Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the 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 guidance document.

FOR FURTHER INFORMATION CONTACT:

Rajeshwari Sridhara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1210, Silver Spring, MD 20903–0002, 301–796–2070; or

Peter Bross, Center for Biologics Evaluation and Research (HFM–755), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics.'' FDA is developing guidance on oncology endpoints through a process that includes public workshops of oncology experts and discussions before FDA's Oncologic Drugs Advisory Committee. This guidance provides background information and general principles. The endpoints discussed in this guidance are for drugs to treat patients with an existing cancer. This guidance does not address endpoints for drugs to prevent or decrease the incidence of cancer.

The availability of a draft of this guidance was announced in the **Federal Register** of April 4, 2005 (70 FR 17095). Comments received from industry, professional societies, and consumer groups on the draft guidance have been taken into consideration by FDA in finalizing this guidance, and some of the changes are summarized here. The section on future methods for assessing progression has been clarified based on the comments received and FDA's current thinking and practice. The section on no treatment or placebo control and the section on isolating drug effect in combination also have been clarified based on the comments received and FDA's view that these do not directly concern the selection or evaluation of endpoints. Throughout the guidance document, the language has been condensed and simplified to be concise and clear.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on clinical trial endpoints for the approval of cancer drugs and biologics. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under 0910–0014; the collections of information in 21 CFR part 314 have been approved under 0910–0001, and the collections of information referred to in the guidance for industry entitled ''Special Protocol Assessment'' have been approved under 0910–0470.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

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

Dated: May 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–9345 Filed 5–15–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0185]

Draft Guidance for Industry and Review Staff on Labeling for Human Prescription Drugs—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information; 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 and review staff entitled ''Labeling for Human Prescription Drugs—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information.'' This guidance is intended to help applicants and the review staff in the Center for Drug Evaluation and Research (CDER) at FDA determine when a drug belongs to an established pharmacologic class as well as how to select the appropriate word or phrase (term) that describes the pharmacologic class for inclusion in the *Indications and Usage* section of Highlights of Prescribing Information (*Highlights*) of approved labeling.

DATES: Submit written or electronic comments on the draft guidance by August 14, 2007. 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: William Pierce, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6474, Silver Spring, MD 20993–0002, 301–796–0700.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled ''Labeling for Human Prescription Drugs—Determining Established Pharmacologic Class for Use in the Highlights of Prescribing Information.'' This guidance is intended to help applicants and CDER's review staff determine when a drug belongs to an established pharmacologic class as well as how to select the appropriate word or phrase (term) that describes the pharmacologic class for inclusion in the *Indications and Usage* section of Highlights of Prescribing Information (*Highlights*) of approved labeling, as required by § 201.57(a)(6) (21 CFR 201.57(a)(6)).

In January 2006, FDA published a final rule that amended the requirements for the content and format of labeling for human prescription drug and biological products.[1] The new labeling format is intended to make it easier for health care professionals to access, read, and use the information in prescription drug labeling, thereby facilitating professionals' use of labeling to make prescribing decisions.

The rule requires that the following statement appear under the *Indications and Usage* section of *Highlights* if a drug is a member of an established pharmacologic class:[2]

''(*Drug*) is a (*name of class*) indicated for (*indication(s)*).''

If the drug is not a member of an established pharmacologic class, the statement must be omitted.

Knowing the established pharmacologic class can provide health care professionals with important information about what to expect from a drug and how it relates to other therapeutic options. Such information can also help reduce the risk of duplicative therapy and drug interactions. This draft guidance provides recommendations for identifying the established pharmacologic class and its appropriate term for inclusion in the *Indications and Usage* section of *Highlights*.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. 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 regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen 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: May 10, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–9347 Filed 5–15–07; 8:45 am]

BILLING CODE 4160–01–S

[1]See ''Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products'' (71 FR 3922, January 24, 2006; 21 CFR parts 201, 314, and 601).

[2]See § 201.57(a)(6).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Management Grant Program

Announcement Type: New and Competing Continuation Discretionary Funding Cycle for Fiscal Year 2008.

Funding Announcement Number: HHS–2008–IHS–TMD–0001.

Catalog of Federal Domestic Assistance Number(s): 93.228.

Key Dates: Training: Application Requirements Session: May 8–9, May 23–24, and June 13–14, 2007; Grant Writing Session: June 4–8, 2007.

Application Deadline Date: August 3, 2007.

Receipt Date for Final Tribal Resolution: September 28, 2007.

Review Date: October 1–5, 2007.

Application Notification Date: November 12, 2007.

Earliest Anticipated Start Date: January 1, 2008.

I. Funding Opportunity Description

The Indian Health Service (IHS) announces competitive grant applications for the Tribal Management Grant (TMG) Program. This program is authorized under Section 103(b)(2) and Section 103(e) of the Indian Self-Determination and Education Assistance Act, Pub. L. 93–638, as amended. This program is described at 93.228 in the Catalog of Federal Domestic Assistance.

The TMG Program is a national competitive discretionary grant program pursuant to 45 CFR 75 and 45 CFR 92 established to assist Federally-recognized Tribes and Tribally-sanctioned Tribal organizations in assuming all or part of existing IHS programs, services, functions, and activities (PSFA) through a Title I contract and to assist established Title I contractors and Title V compactors to further develop and improve their management capability. In addition, TMGs are available to Tribes/Tribal organizations under the authority of Public Law (Pub. L.) 93–638 section 103(e) for (1) obtaining technical assistance from providers designated by the Tribe/Tribal organization (including Tribes/Tribal organizations that operate mature contracts) for the purposes of program planning and evaluation, including the development of any management systems necessary for contract management and the development of cost allocation plans for indirect cost rates; and (2) planning, designing and evaluating Federal health programs serving the Tribe/Tribal organization, including Federal administrative functions.

Funding Priorities: The IHS has established the following funding priorities for TMG awards.

- Priority 1—Any Indian Tribe that has received Federal recognition (restored, un-terminated, funded, or unfunded) within the past 5 years, specifically received during or after March 2002.
- Priority II—All other eligible Federally-recognized Indian Tribes or Tribally-sanctioned Tribal organizations submitting a competing continuation application or a new application for the sole purpose of addressing audit material weaknesses. The audit material weaknesses are identified in Attachment A (Summary of Findings and Recommendations) and other attachments, if any, of the transmittal letter received from the Office of the Inspector General (OIG), National External Audit Review Center (NEARC), Department of Health and Human Services (HHS). Please identify the