

recruited through the same internet panel as used for the pretests. Participants will complete the screener questionnaire through an email invitation. This brief screening will take an average of 2 minutes (0.03 hours) per respondent. If, based on this screening, participants qualify for the study, they will be directed to begin Session 1. Recent national estimates of the numbers of adolescent current cigarette smokers, adolescents who are susceptible to initiation of cigarette smoking, young adult current cigarette smokers, and older adult current cigarette smokers informed the estimates of 14.6 percent qualification rate for adults and 7.8 percent qualification rate for adolescents. Applying these estimates and other assumptions from previous experience conducting similar studies to the number of adolescents and adults to be screened results in the desired sample size for the main data collection of 9,760 participants, of which 7,460 will be adults and 2,300 will be adolescents. The three sessions of the main data collection will take an average of 12 minutes (0.20 hours) for Session 1, 8 minutes (0.13 hours) for Session 2, and 5 minutes (0.08 hours) for Session 3, for a total of an estimated 25 minutes (0.42 hours) per respondent. The total estimated burden for the data collection is 6,561 hours (4,692 hours for adults + 1,869 hours for adolescents).

II. References

The following references are on display at 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>.

1. Murphy, S.L., J. Xu, K.D. Kochanek. "Deaths: Final Data for 2010". *National Vital Statistics Reports*, 61(4):37–41, 2013.
2. U.S. Department of Health and Human Services. "The Health Consequences of Smoking: 50 Years of Progress. 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; 2014.
3. Jamal, A., E. Phillips, A.S. Gentzke, et al. "Current Cigarette Smoking Among Adults—United States, 2016". *MMWR Morbidity and Mortality Weekly Report*, 67:53–59, 2018.
4. Centers for Disease Control and Prevention. "Cigarette Smoking—Attributable Morbidity—United States, 2000". *MMWR Morbidity and Mortality Weekly Report*, 52(35):842–844, 2003

5. Substance Abuse and Mental Health Services Administration (SAMHSA). See Table 4.10A in "2016 National Survey on Drug Use and Health: Detailed Tables." Rockville, MD: U.S. Department of Health and Human Services, SAMHSA, Center for Behavioral Health Statistics and Quality; 2017.

Dated: September 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3504]

Tobacco Product Application Review; 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) is announcing a public meeting entitled "Tobacco Product Application Review." This meeting is intended to improve public understanding and provide FDA feedback on the policies and processes for submitting and reviewing tobacco product marketing applications, including the general scientific principles relevant to various application pathways, to assist those considering submitting marketing applications for tobacco products under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The 2-day public meeting will be held on October 22, 2018, from 8:30 a.m. to 4:30 p.m. and on October 23, 2018, from 8:30 a.m. to 3 p.m. Submit either electronic or written comments on this public meeting by December 7, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852, <https://www3.hilton.com/en/hotels/maryland/hilton-washington-dc-rockville-hotel-and-executive-meeting-ctr-IADMRHF/index.html>.

You may submit comments as follows. Please note that late, untimely filed comments may not be considered. The <https://www.regulations.gov> electronic filing system will accept electronic comments until 11:59 p.m. Eastern Time on December 7, 2018.

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 December 7, 2018.

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–2018–N–3504 for "Tobacco Product Application Review." Received comments, 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: Darin Achilles, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 877-287-1373, email: ctpregulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public meeting to improve public understanding and provide FDA feedback on the policies and processes for submitting and reviewing tobacco product marketing applications, including the general scientific principles relevant to various application pathways, to assist those considering submitting marketing applications for tobacco products under the FD&C Act. FDA will present information about the tobacco product application review programs, including

process improvements and observations that may inform further improvements in submissions and review processes. The meeting will include panels of FDA representatives, regulated industry representatives, and other stakeholders, and FDA will seek feedback from the public. This meeting is not intended to communicate any new policies or interpretations regarding tobacco product marketing applications and their review.

FDA expects that parties interested in attending this meeting include, but are not limited to, tobacco product manufacturers, including small business tobacco manufacturers, importers, distributors, wholesalers, and retailers; scientific and medical experts; Federal, State, and local government Agencies; and other interested stakeholders, such as academic researchers and public health organizations.

In addition to the public meeting, FDA is opening a docket as another mechanism to receive feedback on the tobacco product application review process. Timely comments are appreciated to help inform FDA's efforts to continue to build an efficient product review program. FDA is open to receiving feedback and comments on all aspects of the product review process and is requesting specific comment on the following topics:

- Achieving greater efficiencies in review while continuing to protect public health
 - Improving application content
 - Streamlining review processes
 - Refining electronic submission systems
- Reviewing applications for products that are rendered "new" due to changes made to comply with a product standard
- Facilitating applicant consultation with FDA prior to submitting applications
 - Types of questions that would benefit from FDA feedback
 - Meeting request and package content
 - Process from meeting request through post-meeting minutes
- Transparent review process
 - Aspects that are highly transparent
 - Aspects that are not highly transparent
 - Approaches to increase transparency
- Clarity and utility of information provided by FDA to applicants
 - Means of communicating information to applicants
 - Information that is most useful to applicants
 - Timeliness of communication

II. Topics for Discussion at the Public Meeting

Topics to be addressed in the meeting include:

- An overview of the tobacco product marketing application types, including Substantial Equivalence Reports, Substantial Equivalence Exemption Requests, Premarket Tobacco Product Applications, and Modified Risk Tobacco Product Applications;
- Information required and that FDA recommends be included in a tobacco product marketing application;
- Administrative processes involved in the submission and review of a tobacco product marketing application; and
- Other topics relevant to tobacco product marketing applications, including tobacco product master files, meeting requests, grandfathered tobacco product review, and environmental assessments.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please submit electronic registration requests at https://www.surveymonkey.com/r/FDACTPTobacco_Product_Application_Meeting. Requests for registration must include the prospective attendee's name, title, affiliation, and contact information.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting should register by 11:59 p.m. Eastern Time on October 5, 2018. 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. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. If registration reaches maximum capacity, FDA will post a notice closing registration at <https://www.fda.gov/TobaccoProducts/NewsEvents/default.htm>.

If you need special accommodations because of disability, please email Workshop.CTPOS@fda.hhs.gov or call 1-877-287-1373 (Option 5) at least 7 days before the meeting.

Streaming Webcast of the Public Meeting: There will be a webcast for this public meeting. If you would like to attend the meeting via webcast, please submit electronic requests to register at https://www.surveymonkey.com/r/FDACTPTobacco_Product_Application_Meeting. Requests for registration must include the prospective attendee's name, title, affiliation, and contact information.

Archived Webcast and Transcripts: Please be advised that FDA will post the webcast along with complete transcripts on the internet at <https://www.fda.gov/TobaccoProducts/NewsEvents/default.htm> as soon as they are available.

Dated: September 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-4317]

Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.” Specifically, this guidance sets forth FDA’s policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities, and it describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals.

DATES: The announcement of the guidance is published in the **Federal Register** on September 26, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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://](https://www.regulations.gov)

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-2016-D-4317 for “Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.” Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD, 301-796-3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities; Guidance for Industry.” In 2013, the Drug Quality and Security Act created a new section, 503B, of the FD&C Act (21 U.S.C. 353b), which describes a new category of compounders called *outsourcing facilities*. Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in