requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: On an annual basis, Tribal Lead Agencies for the Child Care and Development Fund (CCDF) are required to submit aggregate information on services provided via the CCDF Tribal Annual Report, also known as the ACF–700 report and offers the Office of Child Care (OCC) a glimpse into how CCDF program dollars are being spent. The ACF–700 report captures administrative data about the number of families and children served. The report also contains specific questions that gather programmatic information about Tribal quality activities, coordination of activities with other early childhood programs, use of funds, technical assistance needs, use of the Data Tracker software, and progress toward identified goals. The data derived from this report allows OCC to generate and analyze aggregate information, thereby giving OCC a more comprehensive understanding of Tribal program activities more easily. The data are essential for demonstrating the accomplishments of Tribal child care programs.

Respondents: Tribal Grantees receiving CCDF funding. Tribes that operate child care under Public Law 102–477 Indian Employment, Training, and Related Services Plan are exempt from the ACF–700.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
ACF–700	141 (Tribes with small allocations)	3	19	7,866	2,622
ACF–700	78 (Tribes with medium/large allocations)	3	26	6,474	2,158

Estimated Total Annual Burden Hours: 4,780.

Authority: 42 U.S.C. 9857.

John M. Sweet, Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–00421 Filed 1–11–23; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Management and Budget (OMB) Expedited Review and Public Comment: Revisions to Recordkeeping To Mitigate the Spread of COVID–19 in Head Start (OMB #: 0970–0583)

AGENCY: Office of Head Start; Administration for Children and Families; Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Head Start, Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is requesting expedited review from OMB and inviting public comments on revisions to the recordkeeping requirements under *Recordkeeping to Mitigate the Spread of COVID–19 in Head Start* (OMB #: 0970–0583). A Final Rule requires grant recipients to update their program policies and procedures to include an evidence-based COVID–19 mitigation policy developed in consultation with their Health Services Advisory Committee.

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

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be submitted by emailing *infocollection@acf.hhs.gov*. Identify all requests by the title of the information collection: Recordkeeping to Mitigate the Spread of COVID–19 in Head Start (OMB #: 0970–0583).

SUPPLEMENTARY INFORMATION:

Description: The requirement that grant recipients establish a COVID–19 mitigation policy in their program policies and procedures will go into effect 60 days following the publication of the Final Rule. The use of normal clearance procedures will not allow for this recordkeeping requirement to be approved prior to the effective date of the final rule. Therefore, ACF is requesting that OMB grant a 180-day approval for this request under procedures for expedited processing. A request for review under normal procedures will be submitted within 180 days of the approval for this request. Only the burden related to the new recordkeeping requirement is displayed below. See OMB number 0970–0583 for additional information about existing recordkeeping requirements. This request under normal procedures will include an extension for all record keeping requirements under this OMB number.

Respondents: Head Start Grant recipients.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Responses per respondent	Average burden hours per response	Annual burden hours
Grant Recipient Updating Program Policies and Procedures	1,604	1	8	12,832

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. Comments will be considered and any necessary updates to materials made prior to, and responses provided in, the submission to OMB that will follow this public comment period.

Authority: 88 FR 993.

John M. Sweet Jr.,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–00429 Filed 1–11–23; 8:45 am]

BILLING CODE 4184–40–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–3116]

Photobiomodulation Devices—Premarket Notification Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Photobiomodulation (PBM) Devices—Premarket Notification [510(k)] Submissions.'' This draft guidance provides recommendations on premarket submissions for photobiomodulation devices, which are used in applications such as aesthetics, dermatology, and other general indications. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 13, 2023 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–3116 for ''Photobiomodulation (PBM) Devices—Premarket Notification [510(k)] Submissions.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Photobiomodulation (PBM) Devices—Premarket Notification [510(k)] Submissions.'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jessica Mavadia-Shukla, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4643, Silver Spring, MD 20993–0002, 301–348–1596.

SUPPLEMENTARY INFORMATION:

I. Background

PBM devices, also known as low level light therapy devices, are intended for use in applications such as aesthetics, dermatology, and other general indications. A PBM device is designed to deliver a non-heating dose of light energy into the body to provide clinical benefit to the patient. This draft guidance document provides FDA's recommendations on non-clinical testing, clinical studies, and labeling to support premarket submissions for PBM devices. The recommendations reflect current review practices and are intended to promote consistency and facilitate efficient review of these submissions.