[FR Doc. 2019–24235 Filed 11–5–19; 8:45 am]

**BILLING CODE 4120–01–C**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Expedited OMB Review: Proposed Information Collection Activity; National Human Trafficking Training and Technical Assistance Center (NHTTAC) Evaluation Package (OMB #0970–0519)

**AGENCY:** Office on Trafficking in Persons; Administration for Children and Families; Department of Health and Human Services.

**ACTION:** Request for public comment.

**SUMMARY:** The Office on Trafficking of Persons (OTIP), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting expedited review of an information collection request from OMB for an increase in the number of respondents to the previously approved information collection, National Human Trafficking Training and Technical Assistance Center (NHTTAC) Evaluation Package (OMB #0970–0519, expiration 10/31/2021). This will increase the estimated burden hours from 689 hours to 9,495 hours. In addition, the previously approved SOAR Online participant feedback form has been restructured into a long and a short form to reduce burden for information collected on SOAR Online training participants outside of the NHTTAC learning management system. There are no changes requested to the items on any forms.

**DATES:** ACF is requesting that OMB approve this request under procedures for emergency processing by December 20, 2019.

**ADDRESSES:** Copies of the proposed collection of information can be obtained by emailing *infocollection@acf.hhs.gov.* All requests should identify the title of the information collection. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

**SUPPLEMENTARY INFORMATION:**

*Description:* ACF is requesting that OMB grant a 180 day approval for this request under procedures for expedited processing by December 20, 2019. A request for review under normal procedures will be submitted within 180 days of the approval for this request. These changes are requested due to the passage of the Stop, Observe, Ask, and Respond to Health and Wellness Act of 2018 (Pub. L. 115–398) which expands the SOAR to Health and Wellness Training Program. To meet the provisions of the SOAR to Health and Wellness Act of 2018, OTIP's NHTTAC must expand the administration of SOAR nationwide.

The NHTTAC delivers training and technical assistance (T/TA) to inform and deliver a public health response to trafficking. In applying a public health approach, NHTTAC holistically builds the capacity of communities to identify and respond to the complex needs of all individuals who have been trafficked and address the root causes that put individuals, families, and communities at risk of trafficking. This will ultimately help improve the availability and delivery of coordinated and trauma-informed services before, during, and after an individual's trafficking exploitation, regardless of their age, gender, nationality, sexual orientation, or type of exploitation.

NHTTAC hosts a variety of services, programs, and facilitated sessions to improve service provision to individuals who have been trafficked or who are at risk of trafficking, including The Human Trafficking Leadership Academy (HTLA); the Survivor Fellowship Program; the NHTTAC Call Center; both short-term and specialized T/TA requests (requests that take less than 3 hours or 3 or more hours to fulfill, respectively); OTIP-funded grantees; and information through NHTTAC's website, resources, and materials about trafficking.

*Respondents:* Individuals and organizations such as NHTTAC consultants, training and technical assistance participants, Human Trafficking Leadership Academy program participants, Survivor fellows, OTIP grantees, visitors to the NHTTAC website, NHTTAC-supported conference and meeting attendees, members of the National Advisory Council, and scholarship applicants.

*Annual Burden Estimates:* The following instruments have an increased number of respondents. The number of respondents for all other previously approved instruments remains the same. The increase in respondents increases the overall burden under OMB #0970–0519 from 689 hours to 9,495 hours.

| Instrument | Original estimate—number of respondents | Updated estimate—number of respondents | Number of responses per respondent | Average burden hours per response | Updated annual burden hours |
|---|---|---|---|---|---|
| HTLA Fellowship Pre-Program Feedback | 24 | 36 | 1 | 0.25 | 9 |
| HTLA Fellowship Post-Program Feedback | 24 | 36 | 1 | 0.25 | 9 |
| OTIP Grantee Feedback Form | 50 | 100 | 1 | 0.167 | 17 |
| Short-Term T/TA Feedback Form | 30 | 50 | 1 | 0.167 | 8 |
| Specialized T/TA Feedback Form | 50 | 100 | 1 | 0.25 | 25 |
| Focus Group Demographic Survey | 25 | 50 | 1 | 0.033 | 2 |
| Focus Group Guide | 25 | 50 | 1 | 0.75 | 38 |
| Follow-up Feedback Form | 300 | 500 | 1 | 0.133 | 67 |
| Interview Guide | 25 | 65 | 1 | 0.75 | 49 |
| Pilot Feedback Form | 25 | 50 | 1 | 0.15 | 8 |
| SOAR Blended Learning Participant | 30 | 130 | 1 | 0.15 | 20 |
| SOAR Online Participant Feedback Long Form | 1,500 | 5,300 | 1 | 0.1 | 530 |
| SOAR Online Participant Feedback Short Form | | 1,000,000 | 1 | 0.0083 | 8,300 |
| SOAR Organizational Feedback Form | 20 | 40 | 1 | 0.133 | 5 |

*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:** 22 U.S. Code 7104 and 22 U.S. Code 7105(c)(4).

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–2778]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA 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:** Fax written comments on the collection of information by December 6, 2019.

**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 0910–0298. 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*.

**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.

### Threshold of Regulation for Substances Used in Food-Contact Articles—21 CFR 170.39

*OMB Control Number 0910–0298—Extension*

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless one of the following is applicable: (1) It conforms to an exemption for investigational use under section 409(j) of the FD&C Act; (2) it conforms to the terms of a regulation prescribing its use; or (3) in the case of a food additive that meets the definition of a food-contact substance in section 409(h)(6) of the FD&C Act, there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

The regulations in § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The Agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 part per billion. The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

To determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) The chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption from regulation as a food additive; (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance; (5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use. We use this information to determine whether the food-contact substance meets the threshold criteria.

*Description of Respondents:* Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (*i.e.,* food packaging and food processing equipment) or of the articles themselves.

In the **Federal Register** of June 21, 2019 (84 FR 29209), 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 170.39 | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Threshold of regulation for substances used in food-contact articles | 7 | 1 | 7 | 48 | 336 |

[1] 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 made no adjustments. We estimate that approximately seven requests per year will be submitted under the threshold of regulation exemption process of § 170.39, for a total of 336 hours. In the **Federal Register** of June 21, 2019, we estimated four requests per year. In reconsideration of the two to three requests that were received but did not become effective, we retain our previous estimate of seven requests per year, with