

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

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

Survey type	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
In-depth Interviews, Cognitive Interviews Screener	45	1	45	0.083 (5 minutes) .....	4
In-depth Interviews, Cognitive Interviews .....	9	1	9	1 .....	9
In-depth Interviews Screener .....	900	1	900	0.083 (5 minutes) .....	75
In-depth Interviews .....	180	1	180	1 .....	180
Survey Cognitive Interviews Screener .....	45	1	45	0.083 (5 minutes) .....	4
Survey Cognitive Interviews .....	9	1	9	1 .....	9
Pretest survey screener .....	750	1	750	0.083 (5 minutes) .....	62.25
Pretest survey .....	150	1	150	0.25 (15 minutes) .....	38
Self-Administered Surveys—Study Screener .....	75,000	1	75,000	0.083 (5 minutes) .....	6,225
Self-Administered Surveys .....	15,000	1	15,000	0.25 (15 minutes) .....	3,750
Focus Group/Small Group, Cognitive Groups Screener.	180	1	180	0.083 (5 minutes) .....	15
Focus Group/Small Group, Cognitive Groups .....	60	1	60	1.5 (90 minutes) .....	90
Focus Group/Small Group Participant Screening ...	720	1	720	0.083 (5 minutes) .....	60
Focus Group/Small Group Discussion .....	240	1	240	1.5 (90 minutes) .....	360
Total .....					10,881.25

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

This is a new collection of information whose total estimated annual burden is 10,881.25 hours. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new individual survey will vary, depending on the nature of the compliance efforts and the target audience.

Dated: March 28, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-1107]

#### Youth Tobacco Cessation: Science and Treatment Strategies; Public Scientific Workshop; Request for Comments

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

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

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public scientific workshop entitled “Youth Tobacco Cessation: Science and Treatment Strategies.” The purpose of the workshop is to discuss the unique

challenges associated with youth tobacco addiction and cessation, and the current science regarding youth tobacco use and addiction as well as treatment strategies to support youth tobacco cessation.

**DATES:** The public scientific workshop will be held on May 15, 2019, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this workshop by May 31, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public scientific workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993-0002. Entrance for public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 31, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 31, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the

delivery service acceptance receipt is on or before that date.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and

Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA–2019–N–1107 for “Youth Tobacco Cessation: Science and Treatment Strategies.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Allison Hoffman, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3138, Silver Spring, MD 20993, 301–796–9203, [OMPTFeedback@fda.hhs.gov](mailto:OMPTFeedback@fda.hhs.gov) (please use “Youth Tobacco workshop” as the subject line).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Nearly all tobacco product use begins during youth and young adulthood (Ref. 1). In 2017–2018, there was an alarming increase in tobacco product use among adolescents, primarily driven by e-cigarette use (Refs. 2 and 3). Youth tobacco use raises a number of health concerns including risk of addiction to nicotine early on in life, potential harm to the developing adolescent brain, and exposure to chemicals, including carbonyl compounds and volatile organic compounds known to have adverse health effects. The full range of possible health effects is not yet completely understood (Ref. 4).

On April 24, 2018, FDA announced its Youth Tobacco Prevention Plan.<sup>1</sup> This plan focuses on three key strategies: Prevention of youth access to tobacco products, curbing the marketing of tobacco products aimed at youth, and educating teens about the dangers of using any tobacco products, as well as educating retailers about their key role in protecting youth.<sup>2</sup> FDA recently launched an expansion of its “The Real Cost” campaign to educate youth on the dangers of e-cigarette use<sup>3</sup> and increased enforcement actions to address this critically important public health concern.<sup>4</sup>

In addition to the prevention of initiation, which will be the cornerstone of any successful effort to curb youth tobacco use, FDA is also exploring additional approaches to address this issue. On January 18, 2019, FDA held an open public hearing entitled “Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies,”<sup>5</sup> which requested information on the potential role of drug therapies to support cessation and the issues impacting the development of such therapies for

youth. FDA appreciates that youth have unique challenges when it comes to addiction and cessation, and that they may respond differently to treatments as compared to adults.

The challenge of developing evidence in pediatric populations exists in many therapeutic areas. FDA is committed to addressing this issue. Therefore, FDA has issued grants to the Institute for Advanced Clinical Trials for Children (I–ACT for Children) and the Duke Clinical Research Institute (DCRI) to establish a Global Pediatric Clinical Trials Network to facilitate clinical trials of new drugs and devices for children. As a part of this work, I–ACT for Children and DCRI are hosting this public scientific workshop, in collaboration with FDA, to facilitate the development of evidence to support youth tobacco cessation efforts, and will result in a written report. This scientific workshop intends to explore many of the scientific issues brought up during the recent public hearing on this topic.

##### II. Topics for Discussion at the Public Scientific Workshop

This public scientific workshop will gather scientific information and stimulate discussion about the current science regarding youth tobacco use and addiction, and treatment strategies to support youth tobacco cessation with a focus on e-cigarette cessation. This is because e-cigarettes are the tobacco products most commonly used by youth (Ref. 5) and there continues to be a rampant rise in use. According to data from the FDA/CDC 2018 National Youth Tobacco Survey, more than 3.6 million middle and high school students were current e-cigarettes users in 2018, representing a substantial increase of more than 1.5 million students in one year (Ref. 3). Furthermore, data recently published in JAMA Network Open showed that youth e-cigarette users are more likely to transition to conventional cigarettes, as compared to non-users (Ref. 6). The workshop is intended to explore the challenges of treating youth tobacco addiction and promoting cessation. In particular, the workshop will highlight differences in treatment strategies needed in youth as opposed to adults. The workshop will include presentations and panel discussions regarding substantive scientific information specifically relating to the unique factors impacting youth tobacco use and addiction and challenges associated with youth tobacco cessation. Topics to be addressed include (1) the basic science of tobacco addiction in adolescents, (2) current state of behavioral and pharmacotherapy cessation strategies in adolescents (e.g.,

<sup>1</sup> <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm605432.htm>.

<sup>2</sup> <https://www.fda.gov/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm608433.htm>.

<sup>3</sup> <https://www.fda.gov/tobaccoproducts/publichealtheducation/publiceducationcampaigns/therealcostcampaign/default.htm>.

<sup>4</sup> <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620788.htm>.

<sup>5</sup> <https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm620744.htm>.

clinical trial experience to date, use of technology and social media, impact of social factors), and (3) the development of strategies to generate robust evidence to address youth tobacco cessation (e.g., clinical trial design, measures of adolescent addiction, selection of endpoints, subpopulation and comorbidity considerations, and patient recruitment and retention). Presenters may include, but are not limited to, staff from FDA's Center for Tobacco Products, FDA's Center for Drug Evaluation and Research, industry, and academia. There will be opportunities for the audience to ask questions during this workshop.

### III. Participating in the Public Scientific Workshop

**Registration:** To register for the public scientific workshop, please visit the following website by May 13, 2019: <https://youth-tobacco-cessation.eventbrite.com>. Please provide complete contact information for each attendee, including name, affiliation, and email address.

Registration is free and based on space availability. Persons interested in attending this workshop must register by May 13, 2019, 5 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. You may choose not to register, however seating is limited, and space will be available on a first-come, first-served basis.

If you need special accommodations because of a disability, please contact Allison Hoffman (see **FOR FURTHER INFORMATION CONTACT**) no later than May 8, 2019.

Persons attending FDA's meetings are advised that the Agency is not responsible for providing access to electrical outlets.

**Streaming Webcast of the Public Scientific Workshop:** This public scientific workshop will also be webcast. To register for the streaming webcast of the workshop, please visit the following website by May 13, 2019: <https://youth-tobacco-cessation.eventbrite.com>.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document

publishes in the **Federal Register**, but websites are subject to change over time.

### IV. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. U.S. Department of Health and Human Services (2014). "The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General, 2014." Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. (Available at: <https://www.surgeongeneral.gov/library/reports/50-years-of-progress/index.html>.)
2. Cullen, K.A., B.K. Ambrose, A.S. Gentzke, et al. (2018). "Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011–2018." *MMWR Morbidity and Mortality Weekly Report*, 67:1276–1277. DOI: <http://dx.doi.org/10.15585/mmwr.mm6745a5>. (Available at: <https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm>.)
3. Gentzke, A.S., M. Creamer, K.A. Cullen, et al. (2019). "Vital Signs: Tobacco Product Use Among Middle and High School Students—United States, 2011–2018." *MMWR Morbidity and Mortality Weekly Report*, 68:157–164. DOI: <http://dx.doi.org/10.15585/mmwr.mm6806e1>. (Available at: <https://www.cdc.gov/mmwr/volumes/68/wr/mm6806e1.htm>.)
4. U.S. Department of Health and Human Services (2016). "E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General." Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health. (Available at: [https://e-cigarettes.surgeongeneral.gov/documents/2016\\_sgr\\_full\\_report\\_non-508.pdf](https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf).)
5. Wang, T.W., A. Gentzke, S. Sharapova, et al. (2018). "Tobacco Product Use Among Middle and High School Students—United States, 2011–2017." *Morbidity and Mortality Weekly Report (MMWR)* 67:629–633. DOI: <https://doi.org/10.15585/mmwr.mm6722a3> (Available at <https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a3.htm>.)
6. Berry, K.M., J.L. Fetterman, E.J. Benjamin, et al. (2019). "Association of Electronic Cigarette Use With Subsequent Initiation of Tobacco Cigarettes in US Youths."

JAMA Netw Open 2(2):e187794. DOI: <https://doi.org/10.1001/jamanetworkopen.2018.7794> (Available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723425>.)

Dated: March 27, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–D–2032]

### Limited Population Pathway for Antibacterial and Antifungal Drugs; Public Meeting; Request for Comments

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

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

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled "Limited Population Pathway for Antibacterial and Antifungal Drugs." The purpose of the meeting is to provide a public forum for FDA to listen to comments on the draft guidance for industry, "Limited Population Pathway for Antibacterial and Antifungal Drugs," that was published in the **Federal Register** on June 13, 2018. FDA is also reopening the comment period on this draft guidance for comments to be submitted for consideration before we finish work on the final version of the guidance.

**DATES:** The public meeting will be held on July 12, 2019, from 9 a.m. to 3 p.m. Eastern Time. Submit either electronic or written comments by August 12, 2019, to ensure that the Agency considers your comments on the draft guidance before it finishes work on the final version of the guidance. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503A (the Great Room), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.