

# C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

July 3, 2002

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

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

Re: Docket Nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201

The Cosmetic, Toiletry, and Fragrance Association (CTFA) submits these comments in response to the Food and Drug Administration's partial delay of the compliance dates for certain products subject to its final rule that establishes standardized format and content requirements for the labeling of over-the-counter (OTC) drug products (Drug Facts Rule) under 21 CFR 201.66.

Founded in 1894, CTFA is the national trade association representing the personal care products industry. Our membership includes approximately 275 active member companies that manufacture or distribute personal care products. We also represent approximately 275 additional associate members who provide goods and services to manufacturers and distributors of personal care products. Although many of the products of CTFA members are regulated solely as cosmetics, a significant number of our members' products are regulated both as cosmetics and as drugs. These products, hereafter "cosmetic-drugs," claim and provide both cosmetic and drug benefits that are highly valued by consumers. They include antidandruff shampoos; antiperspirant/deodorants; skin protectants; antimicrobial soaps; and sunscreen products.

CTFA is requesting that the scope of the partial delay of the compliance dates for the Drug Facts Rule include cosmetic-drugs with no dosage limitations. Specifically, since most cosmetic-drugs are not measured by dosage, CTFA requests that FDA recognize that the scope of the delay published in the *Federal Register* of April 5, 2002 (67 FR 16304) includes cosmetic-drug products with no dosage limitation that: (1) contain two ounces or less (by weight or liquid measure); and (2) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear labeling to meet

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the requirements set forth in sections 201.66(d)(1) to (d)(9) and therefore qualify for the labeling modifications set forth in section 201.66(d)(10). This proposed definition for convenience-size drug products is consistent with the agency's stated definition for compliance under the implementation chart for the OTC labeling rule by preserving the size limitations of section 201.66(d)(10), but replaces a limitation of dose with one of content instead.

CTFA will submit additional comments in response to a proposed rule that FDA intends to publish in a future issue of the *Federal Register* to amend the Drug Facts Rule by defining "convenience-size" OTC drug packages and addressing Drug Facts labeling requirements for these products. In the meantime, we believe it is critical that FDA recognize that modified labeling requirements are essential for all OTC drugs – including cosmetic-drugs – sold in convenience sizes. A proposed definition of a convenience size drug product must be sufficiently comprehensive to include OTC drug products without dosage limitations<sup>1</sup> as well. To do otherwise would treat two OTC products of the same size/intended use differently.

There is simply no question that FDA's delay of the effective date and reconsideration of the labeling requirements for "convenience-size" OTC products must apply to all similarly-situated "convenience-size" products. To limit the delay and reconsideration to only one part of the product category (as defined by FDA to be those with no more than two doses and limited available labeling space) and not include other "convenience-size" products that have no dosage limitations is highly arbitrary and therefore legally improper. *Bracco Diagnostics v. Shalala*, 963 F.Supp. 20, 27-28 (D.D.C. 1997).

#### FDA's rationales for the Drug Facts Rule do not apply to cosmetic-drug products

From the beginning FDA's objective for requiring standardized format and content requirements for all OTC drug products has been to simplify and standardize OTC drug product labeling to ensure their safe and effective use. The agency has identified four areas of concern regarding changing patterns of OTC drug use as evidence of the need for standardized OTC drug labeling:

- Increased availability of more potent medicines.
- Increased consumer self-diagnosis and self-medication.

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<sup>1</sup>In our comments to FDA's proposed labeling rule for OTC drug products filed October 6, 1997, we proposed to define "dosage limitation" as "a set of limitations on the size, frequency, and number of doses required in the labeling of a product marketed either pursuant to a Tentative Final Monograph, where applicable, or Final Monograph for an OTC Drug Product Category or a specific New Drug Application approval." See page 14, exhibit A.

- The possibility of increased or inappropriate use of OTC drug products by the elderly.
- The possibility of increased adverse reactions and misuse of OTC drug products.

These rationales do not apply to cosmetic-drug products, which have a long history of safe and appropriate use by consumers. Unlike OTC drug products that are purchased solely for their therapeutic benefits, cosmetic-drug products are used often on a daily or more frequent basis, because they provide several important cosmetic as well as drug benefits.

Concerns about increased consumer self-diagnosis and self-medication are not relevant to cosmetic-drug products. Based on their long history of safe use and preventative benefits, the issue for cosmetic-drug products, most especially sunscreens, is not one of consumer misuse, but rather consumer under use. This issue is true for all segments of the population including the elderly.

Likewise, concerns about product line extensions or inadvertent overdosing of drug ingredients in cosmetic-drug products with no dosage limitations do not exist because they are not subject to dosage limitations. Overall these products provide high therapeutic indices, are extremely low risk, provide a favorable public benefit, and require few specific warnings.

Concerns regarding the possibility of increased adverse reactions and misuse of cosmetic-drug products are allayed by the fact that these products have been marketed for many years prior to implementation of the labeling changes required by the Drug Facts Rule. They have complied with the labeling requirements for both drugs and cosmetics, and consumers have used them safely to their benefit. For these reasons, CTFA urges FDA to include cosmetic-drugs with no dosage limitations in its definition of "convenience-size" drug products.

From the beginning of the Drug Facts rulemaking, CTFA has urged relief for convenience and small package sizes

CTFA has consistently requested modification of the labeling requirements for cosmetic-drug products without dosage limitations to ensure their availability in convenient, easy-to-use packaging. In our comments to the proposed OTC labeling rule filed October 6, 1997, we proposed a small package exemption from the Drug Facts Rule for all cosmetic-drug products. We proposed the following amendment to define a "small package" as:

“(7) A small package means any outer package:

- (i) if the total surface area available to bear labeling is less than 12 square inches (including the principal display panel); or
- (ii) if more than 60% of its total surface area available for labeling on the back and side panels, if any, (excluding the principal display panel) must be used to satisfy the ‘content requirements’ as described in proposed section 201.66©; or
- (iii) that is a trial size package, packette, or single use unit.”

CTFA continues to assert that previous and existing labeling for cosmetic-drug products without dosage limitations is more than sufficient to ensure their safe and effective use. We therefore welcome the agency’s recognition of the need to address the Drug Facts labeling requirements for “convenience-size” OTC drug packages as an important rulemaking applicable to *all* OTC drug products, including cosmetic-drugs. CTFA encourages FDA to consider a broad and inclusive definition for “convenience-size” OTC drug products recognizing that there is a public health need to ensure that consumers have access to medically relevant information consistent with the retail environment in which they are sold.

CTFA’s proposals for reduced labeling for specific monograph drug products are separate and independent

CTFA’s request that FDA include cosmetic-drug products in any proposed definition of convenience-size drug products *is separate and independent* of our proposals for reduced labeling for specific monograph rulemakings now and in the future.<sup>2</sup> We consider our proposals for reduced labeling to be monograph-specific, based on the specific issues of each particular rulemaking, and make those proposals for all such products, regardless of package size.

### Conclusion

It is logical to conclude that FDA consideration of a “convenience-size” OTC drug product includes cosmetic-drug products with no dosage limitations. Clearly, concerns of safety apply considerably less to this category of OTC products, not only because of their high safety profile and no-dosage requirements, but also because of their long history of compliance with the labeling requirements of both cosmetic and drug regulations.

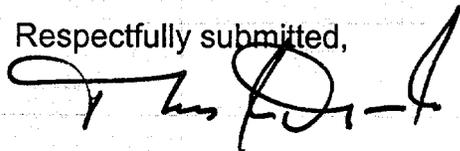
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<sup>2</sup> To date, CTFA has filed comments that propose reduced labeling requirements for sunscreen and antiperspirant products.

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We look forward to continued dialogue with the agency on these issues which are of critical importance to our members.

Respectfully submitted,



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Attachments

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