

Current actions: On November 14, 2023, the Board published a notice in the **Federal Register** (88 FR 78025) requesting public comment for 60 days on the extension, without revision, of the FR 2835 and FR 2835a. The comment period for this notice expired on January 16, 2024. The Board received one comment.

Detailed Discussion of Public Comments

The Board received one comment on the FR 2835 and FR 2835a from the U.S. Department of Commerce Bureau of Economic Analysis (BEA). BEA was in strong support of the continued collection of the FR 2835 and FR 2835a data. The Board will adopt the extension, without revision of the FR 2835 and FR 2835a as originally proposed.

Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2024-07091 Filed 4-2-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; 2024 National Survey of Early Care and Education Longitudinal Follow-Ups (Office of Management and Budget #: 0970-0391)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity to be conducted September 2024 through May 2025 as a follow-up of the 2024 National Survey of Early Care and Education (NSECE).

Statement posted at <https://www.federalreserve.gov/apps/reportingforms/home/review>. On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 2835 and FR 2835a.

The objectives of the 2024 NSECE Longitudinal Follow-ups are to build on the design and implementation of the 2024 NSECE to collect urgently needed information on the following two topics relevant to early care and education (ECE) policy: (1) how households learn about and make use of financial assistance in seeking and selecting ECE, with additional focus on paid individual care arrangements; and (2) patterns of retention and attrition among individuals in the center-based ECE workforce.

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 above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing OPREinfocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The 2024 NSECE Longitudinal Follow-ups will consist of two nationally representative surveys:

1. a survey of households (1) with incomes under 300 percent of the federal poverty level (FPL) and with at least one resident child under the age of 9 years and/or (2) who had used paid care by an individual in the spring of 2024 (2024 NSECE Household Follow-up)

2. a survey of individuals who were employed in early 2024 in center-based ECE programs working directly with children in classrooms serving children age 5 years and under, not yet in kindergarten (2024 NSECE Workforce Follow-up).

Participants will be drawn from respondents to the 2024 NSECE Household and Workforce surveys.

The 2024 NSECE Longitudinal Follow-up data collection efforts will provide urgently needed information that will expand the potential of the 2024 NSECE data to describe: (1) households' search for and use of financial assistance for ECE (including assistance for paid individual care arrangements); and (2) employment experiences of individuals who have recently worked in center-based ECE classrooms. The household follow-up in

Fall 2024 will re-interview households participating in the 2024 NSECE who (1) report using paid individual ECE or (2) report incomes below 300 percent of the FPL and have at least one resident child under age 9 years. The workforce follow-up in early 2025 will re-interview individuals who participated in the 2024 NSECE workforce survey (*i.e.*, served as center-based classroom-assigned instructional staff between January and July 2024). Both follow-up surveys are designed to collect in-depth information that was not feasible to collect in the 2024 NSECE and which can be uniquely collected through re-interviews of selected 2024 NSECE participants. The household follow-up will include information about households' awareness of and experience with publicly funded ECE programs, how households selected ECE arrangements for Fall 2024, and who provided paid individual care to the households' children in early 2024. The workforce follow-up will include information about the experiences of ECE instructional staff over time, where workers who leave ECE employers or the ECE sector go and why they leave, and workers' experiences in various ECE settings throughout their ECE careers. Accurate data on families with young children and the experiences of ECE workers are essential to assess the current landscape of ECE, and to provide insights to advance ECE policy and initiatives. The household follow-up will be fielded using multi-mode survey methodologies in Fall 2024, and the workforce follow-up will be fielded using multi-mode survey methodologies in the first half of 2025. Both follow-ups will enhance the value of the 2024 NSECE by expanding the potential utility of those data to describe household and worker experiences over time and to address additional information needs.

Respondents: 1. Households participating in the 2024 NSECE and either a. reporting a paid individual ECE arrangement in the 2024 NSECE, or b. having at least one resident child under age 9 and who reported incomes under the 300 percent Federal poverty level in the 2024 NSECE. 2. Individuals who participated in the 2024 NSECE survey of center-based classroom-assigned instructional staff (workforce).

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total/annual burden (in hours)
2024 NSECE Household Follow-up Questionnaire	3,750	1	.36	1,350
2024 NSECE Workforce Follow-up Questionnaire (Classroom Staff)	5,550	1	.33	1,832

Estimated Total Annual Burden Hours: 3,182.

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.

Authority: Child Care and Development Block Grant Act of 1990, as amended by the CCDBG Act of 2014 (Pub. L. 113–186), Social Security Act, section 418 as extended by the Continuing Appropriations Act of 2017 and the TANF Extension Act of 2019. Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1245]

Data Integrity for In Vivo Bioavailability and Bioequivalence Studies; Draft 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 draft guidance for industry entitled “Data Integrity for In Vivo Bioavailability and

Bioequivalence Studies.” The purpose of this guidance is to provide recommendations to applicants and testing site management on achieving and maintaining data integrity for the clinical and bioanalytical portions of bioavailability (BA) and bioequivalence (BE) studies submitted in support of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), and the bioanalytical portion of clinical pharmacologic studies supporting Center for Drug Evaluation and Research-regulated biologic license applications (BLAs) as well as amendments and supplements to these applications. In addition, the recommendations in this guidance apply to the bioanalytical portion of nonclinical studies. FDA also encourages applicants and testing sites to consider these recommendations when conducting other studies, including in vitro and pharmacology and toxicology studies.

DATES: Submit either electronic or written comments on the draft guidance by June 3, 2024 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–2024–D–1245 for “Data Integrity for Bioavailability and Bioequivalence Studies at Testing Sites.” 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