workshop-06232021-06232021. Registration may be performed at any time before or during the workshop.

Requests for Oral Presentations: During online registration you may indicate if you wish to present your public comments. Public comment presentation requests must be submitted by 11:59 p.m. Eastern Time at the end of April 30, 2021. 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 workshop. Following the close of registration on April 30, 2021, at 11:59 p.m. Eastern Time, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin; we will select and notify participants by May 21, 2021. All requests to make oral presentations must be received by the close of registration on April 30, 2021. If selected for presentation, any presentation materials must be emailed to *GDUFARegulatoryScience@fda.hhs.gov* no later than June 18, 2021, 11:59 p.m. Eastern Time. 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 be webcast. Please register online (as described above) to attend the workshop remotely. Unless scheduled to participate in advance, attendees will not be able to speak or make presentations during the public comment period or during any other session of the workshop. To join the workshop via the webcast, please go to *https://www.fda.gov/drugs/news-events-human-drugs/fy-2021-generic-drug-science-and-research-initiatives-public-workshop-06232021-06232021.*

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: As soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov* or at *https://www.fda.gov/gdufaregscience.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). Closed caption scrolling text will be generated by the Adobe Connect system and displayed in real time. The closed caption scrolling text will also display when streaming the recorded presentations for viewing at a later date.

Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06096 Filed 3–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1862]

The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Public Meeting; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice entitled ''The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Public Meeting; Request for Comments'' that appeared in the **Federal Register** of October 28, 2020. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice published on October 28, 2020 (85 FR 68342). Submit either electronic or written comments by June 22, 2021 to ensure that the Agency considers your comment.

ADDRESSES: 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 June 22, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 22, 2021. 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–2020–N–1862 for ''The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security; Public Meeting; Reopening of Comment Period.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Kristle Green, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3130, *CDERODSIRPublicMeetings@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 28, 2020 (85 FR 68342), FDA published a notice with a 60-day comment period to announce and request comments on a virtual public meeting entitled ''The Drug Supply Chain Security Act Pilot Project Program and Enhanced Drug Distribution Security'' held on December 8 and 9, 2020. FDA is reopening the comment period until June 22, 2021.

The Agency believes that an additional 90 days will allow adequate time for interested persons to submit comments. Materials from the public meeting are on FDA's website at *https://www.fda.gov/drugs/news-events-human-drugs/drug-supply-chain-security-act-pilot-project-program-and-enhanced-drug-distribution-security.*

Dated: March 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06053 Filed 3–23–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–M–3841, FDA–2018–M–3842, FDA–2018–M–3983, FDA–2018–M–4033, FDA–2018–M–4205, FDA–2018–M–4580, FDA–2018–M–4582, FDA–2018–M–4665, FDA–2018–M–4777, FDA–2018–M–4778, FDA–2018–M–4779, FDA–2018–M–4780, FDA–2018–M–4916, FDA–2019–M–0027, FDA–2019–M–0028, FDA–2019–M–0505, FDA–2019–M–0645, FDA–2019–M–0802, FDA–2019–M–0885, FDA–2019–M–0995, FDA–2019–M–1214, FDA–2019–M–1251, FDA–2019–M–1310, FDA–2019–M–1313, FDA–2019–M–1465, FDA–2019–M–1506, FDA–2019–M–1582, FDA–2019–M–1763, FDA–2019–M–1848, FDA–2019–M–1979, FDA–2019–M–1998, FDA–2019–M–2052, FDA–2019–M–2193, FDA–2019–M–2408, FDA–M–2522, FDA–2019–M–2560, FDA–2019–M–2561, FDA–2019–M–2671, FDA–2019–M–2732, FDA–2019–M–2753, FDA–2019–M–2782, FDA–2019–M–3309, FDA–2019–M–3513, FDA–2019–M–3652, FDA–2019–M–3845, FDA–2019–M–3863, FDA–2019–M–3844, FDA–2019–M–4007, FDA–2019–M–4153, FDA–2019–M–4186, FDA–2019–M–4238, FDA–2019–M–4928, FDA–2019–M–4978, FDA–2019–M–5393, FDA–2019–M–5438, FDA–2019–M–5534, FDA–2019–M–5605, FDA–2019–M–5683, FDA–2019–M–5741, FDA–2019–M–5857, FDA–2019–M–5961, FDA–2020–M–0097, FDA–2020–M–0107, FDA–2020–M–0108, FDA–2020–M–0495, FDA–2020–M–0985, FDA–2020–M–0984, FDA–2020–M–0986, FDA–2020–M–1083, FDA–2020–M–1115, FDA–2020–M–1116, FDA–2020–M–1175, FDA–2020–M–1213, FDA–2020–M–1214, FDA–2020–M–1267, FDA–2020–M–1286, FDA–2020–M–1290, FDA–2020–M–1299, FDA–2020–M–1300, FDA–2020–M–1311, FDA–2020–M–1358, FDA–2020–M–1367, FDA–2020–M–1410, FDA–2020–M–1420, FDA–2020–M–1527, FDA–2020–M–1583, FDA–2020–M–1600, FDA–2020–M–1612, FDA–2020–M–1613, FDA–2020–M–1715, FDA–2020–M–1724, FDA–2020–M–1726, FDA–2020–M–1748, FDA–2020–M–1752, FDA–2020–M–1760, FDA–2020–M–1821, FDA–2020–M–1783, FDA–2020–M–1822, FDA–2020–M–1828, FDA–2020–M–1830, FDA–2020–M–1829, FDA–2020–M–1835, FDA–2020–M–1838, FDA–2020–M–1868, FDA–2020–M–1986, FDA–2020–M–2021, FDA–2020–M–2288, FDA–2020–M–2248, and FDA–2020–M–2339]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing a list of premarket approval applications (PMAs) that have been approved from October 1, 2018, through December 31, 2020. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the internet and the Agency's Dockets Management Staff.

ADDRESSES: You may submit comments 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://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 Nos. FDA–2018–M–3841, FDA–2018–M–3842, FDA–2018–M–3983, FDA–2018–M–4033, FDA–2018–M–4205, FDA–2018–M–4580, FDA–2018–M–4582, FDA–