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

B may elect to receive benefits through either the existing Medicare fee-for-service program or a Part C M+C plan. The regulations implementing these sections was published on June 26, 1998. The regulations revising these sections was published on February 17, 1999 and June 29, 2000.; *Frequency:* Other: as needed; *Affected Public:* Business or other for-profit, Individuals or Households, Not-for-profit institutions, Federal Government, and State, Local, or Tribal Government; *Number of Respondents:* 2,450; *Total Annual Responses:* 7,657,534; *Total Annual Hours:* 2,120,006.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at *http://www.hcfa.gov/regs/prdact95.htm,* or E-mail your request, including your address and phone number, to *Paperwork@hcfa.gov.* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: April 24, 2001.

John P. Burke, III,

HCFA Reports Clearance Officer, HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–11967 Filed 5–11–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF THE INTERIOR

National Park Service

Record of Decision: Final Environmental Impact Statement; Lake McDonald/Park Headquarters Wastewater Treatment System Rehabilitation, Glacier National Park, A Unit of Waterton-Glacier International Peace Park Flathead and Glacier Counties, MT

The Department of Interior, National Park Service (NPS) has prepared this Record of Decision on the Final Environmental Impact Statement on the Lake McDonald/Park Headquarters Wastewater Treatment System Rehabilitation for Glacier National Park, Montana. This Record of Decision is a statement of the decisions made as a result of environmental and socioeconomic analysis and consideration of public input. It describes the following: project background, the preferred alternative, other alternatives considered, the National Park Service decision and the basis for the decision, the environmentally preferable alternative, mitigation measures and the involvement of public, agencies and other nations.

Project Background

Glacier National Park (Park) attracts about 1.7 million visitors annually. Approximately 60 percent of these visitors enter the Park through the west entrance. The existing Lake McDonald wastewater treatment facility serves developed areas at Lake McDonald Lodge, Apgar Village, Sprague Creek, Apgar and Fish Creek Campgrounds, and Park Headquarters, park maintenance area, seasonal park and concession staff and year-round park employee residences.

In 1996, the Park determined that improvements and upgrades to the wastewater facility and collection system were needed to restore the original treatment capacity and protect resources from potential damage due to accidental wastewater discharges. Since 1997, the Park has upgraded lift stations at Lake McDonald Lodge and Sprague Creek Campground and has replaced the sewage collection system and made other improvements as necessary. The purpose of the proposed project is to rehabilitate and improve the existing wastewater treatment facility because it is no longer meeting its original treatment objectives or operating at the capacity it was originally designed for. In addition, the existing spray field used as part of the treatment process, is within the 100-year floodplain of McDonald Creek and the Middle Fork of the Flathead River and is only able to operate seasonally due to snow cover and or a high water table. The existing sewage storage lagoon is inadequate to store all the winter flow and precipitation during wet years, until the spray field is operational in the summer.

Decision (Selected Action)

The National Park Service will implement Alternative 3 as described in the Final Environmental Impact Statement on the Lake McDonald/park Headquarters Wastewater Treatment System Rehabilitation, with some minor clarifications and changes as indicated below to replace the existing wastewater treatment system with an advanced tertiary treatment wastewater facility that achieves the highest level of nutrient and pathogen removal of all the alternatives considered. The proposed wastewater treatment plant (WWTP) will incorporate sequencing batch reactors for nitrogen and phosphorus removal combined with chemicals that will remove additional phosphorus and suspended solids. In addition, UV disinfection will be used to kill pathogens prior to discharge. The proposed facility will require enlargement of the existing WWTP building to 60 feet × 100 feet. This method will insure that nutrients will be removed in accordance with treatment levels established by EPA and regulated by Montana DEQ.

In response to public comment received on the FEIS, the method for discharging the effluent has been changed from what was described in the FEIS. During the late spring, summer and early fall, when the plant will be treating up to 250,000 gallons of waste per day, the effluent will be treated to meet Montana DEQ standards for surface water discharge and will be disposed of by spray irrigation. Approximately 30 acres of the existing 58 acre spray field will be refurbished with new heads, pumps and controls and will cost approximately $150,000. Since the effluent will be treated to surface water discharge standards, irrigating the meadow by using the spray field is not part of the treatment process. However, it will provide a polishing effect. Any remaining nitrogen and phosphorus allowed by the discharge permit will be taken up by the plants and not enter the groundwater.

During the winter, when the plant will treat up to 12,000 gallons of waste per day, the effluent will be treated to a higher level to meet EPA underground injection control standards. To meet these higher standards, the effluent will be disinfected with ozone prior to filtration and then UV prior to discharge into an exfiltration gallery. The gallery (also known as a groundwater injection system) will be located southwest of the horse barn, within the vicinity of the existing spray field. The new plant's biological nutrient removal, filtration and disinfection process will achieve treatment standards set by EPA and regulated by DEQ. Chlorine and the disinfection by-products produced by chlorine will not be used or generated. Treated effluent discharges will meet Montana DEQ non-degradation water quality requirements in addition to EPA's underground injection control requirements.

The new site for the exfiltration gallery is within the area analyzed as part of the affected environment in the DEIS and FEIS. This site was not surveyed for the velvetleaf blueberry, although according to the park's