DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

June 1, 1995

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Dear Dr. McEwen:

This responds to your letters dated March 14, 1995 and May 24, 1995, concerning international harmonization of cosmetic ingredient labeling names. Specifically, you request that the Food and Drug Administration (FDA) permit the interim use of selected "harmonized" names until such time that the changes can be considered as part of a petition to adopt new names for ingredient labeling to facilitate the use of common terminology for the naming of certain cosmetic ingredients between the United States (U.S.) and the European Union (EU). You also indicate that you are seeking a letter from FDA stating that "... the agency will not take action against labels using such new harmonized INCI names after they suitably published."

In your letter you note that the European Cosmetic, Toiletry and Fragrance Association (COLIPA) recently informed the Cosmetic, Toiletry, and Fragrance Association (CTFA) that the Legal Services of the EU Commission has accepted the names in CTFA's International Cosmetic Ingredient Dictionary (ICID) without translation. These names, which are now designated as International Nomenclature Cosmetic Ingredient (INCI) names, will be used by EU members to identify ingredients in the EU Inventory of cosmetic ingredients and are expected to be the basis for ingredient labeling on products that will be required in the EU in 1997.

You further indicated that the EU is requiring that selected groups of INCI names must comply with the EU Cosmetic Directive in order to minimize confusion from certain common names in the EU where nine different languages are spoken, and that these requirements will require significant changes in some parts of the ICID.

As outlined in your correspondence, a summary of the ingredient categories that will require changes is as follows:

1. COLORANTS: Annex IV of the EU Cosmetics Directive identifies all colorants (with a few exceptions) by their Color Index (CI) Number. The EU will require that the CI Number be used in the EU for the declaration of all color additives in ingredient labeling.

   To address this requirement, CTFA is proposing that color additive declaration in products intended for distribution and sale in the United States be permitted to use a dual declaration in the required ingredient statement. CTFA provides an example as shown:

   Harmonized INCI Name: FD&C Green No. 3 (CI 42053)

2. DENATURED ALCOHOL (Ethyl Alcohol): The EU currently accepts the term "Alcohol Denat." for the purpose of declaring the presence in cosmetic products of ethyl alcohol that has been denatured in accordance with any of the national regulations of the nine countries of the EU.

   CTFA notes that, in the U.S., there are currently 26 SD Alcohols and 1 CD Alcohol listed in the Cosmetic Ingredient Dictionary, according to the names established by the Bureau of Alcohol, Tobacco, and Firearms regulations (27 CFR 20.11 and 21.32 through 21.81). For any given SD or CD formulation identified in the regulations, there are a wide variety of substances that may be added for denaturing the alcohol. For example, in reference to SD Alcohol 38B, the regulations allow the use of one or more of over 40 different substances ranging from anethole and anise oil to turpentine or wintergreen oil.

   CTFA notes that cosmetic firms doing business in international markets have stated that it is essential that a single labeling name be established for alcohols containing denaturing ingredients.

   To address this issue, CTFA proposes that the single term "Alcohol Denat." be permitted for use in the identification of all denatured alcohols for the purpose of label declarations for products intended for distribution and sale in the United States.

3. PLANT EXTRACTS: In order to achieve international harmonization with regard to the naming of plant extracts and to minimize confusion from U.S. common names for plant

materials, the EU Inventory identifies ingredients derived from plant sources by their genus/species name using the Linne system.

CTFA proposed that the genus/species names, using the Linne system, be allowed for the purpose of declaring these ingredients on the labels of products intended for distribution and sale in the United States. The following is provided as an example:

Current US INCI Name --- Orange Peel Extract

Proposed Harmonized INCI Name --- Citrus Sinensis Peel Extract

On May 24, 1995, CTFA revised its proposal regarding labeling names for plant extracts. To achieve an orderly conversion to the new labeling name, CTFA proposes that a transition period be established to educate the public to the new names for plant extracts. This process would include:

1. Use of Dual Labeling Names: Cosmetic firms would be permitted to voluntarily list plant extracts by their proposed Linne INCI name followed by the current English plant name in parentheses (e.g., "Citrus Sinensis (Orange) Peel Extract").

2. FDA Permission to Use Dual Names: During this transition period, FDA would permit the use of the dual name declarations with the transition period being in effect until such time as the changes are recognized by FDA.

3. Joint CTFA/FDA Consumer Education Program: CTFA and FDA would jointly develop and distribute consumer information materials that would cross reference the current English INCI names and the proposed Linne INCI Name.

CTFA is proposing these changes in the labeling requirements for products intended for distribution and sale in the United States as a mechanism for fostering international harmonization to facilitate the marketing of cosmetics in the EU and the United States.

Cosmetic Ingredient Labeling

FDA established the requirement for cosmetic ingredient declarations on product labeling under the authority of Section 5 of the Fair Packaging and Labeling Act (FPLA) (21 CFR 701.3). The FPLA provides authority to promulgate regulations "necessary to prevent the deception of consumers or to facilitate value comparisons." To accomplish these goals, the regulation requires that the ingredient declaration "...appear with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase..." (21 CFR 701.3(b)). Further, Section 5(c)(3)(B) requires the use of "the common or usual name" for identification of each such ingredient included in the preparation.

In finalizing the regulations implementing cosmetic ingredient declaration requirements under FPLA (38 FR 3523, October 17, 1973), the Commissioner concluded that -

> Cosmetic ingredient labeling is necessary to prevent the deception of consumers and to facilitate value comparisons. Ingredient labeling can be meaningful in preventing consumer deception by precluding product claims that are unreasonable in relation to the ingredients present and by providing consumers with additional information that can contribute to a knowledgeable judgement regarding the reasonableness of the product.
>
> While ingredient identity may not be the sole determinant of a product's value to a consumer, it is one important criterion of a product's value in comparison with others. The presence of a substance to which a consumer is allergic or sensitive, for example, may render the product worthless to that consumer.

Preventing deception and facilitating value comparisons for cosmetic products entails providing information that will allow the consumer to (1) compare one product to another, (2) evaluate the price of the product based on this composition, and (3) determine whether the product contains ingredients that are harmful to the user. The successful accomplishment of these purposes requires that all cosmetic labelers use the same name for the same ingredient, and that the name used to identify the ingredient is the common or usual name. In the case of cosmetic ingredients, the common or usual name may be the chemical name traditionally employed by the industry or the name recognized by the consumer where such name recognition has been established over a period of time.

The Cosmetic Ingredient Dictionary (CID)

Cosmetic raw materials are supplied to the cosmetic industry under a wide variety of trade names and nomenclature schemes. It is not uncommon for the same cosmetic ingredient to be sold by several different suppliers under different trade names and, in some cases, different chemical identifications. Thus, the selection of an acceptable name for the ingredient can be challenging for a cosmetic manufacturer.

As a means of imposing order on this process, the CTFA has, over the years, compiled and published a Cosmetic Ingredient Dictionary (CID).* For each cosmetic ingredient, the CID provides a listing (monograph) that includes the name and a brief description of the identity of the ingredient, a listing of tradenames under which the ingredient may be marketed, and any applicable regulatory citations. The CID has served primarily as a resource for identification of acceptable names for cosmetic ingredients. The presence of an ingredient in the CID has never constituted approval or endorsement by either CTFA or FDA nor provided any assurance of safety for the ingredient.

The Cosmetic Ingredient Dictionary (CID) and International Harmonization

The names of the cosmetic ingredients cited in CID monographs are established according to "Nomenclature Conventions" that have been developed and refined over the years by the CTFA International Nomenclature Committee. These conventions serve as rules for determining a suitable name for an ingredient in response to requests from raw material suppliers. Cosmetic ingredients that have been accepted for inclusion in the CID by the Committee are identified by the respective "CTFA Adopted Name."

In the Preface to the 5th Edition of the ICID (ICID-5), CTFA stated that "...the establishment of a uniform science-based nomenclature system is the major objective of the Dictionary..." CTFA has also acknowledged its interest in promoting international harmonization in world trade in the Preface to ICID-5, especially since other countries have in recent years recognized the ICID in their respective laws and regulations as the primary source of names for ingredients of cosmetics, toiletries, and other personal care products.

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* Beginning in 1991, with publication of the Fourth Edition, CTFA changed the name to the International Cosmetic Ingredient Dictionary (ICID).

FDA has also been active in promoting international harmonization of world trade. FDA published a Federal Register notice on November 28, 1994 (59 FR 60870) announcing the availability of a "Draft Policy on Standards" with respect to international harmonization. This announcement described the agency's goals and general principles designed "to encourage the initiation and support of efforts ... that will further the international harmonization of standards and policies for the regulation of products for which FDA has authority."

Among the general principles included in the FR announcement is the statement that "The harmonization activity should further FDA's mission to protect the public health by, among other things, ensuring that ... cosmetics are safe ... and that these products are labeled truthfully and informatively." Further, "The agency's primary goal in all of its international harmonization activities is to preserve and enhance its ability to accomplish its public health mission. Global harmonization is also approached with the aim of enhancing regulatory effectiveness, by providing more consumer protection with scarce government resources, and increasing worldwide consumer access to safe, effective, and high quality products."

CTFA Color Additive Harmonization Proposal

CTFA proposes that the identification of color additives in cosmetic ingredient declarations on products intended for distribution in the United States be allowed to include a "parenthetical" declaration of the Color Index (CI) Number in addition to the name of the color as listed in 21 CFR parts 73, 74 and 82. Currently, the dual designation of ingredients by use of parenthetical declarations is not permitted.

This proposal, which extends the system currently used in ICID-5, would seem to facilitate international harmonization by allowing a labeling system suitable for multiple markets. The use of dual declarations for color additives by US and EU designations would be unlikely to mislead or confuse consumers in the US marketplace since product labeling will continue to include as the primary declaration terms already recognized by consumers. However, the establishment of an alternative nomenclature scheme requires amendment of the applicable regulations through rulemaking.

As you are aware, color additives intended for use in the United States must be specifically approved for such use. Color additives are the only ingredients used to formulate cosmetic products that are subject to approval before they can be used. For the purposes of label declarations, the names that must be used for color additives are established in the regulations that

approve their use. In some cases, FDA has allowed the use of abbreviated or shortened names as a means to conserve space on product labels, provided the abbreviated name still conveys to the consumer the necessary information to properly identify the ingredient. Commercial or trade names are not permitted.

In the case of color additives that are subject to certification, special names have been established that are unique to the additive. These names can be used only after the additive has been determined to comply with the chemical and identity specifications in the listing regulation and has been issued a certification lot number by FDA. This requirement applies to each and every batch of color additive intended for use in the US.

The monographs in ICID-4 for color additives subject to certification (i.e., listed in 21 CFR part 74 and 82) include a statement about the regulatory name assigned to batches of the color additive that have been certified by the FDA. For example, the monograph in ICID-4 for FD&C Yellow No. 6 (page 206) includes the statement:

> The name FD&C Yellow No. 6 can be used only when applied to batches of color that have been certified according to United States certification regulations. The CTFA Adopted Name for non-certified batches of this color is Sunset Yellow.

The identical monograph in ICID-5 (page 273) includes the following statement:

> The INCI Name, FD&C Yellow No. 6, is the name assigned to batches of this colorant that have been certified by the U.S. FDA. The INCI Name for this colorant that has not been certified by the U.S. FDA is Sunset Yellow. ... The INCI Name, CI 15985, will have to be used on package labels in all European Community (EC) Member States when used as a cosmetic colorant under regulations established in the Cosmetics Directive 76/768/EEC once the 6th Amendment to this Directive goes into effect.

According to this statement, common names for batches of the same colorant that have not been certified by the FDA are adopted as alternate INCI names, and the CI number for the color additive will be required on product packaging labels intended for distribution in the EC once the 6th Amendment to the Cosmetics Directive goes into effect.

Designation of color additives in this manner in ICID monographs may suggest that there is an equivalence between the certified color additive and the matching color additive identified in the EU by the corresponding CI Number (which may either be certified or noncertified). In a letter to FDA dated February 8, 1995, CTFA correctly observed that references in the ICID to the technical names for the "non-certified" batches of color additives were added to each respective monograph because of concerns expressed by FDA that, without such clarification, firms may mistakenly believe that non-certified batches of color additive may be used as an approved colorant in the United States. However, the disclaimers in ICID-4 and ICID-5 only refer to matters of nomenclature. The disclaimer does not state that, with the exception of hair colors, only color additives that have been certified, and issued a certification lot number by FDA, may be used in cosmetic products intended for distribution in the United States. Without a clearer statement on this matter, we believe that there is a high potential for confusion on the part of cosmetics manufacturers and suppliers doing business in the international arena.

The change proposed by CTFA for declaration of color ingredients on product labels also applies to color additives exempt from certification which are listed in 21 CFR part 73. For these colors, there is no requirement that each batch of color be submitted to FDA for examination to ensure compliance with applicable chemical and identity specifications. However, certification-exempt color additives used in cosmetics must still comply with all applicable regulations, including the use of the name identified in the listing regulation.

Examination of the individual CID monographs finds that ICID-4 addresses certification-exempt colors only to a very limited degree, and that ICID-5 provides incomplete information about the regulatory requirements for these additives in the U.S. For example, the ICID-4 monograph for the color additive Iron Oxides (21 CFR 73.2250) (page 257) only includes the regulatory citation for the additive and makes no mention of its use as a pigment for coloring cosmetic products or the regulatory requirements for its use. The ICID-5 monograph for Iron Oxides (page 336) includes the following statement:

> The INCI Name, Iron Oxides, is assigned to the colorant that meets U.S. color additive specifications. ... The INCI Names, CI 77489, CI 77491, CI 77492 or CI 77499, will have to be used on package labels in all European Community (EC) Member States when used as a cosmetic colorant under

regulations established in the Cosmetics Directive 76/768/EEC once the 6th Amendment to this Directive goes into effect.

As with the certified color monographs, designation of color additives in this manner suggests that there is an equivalence between the color additive intended for use in the U.S. and the matching color additive identified in the EU by the corresponding CI Number. This suggestion is true only if the additive meets the chemical and identity specifications listed in the CFR. Without a clearer statement to address this matter, there is a high potential for confusion on the part of cosmetics manufacturers and suppliers doing business in the international arena.

There are also several issues relating to inclusion of the CI Number in parenthesis after the name adopted in the U.S. An FDA advisory opinion dated September 26, 1985 noted that: "The Food and Drug Administration ... concludes that the addition of parenthetical statements of origin, function, or alternate ingredient name, after the name of an ingredient in a cosmetic declaration, is inappropriate and inconsistent with the requirements and purposes of 21 CFR 701.3." Among the reasons given for this opinion was the belief that, since the purpose of an ingredient declaration is to identify the ingredients of the product in a uniform manner, parenthetical statements that significantly increase the size of the declaration and reduce the continuity in ingredient identification are likely to detract from that purpose. Additionally, FDA reasoned that the disclosure of other chemical or technical names for an ingredient could confuse consumers more than enlighten them.

Since that time, however, other rulemaking proceedings have addressed the issue of parenthetical statements in product labeling. In a Final Rule published on March 28, 1995 (60 FR 15871), FDA revised its regulations to recognize the acronym "DATEM" on product package labels as the alternate common or usual name of the ingredient diacetyl tartaric acid esters of mono- and diglycerides (a direct food additive utilized as a dough modifier/conditioner for baked goods). In an earlier Final Rule (54 FR 13168, March 31, 1989), FDA had permitted the use of "DATEM", immediately following the name of the ingredient. At the time, FDA stated that "...public exposure over a period of time could lead to eventual acceptance of the acronym as an alternate usual and customary name...."

By the time that the Proposed Rule leading to the 1995 Final Rule was published on December 1, 1994 (59 FR 61560), the petitioner had demonstrated that: 1) the dual parenthetical declaration on

package labeling had been used on the labels of a majority of baked goods products utilizing this ingredient, many of them distributed nationally and consumed by the public on a daily basis for five (5) years; 2) the term "DATEM" had been used in the scientific and trade literature for a period of at least 15 years; and, 3) the term "DATEM" was widely enough accepted in scientific circles to be used as an indexing term for a scientific on-line literature retrieval search.

FDA's actions with respect to "DATEM" were consistent with its earlier decision in adopting "canola oil" as the alternate common or usual name for low erucic acid rapeseed oil (53 FR 36067 and 53 FR 52681). In that rulemaking, the agency found that, after a period of dual parenthetical declaration of approximately five (5) years, it could be concluded that "...there has been sufficient exposure to the term 'canola oil' to allow the American consumer to recognize and understand the term..."

Thus, if CTFA petitions the agency to amend the cosmetic ingredient labeling regulations to specifically provide for the declaration of color additives by their official names and the EC Color Index designations in the ingredient statement, we would be unlikely to object, during consideration of the petition, to products intended for sale and distribution in the United States that bear such a dual declaration in the ingredient statement.

Considering the factors discussed above, we also believe that the disclaimer contained in each respective color additive monograph in ICID-6 and subsequent editions of the ICID, should be modified to effectively alert manufacturers of finished cosmetic products (other than hair dyes) intended for sale in the United States that, although a dual declaration for the color additive name might be used for cosmetic labeling purposes, U.S. law requires the use of only color additives in their products that are in full compliance with applicable regulations. The use of an uncertified, and therefore unapproved, color additive in a cosmetic renders such product adulterated within the meaning of the Federal Food, Drug and Cosmetic Act (FD&C Act).

<u>CTFA Denatured Alcohols Harmonization Proposal</u>

In the EU, the term "Alcohol Denat." is the accepted name for ingredient labeling of alcohols that have been denatured in accordance with any of the national regulations of the nine countries of the EU. In the United States, however, Specially Denatured Alcohols (SD Alcohols or SDA) bear names and acceptable compositions established by regulations published by the Bureau of Alcohol, Tobacco, and Firearms in formularies given at 27 CFR 21.32-21.81. For a given SDA formulation, several alternative specific denaturants may be utilized in alcohol-containing products marketed in the U.S.

Designation of denatured alcohol ingredients using either "SD Alcohol 40-B," "Alcohol Denat.," or "SDA 40-B" appears to be equally likely to contribute to preventing consumer deception or facilitating value comparison at point of purchase, assuming that the name chosen is consistently applied to identify the ingredient, and that the name has meaning to the consumer. However, the establishment of an alternative nomenclature scheme requires amendment of the applicable regulations through rulemaking.

CTFA should petition the agency and suggest a mechanism that will provide for consistent nomenclature for denatured alcohol ingredients in cosmetics and ensure that only appropriate ingredients are used in formulating the different product types.

If such a petition if filed, FDA would be unlikely to object, during consideration of such a petition, to cosmetics intended for sale and distribution in the United States that bear the term "Alcohol Denat." as a description of the denatured alcohol ingredients used in formulation of the product.

CTFA Harmonized Plant Extracts Proposal

CTFA proposes that plant extracts be identified using the Linne System (genus/species) of taxonomic nomenclature followed by the current English plant name in parenthesis. Acceptance of this proposal would allow all plant extract names to be declared on product labels using Latin names with their common English equivalents appearing secondarily in parentheses.

As discussed previously, the FPLA requires that "...packages [of consumer commodities] and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons...." Ingredient labeling of consumer commodities intended for sale in the United States is required by the FPLA, which states "... that the label on each package [shall] bear (A) the common or usual name of such consumer commodity, if any, and (B) in case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed in order of decreasing predominance..." (FPLA, Section 5(c)(3)).

The use of Latin names as the primary identifying term for plant extract ingredients, with the current common name appearing imbedded in parenthesis, would not be consistent with the FPLA. The statute requires the use of the common or usual name, and there is no way that such requirement can be considered to be met by placement of the recognized common or usual name in

parentheses after the Latin name. Nor is the agency willing to accept the Latin name as the common or usual name of such ingredients. Such a change would be confusing to consumers and would not prevent deception or facilitate value comparisons.

FDA recognizes the potential importance and benefit of international harmonization of the marketplace to the cosmetic industry and will support such efforts in a manner consistent with the policy statement recently published in the Federal Register (59 FR 60870). However, we cannot accept the current CTFA proposal that the genus/species names, using the Linne system in the primary position with the English plant name in parenthesis, be allowed for the purpose of declaring botanical ingredients on the labels of products intended for distribution and sale in the United States.

With respect to the designation of color additives, CTFA has proposed that the alternative declaration using the Color Index Number be declared in parenthesis after the primary common or usual name. As an alternative approach to using the Latin name as the primary designation, CTFA may wish to consider a similar approach for dual declaration of plant extract ingredients, where the current common or usual name is stated as the primary designation followed in parenthesis by identification using the Linne System (genus/species) of taxonomic nomenclature. Whatever approach CTFA chooses to propose, the establishment of an alternative nomenclature scheme requires amendment of the applicable regulations through rulemaking.

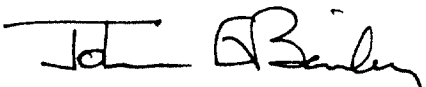
If CTFA petitions the agency to amend the cosmetic ingredient labeling regulations to specifically provide for the declaration of plant extracts by their common or usual name followed in parenthesis by their Linne INCI name in the ingredient statement, we would be unlikely to object during consideration of the petition to products intended for sale and distribution in the United States that bear such a dual declaration in the ingredient statement.

In your letter, you also mention the need for an orderly conversion to new labeling names for plant extracts and propose that a transition period be established to educate the public to the new names. You identify the transitional process as a "joint FDA/CTFA voluntary program" that includes the three elements described above. Clearly, the establishment of an effective transitional plan for such a significant change in cosmetic product labeling is critical to ensuring that the requirements of the FPLA are met. We agree that an orderly conversion can take the form of a collaborative effort between CTFA and FDA. However, no conversion can take place until there is evidence that American consumers accept and understand the terminology that you would have accepted as the new common or usual names.

Moreover, CTFA must provide a detailed description of the proposed transitional plan before we can consider any agency participation in the program. FDA has only limited resources available for the cosmetics program and must consider prioritization of work among many different, competing areas before committing to any new projects. FDA would certainly consider distributing to the public "...consumer informational materials which would cross reference the current English INCI names and the proposed Linne INCI Name." We would expect that such materials will include a comprehensive list of botanical ingredients used in cosmetic products that cross references the current English INCI names and the proposed Linne INCI Name.

I trust that the above comments on CTFA's March 14, 1995 and March 24, 1995 proposals on "International Harmonization of Cosmetic Nomenclature" are helpful. Although we cannot fully endorse all of the changes proposed in your letters, we agree that use of this universal nomenclature by the worldwide cosmetic industry would enhance uniformity in ingredient labeling. Please feel free to contact this office should you have any additional questions on this matter.

Sincerely,



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