III. Electronic Access

Persons with access to the internet may obtain the guidance 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: June 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13520 Filed 6–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the supplemental application for RINVOQ (upadacitinib), approved March 16, 2022, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the approval of product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the supplemental application for RINVOQ (upadacitinib), approved March 16, 2022, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about RINVOQ (upadacitinib), approved March 16, 2022, go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: June 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13607 Filed 6–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2565]

Agency Information Collection Activities; Proposed Collection; Comment Request; 510(k) Third-Party Review Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 510(k) Third-Party Review Program.

DATES: Submit either electronic or written comments on the collection of information by August 23, 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 August 23, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 23, 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 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–2016–D–2565 for ''Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 510(k) Third-Party Review Program.'' 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: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

510(k) Third-Party Review Program

OMB Control Number 0910–0375—Extension

Section 523 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360m), directs FDA to accredit persons in the private sector to review certain premarket notifications (510(k)s; see 21 U.S.C. 360(k)). Participation in the 510(k) third party (3P510k) review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually 3 years.

Respondents to this information collection are businesses or government, and can be for-profit or not-for-profit organizations.

The guidance ''510(k) Third-Party Review Program, Guidance for Industry, Food and Drug Administration Staff and Third Party Review Organizations'' (March 2020) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-third-party-review-program*) is intended to provide a comprehensive look into FDA's current thinking regarding the 3P510k review program. This guidance document also reflects section 523 of the FD&C Act, which directs FDA to issue guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. The 3P510k review program is intended to allow review of devices by third-party 510k review organizations (3PROs) to provide manufacturers of these devices an alternative review process that allows FDA to best utilize our resources on higher risk devices.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; guidance document section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Requests for accreditation (initial); Section VI	1	1	1	24	24
Requests for accreditation (re-recognition); Section VI	3	1	3	24	72
510(k) reviews conducted by accredited third parties; Section VI	9	14	126	40	5,040
Complaints; Section VII	1	1	1	0.25 (15 minutes)	1
Total					5,137

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Totals have been rounded.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; guidance document section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
510(k) reviews; Section VII	9	14	126	10	1,260
Records regarding qualifications to receive FDA recognition as a 3PRO; Section VII	9	1	9	1	9
Recordkeeping system regarding complaints; Section VII	9	1	9	2	18
Total					1,287

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Estimated Annual Recordkeeping Burden

510(k) reviews: The 3PROs should retain copies of all 510(k) reviews and associated correspondence. Based on FDA's recent experience with this program, we estimate the number of 510(k)s submitted for 3P510k review to be 126 annually; approximately 14 annual reviews for each of the 9 3PROs. We estimate the average burden per recordkeeping to be 10 hours.

Records regarding qualifications to receive FDA recognition as a 3PRO: Under section 704(f) of the FD&C Act (21 U.S.C. 374(f)), a 3PRO must maintain records that support their initial and continuing qualifications to receive FDA recognition, including documentation of the training and qualifications of the 3PRO and its personnel; the procedures used by the 3P510k review organization for handling confidential information; the compensation arrangements made by the 3PRO; and the procedures used by the 3PRO to identify and avoid conflicts of interest. Additionally, the guidance states that 3PROs should retain information on the identity and qualifications of all personnel who contributed to the technical review of each 510(k) submission and other relevant records. Because most of the burden of compiling the records is expressed in the reporting burden for requests for accreditation, we estimate the maintenance of such records to be 1 hour per recordkeeping annually.

Recordkeeping system regarding complaints: Section 523(b)(3)(F)(iv) of the FD&C Act requires 3PROs to agree in writing that they will promptly respond and attempt to resolve complaints regarding their activities. The guidance recommends that 3PROs establish a recordkeeping system for tracking the submission of those complaints and how those complaints were resolved, or attempted to be resolved. Based on our experience with the program and the recommendations in the guidance, we estimate the average burden per recordkeeping to be 2 hours annually.

Based on our experience with the program since our last request for OMB approval, we have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden.

Dated: June 15, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13521 Filed 6–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1152]

Considerations for Rescinding Breakthrough Therapy Designation; Draft Guidance 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 a draft guidance for industry entitled ''Considerations for Rescinding Breakthrough Therapy Designation.'' This guidance explains how, during its evaluation of a drug development program, FDA may consider whether to rescind a breakthrough therapy designation (BTD) that has been granted. The guidance is consistent with, and supplements, the information on BTD contained in the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (May 2014) and in other BTD policies and procedures of the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) to expedite the development and review of a breakthrough therapy.

DATES: Submit either electronic or written comments on the draft guidance by August 23, 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