I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Product Identifiers Under the Drug Supply Chain Security Act: Questions and Answers.'' The DSCSA (Title II of Pub. L. 113–54) was signed into law on November 27, 2013. Section 202 of the DSCSA, which added sections 581 and 582 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee and 360eee–1), set forth new definitions and requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of product through the pharmaceutical distribution supply chain.

A product identifier is defined under section 581(14) of the FD&C Act as a standardized graphic that includes the product's standardized numerical identifier (composed of the National Drug Code and a unique alphanumeric serial number), lot number, and expiration date, in both human- and machine-readable formats. Under sections 582(b)(2)(A) and 582(e)(2) of the FD&C Act, respectively, manufacturers and repackagers are required to ''affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce.''

In the **Federal Register** of September 20, 2018 (83 FR 47626), FDA announced the availability of the draft guidance of the same title dated September 20, 2018. FDA received several comments on the draft guidance and considered those comments as we finalized the guidance. Among the key substantive changes, we revised the recommendations regarding the expiration date format—specifically, we no longer recommend using a space between the day, month, and year; we now recommend using a hyphen or forward slash between the expiration date elements. In addition, we also modified our statements regarding use of the human-readable GS1 Global Trade Identification Number to explain the importance of the three segment NDC format for patient safety. We also clarified how to affix or imprint multiple barcodes on the label with sufficient space to avoid confusion in reading or scanning. We made additional, editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 20, 2018.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Product Identifiers Under the Supply Chain Security Act: Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: May 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–11733 Filed 6–3–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0476]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 6, 2021.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0476, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: ASPA COVID–19 Public Education Campaign Market Research.

Type of Collection: OMB #0990–0476.

Abstract: U. S. Department of Health and Human Services (HHS), the Office of the Secretary, the Office of the Assistant Secretary for Public Affairs (ASPA), is requesting an extension on a currently approved collection that includes three components: 1. COVID–19 Current Events Tracker; 2. Foundational Focus Groups; and 3. Copy Testing Surveys. Together, these efforts support the development and execution of the COVID–19 Public Education Campaign. The broad purpose of each effort is as follows:

Current Events Tracker

The primary purpose of the COVID–19 Current Events Tracker (CET) survey is to continuously track key metrics of importance to the Campaign, including vaccine confidence, familiarity with and trust in HHS, and the impact of external events on key attitudes and behaviors. Tracking Americans' attitudes about, perceptions of, and behavior toward the COVID–19 pandemic will inform the Campaign of key metrics around vaccine confidence and uptake, as well as towards vaccine messengers such as HHS and key public health officials. It will also inform changes in messaging strategies necessary to effectively reach the entire U.S. population or specific subgroups.

The weekly tracking of this information will be critical for the Campaign's ability to respond to shifting events and attitudes in real-time, helping guide the American public with accurate information about the vaccine rollout as well as on how to take protective actions.

Foundational Focus Groups

ASPA is collecting information through the COVID–19 Public Education Campaign Foundational Focus Groups to inform the Campaign about audience risk knowledge, perceptions, current behaviors, and barriers and motivators to healthy behaviors (including COVID–19 vaccination). Ultimately these focus groups will provide in-depth insights

regarding information needed by Campaign audiences as well as their attitudes and behaviors related to COVID–19 and the COVID–19 vaccines. These will be used to inform the development of Campaign messages and strategy.

Copy Testing Surveys

Prior to placing Campaign advertisements in market, ASPA will conduct copy testing surveys to ensure the final Campaign messages have the intended effect on target attitudes and behaviors. Copy testing surveys will be conducted with sample members who comprise the target audiences; these surveys will assess perceived effectiveness of the advertisements as well as the effect of exposure to an ad on key attitudes and behavioral intentions. The results from these surveys will be used internally by ASPA to inform decisions on Campaign messages and materials; for example, to identify revisions to the materials or determine which advertisement to move to market.

Need and Proposed Use: In light of the current COVID–19 crisis, this information is needed given the impact of the pandemic on the nation. The Secretary of the Department of Health and Human Services (HHS) has declared a public health emergency effective January 27, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d [1]) and renewed it continually since its issuance (see links to the determination here and here). Additionally, in accordance with 5 CFR 1320.13, HHS previously requested emergency submissions (sections 1320 (a)(2)(ii) and (2)(iii) of the federal regulations.

ESTIMATED ANNUALIZED BURDEN HOUR TABLE

	CET	Foundational focus groups	Copy testing survey
Hours to screen	N/A	.09	0.03
Screening completes (per wave)	N/A	2,500	6,700
Screening participants (total/screened out)	N/A	20,000/19,136	53,600/45,600
Hours to complete survey/group	0.12	1.5	0.33
Participants (per wave/round)	1,000	108	1,000
Number of waves/rounds	92	8	8
Burden per wave/round	120	387	330
Total participants	92,000	864	8,000
Total respondents *	92,000	20,000	53,600
Total burden hours	11,040	3,096	4,248

* Total respondents = total participants for each effort + total people screened out.

Sum of All Studies

Total Respondents: 165,600.
Total Burden Hours: 18,384.

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2021–11723 Filed 6–3–21; 8:45 am]

BILLING CODE 4150–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Integrated Preclinical/Clinical AIDS Vaccine Development Program (IPCAVD) (U19 Clinical Trial Not Allowed).

Date: June 30, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G36, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Poonam Pegu, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC–9823, Rockville, MD 20892, 240–292–0719, *poonam.pegu@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 28, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–11711 Filed 6–3–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; SARS-CoV–2, COVID–19 and Consequences of Alcohol Use (RFA AA 21–002, AA 21–003 and AA21–004).

Date: July 15–16, 2021.

Time: 9:00 a.m. to 6:00 p.m.