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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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September 17, 2001

E. EDWARD KAVANAUGH
PRESIDENT

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

Re: Program Priorities in the Center for Food Safety and Applied Nutrition; Docket No. 98N-0350

Dear Sir or Madam:

The following Comments are submitted by The Cosmetic, Toiletry, and Fragrance Association (CTFA) in response to the request for comments on Program Priorities for FDA's Center for Food Safety and Applied Nutrition (CFSAN) for the Fiscal Year 2002 (October 1, 2001 to September 30, 2002) (66 Fed. Reg. 37480 [July 18, 2001]). 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 approximately 580 members involved in the formulation, manufacture, distribution and marketing of personal care products. Approximately one-half of those members are active members that manufacture and distribute cosmetics, toiletries and fragrances. The remaining one-half are associate members that provide goods, such as cosmetic raw ingredients, or services to our active members.

The cosmetic industry takes pride in its strong safety record and long history of successful self-regulation. Our self-regulatory programs are not only effective but save scarce government resources. Working with CFSAN, CTFA has supported many voluntary self-regulatory programs, such as the Cosmetic Ingredient Review (CIR), that have helped to ensure that consumers have a wide selection of safe cosmetic products from which to choose. Several decades of self-regulation backed by an effective regulatory presence in CFSAN have produced an industry with products that former FDA Commissioner David Kessler referred to as "as safe as they come."

CTFA has also strongly supported full funding for the cosmetic regulatory program in CFSAN. When that program was threatened by budget cuts in recent years, we urged Congress to restore adequate funding for cosmetic regulation to CFSAN. We continue

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to strongly believe that a properly-funded, credible "cop on the beat" is necessary to ensure that all cosmetic products meet the high standards of safety that the public, the FDA and our own industry demand.

The following are CTFA's proposals for issues to be included in CFSAN's 2002 Program Priorities:

1. Propose a Draft Guidance on AHA-containing Products

This item was on CFSAN's "A List" for 2001 and may be completed before the 2002 Priorities are published. However, since it is very important to the industry that this matter be completed pursuant to CTFA's Citizen Petition filed on June 29, 2000, we are including it as the first priority in our proposals for the coming year. Although CFSAN has chosen to handle this matter through a guidance as opposed to a regulation, we urge FDA to adopt the labeling language proposed in CTFA's Citizen Petition and to continue to give this matter a high priority in 2002.

2. Establish a Framework for Evaluating Ingredients Found by CIR to Have Insufficient Data

Action on the "insufficient data" issue also was proposed as an "A List" priority in 2001 in the form of a draft guidance for issuance of Section 740.10 warnings for such products. We urge the Agency not to omit the important intermediate step of determining the "framework" for determining which, if any, of the ingredients that have an "insufficient data" finding merit consideration for a Section 740.10 warning. This process would include an evaluation of what criteria should be applied in evaluating these ingredients – a risk assessment – and the time that should be allowed for additional data to be supplied and reviewed by CIR before imposing the Section 740.10 labeling requirement.

CTFA believes it is very important that the industry and other interested parties have an opportunity for dialogue with FDA on this "framework" before FDA establishes a preliminary guidance on when a Section 740.10 labeling requirement would be imposed. This would be entirely consistent with the approach FDA has publicly discussed with industry over the past two years.

3. Implement the WEB-based, Interactive Voluntary Cosmetic Registration Program (VCRP)

CTFA again urges CFSAN to act as quickly as possible to implement enhancements in the Voluntary Cosmetic Registration System. This matter was on the "A List" of 2001 CFSAN Priorities, and we believe it should remain a very high priority until completed.

CTFA has always viewed the VCRP to be an important part of the cooperative, voluntary efforts between FDA and the industry, and we believe this more efficient, user-friendly approach to cosmetic registration will encourage broader participation in this program.

CTFA stands ready to cooperate with the Agency in whatever way necessary to complete testing of this program and implement the system.

4. Replace the current language of 21 CFR 701.3 (c)(2) with the following language:

In the absence of a name specified in §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's Cosmetic website, http://www.cfsan.fda.gov/~dms/cos-toc.html, the name adopted for that ingredient in the following compendia shall be allowed, 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, NW, Washington, DC 20036, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW, 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, NW, suite 700, Washington, DC 20408).

(iii) The most current edition, including supplements, or 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, NW, 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, Food and Drug Administration, 200 C Street SW, Washington,

DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW, 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, NW, suite 700, Washington, DC 20408).

This action would implement a "B List" Priority from 2001. Making this change will recognize that there are continual changes in the compendia cited, with about 2000 new ingredients being added to the International Cosmetic Ingredient Dictionary and Handbook each year, for example, and will provide for stability in the adoption of nomenclature for industry to use on cosmetic labels. It will also provide the option for the Food and Drug Administration, through review of the changes and additions in nomenclature made each year, to specify alternative names that must be used for labeling purposes, through the ability to publish alternative names on the Center for Food Safety and Applied Nutrition's Cosmetic website.

CTFA also encourages FDA to adopt a plan that would eventually allow for the labeling of colors using the Colour Index Number, to provide for harmonization of color labeling nomenclature throughout the world. Such a plan might include voluntary labeling with both the Colour Index Number and the currently allowed abbreviated name, to provide a transition. During this transition, information could be provided by CTFA to consumers, the industry, and the medical community, explaining the change and providing cross-references for comparison purposes. There would be no need to change the color additive names in the regulations or their marketing or trade names. The only change needed would be with the names allowed on the cosmetic product label. As this would not affect the regulation of cosmetics, or what colorants are allowed in the U.S., there should be no concern after a suitable period of consumer, industry, and medical profession education.

5. Provide Sufficient Resources for Participation in International Harmonization Efforts

As we have commented in past years, CTFA believes it is very important for representatives of the Office of Cosmetics and Colors to be directly involved in international harmonization initiatives. The cosmetic industry is a global industry, and it is critical that FDA participate in discussions with other governmental bodies and the industry to determine where harmonization of regulatory requirements can be accomplished. Those with expertise in cosmetic regulation must be involved.

In addition to the Cosmetics Harmonization and International Cooperation Program (CHIC), the planned involvement of FDA should also include the Trans Atlantic Business Dialogue (TABD). This initiative provides an opportunity for very high-level discussions between business and government that can lead to more efficient and consistent regulation of cosmetics throughout the world.

6. Revise the System for Reporting Consumer Complaints for Cosmetic Products

CTFA again urges FDA to take this important step to prevent misleading information about cosmetic products from reaching the public and the media.

FDA currently compiles complaint information on cosmetic products as it is reported by the complainant, often without a follow-up investigation to determine whether it is accurate and whether the product identified is the actual cause of the adverse reaction reported. This procedure has the potential, realized in some cases, to cause unjustified public concern about cosmetic products.

CTFA urges CFSAN to undertake a priority review and revision of this process to ensure that mistaken or misleading allegations of safety problems with cosmetic products do not reach the public with the apparent endorsement of the Agency.

Conclusion

CTFA believes that the process of soliciting comment regarding yearly Program Priorities before they are published by the Agency is an important step in improving the dialogue between industry and government. We appreciate the willingness of CFSAN and the Office of Cosmetics and Colors to consider the industry's views, and will provide further information as necessary while the final 2002 Program Priorities are being developed. Please do not hesitate to contact us.

Respectfully submitted,

E. Edward Kavanaugh
President

cc: Joseph Levitt
Raymond Decker