



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1894]

Agency Information Collection Activities; Proposed Collection; Comment Request; Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation B12 Pediatric Device Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collections associated with the “Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation (CERSI) B12 Pediatric Device Survey.”

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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-N-1894 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation B12 Pediatric Device

Survey.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’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 minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation (CERSI) B12

Pediatric Device Survey

OMB Control Number 0910-0912--Reinstatement

Despite numerous legislative, regulatory, and scientific efforts, there has been little change in the number of devices approved for use in pediatric patients. This has often led to

devices being adapted for use in children without an appropriate level of evidence, exposing them to inconsistent benefit risk profiles. This health inequity highlights the need for devices that are designed, evaluated, and labeled for pediatric patients. To address these challenges, this collection is being done to survey industry and other key stakeholders in the medical device ecosystem to identify the barriers that prevent product developers from entering the pediatric device market as well as the proper incentives that would motivate them to innovate and sustain within this market.

This survey is a followup to the public meeting that FDA held in August 2018, entitled, “Pediatric Medical Device Development.” As mandated by section 502(d) of the FDA Reauthorization Act of 2017 (Pub. L. 115-52) the meeting was convened to address several topics, including consideration of ways to: (1) increase FDA assistance to medical device manufacturers in developing devices for pediatric populations that are approved or cleared, and labeled, for their use and (2) identify current barriers to pediatric device development and incentives to address such barriers.

Feedback from this meeting clarified the need to better understand factors influencing suboptimal engagement and participation by diverse innovators in the pediatric medical device space. Information garnered from this survey may help inform strategic plans to optimize existing programs for the needs of pediatric medical device innovators and develop new programs that will support sustained development in this space.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours ²
Phone Survey	17	1	17	0.5 (30 minutes)	9
Online Survey	56	1	56	1	56
Total					65

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Rounded to the nearest hour.

The targeted groups for this collection of information include representatives from the medical device industry, academia, recipients of funding under section 305 of the Pediatric

Medical Device Safety and Improvement Act of 2007 (Pub. L. 110-85; 42 U.S.C. 282 note), and trade organizations, medical provider organizations, organizations and individuals involved with financing and reimbursement associated with medical devices, pediatric healthcare leaders, clinicians who regularly use medical devices in caring for children, and organizations and individuals representing patients and consumers.

Phone survey: Respondents participating in the phone survey will be executives from companies either producing products in pediatrics or from companies that produce products that could be used in pediatrics. Executives will be invited to engage in the 30-minute phone survey.

Online survey: The 1-hour online survey will be administered to leaders within pediatric companies and key decision makers in the pediatric medical device industry (e.g., venture capitalists, banking investors, leaders in children's hospitals and research networks, and pediatric patient advocates).

Substantial turnover in the graduate students administering the survey made it necessary to bring in a new cohort of students and train them in the issues relevant to the survey. As a result, we were unable to field the B12 Pediatrics survey before the OMB approval expiration date and are seeking a reinstatement to complete data collection. To better ensure timely completion of the data collection, the Yale CERSI team has shifted responsibility for conducting the survey and other aspects of the study to a Yale Staff Associate Research Scientist.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: May 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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