DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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: Endocrinologic and Metabolic 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 September 25, 26, and 27, 2002, from 8 a.m. to 5 p.m.

Location: Hilton, The Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Kathleen Reedy or LaNise Giles, 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, FAX 301–827–6776, or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 25, 2002, the committee will discuss appropriate designs for clinical trials of new osteoporosis treatments. On September 26, 2002, the committee will discuss the safety and efficacy of biologic licensing application BL 103979, FABRAZYME (agalsidase beta, Genzyme Corp.) for the treatment of Fabry's disease. On September 27, 2002, the committee will discuss the safety and efficacy of biologic licensing application BL 103977, REPLAGAL (agalsidase alfa, Transkaryotic Therapies) for the treatment of Fabry's disease.

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 September 17, 2002. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 17, 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 LaNise Giles 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: July 22, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–19375 Filed 7–31–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dental Products Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Dental Products Panel of the Medical Devices 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 August 22, 2002, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Pamela D. Scott, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12518. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval application for a total temporomandibular joint prosthesis for reconstruction of the temporomandibular joint.

Background information, including the agenda and questions for the committee, will be available to the public one business day before the meeting, on the Internet at http://www.fda.gov/cdrh/panelmtg.html. Material for the August 22, 2002, meeting will be posted on August 21, 2002.

Procedure: On August 22, 2002, from 8 a.m. to 5 p.m., the meeting is open to the public. 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 August 5, 2002. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before August 19, 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.

Closed Committee Deliberations: On August 22, 2002, from 5 p.m. to 6 p.m., the meeting will be closed to permit FDA staff to present to the committee trade secret and/or confidential commercial information regarding dental device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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 AnnMarie Williams, Conference Management Staff, at 301–594–1283, ext. 113, 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: July 25, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

[FR Doc. 02–19374 Filed 7–31–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Young Drivers Intervention Study

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 5, 2002, pages 16407–16408, and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Young Drivers Intervention Study, OMB No. 0925–0467. *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* This study will assess the effectiveness of a parent-based education program to increase parental restrictions on newly licensed teens' early driving and to decrease young driver risk. The primary objectives of the study are to determine if parents can be persuaded to increase restrictions on teens' driving under high-risk conditions (e.g., at night and with teen passengers) and to use a parent-teen driving agreement, and to determine if doing so decreases adolescent citations and crashes. The findings will provide valuable information concerning: (1) Whether parental actions to monitor and control the driving behavior of their teenage children reduce the number of motor vehicle crashes and citations; (2) the effectiveness of the use of educational persuasive communications and a parent-teen driving agreement in promoting parental restrictions of adolescents' driving behavior; and (3) the effectiveness of this intervention in reducing motor vehicle crashes among teens. *Frequency of Response:* 4 or 5 times over two years (*i.e.*, when teens get a learner's permit, when teens get a driver's license, and 3 months, 6 months, and 12 months postlicensure). *Affected Public:* Teenagers under age 16 years 9 months who get a learner's permit at any of the sites of the Connecticut Department of Motor Vehicles and one of their parents. *Type of Respondents:* Teenagers and Parents. The annual reporting burden is as follows: *Estimated Number of Respondents:* 9519; *Estimated Number of Responses per Respondents:* 1.6522; *Average Burden Hours Per Response:* .5; and *Estimated Total Annual Burden Hours Requested:* 7,864. The annualized cost to respondents is estimated at: $78,640 (based on $10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Teenagers and Parents	9519	1.6522	.50	7864

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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Office for NIH. 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, DESPR, NICHD, NIH, 6100 Executive Blvd., Rm 7B05, MSC 7510, Bethesda, MD 20892–7510; (301) 493–5674; email: *mortonb@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: July 26, 2002.

Kathleen Wilburn,

Project Clearance Liaison, NICHD, National Institutes of Health.

[FR Doc. 02–14397 Filed 7–31–02; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent