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:

1. 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.

2. 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 INFORMATION, will be available for public viewing. FDA will also not make public any 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.


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, 1To 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.”
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.


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.

<table>
<thead>
<tr>
<th></th>
<th>CABS</th>
<th>MOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hours to complete survey</td>
<td>0.58</td>
<td>0.17</td>
</tr>
<tr>
<td>Participants (per wave)</td>
<td>4,000</td>
<td>5,000</td>
</tr>
<tr>
<td>Number of waves (per year)</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Total respondents per year</td>
<td>12,000</td>
<td>60,000</td>
</tr>
<tr>
<td>Total burden hours per year</td>
<td>6,960</td>
<td>10,200</td>
</tr>
</tbody>
</table>

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