purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–15623 Filed 7–21–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Office of Community Services (OCS) Community Economic Development (CED) Standard Reporting Format (Office of Management and Budget) (OMB) #0970–0386)

AGENCY: OCS, Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS).

ACTION: Request for public comments.

SUMMARY: OCS is requesting a three-year extension of the semi-annual reporting format for CED grant recipients, the Performance Progress Report (PPR), which collects information regarding the outcomes and management of CED projects (OMB #0970–0386, expiration February 28, 2023). There are minor changes requested to the form to provide clarity to users completing the form.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act (PRA) of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OCS will continue collecting key information about projects funded through the CED program. The legislative requirement for this program is in Title IV of the Community Opportunities, Accountability and Training and Educational Services Act (COATS Human Services Reauthorization Act) of October 27, 1998, Public Law 105–285, section 680(b) as amended. The PPR collects information regarding the outcomes and management of CED projects. OCS will use the data to critically review the overall design and effectiveness of the program.

The PPR will continue to be administered to all active grant recipients of the CED program. Grant recipients will be required to use this reporting tool for their semi-annual reports to be submitted twice a year. Through a previous renewal, the current PPR replaced both the annual questionnaire and other semi-annual reporting formats, which resulted in an overall reduction in burden for the grant recipients, significantly improved the quality of the data collected by OCS, and allowed grant recipients to become accustomed to this format. OCS seeks to renew this PPR to continue to collect quality data from grant recipients. To ensure the burden on grant recipients is not increased, but that the information collected demonstrates the full impact of the program, OCS has conducted an in-depth review of the forms and requests minor changes to the PPR to provide clarity to users filling out the form.

Respondents: Active CED Grant Recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
PPR for Current OCS–CED Grant Recipients	91	2	1.5	273

Estimated Total Annual Burden Hours: 273.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 680(a)(2) of the Community Services Block Grant (CSBG) Act, 42 U.S.C. 9921.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–15615 Filed 7–21–22; 8:45 am]

BILLING CODE 4184–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0823]

Real-Time Oncology Review; 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 ''Real-Time Oncology Review (RTOR).'' The purpose of this guidance is to provide recommendations to applicants on the process for submission of selected new drug applications (NDAs) and biologics license applications (BLAs) with oncology indications for review under RTOR.

DATES: Submit either electronic or written comments on the draft guidance by September 20, 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–2022–D–0823 for ''Real-Time Oncology Review.'' 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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 requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: R. Angelo De Claro, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2173, Silver Spring, MD 20993, 301–796–4415; 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

FDA is announcing the availability of a draft guidance for industry entitled ''Real-Time Oncology Review.'' The purpose of this guidance is to provide recommendations to applicants on the process for submission of selected NDAs and BLAs with oncology indications for review under RTOR.

The FDA Oncology Center of Excellence, in collaboration with the Office of Oncologic Diseases, commenced the RTOR program in February 2018 to facilitate earlier submission of topline results (*i.e.,* efficacy and safety results from clinical studies before the study report is completed) and datasets, after database lock, to support an earlier start to the FDA application review. The intent of RTOR is to provide FDA reviewers earlier access to data, to identify data quality and potential review issues, and potentially provide early feedback to the applicant, which can allow for a more streamlined and efficient review process. RTOR also involves early engagement with the applicant to discuss the submission timelines for RTOR components and the full application submission. RTOR does not alter the review performance goals and timelines associated with the applications, including those described in the Prescription Drug User Fee Amendments. Participation by the applicant is voluntary and acceptance into the program does not guarantee or influence approval of the application, which is subject to the same statutory and regulatory requirements for approval as applications that are not included in RTOR.

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 ''Real-Time Oncology Review.'' 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 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control

number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15676 Filed 7–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1252]

Panray Corp. Sub Ormont Drug and Chemical Co., Inc., et al.; Withdrawal of Approval of Three New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new drug applications (NDAs) from multiple holders of those NDAs. The basis for the withdrawal is that these NDA holders have repeatedly failed to file required annual reports for the identified NDAs.

DATES: Approval is withdrawn as of July 22, 2022.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of December 27, 2021 (86 FR 73296), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of three NDAs because the holders of those NDAs had repeatedly failed to submit the required annual reports for those NDAs. The holders of those NDAs did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by those holders of the NDAs not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of their NDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the three applications listed in table 1 of this document.

TABLE 1—APPROVED NDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Drug	NDA holder
NDA 008284	Cortisone Acetate Tablets, 5 milligrams (mg) and 25 mg	Panray Corp. Sub Ormont Drug and Chemical Co., Inc., 520 South Dean St., Englewood, NJ 07631.
NDA 009659	Hydrocortisone Tablets, 10 mg and 20 mg	Do.
NDA 019503	Triamcinolone Acetonide Suspension, 3 mg/milliliters (mL)	Parnell Pharmaceuticals Inc., 111 Francisco Blvd., San Rafael, CA 94901.

FDA finds that the holders of the NDAs listed in table 1 have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, FDA finds that the holders of the NDAs have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the NDAs listed in table 1 and all amendments and supplements thereto is hereby withdrawn as of July 22, 2022.

Dated: July 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15629 Filed 7–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0414]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 22, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://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. The OMB control number for this information collection is 0910–0601. Also include the FDA docket number found in brackets in the heading of this document.

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.*