activity. The avoidable medical costs of obesity exceed $50 billion each year, well over 5 percent of total U.S. health expenditures, at a time when we can ill afford these costs. The total economic costs of obesity approach $100 billion each year.

Helping consumers improve their diets is one of the nation's most pressing public health problems and an increasingly urgent part of FDA's activities. The consequences of poor diets, including the growing prevalence of excess weight and growing risks of diabetes, high blood pressure, heart disease, arthritis, respiratory difficulties, and many cancers that go along with excess weight, are endangering and diminishing the lives of millions of Americans. The challenge confronting the Government, researchers, the food and restaurant industry, consumers, the medical community, schools, and the public health communitym is to determine what kind of information and assistance the public needs in order to help them improve their dietary choices and reduce the incidence of overweight and obesity.

To address the problem of obesity and to meet the challenge of helping Americans improve their diet and nutrition, Secretary Tommy G. Thompson has led the Department of Health and Human Services (DHHS) in its efforts to encourage healthy habits such as nutritious diets, more exercise, and healthy choices. Secretary Thompson has challenged DHHS agencies and the leadership of the public health community to intensify their efforts to realize these improvements.

On July 30, 2003, Secretary Thompson held a roundtable discussion on obesity and nutrition with leading scientific experts in obesity and weight management. The Secretary's roundtable on obesity/nutrition was intended to enhance a DHHS discussion with leading thinkers and experts in the public health community on the role that DHHS can play in reducing or reversing the weight gain that leads to obesity. The roundtable dialogue centered on five key questions, which are the foundation of the questions on which FDA seeks input in the forthcoming public meeting.

On August 11, 2003, FDA's Commissioner of Food and Drugs, Mark B. McClellan established FDA's Obesity Working Group to confront the current obesity epidemic in the United States and to develop new and innovative ways to help consumers lead healthier lives through better nutrition. Dr. Lester M. Crawford, FDA's Deputy Commissioner, is the Chair of the working group, and Mr. Joseph Levitt, Director of FDA's CFSAN office, is the Vice Chair. As a part of his charge to the working group, Commissioner McClellan directed that it provide for an active dialogue with external stakeholders including consumer groups, academia, the medical community, and the food and restaurant industry, on developing a framework for messages to consumers about reducing obesity and achieving better nutrition. This public meeting is one of the avenues that the working group is using to initiate this dialogue.

II. Scope of Discussion and Format

The scope of this public meeting will be limited to the following questions:

1. What is the available evidence on the effectiveness of various education campaigns to reduce obesity?
2. What are the top priorities for nutrition research to reduce obesity in children?
3. What is the available evidence that FDA can look to in order to guide rational, effective public efforts to prevent and treat obesity by behavioral or medical interventions, or combinations of both?
4. Are there changes needed to food labeling that could result in the development of healthier, lower calorie foods by industry and the selection of healthier, lower calorie foods by consumers?
5. What opportunities exist for the development of healthier foods/diets and what research might best support the development of healthier foods?
6. Based on the scientific evidence available today, what are the most important things that FDA could do that would make a significant difference in efforts to address the problem of overweight and obesity?

This meeting will include an opening session during which FDA will present a discussion of obesity and related issues associated with the tools available to the agency to assist consumers to improve their diets. The agency may ask experts to provide presentations on specific issues. Individuals who have registered to give oral presentations in advance of the meeting will be provided with the opportunity to speak following the opening session. A schedule of oral presentations will be available at the meeting.

III. Comments

To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of this meeting will remain open for 30 days after the meeting. Interested persons may submit to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments by November 21, 2003. You may also send comments to the Division of Dockets Management via e-mail to *FDADockets@oc.fda.gov.* or on FDA's Web site at *http://www.fda.gov/oc/opacom/hottopics/obesity.html*.

You should annotate and organize your comments to identify the specific questions to which your comments refer. Submit two paper copies of comments, identified with the docket number found in brackets in the heading of this document. Individuals may submit one paper copy. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Comments may be placed on the Internet and, if so, will be available for public viewing.

IV. Transcripts

You may request a transcript of the meeting in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. You may examine the transcript of the meeting after November 10, 2003, at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, as well as on FDA's Web site at *http://www.fda.gov/oc/opacom/hottopics/obesity.html*

Dated: October 6, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25645 Filed 10–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; 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: Clinical Pharmacology Subcommittee of the

Advisory Committee for Pharmaceutical Science.

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 November 17, 2003, from 8:30 a.m. to 5:30 p.m.; and on November 18, 2003, from 8:30 a.m. to 1:30 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Hilda Scharen, 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, or e-mail: *SCHARENH@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 17, 2003, the subcommittee will discuss: (1) Quantitative analysis using exposure-response: Proposal for End-of-Phase2A (EOP2A) meeting and use of clinical trial simulation for PK-QT study design; and (2) pediatric decision tree: Examples for applying the pediatric decision tree. On November 18, 2003, the subcommittee will discuss the pediatric decision tree: (1) Use of clinical trial simulation in pediatric population pharmacokinetics study design; (2) drug interactions; and (3) pharmacogenetics: Integration into new drug development.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by November 6, 2003. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12 noon on November 17, 2003, and 12:30 p.m. and 1 p.m. on November 18, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 6, 2003, 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 Hilda Scharen 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: October 2, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–25446 Filed 10–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Board to the Food and Drug Administration; 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: Science Board to the Food and Drug Administration.

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 November 6, 2003, 8 a.m. to 4:30 p.m.

Location: Food and Drug Administration, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Contact Person: Jan Johannessen, Office of the Commissioner, Food and Drug Administration, HF–33, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, *jjohannessen@fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12603. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Board will hear about and discuss FDA's Food Security Program.

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 October 22, 2003. 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 October 22, 2003, 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 Jan Johannessen 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: October 3, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–25555 Filed 10–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0434]

Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Approval Applications: Effect on FDA Review Clock and Performance Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Approval Applications: Effect on FDA Review Clock and Performance Assessment.'' This guidance describes how the Food and Drug Administration (FDA) will assess its performance in the premarket approval application (PMA) program relative to the goals that accompany the authorization of medical device user fees. This guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).