

Guidance for Industry

Alternative to Certain Prescription Device Labeling Requirements

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

Office of Compliance

Preface

Public Comment

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Such comments will be considered when determining whether to amend the current guidance.

After 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions may be submitted at any time for Agency consideration to, Casper E. Uldriks, Office of Compliance, 2094 Gaither Road, Rockville, Maryland 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Casper Uldriks at (301) 594-4692, or via FAX at (301) 594-4610.

Additional Copies

World Wide Web/CDRH/ home page at <http://www.fda.gov/cdrh/comp/rxlabeling.pdf> or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1150 when prompted for the document shelf number.

Guidance¹ for Industry and FDA on Alternative to Certain Prescription Device Labeling Requirements

Introduction

Prescription devices do not require adequate directions for use by a lay person as long as the device's labeling bears the statement, "Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner)." (See 21 Code of Federal Regulations (CFR) sec. 801.109(b)(1)). Without this prescription statement, the agency could consider the device misbranded under section 502(f)(1) of the Food, Drug, and Cosmetic Act (the act). A misbranded device is prohibited from entering into domestic commercial distribution.

The FDA Modernization Act of 1997 (FDAMA) amended the act to require, at a minimum, that before dispensing, the labels of prescription drug products contain the symbol statement "Rx only" instead of the "Caution: law prohibits dispensing without prescription." (See section 126 of FDAMA.) The guidance for industry addressing this labeling change for drugs was issued by the Center for Drug Evaluation and Research (CDER) in consultation with the Center for Biologics Evaluation and Research and announced on March 13, 1998, in the **Federal Register**. [63 FR 12473]

FDAMA did not require this labeling change for prescription devices. However, manufacturers, repackers, relabelers, and distributors of prescription devices may wish to use the same symbol statement "Rx only" as an alternative to the prescription labeling requirements, under sec. 801.109.

¹This document is intended to provide guidance. It represents the Agency's current thinking on the above. 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. DISCUSSION

The amendment of prescription drug labeling requirements by FDAMA simplifies the labeling requirements in that the “Rx only” symbol statement replaces the prescription legend statement “Caution: Federal law restricts...” The meaning conveyed by the symbol statement “Rx only” and the text of the statement “Caution: Federal law restricts ...” conveys, by custom and practice, essentially the same restrictive meaning regarding the professional authorization required to use a prescription product.

III. FDA POLICY

Alternative Prescription Labeling Statement

CDRH would like to minimize the burden on manufacturers, repackers, relabelers and distributors that face a variety of labeling requirements and changes. Therefore, CDRH, in its enforcement discretion, does not intend to object to the use of the statement “Rx only” as an alternative to the prescription device labeling statement “Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner).” It is important to note that FDA intends to exercise its enforcement discretion only for the labeling alternative “Rx only.” “Only” needs to immediately follow “Rx.” However, the symbol statement “Rx only” does not necessarily need to be bracketed in quotation marks, and the word “only” may appear in upper or lower case letters, for example, Rx only, Rx Only, or Rx ONLY.

IV. FREQUENTLY ASKED QUESTIONS

1. Are there any size restrictions?

FDA intends to exercise its enforcement discretion only if the symbol statement “Rx only” appears prominent and conspicuous. Where space permits, the statement should appear on the main panel of the container label and device labeling. The statement should be prominent and conspicuous, whether by the font size, the use of capital letters or bold print, as described in section 502(c) of the act and the related regulatory requirements for medical device labeling found in 21 CFR 801.15.

2. When can alternative labeling be implemented?

For prescription devices in commercial distribution, the alternative labeling may be implemented at the discretion of the firm responsible for labeling. For pending (unapproved) premarket submissions, the alternative labeling may be implemented once the firm is notified that the product may be marketed.

Labeling described in future premarket submissions, and in submissions made in conjunction with changes to devices already approved for commercial distribution, may include the use of the “Rx only” symbol as an alternative to the prescription device labeling statement.

3. **May a firm use “Rx only” in one part of the labeling and state the standard regulatory text (“Caution: federal law...”) in other parts of the labeling?**

We do not intend to object to using both prescription device labeling statements. Firms may implement the alternative labeling for different reasons, e.g., a decision to deplete existing labeling, the need for space for other labeling information, or the need to coordinate with production or future distribution plans. The symbol statement “Rx only” conveys essentially the same message as the standard regulatory text. So, we do not intend to object if a firm uses a combination of the two prescription statements in its labeling.

4. **What about labeling requirements for in vitro diagnostics (IVD’s)?**

In vitro diagnostic devices must comply with the labeling requirements in 21 CFR 809.10. If the premarket submission for a device did not specifically make a claim and provide data to support an intended lay use, current labeling should include the statement "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner." All in vitro diagnostic devices that would require this statement, including in vitro diagnostics labeled, “for professional use” or “for prescription home use,” fall within the scope of this guidance and may substitute “Rx only” for the longer caution statement.

Prescription home use in vitro diagnostics are those prescribed by a licensed practitioner for use in the home; professional use in vitro diagnostics are those used within the confines of a "licensed laboratory" as defined by the Clinical Laboratory Improvement Amendments of 1988.