C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

September 20, 1996

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Petition: International Cosmetic Ingredient Dictionary - Harmonization of Ingredient Labeling Names and Recognition of the Sixth Edition (1995).

Dear Sir or Madam:

The Cosmetic, Toiletry, and Fragrance Association (CTFA)[1] submits this petition under section 5(c)(3) of the Fair Packaging and Labeling Act, 15 U.S.C. § 1454; section 701(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 371 (e); and Food and Drug Administration (FDA) regulations, 21 C.F.R. § 701.3 (c)(2)(i), requesting the Commissioner of Food and Drugs to amend 21 C.F.R. § 701.3 (c)(2)(i) to: (1) recognize revisions in selected International Nomenclature Cosmetic Ingredient (INCI) labeling names that are currently listed in the Sixth Edition (1995) of CTFA's International Cosmetic Ingredient Dictionary (the Dictionary) as suitable for the purpose of cosmetic ingredient labeling; (2) recognize the dual listing of "may contain" as set out in 21 C.F.R. § 701.3 (g) and the symbol "+/-" to signify that some batches of a product may or may not contain one or more color additives for reasons of color matching; and (3) amend 21 C.F.R. § 701.3 (c)(2)(i) to recognize the International Nomenclature Cosmetic Ingredient

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[1] CTFA is the national trade association representing the cosmetic, toiletry, and fragrance industry. Founded in 1894, CTFA has an active membership of approximately 250 companies that manufacture or distribute the vast majority of finished personal care products marketed in the United States. CTFA also includes approximately 270 associate member companies, including manufacturers of raw materials, trade and consumer magazines, and other related industries.

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SECURING THE INDUSTRY'S FUTURE SINCE 1894

(INCI) names in the Sixth Edition of the Dictionary as suitable for the purpose of cosmetic ingredient labeling.

Second, this petition requests FDA to delete 21 C.F.R. § 701.3 (c)(2)(i)(a),(b), and (c), which pertain to names and definitions contained in the Second Edition of the CTFA Cosmetic Ingredient Dictionary (1977) that were, respectively, not adopted for cosmetic ingredient labeling; adopted provided their monographs were revised to more fully describe their chemical composition; and names adopted for a specified period of time. The above- referenced changes and corrections, to the extent that they were technically feasible, were published in 1991 in the Fourth Edition of the Dictionary.

Third, CTFA requests a statement from FDA specifically permitting and encouraging the use of the nomenclature in the Sixth Edition of the Dictionary while this rulemaking is in progress as a means of encouraging international harmonization of cosmetic ingredient labeling names.

This petition requests that the FDA adopt certain revisions in the currently recognized ingredient labeling names for four categories of ingredients to permit cosmetic manufacturers marketing products intended for sale in both the United States and the European Union (EU) to use a common ingredient statement on package labels. In addition, this petition requests that the ingredient statement on cosmetic packages be permitted to list certain ingredients under dual labeling names and that the manner of identifying color additives that may or may not be present in some shaded products by using the phrase "may contain" be permitted to also use the symbol "+/-" parenthetically during a transitional period to permit international harmonization.

CTFA is requesting the adoption of some of these revisions at this time at the request of the FDA as set out in its letter to CTFA dated June 1, 1995, concerning international harmonization of cosmetic ingredient labeling names. The June 1, 1995, letter was in response to letters from CTFA dated March 14, 1995, and May 24, 1995, requesting that FDA permit the interim use of selected "harmonized" names until such time that the changes can be considered as part of a petition requesting the adoption of revised labeling names. In its letter to CTFA, the FDA stated that the

agency would be unlikely to object to the use of the revised names during consideration of a petition to amend applicable regulations through rule-making. There are four categories of ingredients for which revisions of labeling names or the use of "dual" names on package labels are requested, namely, colorants, denatured alcohol, botanically-derived ingredients, and EU trivial or common names to be used exclusively in the EU.

A. ACTION REQUESTED

(1) Amendment of Regulation to Permit Dual Declaration of U.S. and EU Approved Colorants.

The Code of Federal Regulations 21 C.F.R. § 701.3(c)(2) state that in the absence of a name specified at § 701.30 the name adopted for that ingredient at 21 C.F.R. § 701.3 (c)(2)(i) shall be used. The compendium listed at this reference is the CTFA Cosmetic Ingredient Dictionary, Second Edition (1977). For cosmetic colorants approved by the FDA, the currently recognized names in the Sixth Edition of the Dictionary , are those listed at 21 C.F.R. § 73, 74, and 82.

CTFA requests that firms marketing the same formulation in the U.S. and EU be permitted to identify the U.S. approved colorants by the name listed in the C.F.R., followed by the name specified in the EU Inventory of Cosmetic Ingredients listed parenthetically. The names for colorants listed in the EU Inventory are listed in Annex IV of the Sixth Amendment to the Cosmetics Directive 76/768/EEC. With few exceptions, colorants are listed in Annex IV by their Colour Index number. Examples of the dual listing requested for colorants are:

FD&C Green No. 3 (CI 42053)
Ext. D&C Violet No. 2 (CI 60730)
Ultramarines (CI 77007)
Bismuth Oxychloride (CI 77163)

A letter from FDA, dated June 1, 1995, expressed concern that the individual monographs in some editions of the Dictionary provided incomplete information about the regulatory status of colorants approved for use in the U.S. FDA requested that CTFA remedy this by using appropriate disclaimers in each respective color additive monograph in the upcoming Sixth Edition and subsequent editions of the Dictionary. FDA requested that the monographs for colorants alert

manufacturers of finished cosmetic products (other than hair dyes) intended for sale in the U.S. that U.S. law requires the use of only those color additives that are in full compliance with applicable regulations.

CTFA agreed with FDA that additional information concerning the regulatory status of colorants could be provided to prevent the use of uncertified and therefore, unapproved colorants in cosmetic products offered for sale in the U.S. To accomplish this, the monographs in the Sixth Edition of the Dictionary for each colorant that is approved for use in the U.S. and the EU contains guidance regarding its regulatory status. In addition, information has been added to the monographs for coal-tar hair dyes to assure that these colorants, which are exempt from the color additive provisions of the FD&C Act, are not inadvertently used in violation of FDA regulations. Finally, to further assure compliance with FDA requirements for colorants, each pertinent monograph for colorants in the Sixth Edition of the Dictionary refers labelers to the Introduction of the Dictionary, where a full discussion appears on the regulatory status of colorants for products offered for sale in the U.S. Attachment 1 provides examples of monographs for colorants with the disclaimers as they appear in the Sixth Edition.

CTFA believes that the precautions provided and the disclaimers listed in the Sixth Edition will assure that firms using the dual listing of colorants on product labels will be in compliance with color additive regulations applicable in the U.S. In addition, the approach used in the Sixth Edition for colorants, more than satisfies FDA's concerns as expressed in its letter to CTFA dated June 1, 1995.

(2) Amendment of Regulation to Recognize a New Labeling Name for Denatured Alcohols.

The currently adopted labeling names for denatured alcohols in the U.S. are those established by the U.S. Department of the Treasury, Bureau of Alcohol, Tobacco, and Firearms regulations at 27 C.F.R. § 20.11 and §§ 21.32 through 21.81. The Sixth Edition currently lists 26 SD Alcohols and 1 CD Alcohol as labeling names for cosmetic products offered for sale in the U.S. Ethyl alcohol that is not denatured is identified for ingredient labeling by its common name, Alcohol.

Each country has its own requirements for assuring that alcohol used for purposes other than for beverages for human consumption, is not used in a manner contrary to the national laws. These regulations prescribe the manner in which alcohol may be denatured to be rendered not potable for human consumption and otherwise meet national requirements.

In the U.S., the labeling names utilize the terms "SD" (standard denatured) or "CD" (completely denatured) followed by the word "Alcohol" and the formulation designation as prescribed in 27 C.F.R. §§ 20 and 21, e.g., SD Alcohol 38B. In the EU, the name "Alcohol Denat." appears in the EU Inventory of Cosmetic Ingredients as the labeling name for alcohols that have been denatured in accordance with any of the national regulations of the fifteen Member States of the EU.

To achieve international harmonization of labeling names for denatured alcohols, CTFA requests that the FDA adopt the name "Alcohol Denat." for ingredient labeling in the U.S. to represent all denatured alcohols currently recognized for ingredient labeling. To assure that the appropriate denaturing ingredients are used in the U.S. for different product categories as prescribed by regulation, CTFA proposes to expand the monograph information sources and definition for "Alcohol Denat." in future editions of the Dictionary to identify the source of appropriate formulations in compliance with 27 C.F.R. §§ 20 and 21.

(3) Establishment of Interim Labeling Names for Botanically-Derived Ingredients.

CTFA requests that new interim labeling names be adopted for botanically-derived ingredients that have not undergone significant chemical modification. The types of ingredients in this category include extracts, juices, waxes, gels, oils, saps, tars, gums, unsaponifiables, proteins, starches, and resins. In previous editions of the Dictionary, the labeling names for botanicals were derived from the common names of the plant followed by the plant part (if applicable) and the type of preparation, e.g., extract, oil or wax. Where a plant did not have a widely known common name, the labeling name was based on the Linné system using the genus or the genus and species name of the plant.

Because of the national language preeminence concerns in the EU Member States, new labeling names for botanicals were established in the EU Inventory of Cosmetic Ingredients. These names

are different from those that are currently recognized for labeling in the U.S. The labeling names in the EU are based on the Linné system in which, in general, the genus/species names of the plant are used.

As an interim step to further harmonization, CTFA proposes that botanicals be identified by dual names in which the U.S. common name appears first (when such name is widely recognized) followed by the Linné system genus/species name in parentheses, followed by the plant part (if applicable), followed by the type of preparation, such as extract, oil or wax. Examples of the labeling names for a botanical are:

Previous name: Peach Leaf Extract
EU name: Prunus Persica
New interim name: Peach (Prunus Persica) Leaf Extract
Future international name: Prunus Persica Leaf Extract

The new interim names for botanicals as published in the Sixth Edition of the Dictionary have met with wide acceptance by industry and by the scientific and medical communities both in the U.S. and the EU. This approach has also received the strong support of Colipa, the trade organization representing the national trade associations in the EU Member States. Examples of monographs from the Sixth Edition representing the new interim names for botanicals may be found in Attachment 2.

FDA's letter of June 1, 1995, and CTFA's letter of May 24, 1995, discuss the issue of an orderly conversion and a transition period to be established to educate the public to the new botanical names. During the transition period, CTFA proposes that: cosmetic firms be permitted to voluntarily use the new interim names; FDA permit the use of dual name declarations until such time as the changes are recognized by FDA; and a joint CTFA and FDA consumer education program be implemented whereby pertinent information for consumers and other members of the public, such as the medical community, would be made available.

In regard to the orderly conversion to the new labeling names, CTFA has already sent a notice to over 9,000 dermatologists of the American Academy of Dermatology through CTFA's publication

"On-Call." CTFA has made presentations at meetings on dermatology, in both the U.S. and abroad, to publicize these labeling changes. CTFA will be making additional presentations in the future to further promote an international understanding of this matter.

In addition, CTFA will provide the pertinent background information to the FDA and will actively participate in the preparation of consumer literature or a publication of FDA's choice, such as the "FDA Consumer Magazine," describing the new and revised labeling names for cosmetic products.

(4) Amendment of Regulation to Permit Dual Declaration of EU Trivial Names and U.S. Labeling Names.

CTFA requests that firms marketing the same formulation in the U.S. and the EU be permitted to identify ingredients, referred to as "trivial" names in the EU, using dual labeling names. One name would be the currently recognized name for ingredient labeling in the U.S., the other the "trivial" or common Latin name, listed in the EU Inventory of Cosmetic Ingredients.

The so-called "trivial" names are based on names used in the European Pharmacopoeia which should be well-known throughout the EU, where 15 different languages are spoken. The EU Inventory of Cosmetic Ingredients currently lists 57 EU trivial names. The monographs in the Sixth Edition identify each EU trivial name and its corresponding U.S. labeling name or names. In addition, the monographs for U.S. labeling names also identify the corresponding EU trivial name if such name is listed in the EU Inventory. Examples of the dual U.S. and EU trivial labeling names are:

US name: Water
EU name: Aqua
Dual label name: Water (Aqua)

US name: Egg Powder
EU name: Ovum
Dual label name: Egg (Ovum) Powder

Attachment 3 provides appropriate examples of monographs of EU trivial names and their corresponding U.S. labeling names.

(5) Establishment of the Interim Use of the Symbol "+/-" With the Phrase "may contain."

Under 21 C.F.R. § 701.3 (g)(1) and (2), a declaration of ingredients may include an ingredient not in the product if the ingredient is identified by the phrase "may contain" and other requirements are also met. This provision is intended to allow color matching of selected shaded products and applies only to color additives under specific conditions specified in the regulation.

CTFA requests that the phrase "may contain" be replaced by the symbol "+/-" after a transitional period. The transitional period will allow consumers to become familiar with the new symbol. During the transitional period, the following dual designation will be used in labeling: "May Contain (+/-)." During the transitional period CTFA will promote projects to educate the public about the use of the new symbol.

(6) Amendment of Regulation to Recognize Sixth Edition of Dictionary.

The existing regulation, 21 C.F.R. § 701.3(c)(2), states.that in the absence of a name specified by the Commissioner in 21 CFR § 701.30, the primary nomenclature source for identifying a cosmetic ingredient in a label declaration shall be:

> (i) CTFA (Cosmetic Toiletry and Fragrance Association) Cosmetic Ingredient Dictionary, Second Ed., 1977 (available from The Cosmetic, Toiletry, and Fragrance Association, 1110 Vermont Avenue, N.W., Suite 800, Washington, DC 20005, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408, which is incorporated by reference except for the following deletions and revisions:

CTFA requests that 21 C.F.R. § 701.3(c)(2) be amended to read as follows:

> (i) International Cosmetic Ingredient Dictionary, Sixth Ed., 1995 (available from The Cosmetic, Toiletry, and Fragrance Association, 1101 17th Street N.W., Suite 300, Washington, DC 20036, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408, which is incorporated by reference.

A copy of the Sixth Edition (1995) of the Dictionary (Volumes 1 and 2) accompany this petition.

CTFA requests that a Federal Register notice proposing this amendment be published as soon as

possible, and that after a reasonable comment period, a final order be expeditiously published. CTFA also requests that the effective date of the final regulation be stated as follows:

> Compliance with this regulation may begin immediately. All cosmetic product labeling ordered after twelve months following publication of the final order in the Federal Register shall comply with the amended regulation.

This would be consistent with the effective date set by the agency in the final order recognizing the Second Edition (1977) of the CTFA Dictionary, 45 Fed. Reg. 3574 (January 18, 1980), and would insure the least disruption to cosmetic companies, consistent with the goal of achieving a smooth transition to the use of the most current and comprehensive source of nomenclature.

B. STATEMENT OF GROUNDS

1. Importance of Harmonization.

Cosmetic ingredient labeling under the Sixth Amendment to the EU Cosmetics Directive 76/768/EEC is scheduled to become effective in January 1997. This law recognizes, with some exceptions, the cosmetic labeling names listed in the Sixth Edition of the Dictionary. The exceptions are associated with the four categories of ingredients that are the subject of this petition and the use of the symbol "+/-" in conjunction with the phrase "may contain."

FDA also recognized the importance and benefits of international harmonization of regulatory requirements for consumer commodities when it indicated that it will support such efforts in a manner consistent with its policy as recently published in the Federal Register, 59 Fed. Reg. 60870-6 (November 28, 1994). In this notice, the FDA announced that one of its goals was to minimize or eliminate inconsistent international standards.

This petition requests a uniform standard of nomenclature for products intended for sale in international markets. In addition, it will promote another goal stated by FDA, namely, the assurance of consumer protection. CTFA believes that uniform nomenclature standards will benefit consumers and the medical community by assuring a common name for cosmetic ingredients regardless of their source or country of origin.

In its policy statement on international harmonization, the FDA also noted that among the general principles that should guide the agency's efforts are the following: the activity should promote U.S. interests in foreign countries; the agency should accept, where permissible, equivalent standards; and such activities should be open to the public. This petition meets or exceeds these principles. It is clearly in the economic interest of the U.S. for cosmetic firms to have a uniform standard for product labels, that will promote uniformity and enhance consumers' ability to make value comparisons. The rule-making procedures associated with the petition process will provide the opportunity for consideration of the views of all interested parties.

The revisions of ingredient names provide equal or more information for the consumer on which to base value comparisons. For example, in the case of the proposed new labeling names for botanicals, the genus/species identification is often more specific than the current common plant name. Dermatologists have indicated that the genus/species identifications of botanical ingredients are of greater value because those are the names that most often appear in the scientific literature when issues of safety of an ingredient come under review.

2. Use of the Symbol "+/-".

In a letter to FDA dated August 2, 1995, CTFA requested that the phrase "may contain" be replaced by the symbol "+/-." The phrase "may contain" as provided in 21 C.F.R § 701.3 (g)(1)and(2) is intended to permit "color matching" for a very limited number of product categories, i.e., shaded products. In its letter dated January 17, 1996, the FDA advised that it is not aware of any information that convincingly demonstrates that the substitution requested would be understood. Further, the agency expressed the view that without an appropriate basis for establishing that the proposed symbolic representation is, in fact, accepted and understood by American consumers, it must conclude that such a change would be confusing and would not prevent deception or facilitate value comparisons. FDA suggested that CTFA may want to petition for a step-wise alternative approach that provides a period of reeducation of the public to the proposed symbolic representation. In addition, the agency requested that evidence be generated to substantiate that the American consumer has, in fact, accepted and understands the meaning of the new symbolic alternative.

CTFA is petitioning for a step-wise replacement of the phrase "may contain" with the symbol "+/-" to include a transitional period to allow consumers to become familiar with the new symbol.

However, CTFA disagrees that it is necessary to provide evidence that consumers understand the new symbol after the transitional period. CTFA believes that dual listing of the symbolic representation along with the term "may contain" during a transitional period of use will be sufficient. CTFA also believes that FDA's conclusion that the symbolic representation will prevent consumer from making value comparisons is flawed.. The use of the phrase "may contain" in ingredient labeling is intended to permit color matching and to permit firms to market specified shaded products in which some batches of a product may not contain a color additive. CTFA does not understand how the absence of a color additive in a given product would be confusing, deceptive, and prevent consumers from making value comparisons, especially since the facts are disclosed in labeling. No issue of safety is involved. The agency should support this change in line with its stated policy of supporting international harmonization as long as agency's goals of product safety and truthful and informatively labeled products are not compromised.

In addition, it would be very costly and difficult to substantiate, in a meaningful way, that the American consumer accepts and understands the use of the "+/-" symbol.

3. Recognition of the Sixth Edition (1995) of the Dictionary.

In 1972, CTFA published the First Edition of the CTFA Cosmetic Ingredient Dictionary (in 1993 the title was changed to the International Cosmetic Ingredient Dictionary) which was adopted by the FDA at 21 C.F.R. § 701.3(c)(2) as the source of uniform cosmetic ingredient names for ingredient labeling of cosmetic package labels. In 1977 CTFA published the Second Edition of the CTFA Cosmetic Ingredient Dictionary. FDA amended 21 C.F.R. § 701.3(c)(2) to recognize this compendium in 1980 (45 Fed. Reg. 3574-78, January 18, 1980). These editions of the Dictionary were compiled through joint efforts by the cosmetic industry and the FDA. Without these efforts, uniform and meaningful cosmetic ingredient labeling would not be possible.

CTFA further reaffirmed its commitment to consumers and other members of the public by regularly

publishing expanded and updated editions of the Dictionary, namely, the Third Edition (1982) and Supplement (1985), the Fourth Edition (1991), the Fifth Edition (1993) and the Sixth Edition (1995). CTFA submitted petitions for the Third Edition in 1982, the Third Edition and Supplement in 1985, and the Fourth Edition in 1991. Although the FDA did not act on these petitions, the agency did provide information to clarify its views on some complex nomenclature issues that were pending to serve as guidance for future editions. The guidance provided by the agency was used to revise and expand the information that has now been published in the Sixth Edition (1995) of the Dictionary.

In 1996, the European Commission published, with few exceptions, the names in the Sixth Edition of the Dictionary for inclusion in the EU Inventory of Cosmetic Ingredients, the source of labeling names for the 15 countries of the EU. In addition, Japan, South Korea, Australia, Canada, Saudi Arabia, Brazil, Mexico, Singapore, Norway, Thailand and the Philippines have cited the Dictionary as a source of names for ingredient labeling or for other purposes in their national laws or regulations. The use and acceptance of the Dictionary by many countries around the world reaffirms it as the most authoritative compendium for uniform nomenclature for cosmetic ingredient labeling purposes.

The recognition of the Sixth Edition outside of the U.S. has led to a substantial increase in the number of INCI labeling names in the Dictionary. The number of INCI labeling names in the Sixth Edition increased from 6,150 to 7,637 since publication of the Fifth Edition in 1993. This trend in the expansion of the Dictionary will continue as ingredient labeling becomes mandatory under the laws of many other nations. With the advent of international harmonization as an essential element of international trade, U.S. cosmetic firms need the prompt recognition of the current edition of the Dictionary.

CTFA recognizes that resources at the agency are limited and are unlikely to increase in the foreseeable future. CTFA believes that it is incumbent on the FDA to speed the review and adoption of the current and future editions of the Dictionary. For the past 23 years, representatives of the FDA and CTFA have worked closely together to establish uniform and informative nomenclature for cosmetic product labels. FDA requests to modify labeling names or definitions have been

accepted by CTFA and its International Nomenclature Committee when such requests were shown to have a sound technical basis and to provide consumers with more informative and understandable names. To this end, CTFA proposes that FDA accept the Sixth Edition and future editions of the Dictionary as they are published with the proviso that any labeling names or definitions not acceptable to the agency be identified through rulemaking. This could be done in several ways. One way would be to add this language at the end of 21 C.F.R. § 701.3 (c)(2)(i): "... except for the following revisions." Another approach would be for the FDA to utilize 21 C.F.R. 701.30, under which the Commissioner establishes names for the purpose of cosmetic ingredient labeling. Either approach provides wide latitude for the FDA to exercise its prerogatives for selecting labeling names without delaying the recognition of the current and future editions of the Dictionary.

4. Fair Packaging and Labeling Act.

If implemented, the revisions requested in this petition will promote open commerce between nations that is free of artificial regulatory restraints that often impede efficient international trade.

Ingredient labeling published under the authority of the Fair Packaging and Labeling Act is intended to prevent the deception of consumers and facilitate value comparisons. Nothing requested in this petition will undermine these objectives.

Harmonization of cosmetic ingredient labeling names is a critically important issue facing the cosmetic industry in the U.S. Without harmonization, cosmetic firms in the U.S. and EU will not be able to have a common cosmetic product label for two of the largest world markets. The increased costs of production necessitated by different labeling names for each market cannot be justified.

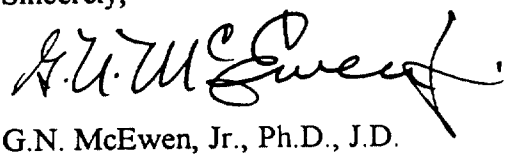
C. ENVIRONMENTAL IMPACT

Pursuant to FDA regulations, 21 C.F.R. Sec. 25.24, an environmental impact analysis report is not required for this citizens petition.

D. CERTIFICATION

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all the information and views on which it relies. There are no data or information known to the Petitioner that is unfavorable to the petition.

Sincerely,



G.N. McEwen, Jr., Ph.D., J.D.
Vice President -Science

Attachment 1 Sample monographs of Colorants from Sixth Edition of the Dictionary.
Attachment 2 Sample monographs of Botanicals from Sixth Edition of the Dictionary
Attachment 3 Sample monographs of EU Trivial Names from Sixth Edition of the Dictionary
Attachment 4 Copy (2 volume set), International Cosmetic Ingredient Dictionary, Sixth Edition (1995)