imported foods when necessary to deter premature and illegal entry into the United States; and (6) enhance enforcement against violations of U.S. laws related to the importation of foods, including through the imposition of civil monetary penalties.

The public meetings also will include an overview of the President's directive and a review of the new operational procedures proposed to accomplish each of the six objectives. The meetings will provide a forum for discussion of the proposed procedures. In addition to a plenary session, the meetings will provide the opportunity for additional discussion of the specific objectives. Three breakout sessions to discuss the following are planned: (A) Secured storage, increased bonds, enforcement activities; (B) destruction and marking of refused foods; and (C) standards for the use of private laboratories. The U.S. Customs Service will jointly present the objectives with FDA. Transcripts of the public meetings are not planned.

If you would like to attend a public meeting, send registration information (including name, title, firm name, mailing address, telephone number, fax number, e-mail address, and selection of breakout session A, B, or C) to the contact person listed for the meeting you wish to attend at least 7 days prior to the meeting date. Attendance will be limited due to seating capacity. There is no registration fee for this meeting.

Meeting Address	Date and Local Time	FDA Contact Person
IRVINE: Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612.	Thursday, February 10, 2000, 9 a.m. to 12 noon.	Irene Gomez, 222 West 6th St., suite 700, San Pedro, CA 90731, 310–831–6123, ext. 103, e-mail: igomez@ora.fda.gov.
WASHINGTON: Hubert H. Humphrey Bldg., 200 D St. SW., rm. 800, Washington, DC 20204.	Thursday, February 17, 2000, 9 a.m. to 12 noon.	Peter A. Salsbury, Executive Operations Staff (HFS–022), 200 C St. SW., Washington, DC 20204, 202–205–4299, e-mail: psalsbur@bangate. fda.gov.

Dated: January 12, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–1410 Filed 1–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99P–1720]

Approval of an Alternate Requirement of the User Labeling Requirements for Devices Containing Dry Natural Rubber that Contact Humans; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Approval of an Alternative Requirement of the User Labeling Requirements for Devices that Contain Dry Natural Rubber that Contact Humans.'' FDA granted a petition submitted by the Health Industry Manufacturers Association (HIMA), on behalf of in vitro diagnostic device (IVD) manufacturers, that requested a variance from placing the warning statement about dry natural rubber on the immediate IVD package (vial) label. FDA is announcing the availability of its response to HIMA's petition in order to inform affected manufacturers and the public.

ADDRESSES: Submit written requests for single copies on a 3.5 diskette of the document entitled ''Approval of an Alternate Requirement of the User Labeling Requirements for Devices that Contain Dry Natural Rubber that Contact Humans'' to the contact person named below. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the alternative requirement document.

FOR FURTHER INFORMATION CONTACT: John J. Farnham, Center for Devices and Radiological Health (HFZ–321), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20852, 301–594–4616.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 30, 1997 (62 FR 51021), FDA issued a final rule, codified in 21 CFR § 801.437(e), requiring labeling statements on medical devices containing dry natural rubber that are intended to contact or likely to contact humans. The rule became effective on September 30, 1998. On June 3, 1999, HIMA requested a variance for in vitro diagnostic products that have vial labels too small to accommodate the required statement. The petition said that manufacturers of the products could place the warning on the outer package, as well as on a package insert. On September 10, 1999, FDA issued a letter granting HIMA's petition.

II. Electronic Access

In order to receive the document entitled ''Approval of an Alternative Requirement of the User Labeling Requirements for Devices that Contain Dry Natural Rubber that Contact Humans,'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from the touch-tone telephone. At the first

voice prompt press 1 to access the Division of Small Manufacturers Assistance (DSMA) Facts, at second voice prompt press 2, and then enter the document number (1148) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the alternative requirement may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphic, 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 ''Approval of an Alternative Requirement of the User Labeling Requirements for Devices that Contain Dry Natural Rubber that Contact Humans,'' 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, labeling matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The document entitled ''Approval of an Alternative Requirement of the User Labeling for Devices that Contain Dry Natural Rubber that Contact Humans'' will be available at http://www.fda.gov/cdrh.

Dated: January 9, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–1409 Filed 1–20–00; 8:45 am]

BILLING CODE 4160–01–F

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.

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