

C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

July 26, 2002

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

E. EDWARD KAVANAUGH
P R E S I D E N T

Re: Petition for Stay of Action and Reconsideration of Effective Date;
Docket No. 78N-0038

Dear Sir or Madam:

This petition is filed on behalf of The Cosmetic, Toiletry, and Fragrance Association (CTFA)¹ and The Consumer Healthcare Products Association (CHPA)² in accordance with 21 C.F.R. 10.33(b) and 10.35(b) for reconsideration and stay of the effective date of a Technical Amendment to the Final Monograph for Sunscreen Drug Products for Over-the-Counter Human Use. The current effective date, September 1, 2002, should be stayed immediately and the effective date for these requirements should be extended for one year to September 1, 2003.

A. Decision Involved

On June 20, 2002, FDA published a Technical Amendment to the Final Monograph for Sunscreen Drug Products for Over-the-Counter Human Use (hereafter the "Sunscreen Monograph") 67 Fed. Reg. 41821. This Technical Amendment amended 21 C.F.R. Sections 352.10 (ingredient listing) and 352.20 (permitted combinations) to change the names of four sunscreen active ingredients to conform to changes by the United States Pharmacopoeia (USP) in the compendial names of these ingredients. By the terms of the Technical Amendment, the USP names become effective on September 1, 2002.

In the changes adopted, menthyl anthranilate became meridimate, octyl salicylate became octisalate, octyl methoxycinnamate became octinoxate, and phenylbenzimidazole sulfonic acid became ensulizole. The Technical Amendment specifically requires that any sunscreen drug product initially introduced or initially delivered for introduction into interstate commerce after September 1, 2002 bear the new established names to remain in compliance with the Food, Drug, and Cosmetic Act.

¹ CTFA is the national trade association representing the personal care product industry. Founded in 1894, the association represents approximately 600 companies that play a role in the manufacture and distribution of personal care products. These products include both cosmetics and OTC drugs such as sunscreens.

² Founded in 1881, CHPA represents manufacturers and distributors of nonprescription medicines and dietary supplements with over 200 members in different sectors of the self-care industry.

This labeling revision takes effect less than three months after its publication in the *Federal Register*.

B. Action Requested

CTFA requests that FDA immediately stay the effective date for these ingredient name changes and publish an amended regulation giving manufacturers an additional year, until September 1, 2003, to incorporate these ingredient name changes on product labels. In the alternative, CTFA requests that FDA provide notice to the industry that the Agency will exercise its enforcement discretion to not require these name changes to appear on all sunscreen product labels introduced into interstate commerce before September 1, 2003.

C. Statement of Grounds

FDA's publication of the Technical Amendment has given sunscreen manufacturers using these four active ingredients little more than sixty days to make changes to their product labels. This is inadequate time to make the required labeling changes.

It might be argued that industry has had time to prepare because USP action predated FDA action. That is not a valid argument in this instance, because of uncertainty over timing of the Agency's action to implement the USP name changes in the context of its announced intent to publish a proposed amendment to the Sunscreen Monograph that will require additional labeling changes. According to the current Semiannual Regulatory Agenda, that amendment is expected to be published in April 2003. This situation is not the normal course for a final monograph, but instead is a "final monograph" that has been undergoing reconsideration and awaiting amendment from almost the very moment it was published. The issues being reconsidered will involve significant changes in labeling requirements for all sunscreen products. It therefore is not unreasonable for a company to defer initiating label changes until FDA publishes a formal notice to implement the changes.³

In extending the effective date for the Sunscreen Monograph indefinitely, the Agency has emphasized its goal – one that the industry supports – of minimizing the number of labeling changes that are required for sunscreen products. 66 Fed. Reg. 67485, 67486

³ Because the USP is a membership organization, for some companies publication of this notice by FDA on June 20, 2002 was the first formal notice they received that this change would be required.

(December 31, 2001). It is not unreasonable – in furtherance of the same goal – for a company to wait to take action to modify its label until FDA publishes a final regulation.

When FDA's regulation was published, CTFA immediately contacted FDA to make the Agency aware of the impossibility of compliance in such a short time. FDA officials asked CTFA to contact USP to determine whether that organization was in a position to delay its effective date. Consultations with the General Counsel of USP and Chair of the USP Nomenclature Committee resulted in the conclusion that USP would not be in a position to take action. We were advised that USP does not have a timely procedural mechanism available to do so, and that our only recourse was with FDA. Therefore, action by FDA to stay the effective date of its Technical Amendment, or, at a minimum, to indicate that it will exercise its enforcement discretion to defer the requirement that labels reflect the new names is necessary.

A delay of one year until September 1, 2003 will provide the opportunity for sunscreen manufacturers to deplete their existing label inventory and comply with the Technical Amendment. To do so would be consistent with previous Agency actions. For example, FDA amended the final monograph for OTC nasal decongestant drug products to add the ingredient levmetamfetamine (formerly 1-desoxyephedrine) and to classify this ingredient as safe and effective for OTC use:

The only labeling change that is necessary at this time is to change the established name from 1-desoxyephedrine to levmetamfetamine as a result of the 6th Supplement to USP 23 (ref. 2). A number of manufacturers of these products have already made this change as new labeling needed to be prepared. *The agency believes that an effective date of 1 year from the date of this publication will provide manufacturers of the remaining products sufficient time to incorporate the name change during a future manufacturing cycle.* [emphasis added]
63 Fed. Reg. 40647, 40649 (July 30, 1998).

Action to provide an additional year to comply would be entirely within the letter and spirit of FDA policy allowing time for an orderly depletion of existing labels before requiring new labels to appear. The FDA Compliance Policy Guide for compendium revisions and deletions specifically states that:

regulatory action is not indicated based solely on the continued use of existing stocks of old labels bearing the old USP or NF designated provided that the firm makes arrangements to revise labels in a

reasonable period of time, and the drug meets the monograph requirements of the current compendium. (CPG 7132.02)

This guidance recognizes that the product can be safely used by the consumer while the old labels are used.

Failure to extend the deadline for relabeling will unnecessarily disrupt the supply of sunscreen products. Two of the ingredients involved are used widely in sunscreen products. There are literally thousands of SKUs (stockkeeping units) (individual product, package, and size) of product in the market that are intended to be used as sunscreens. These include a wide variety of products that provide sunscreen protection to consumers in all activities in their daily lives where they are exposed to ultraviolet radiation.

Relabeling sunscreen products that contain one of the affected ingredients is a major undertaking that cannot be accomplished in a few months. Most labels are silkscreened or printed on the immediate product container which have been ordered from suppliers well in advance. Furthermore these products are manufactured and distributed in advance of the "sunscreen" season to ensure their timely distribution throughout marketing channels.

There is simply no reason to force an abrupt and expensive disruption of the supply of sunscreen products in the marketplace to implement a technical labeling change that will not in any way adversely affect the safety of consumers or the ability of consumers to obtain effective sunscreen protection. Our request for a delay of the compendial name changes does not affect the strength, quality, or purity of the drug or represent a change in analytical procedures as stated in the USP monograph. To the extent consumers need to know about the presence of a particular ingredient in order to use it or avoid it, those consumers would be familiar with the old names, not the new names, so nothing is lost.

D. Timeliness of Petition

Sections 10.33(b) and 10.35(b) of the FDA procedural regulations state that a petition for administrative reconsideration or for stay of action is ordinarily to be filed within thirty days after the date that a regulation is published in the *Federal Register*. Both provisions state, however, that a petition may be accepted by the Commissioner at a later date for good cause.

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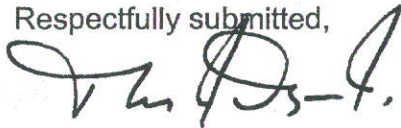
As explained in this matter, CTFA contacted the USP first at the recommendation and advice of FDA. Following these discussions, petitioners decided it would be appropriate to submit this petition for reconsideration and stay of the effective date because the required action is imminent.⁴ Petitioners request the Commissioner to exercise the discretion set forth in the applicable regulations to consider the requested relief as expeditiously as possible.

E. Conclusion

In summary, industry raises no substantive objection to the name changes required for these sunscreen ingredients, but believes the deadline proposed for changing a very large number of labels is unreasonable and should be extended to September 1, 2003.

Please feel free to contact the undersigned if you have questions or need more information regarding this issue.

Respectfully submitted,



Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel
CTFA

cc: Charles Ganley, M.D.
Gerald M. Rachanow
John Lipnicki
Eve Bachrach, CHPA

⁴ It is submitted well within the comment period for the regulation on these name changes ending on August 19, 2002.