

United States Food and Drug Administration

Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation B12 Pediatric
Device Survey

OMB Control No. 0910-0912
Reinstatement Without Change

SUPPORTING STATEMENT

Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us, or we) programs.

FDA held a public meeting 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.

We therefore request OMB approval of this reinstatement without change of the pediatric device survey as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

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, fostering a persisting health inequity with respect to pediatric healthcare. To address these challenges, we are surveying industry and other key stakeholders in the medical device ecosystem to identify the barriers that prevent them from entering the pediatric device market as well as the proper incentives that would motivate them to innovate and sustain within this market.

3. Use of Improved Information Technology and Burden Reduction

Initial outreach to survey participants will be conducted via phone (or video call) and/or email. Least burdensome options for completion of the survey will be offered and include live personal assistance via phone (or video call), and a readily available and accessible, on-line survey platform engaged via an anonymized electronic link.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

Relatively few small businesses or other small entities will be impacted. Participation is voluntary, with upfront clarification that choosing not to participate will not impact any interactions with the institution conducting the survey or the FDA. Only the survey team at Yale will be aware of entities within the survey population who have chosen to participate or not participate. As with all survey participants, small businesses or other small entities will be offered least burdensome options for participation as noted above section three of this supporting statement.

6. Consequences of Collecting the Information Less Frequently

This survey is currently planned to be offered for a single round. Not conducting this survey will lead to a persisting knowledge gap for the FDA regarding the perspectives of industry, and other key stakeholders within the medical device ecosystem, for not developing or supporting pediatric medical devices, and regarding what incentives may engender sustained engagement and innovation with respect to pediatric medical device development.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information. The information collected will be voluntary and will not be used for statistical purposes.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice for public comment in the *Federal Register* of May 22, 2024 (89 FR 44993). We received no comments.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR will collect personally identifiable information (PII). The PII collected typically consists of name and contact information. PII is collected on behalf of the FDA by the Yale/Mayo Clinic Centers of Excellence in Regulatory Science and Innovation (CERSI) who will conduct surveys. PII is collected to identify barriers to pediatric device development and incentives to address such barriers. Information collected by CERSI will be summarized into aggregate form, sent in aggregate to FDA (no PII will be included), and destroyed after the study or interview has been completed. Collected PII is used to notify potential respondents of their selection and includes name and contact information. All information collected will be kept secure by CERSI. FDA and CERSI will disclose identifiable information only to the extent authorized by the individual or required by law. CERSI, who will be maintaining information, will destroy it in accordance with applicable records retention and other requirements per contract terms after the aggregate

information has been provided to FDA and the survey has been completed. In keeping with IRB/Human Subjects Research protocols, the FDA clearance process ensures that study data is appropriately secured (e.g., housed on CERSI servers, password protected, separate storage areas for each study, access controlled).

FDA determined that although PII is collected it is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor does not use name or any other personal identifier to retrieve records from the information collected.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden¹

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

¹Totals are 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 (or video call) 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).

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate ¹	Total Respondent Costs
Medical and Health Services Managers	65	\$123.00	\$7,995

¹ Hourly wage rates have been doubled to account for benefits and overhead and rounded to the nearest dollar. Approximate hourly wage rate is based on the Bureau of Labor and Statistics' May 2022 National Occupational Employment and Wage Estimates for Medical and Health Services Managers (occupational code 11-9111) (http://www.bls.gov/oes/current/oes_nat.htm).

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA estimates that two full time equivalent (FTE) positions are needed for the administration of the information collection. Based on an internal cost model, we assume a fully loaded cost of \$297,561 per position. We calculate the annual Federal cost to be \$595,122.

15. Explanation for Program Changes or Adjustments

This is a reinstatement without change of an information collection that FDA did not have an opportunity to complete before the OMB approval expiration date. 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.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA and Yale plan to publish a manuscript that summarizes the data in a peer-reviewed scientific/academic journal.

Numeric data will be tabulated and summarized utilizing basic descriptive statistics, such as measures of frequency, central tendency, dispersion or variation, and position. In addition, inferential, and potentially associational, statistical analysis techniques may be used.

Qualitative data may also be presented in a tabular format, evaluated via analytical methods such as thematic analysis and grounded theory analysis.

Initiation of this survey will begin shortly after OMB approval. The survey, data tabulation, general analysis are expected to take approximately 12-18 months. Drafting and submission of the associated manuscript to a select peer-reviewed journal, potential acceptance by a journal, and final publication is anticipated in the following calendar year.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.