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

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: January 9, 2000.

Linda S. Kahan,

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

[FR Doc. 00–1407 Filed 1–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Health Professions Preparatory, Pregraduate, and Indian Health Professions Scholarship Programs

AGENCY: Indian Health Service, HHS.

ACTION: Update of Standing Notice of Availability of Funds for Health Professionals Preparatory, Pregraduate, and Indian Health Professions Scholarship Programs published in 62 FR 5443, February 5, 1997.

SUMMARY: The Indian Health Service (IHS) announces the availability of approximately $3,750,000 to fund scholarships for the for the Health Professions Preparatory and Pregraduate Scholarship Programs for FY 2000 awards. These programs are authorized by section 103 of the Indian Health Care Improvement Act (IHCIA), Pub.L. 94–437, as amended by Pub.L. 100–713, Pub.L. 102–573, and Pub.L. 104–313. The Indian Health Scholarship (Professions) authorized by section 104 of the IHCIA, Pub.L. 94–437, as amended by Pub.L. 100–713, Pub.L. 102–573, and Pub.L. 104–313, has approximately $7,895,000 available for FY 2000 awards.

Part-time and full-time scholarships will be funded for each of the three scholarships programs for the academic year 2000–2001.

The Health Professions Preparatory Scholarship Grant Program is listed as No. 93.123 in the Office of Management and Budget.

Catalog of Federal Domestic Assistance (CFDA). The Health Professions Pregraduate Scholarship Grant Program is listed as No. 93.971 and the Indian Health Professions Scholarship Grant Program is listed as No. 93.972 in the CFDA.

DATE: The application deadline for both new and continuing applicants is April 1, 2000. If April 1 falls on the weekend, the application will be due on the following Monday. Applications will be considered as meeting the deadline if they are received by the appropriate Scholarship Coordinator on the deadline date or postmarked on or before the deadline date. (Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

Applications: New applicants applying for scholarships under the three programs must use the forms contained in the ''Application for Participation in the IHS Scholarship Program'' (OMB No. 0917–0006, 04/30/2001). Application packets may be obtained by calling or writing to the addresses listed below.

FOR FURTHER INFORMATION CONTACT: Please address application inquiries to the appropriate Indian Health Service Area Scholarship Coordinator, as listed below.

IHS area office and States/locality served	Scholarship coordinator/address
Aberdeen Area IHS: Iowa, Nebraska, North Dakota, South Dakota	Ms. Lila Jean Topalian, Scholarship Coordinator, Aberdeen Area IHS, Federal Building, Room 309, 115 4th Avenue, SE., Aberdeen, SD 57401, Tele: 602–226–7553.
Alaska Area IHS: Alaska	Acting Scholarship Coordinator, Alaska Area IHS, 4141 Ambassador Drive, Rm. 349, Anchorage, Alaska 99508, Tele: 907–729–1332.
Albuquerque Area IHS: Colorado, New Mexico	Ms. Alvina Waseta, Scholarship Coordinator, Albuquerque Area IHS, 5300 Homestead Road, NE, Albuquerque, NM 87110, Tele: 505–248–4513.
Bemidji Area IHS: Illinois, Indiana, Michigan, Minnesota, Wisconsin	Ms. Barbara Fairbanks, Scholarship Coordinator, Bemidji Area IHS, 522 Minnesota Avenue, NW, Bemidji, MN 56601, Tele: 218–759–3350.
Billings Area IHS: Montana, Wyoming	Mr. Sandy MacDonald, Scholarship Coordinator, Billings Area IHS, Area Personnel Office, P.O. Box 2143, 2900 4th Avenue, North, Billings, MT 59103, Tele: 406–247–7210.
California Area IHS: California, Hawaii	Ms. Mona Celli, Scholarship Coordinator, California Area IHS, 1825 Bell Street, Suite 200, Sacramento, CA 95825, Tele: 916–566–7033.
Nashville Area IHS: Alabama, Arkansas, Connecticut, Delaware, Florida, Georgia, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, West Virginia, District of Columbia.	Mr. Jesse Thomas, Scholarship Coordinator, Nashville Area IHS, 711 Stewarts Ferry Pike, Nashville, TN 37214, Tele: 615–736–2436.