DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #0970–0106]

Submission for Office of Management and Budget Review; Low Income Home Energy Assistance Program Carryover and Reallotment Report

AGENCY: Office of Community Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for Public Comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting additional comments on the request for the Office of Management and Budget (OMB) to reinstate approval of the Low Income Home Energy Assistance Program (LIHEAP) Carryover and Reallotment Report (OMB #0970–0106, discontinued June 2025), with changes. Minor changes are proposed to break out awards into three sources and incorporate numbering and wording updates.

DATES:

Comments due September 18, 2025. OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The LIHEAP statute and regulations require LIHEAP grant recipients to report certain information to the U.S. Department of Health and Human Services (HHS) concerning funds forwarded and funds subject to reallotment. The 1994 reauthorization of the LIHEAP statute, the Human Service Amendments of 1994 (Pub. L. 103–252), requires that the Carryover and Reallotment Report for one fiscal year be submitted to HHS by the grant recipient before the allotment for the next fiscal year may be awarded.

In compliance with the Paperwork Reduction Act of 1995 (PRA), ACF discontinued the OMB number in June 2025 prior to the expiration date, to allow for public comment on the extension and revision request prior to OMB review.

ACF is requesting minor changes in the Carryover and Reallotment Report, a form for the collection of data, and the Instructions for Timely Obligation of LIHEAP Regular Block Grant, Reallotted, and Supplemental Funds and Reporting Funds for Carryover and Reallotment. The form clarifies the information being requested and ensures the submission of all the required information. The form facilitates our response to numerous queries each year concerning the amounts of obligated funds. Use of the form is mandatory for prior-year grant recipients that seek current-year LIHEAP funds except for (1) territorial grant recipients that consolidate their LIHEAP programs with the Social Services Block Grant under Public Law 95–134; and (2) tribal grant recipients that have integrated their LIHEAP programs under Public Law 102–477 for administration through the Bureau of Indian Affairs and that draw down funds solely during the integration period.

ACF published a **Federal Register** notice on June 13, 2025 (90 FR 25048) announcing a 60-day comment period to solicit public comment on the renewal of the LIHEAP Carryover and Reallotment Report with changes and the continuation of requiring grant recipients to engage in this data collection annually. ACF did not receive comments on this notice.

Respondents: State governments, tribal governments, territories, and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
LIHEAP Carryover and Reallotment Report	188	1	3	564

Authority: 42 U.S.C. 8626(b)(2)(B).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–15715 Filed 8–18–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–5850]

Approaches to Assessment of Overall Survival in Oncology Clinical Trials; 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 ''Approaches to Assessment of Overall Survival in Oncology Clinical Trials.'' The purpose of this draft guidance is to provide recommendations to sponsors on the assessment of overall survival in randomized oncology clinical trials conducted to support marketing approval of drugs and biological products, with an emphasis on the analysis of overall survival as a prespecified safety endpoint. While the draft guidance discusses situations in which it is appropriate to consider overall survival for the primary endpoint, this draft guidance primarily focuses on statistical or design considerations when overall survival is not the primary endpoint.

DATES: Submit either electronic or written comments on the draft guidance by October 20, 2025 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–2024–D–5850 for ''Approaches to Assessment of Overall Survival in Oncology Clinical Trials.'' 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: Nicole Gormley, Oncology Center of Excellence and Center for Drug Evaluation and Research, Food and Drug Administration, *OCE-Guidances@fda.hhs.gov;* or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Approaches to Assessment of Overall Survival in Oncology Clinical Trials.'' The purpose of this draft guidance is to provide recommendations to sponsors on the assessment of overall survival in randomized oncology clinical trials conducted to support marketing approval of drugs and biological products, with an emphasis on the analysis of overall survival as a prespecified safety endpoint. Overall survival is an objective, clinically meaningful endpoint that can be measured easily and precisely. It is considered a gold standard endpoint in oncology, as prolongation of life in the setting of a life-threatening disease is of clear inherent value, and therefore, overall survival should be prioritized as a primary endpoint when feasible. However, it is often not feasible or practical to include overall survival as the primary endpoint in certain oncology settings. In some indolent diseases or those with extremely efficacious therapeutics that result in long survival times, the follow-up time needed to show superiority of overall survival as the primary endpoint may be impractical. Moreover, overall survival cannot be adequately interpreted in single-arm trials, and the interpretation of the overall survival results can be impacted by crossover, receipt of subsequent therapy, and other intercurrent events. The draft guidance describes considerations for trial design, statistical analysis, subgroup evaluation, and regulatory submission in the context of considering overall survival.

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 ''Approaches to Assessment of Overall Survival in Oncology Clinical Trials.'' 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). 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 draft 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: August 14, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–15796 Filed 8–18–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0709]

Doyal Kalita: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Doyal Kalita for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Kalita was convicted of two felony counts under Federal law. The factual basis supporting Mr. Kalita's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Kalita was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of June 26, 2025 (30 days after receipt of the notice), Mr. Kalita had not responded. Mr. Kalita's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable August 19, 2025.

ADDRESSES: Any application by Mr. Kalita for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2025–N–0709. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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. 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, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On October 9, 2024, Mr. Kalita was convicted as defined in section 306(l)(1) of the FD&C Act (21 U.S.C. 335a(l)(1)), in the U.S. District Court for the District of Massachusetts, when the court accepted his plea of guilty and entered