other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert A. Sargis,**

*Report Clearance Officer.*

[FR Doc. 2018–17768 Filed 8–16–18; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Comment Request

*Proposed Projects:* LIHEAP Carryover and Reallotment Report FRN1 Clearance.

*Title:* Low Income Home Energy Assistance Program (LIHEAP) Carryover and Reallotment Report.

*OMB No.:* 0970–0106.

*Description:* The LIHEAP statute and regulations require LIHEAP grantees to report certain information to 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 grantee before the Allotment for the next fiscal year may be awarded.

We are requesting no changes in the collection of data with the Carryover and Reallotment Report for FY 2018, a form for the collection of data, and the Simplified Instructions for Timely Obligations of FY 2019 LIHEAP 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 voluntary. Grantees have the option to use another format.

*Respondents:* State, Local or Tribal Government.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| Carryover & Reallotment | 177 | 1 | 3 | 531 |
| Estimated Total Annual Burden Hours | | | | 531 |

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

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.

**Robert A. Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2018–17777 Filed 8–16–18; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–0001]**

### Science and Regulation of Live Microbiome-Based Products Used To Prevent, Treat, or Cure Diseases in Humans; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research and the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID) are announcing a public workshop entitled ''Science and Regulation of Live Microbiome-Based Products Used to Prevent, Treat, or Cure Diseases in Humans.'' The purpose of the public workshop is to exchange information with the scientific community about the clinical, manufacturing, and regulatory considerations associated with live microbiome-based products, when administered to prevent, treat, or cure a disease or condition in humans. The public workshop will bring together government Agencies, academia, industry, and other stakeholders involved in research, development, and regulation of live microbiome-based products for such uses.

**DATES:** The public workshop will be held on September 17, 2018, from 9 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at the NIAID Conference Center, 5601 Fishers Lane, Rm. 1D13, Rockville, MD 20852. Entrance for public workshop participants is through the lobby, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.niaid.nih.gov/about/visitor-information.*

**FOR FURTHER INFORMATION CONTACT:** Loni Warren Henderson or Sherri Revell, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1118, Silver Spring, MD 20993, 240–402–8010, email: *CBERPublicEvents@fda.hhs.gov* (subject

line: Live Microbiome-Based Products Workshop).

**SUPPLEMENTARY INFORMATION:**

## I. Background

Live microbiome-based products used to prevent, treat, or cure a disease or condition in humans are biological products. There is increasing interest in the use of such products for the treatment and/or prevention of conditions such as necrotizing enterocolitis and diarrhea. Historically, these products have presented with unique scientific and regulatory challenges.

## II. Topics for Discussion at the Public Workshop

The topics for discussion at the public workshop include the clinical, manufacturing, and regulatory considerations for live microbiome-based products to prevent, treat, or cure a disease or condition in humans, and the objective is to provide a forum for the exchange of information and perspectives on these topics.

## III. Participating in the Public Workshop

*Registration:* To register for the public workshop, please visit the following website: *https://www.eventbrite.com/e/science-and-regulation-of-live-microbiome-based-products-used-to-prevent-treat-or-cure-diseases-in-tickets-44649072578.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by August 28, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Loni Warren Henderson or Sherri Revell no later than September 10, 2018 (See **FOR FURTHER INFORMATION CONTACT**).

Dated: August 13, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–17732 Filed 8–16–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–D–1592]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Controlled Correspondence Related to Generic Drug Development

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, 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:** Fax written comments on the collection of information by September 17, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0797. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10a.m.–12 midnight, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Guidance for Industry: Controlled Correspondence Related to Generic Drug Development

*OMB Control Number 0910–0797—Extension*

This information collection supports the above captioned Agency guidance. FDA has agreed to specific program enhancements and performance goals specified in the Generic Drug User Fee Reauthorization (GDUFA II) Commitment Letter. One of the performance goals applies to controlled correspondence related to generic drug development. The GDUFA II Commitment Letter includes details on FDA's commitment to respond to questions submitted as controlled correspondence within certain timeframes. To support these program goals, we have developed the guidance entitled ''Controlled Correspondence Related to Generic Drug Development.'' The guidance document is intended to facilitate FDA's prompt consideration of controlled correspondence and to assist in meeting the prescribed timeframes by providing procedural recommendations to include the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number and submission date of any previous, related controlled correspondence that was accepted for substantial review and response, if any, as well as a copy of that previous controlled correspondence and FDA's response, if any; (4) the relevant reference listed drug(s), as applicable, including the application number, proprietary (brand) name, manufacturer, active ingredient, dosage form, and strength(s); (5) a statement that the controlled correspondence is related to a potential abbreviated new drug application (ANDA) submission to the Office of Generic Drugs and the ANDA number, if applicable; (6) a concise statement of the inquiry; (7) a recommendation of the appropriate FDA review discipline; and (8) relevant prior research and supporting materials.

The GDUFA II Commitment Letter also includes details on FDA's commitment to respond to requests to clarify ambiguities in FDA's controlled correspondence response within certain timeframes. To facilitate FDA's prompt consideration of the request and to assist in meeting the prescribed timeframes, the guidance document recommends including the following information in the inquiry: (1) Name, title, address, phone number, and entity of the person submitting the inquiry; (2) a letter of authorization, if applicable; (3) the FDA-assigned control number, submission date of the controlled correspondence on which the requestor is seeking clarification, a copy of that previous controlled correspondence, and FDA's response to the controlled correspondence; and (4) the clarifying questions and the corresponding section(s) of FDA's controlled correspondence response on which the requestor is seeking clarification.

In the **Federal Register** of May 22, 2018, (83 FR 23692), we published a 60-day notice requesting public comment on the proposed collection of