EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate *	Total cost burden
Total	NA	54	NA	2,509

* The wage rate in Exhibit 2 is based on May 2019 National Industry-Specific Occupational Employment and Wage Estimates, Bureau of Labor Statistics, U.S. Dept. of Labor. Mean hourly wages for nursing home POCs are located at *https://www.bls.gov/oes/current/naics3_623000.htm*. The hourly wage of $46.45 is the weighted mean of $47.32 (General and Operations Managers 11–1021; N=26) and $44.82 (Medical and Health Services Managers 11–9111; N=14).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 16, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–20418 Filed 9–20–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0104]

Advisory Committee on Immunization Practices (ACIP)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC), announces the following meeting of the Advisory Committee on Immunization Practices (ACIP). This meeting is open to the public. Time will be available for public comment. The meeting will be webcast live via the World Wide Web. A notice of the ACIP meeting has also been posted on CDC's ACIP website: *http://www.cdc.gov/vaccines/acip/index.html*.

DATES: The meeting will be held on September 22, 2021, from 10:00 a.m. to 5:00 p.m., EDT, and September 23, 2021, from 11:00 a.m. to 2:00 p.m., EDT (dates and times subject to change), see the ACIP website for updates: *http://www.cdc.gov/vaccines/acip/index.html*. The public may submit written comments from September 21, 2021 through September 23, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0104 by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H24–8, Atlanta, Georgia 30329–4027, Attn: September 22–23, 2021 ACIP Meeting.

Instructions: All submissions received must include the Agency name and Docket Number. All relevant comments received in conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Stephanie Thomas, ACIP Committee Management Specialist, Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, 1600 Clifton Road NE, MS–H24–8, Atlanta, Georgia 30329–4027; Telephone: (404) 639–8367; Email: *ACIP@cdc.gov*.

SUPPLEMENTARY INFORMATION: In accordance with 41 CFR 102–3.150(b), less than 15 calendar days' notice is being given for this meeting due to the exceptional circumstances of the COVID–19 pandemic and rapidly evolving COVID–19 vaccine development and regulatory processes. The Secretary of Health and Human Services has determined that COVID–19 is a Public Health Emergency. A notice of this ACIP meeting has also been posted on CDC's ACIP website at: *http://www.cdc.gov/vaccines/acip/index.html*. In addition, CDC has sent notice of this ACIP meeting by email to those who subscribe to receive email updates about ACIP.

Purpose: The committee is charged with advising the Director, CDC, on the use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the Director of the Centers for Disease Control and Prevention and appear on CDC immunization schedules must be covered by applicable health plans.

Matters To Be Considered: The agenda will include discussions on COVID–19 vaccine booster doses. Agenda items are subject to change as priorities dictate. A recommendation vote is scheduled. For more information on the meeting agenda visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html*.

Meeting Information: The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html*.

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be

posted on *https://www.regulations.gov*. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: Written comments must be received on or before September 22, 2021.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the September 22–23, 2021, ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EDT, September 20, 2021, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by 12:00 p.m., EDT, September 21, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–20473 Filed 9–17–21; 11:15 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0952]

Final Administrative Orders for Over-the-Counter Monographs; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability on its website of certain final administrative orders (final orders), including for over-the-counter (OTC) drug monographs, that were deemed to be final orders by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which added a new section to the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA is also announcing the process for making these final orders available. Finally, FDA is announcing its plan for withdrawing regulations that established final OTC drug monographs prior to the passage of the CARES act, and withdrawing or making technical changes to the procedures governing the OTC drug review.

DATES: The announcement of the availability on FDA's website of certain final orders as deemed by section 505G of the FD&C Act and other actions related to section 505G is published in the **Federal Register** on September 21, 2021.

ADDRESSES: You may view the final orders in the OTC *Monographs@FDA* portal at *https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm.*

- *Instructions:* For access to the final orders, go to *https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm.* Under the ''Administrative Orders'' banner, click on the desired link under the ''Order ID'' heading and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Helen Lee, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6848.

SUPPLEMENTARY INFORMATION:

I. Background

On March 27, 2020, the CARES Act was signed into law. The CARES Act includes provisions that govern the way certain OTC drugs are regulated in the United States. In particular, the CARES Act added section 505G to the FD&C Act (21 U.S.C. 355g), which reforms and modernizes the OTC drug review process that was established in 1972. Under the OTC drug review, OTC drug monographs (also referred to as OTC monographs) for different therapeutic categories are established. OTC drugs are generally recognized as safe and effective (GRASE) if they meet the conditions of an OTC monograph, including the specified active ingredients, uses (indications), doses, routes of administration, labeling, and testing, along with other applicable requirements.

A. Regulatory Framework for OTC Monograph Drugs Prior to the Passage of the CARES Act

Prior to passage of the CARES Act, OTC monographs were established, revised, and amended using the rulemaking process set out by the Administrative Procedure Act in 21 U.S.C. 553. Final OTC monographs (final monographs) were codified in regulations under title 21 of the CFR. The OTC monograph process was set forth in 21 CFR part 330 (part 330). Prior to establishment of a final monograph, GRASE conditions for a therapeutic category were set forth in proposed rules as tentative final monographs. At the time of the passage of the CARES Act, certain OTC monographs were still at the proposed rulemaking stage, either in whole or in part.

In the course of the OTC drug review, FDA also determined when there was not sufficient evidence to demonstrate certain conditions (*e.g.,* active ingredients for specific uses) were GRASE. In such cases, FDA often expressly codified these determinations that certain conditions were not GRASE (see, *e.g.,* § 310.545 (21 CFR 310.545)). In addition, part 201, subpart G (21 CFR part 201, subpart G), includes specific labeling requirements for certain drugs, including OTC monograph drugs (see, *e.g.,* § 201.326, requiring warnings and other labeling for OTC drug products containing internal analgesic and antipyretic active ingredients).

B. Regulatory Framework for OTC Monograph Drugs Under the CARES Act

The CARES Act added section 505G to the FD&C Act, which revised the framework for the regulation of OTC