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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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

E. EDWARD KAVANAUGH
PRESIDENT

Re: Program Priorities (FY 2004) in the Center for Food Safety and Applied Nutrition: Request for Comments
Docket 98N-0359

Dear Sir or Madam:

The following comments are submitted by The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA") in response to the request for comments on Program Priorities for the Center for Food Safety and Applied Nutrition (CFSAN) for Fiscal Year 2004 (October 1, 2003 to September 30, 2004). 68 Fed. Reg. 33727 (June 5, 2003). Our comments are focused on proposed priorities relating to the regulation of cosmetics by CFSAN.

CTFA is the national trade association representing the cosmetic industry. Founded in 1894, CTFA has almost 600 members involved in formulating, manufacturing, distributing and marketing personal care products. Our members are responsible for manufacturing or distributing the vast majority of personal care products sold in the United States. Approximately one-half of our member companies are active members manufacturing or distributing cosmetics, toiletries and fragrances. The remaining one-half are associate members providing goods, or services to manufacturers or distributors.

The cosmetic industry takes pride in its strong safety record and long history of successful self-regulation. Our self-regulatory programs such as the Cosmetic Ingredient Review are not only very effective – they save scarce government resources. Working with CFSAN and specifically with the Office of Cosmetics and Colors within CFSAN, CTFA has supported many self-regulatory programs that have helped assure that the consumer will benefit from a wide variety of safe products. FDA's support for and participation in these programs has been a key factor in assuring their success.

As in the past, CTFA will continue to urge Congress to maintain adequate funding for cosmetic regulation in CFSAN. We strongly believe that a fully-funded, credible cosmetic regulatory program is necessary. In turn, we urge FDA

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1101 17TH ST., N.W., SUITE 300 WASHINGTON, D.C. 20036-4702
202.331.1770 FAX 202.331.1969
http://www.ctfa.org
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to make it one of its highest priorities to continue to work with the industry to assure the continued success of the Cosmetic Ingredient Review and our other self-regulatory programs.

This year we must add a strong concern that many important issues listed below are taking far longer than appears necessary or are not receiving the attention of CFSAN that is required. While we understand that the Agency will not always agree with us on the exact order of priority for certain matters, we believe it is not unreasonable to expect that color additive petitions or ingredient nomenclature issues that have been around for years be resolved. We also believe it is essential that the Agency address international harmonization issues more seriously and with greater resource commitment than has been done in recent years. These concerns affect many of the issues below, and we urge the Agency to address them.

The following are CTFA's proposals for inclusion in CFSAN's 2004 Program Priorities:

1. Ensure Adequate Resources and Facilities for the Office of Cosmetics and Colors

Despite CFSAN's recent move into new facilities in College Park, Maryland, the Office of Cosmetics and Colors did not benefit from this move. In fact, one could argue that their situation is worse because they are now in "temporary" facilities and are divided between downtown Washington and suburban Chantilly, Virginia. It is our impression that the dislocation resulting from this separation of different functions in the Office of Cosmetics and Colors, the recently completed moves and additional planned office moves in the future are resulting in a distraction from substantive issues that is hurting the ability of the Office to complete important substantive projects discussed in this document.

We urge CFSAN to expedite the steps that need to be taken to move the Office of Cosmetics and Colors into one facility that fulfills the needs of all components of that office. Too often we have heard that "The Move" is diverting the energies of FDA employees from other activities. "The Move" is listed in CFSAN's 2003 "A" List Priorities, giving it equal status with important substantive projects and giving it priority over other issues that are on the "B List" or are unlisted. This should not be allowed to overshadow important priorities for the indefinite future.

Whatever needs to be done should be done quickly to resolve this matter and remove it as a drain on the limited resources available in the Office of Cosmetics and Colors. CTFA will fully support whatever resource allocations are necessary to achieve this goal.

2. Complete Work on a Final Guidance for AHA-Containing Products

Publication of a Draft Guidance on labeling to advise consumers on the need for sun protection in connection with the use of AHA Products was an "A" List Priority that was completed early in December 2002. We urge CFSAN to continue this matter as an "A" List Priority until a Final Guidance is completed.

In June 2000, CTFA filed a Citizen Petition asking FDA to propose a regulation requiring a label statement regarding the use of sunscreen while using an AHA product and for 7 days after use. Specific labeling language was proposed, and the scope of the regulation requested was to apply only to products containing AHA ingredients intended to function as an exfoliant. In December 2002, FDA published a Draft Guidance with modified language that applies to all products containing AHAs. CTFA filed comments on January 31, 2003, taking strong issue with applying the labeling to all AHA products and suggesting certain other modifications to the Guidance. FDA has not yet acted to publish a final Guidance.

Because of the importance of this issue and the length of time it has been pending (over 3 years), we strongly urge that completion of this Guidance be placed on the CFSAN "A" List and that it be made a top priority to be completed well before the end of FY 2004.

3. Allow the Industry to Use Appropriate Ingredient Nomenclature to Facilitate International Harmonization

This is a repeated request for CFSAN attention to an important priority that will benefit the consumer and enhance international harmonization of labeling nomenclature.

a. Colour Index ("CI") Numbers

The Colour Index or "CI" number is recognized throughout most of the world as an appropriate way to label color additives. The FDA nomenclature is required only in the United States.

Designation of colorants on cosmetic product labels using the international CI number was begun in Europe in 1993 to lessen the confusion of providing "common names" in many different languages. Since that time, many countries throughout the world have accepted this approach, rather than requiring their own translations. CTFA and Colipa, the European cosmetic trade association, have both previously requested that FDA recognize the CI nomenclature, but no action has been taken on those requests.

As we advised last year, this matter has now become more urgent because of action proposed by Canadian authorities allowing use of the CI or FDA nomenclature on the condition that if FDA nomenclature is used, it must be translated into French. This will require differing labels for the two countries, as there would be a requirement for both the English and the French in Canada, and there is a prohibition against limited translation of labels in the U.S. However, if FDA allows the CI nomenclature, it would allow the same ingredient declaration to be used both in the U. S., Canada, and in many other countries.

The CI nomenclature is the international standard, and is recognized throughout the world as the appropriate way to designate color additives on the ingredient label. The FDA-required nomenclature poses an increasing barrier to international harmonization. The Canadian requirements only exacerbate the situation, and increase the burden on international trade.

In response to FDA recommendations in 1995, CTFA has fostered consumer education regarding CI Numbers by encouraging companies to include the CI Numbers in their ingredient statements. CTFA also has provided information to all members of the dermatology community through presentations and publications targeted to the American Academy of Dermatology, and to the American Contact Dermatitis Society. CTFA remains prepared to work with FDA to facilitate an even longer period of education for consumers, industry and medical professionals, if necessary, when the labeling for color additives is in transition, ensuring that there is no confusion associated with the change in nomenclature.

FDA has a long history of supporting simplified nomenclature for color additives. For example, by correspondence to the industry, FDA allowed shortened nomenclature (e.g. FD&C Red No. 40 became Red 40). We believe the current issue is easily resolved with no risk to the consumer and minimal regulatory burden to the Agency. CTFA believes that FDA's recognition of this nomenclature system can be accomplished through recognition by the Director of the Office of Cosmetics and Colors, and that no formal rulemaking is necessary. We urge that it be made a FY 2004 "A" List Priority.

b. Botanicals

Latin genus/species names are recognized throughout the world as the most specific form of nomenclature for botanicals. English "common" names are frequently not specific as to species, are confused by the public among differing genera, and are frequently only regionally applied. Additionally, the same genus and species is sometimes known by differing "common" names. The industry has moved to address the concern that use of "common" names for labeling botanical ingredients on cosmetics could be deceptive to English speaking users, and incomprehensible for an international nomenclature system, by providing genus and species names for botanical ingredients.

In 1994, CTFA recognized that the botanical ingredients were becoming increasingly important to the cosmetic industry, with the submission of many more ingredients for assignment of INCI names. In reviewing previously assigned botanical names, it was found that there was not a consistent system of name assignments, due to the fact that the original (1973) procedure of assigning common names had, over the years, become unusable as botanicals without true "common" names began to be presented. The system in 1994 was a patchwork of common names, genera names, and species names.

In an effort to provide more consistent and understandable nomenclature, in 1995 the *International Cosmetic Ingredient Dictionary*, 6th Edition, first began including the Latin genus and species as a parenthetical along with the names then being used. This was envisioned as a first step in moving to assigning the genus and species names as the primary ingredient labeling names. At this time as well, because of national language preeminence concerns in the European Union, it adopted botanical labeling that used only genus and species names. FDA provided a letter to CTFA that it would be unlikely to object to the new labeling names, genus and species as a parenthetical, and that it would consider an amendment to the labeling regulations if CTFA petitioned for one. The use of genus and species as a parenthetical continued through the 1997, 7th Edition of the *Dictionary*.

Also in 1995, CTFA began presentations to the dermatology community on the use of the new botanical nomenclature, and the reasons for including the genus and species as identifiers for botanical ingredients. An explanation of the new labeling was sent to each of the members of the American Academy of Dermatology, printed in the *Cosmetic Industry On Call*, a joint publication of the AAD and CTFA. In 1999, CTFA published a cross reference of botanical "common" to Latin names on its public website.

In the 2000 8th Edition of the *Dictionary*, CTFA began the final phase of the botanicals name change familiarization process by changing the order of presentation to provide the genus and species to the primary name, and putting the "common" name in a parenthetical. Additionally, where the previous "common" name had actually been a genus or species name (Acorus for Acorus Calamus), or where it did not appear in any scientific or medical publication indexed by the National Library of Medicine (Zedoary), or where confusing (Bedstraw), it was dropped as a parenthetical. The cross reference of "common" to Latin names was also included in the 8th Edition, and it also included further modification of the botanical names, in response to requests from FDA that more specific information on the botanicals be included in the name, by the addition of the relevant plant part used to produce the ingredient, and the type of preparation (extract, oil, etc.) to the name. This was continued through the 9th Edition, 2002.

In the 2004 10th Edition of the *Dictionary*, harmonization of botanical nomenclature with the international community is becoming more complete with the recognition of the European Union of the need to include plant part and type of preparation in the botanical name. This change is a part of the first update to the EU Inventory of Cosmetic Ingredients, which has been submitted to the EU Member States for adoption.

CTFA understands that, recently, an FDA official has referenced a previous edition of the *Dictionary*, and offered the opinion that the Latin genus and species names as published in the 8th and 9th Editions would not be acceptable for cosmetic product labeling. CTFA believes that there has been a sufficient time for education of the medical community and the consumer regarding the use of Latin for botanical nomenclature, and that it would be helpful now for the FDA to acknowledge the advantages of these INCI names over the use of the previous names. The primary advantage, of course, is the specificity and minimization of likely confusion from use of "common" names.

CTFA is willing to work with FDA to demonstrate the advantages of the Latin botanical nomenclature system, and to provide FDA with an electronic version of the botanical cross reference to put on its website.

We believe this issue is easily resolved with no risk to the consumer and minimal regulatory burden to the Agency. CTFA believes that FDA's recognition of this nomenclature system can be accomplished through recognition by the Director of the Office of Cosmetics and Colors, and that no formal rulemaking is necessary.

This issue also should be made a CFSAN FY 2004 "A" List Priority.

4. Complete the Review and Listing of Carbon Black as a Color Additive for Cosmetic Use

This is a repeated request for action on a matter originally suggested by FDA over a decade ago. Although FDA chose not to include this matter in its FY 2003 Program Priorities, we again urge that this be made an "A" List Priority and acted on immediately.

In the mid 1970s, FDA delisted Carbon Black as a colorant allowed for use in cosmetics because of a lack of analytical information on the types and quantities of polynuclear aromatic hydrocarbons (PAHs) adsorbed on the Carbon Black. Some of the PAHs had been shown to be carcinogenic in animals. Since there was no ability at that time to show that there were no carcinogenic constituents, FDA felt that it must delist Carbon Black under the Delaney Clause.

Following the adoption of the "constituents policy" used for Green 5, an Agency official suggested that CTFA should petition for the use of Carbon Black and

propose limits for PAHs that would ensure there would be no risk of cancer (a risk less than one/one million). In 1987, pursuant to this suggestion, CTFA filed a Color Additive Petition for Carbon Black, proposing a specification for total PAHs that would result in less than one/one million lifetime risk, even if the entire PAH population was the most potent of the possible PAHs that could be present. From that time to the present, FDA has asked for additional information several times and CTFA has responded to each request.

As we noted last year, this has resulted in a circular process where we are chasing a constantly moving target with no closure. FDA requests information, we supply it, and, after a minimum of 180 days, FDA requests additional information. The cycle has been going on for approximately 15 years.

CTFA believes it is past time that the Agency should come to closure on this issue. Either there is sufficient information or there should be one more final request for information with deadlines set for reaching a final decision.

This should be a FY 2004 CFSAN "A" List priority.

5. Adopt a More Efficient System for Adopting Changes in Cosmetic Ingredient Labeling Nomenclature

Once again, we urge CFSAN to propose an amendment to 21 CFR Section 701.3(c)(2), replacing the current regulation with the following language, to facilitate the use of new cosmetic ingredient nomenclature as it is developed:

In the absence of a name specified in Section 701.30, or specifically adopted by the Food and Drug Administration for the purpose of labeling cosmetic products and published on the Food and Drug Administration's Center for Food Safety and Applied Nutrition website, http://www.cfsan.fda.gov/-dms/cos-toc.html, the name adopted for that ingredient in the following compendia, listed in order as the source to be utilized:

(i) The most current edition, including supplements, of the International Cosmetic Ingredient Dictionary and Handbook, Cosmetic, Toiletry, and Fragrance Association, Inc., Washington, DC, (available from The Cosmetic, Toiletry, and Fragrance Association, Inc., 1101 17th Street, N.W., Washington, DC 20036, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., Suite 700, Washington, DC 20408).

(ii) The most current edition, including supplements, of the United States Pharmacopeia, (available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852,

or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., Suite 700, Washington, DC 20408).

(iii) The most current edition, including supplements, of the National Formulary, (available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., Suite 700, Washington DC 20408).

(iv) The most current edition, including supplements, of the Food Chemicals Codex, (available from the Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740-3835, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., Suite 700, Washington, DC 20408).

(v) The most current edition, including supplements, of USAN and the USP Dictionary of Drug Names (available from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., Suite 700, Washington, DC 20408).

This would implement a matter that has been a "B" List Priority in recent years, but has never been given a higher priority or acted upon. Making this change will recognize that there are continual changes in the compendia cited, with about 2,000 new ingredients added to the *International Cosmetic Ingredient Dictionary and Handbook* each year. It also will provide stability in the adoption of nomenclature for industry to use on cosmetic labels. It also will allow CFSAN, through review of the changes and additions to nomenclature made each year, to specify alternative names that must be used for labeling purposes, by publishing alternative names on CFSAN's cosmetic website.

Through its representative on the International Nomenclature Committee, which also includes a representative of the Canadian Government and European Commission, FDA participates in the naming process and receives all information available on new ingredients to allow an independent decision as to the appropriateness of any particular name assignment. This process provides FDA with ample opportunity to prepare any alternative names that it believes should be used, and to have those listed on its website, prior to publication of the next edition of CTFA's *Dictionary*.

6. Implement the WEB-based Voluntary Cosmetic Registration Program

This was an "A" List Priority for FY 2003 that was not completed. Although FDA and CTFA did work together during 2002 to Beta test the system, it is our understanding that resources have not been available to resolve the issues identified during that testing.

We are concerned that the inability to consistently focus resources on this effort and complete the system may ultimately undermine its chances of success. More than once in the effort to reestablish the Voluntary Cosmetic Registration Program after the termination of the previous paper reporting system in the mid-1990's, CTFA has identified company personnel to participate in the process and has stressed the importance of this voluntary program to a successful partnership with FDA. These persons have made substantial effort to assist the program only to see long delays in FDA action on the program. If work on completing the program is allowed to stall at FDA, it becomes increasingly difficult to convince our members that they should devote their resources to being prepared to participate in the program or that FDA considers this a real priority.

This should be a FY 2004 CFSAN "A" List Priority,

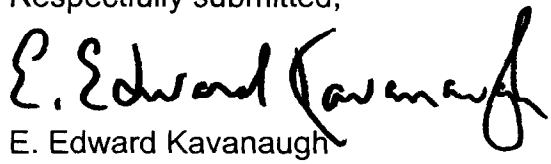
Conclusion

CTFA welcomes the opportunity to submit comments on CFSAN Priorities for the coming year. We believe this is an important opportunity for stakeholders and the Agency to communicate and identify mutually important goals.

This process provides an alternative to more formal procedures such as Citizen Petitions which place an additional burden on Agency resources to produce a response. However, this process is only beneficial if it becomes an effective vehicle to influence CFSAN allocation of resources, and if the resolution of these issues occurs within the time frames identified by the Agency.

We hope that the end of FY 2004 will find many of these proposed goals not only established as priorities but also listed as FY2004 CFSAN accomplishments.

Respectfully submitted,



E. Edward Kavanaugh
President

cc: Joseph A. Levitt
Linda M. Katz, M.D.