

nationally representative survey data to learn more about where parents look for and find information about Child Care and Early Education (CCEE); how parents assess the people, places, or things that may offer CCEE information; what types of CCEE information parents look for; and how parents use information to make CCEE selections. The study aims to gather information that may be used by Child Care Lead Agencies to inform their consumer education efforts.

**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](http://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 [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov). Identify all requests by the title of the information collection.

**SUPPLEMENTARY INFORMATION:**

*Description:* ACF has contracted with NORC to implement this study, which is part of the Consumer Education and Parental Choice in Early Care and Education (CEPC) project. The study will select a nationally representative sample from NORC’s probability-based AmeriSpeak panel. The AmeriSpeak panel provides sample coverage of approximately 97 percent of the U.S. population. It currently contains 48,900 panel members age 13 and over residing in over 40,000 households. U.S. households are randomly selected with a known, non-zero probability from the NORC National Frame, and then recruited by mail, telephone, and by field interviewers face-to-face. NORC’s in-person recruitment enhances representativeness for young adults, lower socio-economic households, non-internet households, and other households that are typically hard to reach for statistical surveys of the population.

We will collect information about (a) where parents look for and find

information about CCEE; (b) how parents assess the people, places, or things that may offer CCEE information; (c) how easy or hard it is for parents to find CCEE information, (d) the types of CCEE information that parents look for and say are helpful in choosing CCEE; (e) information about the last time parents made a decision about CCEE and what information they tried to learn about at that time; (f) parent’s assessments of the CCEE options at the time they made their last CCEE decision; (g) how well parents’ CCEE decision met their family’s needs; and (h) demographic information about families.

*Respondents:* AmeriSpeak panelists who indicated that they have a young child in the household will be invited to complete the survey if they are at least 18 years of age. If a household has two or more panel members who reside in a household with a young child, one will be selected at random to complete the survey, with preference given to parents/legal guardians. Selected panelists will be asked questions to confirm eligibility for the survey, including that the household has at least one child under the age of 6 but not in kindergarten.

*Annual Burden Estimates:*

| Instrument  | Number of respondents (total over request period) | Number of responses per respondent (total over request period) | Average burden per response (in hours) | Total/annual burden (in hours) |
|---|---|--|--|--------------------------------|
| Parent Survey Questionnaire (Section AE Only) ..... | 2,100   | 1  | .08                                    | 168                            |
| Parent Survey Questionnaire (Section A–DA) .....    | 1,500   | 1  | .25                                    | 375                            |

*Estimated Total Annual Burden Hours:* 543.

*Authority:* Child Care and Development Block Grant (CCDBG) Act of 1990, as amended (42 U.S.C. 9857 *et seq.*).

Mary B. Jones,

ACF/OPRE Certifying Officer.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2023–N–3743]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Records; Electronic Signatures**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by February 12, 2024.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0303. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD

20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Electronic Records; Electronic Signatures—21 CFR Part 11**

OMB Control Number 0910-0303—Revision

This information collection supports implementation of statutory and regulatory authorities that govern criteria for the acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Agency regulations in part 11 (21 CFR part 11) provide for the submission of records and reports and establish that information may be submitted to FDA electronically provided that we have stated our ability to accept the records electronically in an Agency-established public docket and that the other requirements of part 11 are met. The regulations apply to records in electronic form that are created, modified, maintained, archived,

retrieved, or transmitted, under any records requirements set forth in Agency regulations and to electronic records submitted under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in Agency regulations.

Regulations in part 11, subpart B (§§ 11.10 through 11.70) require the establishment of standard operating procedures to ensure appropriate use of and precautions for systems using electronic records and signatures, including the following: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; and (3) § 11.50 specifies procedures and controls for persons who use electronic signatures.

Regulations in subpart C (§§ 11.100 through 11.300) require specific controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords.

On March 2, 2023 (88 FR 13018) (Docket No. FDA-2019-N-0646), we revised the regulations. Before using an electronic signature in an electronic record required by FDA, a person must submit a letter of nonrepudiation to FDA (§ 11.100(c)). Letters of nonrepudiation are required under § 11.100(c)(1) to certify that a person's electronic signatures are intended to be the legally binding equivalent of traditional handwritten signatures. The regulations were amended to update the address for submission of a certification in paper form and to provide an option for electronic submission. The regulations were also amended to communicate that information on where to submit the certification may be found on FDA's website, currently available at: <https://www.fda.gov/industry/about-esg/appendix-g-letters-non-repudiation-agreement>.

In the **Federal Register** of September 19, 2023 (88 FR 64441), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| 21 CFR section                                       | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| § 11.100; submission of nonrepudiation letters ..... | 5,000                 | 1                                  | 5,000                  | 1                           | 5,000       |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

| 21 CFR section   | Number of recordkeepers | Number of record per recordkeepers | Total annual records | Average burden per recordkeeping | Total hours |
|--|-------------------------|------------------------------------|----------------------|----------------------------------|-------------|
| § 11.10; controls for closed systems .....                 | 2,500                   | 1                                  | 2,500                | 20                               | 50,000      |
| § 11.30; controls for open systems .....                   | 2,500                   | 1                                  | 2,500                | 20                               | 50,000      |
| § 11.50; signature manifestations .....                    | 5,000                   | 1                                  | 5,000                | 20                               | 100,000     |
| § 11.300; controls for identifications and passwords ..... | 5,000                   | 1                                  | 5,000                | 20                               | 100,000     |
| Total .....  |                         |                                    |                      |                                  | 300,000     |

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

Based on a review of the information collection since our last request for OMB approval, we have increased our estimated burden. We assume 5,000 nonrepudiation letters will be submitted annually. We arrived at this figure by looking at the average number of nonrepudiation letters received through

March 2023. We further assume that half of the estimated respondents will establish controls for open systems and half will establish controls for closed systems. Finally, we assume all respondents will establish controls for the remaining technical specifications required by the regulations.

Dated: January 8, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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