

July 19, 2000

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

Dockets Management Branch (HFA 305)  
Food and Drug Administration  
5630 Fishers Lane, rm.1061  
Rockville, MD 20852

7538  
E. EDWARD KAVANAUGH  
PRESIDENT

**Re: Docket No. 00N-1262; Improving Premarket Review and Approval of Food and Color Additives in the Center for Food Safety and Applied Nutrition**

JUL 19 4 57 PM '00

Dear Sir or Madam:

The Cosmetic, Toiletry, and Fragrance Association (CTFA) is pleased to submit these comments in response to the Food and Drug Administration's (FDA) notice of May 5, 2000 allowing interested parties an opportunity to comment on how the Agency's new resources may be best applied to address the timely approval and safe use of color additives (65 Federal Register 26215).

CTFA, the national trade association representing the personal care industry, includes nearly 300 active member companies that manufacture and/or distribute finished cosmetic products in the United States. Color additives are essential constituents in a large proportion of these products. CTFA membership also includes an almost equal number of associate member companies from related industries. These associate members include manufacturers of color additives used in foods, drugs and cosmetics.

Since implementation of the Color Additive Amendments of 1960 CTFA has played the major role in assuring a wide and safe-for-use palette of color additives for use in personal care products. We have coordinated the major toxicological testing programs mandated by the FDA for these colorants, gathered or developed the necessary chemistry data to develop appropriate specifications and worked through CTFA membership to compile "use" information the agency required for its safety assessments.

CTFA was petitioner for almost the entire 1960 provisional list of color additives suitable for cosmetics and other personal care products. We were also co-petitioners for food and drug colorants. As CTFA continues its efforts to broaden the palette of acceptable color additives or find new uses for the existing list, we welcome the opportunity to share our petitioning experience with FDA personnel to develop a more efficient review system that would better serve industry, assist FDA personnel organizationally, and still ensure a program with safety and scientific credibility.

A problem CTFA has faced in its prior petitioning efforts at FDA is not knowing up front exactly what the requirements will be for the listing of an additive. We have started out with a list of requirements,

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chemical and/or toxicological, completed and reported the work requested and then been told that further data are required. If this were the result of the initial studies opening new areas for questions it would be understandable. However, in many cases it has appeared that insufficient consideration was given in the initial discussions between the various groups of science reviewers. Stronger coordination between the FDA toxicologists and other scientists could alleviate some of these problems.

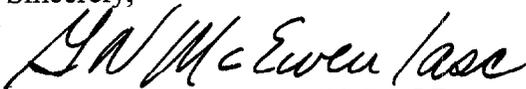
Similar problems causing many months of delay have occurred when one group of reviewers, the toxicologists or chemists, has finished its review and the petitioner learns that the other group of reviewers has not begun. CTFA believes that these problem could be resolved with better communication between the various reviewers, and strong and thorough management from the specific program manager at the agency.

In the past when CTFA was considering submitting a petition to FDA we asked for a preliminary meeting with the appropriate officials at the agency. At that time, we could probably estimate when we expected to have a completed petition delivered to the agency. It may be that in the future FDA could reserve review windows based on these preliminary discussions with industry. It would be the petitioner's responsibility to meet this as any other deadline or lose this window to another agency priority. This could start the review process in a more prompt fashion and allow the agency more opportunity for scheduling various reviews several years in advance. Unannounced or unscheduled petitions would be reviewed on a time available basis.

Because of the enormous and complex workload that is the responsibility of the Office of Premarket Approval, CTFA strongly recommends that the agency consider an outside expert group to assist in the review process. This could ensure the variety of expertise needed across the broad spread of programs that may not be available through adding to the agency's permanent staff.

FDA has asked questions in its May 5 notice that are not easily answered. It may best serve the agency to organize a working group of agency personnel who are responsible for petition reviews, industry representatives who have been involved in the petitioning process, and management personnel who could more completely explore the problems, needs and priorities relating to these important programs.

Sincerely,



Gerald N. McEwen, Jr., Ph.D., J.D.

Vice President - Science

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