Dated: October 25, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E7–21666 Filed 11–2–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0412]

Adolescent Over-the-Counter Drug Product Use; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Consumer Healthcare Product Association (CHPA) are announcing a public workshop entitled ''Adolescent Over-the-Counter (OTC) Drug Product Use.'' The purpose of the workshop is to gain an understanding of current use of OTC drug products by adolescents, including adolescent decisionmaking skills (compared with adult skills) and other factors influencing adolescent OTC drug product use. Information gathered at the workshop and from submitted comments will be used to identify when it would be most appropriate for consumer studies on OTC drugs to enroll adolescents, and to define the type of consumer research and study designs needed to support OTC drug product approval in the adolescent population. The workshop is intended to help inform FDA in its effort to assure the safe and effective use of OTC drug products by adolescents.

DATES: The public workshop will be held on December 6, 2007, from 8:30 a.m. to 5:30 p.m. and on December 7, 2007, from 8:30 a.m. to 3:30 p.m. Register to make an oral presentation during the open public session by November 21, 2007. Submit written or electronic comments by January 31, 2008.

ADDRESSES: The public workshop will be held at the Natcher Conference Center, National Institutes of Health, 45 Center Dr., Bethesda, MD 20892.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/ohrms/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Faith Dugan, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779, FAX: 301–827–4312, e-mail: *Faith.Dugan@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

We are announcing a public workshop on adolescent use of OTC drug products. OTC drugs are FDA-regulated drug products that are available without a prescription. Other health care products (e.g., dietary supplements) are beyond the scope of the workshop. Adolescents use OTC drug products from a wide range of therapeutic categories (including fluoride toothpastes, acne drug products, and pain relievers) and with varying degrees of parental oversight. While clinical and consumer behavior studies for OTC drugs have enrolled various populations, few studies have included adolescents. Therefore, limited information on adolescents' use of OTC drug products has been collected regarding the magnitude of their use, the types of products they use, factors that influence their use, or their ability to understand and follow directions provided on OTC labels.

The desire to learn more about adolescent decisionmaking skills as they relate to the use of OTC drug products has generated interest in holding a public workshop that would convene a group of scientific experts and solicit input from the public. Information gathered at the workshop would help identify methods for assessing adolescent OTC drug use and identify information useful to regulatory decisionmaking.

II. Why Are We Holding This Public Workshop?

This workshop has been developed to further our understanding of the physiological and psychological differences and similarities between adolescents and adults, which may have an impact on adolescents' decisions about OTC drug use and also may define research priorities for assessing the differences in drug use decisions. The workshop is also aimed at designing efforts to encourage appropriate OTC drug product use by adolescents. It is hoped that such efforts will foster appropriate use when adolescents become adults.

III. What Are the Topics We Intend to Address at the Workshop?

We will address the following topics at the workshop:

- OTC drug product use by adolescents;
- Discussion of adolescent neurocognitive development and decisionmaking skills;
- Discussion of how best to communicate product information directed toward adolescents;
- Discussion of future actions and research agendas, including studies regarding consumer behavioral issues; and
- Discussion of mechanisms to promote appropriate and optimal use of OTC drugs by adolescents.

We are interested in hearing comments at the public workshop or receiving written or electronic comments (see section V of this document) on the following questions:

1. What is known about current OTC drug product use by adolescents? Focus on the following information:
   - Magnitude of current use of OTC drugs by adolescents;
   - Product categories commonly used by adolescents;
   - Market use data for such drugs;
   - Consumer behavior studies that have enrolled adolescents; and
   - Factors that influence adolescent's use of OTC products, such as drug class, age, parental involvement and influence, household dynamics, social circumstances, and gender.
2. How does adolescent neurocognitive development influence decisionmaking and behavior as they relate to OTC drug product use?
   - Identify known factors that contribute to how adolescents make health-related decisions;
   - Discuss adolescent behavior patterns, decisionmaking skills, and predictors of risk-taking behavior as they relate to purchase and use of OTC drugs; and
   - Discuss differences between adolescent and adult risk perceptions and decisionmaking and discuss the ages at which identifiable developmental transitions generally occur.
3. What future actions will help promote safe and effective use of OTC drugs by adolescents?
   - Discuss drug categories (e.g., analgesics, acne drugs) for which it would be appropriate to enroll adolescents in clinical and behavioral studies and identify related study design issues (e.g., design, age, informed consent, parental assent, compliance);
   - Assess the need for consumer behavior studies targeted toward adolescents;
   - Explore alternate and effective means of communicating with adolescents, including need for labels

directed toward adolescent age groups; and

• Discuss other potential future actions to promote safe and effective use of OTC drugs by adolescents.

IV. Workshop Attendance and Registration

The Natcher Conference Center is a Federal facility with security procedures for entrance. Workshop attendees will be required to show proper identification and are asked to allow ample time to enter the NIH campus.

There is no fee to attend the workshop, and attendees who do not wish to make an oral presentation do not need to register. Seating will be on a first-come, first-served basis.

If you would like to make an oral presentation during the workshop, you must register by close of business on November 21, 2007. You must provide your name, title, business affiliation (if applicable), address, and type of organization you represent (e.g., industry, consumer organization) to Lee Lemley or Faith Dugan at 301–594–6779 (see **FOR FURTHER INFORMATION CONTACT**). Persons registered to make an oral presentation should check in before the workshop.

If you need special accommodations because of disability, please contact Lee Lemley (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the issues and questions presented in this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Workshop Transcripts

We will prepare a transcript of the workshop. The transcript will be available for review approximately 30 days after the workshop at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday. The transcript will also be available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 30, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–21713 Filed 11–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Oncologic 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 December 5, 2007, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel phone number is 301–977–8900.

Contact Person: Nicole Vesely, 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, 301–827–6793, FAX: 301–827–6776, e-mail: *nicole.vesely@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 5, 2007, from 8 a.m. to 3 p.m., the committee will discuss supplemental biologics license application (sBLA) 125085/91, AVASTIN (bevacizumab), Genentech, Inc., proposed indication, in combination with paclitaxel, for the treatment of patients who have not received chemotherapy for their locally recurrent or metastatic, HER2 negative breast cancer. From 3:30 p.m. to 5 p.m., the committee will meet in closed session.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2007 and scroll down to the appropriate advisory committee link.

Procedure: On December 5, 2007, from 8 a.m. to 3 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 on or before November 21, 2007. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon. Those desiring to make formal oral presentations should notify the contact person 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 on or before November 13, 2007. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 14, 2007.

Closed Committee Deliberations: On December 5, 2007, from 3:30 p.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). During this session, the committee will be briefed on recent and upcoming applications within the Office of Oncology Products.

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