restricted devices. Ordinarily, these categories include promotional messages disseminated by or on behalf of a drug or device firm recommending use of a drug or device or containing some claim of safety or effectiveness for a drug or device. One of the principal requirements for labeling and advertising is the disclosure of risk information (either the full FDA-approved professional labeling or the brief summary). The labeling and advertising rules do not apply to certain other forms of communication by or on behalf of drug and device firms. One of these categories is disease awareness communications.

The Disease Awareness Guidance is intended to eliminate any confusion as to what principles FDA will apply in determining whether communications by or on behalf of drug and device firms qualify as ''labeling''or ''advertising,'' or as disease awareness communications. FDA believes that firms are already engaged in a substantial amount of disease awareness communication aimed at consumers (so-called ''help-seeking'' communications). Manufacturers may, however, be less familiar with disease awareness communications directed at health care professionals. Accordingly, this draft guidance contains examples of materials currently distributed to health care practitioners by government entities and educational organizations about health conditions to help demonstrate to drug and device firms the kinds of disease awareness materials they might also disseminate. FDA believes that this will encourage firms to distribute disease awareness information not only to patients, but also to health care practitioners, thereby encouraging more widespread diagnosis and treatment of under-diagnosed and under-treated health conditions.

The draft guidance also addresses the important issue of when disease awareness communications become subject to FDA regulation as ''labeling'' or ''advertising'' by virtue of their presentation in combination with so-called ''reminder'' advertisements or labeling or product-claim advertisements or labeling.

C. The Device Broadcast Advertising Guidance

In 1999, FDA issued final guidance to industry on a manner in which consumer-directed broadcast advertisements for prescription drugs could satisfy statutory and regulatory requirements for the presentation of risk information. The Device Broadcast Advertising Guidance adopts the same approach for restricted devices, with minor revisions recognizing the differences in statutory provisions relating to prescription drugs and restricted devices.

III. Good Guidance Practices

These draft guidances are being issued consistent with FDA's good guidance practices (GGPs) regulations (21 CFR 10.115). They represent the agency's current thinking on certain issues relating to certain types of communications about medical products and health conditions. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. Alternative approaches may be used if such approaches satisfy the requirements of the applicable statutes and regulations.

IV. Comments

FDA specifically requests comments on the following issues:

1. The Device Broadcast Advertising Guidance, like its CDER counterpart issued in 1999, does not address the meaning of ''major statement'' in §202.1(e)(1) (21 CFR 202.1(e)(1)). Should FDA issue guidance on this issue? If the agency should, what should the guidance provide?

2. The Brief Summary Guidance contemplates that firms will disclose risk information in their consumer-directed print advertisements for prescription drugs in ways that focus on the most serious and the most common risks, and explains that this includes all warnings, all contraindications, and certain precautions and adverse events. Does the draft guidance provide sufficiently concrete advice on this point? If it does not, how should the guidance be revised?

In the guidance documents themselves, FDA requests comments on the following issues:

1. In the Brief Summary Guidance, FDA requests comments, suggestions, or results of research to help the agency assess ways in which risk information can be presented to consumers (e.g., in a text box with accompanying brief summary-type disclosure, or in the main body of the advertisement without such accompanying disclosure).

2. In the Disease Awareness Guidance, FDA requests comments on whether data exist that help establish specific criteria for defining ''close physical or temporal proximity'' to use in evaluating whether bookend-type communications are within FDA's ''labeling'' or ''advertising'' authority under the act.

Interested persons may submit written or electronic comments on the draft guidances to the Division of Dockets Management (see **ADDRESSES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments should identify clearly which guidance they are commenting on. The draft guidances and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines*, or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: February 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–2728 Filed 2–5–04; 9:36 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0277]

Draft Guidance for Industry on Time and Extent Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Time and Extent Applications.'' This guidance is being written to assist those persons interested in adding a new condition to the over-the-counter (OTC) drug monograph system. A time and extent application (TEA) can be submitted for FDA to determine whether a condition is eligible to be considered for inclusion in an OTC drug monograph. This guidance is designed to clarify issues concerning the TEA in an effort to facilitate the application process.

DATES: Submit written or electronic comments on the draft guidance by April 12, 2004. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane,

Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments. See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Matthew R. Holman, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Time and Extent Applications.'' The OTC drug monograph system was established to evaluate the safety and effectiveness of all OTC drug products for the following reasons: (1) Marketed in the United States before May 11, 1972, that were not covered by new drug applications (NDAs), and (2) covered by ''safety'' NDAs that were marketed in the United States before enactment of the 1962 drug amendments to the Federal Food, Drug, and Cosmetic Act (the act). In 1972, FDA began its OTC drug review of the following procedures: (1) To evaluate OTC drugs by categories or classes (e.g., antacids, skin protectants), rather than on a product-by-product basis, and (2) to develop ''conditions'' under which classes of OTC drugs are generally recognized as safe and effective (GRAS/E) and not misbranded.

FDA publishes these conditions in the **Federal Register** in the form of OTC drug monographs, which consist primarily of active ingredients, labeling, and other general requirements. Final monographs for OTC drugs that are GRAS/E and not misbranded are codified in part 330 (21 CFR part 330). Manufacturers seeking to market an OTC drug covered by an OTC drug monograph need not obtain FDA approval before marketing.

Previously, interested persons had to prepare and submit an NDA if they wanted to introduce into the United States an OTC drug condition that had been marketed solely in a foreign country. Companies also had to submit an NDA if their OTC drug products were initially marketed in the United States after the OTC drug review began in 1972. In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule that amended the OTC drug review procedures in part 330 and included additional criteria and procedures for classifying OTC drugs as GRAS/E and not misbranded. The final rule provided procedures for conditions that previously required an NDA for those conditions to become eligible for inclusion in the OTC drug monograph system. This final rule stated that an applicant must first submit a TEA to show marketing ''to a material extent'' and ''for a material time.'' Once FDA has determined eligibility, safety and effectiveness data would be submitted and evaluated. This two-step process allows applicants to demonstrate that eligibility criteria are met before expending resources to prepare safety and effectiveness data.

This draft guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on time and extent applications. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: January 29, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–2729 Filed 2–9–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Availability of Funds for Loan Repayment Program for Repayment of Health Professions Educational Loans

AGENCY: Indian Health Services, HHS.

ACTION: Notice.

SUMMARY: The Administration's budget request for Fiscal Year (FY) 2004 includes $11,923,500 for the Indian Health Service (IHS) Loan Repayment Program (LRP) for health professions educational loans (undergraduate and graduate) in return for full-time clinical service in Indian health programs. It is anticipated that $11,846,474 will be available to support approximately 276 competing awards averaging $43,000 per award for a two year contract.

This program announcement is subject to the appropriation of funds. this notice is being published early to coincide with the recruitment activity of the IHS, which competes with other Government and private health management organizations to employ qualified health professionals. Funds must be expended by September 30 of the fiscal year. This program is authorized by section 108 of the Indian Health Care Improvement Act (IHCIA) as amended, 25 U.S.C. 1601 *et seq.* The IHS invites potential applicants to request an application for participation in the LRP.

DATES: Applications for the FY 2004 LRP will be accepted and evaluated monthly beginning March 12, 2004, and will continue to be accepted each month thereafter until all funds are exhausted. Subsequently monthly deadline dates are scheduled for Friday of the second full week of each month. Notice of awards will be mailed on the last working day of each month.

Loan Repayment Awards will be made only to those individuals serving at facilities which have a site score of 70 or above during the first and second quarters and the first month of the third quarter of FY 2004, if funding is available.

Applicants selected for participation in the FY 2004 program cycle will be expected to begin their service period no later than September 30, 2004.

Applications shall be considered as meeting the deadline if the are either:

1. Received on or before the deadline date; or

2. Sent 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