COSMETIC, TOILETRY and FRAGRANCE ASSOCIATION, INC.
FORMERLY THE TOILET GOODS ASSOCIATION, INC.

December 28, 1973
(73-22)

PRESIDENT'S MESSAGE

1973 was a year of Increased Regulation
Intense Competition
Ingredient and Packaging Shortages
and other major problems.
But, it was also a year of accomplishment - with CTFA members fulfilling their obligation to serve consumers via compliance with the voluntary regulation program, providing quality products at fair prices.

1974 will be a year of More Challenges.
But, CTFA members comprise an industry led by dynamic management - administrative, marketing, scientific and legal - with the knowledge, expertise, flexibility and initiative to meet and conquer every challenge these critical times present.

Your continued support and participation in joint efforts to respond positively to these and new challenges will make the business climate better in 1974.

Best wishes for the New Year,

LEGAL NEWS

INGREDIENT LABELING

CTFA, on behalf of its members, has petitioned the Food and Drug Administration to (1) adopt two amendments to the ingredient labeling regulation, and (2) defer the March, 1974 trigger date.

CTFA has asked FDA to exempt from labeling requirements incidental ingredients present in cosmetics at insignificant levels which have no technical or functional effect.

> Also, due to current shortages, sometimes serious, of many substances used in cosmetics, CTFA has asked that scarce ingredients may be designated by class names rather than individual chemical names.

(A composite list of ingredients in short supply was included in the submission.)

Note

In a December 27 letter to FDA Commissioner Schmidt, CTFA requested that the March 31, 1974 "trigger date" be eliminated, leaving for the time being only the final effective date of March 31, 1975.

> CTFA cited its November 23 petition as the most important reason for delaying the label order date. The petition "clarifies an important area of labeling, whose ambiguity was recognized by the Commissioner in the preamble to this order." Companies, CTFA said, should be permitted to await the outcome of the petition before commiting themselves to labels.
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> In addition, CTFA has filed objections and a request for hearings on color labeling and small size. (ENL, 73-20, Nov. 23, 1973). These issues have not been resolved.

Material shortages were given as the second reason for the deferral. Shortages affect the ingredient labeling situation in two ways: (1) substitutions have to be made for ingredients in short supply, and (2) shortages in plastics and paper supplies are causing delays in obtaining new packaging.

> Related to this, are the many requests for trade secret protection awaiting action by FDA. In these cases, relief from the March 1974 trigger date is dictated by "fairness."

CTFA asked that the March, 1974 date be deferred indefinitely, and warned, "Based on action on the concurrently-submitted petition and on CTFA's pending objections, it may be necessary at a later date to seek relief from the March 31, 1975 effective date."

PRODUCT EXPERIENCE REPORTING

On behalf of its members, CTFA has written Food and Drug Administration (FDA) Commissioner Alexander Schmidt to outline CTFA's interpretation of the term "audit" as used in the final regulation on product experience reporting.

In the final order it states that a filed screening procedure "is subject, upon request by the Food and Drug Administration, to an audit. . .[to] show that the procedure is consistently being applied and that the procedure is not disregarding reportable information."

Neither the final regulation nor the preamble defines an "audit."

In its letter of April 17, 1973 to the Hearing Clerk, CTFA formally proposed screening procedures subject to audit and defined CTFA's use of the term "audit."

According to that letter an audit "does not require that. . .persons maintain any particular records, but does require that sufficient information be available to permit the Commissioner to evaluate the application of the procedures and criteria to representative examples of reported and unreported consumer complaints, and the ratio between all claims received and reportable experience."

In its December 27 letter, CTFA wrote "In our view, the audit concept as proposed by the CTFA is consistent with the regulation as published."

The letter states:

> "Accordingly, we wish to make sure that you and others in FDA are aware that the CTFA, in promoting participation by members in the voluntary program, intends to use its April 17 submission as a baseline for explaining the audit concept. In particular, we intend to reassure members that by participating they do not automatically render all of their complaint files open to FDA in an 'audit'."

CTFA also asked that the date for the first reporting period be deferred until mid-1974. Since (1) reporting forms are not yet available and (2) the final order was not published until October 17, 1973, CTFA is recommending the first report be submitted within 60 days after the January 1 - June 30, 1974 period which would be the first regular reporting period in calendar year 1974, assuming, of course, forms are made available early in 1974.

"The time schedule for Cosmetic Products Unusual Experience Reports will be in accordance with the recommended 15 days following publication and distribution of those report forms."

ASBESTOS IN TALC

CTFA, on behalf of its members, has submitted comments on a proposed method for determining the absence of asbestos in talc. (Federal Register, Vol. 38, No. 188, September 28, 1973.)

> (The regulation would apply to talc in food or drug products or packaging materials. It would not directly affect cosmetics.)

Along with comments, CTFA submitted the final report of the CTFA Talc Subcommittee, dated December 10, 1973. The subcommittee recently completed a review of the optical microscopic method published in the proposal.

CTFA wrote "As a result of round robin testing of five different types of talc, the subcommittee concluded that the proposed method does not provide a truly reliable means for the detection of asbestos in talc."

As a result of its review of several alternative methods to detect chrysolite and tremolite in talc, the subcommittee "feels confident that a feasible method can be developed, and recommends a collaborative effort between FDA and industry to develop such a method.

CTFA noted that "the questions concerning asbestos detection and the relationship of asbestos to human health are indeed complex ones." The letter cites points made at a conference sponsored in November by the National Institute of Environmental Health Sciences and the Environmental Protection Agency.

In light of this information, CTFA urged deferment of promulgation of the proposal until certain key issues are resolved.

MINNESOTA PACKAGING HEARINGS

On December 20 and 21 the Minnesota Pollution Control Agency held hearings on the Revised Guidelines for Packaging Review. A copy of the Guidelines was mailed to you on December 4, 1973.

The CTFA testified at the hearings. The statement emphasized the inequities of employing the seven-digit SIC Code for cosmetics and toiletries and urged adoption of the five-digit code in its place. The seven-digit code would place severe restrictions on exemptions granted to new or revised packaging under the grandfather clause. Use of the seven-digit code would result in Agency review of a greater number of packaging changes.

If you plan to submit a written statement, we urge that you consider stating you support the CTFA statement and the testimony of the Minnesota Association of Commerce and Industry. The hearing record will remain open until January 10, 1974. All written statements should be mailed to:

Minnesota Pollution Control Agency
1935 West County Road B-2
Roseville, Minnesota 55113

If you plan to submit a statement or require additional information, contact Ed Kavanaugh at (202) 393-2070.

INDUSTRY NEWS

CTFA CHAIRMAN J. RICHARD EDMONDSON has been named Vice-President of the Bristol-Myers Company. He continues as Secretary of the corporation, a post he has held since 1969. Mr. Edmondson began his business career in 1953 with Winthrop, Stimson, Putnam, and Roberts as an associate lawyer. He joined Bristol-Myers in 1959 as Staff Attorney and was named Assistant Corporate Secretary in 1960. He was named Vice-President of Clairol, a division for which he was legal counsel, in 1967.

O.G. KENNEDY has been named Group Vice-President for pharmaceutical and consumer products at Norwich Pharmacal Company. He joined Norwich in 1967 as Executive Vice President and became a Corporate Vice President and member of the Board of Directors of Morton-Norwich in 1969.

PETER H. ENGEL has been named President and Chief Executive of Helena Rubinstein Inc., a subsidiary of Colgate-Palmolive Company. He was formerly a Vice President and General Manager of the Western Hemisphere Division of Colgate-Palmolive International.

At Revlon JACK MOST has been named Corporate Vice-President and Chief Legal Officer. Most, who was formerly a Vice-President of the company, has been in Revlon's legal department for several years. Prior to that he was in the legal department at Pepsi Cola. He succeeds PETER DE LUCA who has been made Vice-President and General Counsel of General Foods.

J.W. DICKINSON, JR. has been named Vice-President of Gillette. He has been Assistant to the President of Gillette's Personal Care Division. He has held a variety of marketing and management positions within Gillette since joining the firm in 1951.

HAROLD SCHWARTZ, Ph.D., is the new President of Food and Drug Research Laboratories, Inc., an independent testing laboratory located in East Orange, New Jersey. He joined the firm after seven years as Director of Sciences of the Mennen Company. Dr. Schwartz, a former chairman and long time member of CTFA's Advisory Committee, took an active role in the development of the CTFA Scientific Department.