DATES: *Comments due within 30 days of publication.* OMB must make a decision regarding 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 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: Section 676 of the CSBG Act requires States, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories applying for CSBG funds to submit an application and plan (CSBG State Plan). The CSBG State Plan must meet statutory requirements prior to OCS awarding CSBG grant recipients (States and territories) with CSBG funds. Grant recipients have the option to submit a detailed plan annually or biannually. Grant recipients that submit a biannual plan must provide an abbreviated plan the following year if substantial changes to the initial plan will occur. OCS is not requesting any changes to this form. As this will be the 11th year of submitting this form, OCS does not anticipate any additional burden.

OCS is also requesting to extend approval of the following information collections, with no changes proposed:

- *CSBG Eligible Entity List.* In alignment with Federal requirements, OCS requests that all grant recipients continue to keep their CSBG Eligible Entity List current, to include maintaining an accurate listing of the CSBG sub-grant recipients (CSBG eligible entities) and current Unique Entity Identifier (UEI) for each recipient listed. This is in alignment with current policies and processes, and therefore OCS does not anticipate any additional burden.
- *Optional survey for the sub-grant recipients (or CSBG-eligible entities).* The American Customer Survey Index (ACSI) is administered biennially. OCS uses the ACSI survey for eligible entities as part of the CSBG performance management framework. The survey focuses on the customer service that the CSBG sub-grant recipients receive from the CSBG grant recipients. The survey is optional, and this will be the seventh time that CSBG sub-grant recipients have the option to complete the survey. There were no revisions to the survey.

OCS anticipates submitting a subsequent revision to this information collection, pending OMB review and approval of a separate but related information collection request (CSBG Annual Report, OMB No. 0970–0492) that is forthcoming and expected in summer 2024 and may result in minor updates to some of these materials.

Respondents: State governments, including the District of Columbia and the Commonwealth of Puerto Rico, and U.S. territories, and local level sub-grant recipients.

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
CSBG State Plan	56	3	28	4,704	1,568
CSBG Eligible Entity List	56	3	1	168	56
Estimated Total Annual Burden Hours for CSBG Grant Recipients					1,624
CSBG ACSI Survey of CSBG Eligible Entities	1,000	2	.15	300	100
Estimated Total Annual Burden Hours for CSBG sub-grant recipients					100
Estimated Total Annual Burden Hours for All Respondents					1,724

Authority: Sec. 676, Public Law 105–285, 112 Stat. 2735 (42 U.S.C. 9908).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–15368 Filed 7–11–24; 8:45 am]

BILLING CODE 4184–27–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–D–2511 and FDA–2024–D–2512]

Dental Composite Resin Devices and Dental Curing Lights—Premarket Notification (510(k)) Submissions Guidances; Draft Guidances 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 two draft guidances entitled ''Dental Composite Resin Devices—Premarket Notification (510(k)) Submissions'' and ''Dental Curing Lights—Premarket Notification (510(k)) Submissions.'' These draft guidance documents provide recommendations for device description, performance testing, and labeling to include in 510(k) submissions for dental composite resin devices and dental curing lights. When final, these guidances will supersede the guidances ''Dental Composite Resin Devices—Premarket Notification [510(k)] Submissions'' dated October 26, 2005 and ''Dental Curing Lights—Premarket Notification [510(k)] Submissions'' dated March 27, 2006. The recommendations in these draft guidances are intended to promote consistency and facilitate efficient review of these submissions. These draft guidances are not final nor are they for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by September 10, 2024 to ensure that the Agency considers your comment on the 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–2511 for ''Dental Composite Resin Devices—Premarket Notification (510(k)) Submissions'' or the Docket No. FDA–2024–D–2512 for ''Dental Curing Lights—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 ''Dental Composite Resin Devices—Premarket Notification (510(k)) Submissions'' or ''Dental Curing Lights—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: Michael Adjodha, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G304, Silver Spring, MD 20993–0002, 301–796–6276.

SUPPLEMENTARY INFORMATION:

I. Background

These draft guidance documents provide recommendations for device description, performance testing, and labeling to include in 510(k) submissions for dental composite resin devices and dental curing lights. Dental composite resin devices are devices intended to fill and restore defects or carious lesions in teeth. The device may be supplied as a two-part base and catalyst system that is self-cured or a one-part system that is cured via photoinitiation. Dental curing lights are devices that emit non-ionizing optical radiation intended to photopolymerize dental restorative resins. These guidances, when final, will supersede ''Dental Composite Resin Devices—Premarket Notification [510(k)] Submissions'' dated October 26, 2005 and ''Dental Curing Lights—Premarket Notification [510(k)] Submissions'' dated March 27, 2006. The recommendations in these draft guidances are intended to promote consistency and facilitate efficient review of these submissions.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on Dental Composite Resin Devices—Premarket Notification (510(k)) Submissions and Dental Curing Lights—Premarket Notification (510(k)) Submissions. They do not establish any rights for any person and are 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. Electronic Access

Persons interested in obtaining copies of the draft guidances may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* These guidance documents are also available at *https://www.regulations.gov* and

https://www.fda.gov/regulatory-information/search-fda-guidance-documents. Persons unable to download an electronic copy of ''Dental Composite Resin Devices—Premarket Notification (510(k)) Submissions (document number GUI00016050)'' or ''Dental Curing Lights—Premarket Notification (510(k)) Submissions (document number GUI00016017)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidances contain no new collection of information, they do 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 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
812	Investigational Device Exemption	0910–0078
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
50, 56	Protection of Human Subjects and Institutional Review Boards	0910–0130

Dated: July 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15337 Filed 7–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Investigational Agent Accountability Record Forms and International Investigator Statement in the Conduct of Investigational Trials for the Treatment of Cancer National Cancer Institute (NCI)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide an opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact Tali Johnson, Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Diagnosis and Treatment, National Cancer Institute, 9609 Medical Center Drive, Bethesda, Maryland 20892 or call non-toll-free number (240) 276–6575 or Email your request, including your address to: *tmjohnson@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires written comments and/or suggestions from the public, and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Investigational Agent Accountability Record Forms and International Investigator Statement in the Conduct of Investigational Trials for the Treatment of Cancer, 0925–0613, Expiration Date 1/31/2025, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a request for OMB to approve the revision of the collection titled ''Investigational Agent Accountability Record Forms in the Conduct of Investigational Trials for the Treatment of Cancer National Cancer Institute (NCI)'' for an additional three years of data collection. The U.S. Food and Drug Administration (FDA) holds the National Cancer Institute (NCI), Division of Cancer Treatment and Diagnosis/Cancer Therapy Evaluation Program (NCI/DCTD/CTEP), and the Division of Cancer Prevention (DCP) responsible as a sponsor of investigational drug trials, to assure the FDA that investigators in its clinical trials program are maintaining systems for accountability. Data obtained from the Investigational Agent Accountability Record Forms (aka. Drug Accountability Record Forms—DARF) are used to track the dispensing of investigational anticancer agents from receipt from the NCI to dispensing or administration to patients. Requirements for tracking investigational agents under an Investigational New Drug Application are outlined in title 21 Code of Federal Regulations (CFR) part 312. NCI and/or its auditors use this information to ensure compliance with federal regulations and NCI policies. This revision removes the International Investigator Statement (IIS) form as it was transitioned to the CTEP Branch and Support Contracts Forms and Surveys (OMB#0925–0753) submission.

OMB approval is requested for 3 years. There are no costs to respondents