

distribution of the device is in the interests of the public health. Section 812.36(f) identifies the reports required to allow FDA to monitor the size and scope of the treatment IDE, to assess the sponsor's due diligence in obtaining marketing clearance of the device and to ensure the integrity of the controlled clinical trials.

Section 812.140 lists the recordkeeping requirements for investigators and sponsors. FDA requires this information for tracking and oversight purposes. Investigators are required to maintain records,

including correspondence and reports concerning the study; records of receipt, use or disposition of devices; records of each subject's case history and exposure to the device; informed consent documentation; study protocol and documentation of any deviation from the protocol. Sponsors are required to maintain records including correspondence and reports concerning the study; records of shipment and disposition; signed investigator agreements; adverse device effects information; and, for a nonsignificant risk device study, an explanation of the

nonsignificant risk determination, records on device name and intended use, study objectives, investigator information, investigational review board (IRB) information, and statement on the extent that good manufacturing practices will be followed.

The most likely respondents to this information collection will primarily be medical device manufacturers, investigators, hospitals, health maintenance organizations, and businesses.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
812.10	1	1	1	1	1
812.20, 812.25, and 812.27	600	0.5	275	80	22,000
812.35 and 812.150 (reports for significant risk studies)	600	7.8	4700	6	28,200
812.150 (reports for non-significant risk studies)	600	0.017	10	6	60
812.36(c)	1	1	1	120	120
812.36(f)	1	2	2	20	40
Total					50,421

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record-keeper	Total Hours
812.140 Original	600	0.5	275	10	2,750
812.140 Supplemental	600	7	4,700	1	4,700
812.140 Non-significant	600	1	600	6	3,600
Total					11,050

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 18, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-8125 Filed 5-25-06; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee. This meeting was announced in the **Federal Register** of April 19, 2006 (71 FR 20111). The amendment is being made to reflect a change in the *Procedure* portion of the document, specifically due to a change in the scheduling of the oral presentations

from the public. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:**

Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184, ext. 176, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512521. Please call the Information Line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of April 19, 2006, FDA announced that a meeting of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee would be held on June 2, 2006, from 8:30 a.m. to 3:30 p.m. On page 20111, in the second and third columns, the *Procedure* portion is amended to read as follows:

*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 May 19, 2006. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of the committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. 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 May 19, 2006.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: May 18, 2006.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E6-8088 Filed 5-25-06; 8:45 am]

BILLING CODE 4160-01-S

**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.

**Tetrahalogenated Compounds Useful as Inhibitors**

*Description of Technology:* Cancer is the second leading cause of death in United States and it is estimated that there will be approximately 600,000 deaths caused by cancer in 2006. A major drawback of the existing chemotherapies is the cytotoxic side-effects that are associated with them. Thus, there is a need to develop new therapeutic approaches with reduced side-effects.

Anti-angiogenic therapy is a recent approach in cancer therapeutics targeting the formation of blood vessels that are necessary for tumor growth. Recently, the anti-angiogenic molecule bevacizumab (Avastin) has gained approval from the FDA for the first-line treatment of metastatic colon cancer in combination with standard chemotherapy. Another promising anti-angiogenic molecule is thalidomide. Thalidomide has been approved as an anti-cancer agent and for other use in Europe and Australia. However, its use as a drug has been limited by its effect as a teratogen, necessitating the development of new thalidomide analogs with improved efficacy and reduced toxicity.

This technology describes synthesis of several tetrahalogenated thalidomide derivatives that are potentially more anti-angiogenic than thalidomide. More specifically, two series of analogs based on two major common pharmacophores have been synthesized. One series preserves the thalidomide common structure, while the other series contains a different common structure

(tetrafluorobenzamides). Several analogs from both series have shown significant anti-angiogenic properties, *in vitro*. This technology has therapeutic potential for a broad spectrum of cancer related diseases alone, or in combination with existing therapies.

*Applications:* Novel tetrahalogenated thalidomide analogs containing the thalidomide pharmacophore with improved anti-angiogenic activity; Novel tetrahalogenated thalidomide analogs containing a different common structure (tetrafluorobenzamides) with considerable anti-angiogenic activity; Use of the compounds for the treatment of several cancers; Use of the compounds for the treatment other diseases including autoimmune diseases.

*Market:* 600,000 deaths from cancer related diseases estimated in 2006. The technology platform involving novel anti-angiogenic small molecule cancer therapy technology has a potential market of more than 2 billion U.S. dollars. The technology platform has additional market in treating several other clinical problems such as autoimmune diseases.

*Development Status:* The technology is currently in the pre-clinical stage of development.

*Inventors:* William D. Figg (NCI), Erin Lepper (SAIC), *et al.*

*Publications:*

SS Ng *et al.*, "Antitumor effects of thalidomide analogs in human prostate cancer xenografts implanted in immunodeficient mice," *Clin Cancer Res.* 2004 Jun 15; 10 (12 Pt 1):4192-7.

WL Dahut *et al.*, "Randomized phase II trial of docetaxel plus thalidomide in androgen-independent prostate cancer," *J Clin Oncol.* 2004 Jul 1; 22 (13): 2532-9.

S Kumar *et al.*, "Antimyeloma activity of two novel N-substituted and tetrafluorinated thalidomide analogs," *Leukemia* 2005 Jul; 19 (7):1253-61.

*Patent Status:* U.S. Provisional Application filed 13 Apr 2006 (HHS Reference No. E-080-2006/0-US-01).

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

*Licensing Contact:* David A. Lambertson, PhD.; 301-435-4632; [lambertson@od.nih.gov](mailto:lambertson@od.nih.gov).

*Collaborative Research Opportunity:* The National Cancer Institute, Center for Cancer Research, Medical Oncology Branch, Molecular Pharmacology Section is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize tetrafluorinated compounds as anti-cancer therapeutics.