

Drug Evaluation and Research, by the Commissioner.

Dated: June 11, 2007.

**Douglas C. Throckmorton,**

*Deputy Director, Center for Drug Evaluation and Research.*

[FR Doc. E7-12494 Filed 6-27-07; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Dermatologic and Ophthalmic Drugs Advisory Committee and the Drug Safety and Risk Management 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 Committees:** Dermatologic and Ophthalmic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

**General Function of the Committees:** To provide advice and recommendations to the agency on FDA's regulatory issues.

**Date and Time:** The meeting will be held on August 1, 2007, from 8 a.m. to 12:30 p.m.

**Location:** Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy, Gaithersburg, MD.

**Contact Person:** Sohail Mosaddegh, 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, e-mail: [Sohail.Mosaddegh@fda.hhs.gov](mailto:Sohail.Mosaddegh@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512534 or 3014512535. 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:** The committees will meet in joint session to be briefed on iPLEDGE, the risk management program for isotretinoin products. Presentations will provide updates on risk management activities for isotretinoin since the full implementation of iPLEDGE on March 1, 2006.

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:** 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 July 11, 2007. Oral presentations from the public will be scheduled between approximately 10:15 a.m. and 11:15 a.m. 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 July 2, 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 July 3, 2007.

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 John Lauttman, 301-827-7001, 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: June 21, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E7-12501 Filed 6-27-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Data Collection; Comment Request; National Physician Survey of Practices on Diet, Physical Activity, and Weight Control

**SUMMARY:** In compliance with the provisions of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comments on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) 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: Physician Survey of Practices on Diet, Physical Activity, and Weight Control. **Type of Information Collection Request:** NEW. **Need and Use of Information Collection:** This study will obtain current, national data on primary care physicians' knowledge, attitudes, and practices related to diet, physical activity, and weight control. Obesity, poor diet, and lack of physical activity are becoming recognized as major public health problems in the United States, and have been linked to increased risk, adverse prognosis, and poor quality of life for cancer and many other chronic diseases. The data collected in this study will support and further NCI work in monitoring and evaluating providers' cancer prevention knowledge, attitudes, and practices and their impact on population health, as well as enable monitoring of progress toward major cancer control goals. Data from the survey will be used to profile existing physician practice, understand barriers to counseling and referral, and to inform methods for improving the utilization of these services for adults and children. Two questionnaires, one sent to physicians and one sent to their practice administrators, will be administered by mail or telephone to a randomly-selected national sample of 2,000 physicians belonging to primary care specialties. Study participants will be 2,000 practicing physicians who are family practitioners, general internists, pediatricians, and obstetrician/gynecologists and 2,000 practice administrators.

The annual reporting burden is as follows: *Estimated Number of Respondents:* 4,000; *Estimated Number of Responses per Respondent:* 1;

*Average Burden Hours Per Response:* .333; and *Estimated Total Annual Burden Hours Requested:* 1,332. The annualized cost to respondents is

estimated at: \$65,048. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

| Type of respondent                   | Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per response | Estimated total annual burden hours |
|--------------------------------------|---------------------------------|----------------------------------------------|-----------------------------------|-------------------------------------|
| Physician .....                      | 2000                            | 1                                            | 0.333                             | 666                                 |
| Medical Practice Administrator ..... | 2000                            | 1                                            | 0.333                             | 666                                 |
| Total .....                          | 4000                            | 1                                            | .....                             | 1,332                               |

\*Hourly earnings data are taken from the National Compensation Survey: Occupational Wages in the United States, June 2005, U.S. Department of Labor, U.S. Bureau of Labor Statistics.

**Request for Comments:** Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (a) Whether the proposed collection of information is necessary for the performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:**

Send comments to Ashley Wilder Smith, PhD, M.P.H., Health Sciences Specialist, National Cancer Institute, 6130 Executive Blvd., MSC 7344, Executive Plaza North, Room 4090, Bethesda, MD 20892-7344. Telephone: 301-451-1843; E-mail: [smithas@mail.nih.gov](mailto:smithas@mail.nih.gov).

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication should be received by August 27, 2007.

Dated: June 20, 2007.

**Ashley Wilder Smith,**

National Cancer Institute Task Order Monitor,  
National Institutes of Health.

[FR Doc. E7-12535 Filed 6-27-07; 8:45 am]

BILLING CODE 4140-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Inventions;  
Availability for Licensing**

**AGENCY:** National Institutes of Health,  
Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are 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 applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

**Orally Active Derivatives of 1,3,5(10)-estratriene**

**Description of Technology:** The utility of estrogenic substances in the practice of medicine is well documented. Estrogens may be used for the replacement of the natural hormone estradiol in hypogonadism, and following the removal of the ovaries or cessation of ovarian activity during menopause. They are also widely employed as a component of oral contraceptives. However, orally-active synthetic estrogens are associated with a number of side effects, such as: Enhanced risk of endometrial carcinoma; induction of malignant carcinoma, especially in the cervix, breast, vagina and liver; promotion of gallbladder disease, thromboembolic and thrombotic diseases, myocardial infarction, hepatic adenoma, elevated blood pressure, and hypercalcemia; and reduced glucose tolerance.

The NIH announces a new family of novel, active estrogens that are nitrate

esters of estradiol. These nitrate esters possess enhanced estrogenic activity following oral administration and lack a 17-ethynyl alcohol, which has been implicated in many side effects attributed to other synthetic estrogens. It is anticipated that these esters could be used in all instances where estrogen is prescribed as a treatment.

**Applications:** Hormone replacement therapies; Oral contraceptives.

**Market:** The hormone replacement market exceeds one billion dollars per year, and the oral contraceptive market is more than three billion dollars per year.

**Development Status:** Early stage.

**Investors:** Hyun K. Kim *et al.* (NICHD).

**Patent Status:** U.S. Patent 5,554,603 issued 10 Sep 1996 (HHS Reference No. E-137-1993/0-US-01); Foreign counterparts in Australia, Canada, Japan, and Europe.

**Licensing Status:** Available for exclusive or non-exclusive licensing.

**Licensing Contact:** Tara L. Kirby, PhD; 301/435-4426; [tarak@mail.nih.gov](mailto:tarak@mail.nih.gov).

**Methods of Inducing Immune Tolerance Using Immunotoxins**

**Description of Invention:** The invention concerns immunotoxins and methods of using the immunotoxins for the treatment of rejection response in a patient, including graft-versus-host disease and transplantation of organs, tissues and cells into a host. In a specific embodiment of the invention, the transplant involves pancreatic islet cells. The immunotoxins are targeted via an antibody that is specific to T cells. This allows the specific ablation of resting T cells, resulting in an accentuation of immune tolerizing responses and an increased tolerance to transplants and grafts. The toxin portion of the immunotoxin is genetically engineered to maintain bioactivity when recombinantly produced in *Pichia pastoris*. Data are available in transgenic animals expressing human CD3ε which