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# OTC Sunscreen Drug Products: toward greater protection

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Man has long cherished the warmth, brilliance, and splendor of the sun. In modern American culture, this attraction has manifested itself in our love for suntanning. One would be hard-pressed to find an American who has not daydreamed about sunbathing on a tropical beach. Recent evidence suggests, however, that our reverie is haunted by harmful radiation from the sun.<sup>1</sup> Most obviously, overexposure of the skin to sunlight causes sunburn, but there are many other adverse effects of solar radiation. Skin exposure to solar radiation increases the risk of skin cancer, promotes premature aging of the skin (photo aging), exacerbates photosensitivity diseases, decreases the body's immune response, and interacts adversely with common drugs.<sup>2</sup> Adding to our worries about skin cancer, the incidence of skin cancer increased by a startling rate during the last decade.<sup>3</sup> The annual incidence of carcinoma (generally, a non-fatal skin cancer) increased from 600,000 people in 1990 to over a million people today; by the year 2000, the lifetime incidence of melanoma (a potentially fatal skin cancer) is expected to exceed one in 90.<sup>4</sup> In deed, the sun may be leaving an indelible mark not only on the hearts of Americans but also our skin.

Despite this formidable evidence, our love for the sun has not be thwarted. Instead, Americans avidly pursue means to cope with the dangers of the sun as public awareness of and concern over the risks of skin cancer

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<sup>1</sup> FDA Commissioner David A. Kessler, M.D., May 11, 1993, (There is overwhelming evidence that exposure to radiation from the sun is a health hazard.)

<sup>2</sup> J. Michael Wentzell, *Sunscreens: the ounce of prevention*, American Family Physician, Apr. 1, 1996, at 1713; see also 58 Fed. Reg. 28285.

<sup>3</sup> Patrick R. Jones, *Protecting the Consumer from Getting Burned*, 20 American Journal of Law & Medicine 317, 318 (1994).

<sup>4</sup> Wentzell, supra note 2.

and premature skin aging due to exposure to the sun increases.<sup>5</sup> This trend explains why there have been over 150 brands of sunscreens available on the market, with the current market estimated to be worth more than a half a billion dollars per year.<sup>6</sup> It is now well-recognized that proper use of sunscreens will help prevent the occurrence of skin cancer and premature aging of the skin.<sup>7</sup> In fact, many health reports list sunscreens, second only to avoidance of the sun, as an effective way of dealing with the risks associated with sun exposure.<sup>8</sup>

It is important, however, for the public to know that sunscreens are not a panacea for the adverse effects of solar radiation and that they are not a substitute for avoidance of the sun. Along with the many benefits attributed to sunscreen products, there is also the risk that these products create a false sense of security among consumers. Consumers have also been susceptible to being misled about the promoted uses and relative value of sunscreen products. Finally, consumers have not always been well-informed about how and when such products should be applied. In regulating sunscreen products, the Food & Drug Association (FDA) has taken up many of these concerns as it seeks to ensure that such products are safe and effective and not misbranded. Relief and guidance from the FDA have come in the form of the Tentative Final Monograph (“TFM”) for Over-the-Counter (“OTC”) Sunscreen Drug Products, a comprehensive regulation of OTC sunscreen drug products, which, in its final form, will be codified in 21 C.F.R. §352.

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<sup>5</sup> T. Carpenter *et al*, *Protection from Sun Protectors*, Drug & Cosmetic Industry, March 1, 1996, at 56; *see Jones, supra* note 3 at 319.

<sup>6</sup> Wentzell, *supra* note 2; Elif Sinanoglu, *Don't Get Burned When Buying Sunblock*, Money, July 1994, at 121.

<sup>7</sup> Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph, 58 Fed. Reg. 28194, 28298 (1993) (to be codified at 21 C.F.R. § 352.52 (e)(6)); for additional sources, *see references listed at 58 Fed. Reg. 28194, 28223 (1993) (references 1-18) and 58 Fed. Reg. 28194, 28237 (references 1-11)*.

<sup>8</sup> Paula Kurtzweil, *Seven Steps to Safer Tanning*, FDA Consumer, June 1, 1996, at 6; Peter H. Rheinstein, *Seven Tips for Sun Sense*, American Academy of Family Physicians, Sep. 15, 1996, at 1385.

This paper first seeks, in background, to discuss the role of the TFM system in regulating sunscreen products. It will then both examine two prominent controversies, namely the problem of UVA protection and the proposed cap on SPF values, and then assess the related deficiencies of the current labeling scheme under the TFM for OTC Sunscreen Drug Products. Finally, the paper will discuss the barriers to more comprehensive protection in sunscreen products.

## Background

### *Sunscreen: Drug or Cosmetic*

Sunscreen products are regulated as drugs by the FDA.<sup>9</sup> Products which make protective claims relating to sun exposure must conform to the TFM requirements.<sup>10</sup> The TFM lists the terms which would constitute such a claim, including sunscreen, sunblock, sunshield, SPF, an SPF value, etc.<sup>11</sup> This requirement applies, typically, to traditional beach products which have active sunscreen ingredients and are intended to prevent sunburn and protect the skin from the harms of solar radiation. For this reason, such products fall under the definition of drug in section 201 (g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the “FD&C Act”).<sup>12</sup> They are also drugs under section 201 (g)(1)(C) of the FD&C Act because they affect the body’s physiological response to radiation in that they lessen its erythema reaction.<sup>13</sup>

There are two types of products, however, that present unique problems regarding how they should be

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<sup>9</sup> 58 Fed. Reg. 28194, 28195 (1993); the definitions for drugs and cosmetics are found in section 201 of the Federal Food, Drug, and Cosmetic Act. See 21 U.S.C. §321 (g), (I).

<sup>10</sup> 58 Fed. Reg. 28194, 28204-28205 (1993).

<sup>11</sup> Id.

<sup>12</sup> 21 U.S.C. 321 (g)(1)(B); see 58 Fed. Reg. 28194, 28195 (1993).

<sup>13</sup> 21 U.S.C. 321 (g)(1)(C); see 58 Fed. Reg. 28194, 28195 (1993).

defined and regulated. The first group can be described as beach products which do not contain any active sunscreen ingredients listed in the TFM for OTC Sunscreen Drug Products and which do not make any therapeutic or protective claims (e.g., suntan lotion). These products are not drugs. However, the FDA is proposing, under 21 U.S.C. 321 (n), 362 (a), and 371 (a), to amend the cosmetic regulations in 21 C.F.R. Part 700 so as to require these products to display the following warning: Warning – This product does not contain a sunscreen and does not protect against sunburn.<sup>14</sup> This will ensure that such products are used safely and will not be confused with sunscreen drug products.

The other highly debated category of sunscreen related products are those which are not traditional beach products but which contain at least one active sunscreen ingredient listed in the TFM for OTC Sunscreen Drug Products (e.g., hair spray, nail polish, or lipstick). For these products, which are generally perceived as cosmetics, the distinction is again based on each product's intended use and how it is represented to the public. Any product containing sunscreen active ingredients and displaying sunscreen labeling claims is a drug. Accordingly, the FDA will not regulate these products as drugs under certain circumstances; most importantly, the term sunscreen must not be used, no SPF value can given, and the ingredient is mentioned without any protective claims and only by its cosmetic name in the ingredient list.<sup>15</sup>

There are several reasons why the FDA would want to classify a product as a drug. In general, drug regulations are more stringent. Features of the FD&C Act that distinguish the regulation of drugs from that of cosmetics are as follows: a drug must be approved by the FDA as safe and effective for those uses indicated on its label;<sup>16</sup> adverse effects and product-related injuries must be reported to the FDA;<sup>17</sup> drugs and drug manufacturing facilities must be registered with the FDA.<sup>18</sup> Additionally, manufacturers of drugs

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<sup>14</sup> 58 Fed. Reg. 28194, 28207 (1993).

<sup>15</sup> 58 Fed. Reg. 28194, 28205 (1993).

<sup>16</sup> 21 U.S.C. §321(p), §355.

<sup>17</sup> Id., §355.

<sup>18</sup> Id., §360.

must follow current good manufacturing practices under the stricter adulteration standards.<sup>19</sup> Finally, the FDA can preclude the use of certain ingredients.

### *The OTC drug monograph system*

The FDA is dedicated to the task of ensuring the safety and effectiveness of marketed drugs. As part of this mission, it requires the premarket approval of new drugs through the submission of a new drug application (“NDA”). However, NDA premarket approval only pertains to new drugs, and not all drugs fall under this definition.<sup>20</sup> In 1972, the FDA established the OTC drug monograph system for OTC drug review.<sup>21</sup> Through this process, the FDA aspired to examine the safety and effectiveness of all OTC drug products marketed in the United States before 1972 that had not been scrutinized as NDAs, as well all OTC drug products that had been covered by NDAs but which were marketed before the enactment of the 1962 amendments to the Act which required testing for effectiveness.<sup>22</sup> Given the agency’s limited resources, the FDA determined that the OTC drug review would be performed most efficiently if OTC drugs were evaluated on a class rather than individual basis.<sup>23</sup>

These monographs embody the FDA’s comprehensive regulation regarding a class of OTC drug products (such as sunscreens) and establish the conditions under which such class is generally recognized as safe and effective and not misbranded, including both the requirement or exclusion of active ingredients, combinations

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<sup>19</sup> Id., §351.

<sup>20</sup> A drug is a new drug if it is not generally recognized as safe and effective for its indicated uses or if it has not been used to a material extent or for a material time under such conditions (i.e., uses). See 21 U.S.C. §321 (p).

<sup>21</sup> Now codified at 21 C.F.R. part 330.

<sup>22</sup> Eligibility Criteria for Considering Additional Conditions in the Over-the-Counter Drug Monograph System, Advance Notice of Proposed Rulemaking, 61 Fed. Reg. 51625, 51626 (1996).

<sup>23</sup> Id.

of active ingredients, labeling, etc. When a final monograph is adopted, it is published under 21 C.F.R. part 330. The regulations are generally not enforced, however, until the final monograph is published.<sup>24</sup>

In 1978, the FDA published an advance notice of proposed rulemaking (“ANPR”) to establish a monograph for OTC sunscreen drug products.<sup>25</sup> In 1993, the FDA furthered the ANPR with its tentative final monograph for OTC sunscreen drug products to be codified at 21 C.F.R. part 352.<sup>26</sup> The TFM has been followed by two proposed amendments, but the FDA has not made its determination on a final monograph for OTC sunscreen drug products.

### **Sunscreen Drug Product Labeling Scheme**

One of the major goals of the FDA in regulating OTC sunscreen drug products is to ensure that consumers can reliably identify the amount of protection the sunscreen product provides from exposure to the sun. The TFM for OTC Sunscreen Drug Products has established labeling requirements to accomplish this end. These require that traditional sunscreen products provide a sun protection factor value (“SPF”) accompanied by its product category designation (“PCD”), which will describe the product’s SPF value as minimal, moderate, high, very high, or ultra high.<sup>27</sup> SPF is defined as the ratio of the amount of energy required to produce a minimal sunburn through the applied sunscreen to the amount of energy required to produce the same amount of sunburn without any sunscreen.<sup>28</sup> In essence, this means that a person who uses a sunscreen

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<sup>24</sup> Food & Drug Administration, *FDA Compliance Guide*, §7132 (b)(15).

<sup>25</sup> 43 Fed. Reg. 38206 (1978).; for authority, see 21 C.F.R. 330.10 (a) (6).

<sup>26</sup> 58 Fed. Reg. 28194 (1993).

<sup>27</sup> 58 Fed. Reg. 28194, 28219 (1993).

<sup>28</sup> *Id.*; 58 Fed. Reg. 28194, 28295 (1993).

with SPF 2 could remain exposed to the sun twice as long as he ordinarily could before suffering minimal sunburn; a person who uses an SPF 30 could remain exposed thirty times as long. In addition, the FDA has recommended a Sunscreen Product Guide (“SPG”) to appear on the labeling of all such products. The SPG is intended to allow consumers to ascertain which SPF level is appropriate for their skin type.<sup>29</sup> There are, of course, many problems with the labeling system proposed under the TFM for OTC Sunscreen Drug Products, including the issues of UVA protection and limitation of SPF values.

#### *The UVA Radiation Problem*

Much debate has focused on the need for protection from UVA radiation and the issue of appropriate labeling. Ultraviolet (“UV”) radiation, which causes most of the adverse effects of solar radiation, ranges between 200 and 400 nm and is divided into three bands: UVC (200 - 290 nm), UVB (290 - 320 nm), and UVA (320 to 400 nm). Of these three types of UV radiation, only UVB and UVA penetrate the earth’s atmosphere to reach the its surface. Because the definition of sunscreen active ingredients pertains directly only to UVB rays, SPF values do not give a clear indication of protection afforded against UVA rays.<sup>30</sup> In fact, the TFM for OTC Sunscreen Drug Products does not even require sunscreen products to protect against UVA rays.

Originally, experts believed that only UVB caused cancer, and hence sunscreens were formulated only to protect against UVB.<sup>31</sup> The theory was that sunscreens should protect skin from burning (which was then

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<sup>29</sup> 58 Fed. Reg. 28194, 28217 (1993).

<sup>30</sup> 58 Fed. Reg. 28194, 28295 (1993) (defining active ingredients based on absorption of UV radiation from 290 to 320 nm).

<sup>31</sup> 58 Fed. Reg. 28194, 28232 (1993).



believed to be caused solely by UVB) and to allow tanning from UVA rays.<sup>32</sup> Evidence now shows that both UVA and UVB cause sunburn, premature aging of the skin, skin cancer.<sup>33</sup> Although UVA is less harmful than UVB per dose, the amount of UVA that reaches the earth's surface is vastly greater than that amount of UVB, and UVA radiation penetrates the skin more efficiently than UVB.<sup>34</sup> UVA rays may account for more than 15% of the adverse effect solar radiation has on human skin that is exposed to the sun.<sup>35</sup> In deed, there is no such thing as a risk-free tan.<sup>36</sup>

The most alarming consequence of the FDA's inability to deal with the issue of UVA radiation is that it has given sunscreen users a false sense of security. Consumers who rely solely upon SPF values to assess the effectiveness of a sunscreen product may be inclined to remain exposed to the sun for longer periods of time as a result of their confidence in the product they use. These consumers are thus beguiled into increasing their exposure to UVA radiation. In some situations, the overall effect could be that the consumer actually increases his risk of cancer relative to what would have arisen under the more moderate exposure to the sun that would have occurred had the consumer not been lulled into a false sense of security. Therefore, FDA must devise a system that promotes the use of broad spectrum sunscreens (i.e., sunscreens that adequately protect against both UVB and UVA radiation).

The FDA is devising labeling requirements for products that purport to protect skin from UVA radiation in order to ensure that such products are not misleading and offer adequate UVA protection. The TFM states that products claiming to protect skin from UVA rays must contain ingredients that protect against UV

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<sup>32</sup> *Id.*; see *Jones, supra note 3 at 320.*

<sup>33</sup> 58 Fed. Reg. 28194, 28233 (1993); 59 Fed. Reg. 160042, 16043 (1994).

<sup>34</sup> *Wentzell, supra note 2; 58 Fed. Reg. 28194, 28233 (1993).*

<sup>35</sup> 58 Fed. Reg. 28194, 28233 (1993).

<sup>36</sup> See *Wentzell, supra note 2; 58 Fed. Reg. 28194, 28288 (1993).*

radiation extending up to 360 nm.<sup>37</sup> A sunscreen product that provides protection against UVB and UVA radiation up to this level of the spectrum (360 nm) may be characterized as a broad spectrum sunscreen.<sup>38</sup>

However, the FDA has not been able to establish a method for determining UVA protection and has tentatively recommended using a testing method similar to the one suggested by Lowe *et al.*<sup>39</sup> In addition, although the FDA requires broad spectrum products to protect against UV rays between 290 and 360 nm, the FDA has not been able to determine which part of the UVA spectrum actually presents significant health risk.<sup>40</sup> Supported by evidence, the FDA believes that the longer UVA wavelengths (340 to 400 nm) are less hazardous than the shorter UVA wavelengths (320 to 340 nm).<sup>41</sup> The same evidence suggests, however, that longer wavelength UVA rays can cause both tissue damage and tumors.<sup>42</sup> The defining band at 360 nm is a tentative compromise, and even the FDA admits that UVA or broad spectrum labeling could be misleading.<sup>43</sup>

### *SPF Cap Controversy*

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<sup>37</sup> 58 Fed. Reg. 28194, 28233 (1993).

<sup>38</sup> *Id.*

<sup>39</sup> 58 Fed. Reg. 28194, 28250 (1993); 59 Fed. Reg. 16042 (1994); Lowe, N. J. et al., *Indoor and Outdoor Efficacy Testing of a Broad Spectrum Sunscreen Against Ultraviolet A Radiation in Psoralen-sensitized Subjects*, 17 *Journal of the American Academy of Dermatology* 224 (1987).

<sup>40</sup> See Discussion of Ultraviolet A-Protection Claims and Testing Procedures for Over-the-Counter Sunscreen Drug Products, Notice of Public Meeting and Reopening of the Administrative Record, 59 *Fed. Reg.* 16042 (1994).

<sup>41</sup> 59 Fed. Reg. 16042 (1994); McKinlay, A.F., and B. L. Diffey, *A Reference Action Spectrum for Ultraviolet Induced Erythema in Human Skin*, 6 *CIE Journal* 17 (1987).

<sup>42</sup> F-D-C Reports, *The Tan Sheet*, May 17, 1993, at 12-14.

<sup>43</sup> See *Id.*

Another area of reform for sunscreen labeling, which the FDA hopes will ensure safer and more effective use, has been the proposed cap on SPF values to a level of 30.<sup>44</sup> This proposal came as higher SPF values began to dominate the market.<sup>45</sup> According to the FDA, the benefits of SPF values above 30 are negligible. The FDA has accepted evidence that shows a sunscreen product with SPF of 30 blocks 96.7% of the UVB radiation to which skin would be exposed without any protection; an SPF 40 sunscreen product increases this level of protection to 97.5% of UVB radiation, and an SPF 70 would block only 98.7 % of UVB radiation.<sup>46</sup> The FDA weighs these minimal additional benefits against the potential health risks associated with products of SPF values above 30. Chemical ingredients of sunscreen products can cause skin irritation.<sup>47</sup> In addition, higher concentrations of some ingredients could prove toxic.<sup>48</sup> The FDA believes that, although SPF values higher than 15 are necessary for some consumers in some situations, the risk of added ingredients outweigh the negligible benefits of products with SPF values above 30.<sup>49</sup>

Not all manufacturers of sunscreen products have opposed the FDA's decision to impose this limit; in fact, some companies have actually supported limiting SPF values.<sup>50</sup> These manufacturers believed that a cap would end the futile race toward higher SPF values, which they claim both mislead consumers about the marginal benefits of these products and, perhaps more crucially, cause them to focus solely on SPF values without considering the importance of broad spectrum products.<sup>51</sup> A cap would thus cause manufacturers to produce more well-balanced products that offered more UVA protection and less irritation.<sup>52</sup>

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<sup>44</sup> 58 Fed. Reg. 28194, 28223, 28227 (1993).

<sup>45</sup> Jones, *supra* note 3 at 319; F-D-C Reports, *The Tan Sheet*, Oct. 18, 1993, at 10-12.

<sup>46</sup> 58 Fed. Reg. 28194, 28225 (1993).

<sup>47</sup> 53 Fed. Reg. 28194, 28225 (1993).

<sup>48</sup> *Id.*

<sup>49</sup> See 58 Fed. Reg. 28194, 28223, 28227 (1993).

<sup>50</sup> F-D-C Reports, *The Tan Sheet*, Nov. 22, 1993, at 21-22.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.*

Other manufacturers, however, have protested the FDA's decision to limit SPF values at 30.<sup>53</sup> First, higher SPF values can help compensate for consumers' failure to apply sunscreen products properly.<sup>54</sup> In addition, these manufacturers argue that there is no merit to the FDA's safety concerns regarding SPF values higher than 30 because the TFM already limits the concentration of active ingredients (either alone or in combination) to safe levels.<sup>55</sup>

Upon analyzing the arguments, the FDA's decision to cap SPF values at 30 appears to be unwarranted. The posited safety concerns seem dubious. First, despite the FDA's assessment that 30 was an appropriate break, it still proposed a warning consumers to discontinue use if adverse effects, such as skin irritation, were to occur.<sup>56</sup> Obviously, then, the safety concerns for products with SPF values above 30 also exist for products with SPF values of 30 and below. The FDA could allow higher SPF values and require the same safety warning.

The counter-argument is that the risk from added active ingredients in products with SPF greater than 30 outweigh the benefits of added protection.<sup>57</sup> However, this proposition requires the assumption that higher SPF values require higher concentrations of active ingredients. Oddly, however, the FDA rejected this notion when it earlier justified SPF values above 15.<sup>58</sup> Finally, as already mentioned, the TFM sets maximum concentration levels for the safe and effective use of active ingredients in sunscreen products.<sup>59</sup> Surely the

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<sup>53</sup> F-D-C Reports, *The Tan Sheet*, Feb. 21, 1994, at 10-11.

<sup>54</sup> *Id.*

<sup>55</sup> See 58 Fed. Reg. 28194, 28295 (1993) (to be codified at 21 C.F.R. §352.10, §352.20).

<sup>56</sup> 58 Fed. Reg. 28194, 28227 (1993).

<sup>57</sup> 58 Fed. Reg. 28194, 28227 (1993); Wentzell, *supra* note 2.

<sup>58</sup> 58 Fed. Reg. 28194, 28226 (1993) (The agency agrees that advances in formulation technology have allowed manufacturers to develop products with relatively low levels of sunscreen active ingredients and still achieve high SPF values. The agency is aware of studies demonstrating the importance of the vehicle on the final performance of a sunscreen product. There is a lack of data showing a significant relationship between sunscreen ingredient concentration and the final SPF of a product.... The study demonstrated that formulation and vehicle design have a profound effect on SPF values.)

<sup>59</sup> See 58 Fed. Reg. 28194, 28295 (1993) (to be codified at 21 C.F.R. §352.10, §352.20).

FDA does not doubt the safety of these concentration limits.

The FDA's actual motivation in setting the SPF limit must therefore be based on the FDA's desire to keep prices of sunscreen products down and to eliminate consumer misperceptions that are caused by higher SPF values. A cap on SPF values will bring the manufacturers' race for higher SPF values to an end and, therefore, stabilize sunscreen prices.<sup>60</sup> Although the goal might be to give people a greater opportunity to purchase sunscreen products by promoting affordable prices and, thus, ensuring that more people used sunscreens, the policy is paternalistic and grossly interferes with consumer autonomy.

Secondly, the policy does not effectively respond to problems concerning public misperception. For example, even if the FDA believes that the public's fixation on SPF values has caused consumers to overlook the need for UVA protection, a cap on SPF values does not inherently correlate with the promotion of broad spectrum products. Therefore, rather than limitations on SPF values, the public needs a more explicit promotion of broad spectrum products.

Lastly, the FDA's agenda could simply be to clarify the public's understanding of SPF values; for most consumers do not understand the problem of diminishing returns on the benefits of SPF values above 30. Nevertheless, the FDA's labeling system under the TFM for OTC Sunscreen Drug Products is inherently susceptible to consumer error in that it depends upon consumers' ability to accurately evaluate their skin type in relation to the SPG.<sup>61</sup> A more appropriate way of avoiding consumer confusion would be for the FDA to adopt more accurate descriptions for the PCD and SPG, such as those suggested by the American Academy of Dermatology.<sup>62</sup>

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<sup>60</sup> F-D-C Reports, *The Tan Sheet*, Nov. 22, 1993, at 21-22.

<sup>61</sup> See 58 *Fed. Reg.* 28194, 28217 (1993).

<sup>62</sup> F-D-C Reports, *The Tan Sheet*, Apr. 18, 1994, at 21 (recommending the following PCD changes: minimal (SPF 4-8), moderate (SPF 8-12), and good (SPF 15)).

## Promoting More Comprehensive Protection

From these regulatory proposals concerning SPF values and broad spectrum sunscreens, it is apparent that the FDA wishes to promote more comprehensive and effective sunscreens protection while ensuring that these products do not pose any unnecessary risk of adverse skin reaction. The FDA must reconsider many of its policies, however, if it is to accomplish this task. One approach that requires further consideration and development is the use of physical sunscreens (i.e., blockers) which reflect or scatter UV radiation. Sunscreen ingredients are generally classified as either chemical (organic) or physical (inorganic).<sup>63</sup> Functionally, these two categories are fundamentally different in that chemical sunscreen ingredients absorb UV radiation, while physical sunscreen ingredients reflect or scatter UV radiation.<sup>64</sup> Each type also has its unique advantages and disadvantages. Most notably, high levels of organic ingredients in sunscreen products can cause sensitization and irritation of skin; inorganic ingredients, however, have far less potential for adverse skin reaction.<sup>65</sup> Physical sunscreens also generally protect against a broader spectrum of UV radiation, including UVA.<sup>66</sup> Unlike chemical sunscreen ingredients, however, physical sunscreens are not invisible after application and offer little water resistance.<sup>67</sup>

The most critical problem with physical sunscreen ingredients is that they tend to clump when heated.<sup>68</sup>

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<sup>63</sup> Discussion of the Photochemistry and Photobiology of Sunscreens, Public Meeting and Reopening of the Administrative Record, 61 Fed.Reg. 42398, 42399 (1996); Wentzell, *supra* note 2.

<sup>64</sup> Id.

<sup>65</sup> Wentzell, *supra* note 2; Carpenter et al, *Protection from Sun Protectors*, Drug & Cosmetic Industry, Mar. 1, 1996, at 56; O'Lenick et al., *Dimethicone copolyop phosphate: an additive that increases SPF*, Soap-Cosmetic-Chemical Specialties, May 1, 1996, at 54.

<sup>66</sup> Wentzell, *supra* note 2.

<sup>67</sup> Id.; Carpenter, *supra* note 5.

<sup>68</sup> Carpenter *supra* note 5, ; O'Lenick, *supra* note 2.

This makes it difficult to maintain high SPF values with physical sunscreens and can result in undesired aesthetic results.<sup>69</sup> To deal with this problem, manufacturers disperse physical sunscreen ingredients within the formulation, which in general are organic.<sup>70</sup> In order to afford effective protection, the physical sunscreen must remain properly dispersed in the formula.<sup>71</sup> Available formulation vehicles include sprays, gels, and emollient bases; most popular is the oil-in-water emulsion.<sup>72</sup>

Another approach completely circumvents the dispersal of physical sunscreens and simply seeks to reduce organic contact with the skin. This can be achieved either by encapsulation strategies, which unfortunately can be very expensive, or through the use of polymers, which fix organic actives to the outer layers of the skin.<sup>73</sup> This results in less skin irritation.

Before manufacturers can explore these opportunities, there are several regulatory impediments that the FDA must remove. First, the FDA's definition of active sunscreen ingredient is remarkably incomplete. The TFM for OTC Sunscreen Drug Products defines sunscreen active ingredients with by focusing on the absorption of UV radiation.<sup>74</sup> The definition does not consider an ingredients ability to scatter or reflect UV radiation. This definition excludes some sunscreen ingredients which are highly effective. Most obviously, the definition does not include physical sunscreen ingredients, because they reflect and scatter UV radiation rather than absorb. The FDA has recognized that the definition of active ingredients needs to be modified to incorporate the ingredients that amply absorb, reflect, or scatter UV radiation.<sup>75</sup>

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<sup>69</sup> Wentzell, *supra* note 2; Carpenter, *supra* note 5; O'Lenick, *supra* note 58.

<sup>70</sup> Carpenter, *supra* note 5; O'Lenick, *supra* note 58.

<sup>71</sup> Carpenter, *supra* note 5; O'Lenick, *supra* note 58; Wentzell, *supra* note 2.

<sup>72</sup> Wentzell, *supra* note 2; O'Lenick, *supra* note 58.

<sup>73</sup> Carpenter, *supra* note 5.

<sup>74</sup> 58 Fed. Reg. 28194, 28295 (1993) (to be codified at 21 C.F.R. §352.3) (Sunscreen active ingredient. An active ingredient that *absorbs* at least 85 percent of the radiation in the UV range at wavelengths from 290 to 320 nanometers, but may or may not transmit radiation at wavelengths longer than 320 nanometers.) (emphasis added).

<sup>75</sup> Sunscreen Drug Products for Over-the-Counter Human Use; Amendment to the Tentative Final Monograph, 61

Another hurdle which should be eliminated is the minimum dosage requirements for permitted combinations of active ingredients in sunscreen products. The FDA's objective is to ensure that each ingredient used contributes significantly to the overall effectiveness of the product when combinations are used.<sup>76</sup> However, the FDA admits that it is unaware of any method for determining each ingredient's contribution to the effectiveness of a combination sunscreen product.<sup>77</sup> Therefore, the minimum concentration levels established are inherently arbitrary and conflict with the FDA's general position of promoting the lowest effective dose of active drug ingredients.<sup>78</sup>

Because minimum concentration requirements discourage manufacturers from creating innovative formulations, which would lower the risk of adverse reaction, the FDA should rely upon total product performance in determining effectiveness of a particular ingredients concentration level. This should be gauged by SPF testing and an appropriate test for UVA protection. The need for more innovative products outweighs the FDA's concern that consumers will be duped into purchasing these products based on the inclusion of a particular ingredient or combination. First, there is no evidence to show that consumers rely upon ingredient listing more so than SPF values in determining which product to buy. Moreover, the FDA has not established a relationship between the minimum concentration requirements and an ingredient's effectiveness in a particular combination; therefore, the FDA cannot determine whether consumers are being misled about a particular ingredient's contribution to the effectiveness of a combination sunscreen product.

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*Fed. Reg. 48645, 48646 (1996).*

<sup>76</sup> 58 Fed. Reg. 28194, 28214 (1993). Note that safety considerations are not relevant to this debate because it is well recognized that the FDA establishes maximum concentration levels active ingredients, both alone and in combination, which ensures the safety of such products. *Id.*, at 28295-28296 (to be codified at 21 C.F.R. §§352.10, 352.20).

<sup>77</sup> *Id.*

<sup>78</sup> F-D-C Reports, *The Tan Sheet*, Oct. 28, 1996, at 11-12.



The final barrier is the difficulty of getting products approved of as safe and effective for a particular use and thus included in the sunscreen monograph. For example, until recently, only one physical sunscreen ingredient was approved by the FDA in the TFM for OTC Sunscreen Drug Products.<sup>79</sup> The plan to propose an amendment to the sunscreen drug products tentative final monograph to include zinc oxide as an active ingredient will have a profound effect on the FDA's definition of sunblock.<sup>80</sup> It has taken many years, however, to have zinc oxide included in the sunscreen drug product tentative final monograph.

Currently, there are two pertinent ways for drugs to attain OTC status: through the NDA process and through the monograph procedure.<sup>81</sup> The NDA process is very costly (requiring clinical studies, reporting of post-market adverse reactions, etc).<sup>82</sup> In most circumstances, there is not enough economic incentive for a manufacturer to undergo the NDA process; thus, in most situations, a manufacturer would simply prefer to have a OTC drug approved under the monograph system.<sup>83</sup>

To avoid NDA approval requirements, the product must not be a new drug as defined by section 201 (p) of the FD&C Act.<sup>84</sup> Thus, the product must be generally recognized as safe and effective for its labeled conditions and must have been used to a material extent and for a material time under such conditions.<sup>85</sup>

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<sup>79</sup> Compare 58 Fed. Reg. 28194, 28240 (1993) (requiring a product to contain titanium dioxide to be labeled a sunblock, which must also reflect or scatter UV rays and have an SPF of at least 12) and 61 Fed. Reg. 42398, 42399 (1996) (maintaining titanium dioxides status as safe and effective sunblock ingredient but denying zinc oxide such status under Category I) with F-D-C Reports, *The Tan Sheet*, Nov. 25, 1996, at 8-9 (reporting the FDA's conclusion to confer zinc oxide Category I status after sufficient evidence demonstrated that zinc oxide safely and effectively blocks UV radiation in both the UVB and UVA wavelengths).

<sup>80</sup> Compare 58 Fed. Reg. 28194, 28240 (1993) (establishing the requirements of a product labeled sunblock) and *Id.*, 28295 (defining sunscreen opaque sunblock) with Cynthia Robins, *Common Sense Skin Care Fashion Thursday*, *San Francisco Examiner*, May 9, 1996 (quoting Dr. Mark Mitchnick, medical director of SunSmart, who asserts, although prematurely, that a sunblock must have an SPF of 12 and contain a physical sunscreen like zinc oxide).

<sup>81</sup> 61 Fed. Reg. 51625, 51629 (1996); See Stephen P. Mahinka, Esq. and Elizabeth Bierman, Esq., *Direct-to-OTC Marketing of Drugs: Possible Approaches*, 50 Food & Drug L.J. 49 (1995).

<sup>82</sup> *Id.*

<sup>83</sup> For a detailed discussion on the relative advantages and disadvantages of both the NDA and monograph process, see Mahinka and Bierman, *supra* note 74. See also, Greff at 250-251.

<sup>84</sup> 21 U.S.C. 321 (p); 61 Fed. Reg. 51625, 51626 (1996).

<sup>85</sup> *Id.*

The greatest difficulty is that the FDA has interpreted the marketing requirements of section 201 (p) (i.e., used to a material extent and for a material time) to mean marketing in the United States.<sup>86</sup> Although foreign marketing data has been utilized as additional information by the FDA, the agency takes the position that the marketing of an OTC drug in a foreign country, but never the United States, does not satisfy [the marketing requirements].<sup>87</sup>

This strict policy unnecessarily delays the use of many potential sunscreen ingredients and prevents manufacturers from developing more comprehensive sunscreen products. For example, the policy was a significant issue in the attempted promotion of Parsol 1789 (avobenzone) as an active sunscreen ingredient. Parsol 1789 was finally approved for certain conditions in the TFM for OTC Sunscreen Drug Product.<sup>88</sup> This occurred only after there was sufficient U.S. marketing data from two avobenzone containing products, Schering-Plough's Shade UVAGuard and Herbert's Photoplex, which had received NDA approval.<sup>89</sup> However, because manufacturers will not sustain the costs of the NDA process for all potential sunscreen ingredients, many potential sunscreen ingredients (for which there is only foreign market data to demonstrate their safety and effectiveness) are not included in the TFM for OTC Sunscreen Drug Products and will remain out of sunscreen drug products.

Recently, the FDA gave an advance notice of proposed rulemaking to amend its regulations and accept foreign marketing data alone as sufficient for consideration of additional conditions (i.e., active ingredients, indications, dosage form, dosage strength, route of administration, active ingredient combination, or any combination of these conditions) in the OTC drug monograph system.<sup>90</sup>

The FDA is focusing on three basic issues: the nature of the marketing or use, the amount of marketing

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<sup>86</sup> 61 Fed. Reg. 51625, 51626 (1996).

<sup>87</sup> Id. at 51627.

<sup>88</sup> 61 Fed. Reg. 48645 (1996).

<sup>89</sup> Id., at 48646.

<sup>90</sup> 61 Fed. Reg. 51625, 51627 (1996).

time, and the extent of distribution and use in marketing. The first issue inquires which countries should be accepted, what type of adverse effect reporting system should be required, and the type of drug administration which should be considered (i.e., whether the product was marketed by prescription, through pharmacists, OTC, etc).<sup>91</sup> The second issue questions what amount of marketing time qualifies as material time. The FDA is proposing a minimum of five years of marketing.<sup>92</sup> The final issue questions what extent of distribution and use qualifies as for a material extent.<sup>93</sup>

Overall, in reevaluating the value of foreign marketing data as an exclusive source of approval for additional drug conditions in the OTC drug monograph system, it appears that the FDA is mostly concerned with safety risks. It wants data sufficient for confirming the safeness of a potential OTC drug condition. The establishment of new eligibility criteria will have a tremendous impact on the production of sunscreens, and the sooner the FDA resolves these issues, the sooner more comprehensive sunscreen products will become available to American consumers.

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<sup>91</sup> *Id.*

<sup>92</sup> *Id.*, at 51629.

<sup>93</sup> *Id.*