



January 17, 1996

G.N. McEwen, Jr., Ph.D., J.D.  
Vice-President - Science  
Cosmetic, Toiletry, and Fragrance Association  
1101 17th Street, N.W., Suite 300  
Washington, D.C. 20036-4702

Dear Dr. McEwen:

This responds to your letter dated August 2, 1995, concerning a suggestion related to the international harmonization of cosmetic ingredient names, intended for the labeling of cosmetic product packages. Specifically, you request that the term "may contain", currently authorized under 21 CFR 701.3(g) for the labeling of "shaded" products (*i.e.*, color cosmetics which are identical in composition other than with respect to the color additive) be replaced with a symbolic alternative "+/-". In your letter, you explain that this proposal has been promulgated by the European Cosmetic, Toiletry, and Perfumery Association (COLIPA) as part of their attempt to develop a cosmetic nomenclature system that relies as little as possible on any particular national language. You also note that COLIPA has confidence that the proposed symbol "+/-" is internationally understood as an equivalent alternative to "may contain" and will convey the necessary information to their European consumers.

As discussed previously in our letter to you dated June 1, 1995, FDA established the requirement for cosmetic ingredient declarations on product package labeling under the authority of Section 5 of the Fair Packaging and Labeling Act (FPLA) [*c.f.*, Section 5(c)(3)(B)].

Regulations published by FDA to implement this statutory authority provide that a declaration of cosmetic ingredients may include an ingredient not actually in the product, if the ingredient is identified by the phrase "may contain", and that ingredient is a color additive added to some batches of the product for purposes of color matching, or, alternatively, if it is the sole point of compositional difference between several "shaded" cosmetics [i.e., 'color cosmetics' belonging to one of the several cosmetic product category codes defined at 21 CFR 720.4(c)(3), (7), and (8)(v)] that may be part of an assortment (or brand range) of similar products that are intended for the same use, and that are sold by the manufacturer or distributor under a single common brand or trade name [21 CFR 701.3(g)].

The phrase "may contain" in the foregoing regulation establishes a contingency that must be satisfied by a specific conditional test (i.e., whether or not a product among several similar products actually contains a particular color additive). Analogous contingencies, which allow ingredients sometimes used in a food product under corresponding circumstances to be declared on product package labeling using analogous qualifying descriptors such as "or", "and/or", "contains one or more of the following:", or "used as needed", are also found in several current food labeling regulations [e.g., 21 CFR 101.4(b)(16)-(19) and 21 CFR 150.140(e)(2)(ii)]. In none of these cases, however, do the regulations provide for the use of a symbolic representation as an acceptable substitute for the literal English language phrase.

FDA is not aware of any information that convincingly demonstrates that substitution of a "+/-" for the term "may contain" will be understood, and will convey the necessary literal information to consumers in the U.S., since such abbreviated and symbolic nomenclature is less specific, may be more ambiguous, and may connote alternative and unintended phrases or interpretations. Nor has CTFA presented evidence that the proposed "+/-" symbol will convey the same meaning to

consumers as the term "may contain". Viewed from the perspective of FPLA, without an appropriate basis for establishing that the proposed symbolic representation of "may contain" is, in fact, accepted and understood by the American consumer, the Agency must conclude a priori that such a change would be confusing to consumers and would not prevent deception or facilitate value comparisons.

CTFA has previously proposed in its letter to FDA dated May 24, 1995 that color additives be declared on cosmetic product package labels during a suitable period of transition and conversion using the Color Index (CI) numbers in parentheses after the primary common or usual name currently required by regulation. Similarly, the Agency has suggested in its reply to CTFA dated June 1, 1995 that CTFA may wish to consider employing a similar system of "dual declaration" for the Latin (Linne) equivalents to common or usual English renderings of plant extract and other botanical names, when these ingredients are declared on cosmetic product package labels.

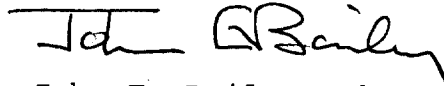
With respect to the current CTFA suggestion, an analogous transition period during which the symbolic "+/-" follows the literal term "may contain" in parentheses may be a reasonable approach for educating consumers concerning the use of the "+/-" symbol. However, please be advised that use of the phrase "may contain" is codified at 21 CFR 701.3(g), and whatever alternative nomenclature scheme or transitional approach CTFA chooses to propose, will require amendment of the applicable existing regulations through rulemaking.

In conclusion, FDA continues to recognize the potential importance and benefit of international harmonization of the marketplace to the cosmetic industry, and the Agency will support such efforts in a manner consistent with the policy statement recently published in the Federal Register (59 FR 60870). However, FDA cannot accept your suggestion to replace the use of the currently authorized term "may contain" with the symbolic

alternative "+/-". CTFA may instead wish to consider petitioning for a stepwise alternative approach that provides a period for reeducation of the public to the proposed symbolic representation, together with a process by which evidence will be generated to substantiate that the American consumer has, in fact, accepted and understands the meaning of the new symbolic alternative.

I trust that the above comments on CTFA's August 1, 1995 proposal on "International Harmonization of Cosmetic Nomenclature" are helpful. Please feel free to contact this Office again should you have any additional questions on this matter.

Sincerely,



John E. Bailey, Ph.D.  
Acting Director  
Office of Cosmetics and Colors  
Center for Food Safety  
and Applied Nutrition  
U.S. FOOD & DRUG ADMINISTRATION

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