

THE INDUSTRY'S RESPONSE TO FDA'S PROPOSED RULES

IN MY FIRST COLUMN (February, 2008 p. 38-41), I addressed the salient features in the FDA's Amendment of the Final Monograph's Proposed Rule (Vol. 72, No. 165, Aug. 27, 2007).



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This column will highlight the response of the sun care industry, its relevant organizations such as the Personal Care Product Council (The Council), Japan Cosmetic Industry Association, the German Society of Cosmetic Chemists (DGK), American Academy of Dermatology and the Skin Cancer Foundation, as well as consumer groups such as the Environmental Working Group and the Citizens for Sun Protection and my own

personal views on why the proposed final rules need amending prior to their adoption.

Today, information is disseminated

at an extremely rapid pace, yet one must carefully decipher the scientifically and factually sound data from the unverified information contained in blogs and other internet communications. A Google search of the phrase "sunscreens" will yield a wealth of information including the FDA regulations, technical developments, new innovations, the Vitamin D issue, the safety and efficacy of sun care products, the effect of sunscreens on coral reefs, the study reporting that oxybenzone levels were detected in 97% of those tested and more. This information, factual and fictional, written by experts and laymen, is available on the internet without filter, supervision or peer review evaluation. This is a recipe for disaster and must be addressed and countered with campaigns by experts and major scientific and industry organizations. Left unchecked, this will only add to the chaos and confusion about the use and efficacy of sunscreens as a viable and necessary regimen in combating the epidemic rise of skin cancer.

The popular debate about sunscreens is mirrored by troubles expressed in the professional world. Unfortunately, disseminating dissenting views on the FDA's proposed final rules may pour gasoline on this raging fire, but one must present the facts as they stand today in the hope of reaching a consensus. Understanding between the FDA, the industry, the academicians and dermatologists, the relevant organizations and the interested public at large is paramount. I urge all interested parties to

We must create strict regulations to protect consumers and practitioners in the field.

conclude their findings as soon as possible so that we can create strict regulations that will ultimately protect both the consumer and the practitioner in the field. The FDA had extended the time to respond and offer comments by one month to Dec. 26, 2007. Those comments have been filed. Even though many companies and organizations, including The Council, have

requested a nine-month extension, the FDA has not, as of the writing of this column, granted an extension.

Glaring Disagreements

The first glaring disagreement within the industry has been the inability of The Council to issue a unified view in response to the FDA on the subject of in-vitro UVA testing. As mentioned in my first column, there are two industry positions on the proposed in-vitro UVA testing. The first position is held by Procter & Gamble, Unilever and Ciba; the second by Avon, Beauty Avenues, Estée Lauder, Johnson & Johnson, L'Oréal USA, Mary Kay, Revlon, Schering-Plough and Shiseido. On that point, the AAD, the Skin Cancer Foundation, Japan's JCIA and Germany's DGK offer many suggestions for improvement but seem to request an alternative in-vitro UVA testing procedure, namely the Critical Wavelength. Below are The Council's salient features in their petition to the FDA on its proposed in-vitro UVA testing procedure.

I. Industry UVA position supporting the FDA with modifications:

Ciba, one of the three companies represented in this industry position, has written extensively to the FDA on the topic, generally in support of its proposal for UVA testing and labeling. However, Ciba requested more details about the in-vitro method, in particular regarding:

with that of the FDA's in-vitro UVA procedure due to:

1. The FDA's assumption that the UVA I radiation, in the UVA I/UV proportionality test method is of equal biological consequence to UVB and UVA I radiation.
2. The FDA's test has not been val-

dealing with:

1. Sun Protection Factor
2. UVA
3. Anti-aging
4. Labeling
5. Ingredients
6. Implementation
7. Economic impact
8. Sunscreens containing AHA
9. Nanotechnology and Sunscreens



Proper protection when you're young is key to reducing the chances of skin cancer.

1. Substrate
2. Application amount
3. Irradiation dose

The companies have also expressed concern that the proposal could permit products with no stated UVA protection factor to nevertheless be called a sunscreen. They propose that to be labeled as a sunscreen, the minimum requirements are: SPF 15 with a UVA rating of 3 stars.

II. Industry UVA position opposed to the FDA's in-vitro UVA protocol

The remaining participating companies in The Council insist that the proposed in-vitro test methodology suggested by the FDA is inappropriate, and contrary to the primary purpose of providing meaningful UVA protection to the consumer. They propose to substitute the critical wavelength computation

idated and contains several technical elements that are inappropriate for accurate measurements (substrate, application quantity, pre-irradiation dose, variability, light source and number of measurements needed).

3. The FDA's procedures would not be in harmony with internationally recognized in-vitro testing parameters.

4. The fact that it would be virtually impossible to achieve the 0.95, four-star UVA rating for the proposed FDA in-vitro test method for all but the lowest SPF protection products.

All the companies represented in The Council agree on the balance of their critical review of the other issues addressed in the FDA's proposed amendment of the Final Monographs Proposed Rule.

Specifically, The Council has addressed the issues

In the interest of being brief, yet precise, the reader is urged to read the document submitted by The Council to the FDA.

One important issue that warrants highlighting is the disagreement between The Council and the FDA regarding the degree of economic impact on the industry by implementing these proposed rules. The proposed labels and compliance with the monograph will cost manufacturers substantially more than what the FDA suggests. Specifically:

1. Retesting products for UVA protection will cost manufacturers approximately \$12,000 per product or \$32.9 million. The FDA projects costs of \$2,400 per product with a total projected cost of \$5.4 million dollars. While this may be a boon for testing companies, it is a cost that none but the major manufacturers can bear—barely! This will prohibitively narrow the playing field, marking the disappearance of young entrepreneurs, with potentially brilliant ideas, from the scene.

2. Relabeling will cost manufacturers approximately \$90 million (\$15,000 per sunscreen SKU). This is double the FDA's projection of \$47.5 million (\$7,600 per SKU). Ironically, this may be an opportunity for entrepreneurs to enter the market since they will not have the added cost of relabeling their products like the current manufacturers who are required to comply with the regulations. This will, however, force many of the small to intermediate manufacturers and distributors of sun care products to abandon a large number of their SKUs, if not depart from this industry altogether.

New, improved and more importantly, final and definitive regulations are warranted immediately for all

What is the economic impact of the new proposal?

involved. The economic impact will not only affect the consumer with higher, perhaps unaffordable, prices, but may also deprive them of the innovative new products and ideas from new entrepreneurs and investors.

Unprecedented Interest

This process that was initiated with the FDA's August 27, 2007 publication in the Federal Register has spurred an unprecedented interest among consumers and industry groups. It is virtually impossible to list a fraction of the submissions and comments. The reader must consult the FDA's Docket No. 1978N-0038, Regulatory Information No 0910-AF43. Other interesting comments supplied by cosmetic companies, individuals and organizations include Johnson & Johnson which agrees with many of The Council proposed changes but requests other modifications, including perhaps raising the SPF cap to 85. Joe Stanfield and Robert Sayre independently submitted comments on UVA in-vitro testing procedural modifications and recommendations for solar simulators used respectively.

The Environmental Working Group (EWG) recommends the following improvements to the monograph:

1. The final implementation of the rules should be concluded in one year.
2. The proposed UVA-protection relies on measurements not directly related to health.
3. Revisions made to protect consumers from the use of anti-inflammatory agents in sunscreens that can artificially boost SPF ratings.
4. Require manufacturers to identify and ensure the safety of all photo-degradation products of sunscreens.
5. The approval of safe and effective sunscreens used in other parts of the world.
6. Address misleading claims in the monograph including "chemical free," "non-chemical" and "PABA-free."

Though I do not necessarily agree with everything that EWG advocates, I must admit that most of their concerns listed above are reasonable. My

personal concerns with this whole process of regulations in the U.S. can be summed up as follows:

1. The process has been dragging on for too long to the detriment of the U.S. consumer.
2. The lack of a process that speeds-up the evaluation of new and improved active ingredients other than a New Drug Application (NDA) is unrealistic. If you review our filters currently approved in the U.S. (17 in total) you will immediately discover that they are woefully inadequate.
3. The lack of superior UV filters forces manufacturers and suppliers to by-pass the regulations to insure that the consumer is adequately protected. For example, since Avobenzene is



All the debate could hurt sunscreen sales.

nearly the "only game in town" for superior UVA protection, its photostability has created a whole new industry of photostabilizers and triplet-triplet or excited state quenchers to improve its performance. With the availability of superior UVA I filters none of these so called inactive ingredients would be necessary.

4. Other forms of SPF and UVA boosters have been used to complement the deficient and limited UVA and UVB filters available. Again,

ingredient suppliers have scrambled to offer natural ingredients that boost the SPF, or added microspheres and polymers that physically alter the characteristics of the formulations to increase the path length and boost the SPF. For a complete description of SPF boosters, read my article in HAPPI (p. 77, Oct. 2007).

It is my hope that the FDA's final monograph be issued soon and that it addresses not only the concerns of the cosmetic companies and their organizations on testing, labeling and economical impact but those of the consumer as well. The Final Monograph should include:

1. Approval through the TEA process of the six European filters (including two UVA filters).
2. Allowance for a new mechanism for the approval of new and innovative UV filters and also to disallow inadequate or unsafe UV filters that are currently approved.
3. Regulating the thriving industry that promotes ingredients, UV active or not, that artificially boost the SPF of sunscreen formulations.
4. Allowance for a mechanism, simpler than the time-consuming citizens petition, for both industry and consumer concerns to be addressed promptly and inexpensively.
5. Allowance for exceptions or incentives for new entrepreneurs to offer their new ideas and innovations for better sun care protection with the minimal of expenditures and excessive costs. An equivalent mechanism currently exists in the pharmaceutical industry for orphan drugs targeting "rare and uncommon" diseases.

The popular confusion about the use and efficacy of sunscreens as a viable regimen in combating skin damage is compounded by the professional debate surrounding the FDA's proposed Final Monograph. All interested parties will benefit from a consensus that can only be reached through communication and response.

Until my next column, I look forward to receiving your comments and suggestions. Please visit my website at www.alpharnd.com. ●