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]

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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