This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by July 13, 2001. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 13, 2001. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information 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 and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 2001.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 01–12025 Filed 5–11–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–3082]

International Conference on Harmonisation; Choice of Control Group and Related Issues in Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''E10 Choice of Control Group and Related Issues in Clinical Trials.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance sets forth general principles that are relevant to all controlled trials and are especially pertinent to the major clinical trials intended to demonstrate drug (including biological drug) efficacy. The guidance describes the principal types of control groups and discusses their appropriateness in particular situations. The guidance is intended to assist sponsors and investigators in the choice of control groups for clinical trials.

DATES: This guidance is effective May 14, 2001. Submit written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and 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), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX: 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert Temple, Center for Drug Evaluation and Research (HFD–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758.

Regarding the ICH: Janet J. Showalter, Office of International Affairs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In accordance with the agency's regulation on good guidance practices (GGP) (21 CFR 10.115; 65 FR 56468, September 19, 2000), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedures for publishing ICH guidances. Beginning April 2000, we no longer include the text of ICH guidances in the **Federal Register**. Instead, we will publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance is placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). Draft ICH guidances are left in the original ICH format. Final guidances are reformatted to conform to the GGP style before publication.

In the **Federal Register** of September 24, 1999 (64 FR 51767), FDA published a draft tripartite guidance entitled ''E10 Choice of Control Group in Clinical Trials.'' The notice gave interested persons an opportunity to submit comments by December 23, 1999.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in July 2000.

This guidance sets forth general principles that are relevant to all controlled trials and are especially pertinent to the major clinical trials intended to demonstrate drug (including biological drug) efficacy. The guidance includes a description of the five principal types of controls, a discussion of two important purposes of clinical trials, and an exploration of the critical issue of assay sensitivity, i.e., whether a trial could have detected a difference between treatments when there was a difference, a particularly important issue in noninferiority/equivalence trials. In addition, the guidance presents a detailed description of each type of control and considers, for each: (1) Its ability to minimize bias; (2) ethical and practical issues associated with its use; (3) its usefulness and the quality of inference in particular situations; (4) modifications of study design or combinations with other controls that can resolve ethical, practical, or inferential concerns; and (5) its overall advantages and disadvantages.

This guidance represents the agency's current thinking on the choice of control group in clinical trials. 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 Dockets Management Branch (address above) written comments on the guidance at any time. 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. The guidance and received comments may be seen in the Dockets Management Branch 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 http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/publications.htm.

Dated: May 4, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–12026 Filed 5–11–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 6, 2001, 8 a.m. to 5 p.m..

Location: Holiday Inn, 8120 Wisconsin Ave., Bethesda, MD.

Contact: Sandra Titus, Food and Drug Administration, Center for Drug Evaluation and Research, (HFD–21), 5600 Fishers Lane, Rockville MD 20857, 301–827–7001, e-mail: Tituss@ cder.fda.gov. FAX 301–827–6801, or FDA Advisory Committee Information Line at 1–800–741–8138 (301–443–0572 in the Washington, DC area) code 12543. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 6, 2001, the committee will consider the safety and efficacy of new drug application (NDA) 21–196, Xyrem® (sodium oxybate, Orphan Medical, Inc.) proposed to reduce the incidence of cataplexy and to improve the symptom of daytime sleepiness for persons with narcolepsy. A main focus of the deliberations will be on risk management issues.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 29, 2001. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 29, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Background material from the sponsor and FDA will be posted 24 hours before the meeting at the Peripheral and Central Nervous System Drugs Advisory Committee docket site at http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2001 and scroll down to the Peripheral and Central Nervous Systems Drugs meetings.) This is the same Web site where you can find the minutes, transcript, and slides from the meeting. This material is generally posted about 3 weeks after the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 8, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–12085 Filed 5–10–01; 10:28 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–267]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Medicare Plus Choice Program Requirements Referenced in 42 CFR 422.000–422.700; *Form No.:* HCFA–R–0267 (OMB# 0938–0753); *Use:* Section 4001 of the Balanced Budget Act of 1997 added sections 1851 through 1859 to the Social Security Act to establish a new Part C of the Medicare Program, known as the Medicare+Choice program. Under this program, every individual entitled to Medicare Part A and enrolled under Part