

General Function of the Committee: The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex scientific and technical issues important to the FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science, input into the Agency's research agenda, on upgrading its scientific and research facilities, and training opportunities. It will also provide, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on March 4, 2015, from 8:30 a.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503 B and C) Silver Spring, MD 20993-0002. For those unable to attend in person, the meeting will also be Webcast. The link for the Webcast is available at <https://collaboration.fda.gov/sb315/>. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Martha Monser, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3309, Silver Spring, MD 20993-0002, 301-796-4627, martha.monser@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). 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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The Science Board will be provided with a progress report or a final draft report the Commissioner's Fellowship Program Evaluation subcommittee and will hear a progress

report from Science Moving Forward subcommittee. The Science Board will be asked to provide feedback on FDA's public access policy. FDA will seek the Science Board's input regarding approaches to regulatory science training coordination. The Science Board will be provided with a follow up on FDA's activities regarding the re-introduction of bovine heparin and will hear an overview of science-related activities from one of the centers. A recipient of one of the Fiscal Year 2014 Scientific Achievement Awards (selected by the Science Board) will provide an overview of the activities for which the award was given.

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 meeting 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 February 25, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 1:30 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 February 17, 2015. 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 February 18, 2015.

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 Ms. Martha Monser 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: December 23, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-30516 Filed 12-29-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1936]

Electronic Cigarettes and the Public Health; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Tobacco Products, is announcing a public workshop to obtain information on electronic cigarettes and the public health. This will be the second in a series of three workshops. The workshop will include presentations and panel discussions about the current state of the science and will focus on individual health impacts. FDA intends to follow this workshop with an electronic cigarette workshop on population health effects.

DATES AND TIMES: The public workshop will be held on March 9, 2015, from 8 a.m. to 5 p.m. and on March 10, 2015, from 8 a.m. to 5 p.m. Individuals who wish to attend the public workshop must register by February 20, 2015.

LOCATION: The public workshop will be held at the Marriott Inn and Conference Center, University of Maryland University College, Potomac Ballroom, 3501 University Blvd. East, Hyattsville, MD 20783. The conference center's telephone number is 301-985-7300.

CONTACT PERSON: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm.

G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, email: workshop.CTPOS@fda.hhs.gov.

Registration to Attend the Workshop:

If you wish to attend the workshop in person or by Webcast, you must register by submitting an electronic or written request no later than February 20, 2015. Please submit electronic requests at <https://www.surveymonkey.com/s/CTP-March-Workshop>. Persons without Internet access may send written requests for registration to Caryn Cohen (see *Contact Person*). Requests for registration must include the prospective attendee's name, title, affiliation, address, email address if available, and telephone number. Registration is free and you may register to attend in person or view the live Webcast. Seating and viewership are limited, so early registration is recommended. FDA may limit the number of registrants from a single organization and the total number of participants if registration reaches full capacity. For registrants with Internet access, confirmation of registration will be emailed to you no later than February 23, 2015. Onsite registration may be allowed if space is available. If registration reaches maximum capacity, FDA will post a notice closing registration at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm>. If you need special accommodations due to a disability, please contact Caryn Cohen (see *Contact Person*) no later than March 2, 2015.

Presenters and Panelists: FDA is interested in gathering scientific information from individuals with a broad range of backgrounds on the scientific topics to be discussed at the workshop. To be considered as a presenter, please provide the following:

- A brief abstract for each presentation. The abstract should identify the specific topic(s) to be addressed and the amount of time requested.
- A one page biosketch that describes and supports the speaker's scientific expertise on the specific topic(s) being presented, nature of the individual's experience and research in the scientific field, positions held, and any program development activities.

Panelists will discuss their scientific knowledge on the questions and presentations in each session. To be considered to serve as a panelist, please provide the following:

- A one page biosketch that describes and supports the speaker's scientific expertise on the specific topic(s) being presented, nature of the individual's experience and research in the scientific

field, positions held, and any program development activities.

If you are interested in serving as a presenter or panelist, please submit the requested information, along with the topic on which you would like to speak, to workshop.CTPOS@fda.hhs.gov by January 22, 2015.

Oral Presentations by Members of the Public: This workshop includes a public comment session. Persons wishing to present during the public comment session must make this request at the time of registration and should identify the topic they wish to address from among those topics under consideration that are identified in section II. FDA will do its best to accommodate requests to present. FDA urges individuals and organizations with common interests to consolidate or coordinate their comments, and request a single time for a joint presentation. For those requesters with Internet access, Caryn Cohen (see *Contact Person*) will email you regarding your request to speak during the public comment period by February 23, 2015.

Transcripts: A transcript of the proceedings will be available after the workshop at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm> as soon as the official transcript is finalized. It will also be posted to the docket at <http://www.regulations.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop to gather scientific information and stimulate discussion among scientists about electronic cigarettes (e-cigarettes). The focus of this workshop will be the impact of e-cigarettes on individual health, including user exposure, topography, abuse liability, dependence, and short and long-term health effects. A workshop focusing on product science, product packaging, constituent labeling, and environmental impact was held in December 2014. FDA intends to follow this workshop with an additional workshop that will address the impact of e-cigarettes on the population, including discussions of product appeal (e.g., impact of advertising, marketing, flavorings, consumer perceptions) and product safety labeling.

On April 25, 2014, FDA published a proposed rule to extend its tobacco product authorities to additional products that meet the statutory definition of "tobacco product" "Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act), as Amended

by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (79 FR 23141, April 25, 2014, Docket No. FDA-2014-N-0189) (proposed deeming rule). If the proposed deeming rule is finalized as proposed, e-cigarettes that are tobacco products would be subject to FDA regulation under the FD&C Act. As stated in the proposed deeming rule, FDA "is aware of the recent significant increase in the prevalence in e-cigarette use" (79 FR 23141 at 23152), and there is much to be learned about these relatively new entrants to the market.

These workshops are intended to better inform FDA about these products. Should the Agency move forward as proposed to regulate e-cigarettes, additional information about the products would assist the Agency in carrying out its responsibilities under the law. This would be true regardless of the details of any such final rule. Accordingly, FDA is working to obtain such information now rather than waiting for the conclusion of the deeming rulemaking.

Participants should note that this workshop is not intended to inform the Agency's deeming rulemaking. All comments regarding the proposed deeming rule were to be submitted to the Agency by August 8, 2014 (Docket No. FDA-2014-N-0189). As such, the scope of this workshop is limited to the topics presented in Section II.

At the start of the first workshop in this series, FDA announced via a **Federal Register** notice the opening of a docket for submission of written comments regarding all three workshops (see Establishment of a Public Docket; Electronic Cigarettes and the Public Health Workshop, Docket No. FDA-2014-N-1936, <http://www.gpo.gov/fdsys/pkg/FR-2014-12-02/pdf/2014-28261.pdf>). Regardless of attendance at the public workshops, interested persons are invited to submit comments to the docket. Comments submitted to the docket will not be added to other dockets, such as the docket for the proposed rule deeming additional tobacco products subject to the FD&C Act.

II. Topics for Discussion

The public workshop will include presentations and panel discussion regarding e-cigarettes and the public health, specifically relating to the impact of e-cigarettes on individual health. Topics to be addressed include, for example: (1) Topography; (2) exposures and toxicological considerations; (3) pharmacokinetics

and pharmacodynamics of nicotine exposure in users; (4) abuse liability and dependence; (5) short and long-term health effects in users; (6) considerations for high risk or vulnerable populations; and (7) human factors. Additional information related to workshop presentations and discussion topics, including specific questions to be addressed at the workshop, can be found at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm238308.htm>.

Dated: December 22, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding Is Sought 42 CFR Part 50 Subpart F and Responsible Prospective Contractors 45 CFR Part 94 (OD)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director (OD), National Institutes of Health (NIH), will publish

periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To submit comments and for further information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Kathy Hancock, Assistant Grants Compliance Officer, Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration (OPERA), 6705 Rockledge Drive, Room 3523, Bethesda, MD 20892, or call non-toll-free number (301) 435-1962, or Email your request, including your address to: FCOICompliance@

mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

DATES: *Comment 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.

Proposed Collection: Title: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought 42 CFR part 50 Subpart F and Responsible Prospective Contractors 45 CFR part 94 OMB# 0925-0417, Expiration Date: 02/2015, EXTENSION, National Institutes of Health (NIH), Office of the Director (OD).

Need and Use of Information Collection: This is a request for OMB Approval for an extension of the information collection and recordkeeping requirements contained in the final rule 42 CFR part 50, subpart F and 45 CFR part 94. The purpose of these regulations is to promote objectivity in research by requiring institutions to establish standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under PHS grants, cooperative agreements and contracts will be free from bias resulting from Investigator financial conflicts of interest.

OMB approval is requested for an extension of 3 years. There are operating costs and/or maintenance costs per response. The total estimated annualized burden hours are 676,130.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent based on applicable section of regulation	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Reporting				
Initial Reports under 42 CFR 50.605(b)(1) and (b)(3) or 45 CFR 94.5(b)(1) and (b)(3) from Awardee Institutions	950	1	2	1,900
Subsequent Reports under 42 CFR 50.605(a)(3)(iii) and (b)(2) or 45 CFR 94.5(a)(iii) and (b)(2) from Awardee Institutions	50	1	2	100
Mitigation Reports under 45 CFR 94.5(a)(3)(iii) and (b)(2) from Awardee Institutions	5	1	2	10
Annual Report under 42 CFR 50.605(b)(4) or 45 CFR 94.5(b)(4) from Awardee Institution	950	1	1	950
Subsequent Reports under 42 CFR 60.606(a) or 45 CFR 94.6(a) from Awardee Institution	20	1	10	200
Record Keeping				
Under 42 CFR 50.604(i) or 45 CFR 94.4(i) from Awardee Institutions	2,000	1	4	8,000
Disclosure				
Under 42 CFR 50.604(a) or 45 CFR 94.4(a) for Investigators	3,000	1	81	243,000
Under 42 CFR 50.604(b) or 45 CFR 94.4(b) for Investigators	38,000	1	30/60	19,000
Under 42 CFR 50.604(b) or 45 CFR 94.4(b) for Institutions	2,000	1	6	12,000