



July 07, 1997

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

Re: Docket No. 96P-0347

Dear Dr. McEwen:

This letter is in response to the citizen petition you submitted, dated September 20, 1996, titled "International Cosmetic Ingredient Dictionary - Harmonization of Ingredient Labeling Names and Recognition of the Sixth Edition (1995)". This petition requested, among other actions, that the Food & Drug Administration (FDA) amend the cosmetic regulations at 21 CFR 701.3 (c)(2)(i) to permit dual label declaration of color additives in use within the U.S. and the EU for cosmetic applications; the petition also requested that similar regulatory discretion facilitating international harmonization of cosmetic labeling be allowed for other categories of cosmetic ingredients formulated in products intended for marketing in both the U.S. and EU, including denatured alcohols, botanical ingredients, and "trivial" EU ingredient names. The petition also requested that FDA recognize the symbol "+/-" as an acceptable alternative for the phrase "may contain" in 21 CFR 701.3 (g) to signify that some batches of "shaded color cosmetic products" may or may not contain one or more color additives for reasons of color matching. Additionally, the petition requested that the agency amend 21 CFR 701.3 (c)(2)(i) to recognize the 6th Edition of the *CTFA International Cosmetic Ingredient Dictionary* (ICID-6) for purposes of cosmetic product package ingredient labeling declaration.

The purpose of this letter is to advise you, in accordance with 21 CFR 10.30 (e), that we have not been able to reach a decision on your petition within the first 180 days of the filing of the petition, because of the limited availability of resources and other agency priorities.

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Please be assured that your Petition is under active review at the present time, and a more substantial response reflecting the agency's determination of the merits of the several elements of the Petition will be forthcoming as soon as possible.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Bailey", with a horizontal line extending to the left.

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