committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–11327 Filed 5–25–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review: Adoption and Foster Care Analysis and Reporting System (AFCARS) (OMB #0970–0422)

AGENCY: Children's Bureau, Administration for Children and Families, Department of Health and Human Services (HHS).

ACTION: Request for public comments.

SUMMARY: The Children's Bureau (CB), the Administration for Children and Families (ACF) is requesting a three-year extension of the data information collection for the Adoption and Foster Care Analysis and Reporting System (AFCARS) that was implemented as part of the AFCARS final rule published in May 2020 (85 FR 28410). There are no proposed changes to the data information collection published as the regulation in May 2020. The estimated time per response related to record keeping has been revised since the previous published notice (88 FR 16449) due to feedback from the State and Tribal reporting agencies.

DATES: *Comments due within 30 days of publication.* 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: State and Tribal title IV–E agencies are required to report AFCARS case-level information on all children in foster care and children who have been adopted or placed in a guardianship with title IV–E agency involvement. The data collected will inform policy decisions, program management, and responses to Congressional and Departmental inquiries. Specifically, the data are used for short/long-term budget projections, trend analysis, child and family service reviews, and to target areas for improved technical assistance. The data will provide information on the number of children in foster care, the reasons they enter and exit care, and how to prevent their unnecessary placement in foster care. Specifically, the data include information about children who enter foster care, their entries and exits, placement details, and foster/adoptive parent information. This extension request is unrelated to any potential new regulatory activity that may occur subsequently. This request is for public comment on the burden calculations. It does not seek comment on the data elements that have been through the rulemaking process.

Respondents: Title IV–E State and Tribal Child Welfare Agencies.

Annual Burden Estimates

The following annual burden estimates have been updated to reflect feedback received from the States and Tribes after the first notice published on May 15, 2023 (88 FR 16449). This feedback encouraged ACF to increase the estimated hours per response for recordkeeping.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
AFCARS—Recordkeeping	69	3	17,076	3,534,732	1,178,244
AFCARS—Reporting	69	6	17	7,038	2,346

Estimated Total Annual Burden Hours: 1,180,590.

Authority: Section 479 of the Social Security Act and 45 CFR 1355.44–45.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–11291 Filed 5–25–23; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0737]

Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures; 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 a final guidance entitled ''Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures.'' This guidance document provides recommendations that may help manufacturers comply with the special controls related to non-clinical performance data for gynecologic and general laparoscopic power morcellation containment systems (''tissue containment systems''). Tissue containment systems are used to enable isolation and containment of tissue during a power morcellation procedure performed following a laparoscopic procedure for the excision of benign tissue that is not suspected to contain malignancy.

DATES: The announcement of the guidance is published in the **Federal Register** on May 26, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–0737 for ''Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures.'' 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 guidance document entitled ''Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures'' 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: Prasanna Hariharan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2222, Silver Spring, MD 20993–0002, 301–796–2689 or by email at *prasanna.hariharan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document provides recommendations that may help manufacturers comply with the special controls related to non-clinical performance data for gynecologic and general laparoscopic power morcellation containment systems (''tissue containment systems''). Tissue containment systems are used to enable isolation and containment of tissue during a power morcellation procedure performed following a laparoscopic procedure for the excision of benign tissue that is not suspected to contain malignancy. This guidance recommends non-clinical test methods that may help manufacturers meet the non-clinical performance data requirements identified in the special controls codified in § 884.4050(b)(4) (21 CFR 884.4050(b)(4)) (for gynecologic use) and § 878.4825(b)(4) (21 CFR 878.4825(b)(4)) (for general use), and also includes other non-clinical testing recommendations to support a 510(k) submission/substantial equivalence determination. The recommendations in this guidance are based on FDA's experience evaluating the safety and effectiveness of tissue containment systems. However, manufacturers may use alternative approaches and provide different documentation so long as their approach and documentation satisfy premarket submission requirements in applicable statutory provisions and regulations.

A notice of availability of the draft guidance appeared in the **Federal Register** of June 21, 2022 (87 FR 36859). FDA considered comments received and revised the guidance as appropriate in response to the comments, including a clarification that material permeability testing is recommended to aid in demonstrating substantial equivalence but is not required in the special controls in § 884.4050(b)(4) and § 878.4825(b)(4); specifying that aged samples may be subject to accelerated or real time aging; and indicating that a manufacturer conducting final finished testing of a tissue containment system with multiple device sizes may use the worst-case size sample(s), but, if doing so, should provide a justification for the

choice of worst-case size sample(s) in its submission.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures.'' 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. Electronic Access

Persons interested in obtaining a copy of the guidance 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.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00019015 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new 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 the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions	0910–0756

Dated: May 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11260 Filed 5–25–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0934]

Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products; 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 final guidance for industry entitled ''Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products.'' The guidance represents the current thinking of FDA on adjusting for covariates in randomized clinical trials for drugs and biological products. The guidance discusses general recommendations for performing covariate adjustment, recommendations for performing covariate adjustment using linear models, and recommendations for performing covariate adjusting using nonlinear models. The guidance is intended to facilitate covariate adjustment in the analysis of randomized clinical trials of drugs and biological products and to clarify recommendations for its use. The guidance finalizes the revised draft guidance entitled ''Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products'' issued on May 21, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on May 26, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2019–D–0934 for ''Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products.'' 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