DATE OCTOBER 12, 1972 FOR FRED ROESCH

ATT:

WHITTAKER, CLARK & DANIELS, INC.

SUBJ: C.T.F.A. - VOLUNTARY REGULATION SEMINAR ON PRODUCT INGREDIENT DISCLOSURE COMPLIANCE F.D.A.

INTER – OFFICE CORRESPONDENCE

Dear Fred:

Attached is a complete packet of information given out at the seminar, October 6,1972. It contains:

1. Program
2. Voluntary ingredient statement forms
3. Directions for completions.

This seminar was conducted by:

1. Dr. Norman Eskin, CTFA
2. Dr. Harold Schwartz, The Mennen Company
3. Dr. E. Richardson, F.D.A.
4. Dr. J. Wenninger, F.D.A.

Dr. Richardson, you will recall, has worked in the industry.

The bulk of the meeting was devoted to the ways one would disclose his formula and the methods one could use to keep his formula "secret". All of this information is covered in the instructions. However, in order to keep a formula "secret" it must meet the following test.

It is:
Unique
Important to the product
Not known to competitors

Should you not meet the test, you could then withdraw the application without prejudice.

It should be noted that even if confidentiality is allowed the F.D.A. could release this information under certain circumstances (litigation, public pressure, etc.)

Obviously the main thrust of the meeting was regarding this confidentiality point. Many of the members of the industry appear to feel threatened inasmuch as they feel this industry is based on unique combinations of well known ingredients.

I posed the question to the panel as to "why one has to justify a request for confidentiality and who passes judgment". This was not adequately replied to.

It appears that the industry volunteering to disclose will then forestall such people as Senator Eagleton and Virginia Knauer who believe all information should be in the public domain.

PLAINTIFF'S EXHIBIT
WCD-193

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The August 11, 1972 Federal Register, Volume 37 contains guideline for cosmetic product ingredient labeling. In order to avoid confusion of acceptable ingredient names CTFA have developed a dictionary which will be available at a modest fee sometime after January 1, 1973.

The effective date for voluntary regulation is now, or in the case of a new product, 180 days after initial marketing.

Dr. Schwartz briefly reviewed the present talc situation. He explained that any of the people "picked up" for excess amounts of asbestos would be reviewed again if they would send current production products to Dr. Lewin of N.Y.U. This is done on the basis that many items surveyed were several years old.

The possibility of theft of formulas or a Pentagon paper type if disclosed will not be possible under the F.D.A. computor system which fractions the information in several computor banks which can only be brought together with certain key knowledge and steps.

Our responsibility as a supplier would be only if our customers used an ingredient from us and they did not know the composition. They would then request we relate this data to the F.D.A.

This was a very well attended seminar. The crux of the problem is that if the industry does not voluntarily regulate itself, someone else will. All in attendance agreed the former is the prudent strategy.

The serious shortcomings of disclosure of confidentiality information is the major single concern. The consensus of opinion appeared to be if you truly have a unique product, do not disclose it by registering. It is a voluntary program.

DICK LONCAR

DL: mv
enclosure