Enforcement Policy — OTC Sunscreen Drug Products Marketed Without an Approved Application

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

May 2018
Compliance

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Contains Nonbinding Recommendations

Enforcement Policy — OTC Sunscreen Drug Products Marketed Without an Approved Application Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance describes FDA's enforcement approach with respect to over-the-counter (OTC) sunscreen products marketed without approved applications during the period before a final sunscreen monograph becomes effective. It is intended for manufacturers who market OTC sunscreen drug products without an approved application.[2] OTC sunscreens are not yet the subject of an effective final monograph, and we continue to evaluate information relevant to defining conditions under which such products are generally recognized as safe and effective (GRASE) and not misbranded. However, OTC sunscreens marketed without approved applications and containing specified active ingredients (see section II., Background) are subject to labeling and testing requirements located at 21 CFR 201.327. Several other ongoing and planned rulemaking proceedings will also address these products.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

[1] This guidance has been prepared by the Division of Nonprescription Drug Products in the Center for Drug Evaluation and Research at the Food and Drug Administration.

[2] See section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355). Approved applications under section 505 include both new drug applications and abbreviated new drug applications. Some OTC sunscreen products are currently marketed under approved applications. This guidance does not address those products.

II. BACKGROUND

We have previously published a number of *Federal Register* notices related to OTC sunscreen products. They can be found on the Rulemaking History for OTC Sunscreen Drug Products web page.[3] Rather than discuss all the proceedings, we summarize those that are most relevant to the enforcement policy described in this guidance.

In 1978, we published an advance notice of proposed rulemaking (ANPR) that included recommendations from an advisory review panel[4] on the safe and effective use of OTC sunscreen products (43 FR 38206). In the ANPR, we stated that the panel recommended 21 sunscreen active ingredients be determined as GRASE. The panel recommended all sunscreen products have sun protection factor (SPF) values of 2 or higher. The panel also recommended a maximum labeled SPF value of 15. The panel did not address broad spectrum protection,[5] nor did the panel address insect repellent-sunscreen combination products. The panel discussed OTC sunscreen products formulated as oils, lotions, creams, gels, butters, pastes, sticks, ointments, and sprays, but did not recommend classifying any specific dosage forms as GRASE for sunscreens.

In 1993, we published a proposed rule that included our proposed GRASE conditions for OTC sunscreen products (58 FR 28194). We proposed as GRASE the same active ingredients included in the ANPR except padimate A (i.e., 20 proposed GRASE ingredients). We proposed a minimum SPF value of 2, as recommended by the panel in the ANPR, and proposed a maximum labeled SPF value of 30. We did not propose broad spectrum protection requirements or address insect repellent-sunscreen combination products. When discussing proposed directions for use to be included in labeling, we mentioned several dosage forms, including sprays, creams, gels, lotions, and oils, but did not expressly discuss in what dosage forms sunscreens would be considered GRASE and not misbranded.

In 1994, we published an amendment to the 1993 proposed rule (59 FR 29706) to include in the monograph only those active ingredients that, in 1993, we had proposed as GRASE for sunscreen use and that had existing United States Pharmacopeia (USP) monographs or for which interest in developing USP monographs had been expressed. We proposed two additional sunscreen active ingredients as GRASE for use in sunscreens after the 1993 proposed rule. In 1996, we proposed adding avobenzone as a GRASE active ingredient (61 FR 48645). In 1998, we proposed adding zinc oxide as a GRASE active ingredient (63 FR 56584).

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[3] https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm072134.htm

[4] The panel was a group of experts on sunscreens from outside FDA that we created to give us advice on developing an OTC sunscreen monograph.

[5] Broad spectrum protection means protection against ultraviolet B (wavelengths of 290 to 320 nanometers) and ultraviolet A radiation (wavelengths of 320 to 400 nanometers).

In 1999, we published a final rule that resolved most of the issues in the 1993, 1996, and 1998 proposed rules (64 FR 27666). The final rule established a sunscreen monograph (21 CFR part 352) with an effective date of May 21, 2001. We included as GRASE conditions for sunscreens the following active ingredients and maximum concentrations:[6]

- Aminobenzoic acid (PABA), 15 percent
- Avobenzone, 3 percent
- Cinoxate, 3 percent
- Dioxybenzone, 3 percent
- Ensulizole, 4 percent[7]
- Homosalate, 15 percent
- Meradimate, 5 percent[8]
- Octinoxate, 7.5 percent[9]
- Octisalate, 5 percent[10]
- Octocrylene, 10 percent
- Oxybenzone, 6 percent
- Padimate O, 8 percent
- Sulisobenzone, 10 percent
- Titanium dioxide, 25 percent
- Trolamine salicylate, 12 percent
- Zinc oxide, 24 percent

We concluded that these ingredients at these concentrations could also be used in combination with each other as long as each active ingredient contributes a minimum SPF of 2 to the finished product, except that avobenzone may not be combined with aminobenzoic acid (PABA), ensulizole, meradimate (methyl anthranilate), padimate O, titanium dioxide, and zinc oxide (see 21 CFR 352.20, now stayed; 64 FR 27666 at 27687–88). We identified the same dosage forms in the 1999 final rule as were included in the ANPR and 1993 proposed rule (21 CFR 352.52(d)

[6] 21 CFR 352.10, now stayed; 64 FR 27666 at 27687. The active ingredient names used in this list are the current established names for these active ingredients. Subsequent to the publication of the 1999 final rule, we issued another final rule in 2002 to amend the names used for four of those ingredients, to make them consistent with renaming of those ingredients in the corresponding USP monographs (67 FR 41823). Under section 502(e) of the FD&C Act, drug labels are required to bear the established name of each active ingredient, and, if FDA has not designated an official name under section 508 of the FD&C Act, the compendial name is the established name. Consequently, to comply with section 502(e) of the FD&C Act, sunscreen drug products must bear the current compendial names for their active ingredients, and those are used in the text above. However, because the 2002 final rule that changed those names was published after the effective date of part 352 was stayed, those amendments have not yet been incorporated into the published monograph regulation.

[7] Referred to in the 1999 final rule as phenylbenzimidazole sulfonic acid. See footnote 6.

[8] Referred to in the 1999 final rule as menthyl anthranilate. See footnote 6.

[9] Referred to in the 1999 final rule as octyl methoxycinnamate. See footnote 6.

[10] Referred to in the 1999 final rule as octyl salicylate. See footnote 6.

and 352.72(e)). We raised the maximum labeled SPF value to 30. We did not address broad spectrum protection requirements or insect repellent-sunscreen combination products.

In 2000, we delayed the effective date for the 1999 final rule until December 31, 2002 (65 FR 36319). In 2001, we stayed the December 31, 2002, effective date of the 1999 final rule indefinitely (66 FR 67485). We delayed the effective date because we had not yet established ultraviolet A (UVA)/broad spectrum testing and labeling requirements for OTC sunscreen products. We decided to include these requirements in the monograph before making it effective. Therefore, there has never been an OTC drug monograph in effect for sunscreen products.

In 2007, we published a proposed rule (72 FR 49070) to amend the 1999 final rule to address formulation, labeling, and testing requirements for both ultraviolet B (UVB) and UVA radiation protection. We proposed UVA/broad spectrum testing and labeling requirements (which had not been established in 1999), so that all OTC sunscreen products marketed under the sunscreen monograph would be tested and labeled for the level of UVB and UVA radiation protection provided. We also proposed to increase the maximum specific labeled SPF value to 50+ and revise the associated labeling to "UVB SPF 50+" (or "UVB SPF 50 plus") in this rulemaking.

In 2007, we also published an ANPR requesting information and comment on specific topics including the effectiveness and safety of sunscreen products when combined with certain insect repellent ingredients (72 FR 7941).[11] We stated that, historically, we had not objected to the marketing of insect repellent-sunscreen drug products pending the establishment of an effective final sunscreen monograph if the products contained sunscreen ingredients included in the FDA OTC sunscreen rulemaking and an insect repellent registered with the Environmental Protection Agency (EPA) (72 FR 7941 at 7943). We stated that final regulations for insect repellent-sunscreen products would be based on information and comments submitted in response to the 2007 ANPR.

In 2011, we published a final rule codified in § 201.327 (76 FR 35620) that established labeling and testing requirements for OTC sunscreen products marketed without approved applications and containing the ingredients specified in the stayed 1999 final rule (see above). For these *covered* products, the final rule specified labeling and testing methods for establishing SPF, broad spectrum protection, and water resistance claims. It also addressed other labeling elements, including directions for use and warnings.

The 2011 final rule also identified specific claims that either would render a covered product misbranded or that would not be allowed on any OTC sunscreen product marketed without an approved application. These include:

- Claims in labeling or promotional materials that suggest or imply that the use, alone, of any sunscreen reduces the risk of or prevents skin cancer or early skin aging (§ 201.327(c)(3))

[11] The Environmental Protection Agency regulates insect repellents under the Federal Insecticide, Fungicide, and Rodenticide Act.

- Claims such as "sunblock," "sweatproof," and "waterproof" (§ 201.327(g))

- Claims for instant protection or protection immediately upon application (21 CFR 310.545(a)(29)(ii))

- Claims for "all-day" protection, or extended wear claims citing a specific number of hours of protection that is inconsistent with the directions for application in § 201.327 (§ 310.545(a)(29)(ii))

In 2011, we also published a proposed rule that again proposed to limit the maximum labeled SPF value for OTC sunscreen products marketed without approved applications to "50+" (76 FR 35672). Although FDA received data regarding tested SPF values as high as 80, the record continued to lack data demonstrating that sunscreen products with SPF values above 50 provide additional clinical benefit.

In 2011, we also published an ANPR requesting additional data on OTC sunscreen products in certain dosage forms. We listed those dosage forms of OTC sunscreen products that we then considered potentially eligible for inclusion in the OTC sunscreen monograph (i.e., oils, lotions, creams, gels, butters, pastes, ointments, sticks, and sprays). For sprays, we requested additional data to address remaining questions about effectiveness and safety. We also invited comment on potential labeling and testing conditions for sunscreens in spray dosage forms, contingent on receiving additional data that would be needed to allow their classification as GRASE for sunscreens. We also identified certain dosage forms that we did not consider eligible for review for potential inclusion in the OTC sunscreen monograph.

III. ENFORCEMENT POLICY

In the absence of an effective final OTC monograph for sunscreen products, we have historically exercised enforcement discretion with respect to certain OTC sunscreen products marketed without approved new drug applications. We intend to continue this enforcement policy for certain OTC sunscreen products under the circumstances described in this guidance. Sections III.A through D describe the circumstances under which we do not intend to pursue enforcement action with respect to certain OTC sunscreen products marketed without approved applications until a final OTC sunscreen monograph becomes effective. Section III.E., Dosage Forms, describes our approach to sunscreen products formulated in certain dosage forms, particularly sprays. Section III.F., Insect Repellent-Sunscreen Combination Products, describes our approach to products that contain both a sunscreen and an insect repellent, and section III.G, OTC Sunscreen Products Not Covered by the Intended Enforcement Discretion Policy, describes sunscreen products that do not fall within the intended exercise of enforcement discretion described in this guidance.

Manufacturers should examine sections III.A through F to determine which section(s) of the guidance apply to their products. If the recommendations provided in more than one section

apply to a single sunscreen product, our enforcement policy is premised on manufacturers following all applicable recommendations for such product.

A. General Enforcement Policy

Unless the failure to pursue regulatory action poses a potential health hazard to the consumer, we do not intend to object to the marketing without an approved application of OTC sunscreen products[12] that have all the following characteristics:

- Contain as sunscreen active ingredients only the active ingredients or combinations of active ingredients listed in section II., Background (previously included in 21 CFR 352.10 and 352.20, which are now stayed)[13]

- Do not make claims addressed in §§ 201.327(c)(3) and (g) and 310.545(a)(29)(ii)

- Comply with the requirements for OTC drugs under 21 CFR part 201 and 21 CFR 330.1, requirements for adverse event reporting for OTC drugs in the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379aa), and provisions of the FD&C Act addressing adulteration

- Follow applicable labeling and testing requirements for OTC sunscreens in § 201.327 except as specific recommendations of this guidance address below

B. Broad Spectrum Testing

Current regulations specify an in vitro broad spectrum test procedure for assessing protection across both UVA and UVB regions of the UV spectrum (§ 201.327(j)). Certain labeling elements in § 201.327 apply only to products that are determined to be "Broad Spectrum" in accordance with this test procedure. FDA is aware that not all sunscreen active ingredients provide substantial protection against UVA wavelengths, and that OTC sunscreen products that do not contain certain ingredients are not likely to pass the broad spectrum test criteria. A covered sunscreen does not need to have been tested in accordance with § 201.327(j) so long as it does not bear any labeling that § 201.327 permits only for products that pass the broad spectrum test, or that otherwise suggests that the product provides broad spectrum protection or helps to decrease the risk of skin cancer or premature skin aging.

[12] We note that cosmetic products labeled with sunscreen claims (including an SPF value) are regulated as drugs. See 21 CFR 700.35.

[13] We note that both § 201.327(h) and 21 CFR 347.20(e) anticipate the combining of the sunscreen active ingredients previously included in § 352.10 with certain skin protectant active ingredients. Nothing in this guidance is meant to suggest any alteration in FDA's prior approach to these products.

C. SPF Testing

Among other provisions, current FDA regulations require that labeling for covered OTC sunscreen products bear SPF values determined in accordance with the SPF testing requirements in § 201.327(i). Therefore, SPF testing for covered sunscreen products must be conducted according to the method specified in § 201.327(i).

D. Products Labeled With SPF Values Higher Than 50

Both the 2007 and 2011 proposed rules would have required OTC sunscreen products with SPF values higher than 50 to be labeled as "SPF 50+" or "SPF 50 plus." In the absence of a final rule addressing maximum SPF claims, we remind manufacturers that, for covered sunscreen products labeled with specific SPF values higher than 50, the values reflected in labeling must also be determined according to SPF testing as described in § 201.327. (See also section III.C., SPF Testing.)

E. Dosage Forms

In the 2011 ANPR on dosage forms of OTC sunscreen products, we listed the following dosage forms as eligible for potential inclusion in the OTC sunscreen monograph:

- Oils
- Lotions
- Creams
- Gels
- Butters
- Pastes
- Ointments
- Sticks
- Sprays

In advance of a final rule addressing these dosage forms, we generally do not intend to initiate enforcement action for OTC sunscreen products formulated in any of the listed dosage forms if they comply with effective legal requirements and follow the recommendations of this guidance. As stated in the 2011 ANPR, we tentatively conclude that the record is sufficient to support including these dosage forms, except for sprays, in the future OTC sunscreen final monograph under the conditions of labeling and testing included in § 201.327. For this reason, pending further rulemaking action on sunscreen products in spray dosage forms, we do not intend to object if manufacturers include the additional warning and directions discussed in the 2011 ANPR, including the variation from the direction in § 201.327(e)(1)(ii):

- ***Warnings:***

When using this product keep away from face to avoid breathing it.

- ***Directions:***
  - spray liberally [*or* generously] and spread evenly by hand 15 minutes before sun exposure. *(This direction can be provided in lieu of that described in § 201.327(e)(1)(ii).)*
  - hold container 4 to 6 inches from the skin to apply.
  - do not spray directly into face. Spray on hands then apply to face.
  - do not apply in windy conditions.
  - use in a well-ventilated area.

This labeling is intended to ensure that consumers use sunscreen sprays safely and effectively.

The 2011 ANPR also raised certain questions regarding both broad spectrum and SPF testing for sunscreen products in spray dosage forms. At the present time, however, all sunscreen products covered by the final rule are subject to the testing methods in § 201.327(i) and (j), regardless of dosage form. Therefore, pending further rulemaking on testing requirements specifically for sprays, sunscreens formulated as sprays must be tested according to § 201.327. (See also sections III.B., Broad Spectrum Testing, and III.C., SPF Testing.)

The 2011 ANPR also listed those dosage forms that we did not consider eligible at that time for review for potential inclusion in the OTC sunscreen monograph:

- Wipes
- Towelettes
- Powders
- Body washes
- Shampoos

OTC sunscreen products in dosage forms not eligible for the OTC Drug Review that are marketed without approved applications are not within the policy of enforcement discretion described in this guidance.

F. Insect Repellent-Sunscreen Combination Products

Some sunscreen drug products subject to § 201.327 also contain an insect repellent regulated by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.). Some of the labeling requirements in § 201.327 may conflict with EPA's labeling requirements for insect repellents, as discussed in the 2007 ANPR. Pending further rulemaking action on these products, we encourage manufacturers to comply with § 201.327 as closely as possible.[14]

[14] For such products that are formulated as sprays, manufacturers should also examine the recommendations for spray dosage forms in section III.E., Dosage Forms.

G. OTC Sunscreen Products Not Covered by the Intended Enforcement Discretion Policy

Not all sunscreen products lacking approved applications fall within the intended exercise of enforcement discretion described in this guidance. These include products marketed without an approved application that have any of the following characteristics:

- Pose a potential health hazard to the consumer.

- Contain, as sunscreen active ingredients, active ingredients or combinations of active ingredients not included in the list in section II., Background (and previously included in § 352.10 or § 352.20, which are now stayed). These include OTC sunscreen products containing any sunscreen active ingredient that FDA is considering for inclusion in the OTC sunscreen monograph under a pending request pursuant to the Sunscreen Innovation Act (SIA).[15,16] (Note, however, that nothing in this guidance alters the fact that an OTC sunscreen product may be legally marketed as authorized by a final sunscreen order issued under the SIA or under a new drug application approved under section 505 of the FD&C Act (21 U.S.C. 355).)

- Make claims that render a product misbranded or are not permitted on any OTC sunscreen marketed without an approved application, according to §§ 201.327(c)(3) and (g) and 310.545(a)(29)(ii).

- Are formulated in dosage forms that are not eligible for the OTC Drug Review.

- Contain an insect repellent ingredient that is not registered by EPA.

[15] See section 586 of the FD&C Act (21 U.S.C. 360fff).

[16] For more information about the regulatory status of these active ingredients, see the Sunscreen Innovation Act (SIA) web page at https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/ucm434782.htm.