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: *JAINS@CDER.FDA.GOV*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12535. Please call the Information Line for up-to-date information on this meeting.

Dated: October 2, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–25449 Filed 10–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0338]

Food and Drug Administration Obesity Working Group; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting: Public Meeting on Obesity. The topic to be discussed involves issues within FDA's jurisdiction related to obesity and nutrition. The purpose of this public meeting, which is being sponsored by FDA's Obesity Working Group, is to discuss FDA's role and responsibilities in addressing the major public health problem of obesity, to focus on issues related to promoting better consumer dietary and lifestyle choices that have the potential to significantly improve the health and well-being of Americans, and to obtain stakeholder views on how best to build a framework for messages to consumers about reducing obesity and achieving better nutrition.

The agency has developed a web page for this initiative where interested persons can register to attend and/or make an oral presentation at the meeting, submit comments, and obtain related information. This Web Site is located at *http://www.fda.gov/oc/opacom/hottopics/obesity.html*.

DATES: The meeting will be held on October 23, 2003, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by October 17, 2003 at 5 p.m. Submit written comments by November 21, 2003.

ADDRESSES: The meeting will be held at the Jack Masur Auditorium, Warren Grant Magnuson Clinical Center (Bldg. 10), National Institutes of Health (NIH), 9000 Rockville Pike, Bethesda, MD. Important information about transportation and directions to the NIH campus, parking, and security procedures are found at *http://www.nih.gov/about/visitor/index.htm*.

Visitors must show two forms of identification, one of which must be a government-issued photo identification such as a Federal employee badge, driver's license, passport, green card, etc. If you are planning to drive to and park on the NIH campus, you must enter at the South Dr. entrance of the campus which is located on Wisconsin Ave. (the Medical Center Metro entrance), and allow extra time for vehicle inspection. Detailed information about security procedures is located on *http://www.nih.gov/about/visitorsecurity.htm*.

FOR FURTHER INFORMATION CONTACT:

For General Information: Brian R. Somers, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration (HFS–820), 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1692, FAX: 301–436–2636, e-mail: *Brian.Somers@CFSAN.FDA.GOV*.

For Registration Information: Patricia A. Alexander, Office of Regulatory Affairs (HFC–150), 5600 Fishers Lane, Rockville, MD 20857, 301–827–6328, FAX: 301–443–2143, e-mail: *registration@ora.fda.gov*.

Registration and Requests for Oral Presentations

If you would like to attend the meeting, you must register with the appropriate contact person (*see* **FOR FURTHER INFORMATION CONTACT**) by October 17, 2003, at 5 p.m. by providing your name, title, organizational affiliation, address, telephone, fax number (optional), and e-mail address (optional). Registration will be conducted on a first-come, first-served basis, and seating will be limited. To expedite processing, this registration information may also be faxed or e-mailed to Patricia A. Alexander (*see* **FOR FURTHER INFORMATION CONTACT**). If you need special accommodations due to a disability, please contact Patricia A. Alexander (*see* **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

If, in addition to attending, you wish to make an oral presentation during the meeting, you must inform Patricia A. Alexander (*see* **FOR FURTHER INFORMATION CONTACT**) when you register and submit the following items: (1) A brief written statement of the general nature of the views you wish to present, (2) the names and addresses of all persons who will participate in the presentation, and (3) an indication of the approximate time that you request to make your presentation. FDA asks that groups having similar interests consolidate their comments and present them through a single representative. Scheduled speakers should provide two copies of their presentation for the docket at the meeting. The agency requests that speakers annotate and organize their presentations to specifically identify which of the six questions (*see* **SUPPLEMENTARY INFORMATION**) are addressed in their presentations.

The agency will allocate the time available for the public meeting among persons who have preregistered to give an oral presentation. If time permits, FDA may allow interested persons attending the meeting who did not preregister to give a presentation to make an oral presentation at the end of the meeting.

After reviewing the requests for oral presentations and accompanying information, FDA will schedule each appearance and notify each participant of the time allotted to the person and the approximate time the person's oral presentation is scheduled to begin. The presentation schedule will be available at the meeting. After the meeting, it will be placed on file in the Division of Dockets Management under the docket number found in brackets in the heading of this document.

SUPPLEMENTARY INFORMATION:

I. Background

Obesity is a growing and urgent public health problem in the United States. There have been steady and substantial increases in adult obesity in the United States since the late 1980s. Today, almost two-thirds of all Americans are overweight; in 1988 through 1992, less than 56 percent were overweight. In 1988 through 1992, less than 23 percent of American adults were obese and by 1999 through 2000, the figure had increased by a quarter, to over 30 percent. The trends for children are even more worrisome. Recent research by the U.S. Centers for Disease Control and Prevention shows that 13 percent of children aged 6 to 11 are overweight—almost double the rate of two decades ago. World Health Organization surveys show that weight is on the rise all over the world. The health of Americans suffers as they get heavier. According to some estimates, at least 300,000 deaths each year are associated with cases of heart disease, diabetes, cancer, and other serious chronic diseases that, in many instances, result from unhealthy nutritional choices and lack of physical

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]

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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