

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 § 10.20 (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:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory

review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, RECARBRIO. RECARBRIO is a combination of cilastatin, imipenem, and relebactam indicated in patients 18 years of age and older who have limited or no alternative treatment options for the treatment of the following infections caused by susceptible gram-negative bacteria: Complicated urinary tract infections, including pyelonephritis, and complicated intra-abdominal infections. Approval of these indications is based on limited clinical safety and efficacy data for RECARBRIO. Subsequent to this approval, the USPTO received a patent term restoration application for RECARBRIO (U.S. Patent No. 8,487,093) from Merck Sharp & Dohme Corp., and the USPTO requested FDA’s assistance in determining the patent’s eligibility for patent term restoration. In a letter dated January 4, 2021, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of RECARBRIO represented the first permitted commercial marketing or use of relebactam, one of the three active ingredients in the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

##### II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for RECARBRIO is 3,200 days. Of this time, 2,957 days occurred during the testing phase of the regulatory review period, while 243 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* October 13, 2010. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on October 13, 2010.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* November 16, 2018. FDA has verified the applicant’s claim that the new drug application (NDA) for

RECARBRIO (NDA 212819) was initially submitted on November 16, 2018.

3. *The date the application was approved:* July 16, 2019. FDA has verified the applicant’s claim that NDA 212819 was approved on July 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 application for patent extension, this applicant seeks 1,218 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 No. 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 28, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021-24068 Filed 11-3-21; 8:45 am]

**BILLING CODE 4164-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2021-D-0775]

#### Content of Premarket Submissions for Device Software Functions; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled “Content of Premarket Submissions for Device Software Functions.” This guidance document is intended to provide information regarding the recommended documentation sponsors should include in premarket submissions for FDA’s evaluation of the safety and effectiveness of device software functions, which are functions that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act (FD&C Act). When final, this document will replace FDA’s “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued on May 11, 2005, and it will update FDA’s thinking related to the documentation FDA recommends sponsors include for the review of device software functions in premarket submissions. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by February 2, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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://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-D-0775 for “Content of Premarket Submissions for Device Software Functions.” 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, 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.

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

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Content of Premarket Submissions for Device Software Functions” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

#### **FOR FURTHER INFORMATION CONTACT:**

Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993-0002, 301-796-5528; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The purpose of this draft guidance is to describe FDA’s thinking on the recommended documentation sponsors should include in premarket submissions for FDA’s evaluation of the safety and effectiveness of device software functions. This thinking recognizes recent changes to the Federal Food, Drug, and Cosmetic Act (FD&C Act) made by the 21st Century Cures Act (Pub. L. 114-255), which amended section 520 of the FD&C Act (21 U.S.C. 360) and excludes certain software functions from the device definition. It also considers the rapidly evolving nature of digital health and recent FDA-recognized consensus standards related to software.

This draft guidance identifies the software information generally necessary for evaluating the safety and effectiveness of a device in a premarket submission. The recommendations in this draft guidance also may help facilitate FDA’s premarket review. This draft guidance describes information that typically would be generated and documented during software development, verification, and design validation. The least burdensome approach was applied to identify the minimum amount of information that, based on our experience, would generally be needed to support a premarket submission for a device that uses software. During premarket review, FDA may request additional information that is needed to evaluate the submission.

When final, this document will replace FDA’s “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued on May 11, 2005, and it will update FDA’s thinking related to the documentation recommended for the review of device software functions in premarket submissions.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Content of Premarket Submissions for Device Software Functions.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**II. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.fda.gov/vaccines-blood->

*biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances*. Persons unable to download an electronic copy of “Content of Premarket Submissions for Device Software Functions” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 337 and complete title to identify the guidance you are requesting.

**III. Paperwork Reduction Act of 1995**

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E .....	Premarket notification .....	0910–0120
814, subparts A through E .....	Premarket approval .....	0910–0231
814, subpart H .....	Humanitarian Device Exemption .....	0910–0332
812 .....	Investigational Device Exemption .....	0910–0078
“De Novo Classification Process (Evaluation of Automatic Class III Designation)”.	De Novo classification process .....	0910–0844
800, 801, and 809 .....	Medical Device Labeling Regulations .....	0910–0485
820 .....	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation .....	0910–0073

Dated: October 29, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–24061 Filed 11–3–21; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2021–N–1112]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Interstate Shellfish Dealer’s Certificate and Other Records Related to Participation in the National Shellfish Sanitation Program**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Interstate Shellfish Dealer’s Certificate as well as the collection of other records related to participation in the National Shellfish Sanitation Program (NSSP).

**DATES:** Submit either electronic or written comments on the collection of information by January 3, 2022.

**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 January 3, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2022. 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