

**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 May 24, 2012, from 8 a.m. to 6 p.m.

**Location:** Hilton Washington, DC North/Gaithersburg, Montgomery Rm., 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel telephone number is 301-977-8900.

**Contact Person:** Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1611, Silver Spring, MD 20993-0002, 301-796-3063, [Jamie.Waterhouse@fda.hhs.gov](mailto:Jamie.Waterhouse@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. 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 May 24, 2012, the committee will discuss current knowledge about the safety and effectiveness of the AMPLATZER ASO Device & Gore HELEX ASD Occluder as transcatheter Atrial Septal Defect (ASD) occluders used for the closure of secundum atrial septal defects. The AMPLATZER Septal Occluder (ASO) Device was the first device introduced to the US market in 2001 followed by the Gore HELEX device in 2006. With more widespread use of these devices, more information has become available regarding adverse events. These events range from rare life-threatening events to more common events that are perceived to have less severe clinical sequelae. Many of these events were evident in the premarket studies; however, rare events such as erosion were not seen. The purpose of discussion of these events is: (1) To discuss the significance of these events in the overall context of the disease and existing treatment options; (2) to discuss whether additional measures should be taken to improve protection of the public health (e.g., additional study and/or data analyses, labeling changes); and (3) to communicate to patients and physicians what is and is not known about device treatment options.

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/AdvisoryCommittees/Calendar/default.htm>. 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 May 16, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making 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 9, 2012. 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 May 11, 2012.

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 AnnMarie Williams, Conference Management Staff at [AnnMarie.Williams@fda.hhs.gov](mailto:AnnMarie.Williams@fda.hhs.gov), 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 23, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012-7407 Filed 3-27-12; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0121]

#### Small Entity Compliance Guide: Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products—Small Entity Compliance Guide" for a final rule published in the **Federal Register** of February 2, 2012. This small entity compliance guide (SECG) is intended to set forth in plain language the requirements of the regulation and to help small businesses understand and comply with the regulation.

**DATES:** Submit either electronic or written comments on the SECG at any time.

**ADDRESSES:** Submit written requests for single copies of the SECG entitled "Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products—Small Entity Compliance Guide" to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Gerie Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373, [gerie.voss@fda.hhs.gov](mailto:gerie.voss@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:****I. Background**

In the **Federal Register** of February 2, 2012 (77 FR 5171), FDA issued a final rule regarding further amendments to the general regulations of the FDA to incorporate tobacco products. FDA examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the rule would have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121), FDA is making available this SECG stating in plain language the legal requirements of the February 2, 2012, final rule, set forth in 21 CFR parts 1, 7, and 16, amending the FDA's general regulations to ensure that tobacco products are subject to the same general requirements that apply to other FDA-regulated products.

FDA is issuing this SECG as level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments 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.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/TobaccoProducts/GuidanceCompliance/RegulatoryInformation/default.htm> or <http://www.regulation.gov>.

Dated: March 23, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-7455 Filed 3-27-12; 8:45 am]

**BILLING CODE 4160-01-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.

**Lenalidomide Analogs for the Treatment of Neurodegenerative Disorders and Cancer**

*Description of Technology:* Inflammatory processes associated with the over-production of tumor necrosis-alpha (TNF- $\alpha$ ), a potent activator of the immune system accompany numerous neurodegenerative diseases. TNF- $\alpha$  has been validated as a drug target with the development of the inhibitors Enbrel and Remicade (fusion antibodies) as prescription medications. Both, however, are large macromolecules that require direct injection and have limited brain access. The classical drug, thalidomide is being increasingly used in the clinical management of a wide spectrum of immunologically-mediated and infectious diseases, and cancers. The NIA inventors developed and assessed novel thio analogs of lenalidomide (Cellegene's Revlimid and an analog of thalidomide) as immunomodulatory agents, with the

potential to reduce chronic systemic and central nervous system inflammation. These compounds were synthesized and evaluated for their TNF- $\alpha$  inhibitory activity. This invention was extended from the inventors' prior work to develop potent compounds to reduce neuroinflammation as a treatment strategy for neurodegenerative disorders. The current studies focus the compounds activity in classical models of neurodegeneration as well as cancer.

*Potential Commercial Applications:*

- Treatment for blood disorders (myelodysplastic syndrome), cancer (multiple myeloma), inflammatory processes and erythema
  - Immunomodulatory agents
  - Reduce chronic systemic and central nervous system inflammation
- Competitive Advantages:*
- Effective smaller molecular weight compound that can enter brain among current agents
  - Experimental therapeutic to reduce inflammation systematically and within the brain
  - Effective in reducing proinflammatory cytokines than existing agents

*Development Stage:*

- Prototype
- Clinical
- In vitro data available
- In vivo data available (animal)

*Inventors:* Nigel H. Greig, Weiming Luo, David Tweedie, Harold W. Holloway, Qian-sheng Yu (all of NIA).

*Publication:* Luo W, et al. Design, synthesis and biological assessment of novel N-substituted 3-(phthalimidin-2-yl)-2,6-dioxopiperidines and 3-substituted 2,6-dioxopiperidines for TNF-alpha inhibitory activity. *Bioorg Med Chem.* 2011 Jul 1;19(13):3965-3972. [PMID 21658960]

*Intellectual Property:* HHS Reference No. E-045-2012/0—U.S. Patent Application No. 13/310,242 filed 02 Dec 2011.

*Related Technologies:* HHS Reference No. E-189-2003/0—

- U.S. Patent No. 7,973,057 issued 05 Jul 2011
  - U.S. Application No. 13/153,355 filed 03 Jun 2011
  - and related international patents/patent applications
- Licensing Contact:* Whitney Hastings, Ph.D.; 301-451-7337; [hastingsw@mail.nih.gov](mailto:hastingsw@mail.nih.gov).

**Use of Englerin A, a Small Molecule HSF1 Activator, for the Treatment of Diabetes, Obesity, and Other Diseases Associated With Insulin Resistance**

*Description of Technology:* Insulin resistance is a causative factor for type