Joe DiNardo
[redacted]

Re: Docket No. FDA-2020-P-1297

Dear Mr. DiNardo:

This letter responds to your citizen petition, which was received by the Food and Drug Administration (FDA or Agency) on April 16, 2020 (Petition). In the Petition, you request that FDA "immediately enforce the newly finalized sunscreen monograph as detailed in the CARES Act" (Petition at 1). Your Petition asserts that this monograph imposes a limit of 30 on maximum sun protection factor (SPF) values that may be used for sunscreen products marketed without an approved application (Petition at 1) and prohibits a number of claims about sunscreens that various entities have made (Petition at 1-2).

For the reasons described below, the Petition is denied.

I. BACKGROUND

OTC sunscreen drugs are topically applied products indicated to help prevent sunburn; some are also indicated to decrease the risk of skin cancer and early skin aging caused by exposure to the sun's ultraviolet radiation (when used as directed with other sun protection measures).

On March 27, 2020, section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h) was added by the enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).[1] Section 505G established that, as of the date of enactment of the CARES Act, a sunscreen drug that satisfies certain requirements is deemed to be generally recognized as safe and effective and not a new drug.[2] The CARES Act created a "final administrative order" for sunscreens (the Deemed Final Order) consisting of "the requirements specified in [part 352 (21 CFR part 352)], as published on May 21, 1999,[3]. . . except that the applicable requirements governing effectiveness and labeling [are] those specified in [§ 201.327 (21 CFR 201.327)]," which the CARES Act established as "the applicable requirements in terms of conformity with a final monograph" for these sunscreen drugs.[4] The CARES Act also

[1] Public Law 116-136, 134 Stat. 281 (March 27, 2020).
[2] Section 505G(a)(1)(A)(i) and 505G(a)(2) of the FD&C Act; but see section 505G(m)(2) of the FD&C Act.
[3] The CARES Act specifies that these requirements begin at page 27687 of volume 64 of the *Federal Register*.
[4] Section 505G(a)(2) of the FD&C Act. Complementary to these requirements for conformity to the specified final monograph, section 505G of the FD&C Act 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

requires FDA to amend and revise this Deemed Final Order using the order process established by the new law, and to issue a proposed order proposing these revisions by September 27, 2021. FDA issued this proposed order today. It is available at https://www.regulations.gov under Docket No. FDA-1978-N-0018 and on FDA's monograph reform portal at https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm.

II. DISCUSSION

We interpret your Petition to be a request for the Agency to initiate enforcement action or a related regulatory activity. Decisions with respect to such matters are generally made on a case-by-case basis and are within the discretion of the Agency. Requests for the Agency to initiate enforcement action and related regulatory activity are not within the scope of FDA's citizen petition procedures (see § 10.30k (21 CFR 10.30(k))). Therefore, in accordance with § 10.30(e), your Petition is denied.

In addition, we note that your Petition misconstrues the scope of the Deemed Final Order for sunscreens, which, since the enactment of the CARES Act, governs the SPF requirements, among other things, for sunscreen products marketed without an approved application. As noted above, the requirements of the Deemed Final Order consist of those requirements in the May 21, 1999, version of part 352 that did not govern effectiveness and labeling, as well as the requirements specified in § 201.327. Because the only provisions in the May 21, 1999, version of part 352 addressing maximum SPF values were labeling provisions (see 64 FR 27662 at 27688, establishing § 352.50), those provisions did not become part of the Deemed Final Order and were instead superseded by the labeling requirements set forth in § 201.327, which do not include any maximum labeled SPF requirement. There is therefore no maximum labeled SPF requirement in the Deemed Final Order.

FDA has proposed to address maximum SPF requirements in the proposed order issued today. As discussed in the proposed order, because of evidence showing meaningful clinical benefit associated with broad spectrum sunscreen products with an SPF of 60, FDA has proposed to establish a maximum labeled SPF value of SPF 60+.[5] Given the lack of data showing that sunscreens with SPF values *above* 60 provide additional meaningful clinical benefit, FDA has proposed not to allow labeled SPF values higher than 60+. These proposals are discussed in section VI.E.ii of the proposed order.

As also discussed in section VI.E.ii of the proposed order, although we have proposed a cap for SPF labeling of SPF 60+, we have proposed to permit the marketing of sunscreen products formulated with SPF values up to 80. This formulation margin is intended to: (1) provide formulation flexibility that we hope will help facilitate the development of products with greater Ultraviolet A protection, which (as discussed in further detail in the proposed order) is a key FDA concern and (2) more fully account for the range of variability in SPF test results (discussed further in sections VI.E.ii.4.II and III of the proposed order) for sunscreen products labeled SPF

505G(b) of the FD&C Act (see section 505G(b)(8) and (k)(2)). The resulting document (the Deemed Final Order) is available at https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm.

[5] We note that the proposed maximum labeled SPF value is 60+ rather than 60 because we are separately proposing to limit the maximum determined SPF value of monograph sunscreens to 80.

60+. We are proposing not to allow the marketing (without an approved application) of sunscreen products formulated with SPF values above SPF 80.

We note that FDA is accepting comments on its maximum SPF (and other) proposals described in the proposed order. If you are interested in submitting comments on this matter, please see the instructions on how to do so in the notice of availability for the proposed order (available at https://www.regulations.gov under Docket No. FDA-1978-N-0018).

III. CONCLUSION

For the reasons described above, your Petition requesting that FDA "immediately enforce the newly finalized sunscreen monograph as detailed in the CARES Act" is denied.

Sincerely,

Douglas C. Throckmorton -S

Digitally signed by Douglas C. Throckmorton -S
Date: 2021.09.24 10:33:19 -04'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research