notification; (3) consignee(s) of products for further manufacture; (4) additional product information; (5) updated product disposition; and (6) industry recall contacts. This information is requested by CBER through email notification to the submitter of the BPD report. This information is used by CBER for recall classification purposes. CBER estimates that 3 percent of the total BPD reports submitted to CBER would need additional information submitted in the addendum. CBER further estimates that it would take between 10 and 20 minutes to complete the addendum. For calculation purposes, CBER is using 15 minutes.

Activities such as investigating, changing standard operating procedures or processes, and follow up are currently required under parts 211 (approved under OMB control number 0910–0139), 606 (approved under OMB control number 0910–0116), 820 (approved under OMB control number 0910–0073), and 1271 (approved under OMB control number 0910–0543) and, therefore, are not included in the burden calculation for the separate requirement of submitting a deviation report to FDA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
600.14; Reporting of product deviations by licensed manufacturers	3486	103	6.864	707	2	1,414
606.171; Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments, and transfusion services	3486	2,008	6.883	13,821	2	27,642
1271.350(b); HCT/P deviations	3486	80	2.575	206	2	412
Web-based Addendum	[2] 3486A	66	6.69	442	0.25	110.5
Total				15,176		29,578.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Three percent of the number of respondents ((2,008 + 103 + 80) × 0.03 = 66) and total annual responses to CBER ((13,821 + 707 + 206) × 0.03 = 442).

Our estimated burden for the information collection reflects an overall decrease of approximately 65,014 hours and a corresponding decrease of 34,152 responses. We attribute this adjustment to a decrease in the number of deviation reports we received in FY 2021 from licensed manufacturers and unlicensed registered blood establishments under § 606.171. This is likely due to our issuance of the revised guidance document entitled ''Biological Product Deviation Reporting for Blood and Plasma Establishments'' (85 FR 14682, March 13, 2020), which provided blood and plasma establishments with revised recommendations related to BPD reporting. The revised guidance provided a less burdensome policy for reporting BPDs that is consistent with public health and eliminated the reporting of post donation information (PDI) events as BPD reports because these reports were no longer unexpected or unforeseeable. Given the substantial number of PDI reports FDA has received, the Agency is aware that these events occur, and the submission of additional PDI reports to FDA is unlikely to facilitate the identification of manufacturing or safety issues.

Dated: June 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13086 Filed 6–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0721]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and Issue Certifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by July 18, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0750. 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–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and Issue Certifications—21 CFR Part 1, Subpart M

OMB Control Number 0910–0750—Extension

This information collection helps to implement FDA's Accredited Third-Party Certification Program (also referred to as the third-party food program), established and administered under section 808 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384d), and codified in 21 CFR part 1, subpart M (21 CFR parts 1.600 through 1.725) of Agency regulations. The regulations communicate eligibility criteria, assessment standards, and establish procedures and requirements

for participation. For more information visit our website at *https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program.*

Under the third-party food program, accreditation bodies (ABs) apply to FDA for recognition. Recognized ABs accredit third-party certification bodies (CBs) under the program, except in limited circumstances. The accredited CBs conduct food safety audits and issue food or facility certifications to eligible foreign entities. FDA uses certifications issued by accredited third-party auditors/CBs in deciding whether to admit certain imported food (both food for human and other animals) into the United States. Under the third-party program, FDA may grant recognition of an AB for up to 5 years from the date of recognition. Current third-party program AB participants are recognized for the duration from 2018 to 2023 and will need to submit renewal of recognition applications to continue their participation.

There are approximately 200,000 foreign food (both food for human and other animals) exporters who offer their food products for import into the United States. These foreign food exporters include approximately 130,000 food production facilities and approximately 71,000 farms. A proportion of these foreign food exporters may offer food subject to mandatory certification requirements under section 801(q)(3) of the FD&C Act (21 U.S.C. 381(q)(3)). In that case, to continue exporting food products into the United States, eligible entities must either obtain certification from a CB accredited under the third-party program, or obtain certification from a foreign government designated by FDA. We assume in any given year, 75 foreign food exporters will be subject to requirements in section 801(q) of the FD&C Act.

Participating in the third-party accreditation program helps reduce the number of redundant audits necessary to assess compliance with food safety requirements of the FD&C Act and applicable regulations. Required data elements are submitted using FDA's Unified Registration Listing System (FURLS), an electronic portal (Forms FDA 3997 for ABs and 3997a for CBs) that enables respondents to complete data fields and provide information to FDA electronically. The AB and CB portals provide a standardized format for entering information, prompting respondents for input and facilitating FDA's review of the submittal. Instructions may be accessed at *https://www.fda.gov/food/importing-food-products-united-states/accredited-third-party-certification-program.*

Respondents to the collection of information are eligible entities seeking audits, certification, and/or recertification by accredited CBs participating in the third-party program, and ABs and CBs seeking to comply with the recognition requirements. An eligible entity is a foreign entity in the import supply chain of food for consumption in the United States that chooses to be subject to a food safety audit conducted by an accredited third-party CB.

In the **Federal Register** of February 16, 2022, (87 FR 8846), 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 [1]

21 CFR part 1, subpart M	Number of respondents	Number of responses per respondent [2]	Total annual responses	Average burden per response [2]	Total hours
AB applications, renewals, notifications, revocations	25	11.36	284	3.18	903
CB certifications, regulatory audits and assessments, notifications.	208	147.29	30,638	0.25 (15 minutes)	7,661
CB applications for direct accreditation & renewal	1	1	1	90	90
Total			30,923		8,654

[1] We estimate no capital costs or operating and maintenance costs for the information collection.
[2] Figures rounded to the nearest one, one-hundred as calculated based on total number of records and hours.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part 1, subpart M	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping [2]	Total hours
AB documenting certification procedures; maintaining applicable records.	25	426.56	10,664	0.25 (~15 minutes)	2,677
AB establishing and updating public list of CBs	25	1	25	52.8	1,320
CB documenting procedures for accreditation; maintaining applicable records (audits, certifications, serious risks).	208	112.72	23,446	0.35 (~20 minutes)	8,228
CB establishing & updating public list of eligible entities.	208	1.31	273	44.19	12,064
Contract modification [2]	7	9	63	2	126
Total			34,471		24,415

[1] We estimate no capital costs, or operating and maintenance costs for the information collection.
[2] Figures rounded to the nearest one, one-hundred as calculated based on total number of records and hours.

We include in our estimate reporting burden attributable to required submissions, including notifications, to FDA; and recordkeeping burden attributable to the time we assume necessary for searching data sources, and preparing and maintaining records described in the applicable regulations. We estimate that 25 ABs will accredit

CBs who conduct food safety audits of foreign eligible entities that offer food for import to the United States. We also estimate the 208 accredited CBs will participate in the third-party program. In addition, we expect that one CB will apply and participate in the third-party program via direct accreditation by FDA. Finally, we attribute nominal burden to recordkeeping attendant to contractual modifications that may be part of accreditation.

Based on a review of the information collection since last OMB approval, we have made only nominal adjustments to our burden estimate.

Dated: June 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13071 Filed 6–16–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Request for Information: Early Hearing Detection and Intervention Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of request for public comment.

SUMMARY: HRSA's Early Hearing Detection and Intervention (EHDI) Program is requesting input from the public to inform future EHDI program development.

DATES: Submit comments no later than July 18, 2022.

ADDRESSES: Submit electronic comments to *ehdi@hrsa.gov.* Please submit your response only one time by July 18, 2022.

FOR FURTHER INFORMATION CONTACT: Sandra Battiste, MPH at *ehdi@hrsa.gov* or (301) 443–0223.

SUPPLEMENTARY INFORMATION: HRSA's EHDI Program, authorized under 42 U.S.C. of the Public Health Service Act, seeks to enable states, jurisdictions, families, and clinical, educational, and social service providers to develop coordinated systems of care so that newborns, infants, and young children who are deaf or hard of hearing are identified as early as possible and receive the services they need. Early involvement can help these children meet age-appropriate language, literacy, social-emotional, and other developmental milestones. HRSA currently funds 59 states and jurisdictions [1] through the EHDI grants program in order to (1) increase health professionals' engagement with and knowledge of the EHDI system,[2] (2) improve access to early intervention services and language acquisition, and (3) improve family engagement, partnership, and leadership in EHDI systems. The HRSA-funded National Technical Resource Center supports states and territories by providing technical assistance and resources in order to meet EHDI program goals and objectives.

HRSA investments also support family engagement and workforce development related to EHDI. For example, the Family Leadership in Language and Learning program aims to strengthen family leadership and inclusion of families, parents and caregivers of children who are deaf or hard of hearing within the EHDI system. In addition, HRSA funds the Leadership Education in Neurodevelopmental and Related Disabilities program, authorized under the Public Health Service Act, to support workforce development through audiology training grants. More information about the HRSA EHDI program is available online at: *https://mchb.hrsa.gov/maternal-child-health-initiatives/early-hearing-detection-and-intervention.html.*

Responses

HRSA is seeking responses that address the following questions. A response to each question is not required.

1. What strategies or programs are needed to support EHDI programs to ensure that all newborns are screened by 1 month of age, a diagnosis is made by 3 months of age, and children who are deaf or hard of hearing are enrolled in and start to receive intervention services by 6 months of age?

2. What strategies should be considered to support the timely identification and receipt of services for young children up to age 3?

3. What strategies should be considered to ensure that infants and young children receive screening and diagnosis services that are high quality and evidence-based?

4. What strategies should be considered to ensure that providers collect and report high quality data on hearing screening, diagnosis, and follow-up to EHDI programs for public health surveillance?

5. What strategies or programs would ensure that families of children who are deaf or hard of hearing receive information that is accurate, comprehensive, up-to-date, and evidence-based, as appropriate, to allow families to make important decisions for their children in a timely manner, including decisions with respect to the full range of assistive hearing technologies and communications modalities, as appropriate?

6. What strategies would help ensure families, parents, and caregivers are continuously engaged as active partners in the EHDI system?

7. What approaches that foster family-to-family and deaf and hard of hearing consumer-to-family supports by families and adults who are deaf or hard of hearing should be considered?

8. What new evidence-based or promising approaches that help deaf or hard of hearing children meet language, literacy, social, emotional, and other developmental milestones should be considered within EHDI Programs/the EHDI system?

9. How has COVID–19 impacted the EHDI system of care, including the ability of EHDI programs to share or report information in a timely manner? Are there any notable promising practices or approaches used in response that should be further explored?

10. What ongoing and emerging gaps in access to services are present within the EHDI system? Are there populations that are experiencing inequities in access to timely identification and receipt of services? What approaches should be used to address these gaps?

Respondents can also provide additional comments or recommendations that are not specifically linked to the questions above. All responses may but are not required to identify the individual's name, address, email, telephone number, professional or organizational affiliation, background or area of expertise (*e.g.,* program participant, family member, clinician, public health worker, researcher, EHDI Coordinator, etc.), and topic/subject matter. Information obtained as a result of this request for information (RFI) may be

[1] For the purpose of this request for information, the term ''jurisdiction'' includes the District of Columbia, the Republic of the Marshall Islands, the Federated States of Micronesia, the Republic of Palau, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

[2] For the purpose of this request for information, the EHDI system is defined as ''families, consumers, providers, services, and programs that work towards developing coordinated and comprehensive state and territory systems so that families with newborns, infants, and young children who are deaf or hard of hearing receive appropriate and timely services that include hearing screening, diagnosis, and intervention.'' Early Hearing Detection and Intervention Program Notice of Funding Opportunity HRSA–20–047''?