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. 360ee and 360eee–1), set forth new definitions and requirements for manufacturers, repackers, 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 repackers 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In the Federal Register of September 20, 2018 (83 FR 47626), FDA announced the availability of the draft guidance of the same title dated September 20, 2018. FDA received several comments on the draft guidance and considered those comments as we finalized the guidance.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 The guidance announced in this notice finalizes the draft guidance dated September 20, 2018.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


Dated: May 26, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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

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

*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
(IPCAV D) (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)


Tyesha 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

Date: July 15–16, 2021.

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