

information for sponsors to consider in developing information to support a marketing application for a pen, jet, or related injector device intended for use with drugs or biological products. The marketing application would typically be a premarket notification submission (510(k)) or a premarket approval (PMA) application for the injector alone. For a combination product that includes the injector, the marketing application would typically be a new drug application (NDA) or a biological licensing application (BLA). The guidance announced in this notice finalizes the draft guidance of the same title dated April 2009 and published under Docket No. FDA-2009-D-0179.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the Office of Combination Products at 301-796-8930. 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:** Patricia Y. Love, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a document entitled "Guidance for Industry and FDA Staff: Technical Considerations for Pen, Jet, and Related Injectors Intended for Use With Drugs and Biological Products" dated June 2013. FDA is providing this final guidance document to assist industry in developing technical and scientific information to support a marketing application for a pen, jet, or related injector device. The marketing application would typically be a 510(k) or a PMA application for the injector alone. For a combination product that includes the injector, the marketing application would typically be an NDA

or a BLA. For purposes of this guidance, the term injector includes, but is not limited to, jet injectors, pen injectors, piston syringes, needle-free injectors, mechanically operated injectors, and injectors with computerized or electronic elements.

In the **Federal Register** on April 27, 2009, (74 FR 19094), FDA announced the availability of the draft guidance of the same title. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. The final guidance is largely similar to the draft guidance. The significant changes to the guidance include: Additional information to clarify the bases for the technical and scientific recommendations for general use injectors, injectors intended for a class/family of drugs or biological products, injectors intended for a sponsor's product line, and injectors for use with a specific drug or biological product. The guidance provides additional information to assist developers in considering the relevance of already approved drug or biological product labeling in the development of injectors intended for general use or for use with a class/family or product line, which should assist in developing labeling for the injectors. The document provides links to other Agency documents published since the April 2009 draft guidance. Also, the document contains editorial and terminology changes to improve clarity and readability. The guidance announced in this notice finalizes the draft guidance dated April 2009.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review and have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807 have been approved under OMB control number 0910-0120. The collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231. The collections of information in 21 CFR part 314 have been approved under

OMB control number 0910-0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

**III. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at <http://www.regulations.gov>.

**IV. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/CombinationProducts/default.htm> or <http://www.regulations.gov>.

Dated: May 31, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-13484 Filed 6-6-13; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2013-N-0602]

**Electronic Submission of Tobacco Product Applications and Other Information; Public Workshop; Request for Comments**

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

**ACTION:** Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), Center for Tobacco Products (CTP), is announcing a 1-day workshop to obtain public input on topics related to the potential electronic submission of tobacco product applications and other information. This workshop will focus on the technical aspects of electronic submissions, including potential standards for content, format, and structure. The input from the public workshop may assist the Agency in the potential development and implementation of an electronic submission standard for CTP. FDA is also opening a public docket to receive comments on this topic.

*Date and Time:* The public workshop will be held on July 18, 2013, from 9

a.m. to 3 p.m. Individuals who wish to attend, participate in, or view the free Webcast of the public workshop must register by 5 p.m. EDT on June 21, 2013. Submit either electronic or written comments to the docket by August 19, 2013.

*Location:* The public workshop will be held at 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373.

*Contact Person:* Karen M. Templeton-Somers, Office of Science, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850, 1-877-287-1373, FAX: 240-276-3655, email: [workshop.CTPOS@fda.hhs.gov](mailto:workshop.CTPOS@fda.hhs.gov).

*Registration to Attend the Workshop:* If you wish to attend the workshop, make an oral presentation at the workshop, or view the free Webcast, you must register by submitting an electronic or written request by 5 p.m. EDT on June 21, 2013. Submit electronic requests to <http://www.surveymonkey.com/s/HWY9KNC>. A confirmation email will be sent to your registered email address at least 2 weeks prior to the workshop date. Those without email access may register by contacting Karen M. Templeton-Somers (see *Contact Person*). Registration is free, but early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Onsite registration on the day of the workshop will be based on space availability. CTP plans to provide a free-of-charge, live Webcast of the workshop. Please note that the Webcast link will not be live until the meeting begins at approximately 9 a.m. EDT on July 18, 2013. If registration reaches maximum capacity, FDA will post a notice closing registration for the workshop at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm>.

*Requests for Oral Presentations:* If you wish to make an oral presentation, please state your intention on your registration submission and submit your name, title, company or organization (if applicable), address, telephone number, and email address. FDA has included specific topics for discussion in section II of this document. You should identify by number each discussion topic(s) you wish to address in your presentation, and the approximate desired length of your presentation. FDA is interested in obtaining input from a range of stakeholders and interested parties, including, but not limited to, large and small pharmaceutical manufacturers experienced with electronic Common Technical Document (eCTD); vendors of

software used to support electronic submissions; and large and small tobacco product manufacturers. Individuals and organizations with common interests are urged to coordinate their presentations or request time for a joint presentation. All requests to make oral presentations must be received by the close of registration at 5 p.m. EDT on June 21, 2013. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by June 28, 2013. Presenters must submit any presentation materials to Karen M. Templeton-Somers (see *Contact Person*) via email no later than July 10, 2013. FDA will do its best to accommodate questions during the workshop, although questions from the audience may be limited. In addition, we strongly encourage submitting comments to the docket (see *Comments*).

If you need special accommodations because of disability, please contact Karen M. Templeton-Somers (see *Contact Person*) at least 7 days before the workshop.

*Comments:* Regardless of attendance at the public workshop, interested persons may submit comments on any of the topics for discussion in section II of this document by August 19, 2013. Submit electronic comments 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. 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, and will be posted to the docket at <http://www.regulations.gov>.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background and Workshop Topics**

The purpose of this workshop is to obtain public input from regulated industry and other stakeholders and interested parties on the potential development and implementation of a standardized structure for electronic submission of tobacco product applications and other information. Stakeholders and interested parties could include, but are not limited to, large and small pharmaceutical manufacturers with experience in electronic submissions; vendors of software used to support electronic

submissions; and large and small tobacco product manufacturers. The workshop will focus on technical aspects related to electronic submissions and standards currently used in other FDA centers. The types of submissions potentially subject to any future electronic submission standard may include, but are not limited to, applications for premarket review of new tobacco products (section 910(b)(1) of the Federal Food, Drug, and Cosmetic Act) (the FD&C Act) (21 U.S.C. 387j(b)(1)), modified risk tobacco product applications (section 911(d) of the FD&C Act (21 U.S.C. 387k(d)), and reports submitted under section 905(j) of the FD&C Act (21 U.S.C. 387e(j)). In particular, FDA would like to discuss how available standardized submission structure and technologies facilitate preparation, submission, retrieval, processing, review, and archiving of submissions. For more information on study data standards resources, please see <http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>.

The electronic submission workshop will include discussion on eCTD, which is an International Conference on Harmonization (ICH) specification developed by ICH and its member parties. The eCTD provides an organizational structure for regulatory submissions utilizing comprehensive table of contents headings and hierarchy. Other FDA centers have been receiving submissions in the eCTD format since 2003. For more information on eCTD, please see <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm>.

CTP is interested in receiving input at the workshop and in the docket on the potential standardization of electronic tobacco product submissions. The input from the workshop may assist the Agency in developing and implementing a harmonized electronic submission standard at CTP.

##### **II. Workshop Topics for Discussion**

FDA is seeking public input on the following topics:

- How have other regulated industries standardized the structure of submissions to FDA and how has that facilitated the submission and review process? What aspects may be applicable to tobacco product submissions?
- What technologies do tobacco companies currently use to prepare their submissions? Is a document management system used? Are specific technologies used? Is electronic data capture used in clinical trials or other

studies? What systems and standards currently are used to manage data and documents?

- How are data collected and managed for submission to CTP? Is a laboratory information management system used?
- Are there any technical limitations CTP should consider in developing and implementing any harmonized electronic submission standard?
- Would a pilot program designed to test a modified eCTD be useful?

Dated: June 4, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-13532 Filed 6-6-13; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, PAR Panel: Social Neuroscience and Neuroeconomics of Aging.

*Date:* July 2, 2013.

*Time:* 12:30 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Heidi B Friedman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1012A, MSC 7770, Bethesda, MD 20892, 301-379-5632, [hfriedman@csr.nih.gov](mailto:hfriedman@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 3, 2013.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-13510 Filed 6-6-13; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Cardiovascular Sciences.

*Date:* June 26, 2013.

*Time:* 8:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301-435-5575, [hamannkj@csr.nih.gov](mailto:hamannkj@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, Member Conflict: Risk, Prevention and Health Behavior.

*Date:* June 26-27, 2013.

*Time:* 9:30 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, 301-496-0726, [prenticekj@mail.nih.gov](mailto:prenticekj@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 3, 2013.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-13511 Filed 6-6-13; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee, July 10, 2013, 09:00 a.m. to July 10, 2013, 04:00 p.m., National Institutes of Health, 31 Center Drive, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD, 20892 which was published in the **Federal Register** on April 24, 2013, 78FR24225.

The notice is being amended to change the meeting format and time. The meeting will be held as a virtual meeting on July 10, 2013, 10:00 a.m. to 12:00 p.m. The webinar meeting may be viewed at <http://videocast.nih.gov/>. Please note that the meeting is open to the public and you may attend the virtual meeting in person. The meeting will be broadcast from the National Institutes of Health, 31 Center Drive, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Dated: June 4, 2013.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2013-13518 Filed 6-6-13; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Announcement of Foreign-Trade Zones Test

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** General notice.

**SUMMARY:** This notice announces U.S. Customs and Border Protection's ("CBP's") plan to conduct a voluntary general test regarding certain foreign-trade zone ("FTZ" or "zone") activities. Pursuant to the FTZ test, under