

FDA ISSUES FINAL RULE REGARDING LABELING OF SUNSCREEN PRODUCTS

FDA published in the June 17, 2011 Federal Register a final rule regarding labeling and effectiveness testing for over-the-counter (“OTC”) sunscreen products marketed without approved applications, including cosmetic products with sunscreen claims (“sunscreen products”).¹ The final rule, 21 C.F.R. § 201.327, describes the permitted and required claims, testing procedures on which those claims must be based, and claims that are not permitted or that would render a sunscreen product misbranded. These requirements revise the SPF labeling and testing conditions described in a proposed sunscreen rule issued in 2007 (“2007 proposed rule”). In addition, the final rule lifts the delay of the implementation of the 1999 Drug Facts final rule, and requires all sunscreen products to comply with the content and format requirements of that rule.

The final rule does not address issues related to sunscreen active ingredients or certain other issues regarding the “generally recognized as safe and effective” determination for sunscreen products.² Therefore, the final rule does not finalize the 2007 proposed amendments to the sunscreen monograph, 21 C.F.R. part 352, nor lift the stay on the implementation of the monograph.

Principally, the final rule includes the following requirements:

- The principal display panel must include SPF³ numerical value, “Broad Spectrum” and water resistance effectiveness statements based upon a SPF test, a pass/fail broad spectrum test and a water resistance test specified in the final rule.
- Water resistance claims on the principal display panel must specify either 40 or 80 minutes of effectiveness while swimming or sweating, based on testing. “Waterproof,” “sweatproof,” and “sunblock” claims are not permitted.
- Claims that the product, in combination with other sun protection measures, reduces the risk of skin cancer and early skin aging are permitted only for broad spectrum products with SPF 15 and higher, and these concepts may also be reflected in the “Use” sections of these products’ Drug Facts boxes. Non-broad spectrum products and products with SPF values below 15 can only claim to prevent sunburn and must include a skin cancer/skin aging warning.
- All sunscreen products, including all cosmetic products making an SPF claim, must include the standard Drug Facts information. The only exception to this requirement under the final rule is the standard “small package” reduced labeling permitted by the Drug Facts rule.

¹ Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35620 (June 17, 2011) (to be codified at 21 C.F.R. §§ 201.327, 301.545).

² The final rule applies to sunscreen products containing aminobenzoic acid, avobenzone, cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, oxybenzone, padimate O, sulisobenzene, titanium dioxide, trolamine salicylate, or zinc oxide, alone or in combination. 21 C.F.R. § 201.327.

³ The final rule identifies SPF as an abbreviation for sun protection factor.

The effective date of the final rule and compliance date for sunscreen products is June 18, 2012, except for products with annual sales less than \$25,000 for which the compliance date is June 17, 2013.⁴ The implementation date is the same for the labeling and testing requirements in the final rule, 21 C.F.R. § 201.327, and the requirements in the Drug Facts final rule, 21 C.F.R. § 201.66.⁵ FDA does not expect non-compliant products introduced or delivered for introduction into interstate commerce prior to the compliance date, June 18, 2012, to be removed from the market.⁶ Thus, product delivered to customers, even if in their warehouses, ready to be shipped from manufacturers' warehouses, or imported prior to June 18, 2012 can continue to be shipped and sold.

The major requirements of the final rule and the significant revisions from the 2007 proposed rule are the subject of this Client Alert. The balance of this Alert provides background on sunscreen regulation, and provides additional information on each of the labeling elements and associated testing.

In addition to the final rule, FDA published a proposed rule that would limit the maximum SPF value on sunscreen product labeling to "SPF 50+",⁷ and an advanced notice of proposed rulemaking requesting data for safety and effectiveness information for sunscreen products formulated in certain dosage forms, including sprays.⁸ FDA also published a draft guidance document on its enforcement policy for sunscreen products marketed without an approved application under the final rule and the proposed rule.⁹ These documents will be discussed in a subsequent Client Alert.

BACKGROUND

FDA first addressed sunscreen products in 1978 when it issued an advanced notice of proposed rulemaking that included recommendations from an advisory review panel on the safe and effective use of sunscreen products.¹⁰ In 1993, FDA published a proposed rule for sunscreen products that both identified active ingredients FDA tentatively considered to be generally recognized as safe and effective, and proposed associated labeling and SPF testing to be required for these sunscreen products.¹¹ Six years later in 1999, FDA published a final rule for sunscreen products establishing the sunscreen monograph, 21 C.F.R. part 352.¹² FDA subsequently stayed the implementation of the 1999 final rule indefinitely.¹³

⁴ 76 Fed. Reg. 35620.

⁵ 76 Fed. Reg. 35629.

⁶ 76 Fed. Reg. 35624.

⁷ Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use, 76 Fed. Reg. 35672 (June 17, 2011) (to be codified at 21 C.F.R. § 201.327).

⁸ Sunscreen Drug Products for Over-the-Counter Human Use; Request for Data and Information Regarding Dosage Forms, 76 Fed. Reg. 35669 (June 17, 2011).

⁹ Food and Drug Administration, Draft Guidance for Industry: Enforcement Policy—OTC Sunscreen Drug Products Marketed Without An Approved Application (June 2011).

¹⁰ Sunscreen Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; Notice of Proposed Rulemaking, 43 Fed. Reg. 38206 (Aug. 25, 1978).

¹¹ Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Proposed Rule, 58 Fed. Reg. 28194 (May 12, 1993).

¹² Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph, 64 Fed. Reg. 27666 (May 21, 1999).

¹³ Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Extension of Effective Date; Reopening of Administrative Record, 65 Fed. Reg. 26319 (June 8, 2000); Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Partial Stay; Final Rule, 66 Fed. Reg. 67485 (Dec. 21, 2001).

In March 1999, FDA issued the Drug Facts final rule, 21 C.F.R. § 201.66, which established general labeling format and content requirements for all OTC drugs.¹⁴ Prior to the implementation date for the rule, FDA delayed until further notice the implementation of the Drug Facts rule for sunscreen products.¹⁵

In 2007, FDA issued a proposed rule covering UVA testing and labeling to be required for all sunscreen products and revising the SPF testing and corresponding labeling from the 1999 final rule.¹⁶ The proposed rule did not lift the existing stay of the effective date for the monograph.

PRINCIPAL DISPLAY PANEL LABELING

The principal display panel (“PDP”) of sunscreen products, including cosmetic products with sunscreen claims, must include an effectiveness statement that identifies the SPF value as measured by the SPF testing prescribed by the final rule and identifies whether the product is “broad spectrum” under the final rule’s pass/fail broad spectrum test. The PDP must also identify whether the product provides water resistance of either 40 or 80 minutes.

“Broad Spectrum SPF” Statement

In the 2007 proposed rule, the PDP included a “UVB SPF” value statement and a UVA four-star rating, each followed by one of four descriptors (low, medium, high or highest). Under the final rule, the PDP includes either a “Broad Spectrum SPF” or “SPF” value statement of the SPF level determined from the SPF test described in the rule, depending on whether the product passes the pass/fail broad spectrum test.

For products that pass the broad spectrum test, the PDP must say “Broad Spectrum SPF [insert numerical SPF value resulting from testing].” The Broad Spectrum SPF statement must appear as continuous text with no intervening text or graphic and the entire text must appear in the same font style, size, and color with the same background color.¹⁷ FDA believes that it is important for consumers to evaluate both statements when making a purchase decision. By requiring this information to be presented with identical prominence on the PDP, consumers should be able to quickly and easily identify sunscreen products that provide broad spectrum protection, as well as the SPF of all sunscreen products.¹⁸

For products that do not pass the broad spectrum test, the PDP must say, “SPF [insert numerical SPF value resulting from testing].” The entire text must appear in the same font style, size, and color with the same background color.¹⁹ Including a statement anywhere in the labeling of a product that does not pass the broad spectrum test that suggests or implies that the product provides broad spectrum protection would misbrand that product. FDA cautioned against references to “UVA” or “UVA/UVB” protection on products that do not provide broad spectrum protection. Such labeling would misbrand the products if it misleadingly suggests that the products provide protection that is

¹⁴ Over-The-Counter Human Drugs; Labeling Requirements, 64 Fed. Reg. 13254 (Mar. 17, 1999).

¹⁵ Over-the-Counter Human Drugs; Labeling Requirements; Delay of Implementation Date, 69 Fed. Reg. 53801 (Sept. 3, 2004).

¹⁶ Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph; Proposed Rule, 72 Fed. Reg. 49070 (Aug. 27, 2007) (to be codified at 21 C.F.R. part 352).

¹⁷ 21 C.F.R. § 201.327(a)(1).

¹⁸ 76 Fed. Reg. 35627.

¹⁹ 21 C.F.R. § 201.327(a)(1).

equivalent or greater to that provided by products labeled with “Broad Spectrum SPF” values or is otherwise false or misleading.²⁰

In 2007 FDA proposed including UVA radiation protection information on sunscreen product labeling because it believed that providing consumers with information about the effectiveness of a sunscreen product for UVA and UVB radiation protection is equally important. FDA replaced the proposed UVA star rating with the broad spectrum statement because it deemed the UVA star rating confusing in conjunction with the numerical SPF rating. FDA also determined that the UVA protection should be proportional to the SPF value, which proportionality is now required in the broad spectrum test. Because of this proportionality, there is no longer a need for a separate UVA rating. FDA believes that a clear and standardized “yes/no” indicator regarding broad spectrum protection will enable consumers to make better and more informed purchase decisions. The term “broad spectrum” was chosen as consumers are likely to be familiar with the term because it has been used on some sunscreen product labels for over 20 years. FDA also noted that consumers may recognize the term from public health campaigns and news articles about the importance of broad spectrum UV protection over the last two decades.²¹

As UVA is no longer included in the label, FDA also eliminated the “UVB” reference from the SPF value statement. FDA concluded that neither the term UVB nor the descriptor is necessary for consumers to understand the effectiveness statement. Neither had been included on sunscreen product labels prior to the 2007 proposed rule and consumers had been able to make purchase and use decisions based on SPF values alone.²²

Under the 2007 proposed rule, if a sunscreen product was not tested for or did not protect against UVA radiation, the statement “No UVA protection” would have been required on the PDP. This statement is no longer required. FDA deemed it unnecessary and potentially misleading because the PDP no longer refers to UVA radiation protection. While the final rule does not require a negative statement on the PDP for products that do not pass the broad spectrum test, FDA cautioned that such products may be misbranded if they include statements regarding UVA protection. Such statements may misleadingly imply that the product provides benefits that are similar or superior to those of products labeled with broad spectrum SPF values.²³

Water Resistance Statement

Products that pass the test for water resistance must include on the PDP one of two water resistance statements: 1) “Water Resistant (40 minutes)” for products that provide 40 minutes of water resistance according to the rule’s water resistance test, or 2) “Water Resistant (80 minutes)” for products that provide 80 minutes of water resistance according to the rule’s water resistance test.²⁴

The 2007 proposed rule required PDP statements of “water resistant” and “very water resistant” with information on whether the product provided 40 or 80 minutes of efficacy in the “Uses” and “Directions” sections of the label. FDA revised this requirement because the PDP statement did not clearly and accurately convey to consumers the difference between “water resistant” and “very water resistant” sunscreen products. FDA determined that providing on the PDP specific information about the actual time consumers can expect a sunscreen product to retain its labeled SPF value is likely to be more helpful to consumers because the information is displayed in one place and not on different parts of the labeling. The revised statements, “water resistant (40 minutes)” or “water

²⁰ 76 Fed. Reg. 35644.

²¹ 76 Fed. Reg. 35826.

²² 76 Fed. Reg. 35625.

²³ 76 Fed. Reg. 35628.

²⁴ 21 C.F.R. § 201.327(a)(2).

resistant (80 minutes),” are intended to make it clearer and easier for consumers to understand water resistance as part of their purchase decision. This water resistance information continues to be reinforced by information in the directions regarding reapplication.²⁵

“Sunblock,” “sweatproof” and “waterproof” claims anywhere on the product label will cause the product to be misbranded.²⁶ FDA considers these terms “essentially exaggerations of performance” that cannot be substantiated.²⁷

Educational Statement

The final rule eliminates the PDP educational statement included in the 2007 proposed rule. The proposed statement was “UV rays from the sun are made of UVB and UVA. It is important to protect against both UVB and UVA rays to prevent sunburn and other skin damage.” FDA concluded that the information is not critical for effective use of sunscreen products, particularly because the PDP effectiveness statements no longer refer to UVA and UVB protection.²⁸

DRUG FACTS LABELING

The final rule lifts the stay of implementation of the Drug Facts rule for sunscreen products. All sunscreen products marketed without an approved application, including cosmetic products with sunscreen claims, must now include the Drug Facts information on the side or back panel.

Sunburn and Skin Cancer/Skin Aging Risk Reduction Claims

All sunscreen products must include the indication statement “helps prevent sunburn” under the heading “Uses.”²⁹ This statement replaces the proposed indication that indicated the degree of protection against both UVB and UVA radiation. The proposed indication linked UVB protection only to sunburn prevention and did not expressly link UVA protection to any specific health benefit.³⁰

The final rule permits, for sunscreen products that have broad spectrum SPF values of 15 or higher, the additional indication “if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun.”³¹ FDA has included this indication based on available clinical studies, the fact that UV radiation from the sun is harmful, and the scientific understanding that substantially limiting overall UVB and UVA exposure reduces the risk of skin cancer and early skin aging.³²

Broad Spectrum SPF 15 and higher products must include under the “Directions” heading the following statement: “**Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: [bullet] limit time in the sun, especially from 10 a.m.–2 p.m. [bullet] wear long-sleeved shirts, pants, hats, and sunglasses.”³³

Any 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 will cause the product to be

²⁵ 76 Fed. Reg. 35628.

²⁶ 21 C.F.R. § 201.327(g).

²⁷ 76 Fed. Reg. 35643.

²⁸ 76 Fed. Reg. 35628.

²⁹ 21 C.F.R. § 201.327(c)(1).

³⁰ 76 Fed. Reg. 35629.

³¹ 21 C.F.R. § 201.327(c).

³² 76 Fed. Reg. 35630.

³³ 21 C.F.R. § 201.327(e)(2).

misbranded.³⁴ Similarly, sunscreen products that provide broad spectrum protection with SPF values between 2 and 15 or that do not provide broad spectrum protection should not state or imply that the use of a sunscreen product alone will reduce the risk of skin cancer or early skin aging. Doing so would cause the product to be misbranded.

FDA found it critical that the indication statement regarding skin cancer and early skin aging includes information about using the products as directed and following other sun protection measures. FDA believes that the reference to other sun protection measures is necessary to ensure that the consumer's overall UV exposure is substantially decreased. For a sunscreen to be effective in reducing the risk of skin cancer and early skin aging, consumers must not increase their overall exposure to UV radiation by over reliance on sunscreen use. A consumer who relies on the use of a sunscreen with a broad spectrum SPF value of 15 or higher alone may not obtain a meaningful net decrease from the risk of skin cancer or early skin aging if, because he or she is wearing the sunscreen, the consumer spends more time in the sun and/or wears less protective clothing. In fact, reliance on sunscreen use alone, without also employing other sun protection measures, could actually result in an increase in the consumer's overall UV exposure.³⁵

Products that pass the broad spectrum test but have SPF values of at least 2 and less than 15 and products that do not pass the broad spectrum test must include as the first statement under the "Warnings" heading, "**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging."³⁶ FDA determined that inclusion of this warning is critical to help ensure that consumers do not mistakenly conclude that all sunscreen products have been demonstrated to provide the same benefits. The warning is intended to reinforce the distinction between sunscreen products indicated only for preventing sunburn and sunscreen products that have also been shown to reduce the risk of skin cancer and early skin aging when used as directed with other sun protection measures.³⁷

The optional indication and required direction on sunscreen products with broad spectrum SPF values of 15 or higher and the Skin Cancer/Skin Aging Alert replace the "Sun Alert" in the 2007 proposed rule. As proposed, this warning would have stated, "UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen." Comments argued, and FDA agreed, that this warning included an implied indication that all sunscreen products reduce the risk of skin cancer and skin aging.³⁸

Application and Reapplication Directions

Under the "Directions" heading, the labeling must state, "apply [liberally or generously] [and as an option: 'and evenly'] 15 minutes before sun exposure."³⁹ Any ingredients labeled with "instant protection," "protection immediately upon application," or similar claims are not generally recognized as safe and effective.⁴⁰

³⁴ 21 C.F.R. § 201.327(c)(3).

³⁵ 76 Fed. Reg. 35630.

³⁶ 21 C.F.R. § 201.37(d)(2).

³⁷ 76 Fed. Reg. 35635.

³⁸ *Id.*

³⁹ 21 C.F.R. § 201.327(e)(1).

⁴⁰ 21 C.F.R. § 310.545(a)(29)(ii).

For products that do not satisfy the water resistance test, the labeling must state, “[bullet] reapply at least every 2 hours [bullet] use a water resistant sunscreen if swimming or sweating.”⁴¹ FDA revised the required statement for non-water resistant products to remove reapplication directions concerning swimming and sweating, because “these products should not be used when swimming or sweating.”⁴² Instead, the final rule requires more accurate directions instructing consumers to use a water resistant sunscreen product if swimming or sweating.

For products satisfying the water resistance test, the labeling must state, “reapply: [bullet] after [select one of the following determined by water resistance test: ‘40 minutes of’ or ‘80 minutes of’] swimming or sweating [bullet] immediately after towel drying [bullet] at least every 2 hours.”⁴³

Ingredients labeled with claims for “all-day” protection or extended wear claims citing a specific number of hours of protection that is inconsistent with these directions are not generally recognized as safe and effective.⁴⁴

SMALL CONTAINER LABELING

Under the Drug Facts rule, if the information listed under Drug Facts requires more than 60 percent of the total available surface area, the Drug Facts labeling can be reduced by making the formatting changes specified in 21 C.F.R. § 201.66(d)(10). The final rule continues to allow such reduced labeling for sunscreen products.

The 2007 proposed rule contained reductions in labeling for three types of sunscreen products sold in small packages and intended for use on small areas or the face: 1) sunscreen products sold in small packages and labeled for use specifically on the lips, nose, ears and/or around the eyes, 2) sunscreen-lip protectant combination products sold in small packages, and 3) sunscreen products formulated as lipsticks, lip products that prolong wear of lipstick, lip gloss and lip balms. Although the final rule permits the reduced labeling specified in 21 C.F.R. § 201.66(d)(10), FDA is no longer allowing any additional restrictions in labeling for any sunscreen products.

SPF TESTING

The 2007 proposed rule included the SPF test from the 1999 final rule with revisions to a few test parameters. The final rule revises the description of the SPF test in an effort to make it easier to read and understand and to more closely follow the order in which steps of the SPF testing procedure are conducted. The final rule also revises the proposed SPF test method to be as consistent as possible with the COLIPA SPF test.⁴⁵ For example the final rule includes revisions to the solar simulator specifications, test site and subsite size specifications and number of tests subjects providing valid results consistent with the COLIPA SPF test.⁴⁶

The 2007 proposed rule included two sunscreen standards for use in SPF testing: a 7 percent padimate O/3 percent oxybenzone standard and an 8 percent homosalate standard. For SPF testing

⁴¹ 21 C.F.R. § 201.327(e)(2).

⁴² 76 Fed. Reg. 35638.

⁴³ 21 C.F.R. § 201.327(e)(3).

⁴⁴ 21 C.F.R. § 310.545(a)(29)(ii). While these claims may not be included on products marketed without approved applications, these claims may be substantiated for an individual product by the submission of an adequate data in an NDA.

⁴⁵ The COLPIA SPF test is a joint effort by the cosmetic industry trade associations in Europe, Japan, South Africa, and the United States to harmonize SPF test procedures.

⁴⁶ 21 C.F.R. § 201.327(i).

of sunscreen products with SPF values 2 to 25, either the padimate O/oxybenzone standard or the homosalate standard would have been required. Tests for sunscreen products with SPF values over 15 would have required use of the padimate O/oxybenzone standard. The final rule eliminates the proposed homosalate standard because the padimate O/oxybenzone standard is adequate for validating all test methodologies.⁴⁷

BROAD SPECTRUM TEST

In the final rule, testing involving the UVA radiation protection is referred to as broad spectrum testing. The final rule implements a pass/fail broad spectrum test that captures both UVB and UVA protection for the effectiveness of a sunscreen product, unlike the proposed test that was limited to UVA wavelengths. By requiring that a broad spectrum sunscreen provide both UVB and UVA protection in a pass/fail test, the amount of UVA protection for a sunscreen product that passes the test must increase as the SPF increases. FDA believes proportionality between UVB and UVA protection is important because consumers have been accustomed to basing their purchase decision concerning protection level primarily on the SPF value, and only secondarily on indications of whether or not the sunscreen provides broad spectrum protection.⁴⁸

The final rule implements a pass/fail test based on an *in vitro* critical wavelength method. A product is classified as providing broad spectrum protection if its critical wavelength⁴⁹ is 370 nm or greater. FDA believes the critical wavelength method is appropriate because it is “simple, reproducible, and inexpensive” and “has been used by sunscreen manufacturers to evaluate UVA protection for over a decade and is one of the most commonly used UVA tests.” FDA set the critical wavelength at 370 nm because that wavelength is “sufficiently difficult to achieve and will ensure that sunscreen products meeting this threshold provide a significant amount of broad spectrum protection” but it “is not so difficult to formulate sunscreen products to achieve this critical wavelength that manufacturers cannot develop broad spectrum sunscreen products.” In addition, FDA concluded that most of the harmful effects from the sun are caused by UV radiation in wavelengths below 370 nm.⁵⁰

FDA revised the proposed *in vitro* test, the modified Diffey-Robson ratio, from the 2007 proposed rule because it found that the proposed ratio was not the most appropriate *in vitro* measure of broad spectrum protection, as it placed too much emphasis on absorption in the UVA I part of the spectrum. In agreement with many submission, FDA concluded that the critical wavelength method provides a better measure of broad spectrum protection.⁵¹

In the 2007 proposed rule, FDA stated that an assessment of UVA protection should include determination of both the magnitude and breadth of absorption in the UVA part of the spectrum. FDA proposed an *in vivo* test to evaluate the magnitude of absorption and an *in vitro* test to evaluate the breadth of absorption. The final rule does not require an *in vivo* test. FDA concluded that the proposed *in vivo* Persistent Pigment Darkening test is not necessary to establish that a sunscreen product provides protection against UVA radiation and that the magnitude of absorption over the solar terrestrial UV portion of the spectrum (both UVA and UVB) can be effectively assessed based on the SPF test in combination with a pass/fail broad spectrum *in vitro* test.⁵²

⁴⁷ 76 Fed. Reg. 35646.

⁴⁸ 76 Fed. Reg. 35627.

⁴⁹ The critical wavelength is identified as the wavelength at which the integral of the spectral absorbance curve reaches 90 percent of the integral over the UV spectrum from 290 to 400 nm.

⁵⁰ 76 Fed. Reg. 35651.

⁵¹ 76 Fed. Reg. 35649.

⁵² 76 Fed. Reg. 35649.

WATER RESISTANCE TEST

The water resistance test in the final rule is substantially the same as the test in the 2007 proposed rule; however, the final rule reduces the drying period from 20 minutes to 15 minutes.⁵³ The test involves applying the sunscreen; alternating performing 20 minutes of moderate activity in water and resting out of water without toweling for 15 minutes for a total of 40 or 80 minutes of activity in water; and applying the SPF standard and exposing the test sites to UV doses.⁵⁴

IMPLEMENTATION AND ENFORCEMENT

Covered Products

FDA does not intend to object to the marketing without an approved application of sunscreen products that 1) contain only the active ingredients or combinations of active ingredients listed in FDA's draft guidance document,⁵⁵ 2) do not make claims prohibited in the final rule, 3) comply with the labeling and adverse event reporting requirements for OTC drugs and 4) follow the labeling and testing requirements in the final rule.⁵⁶

Cosmetic products, such as foundations and other makeup preparations, lipsticks and lipglosses, labeled with sunscreen claims, including an SPF value, are regulated as drugs and must therefore be labeled in compliance with the final rule and the Drug Facts rule.⁵⁷

The only exception from the final rule requirements is the reduced Drug Facts labeling permitted by the Drug Facts rule. No other exceptions are contemplated by the rule.

Implementation and Enforcement

The effective date of the final rule and compliance date for all covered products is June 18, 2012, except for products with annual sales less than \$25,000 for which the compliance date is June 17, 2013.⁵⁸ The implementation date is the same for the labeling and testing requirements in the final rule, 21 C.F.R. § 201.327, and the requirements in the Drug Facts final rule, 21 C.F.R. § 201.66.⁵⁹

In the 2007 proposed rule, FDA indicated that sunscreen products that are already distributed by the effective date of the final rule, June 18, 2012, would not be expected to be relabeled or retested in conformity with the final rule conditions unless these products were subsequently relabeled or repackaged after the effective date. Consistently, FDA does not expect non-compliant products introduced or delivered for introduction into interstate commerce prior to the compliance date, June 18, 2012, to be removed from the market.⁶⁰ Thus product imported prior to the compliance date would be protected, as would any product delivered to customers, even if still in customers' warehouses on the effective date. Under the general interpretation of "delivered for introduction into

⁵³ 76 Fed. Reg. 35651.

⁵⁴ 21 C.F.R. § 201.327(i)(7).

⁵⁵ Aminobenzoic acid (PABA), 15 percent; Avobenzone, 3 percent; Cinoxate, 3 percent; Dioxybenzone, 3 percent; Ensulizole, 4 percent; Homosalate, 15 percent; Meradimate, 5 percent; Octinoxate, 7.5 percent; Octisalate, 5 percent; Octocrylene, 10 percent; Oxybenzone, 6 percent; Padimate O, 8 percent; Sulisobenzone, 10 percent; Titanium dioxide, 25 percent; Trolamine salicylate, 12 percent; and Zinc Oxide, 24 percent.

⁵⁶ Food and Drug Administration, Draft Guidance for Industry: Enforcement Policy—OTC Sunscreen Drug Products Marketed Without An Approved Application (June 2011).

⁵⁷ 21 C.F.R. § 700.35.

⁵⁸ 76 Fed. Reg. 35620.

⁵⁹ 76 Fed. Reg. 35629.

⁶⁰ 76 Fed. Reg. 35624.

interstate commerce,” other warehoused product might also be protected, but would have to be evaluated on a case-by-case basis.

SPF Testing Implementation

FDA expects sunscreen products initially marketed after June 17, 2011, to conduct SPF testing in accordance with the final rule and to use the resulting SPF value in labeling by the compliance date. In order to ensure that limited testing laboratory capacity does not result in sunscreen product shortages during the transition to the new rule, FDA intends to exercise enforcement discretion for a period of time with regard to the SPF testing requirements for certain sunscreen products on the market by June 17, 2011.⁶¹

FDA does not intend to initiate enforcement action before June 17, 2013, for sunscreen products that were on the market prior to June 17, 2011 and are labeled with an SPF value determined prior to June 17, 2011, using the SPF test method described in the 1999 final rule or the SPF test method described in the 2007 proposed rule. Such products should otherwise be labeled in compliance with the final rule. FDA does not intend to exercise enforcement discretion for sunscreen products initially marketed prior to June 17, 2011, if they are labeled with an SPF that was generated by a method other than that included in the 2011 final rule, 1999 final rule, or 2007 proposed rule.⁶²

CONCLUSION

The final rule published June 17, 2011 imposes new labeling and testing requirements for all sunscreen drug products marketed without an approved application, including cosmetic products with sunscreen claims. The sunscreen monograph and those sunscreen ingredients generally recognized as safe and effective have not been finalized nor has the stay on the implementation of the monograph been lifted by the final rule.

The labeling claims reflect FDA’s determination that proportional UVA and UVB radiation protection is important and that only “broad spectrum” products of a sufficient SPF, in combination with other sun protection measures, reduce the risk of skin cancer and skin aging. The final rule also regulates water resistance claims and prohibits waterproof or sweatproof claims. These requirements are intended to assist consumers make informed purchasing decisions and to avoid consumers overvaluing the radiation protection provided by certain sunscreen products.

In addition, imbedded in the required labeling for sunscreen products are statements that direct consumers to products that are water resistant, broad spectrum, and have SPF value of 15 or higher. For example, non-water resistant product labeling now must direct consumers to use water resistant products if swimming or sweating. Broad spectrum SPF value of 15 or higher products may direct consumers to use these products, in combination with other sun protection measures, to decrease their risk of skin cancer and early skin aging.

Sunscreen product manufacturers must ensure that products shipped or imported after June 18, 2012 comply with the required labeling and testing; any new product must comply with testing (and thus SPF labeling) immediately. Products with annual sales less than \$25,000 must comply within two years. FDA will exercise discretion for two years with respect to products currently on the market if the SPF value of the product was determined by the tests in the 2007 proposed rule or 1999 final rule.

⁶¹ Food and Drug Administration, Draft Guidance for Industry: Enforcement Policy—OTC Sunscreen Drug Products Marketed Without An Approved Application (June 2011).

⁶² Food and Drug Administration, Draft Guidance for Industry: Enforcement Policy—OTC Sunscreen Drug Products Marketed Without An Approved Application (June 2011).

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