Personal Care Products Council
Committed to Safety, Quality & Innovation

Brief Summary of FDA's 2011 Sunscreen Rulemakings

On June 14, 2011 FDA released the following sunscreen related rulemakings: 1) Final Rule on Effectiveness Testing and Labeling for Over-the-Counter (OTC) Sunscreen Products (Final Rule);[1] 2) Proposed Rule on SPFs above 50; 3) Advance Notice of Proposed Rulemaking (ANPR) on sunscreen dosage forms; 4) Draft Guidance on OTC Sunscreen Drug Products; and 5) Request for Comment on the Final Rule.[2]

Final Rule on Sunscreen Labeling and Efficacy

The Final Rule outlines permitted and required claims, testing procedures required to substantiate those claims, and claims that are not permitted. It is important to note that these rules amend FDA's drug labeling regulations (*i.e.*, 21 CFR 201), and do not finalize the sunscreen monograph (*i.e.*, 21 CFR 352), nor lift the stay on the implementation of the monograph.

Drug Facts Panel Required: 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. This includes combination cosmetic—sunscreen products such as lipsticks, foundations, and daily moisturizers that are labeled as containing an SPF.

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 as specified in regulation.[3] FDA did not provide for any additional labeling relief under the Final Rule.

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1 The Final Rule (76 FR 35620), codified in § 201.327, establishes labeling and testing requirements for OTC sunscreen products marketed without approved applications and containing only the ingredients specified in the stayed 1999 final rule (Aminobenzoic acid (PABA), Avobenzone, Cinoxate, Dioxybenzone, Ensulizole, Homosalate, Meradimate, Octinoxate, Octisalate, Octocrylene, Oxybenzone, Padimate O, Sulisobenzone, Titanium dioxide, Trolamine salicylate, Zinc oxide).

2 All published in the June 17, 2011 Federal Register.

3 21 CFR 201.66(d)(10).

No Ingredient Issues Addressed: The Final Rule does not address issues related to sunscreen active ingredients, including any new active ingredient combinations or any sunscreen active ingredients currently under TEA review.

Effective Date: The Final Rule effective date is June 18, 2012, except for products with annual sales less than $25,000 for which the effective date is June 17, 2013. All products labeled on or after the effective date must meet all final rule requirements (see below for additional time/enforcement discretion for SPF testing).

- FDA did not require 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.
- 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.
- 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.[4]

More Time for SPF Testing: In the Draft Guidance, FDA stated it does not intend to initiate enforcement action before June 17, 2013, for OTC sunscreen products that: i) are subject to the 2011 Final Rule; ii) were on the market prior to June 17, 2011, the date of publication of the final rule; and iii) are labeled with an SPF value determined prior to June 17, 2011, using the SPF test method described in the 1999 final rule[5] or the SPF test method described in the 2007 proposed rule.[6] However, it is important to note that all other labeling and testing requirements must be met prior to June 18, 2012.

SPF Testing

The SPF test method was modified to require a smaller number of test subjects to determine a product's SPF (10) compared to the previous methods that required 20-25 test subjects. The reference control formulation was changed from an SPF 4 formulation to an SPF 15 formulation. The fingercot used for sample application no longer requires pre-saturation with test product. The minimum size of the test site for product application was reduced in area, as was the required minimum area for each individual UV exposure. The distance between exposure sites in the test area was reduced. Product application remained at 2 mg/cm^2 with test results read at 16-

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4 Under the general interpretation of "delivered for introduction into interstate commerce," other warehoused product might also be protected, but would have to be evaluated on a case-by-case basis.

5 64 FR 27666 at 27689-693.

6 72 FR 49070 at 49114-119.

24 hr post-exposure. Solar simulator specifications were harmonized with those in the International SPF Method.

"Broad Spectrum" Testing

FDA has abandoned the "Four Star" rating proposal indicating UVA protection provided on product labels, in favor of a simple "pass/fail" *in vitro* test for "broad spectrum" characteristics – known in the industry as the "Critical Wavelength" test. The proposed test methodology differs from previously published methodology to determine the "critical wavelength" in several attributes, and is different from the ISO *in vitro* UVA test method (in development) as well.

A sunscreen must have a critical wavelength of 370 or higher to be able to make a "broad spectrum" claim. A "Broad Spectrum" claim is necessary in order to make a positive "use" statement regarding prevention of early skin aging and skin cancer on products with an SPF of at least 15, otherwise a warning statement must be used for the product "uses" (see below).

The FDA "Critical Wavelength" test method prescribes use of PMMA plates with a surface roughness from 2 – 7 microns, with a sunscreen application density of 0.75 mg/cm^2, and pre-irradiation of the sample with a fixed 4 MED exposure to solar simulated radiation. The wavelength at which 90% of the UV absorbance area under the curve occurs (when summing from 290 towards 400), is defined as the "critical wavelength", and is a measure of the breadth of the protection provided by the product.

The New Label

Uses (indications)

- helps prevent sunburn
- 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 [PLEASE NOTE: ***the sunscreen must be "Broad Spectrum" and SPF of at least 15 in order to use this statement***]

Warnings

- **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 [PLEASE NOTE: ***this statement is required for products that are not labeled as "Broad Spectrum" or SPF of less than 15***]

Directions (for Broad Spectrum/SPF ≥ 15 and water resistant)

- Apply liberally (or "generously: and may add "and evenly") 15 minutes before sun exposure
- Reapply
    - after 40 (or 80) minutes of swimming or sweating

    - immediately after towel drying
    - at least every 2 hours
- **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 broad spectrum SPF of 15 or higher and other sun protection measures including:
    - limit time in the sun, especially from 10 a.m. – 2 p.m.
    - wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

Directions (for Broad Spectrum and/or SPF ≤ 15 and water resistant)

- Apply liberally (or "generously: and may add "and evenly") 15 minutes before sun exposure
- Reapply
    - after 40 (or 80) minutes of swimming or sweating
    - immediately after towel drying
    - at least every 2 hours
- Children under 6 months of age: Ask a doctor

Directions (for Broad Spectrum/SPF ≥ 15 and not water resistant)

- Apply liberally (or "generously: and may add "and evenly") 15 minutes before sun exposure
- **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 broad spectrum SPF of 15 or higher and other sun protection measures including:
    - limit time in the sun, especially from 10 a.m. – 2 p.m.
    - wear long-sleeve shirts, pants, hats, and sunglasses
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- Children under 6 months: Ask a doctor

Directions (for Not Broad Spectrum and/or SPF ≤ 15 and not water resistant)

- Apply liberally (or "generously: and may add "and evenly") 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- Children under 6 months of age: Ask a doctor

Note: FDA is allowing the optional direction heading ''for sunscreen use'' to appear as the first line under Directions.[7]

Note: 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. FDA did not explicitly allow for a sweat resistance claim.

Proposed Rule on SPFs above 50

Although FDA acknowledged that SPFs higher than 50 have been substantiated and results are validated and repeatable, it is proposing to limit SPF to "50+" unless the agency receives data demonstrating additional clinical benefit for SFPs above 50.

Sunscreens labeled with SPFs above 50 may remain on the market until this proposed rule becomes final, provided they follow the appropriate SPF test. Depending on how this proposed rule is finalized, these products may/may not be able to continue on the market.

Advance Notice of Proposed Rulemaking on Dosage Forms

FDA published an ANPR requesting additional data on OTC sunscreen products in certain dosage forms. The agency listed those dosage forms that it currently considered potentially eligible for inclusion in the OTC sunscreen monograph (*i.e.*, oils, lotions, creams, gels, butters, pastes, ointments, sticks, and sprays).

For sprays, FDA requested additional data to address remaining questions about effectiveness and safety. The agency also encouraged comments 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 generally recognized as safe and effective (GRASE.)

FDA also identified certain dosage forms that it does not consider currently eligible for review for potential inclusion in the OTC sunscreen monograph (*i.e.*, wipes, towelettes, powders, body washes, and shampoos).

Sunscreens, such as those in powder form, may remain on the market until this proposed rule becomes final, provided they follow the appropriate testing and labeling. When this ANPR is eventually finalized, we will know which dosage forms may continue on the market.

[7] The agency's reasoning for this allowance is that consumers who are using these products primarily for cosmetic use may be more likely to understand that they might not receive the intended sun protection if they do not follow the directions in the Drug Facts label.