

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:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Center for Devices and Radiological Health Appeals Processes**

*OMB Control Number 0910-0738—Extension*

This information collection supports implementation of recommendations found in FDA guidance. As discussed in the document entitled “Guidance for Industry and Food and Drug Administration Staff; Center for Devices and Radiological Health (CDRH) Appeals Processes” (July 2019), there are various processes by which appeals requests regarding review of decisions or actions by CDRH may be submitted to the Agency. The guidance is available for download from our website at <https://www.fda.gov/regulatory>

*information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes*. The guidance document provides general format and content recommendations in this regard, discusses applicable regulations with regard to the timing of such submissions, and describes the collection of information not expressly specified under existing regulations such as the submission of the request for review, minor clarifications as part of the request, and supporting information. While CDRH already possesses in the administrative file the information that would form the basis of a decision on a matter under appeal, the submission of information as recommended in the guidance regarding the appeal request itself, as well as data and information relied on by the requestor in the appeal, will help facilitate timely resolution of the decision under review. We are accounting for burden respondents may incur as a result of these Agency recommendations in this collection request. Additional information about the CDRH appeals process is described in the companion guidance entitled “Center for Devices and Radiological Health (CDRH) Appeals Processes: Questions and Answers About 517A—Guidance for Industry and Food and Drug Administration Staff” (March 2020), also available for download from our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a>.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

CDRH Appeals Processes: Guidance for Industry and FDA Staff	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Recommended format and content elements .....	35	1	35	8	280

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate 35 requests will be submitted annually to review decisions and actions by CDRH employees, we attribute one respondent per submission, and we assume each request will take 8 hours to prepare. Based on our evaluation of the information collection since last OMB approval, we have made no adjustments to the currently approved burden estimate.

Dated: February 14, 2022.  
**Lauren K. Roth,**  
*Associate Commissioner for Policy.*  
 [FR Doc. 2022-03546 Filed 2-17-22; 8:45 am]  
**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Docket No. FDA-2007-D-0369]**

**Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website. The guidances identified in this notice were developed using the process described in that guidance.

**DATES:** Submit either electronic or written comments on the draft guidance by April 19, 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–2007–D–0369 for “Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.” 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)).

Submit written requests for single copies of the draft 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 draft guidance document.

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

Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993–0002, 301–796–2398, [PSG-Questions@fda.hhs.gov](mailto:PSG-Questions@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

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

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA’s website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on November 9, 2021 (86 FR 62182). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA’s website.

##### **II. Drug Products for Which New Draft Product-Specific Guidances Are Available**

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Acidinium bromide; Formoterol fumarate.
Apomorphine hydrochloride.
Atropine sulfate.
Brilliant blue G.
Capmatinib hydrochloride.
Cladribine.
Dicyclomine hydrochloride.
Dolutegravir sodium.
Enzalutamide.
Estradiol (multiple referenced listed drugs).
Etelcalcetide.
Flortaucipir F-8.
Fluoroestradiol F-18.
Heparin sodium.
Irinotecan hydrochloride.
Leuprolide acetate (multiple referenced listed drugs).
Mirabegron.
Nusinersen sodium.
Posaconazole.
Progesterone.
Remdesivir (multiple referenced listed drugs).
Ripretinib.
Selpercatinib.
Selumetinib sulfate.
Sodium chloride.
Vasopressin.
Viloxazine hydrochloride.

### III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Apixaban.
Clozapine (multiple referenced listed drugs).
Enzalutamide.
Estradiol.
Gefitinib.
Liothyronine sodium.
Methylprednisolone acetate.
Mycophenolate mofetil.
Osimertinib mesylate.
Ruxolitinib phosphate.
Valbenazine tosylate.

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to <https://www.regulations.gov> and enter Docket No. FDA-2007-D-0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current

thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

#### IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### V. Electronic Access

Persons with access to the internet may obtain the draft guidances at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: February 10, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Proposed Collection: Public Comment Request; Rural Communities Opioid Response Program Performance Measures, OMB No. 0906-0044—Revision

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

**DATES:** Comments on this ICR should be received no later than March 21, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Samantha Miller, the acting HRSA Information Collection Clearance Officer, at (301) 443-9094.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* Rural Communities Opioid Response Program (RCORP) Performance Measures, OMB No. 0906-0044—Revision.

*Abstract:* RCORP is authorized by Section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)) and is a multi-initiative program that aims to: (1) Support treatment for and prevention of substance use disorder (SUD), including opioid use disorder (OUD); and (2) reduce morbidity and mortality associated with SUD, to include OUD, by improving access to and delivering prevention, treatment, and recovery support services to high-risk rural communities. To support this purpose, RCORP grant initiatives include:

- RCORP-Implementation grants to fund established networks and consortia to deliver SUD/OUD prevention, treatment, and recovery activities in high-risk rural communities;
- RCORP-Medication Assisted Treatment Expansion grants to enhance access to medication-assisted treatment within eligible hospitals, health clinics, or tribal organizations in high-risk rural communities;
- RCORP-Neonatal Abstinence Syndrome grants to reduce the incidence and impact of Neonatal Abstinence Syndrome in rural communities by improving systems of care, family supports, and social determinants of health;
- RCORP-Psychostimulant Support grants to strengthen and expand prevention, treatment, and recovery services for individuals in rural areas who misuse psychostimulants; to enhance their ability to access treatment and move towards recovery; and