COMMENTS SUBMITTED BY

Advance Notice of Proposed Rulemaking: Sunscreen Drug Products for Over-the-Counter Human Use; Request for Data and Information Regarding Dosage Forms

Docket No. FDA–1978–N–0018, formerly Docket No. 1978N–0038

October 17, 2011

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Advance Notice of Proposed Rulemaking: Sunscreen Drug Products for Over-the-Counter Human Use; Request for Data and Information Regarding Dosage Forms; Docket No. FDA–1978–N–0018; formerly Docket No. 1978N–0038

The Personal Care Products Council (the Council) and the Consumer Healthcare Products Association (CHPA) are pleased to provide these comments in response to the Food and Drug Administration's (FDA) Advance Notice of Proposed Rulemaking on Sunscreen Drug Products for Over-the-Counter Human Use; Request for Data and Information Regarding Dosage Forms; Docket No. FDA–1978–N–0018, formerly Docket No. 1978N–0038; 76 Fed. Reg. 117 (June 17, 2011) (ANPR).

Based in Washington, D.C., the Council (formerly the Cosmetic, Toiletry and Fragrance Association) is the leading national trade association for the cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the U.S. As makers of a diverse range of products that millions of consumers rely on every day, from sunscreens, toothpaste and shampoo, to moisturizer, lipstick and fragrance, personal care products companies are global leaders committed to product safety, quality and innovation.

CHPA is the 130-year-old-trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements.

The following comments address FDA's request for: 1) data and information on sunscreen spray dosage forms to confirm their eligibility for inclusion in the final sunscreen monograph; and 2) data and information supporting the inclusion of powder sunscreens in the final monograph.

I. Spray Sunscreens

FDA requested data and information on sunscreen spray dosage forms to confirm their eligibility for inclusion in the final monograph. Sunscreen sprays are an important dosage form option for consumers and a safe and effective alternative to other sunscreen forms. In particular, because of their convenience and ease of use, spray products encourage application and reapplication.

The key measures of efficacy for all sunscreen products are the strength of protection (measured by the SPF test), and the breadth of protection (measured by the critical wavelength test). We believe that the data provided within this document strongly supports the standardization of SPF and broad spectrum testing across all dosage forms including sprays.

Regarding safety associated with unintentional inhalation, we are providing particle size data as requested for a variety of spray sunscreen products. The information provided in this document shows that spray products are well within industry standards for safe particle size when dispensed from their respective packages. Based on these data, additional toxicity studies are not warranted.

We support the Agency's efforts to build on existing label directions to help ensure proper usage of sunscreen sprays, as well as in any other dosage form. We urge the Agency to reconfirm sunscreen sprays, which have been marketed for over 50 years, as eligible sunscreen dosage forms.

A. Overview of Spray Sunscreen Packaging Configurations

Sunscreens are delivered in a variety of forms to provide a range of options designed to make sun protection a pleasant and convenient experience for consumers, thus encouraging application and reapplication. Sunscreen sprays consist of multiple components including the sunscreen formulation, valve, actuator, and sometimes a propellant. Spray products come in a variety of dispensing systems: pump sprays, true aerosol sprays, and bag-on-valve sprays. Inside these dispensing systems may be one of

several different formula types: clear (alcohol) sprays, liquids, lotions, or oils. Throughout these comments, any reference to "sprays" includes the various spray configurations, unless noted otherwise

Sunscreen mousses/foams should not be considered as a different dosage form. Mousses are simply aerated emulsions (lotions) and have a formed, semi-solid shape, even if they are dispensed from an aerosol can. Therefore, these "dosage forms" should be considered to be lotions and not sprays. For this reason, these comments do not address mousses/foams.

There are a number of reasons for the appeal of spray sunscreens, including:

- Ability to reach hard to reach places when applying sunscreens without assistance;
- Convenience of reapplication;
- Excellent consumer acceptance, especially for children, and for active adults, especially men.

1. SPF Efficacy and Broad Spectrum Performance Testing

The Agency has asked if the SPF and Broad Spectrum tests should be modified to address sunscreens delivered as a spray. For the reasons below, we believe it is not necessary to modify either test to address sprays; instead, both testing methodologies can and should remain standardized and apply to all eligible sunscreen dosage forms including sprays.

a) SPF Testing

Spray sunscreens were first introduced to the market well before the original Advisory Panel meetings, adding to the sunscreen benefit provided by lotions, gels and creams. When testing for SPF, a consistent factor has been that every sunscreen formulation can be delivered to the test site by weight, and then spread over the test site evenly, regardless of the form or final package delivery configuration. This application by weight (2 mg/cm^2) enables all products to be compared based on the same methodology.

The SPF test method used to evaluate lotion sunscreens as defined in the Final Rule is equally appropriate for quantifying the efficacy of sunscreens that are dispensed in spray form. For the same reason that FDA has prescribed an exact weight of lotion product to be applied to a specified surface area ($2mg/cm^2$), regardless of the amount a consumer might apply in typical use, a measured weight or volume of the spray sunscreen concentrate should also be applied neat to provide a reproducible, quantitative value for labeling SPF.

With a pump spray, the formulation delivered from these packages directly to the skin is the sunscreen formulation, containing no propellant. The formulation delivered directly to the skin from the package is identical to the formulation that is tested for SPF. Similarly, clear liquid and lotion spray products can also be tested without changing the standard SPF method. As new formulas are developed, the liquid form is tested for SPF during the early part of the product development cycle by applying the product to the test site by weight and evenly spreading the product over the test site. At the time in the project when SPF testing is conducted to confirm the efficacy, the product is generally not available in a spray can (the final package or package type may not even be fully identified at that time).

The standard SPF method can be used for all sunscreen dosage forms regardless of how it is packaged, whether ultimately packaged in spray or non-spray packages. Indeed, it is possible that the same liquid, oil or lotion used in an aerosol or pump spray package could also be used in a non-spray form (for example, in a squeeze bottle or in a traditional lotion pump package similar to a hand-lotion).

On a related point regarding consumer use, the Agency has also asked how the protection provided by spray products in consumer use compares to the SPF determined in the laboratory. SPF testing is not conducted on consumer use application levels because each consumer may use each product type differently. Like other non-dosage limited topical OTC products (for example, fluoride toothpaste or dandruff shampoo), there is no agreed upon "consumer use amount" for any product dosage form due to the nature of the products and their wide margin of safety associated with their use. Thus,

the amount of product used is very much a personal choice based on individual needs, preferences and experiences. Consumers have been taught through experience, education by physicians, the media and Public Service Announcements how to use each form of sunscreen in a way that works for them to prevent sunburn and to that end they may use different amounts on different body parts (e.g. legs vs. arms vs. face). Sunscreen products should be tested in an identical manner so that consumers can choose the SPF level that they know from experience works well for them when used as they would normally apply it. Changing the test method based on product form (and thus the related SPF) would result in labeling that would be extremely confusing for consumers.

In summary, we believe that the standard SPF methodology (i.e., in which the test material is weighed and applied evenly across the test site at 2 mg/cm2) is not dependent of product form and therefore, can and should be used for the testing of all sunscreen product forms. This is critical to ensuring that all products can be compared based on standard measures of performance. In addition, it is important to note that the efficacy testing requirements of the EU, ASEAN, MERCOSUR and ISO use a standard testing method across all sunscreen forms (including sprays and powders) for both *in vivo* or *in vitro* sunscreen efficacy testing and do not differentiate testing based on dosage form or consumer habits.

b) Broad Spectrum Testing

Similar to SPF testing, there is no need to modify the Broad Spectrum test method for spray products. The Broad Spectrum test is a standardized method based on measurement of Critical Wavelength. In this test, like the SPF test, it is important to apply a defined amount of formulation to a standard area of the substrate to appropriately measure the Critical Wavelength of a formula, whether it is a lotion, liquid, oil, stick, or spray.

The standardized test is performed on PMMA plates using a method defined by the Agency (Final Rule, Fed. Reg. 76; no. 117, June 17, 2011) in terms of size of application area, density of product application, appropriate technique to achieve even

distribution of product across the surface of the PMMA plate and instrumental specifications to obtain accurate and reproducible readings. The defined application density is delivered to the surface of the plate by weight and then spread evenly across the plate surface. This method of using a defined weight takes into account differences in densities between products and standardizes the method for all dosage forms. An even distribution of the sample across the plate is critical to obtaining accurate data. Thus, the test method as currently defined by the Agency to measure Critical Wavelength should be considered independent of dosage form and is therefore suitable for sprays for the same reasons outlined above for SPF testing.

B. Safety of Spray Sunscreens

For many years, the safety of spray products in particular has been substantiated on the basis of respirability. Respirable particles are those that are able to reach the deep lung - the respiratory bronchioles and alveoli. The critical piece of data in the support of safe use is the particle size distribution (aerodynamic equivalent diameter; AED) of the dispensed spray.

An AED of between 5-10 μm is generally recognized as the value below which particles may be respirable. For example, the International Agency for Research on Cancer (IARC) has defined the respirable fraction as "that fraction of an aerosol with an aerodynamic diameter suitable for penetration into the alveoli/gas exchange region of the lung (typically <10 μm).[1] Other authoritative sources concur with the 10 μm value.[2] Still others, however, have identified 5 μm as the size below which particles may be respired.[3] While it is accepted that particles less than 100 μm may be inhaled, the primary

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[1] IARC Monographs on the Evaluation of Carcinogenic Risks to Human. (1996) Volume 65, pp. 171-172.

[2] American Conference of Governmental Industrial Hygienists (ACGIH) 1993. Threshold limit values for chemical substances and physical agents. ACGIH, Cincinnati, Ohio; U.S. Environmental Protection Agency. PM10 NAAQS Implementation. http://www.epa.gov/ttn/naaqs/pm/pm10_index.html (accessed October 2011).

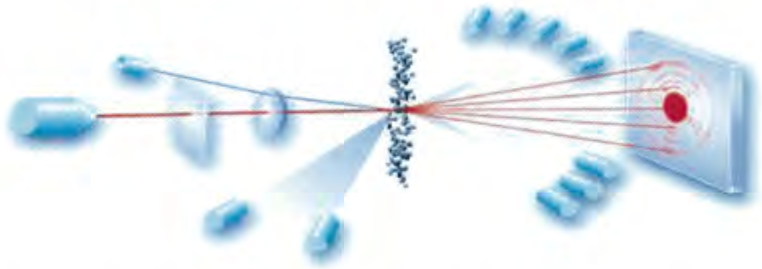
[3] Witschi, H.R. et al. Toxic Responses of the Respiratory System, in Casarett and Doull's Toxicology: The Basic Science of Poisons, C.D. Klaassen, Editor. 2008. McGraw-Hill. New York. p. 609-630; Valentine, R. and Kennedy, G.L. Jr. Inhalation Toxicology, in Principles and Methods of Toxicology, W. W. Hayes, Editor. 2001. Taylor & Francis, Philadelphia, p. 1085 - 1143.

point of contact and residence for particles greater than 5-10 μm would be the nasopharyngeal region and such particles would not penetrate into the deep lung.

In current industry practice, the majority of particles in a product are greater than 10 μm in diameter in order to mitigate inhalation concerns. There are other FDA-regulated products that make similar assumptions with respect to particle sizes in the formulation. For example, the Tentative and Final Monographs on Antiperspirants have recommended that aerosol systems be formulated "so that not less than 90% of emitted particles are greater than 10 μm in diameter."[4]

1. *Determination of Particle Size*

For the spray particle size distributions shown in the histograms attached in Appendices 1-A, 1-B, and 1-C, the method used entails the use of laser diffraction that employs the refractive index (light scatter) of the airborne particulates of the formulation as delivered from its package.



Pictoral of laser diffraction (courtesy of Malvern instruments)

The particle size of spray products is collected using a Malvern Spray Tech Particle Size Analyzer.

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[4] Federal Register. 43: 46694-46732, October 10, 1978, Antiperspirant drug products for over-the-counter human use, establishment of a proposed rule monograph; Federal Register. 47: 36492-36505, August 20, 1982, Antiperspirant drug products for over-the-counter human use, tentative final monograph; Federal Register. 68: 34273-34293, June 9, 2003, Antiperspirant drug products for over-the-counter human use, final monograph.

The data in the histograms are presented in chart form along with specific distribution values. *See* Appendices 1-A, 1-B, and 1-C. The following descriptions should be used when interpreting the specific distribution.

DV(50) = Represents the median value of the distribution, i.e., 50 percent of the particles are smaller than this value.

DV(90) = Represents the particle size at which 90 percent of the particles are smaller than this value.

DV(10) = Represents the particle size at which 10 percent of the particles are smaller than this value.

In all cases, there are small tails in the distribution curves below 10 microns. As these constitute a minimal portion of the particle size distribution, no additional inhalation toxicology studies are considered warranted. The data in the histograms demonstrate that the great majority of airborne formulation sprays, if inhaled, would be deposited in the upper respiratory tract where mucociliary clearance would remove them. The material so removed would be ingested rather than respired. Note: there are no nano-scale metal oxide sunscreen actives used in these formulations.

2. Consumer Safety

The instructions for safe use of spray products are reflected in the product labels of all manufacturers. The product labels communicate directions to the consumer, such as:

- ensure complete and even coverage
- apply "liberally" or "generously", and
- use in "well-ventilated areas"

In summary, the airborne particle size analyses of these spray products (in all cases, > 90% are above 10 um) do not increase the likelihood of deep respiratory exposure and therefore are not of increased safety risk. There is not an inhalation hazard to the consumer when these products are used as directed.

3. *Comments on FDA Proposed Labeling for Spray Sunscreens*

FDA is proposing that the following warning and directions be required for sunscreen spray products.

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

Directions

- 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
- spray [liberally or generously] and spread evenly by hand 15 minutes before sun exposure

With the exception of requiring that the products be "spread evenly by hand" and sprayed on "15 minutes before sun exposure", we support these proposed labeling requirements for sunscreen spray products.

a) Spread evenly by hand

A modified version of the 2011 FDA SPF test method in which the test product is sprayed onto the subject's skin instead of being spread with a finger cot as specified in the method. To measure the effects of rubbing the product into the skin, a second modified FDA SPF test was used in which product was sprayed on and then immediately rubbed into subject's test site. Both modifications were performed side-by-side using a 10 subject panel. *See* Appendix 2.

Table 1 shows a summary of SPF testing done using two modified FDA SPF methods – one a spray-on and rub-in method, the second a spray-on and no rub-in method.

	Clear Spray		Lotion Spray	
	spray on/rub in	spray on/no rub	spray on/rub in	spray on/no rub
Mean SPF	50.20	49.45	51.15	49.65
n	10	10	10	10
SD	4.67	3.91	6.97	6.11
t * SE	2.71	2.27	4.04	3.54
SPF	47	47	47	46

Table 1

Using a paired t-test and a 95% confidence interval ($\alpha = 0.05$), the Mean SPF values achieved using the spray-on and rub-in method are not statistically different from the Mean SPF values achieved using the spray-on and no rub-in method. For these very water-resistant formulations, each of these tests incorporated an 80 minute water immersion step prior to any UV irradiation, in accordance with the 2011 Final Rule.

In addition to the two spray-on methods used in the above test, a third test site was used in which the SPF was conducted as set forth by FDA in the 2011 Final Rule. On this site, the same test products were used but instead of a spray-on application, the products were pipetted on and rubbed in. Results are tabulated in Table 2 below.

	FDA VWR SPF	
	Clear Spray	Lotion Spray
Mean SPF	49.65	48.15
n	10	10
SD	6.11	4.61
t * SE	3.54	2.67
SPF	46	45

Table 2

According to the same paired t-test evaluation ($\alpha = 0.05$), Mean SPF values achieved using the spray-on method and the Mean SPF values achieved using the spray-on and rub in method are not statistically different from the Mean SPF values achieved using the 2011 FDA method for SPF testing. The 2011 FDA SPF test also incorporated an 80 minute water immersion step prior to any UV irradiation, in accordance with the Final Rule.

The results provide evidence that when spraying a sun protection product onto skin and then rubbing it in, there is no change in comparison to a spray-on application with no rub-in. Further, spraying product onto skin and rubbing it in produces no change in effectiveness when compared to the SPF test as set forth in FDA's Final Rule. Therefore, we believe that the modified directions for sprays indicating that the product should be rubbed in are not warranted. These data also illustrate that the standard SPF testing method is appropriate for measuring the SPFs of spray products.

With the exception of the above, we do agree that FDA's proposed warning and directions for use for sprays will help to ensure that consumers understand how to use the products safely and effectively. The Agency should be aware, however, that one standard instruction may not be consistent with consumer behavior for every type of spray or, indeed, for other dosage forms (for example sticks) that already leave a uniform consistent layer on the skin surface without further spreading. Therefore we recommend that the instruction to "spread by hand" be optional:

- spray [liberally or generously] [optional: and spread evenly by hand] ~~15 minutes~~ before sun exposure

b) Apply 15 minutes before sun exposure

In our recent comments to the Agency on the Draft Guidance for Industry on the Enforcement Policy, we strongly recommended for all sunscreen product dosage forms that FDA remove the required direction to "apply 15 minutes before sun exposure".

Sunscreens are composed of active ingredient molecules that absorb, reflect and/or scatter UV rays. When applied to the skin surface, the active ingredients in the sunscreen begin to protect against UV rays penetrating through the sunscreen film by absorbing UV energy. The active ingredients work to prevent sunburn immediately when applied. They do not need to wait 15 minutes in order to function as a sunscreen. For example, when applying a lip balm with sunscreen, the product acts as a sunscreen when applied to the lips. Similarly, lotion, oil or other product type sunscreens also protect against UV when applied. There is no need to wait to obtain the sun protection benefits of such products.

Products that are water resistant also begin to function as a sunscreen immediately when applied on the skin. Because of the polymer content of most of today's water resistant sunscreens, many of these products are also water resistant right after application. However, it is the manufacturer's responsibility to determine if there is a necessity to wait before the product can be immersed in water. There is no reason for sunscreens (water resistant or not) to require a waiting period before they are "active"

sunscreens; the function of blocking UV rays is independent of the need to wait before water immersion.

Merely because the SPF testing protocol specifies that there be a waiting period after application (meant to standardize the testing conditions for all products) does not mean that there needs to be a waiting period before the sunscreen becomes "active" in consumer use. It is well recognized that many consumers apply their product at the beach or pool, and they expect that the product will work when applied. To require a 15-minute waiting period when there is no scientific rationale for such a wait period is not only confusing, but it is also unsupportable from a technical perspective.

In summary, as discussed above, with the exception of requiring that the products be "spread evenly by hand" and sprayed on "15 minutes before sun exposure", we support these proposed labeling requirements for sunscreen spray products.

B. Public Policy Supports Spray Sunscreens

In recent months, there has been a growing debate regarding childcare providers (camp counselors, teachers, etc.) applying sunscreen to children. For example, on June 10, 2011, Maryland health officials published Guidelines encouraging children to apply their own sunscreen and limiting direct sunscreen application by camp counselors and other children in an attempt to address potential issues of inappropriate touching.[5] *See* Appendix 3. This Guideline was later revised to not address the issue of touching; however, the issue of touching as related to sunscreen application continues nationwide. As schools and childcare providers balance issues of liability with the health and wellbeing of the children under their care, we believe the availability of spray sunscreens is critically important and would ask the Agency to adopt appropriate labeling requirements for spray sunscreen products to ensure their continued use.

[5] Available at: http://www.washingtonpost.com/r/2010-2019/WashingtonPost/2011/07/02/Local-Enterprise/Graphics/mdsunscreenpolicy07012011.pdf

II. Powder Sunscreens

Powder sunscreens, mainly available for facial application, are an important tool in the public's daily fight against the dangers of the sun. For many, in particular women, face powders and lip products containing SPF provide a form of sunscreen that can be habitually used on a daily basis and readily reapplied throughout the day. Additionally, FDA's stated basis for excluding powders from the sunscreen monograph – that they were not marketed prior to May 1972 – is incorrect. Powder sunscreens were marketed in the U.S. prior to 1972 (see below).

A. Powder Sunscreens' Safety and Efficacy

The powder form can meet the performance criteria of a sunscreen both in terms of sunburn protection (SPF) and in UVA efficacy, as confirmed by both PFA and in the ability to meet current Critical Wavelength (> 370 nm) requirements. Data illustrating the ability of powders to provide sun protection using standard testing methods are provided in Appendices 4-A (SPF) and 4-B (UVA).

Regarding safety, powders are tested in standardized tests such as the repeated insult patch test (RIPT) and phototoxicity; several examples of such testing are included in this document. Also provided is an example of the safety assessment to support a powder sunscreen formulation for global use via the EU Cosmetic Safety Report evaluation. We find no safety issues surrounding the use of powder sunscreens. See Appendix 5.

Therefore, we believe powder sunscreens meet the conditions for general recognition of safety and effectiveness that are established in the monograph.

As indicated in the ANPR, we understand that, at this time, FDA does not believe powders are an eligible dosage form for inclusion in the sunscreen monograph. We urge that the Agency reconsider this position. Furthermore, as described below, we believe FDA should not prevent powder sunscreens from remaining on the market.

A. Powder Sunscreens Were Marketed in the United States Prior to 1972 and Have Historically Been Understood to Be Covered by the Sunscreen Rulemaking

Unless the monograph explicitly limits dosage forms, any safe and suitable dosage form is permissible. In this case, the sunscreen monograph does not state what dosage forms are or are not included. In fact, historically, FDA has explicitly included all cosmetic sunscreen products within the monograph.

The dosage form of a product is largely a factor of its inactive ingredients. The regulations explicitly state that inactive ingredients are permissible so long as they "...are safe in the amounts administered and do not interfere with the effectiveness of the preparation or with suitable tests or assays to determine if the products meets its professed standards ...." 21 C.F.R. sec. 330.1(e).

In addition, in the ANPR FDA stated that powders were not eligible for review under the sunscreen monograph because the agency lacked evidence that such products existed in the OTC marketplace on or before May 1972. However, we have identified several powder products intended for use as sunscreens marketed prior to May 1972. Powder dosage forms were reviewed by the Advisory Panel as part of its review of sunscreens, indicating that powder sunscreens have long been available and considered effective. Furthermore, FDA has never before excluded powders from the sunscreen rulemaking, despite its knowledge of marketed sunscreen powders (in particular makeup powders).

1. Powder dosage forms were marketed prior to the beginning of the OTC Drug Review in 1972.

At least four products were advertised from 1898 to 1920 as preventing sunburn, two of which contained zinc oxide, a monograph active ingredient.[6] In addition, reference texts identifying products on the market prior to 1972 reference these powder sunscreen products and list titanium dioxide, another monograph active ingredient,[7] as

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[6] 21 C.F.R. § 352.10(r) (stayed).

[7] 21 C.F.R. § 352.10(p) (stayed).

being used in powders. Therefore there is ample evidence that powder sunscreens were marketed prior to the beginning of the drug review in 1972, and that powder sunscreens are properly included in the monograph.[8]

Advertisements for Lablache Face Powder, a tinted powder that "prevents and cures sunburn," were published in at least five magazines in the United States from 1898 to 1906. One advertisement claimed that "Lablache Face Powder not only cures sunburn ..., but it prevents such disagreeable conditions if applied before exposure to the sun." *See* Appendix 6-A. Similarly, Nadine Face Powder, a tinted powder that "prevents sunburn" was advertised in at least twelve United States magazines and newspapers from 1911 to 1920. *See* Appendix 6-B. According to Harvey W. Wiley's 1916 publication *1001 Tests of Foods, Beverages and Toilet Accessories, Goods and Otherwise* (Wiley), both products contained zinc oxide among other ingredients. *See* Appendix 7-A. The Pharmaceutical Record of 1982 also lists Lablache Face Powder as containing, among other ingredients, zinc oxide. *See* Appendix 7-B.

Mennan's Borated Talcum Toilet Powder was advertised in at least nine United States magazines in 1908. The advertisements claimed that "When used daily, Mennen's keeps the skin smooth and healthy, relieves and prevents Sunburn, ... and all skin troubles of summer. Makes possible the attractive, evenly browned complexion without burning." *See* Appendix 6-C. Wiley lists Mennan's Borated Talcum Toilet Powder as containing talc and boric acid, among other ingredients.

Advertisements for Nysis Talcum were published in at least two United States magazines in 1920. The advertisements claim that Nysis Talcum "produc[es] a scarcely

[8] In the ANPR, FDA states, "To determine eligibility for the OTC Drug Review, we must have actual product labeling or a facsimile of labeling that documents the conditions of marketing of the product prior to May 1972 (21 CFR 330.10(a)(2))." 76 Fed. Reg. at 35671. However, the regulation FDA cited sets forth procedures and a preferred format for submitting data in response to a request for information to be reviewed by an advisory panel. Neither this nor any other regulation requires the submission of labeling to support a determination made after the publication of a proposed monograph that a dosage form is covered by that monograph.

visible veil against the light-rays which, acting upon the inner, or true skin, cause sunburn." *See* Appendix 6-D.

Similarly, powder sunscreens were recognized in reference texts prior to 1972. *Cosmetics and Dermatitis*, by Drs. Schwartz and Peck, published in 1946 (Schwartz & Peck),[9] describes a variety of sunscreen preparations, including powders:

> Heavily pigmented preparations (liquids, creams, or powders) will prevent or reduce the passage of the ultraviolet radiation, i.e., cast a shadow upon the portion of the skin to which they are applied. Of course, while preventing sunburn, such preparations will prevent also suntan. Zinc oxide, calamine, and titanium dioxide are most effective in this regard. ...
>
> Powders to prevent sunburn can be prepared by mixing zinc or titanium oxides with magnesium or zinc stearates. The stearates cause the titanium oxide to adhere better to the skin.
>
> Magnesium oxide and precipitated chalk may also be used as extenders for sunburn-preventive powders.

See Appendix 8-A. The 1973 *United States Dispensatory*,[10] a reference describing drugs found in the scientific literature prior to 1973, includes titanium dioxide. The drug is described as an "amorphous powder" that "is used as a protective against sunburn, usually ... in ointments or lotions ... [and] is used also in other protective preparations, and in dusting powders and face powders." *See* Appendix 8-B.

2. ***Powder dosage forms were historically treated by FDA as included in the monograph.***

Sunscreen powders were first addressed by the Advisory Panel in 1978, which recognized the existence of powder dosage forms on the market at that time. Throughout 30 years of rulemaking, FDA has never suggested that powders are not eligible for inclusion in the monograph. The ANPR marked the first time FDA stated explicitly

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[9] Schwartz, L. and S. M. Peck, Cosmetics and Dermatitis 142-46 (Paul B. Hoeber, Inc. 1946)

[10] The United States Dispensatory 1198 (A. Osol and R. Pratt eds., J. B. Lippincott and Co., 1973).

which dosage forms of sunscreen products the agency considered eligible for inclusion in the sunscreen monograph.

On the contrary, FDA has explicitly included all cosmetic and makeup preparations containing sunscreen, which have long included powder formulations. Since 1993, FDA has clearly and explicitly regulated *all* cosmetic sunscreen products, including makeup products, as drugs under the sunscreen monograph. FDA's regulations elsewhere define "make-up preparations (non-eye)" to include "face powders."[11] This definition predates the 1978 panel recommendation and subsequent sunscreen rulemaking.[12] FDA itself referred to this definition of make-up preparations in the preamble to its 2007 proposed rule as defining all makeup products to which the sunscreen monograph applied.[13]

Therefore, FDA was aware of marketed powder sunscreens throughout the 30-year sunscreen rulemaking and has historically and correctly treated powder dosage forms as included in the sunscreen monograph. There is no basis for newly reaching the conclusion that powder dosage forms are not eligible for inclusion in the monograph, as indicated in the ANPR.

FDA first addressed sunscreen products in August 1978, when it issued an advanced notice of proposed rulemaking that included recommendations from an Advisory Panel on the safe and effective use of sunscreen products.[14] The Advisory Panel reviewed effectiveness data on titanium dioxide in powder form. Quoting the texts referenced above, Schwartz & Peck and the *United States Dispensatory*, the Panel stated:

> [Titanium dioxide] is used in ointments and lotions at a concentration of 15 to 25 percent as a protective against

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[11] 21 C.F.R. § 720.4(c)(7) (regarding voluntary cosmetic listing).

[12] 39 Fed. Reg. 10060 (Mar. 15, 1974).

[13] Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph; Proposed Rule, 72 Fed. Reg. 49070, 49077 (Aug. 27, 2007) (to be codified at 21 C.F.R. part 352).

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

> sunburn. It is also used in other protective preparations and in dusting powders and face powders. ...
>
> Schwartz and Peck reported that [h]eavily pigmented preparations (liquids, creams or powders) will prevent or reduce the passage of the UV radiation .... Zinc oxide, calamine, and titanium dioxide are most effective in this regard.[15]

The panel concluded based on this and other information that titanium dioxide is an effective sunscreen ingredient for OTC use. The panel also discussed the application of test materials formulated as oils, lotions, creams, heavy gels, butters, pastes, and ointments, but did not recommend classifying any specific dosage forms as safe and effective.[16] Thus in 1978 the advisory panel and FDA were aware of powder dosage forms that were effective for their intended use as sunscreens.

Throughout the remainder of the sunscreen monograph rulemaking, FDA never indicated that powders are not included, and explicitly included all cosmetic sunscreens which included powder products. Furthermore, when identifying "new" dosage forms in 2007, FDA did not identify powders.

In May 1993, FDA published a tentative final monograph for sunscreen products.[17] The tentative final monograph did not discuss which dosage forms were considered to be safe and effective generally, nor did it discuss powders specifically. However, the proposed rule permitted additional directions "applicable to a particular product (e.g. cream, gel, lotion, oil, spray, etc.)."[18] The preamble noted that the proposed rule "provide[s] that manufacturers can voluntarily expand and supplement these required directions with more detailed instructions applicable to a particular product formulation and dosage form."[19] In specifying the application of test materials when testing a

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[15] *Id.* at 38251.

[16] 43 Fed. Reg. at 38266.

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

[18] *Id.* at 28297.

[19] *Id.* at 28244.

product's SPF value, the tentative final monograph referred to oils, lotions, creams, heavy gels, butters, pastes, and ointments.[20] With regards to the effect of a dosage form on the testing requirements, FDA noted:

> [T]he influence of the vehicle on the effectiveness of a sunscreen drug product is accounted for in the SPF testing procedure because the test is done on the final formulation of a sunscreen product. ... Any product that can demonstrate that it meets the labeled SPF value is considered to be effective.[21]

In the preamble to the tentative final monograph, FDA recognized that cosmetic products containing the term sunscreen, or a similar term, "SPF," and SPF value or other terms referring to the therapeutic attributes of sunscreen ingredients were considered drugs regulated by the monograph.[22] FDA implemented this policy by proposing to amend 21 C.F.R. part 700, "Requirements for Specific Cosmetic Products," to add a new regulation, 21 C.F.R. § 700.35, specifying that cosmetics containing a sunscreen active ingredient and using the term sunscreen or other sunscreen claims in its labeling are drugs subject to the monograph.[23] The proposed regulation referred simply to "cosmetics" generally, and did not limit its application or exclude any type of cosmetic.

In May 1999, FDA published a final rule for sunscreen products establishing the sunscreen monograph, 21 C.F.R. part 352.[24] The final monograph did not discuss which dosage forms were included in the monograph. However, the final monograph retained additional directions "applicable to a particular product formulation (e.g., cream, gel, lotion, oil, spray, etc.),"[25] and referred to oils, lotions, creams, heavy gels, butters, pastes and ointments in specifying the application of test materials when testing a product's SPF

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[20] *Id.* at 28300.

[21] *Id.* at 28215.

[22] 58 Fed. Reg. at 28205.

[23] 58 Fed. Reg. at 28301.

[24] Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph, 64 Fed. Reg. 27666 (May 21, 1999) (to be codified at 21 C.F.R. parts 310, 352, 700 and 740).

[25] *Id.* at 27688

value.[26] The final monograph also retained 21 C.F.R. § 700.35 specifying that cosmetics containing sunscreen ingredients and including the term sunscreen or other sunscreen claims are subject to regulation as a drug, except those qualified by describing the cosmetic benefit provided by the sunscreen ingredient.[27] FDA specifically noted that "the agency gave careful consideration to the wide variety of products marketed for sunscreen uses."[28]

In August 2007, FDA issued a proposed rule amending the monograph.[29] FDA again permitted sunscreen labeling to include "more detailed directions applicable to a particular product formulation (e.g., cream, gel, lotion, oil, spray, etc.)."[30] With regard to the application of test materials, FDA noted:

> FDA is also aware of sunscreen drug products marketed in dosage forms that may not be addressed by current SPF testing procedures. The SPF testing procedure described in § 352.72 (proposed § 352.70) references oils, lotions, creams, gels, butters, pastes, and ointments. FDA invites interested parties to submit SPF testing modifications for new dosage forms (e.g., mousses, foams, and towelettes) in accordance with § 352.77.[31]

The test application rule itself was revised such that it no longer referred to any specific dosage form.[32] The proposed amendments provided no further guidance as to which dosage forms FDA considered covered by the monograph. The proposed amendments did not revise 21 C.F.R. § 700.35, which specified that all cosmetic products containing a sunscreen ingredient and making a sunscreen or SPF labeling claim are regulated as drugs under the monograph.

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[26] *Id.* at 27691

[27] *Id.* at 27693

[28] *Id.* at 27673.

[29] 72 Fed. Reg. 49070.

[30] *Id.* at 49113.

[31] *Id.* at 49094.

[32] *Id.* at 49120.

In the 2011 final labeling rule, FDA removed the referenced dosage forms from the directions, such that the rule states simply "more detailed directions applicable to a particular product formulation may also be included."[33] In addition, the testing procedures do not refer to any specific dosage forms.[34]

Thus throughout the history and in its current form, the monograph's labeling and testing requirements do not distinguish among dosage forms. The definition of sunscreen does not specify a dosage form and the monograph requires only that a sunscreen must be "in a form suitable for topical administration."[35] It does not define a "suitable" form but recognizes that finished dosage forms may vary. Nor do the required directions for use distinguish among dosage forms.

Additionally, the monograph and final labeling rule do not distinguish among dosage forms in terms of effectiveness; they permit any topical dosage form that meets the effectiveness testing requirements. Because powder sunscreens meet the testing requirements specified by FDA, as discussed in section II.A, *supra*, powder sunscreens comply with the terms of the monograph and the 2011 labeling rule. In all material respects, powders are like the dosage forms deemed included in the monograph in the ANPR, lotions, creams, pastes, among others, because they are rubbed onto the skin, adhere to the skin's surface for a period of time, and are effective at reducing skin's exposure to UVA and UVB radiation. They are particularly similar to water-based lotions and pastes, which can have the characteristics of powders after the water vehicle evaporates.

Furthermore, powders have been an internationally recognized sunscreen dosage form for many years. The 1999 JCIA (Japan Cosmetic Industry Association) Standard SPF Method describes two alternative methods for the applications of powders to the test

[33] 21 C.F.R. § 201.327(e).

[34] 21 C.F.R. § 201.327(i).

[35] 21 CFR 352.1(a) (stayed).

site to ensure that the powder is retained on the skin.[36] Both the 2003 and 2006 (updated) International Sun Protection Factor (SPF) Test Methods recognize powders as a valid sunscreen dosage form and specifically outline the parameters for their proper application prior to UV exposures.[37]

Therefore, FDA has never previously excluded powders from the sunscreen monograph despite the fact that manufacturers have marketed safe and effective powder sunscreens throughout the rulemaking, a fact known and recognized by FDA. Manufacturers have justifiably relied on this history to conclude that sunscreens are covered by the monograph. The ANPR marks the first instance in which FDA had indicated it does not believe powders to be included in the monograph. We believe this to be an incorrect conclusion, and as discussed below, a conclusion contrary to the public health.

C. Powder Sunscreens are an Important Source of UV Radiation Protection

Excluding powder sunscreens from the sunscreen monograph would force manufacturers to remove these products from the market, depriving consumers of a vital source of daily protection from sun exposure. Powder sunscreens have been used safely and effectively by consumers for many years and are a preferred sunscreen option for many consumers. Removing these products from the market would be detrimental to public health.

FDA has recognized that many consumers use facial makeup products with sunscreen "as their primary and only source of sunscreen protection for that area of the body."[38] FDA also recognizes that these products are important in addressing consumers' need for sunscreen for frequent incidental sun exposure as contrasted with

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[36] Japan Cosmetic Industry Association, 1999. JCIA Standard SPF Test Method (Revised). Effective date: 1/1/2000.

[37] International Sun Protection (SPF) Test Method, CCTFA, CTFA, JCIA, COLIPA (2006), page 13.

[38] 72 Fed. Reg. at 49091.

intentional exposure such as sunbathing.[39] These separate uses were originally recognized in the preamble to the 1993 tentative final monograph, in which FDA noted distinct categories of sunscreen products: "(1) beach products for occasional use to protect consumers from extreme sunlight conditions, (2) tanning products to aid consumers in acquiring a tan, and (3) non-beach products for daily use to protect consumers from chronic exposures to sunlight (e.g. make-up preparations and lipsticks)."[40]

If sunscreen-containing powder products are not on the market, consumers would be deprived of a dosage form that lends itself to habitual daily use and easy reapplication. This would discourage consumers from using sunscreen – whereas, from the perspective of protection of the public health, FDA should encourage such use. The availability of powder products containing sunscreen is vital to ensuring that women obtain adequate sunscreen protection for the face. Cosmetic powders are a particularly important source of sun protection for the face, as powders are most likely to be reapplied throughout the day.

FDA's recent conclusion that powders are not eligible for inclusion in the monograph, would require manufacturers to stop marketing makeup powders and other cosmetics with SPF claims. Doing so would deprive consumers of a vital source of daily protection against incidental sun exposure.

III. Conclusion

For the aforementioned reasons, we request that FDA continue to allow spray and powder sunscreen dosage forms in the market.

We look forward to an open dialogue with the Agency on these issues, which are of critical importance to our members.

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[39] *Id.* at 49092.

[40] 58 Fed. Reg. at 28195.

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Sincerely,

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Enclosures