(FDA). The meeting will be open to the public.

Name of Committee: Psychopharmacologic 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 May 10, 2002, from 8 a.m. to 4:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD, 301–652–2000.

Contact Person: Sandra Titus, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, e-mail: Tituss@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12544. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider the efficacy of new drug application (NDA) 21–431, acamprosate, (Lipha Pharmaceuticals, Inc.) proposed for the maintenance of abstinence from alcohol in patients with alcohol dependence who have withdrawn from alcohol and want to maintain their abstinence. On May 9, 2002, the background material for this meeting will be posted at the Psychopharmacologic Drugs Advisory Committee docket site at http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year ''2002'' and scroll down to ''Psychopharmacologic Drugs Advisory Committee''.)

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 1, 2002. 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 1, 2002, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sandra Titus at least 7 days in advance of the meeting.

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

Dated: March 27, 2002.

Linda A. Suydam,

Senior Associate Commissioner for Communications and Constituent Relations.

[FR Doc. 02–8195 Filed 4–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0011]

Medical Devices: Draft Guidance on Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA.'' This draft guidance document was developed as a special control to support the classification of intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea into class II and to provide guidance to manufacturers attempting to establish that their intraoral devices for snoring and obstructive sleep apnea are substantially equivalent to a predicate device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to classify these devices. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments concerning this draft guidance by July 5, 2002.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA'' to the Division of Small Manufacturers, International and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning the draft guidance to the Dockets Management Branch (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 information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Susan Runner, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA.'' Intraoral devices to treat snoring are removable medical devices that are fitted in the patient's mouth to reduce or eliminate snoring. In some cases the devices may also be used to treat obstructive sleep apnea. Currently, intraoral devices for snoring and/or sleep apnea are unclassified. FDA is proposing to classify these devices into class II. FDA intends that the draft guidance document, if finalized, will serve as the special control for intraoral devices for snoring and/or obstructive sleep apnea. The draft guidance document offers recommendations to the regulated industry and FDA staff about the content and format of a premarket notification submission (510(k)) for such devices in order to establish safety and effectiveness. The draft guidance document is intended to facilitate the assembly of necessary data, maintain consistency of reviews, and provide for a more efficient regulatory process.

II. Significance of Guidance

The draft guidance represents the agency's current thinking on intraoral devices for snoring and obstructive sleep apnea. 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 applicable statutes and regulations.

The draft guidance document is being issued consistent with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115). The draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Draft Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 1378 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets/default.htm.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding the draft guidance by July 5, 2002. Submit two copies of any comments, 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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 28, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–8348 Filed 4–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: Young Drivers Intervention Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Young Drivers Intervention Study.

Type of Information Collection Request: Revision.

OMB No.: 0925–0467.

Expiration Date: 08/31/2002.

Need and Use of Information Collection: The purposes of this study are (1) to determine the impact of parental actions to monitor and control their adolescents' driving behavior on adolescent driving behavior and motor vehicle crashes, and (2) to test the efficacy of educational persuasive communications in promoting parental restriction of their adolescent's risky driving behavior. The specific questions addressed in this study include: (1) Are parents' perceptions about dangers associated with adolescent driving associated with parental involvement in their adolescent's driving experiences? (2) Is a parent-teen driving agreement an effective way of increasing parental involvement and reducing adolescent risky driving? (3) Does increased parental involvement reduce risky driving behaviors and decrease traffic tickets and crashes among adolescents? A sample of 4000 adolescents and their parents are recruited through department of motor vehicles offices when the teen applies for a learner's permit, randomized to one of two treatment conditions and interviewed by telephone within a few weeks of obtaining a permit and again at licensure, 3-month, 6-months, and 12-months after licensure. Parents are asked about their expectations and parental management practices regarding teen driving. Adolescents are asked about their driving practices, their parents' rules and restrictions regarding driving, and their driving experience. The driving records for each adolescent will be obtained from the state motor vehicle administration and examined at the end of the 24-month period. Parent-teen dyads in Condition #1 receive mailed information about motor vehicle safety. Parents in Condition #2 receive mailed educational newsletters, a videotape, and a model parent-teen driving agreement.

Frequency of Response: On occasion, 2–3 times each year for two years.

Affected Public: Individuals or households.

Type of Respondents: Teenaged children and parents.

The annual reporting burden is as follows:

Estimated number of Respondents: 14134.

Estimated Number of Responses per Respondent: 1.33.

Average Burden Hours Per Response: .50.

Estimated Total Annual Burden Hours Requested: 9399. The annualized cost to respondents is estimated at: $47, 333. There are no capital costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Bruce Simons-Morton, Chief, Prevention Research Branch, Division of Epidemiology, Statistics, and Prevention Research, National Institute of Child Health and