For consistency and accuracy, we have adjusted the respondent estimates for all the ICs from OMB control number 0910–0437, including those that are not affected by the Voluntary Malfunction Summary Reporting Program, to reflect more recent data from calendar year (CY) 2016 (the currently approved estimates are based on CY 2006–2009 data). This adjustment, along with the revisions for the Voluntary Malfunction Summary Reporting Program increases the estimated total burden of OMB control number 0910–0437 by 21,532 hours (currently approved for 46,446 hours; requesting 67,978 hours).

We have added the new burden estimate for the Voluntary Malfunction Summary Reporting Program. This increases the reporting burden estimate by 6,755 hours.

We have revised the burden estimates for ''Manufacturer Reporting'' and ''Supplemental Reports'' to update the respondent estimates using more recent data, as described above, and to reflect the revisions resulting from the availability of the Voluntary Malfunction Summary Reporting Program. We believe the availability of the summary reporting option for manufacturers of certain devices would cause a decrease in the number of individual manufacturer reports for malfunctions submitted under §§ 803.50 and 803.52. However, because we also adjusted the respondent estimates for the ICs using more recent data from CY 2016, the estimated burden for these ICs is an increase of 12,139 hours from the currently approved burden estimates (the previous estimate based on CY 2006–2008 data was 35,166 hours for these ICs only). We attribute the increase to the increase in the number of submissions we received in recent years, rather than the revisions related to the Voluntary Malfunction Summary Reporting Program.

Dated: June 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12336 Filed 6–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1881]

Development of Inhaled Antibacterial Drugs for Cystic Fibrosis and Non-Cystic Fibrosis Bronchiectasis; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Development of Inhaled Antibacterial Drugs for Cystic Fibrosis and Non-Cystic Fibrosis Bronchiectasis.'' The purpose of the public workshop is to discuss the clinical trial design challenges and future considerations for inhaled antibacterial products to treat cystic fibrosis (CF) and non-CF bronchiectasis.

DATES: The public workshop will be held on June 27, 2018, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this public workshop by July 16, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the 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 July 16, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time on July 16, 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 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–2018–N–1881 for ''Development of Inhaled Antibacterial Drugs for Cystic Fibrosis and Non-Cystic Fibrosis Bronchiectasis.'' 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: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop regarding the development of inhaled antibacterial drugs for CF and non-CF bronchiectasis. As such, discussions will focus on challenges and potential paths forward for inhaled antibacterial drugs pertaining to CF and non-CF bronchiectasis.

II. Topics for Discussion at the Public Workshop

FDA is particularly interested in discussing challenges and considerations regarding CF and non-CF bronchiectasis. Discussions are planned around the following topics for each of the disease areas:

- Trial design challenges
- Trial endpoints
- Trial populations, duration of therapy, duration of microbiologic testing and followup
- Device considerations

The Agency encourages health care providers, other U.S. Government Agencies, academic experts, industry, and other stakeholders to attend this public workshop.

III. Participating in the Public Workshop

Registration: Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by June 11, 2018, midnight Eastern Time. To register, please email complete contact information for each attendee, including name, title, affiliation, address, email, and telephone to *InhaledAntibacterialsWorkshop2018@fda.hhs.gov.*

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 workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see **FOR FURTHER INFORMATION CONTACT**) no later than June 19, 2018.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we 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 19, 2018. All requests to make oral presentations must be received by the close of registration on June 15, 2018. If selected for presentation, any presentation materials must be emailed to *InhaledAntibacterialsWorkshop2018@fda.hhs.gov* no later than June 21, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the public workshop: This public workshop will also be webcast at the following site: *https://collaboration.fda.gov/inhaledantibacterials/.*

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.* To get a quick overview of the Connect Pro program, visit *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.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/FDAgov/Drugs/NewsEvents/ucm602331.htm.*

Dated: June 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12341 Filed 6–7–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0529]

Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability (NOA) that appeared in the **Federal Register** of March 16, 2018. In the NOA, FDA requested public comment on the draft concept paper regarding the potential for illicit trade markets to develop in response to a tobacco product standard. The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the NOA published March 16, 2018 (83 FR 11754). Submit either electronic or written comments by July 16, 2018.