COMMENTS SUBMITTED BY

Proposed Rule: Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use
Docket No. FDA–1978–N–0018; formerly Docket No. 1978N–0038

September 15, 2011

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

Re: Proposed Rule: Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use; Docket No. FDA–1978–N–0018; formerly Docket No. 1978N–0038

The Personal Care Products Council (the Council) and the Consumer Healthcare Products Association are pleased to provide these comments in response to the Food and Drug Administration's (FDA) Proposed Rule on Revised Effectiveness Determination; Sunscreen Drug Products for Over-the-Counter Human Use; Docket No. FDA–1978–N–0018; formerly Docket No. 1978N–0038 (Proposed Rule).

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.

The Consumer Healthcare Products Association (CHPA) is the 130-year-old-trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines.

We support the Agency's proposed decision to allow sunscreen products to be labeled with SPFs up to SPF 50+ and understand that higher SPF levels may be considered if supporting data are submitted to the Agency for review. With respect to the

issue of products labeled with SPFs higher than 50+, we understand that individual companies may provide comments regarding same.

However, on the issue of the definition of SPF 50+ and efficacy "ceiling limit": we recommend that the Agency's cap "harmonize" with the EU recommended definition of an SPF 50+ cap as having an SPF 60 or greater as calculated in accordance with FDA approved methodology, and that there be no additional "ceiling limit" on formulation. See Appendix 1 for the EU Commission Directive 2006/647/EC, "COMMISSION RECOMMENDATION of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto".

1. **There should not be a "ceiling limit" for the definition of "SPF 50+".**

A ceiling limit on formulation has already been established and is in effect through the maximum amount of each active ingredient which can be included in a final formulation. The approved concentration limits of the active ingredients create a formulation ceiling. Thus, a "self-imposed" ceiling already exists by virtue of the monograph's permissible levels of active ingredients.

The FDA currently has no safety concerns with the approved monograph active ingredients and monograph levels and combinations that are listed in 21 CFR 352.10 and 21 CFR 352.20. As noted in 21 CFR 352.1(a), "An over-the-counter sunscreen drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part…".

Safety of a formulation does not equate with the SPF of that product. An SPF 15 can be more irritating than an SPF 40 product. Importantly, it is an individual company's responsibility to demonstrate the safety of the products they market.

Given that

- A ceiling on formulation tacitly exists through ingredient maximum levels currently stated in the monograph;

- FDA has stated no safety concerns with active ingredients at levels listed in 21CFR 352.10; and
- Safety of a formulation has not been demonstrated to be a function of SPF level.

FDA has presented no justification for including a ceiling or formulation SPF limits. In regions or countries in which the SPF 50+ cap is in effect, there is no apparent ceiling needed; no formulation "ceiling limits" have been implemented in countries currently utilizing a SPF 50+ cap system.

Introducing an SPF ceiling as part of the SPF 50+ cap definition, could effectively limit the advancement of additional research into sun protection for the masses. As FDA is aware, when the SPF number was first introduced in the 1970's, protection levels were typically of the order of SPF4 to SPF12 with 'sunblocks' achieving no more than SPF15. Improvements in formulation skills and technology, together with the availability of improved sun filter ingredients, has resulted in a steady increase in the SPF number that can realistically be delivered by a sunscreen product. Had a ceiling been introduced concurrently with industry's abilities to formulate to an SPF 15, the technological advancements made in the last 20 to 30 years in the science of UV filters, photoprotection, and related healthcare improvements are unlikely to have been achieved.

2. SPF 50+ Cap should be harmonized with the EU "definition."

We recommend that the Agency's cap "harmonize" with the EU's definition of an SPF 50+ cap as having an SPF 60 or greater as stated in the European Commission's recommendation of September 22, 2006. See Appendix 1, p. 5 section 4, item 14. Harmonization is consistent with FDA's objectives.

The Agency has stated that its role in harmonization and multilateral relations

> ...is to coordinate and collaborate on activities with various international organizations and governments on international standards and harmonization of regulatory requirements.

Recognizing the considerable synergy between its domestic policy and its international policy priorities, FDA is sharpening and focusing its planning for enhanced alignment of FDA and international standards. In recent decades, great changes in the world economy, together with expanded working relationships of regulatory agencies around the globe, have resulted in increased interest in international harmonization of regulatory requirements. Increased international commerce, opportunities to enhance public health through cooperative endeavors, and scarcity of government resources for regulation have resulted in efforts by the regulatory agencies of different nations to work together on standards and harmonize their regulatory requirements. Such harmonization enhances public health protection and improves government efficiencies by reducing both unwarranted contradictory regulatory requirements and redundant applications of similar requirements by multiple regulatory bodies. FDA's goals in participating in international harmonization are:

- To safeguard global public health;
- To assure that consumer protection standards and requirements are met;
- To facilitate the availability of safe and effective products;
- To develop and utilize product standards and other requirements more effectively;
- To minimize or eliminate inconsistent standards internationally.

FDA's harmonization efforts are intended to pool regulators' resources in developing standards for public health protection; reduce industry's compliance costs in the global market, and minimize impediments to bringing safe food and safe and effective treatments to consumers and patients around the world.[1]

In summary, we strongly encourages the Agency to continue in its efforts to recognize and incorporate the benefits of harmonization by adopting the existing global definitions of a "SPF 50+ cap" to be a product having an SPF 60 or greater as calculated in accordance with FDA approved methodology, and that there be no additional "ceiling limit" on the formulation. The SPF 50+ label claim associated with such higher SPF products will be clear to consumers, and will provide those groups of consumers who believe they have or have been advised by their physicians that they have 'special needs', safe and effective products from which they may select.

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1 http://www.fda.gov/InternationalPrograms/HarmonizationInitiatives

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

Please feel free to contact me or Farah K. Ahmed at ahmedf@personalcarecouncil.org or 202-331-1770, if you have any questions or concerns.

Sincerely,

Elizabeth H. Anderson /cnq

Elizabeth H. Anderson
Executive Vice President – Legal and General Counsel

Cc: Michael Scott Furness, Director, Division of Nonprescription Regulation Development, Food and Drug Administration

Capt. Lydia Velazquez, Lead IDS, Senior Regulatory Review Officer, Division of Nonprescription Regulation Development, Food and Drug Administration

Reynold Tan, IDS Chemist, Division of Nonprescription Regulation Development, Food and Drug Administration

Debbie Lumpkins, Lead IDS, Acting Deputy Director, Division of Nonprescription Regulation Development, Food and Drug Administration

Farah K. Ahmed, VP – Associate General Counsel, Personal Care Products Council

Alison Manhoff, Deputy General Counsel, Consumer Healthcare Products Association