registration). Once the account is created, the owner or operator uses the account as long as the establishment is registered. If an owner or operator changes, the new owner or operator creates a new owner or operator account and transfers the ownership of the establishment to their owner or operator account. Once they create an owner or operator account, they use the account for as long as the company is registered. Under § 807.22(b)(4), changes to listing information may be made at times outside of the annual listing requirement period, such as when a change is made to a previously listed device.

The draft guidance entitled ''Transfer of a Premarket Notification (510(k)) Clearance—Questions and Answers'' (December 2014), which contained instructions for the proposed voluntary information collection, has recently been withdrawn. While notification of transfer of ownership information is not currently required, our medical device registration and listing website [1] communicates procedures for notifying FDA of the transfer of a premarket notification (510(k)) clearance from one person to another. The notification is used to ensure public information in FDA's databases about the current 510(k) holder for a specific device(s) is accurate and up to date. Although submission of information regarding the transfer of a 510(k) clearance is not required under the regulations, we regularly receive such notifications from respondents.

We estimate that annually 78 percent of 510(k)s may be initially listed or updated outside of the annual registration requirement (about 4,080 510(k)s per year). We assume it will take 15 minutes for each listing, for a total reporting burden of 1,020 hours.

We estimate 2,033 instances of more than one party claiming to be a 510(k) holder for a specific device as part of annual registration and listing. We determined our estimate by identifying the average number of unique 510(k) device listings entered in FURLS between fiscal years 2017 and 2019 that conflict with a listing already entered by another party (5,304), dividing that number by the number of years (3) and multiplying by the average number of parties claiming to be the 510(k) holder when there is a conflict in the current FURLS database (2.3), then dividing the result by 2 (because only one company per listing will submit the appropriate documentation to show that they are the current 510(k) holder).

The registration and listing website identifies potential documentation a party could submit to FDA to establish the transfer of a 510(k) clearance to a new owner or operator. Based on the amount of time to locate the information, copy it, and submit a copy, we assume it takes respondents an average of 4 hours to establish the transfer of a 510(k) clearance.

The estimate for § 807.25(d) in table 2 of this document (recordkeeping burden) reflects the requirement that owners or operators maintain a historical file containing the labeling and advertisements in use. The estimate for § 807.26 reflects the requirement that owners or operators keep a list of officers, directors, and partners for each establishment. Owners or operators will need to provide this information only when requested by FDA. However, it is assumed that some effort will need to be expended to keep such records current.

The recurring burden for the data collection under § 807.41 (import-related information provided by foreign companies exporting to the United States) was estimated based on data from previous years. Foreign companies identify readily available contact information at the time of registration. After completing their initial registration, they are required to review the importer information annually. When they review the importer information annually, they simply verify the importer information is accurate. If it is and no changes are needed, the foreign establishment's official correspondent checks the certification and submits the annual registration. If they need to make changes to the importer information, they can do so at any time and use a spreadsheet to update more than one importer at a time to their registration. The use of the spreadsheet reduces the burden to the official correspondent of the foreign establishment.

Our estimated burden for the information collection reflects an overall increase of 10,880 hours and a corresponding increase of 28,430 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last 3 years.

Dated: June 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13522 Filed 6–23–22; 8:45 am]

BILLING CODE 4164–01–P

[1] *https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4368]

Assessing the Effects of Food on Drugs in Investigational New Drugs and New Drug Applications—Clinical Pharmacology Considerations; 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 final guidance for industry entitled ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' This guidance provides recommendations to sponsors planning to conduct food-effect (FE) studies for orally administered drug products as part of investigational new drug applications (INDs), new drug applications (NDAs), and supplements to these applications. This guidance finalizes the draft guidance of the same title issued on February 26, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on June 24, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2018–D–4368 for ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' 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 this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Vikram Arya or Brian Booth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1499 or 301–796–1508.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' Food-drug interactions can have a significant impact on the safety and efficacy of the drug and can be manifested in different ways. In some cases, co-administration of a drug with food can increase the systemic exposure of the drug, leading to improved efficacy or higher rates of adverse reactions. In other cases, administration of a drug with food can lower the systemic absorption of a drug, thereby reducing the efficacy. Hence, assessing the effect of food on the absorption of a drug is critical to optimize the safety and efficacy of the product and to determine optimum instructions for drug administration in relation to food.

During new drug development, pharmacokinetic studies to assess the effect of food on the systemic exposure of the drug are conducted to determine: (1) if, and to what extent, food impacts the systemic exposure of the drug; (2) whether food increases or decreases the variability of the systemic exposure of the drug; and (3) if the effect of food is different across meals with different fat or caloric contents. It is important to have as detailed an understanding of the exposure-response relationships of the drug as possible to interpret the results of FE studies. Additionally, an understanding of the various clinical dosing scenarios will be important to characterize the effect of food and to provide adequate instructions for use of the drug.

This guidance finalizes the draft guidance entitled ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations'' issued on February 26, 2019 (84 FR 6151). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include adding a discussion of model-informed drug development approaches to assessing the effects of food on drug exposures and the removal of specific language regarding the timing of food effect studies and food effect studies by population pharmacokinetic analysis.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' 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. 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 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collection of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control numbers 0910–0733 and 0910–0572, and the collections of information related to pharmacogenomic data have been approved under OMB control number 0910–0557.

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.