Dated: November 15, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–25323 Filed 11–19–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–1978–N–0018]**

## Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-The-Counter Human Use; Over-The-Counter Monograph Proposed Order (OTC 000008) Extension of Comment Period

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

**ACTION:** Proposed order; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has extended the comment period for the over-the-counter (OTC) monograph proposed order (order ID OTC000008) entitled ''Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use'' (Proposed Order), which was issued on September 24, 2021. A notice of availability for the Proposed Order appeared in the **Federal Register** of September 27, 2021. FDA issued the Proposed Order to amend and revise the deemed final administrative order concerning nonprescription sunscreen drug products (Deemed Final Order) established by the enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The Proposed Order, if finalized, would replace the Deemed Final Order in its entirety with new conditions under which nonprescription sunscreen drug products would be determined to be generally recognized as safe and effective (GRASE) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). It would also set forth certain characteristics that would establish that a sunscreen drug product is not GRASE. FDA has extended the comment period for the Proposed Order in response to a request for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the Proposed Order issued on September 24, 2021 (86 FR 53322). Submit electronic comments on the Proposed Order by 11:59 p.m. Eastern Time at the end of December 27, 2021.

**ADDRESSES:** You may submit comments to Order ID OTC000008 as follows. Please note that late, untimely filed comments will not be considered. Comments must be submitted electronically on or before December 27, 2021. The *https://www.regulations.gov* will accept comments at any time until 11:59 p.m. Eastern Time at the end of December 27, 2021.

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any information that you or a third party may not wish to be publicly posted, such as medical information or your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment electronically in the manner detailed in *Instructions.*

*Instructions:* All submissions received must include the Order ID Number OTC000008 and the Docket No. FDA–1978–N–0018 for ''Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable on *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—Under section 505G(d) of the FD&C Act (21 U.S.C. 355h(d)), FDA must make any information submitted by any person with respect to this order available to the public upon submission, with limited exceptions. FDA will not make public information pertaining to pharmaceutical quality information, unless such information is necessary to establish standards under which a drug is generally recognized as safe and effective under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)) (see section 505G(d)(2)(B) of the FD&C Act). FDA will also not make public information that is of the type contained in raw datasets (see section 505G(d)(2)(B) of the FD&C Act). To submit a comment with this specific confidential information that you do not wish to be made publicly available, electronically submit two copies of the comment as an attachment to your comment submission. One copy will include the information that you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information. The second copy, which will have the claimed information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Any information marked as ''confidential'' will not be disclosed except in accordance with section 505G(d) of the FD&C Act, and other applicable disclosure law.

*Docket:* For access to the docket to read background documents or the electronic comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

**FOR FURTHER INFORMATION CONTACT:** Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–7945.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of September 27, 2021 (86 FR 53322), FDA announced the availability of an OTC monograph proposed order (order ID OTC000008), issued pursuant to section 505G(b) of the FD&C Act (21 U.S.C. 355g(b)) and section 3854(c)(1) of the CARES Act, entitled ''Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use.'' FDA issued this Proposed Order to amend and revise the Deemed Final Order established by the enactment of the CARES Act, Public Law 116–136 (March 27, 2020).[1] This Proposed Order,

[1] To address nonprescription sunscreen drug products that are also subject to provisions in other monographs, this proposed order also proposes to amend and revise ''OTC Monograph M016, Skin Protectant Drug Products for Over-the-Counter Human Use,'' and to consolidate existing and new provisions that identify sunscreens that are not GRASE in ''Non-Monograph Conditions NM020: Sunscreen Drug Products for Over-the-Counter Human Use.''

if finalized, would replace the Deemed Final Order in its entirety with new conditions under which nonprescription sunscreen drug products would be determined to be GRASE under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)). It would also set forth certain characteristics establishing that a sunscreen drug product is not GRASE under section 201(p)(1) of the FD&C Act.

The original close of the public comment period for this Proposed Order was November 12, 2021. On November 2, 2021, the Agency received a request to extend this comment period by a minimum of 45 days, conveying concern that the original comment period did not provide sufficient time for review of the Proposed Order or for submission of needed updates related to sunscreen active ingredients about which FDA had requested additional data. FDA considered the request and extended the public comment period for the Proposed Order for an additional 45 days, until December 27, 2021.[2] This extension will allow additional time for the public to submit information related to these active ingredients (and other proposed sunscreen conditions) that has become available since the closure of the comment period on the 2019 Proposed Rule ''Sunscreen Drug Products for Over-the-Counter Human Use'' (2019 Proposed Rule).

The Agency reiterates that, as stated in the notice of availability of the Proposed Order published in the **Federal Register** on September 27, 2021, and in the Proposed Order itself, the Agency will consider all comments that were submitted to the public docket for the 2019 Proposed Rule within its comment period to be constructively submitted as comments on the Proposed Order. The Agency requests that commenters do not resubmit comments on this Proposed Order previously submitted on the 2019 Proposed Rule.

Dated: November 16, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–25371 Filed 11–19–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0990–0475]**

### 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 December 22, 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 0990–0475, 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 Evaluation Surveys.

*Type of Collection:* Extension.

*OMB No.:* 0990–0475.

*Abstract:* The Office of the Assistant Secretary for Public Affairs (ASPA), U.S. Department of Health and Human Services (HHS) is requesting an extension on a currently approved collection including two components: 1. COVID–19 Attitudes and Beliefs Survey (CABS), and 2. Monthly Outcome Survey (MOS). Throughout execution of the campaign, this information will primarily be used by ASPA to determine whether the campaign is having the intended impact on target audiences' (*e.g.,* parents, young adults, 65+) knowledge, attitudes, and beliefs as they relate to COVID–19, COVID–19 vaccination, and adherence to preventative behaviors. It will also keep key stakeholders informed of the Campaign's progress. Ultimately, the data will inform a thorough evaluation of the efficacy of the campaign and its impact on vaccine uptake.

**COVID–19 Attitudes and Beliefs Survey (CABS)**

The CABS is a longitudinal survey that will be fielded tri-annually to 4,000 U.S. adults for the duration of the Campaign via NORC at the University of Chicago's AmeriSpeak Panel. The survey will be fielded online, and each fielding period will last between 3 and 6 weeks. Those that respond to wave 1 of the survey will be recontacted in each wave, facilitating a comparison of COVID–19 behavior change over time for a representative sample and evaluation of U.S. adults. Panel members selected to participate in the study will receive one pre-invitation postcard in the mail, one email invitation, and three email reminders to complete the survey in each wave.

**Monthly Outcome Survey (MOS)**

The MOS is a shorter, cross-sectional survey that will be fielded monthly to 5,000 U.S. adults for the duration of the Campaign via the Ipsos KnowledgePanel 5K Omnibus Survey. The survey will be fielded online, and each fielding period will last between 7 and 10 days.

ANNUALIZED BURDEN HOUR TABLE

| | CABS | MOS |
|---|---|---|
| Hours to complete survey | 0.58 | 0.17 |
| Participants (per wave) | 4,000 | 5,000 |
| Number of waves (per year) | 3 | 12 |
| Total respondents per year | 12,000 | 60,000 |
| Total burden hours per year | 6,960 | 10,200 |

*Sum of Both Studies*

*Total respondents per year:* 72,000.
*Total burden hours per year:* 17,160.

**Sherrette A. Funn,**

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

[FR Doc. 2021–25370 Filed 11–19–21; 8:45 am]

**BILLING CODE 4150–25–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection; 60-Day Comment Request; NIH COVID–19 Vaccination Status Form Extension

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork

[2] See *https://www.regulations.gov/document/FDA-1978-N-0018-15828.*