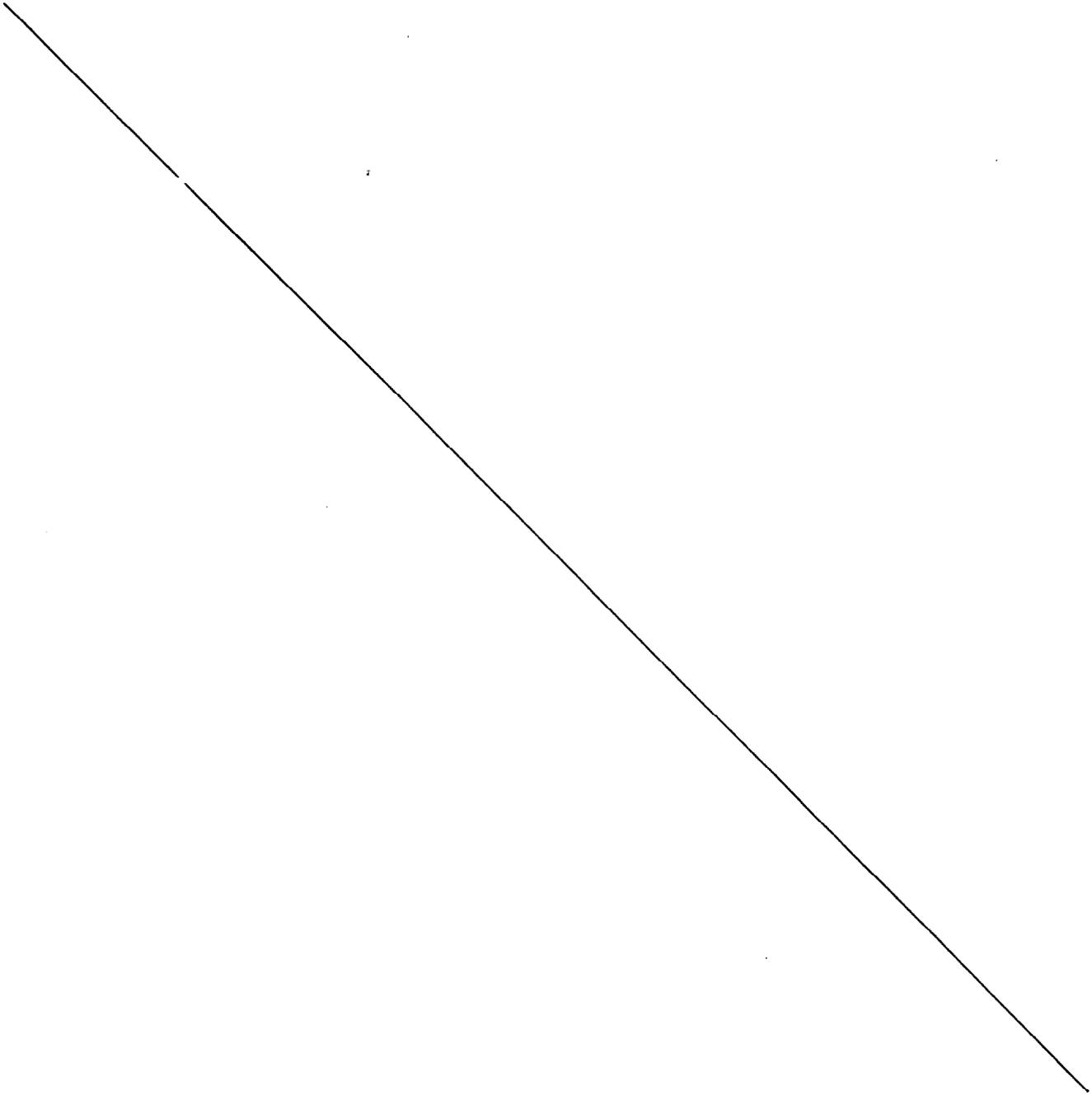
The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's. Public comment before implementation of this guidance is not necessary because the guidance presents a less burdensome policy that is consistent with the public health.

III. Electronic Access

In order to receive "Alternative to Certain Prescription Device Labeling Requirements" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 1150 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance "Alternative to Certain Prescription Device Labeling Requirements," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions,

mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. The guidance “Alternative to Certain Prescription Device Labeling Requirements” will be available at <http://www.fda.gov/cdrh/oc>.



IV. Comments

Interested persons may at any time, submit written comments regarding this guidance document to the contact person listed above. Such comments will be considered when determining whether to amend the current guidance.

Dated: 1/9/00
January 9, 2000

Linda S. Kahan

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Regulations Policy
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LOC [FR Doc. ⁰⁰~~99~~-???? Filed ??-??-⁰⁰~~99~~; 8:45 am]

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