ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual total burden hours
Estimated Annual Burden Hours Total				130,777
Record Keepers				
Care Provider Facility Tour Request (Form A–1A)	216	1	120	432
Authorization for Release of Records (Form A–5)	216	19	20	1,368
Estimated Annual Burden Hours Total				1,800

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores* v. *Reno* Settlement Agreement, No. CV85–4544–RJK (C.D. Cal. 1996).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–20918 Filed 9–24–21; 8:45 am]

BILLING CODE 4184–45–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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of an 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." FDA is issuing this 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). This 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 also sets forth certain characteristics that would establish that a sunscreen drug product is not GRASE.

DATES: Submit electronic comments on the proposed order by 11:59 p.m. Eastern Time at the end of November 12, 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 November 12, 2021. The *https://www.regulations.gov* will accept comments at any time until 11:59 p.m. Eastern Time at the end of November 12, 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

RECEIVED AT CARE MEETING ON 10/20/2021
Committee Chair

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:

I. Background

FDA is announcing the availability of an OTC monograph proposed order (order ID OTC000008), issued pursuant to section 505G(b) of the FD&C Act and section 3854(c)(1) of the CARES Act (Pub. L. 116–136), entitled "Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use." FDA is issuing this proposed order to amend and revise the Deemed Final Order established by the enactment of the CARES Act (March 27, 2020).[1] This 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 GRASE under section 201(p)(1) of the FD&C Act. It also sets forth certain characteristics that would establish that a sunscreen drug product is not GRASE under section 201(p)(1) of the FD&C Act.

In February 2019, FDA issued a proposed rule entitled "Sunscreen Drug Products for Over-the-Counter Human Use" (2019 Proposed Rule).[2] The 2019 Proposed Rule proposed to amend the sunscreen monograph regulation then codified in 21 CFR part 352, which had been stayed since its 1999 issuance, and to put into effect a final monograph for sunscreens.[3] The 2019 Proposed Rule included proposals related to sunscreen active ingredients, maximum sun protection factor (SPF) levels, broad spectrum requirements, dosage forms, labeling, final formulation testing and recordkeeping, sunscreen-insect repellent combinations, and more.

In addition, because the 2019 Proposed Rule identified a need for safety data to support the GRASE status of sunscreens containing certain sunscreen active ingredients—and because FDA expected that the development of these data could take substantially longer than the comment period on the proposed rule—the Agency offered to consider requests to defer further rulemaking on these ingredients while the data were being developed (see 2019 Proposed Rule 84 FR 6204 at 6249). At the end of the comment period on the 2019 Proposed Rule, FDA received a significant number of comments, as well as a request to defer further rulemaking on avobenzone, homosalate, octinoxate, octisalate, octocrylene, oxybenzone, ensulizole, and meradimate while data were being developed to support their GRASE status.

The process for amending the OTC sunscreen monograph was changed by the enactment on March 27, 2020, of section 505G of the FD&C Act, as added by the CARES Act. Among other things, the CARES Act replaced the rulemaking process under which the sunscreen proposed rule had been issued with an administrative order process. In addition, section 505G of the FD&C Act established that, as of the date of enactment of the CARES Act, a sunscreen drug that satisfies certain requirements is deemed to be GRASE and not a new drug. The CARES Act also created a "final administrative order" for sunscreens (the Deemed Final Order) consisting of "the requirements specified in [21 CFR part 352], as published on May 21, 1999[4] . . . except that the applicable requirements governing effectiveness and labeling [are] those specified in [21 CFR 201.327]," which the statute established as "the applicable requirements in terms of conformity with a final monograph" for these sunscreen drugs.[5] The CARES Act directs FDA to amend and revise this Deemed Final Order for sunscreens, and requires that the proposed version of this revised sunscreen order be issued not later than 18 months after the enactment of the CARES Act (*i.e.*, by September 27, 2021).[6] The proposed order that is the subject of this document is being issued consistent with that requirement.

FDA proposes that the conditions laid out in the Deemed Final Order do not ensure that sunscreen drug products are GRASE under section 201(p)(1) of the FD&C Act for the reasons explained in the proposed order. If finalized, the proposed order 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. It also sets forth certain characteristics that would establish that a sunscreen drug product is not GRASE under section 201(p)(1) of the FD&C Act.

In the proposed order, FDA is publishing proposed requirements that are substantively the same as those that the Agency described in the 2019 Proposed Rule, with minor changes, including changes to reflect the enactment of section 505G of the FD&C Act. Similarly, our scientific discussions regarding sunscreens are generally the same as those in the 2019 Proposed Rule. FDA is using this proposed order as a vehicle to efficiently transition its ongoing consideration of the appropriate requirements for OTC sunscreens marketed without approved applications from the previous rulemaking process to the order process created by new section 505G of the FD&C Act.

The 2019 Proposed Rule presented a thorough Agency analysis of publicly available data regarding sunscreens at the time of its issuance. The legal and scientific standards for general recognition of safety and effectiveness underpinning this analysis were not

[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."

[2] The 2019 Proposed Rule (84 FR 6204, February 26, 2019) followed from FDA's announcement in 2011 that "we are considering certain active ingredient safety issues further. . . . In a forthcoming rulemaking, we intend to request additional data regarding the safety of the individual sunscreen active ingredients" ("Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use," 76 FR 35672 at 35673, June 17, 2011).

[3] These proposals included proposed changes to several related regulations, including labeling provisions then codified in 21 CFR 201.327, and to new drug regulations.

[4] This refers to the previously-stayed 1999 final monograph for sunscreens (1999 Final Monograph).

[5] Section 505G(a)(2) of the FD&C Act. Complementary to these requirements for conformity to the specified final monograph, section 505G also deemed the requirements of certain pre-CARES Act monograph rulemaking documents for drugs described by the sunscreen-specific provisions of section 505G(a)(2), as well as "[r]egulations in effect on the day before the date of the enactment of [section 505G], establishing requirements for specific nonprescription drugs marketed pursuant to [section 505G]" to be final administrative orders under section 505G(b) (see sections 505G(b)(8) and 505G(k)(2) of the FD&C Act). The resulting document (the Deemed Final Order) is available in the in the OTC Monographs@FDA portal at *https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm.*

[6] See section 3854(c)(1)(B) of the CARES Act. See also section 505G(b)(8) of the FD&C Act (stating that final monograph orders, specifically including the order consisting of the monograph establishing the conditions of use for sunscreen under section 505G(a)(2), can be "amended, revoked, or otherwise modified in accordance with the procedures of [section 505G(b)]).")

changed by the CARES Act.[7] We are aware that there have been scientific developments in the time since the proposed rule was issued including, among other things, the publication of two new studies on the absorption of sunscreen active ingredients,[8] both of which reinforced the need for the sunscreen ingredient data requested in our proposed rule (and in the proposed order). The comment period on this proposed order affords an opportunity for the public to submit information that has become available since the closure of the comment period on the 2019 Proposed Rule. This includes information that has become available regarding the eight sunscreen active ingredients, identified above, that were the subject of timely requests for deferral in order to conduct studies to generate data first identified as lacking in the 2019 Proposed Rule. We note that if at any time the available evidence becomes sufficient to resolve the uncertainty as to the GRASE status of a sunscreen containing any of these ingredients, FDA intends to proceed to a revised final order reflecting our conclusion as to its status. However, if at the close of the comment period on this proposed order, the available data do not resolve the outstanding questions about each of these ingredients, but the Agency has received satisfactory indication of timely and diligent progress on the necessary studies for a specific ingredient, FDA would be prepared to initially defer issuance of a revised final order on the GRASE status of sunscreens containing that particular active ingredient. Such a deferral would be for a period of not more than 1 year, with a possibility of extension depending on further satisfactory progress with the studies. However, if, in FDA's judgment, studies for any active ingredient do not appear to be proceeding in a timely manner or otherwise do not appear to be productive, the Agency expects that it will proceed to a revised final order on sunscreens containing such particular ingredient after this initial deferral.

As noted above, the Agency also received a significant number of comments to the public docket during the previous public comment period on the proposals described in the 2019 Proposed Rule, which we continue to review. FDA 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 being issued today. To enable the Agency to review and address these comments (and future comments that may be submitted on this proposed order) as expeditiously as possible, we request that commenters do *not* resubmit comments on this proposed order previously submitted on the proposed rule. FDA believes that this approach will allow us to efficiently consider public input as the Agency assesses the appropriate regulatory requirements for nonprescription sunscreens marketed without approved new drug applications.

We emphasize in the proposed order, and here, that the proposed order does not represent a conclusion by FDA that the sunscreen active ingredients included in the 1999 Final Monograph, but proposed in the order as needing additional data, are unsafe for use in sunscreens. Rather, we are requesting additional information on these ingredients so that we can evaluate their GRASE status in light of changed conditions, including substantially increased sunscreen usage and exposure and evolving information about the potential risks associated with these products since originally evaluated. As in the 2019 Proposed Rule, this proposed order also advances proposals addressing the other conditions of use for sunscreen drug products marketed without an approved application, including broad spectrum protection, maximum SPF requirements, dosage forms, labeling, final formulation testing and recordkeeping, sunscreen-insect repellent combinations, and more.

II. Paperwork Reduction Act of 1995

This proposed order is issued under section 505G(b) of the FD&C Act. Chapter 35 of title 44, United States Code does not apply to collections of information made under section 505G of the FD&C Act (see section 505G(o) of the FD&C Act).

III. Electronic Access

Persons may obtain the proposed order at the OTC Monographs@portal at *https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm* or at *https://www.regulations.gov*.

IV. References

The following references are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Matta, M.K., J. Florian, R. Zusterzeel et al., "Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial," *Journal of the American Medical Association*, vol. 323(3), pp. 256–267, 2020 (available at *https://jamanetwork.com/journals/jama/fullarticle/2759002*), accessed August 12, 2021.
2. Matta, M.K., R. Zusterzeel, R.P. Nageswara Matta et al., "Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial," *Journal of the American Medical Association*, vol. 321(21), pp. 2082–2091, 2019 (available at *https://jamanetwork.com/journals/jama/fullarticle/2733085*), accessed August 12, 2021.

Dated: September 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20780 Filed 9–24–21; 8:45 am]

BILLING CODE 4164–01–P

[7] See section 505G(k)(1) of the FD&C Act and 21 CFR 330.10(a)(4).

[8] See "FDA in Brief: FDA Announces Results From Second Sunscreen Absorption Study," available at *https://www.fda.gov/news-events/fda-brief/fda-brief-fda-announces-results-second-sunscreen-absorption-study*, describing Matta, et al. (2020) (Ref. 1), as well as a prior pilot study (Matta, et al. 2019) (Ref. 2).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Criteria for Determining Maternity Care Health Professional Target Areas

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for public comment.

SUMMARY: In accordance with the requirements of the Public Health Service Act, HRSA, authorized by the Secretary of HHS, shall establish the criteria which will be used to determine maternity care health professional target areas (MCTAs) in existing primary care Health Professional Shortage Areas (HPSAs). This notice sets forth the proposed criteria which will be used to identify and score MCTAs.

DATES: Submit written comments no later than November 26, 2021.

ADDRESSES: Written comments should be submitted to *SDMP@hrsa.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Janelle McCutchen, Chief, Shortage Designation Branch, Division of Policy