2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* January 3, 2019. FDA has verified the applicant's claims that the new drug application (NDA) for INREBIC (NDA 212327) was initially submitted on January 3, 2019.

3. *The date the application was approved:* August 16, 2019. FDA has verified the applicant's claims that NDA 212327 was approved on August 16, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,271 days, 1,523 days or 1,796 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket Nos. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 19, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23388 Filed 10–26–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1021]

Notice to Public of Website Location of Center for Devices and Radiological Health Fiscal Year 2022 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the website location where the Agency will post two lists of guidance documents that the Center for Devices and Radiological Health (CDRH or the Center) intends to publish in fiscal year (FY) 2022. In addition, FDA has established a docket where interested persons may comment on the priority of topics for guidance, provide comments and/or propose draft language for those topics, suggest topics for new or different guidance documents, comment on the applicability of guidance documents that have issued previously, and provide any other comments that could benefit the CDRH guidance program and its engagement with stakeholders. This feedback is critical to the CDRH guidance program to ensure that we meet stakeholders' needs.

DATES: Submit either electronic or written comments by November 26, 2021.

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 December 27, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 27, 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–2012–N–1021 for ''Notice to Public of website Location of CDRH Fiscal Year 2021 Proposed Guidance Development.'' 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: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations on the Medical Device User Fee Amendments of 2012, Title II, Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), FDA agreed to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. Among these commitments included:

- Annually posting a list of priority medical device guidance documents that the Agency intends to publish within 12 months of the date this list is published each fiscal year (the ''A-list''), and
- Annually posting a list of device guidance documents that the Agency intends to publish, as the Agency's guidance-development resources permit each fiscal year (the ''B-list'').

The Medical Device User Fee Amendments of 2017 (MDUFA IV), FDA Reauthorization Act of 2017 (Pub. L. 115–52), maintained these commitments.

In addition, to ensure that final guidance documents continue to provide stakeholders with the Agency's current thinking, CDRH annually conducts a staged review of previously issued final guidances in collaboration with stakeholders. CDRH intends to annually provide lists of previously issued final guidances that are subject to review through FY 2025 so that by 2025, FDA and stakeholders will have assessed the applicability of all guidances older than 10 years. For instance, in the annual notice for FY 2023, CDRH expects to provide a list of the final guidance documents that issued in 2013, 2003, 1993, and 1983; the annual notice for FY 2024 is expected to provide a list of the final guidance documents that issued in 2014, 2004, 1994, and 1984, and so on.

FDA welcomes comments on any or all of the guidance documents on the lists as explained in 21 CFR 10.115(f)(5). FDA has established Docket No. FDA–2012–N–1021 where comments on the FY 2022 lists, draft language for guidance documents on those topics, suggestions for new or different guidances, and relative priority of guidance documents may be submitted and shared with the public (see **ADDRESSES**). FDA believes this docket is a valuable tool for receiving information from interested persons. FDA anticipates that feedback from interested persons will allow CDRH to better prioritize and more efficiently draft guidances to meet the needs of the Agency and our stakeholders.

In addition to posting the lists of prioritized device guidance documents, CDRH has identified as a priority, and has devoted resources to, finalization of draft guidance documents. To assure the timely completion or reissuance of draft guidances, in FY 2015 CDRH committed to performance goals for current and future draft guidance documents. For draft guidance documents issued after October 1, 2014, CDRH committed to finalize, withdraw, reopen the comment period, or issue new draft guidance on the topic for 80 percent of the documents within 3 years of the close of the comment period and for the remaining 20 percent, within 5 years. As part of MDUFA IV commitments, FDA reaffirmed this commitment, as resources permit.

Fulfillment of these commitments will be reflected through the issuance of updated guidance on existing topics, withdrawal of guidances that no longer reflect FDA's current thinking on a particular topic, and annual updates to the A-list and B-list announced in this notice.

II. CDRH Guidance Development Initiatives

A. Metrics for FY 2021 A-List and B-List Publication

Stakeholder feedback on guidance priorities is important to ensure that the CDRH guidance program meets the needs of stakeholders. The feedback received on the FY 2021 list was mostly in agreement, and CDRH continued to work toward issuing the guidances on this list. In FY 2021, CDRH published 11 of 27 guidances on the FY 2021 list (8 from the A-list, 3 from the B-list). In addition, FDA is committed to providing timely guidance to support response efforts to the Coronavirus Disease 2019 (COVID–19) pandemic. As such, FDA has shifted resources to issue 5 guidances and 8 guidance revisions in FY 2021, as well as to support other activities to address the pandemic.

B. Finalization of Draft Guidance Documents

Of the 29 draft guidances issued FY 2016 onward, CDRH finalized 79 percent within 3 years of the comment period close and 86 percent within 5 years. In addition, in FY 2021, 5 draft guidances issued prior to October 1, 2015, remain for which no action has been taken yet, and CDRH has been continuing to work towards taking an action on these remaining draft guidances.

Looking forward, in FY 2022, CDRH will strive to finalize, withdraw, or reopen the comment period for 50 percent of existing draft guidances issued prior to October 1, 2016.

C. Applicability of Previously Issued Final Guidance

At the website where CDRH has posted the ''A-list'' and ''B-list'' for FY 2021, CDRH has also posted a list of final guidance documents that issued in 2012, 2002, 1992, and 1982 for our annual review of previously issued final guidances. CDRH is interested in external feedback on whether any of these final guidances should be revised or withdrawn. In addition, for guidances that are recommended for revision, information explaining the need for revision, such as the impact and risk to public health associated with not revising the guidance, would also be helpful as the Center considers potential action with respect to these guidances. CDRH will consider the comments received from this retrospective review when determining priorities for updating guidance documents and will revise these as resources permit.

Consistent with the Good Guidance Practices regulation at 21 CFR

10.115(f)(4), CDRH would appreciate suggestions that CDRH revise or withdraw an already existing guidance document. We request that the suggestion clearly explain why the guidance document should be revised or withdrawn and, if applicable, how it should be revised. While we are requesting feedback on the list of previously issued final guidances located in the annual agenda website, feedback on any guidance is appreciated and will be considered.

In FY 2021, CDRH received comments regarding guidances issued in 2011, 2001, 1991, and 1981 and has withdrawn 1 guidance document because the guidance document was determined to no longer represent the Agency's current thinking. The revision of several guidance documents is also being considered as resources permit.

III. Website Location of Guidance Lists

This notice announces the website location of the document that provides the A- and B- lists of guidance documents, which CDRH is intending to publish during FY 2022. To access these two lists, visit FDA's website at *https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidance-development.* We note that the topics on this and past guidance priority lists may be removed or modified based on current priorities, as well as comments received regarding these lists. Furthermore, FDA and CDRH priorities are subject to change at any time (*e.g.,* newly identified safety issues). The Agency is not required to publish every guidance on either list if the resources needed would be to the detriment of meeting quantitative review timelines and statutory obligations. In addition, the Agency is not precluded from issuing guidance documents that are not on either list.

Dated: October 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23392 Filed 10–26–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0758]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 30, 2021, from 9 a.m. to 5 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0758. The docket will close on November 29, 2021. Submit either electronic or written comments on this public meeting by November 29, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 29, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 29, 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.

Comments received on or before November 15, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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 No. FDA–2021–N–0758 for ''Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA will review this copy, including the claimed confidential information, in its