

Committee of the Progressive Hair Dye Industry

Room 510-11, 60 East 42nd Street

New York, New York 10017

December 2, 1968

Members

COMBE CHEMICAL, INC.
White Plains, N.Y.

ESSEX CHEMICAL CORP.
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MAJESTIC DRUG CO.
New York, N.Y.

PEARSON PHARMACAL CO.
Miami, Fla.

SUN RAY COMPANY
Bronx, New York

Robert A. Kehoe, M.D.

University of Cincinnati
The Kettering Laboratory
College of Medicine - Eden Avenue
Cincinnati, Ohio 45219

Dear Dr. Kehoe:

Your augmented report has been carefully read by me and also by Mr. Ivan Combe. We both feel that you and your colleagues have done a superb job for which we are deeply grateful.

The points we are about to make are intended to fortify rather than to alter your conclusions. Here they are in the order in which they occur in your report:

- (1) The last sentence in the second paragraph of your introduction (Page 1) contains the parenthetical statement; "light shades becoming darker and white hair becoming auburn". While this may be generally true, many of our white-haired customers tell us that their hair becomes light to dark brown rather than auburn. Continued use of the product would result in the auburn shade becoming darker. In any case, the statement might best be omitted unless you would consider it germane to your introduction.
- (2) The sixth paragraph on page seven creates the clear inference that the small furuncle was caused by the application of the prototype product. It doesn't seem likely that you intended this inference because the furuncle did not recur after the applications were resumed.
- (3) We have made some comparisons between Table #1 and Table #3 which may be of interest to you, although we are in no position to determine their validity. Below is a tabulation of the low and high figures on concentration of lead in the two groups:

Table #3 Group

	<u>Low</u>	<u>High</u>	<u>Increase</u>
IF -	0.020	0.065	0.045
IF -	0.010	0.055	0.045
SW -	0.010	0.040	0.030
MB -	0.020	0.045	0.025
FC -	0.015	0.055	0.040
JS -	0.010	0.030	0.020
SB -	0.020	0.040	0.020
LD -	0.015	0.030	0.015
JOS -	0.010	0.030	0.020
NK -	0.015	0.035	0.020
NS -	0.015	0.030	0.015
HR -	0.015	0.045	0.030
Average			0.027

Table #1 Group

	<u>Low</u>	<u>High</u>	<u>Increase</u>
B -	0.027	0.047	0.020
I -	0.015	0.037	0.022
L -	0.010	0.037	0.027
M -	0.013	0.031	0.018
P -	0.009	0.037	0.028
R -	0.008	0.014	0.006
ST -	0.012	0.028	0.016
SU -	0.018	0.036	0.018
SV -	0.026	0.036	0.010
T -	0.024	0.033	0.009
V -	0.021	0.033	0.012
Average			0.017

At A. Kehoe (Cont. page 2)

What seems meaningful to us in the above is that the highest figure in the Table #1 group (0.047) is exceeded by three subjects in the Table #3 group, and the next highest (0.037) is exceeded by seven subjects in the Table #3 group. The average swing between highs and lows in Table #1 group is 0.017 as compared with 0.027 in Table #3. These facts might justify tempering the use of the word "significant" as applied to the four subjects in group #1 who showed an increase in lead content.

In the second paragraph on page eleven you refer to variability in the concentration of lead "in the same degree" as those of Table #1 whereas the variability is considerably greater among the group in Table #3 as compared with Table #1.

- (4) Although the change is on the unfavorable side, we must in all honesty call your attention to the fact that the averages given during the first and second weeks of the control period at the bottom of Table #1 are slightly inaccurate. Evidently, the figures for May 15 were added and then divided by ten. The correct figures for May 15 are 0.023 and for May 20, 0.020.

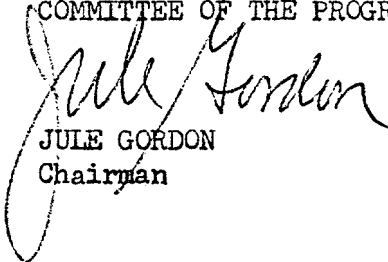
As to the presentation to the FDA, our thinking is that several copies of the report should be mailed to the individual with whom the protocol was worked out and that an early meeting should be requested at which you and Mr. Combe and I would be present. Certainly, Mr. Combe and I would not be equal to the questions that might arise in connection with the report.

We would like to have 20 copies of the final report and, of course, would expect these and all other out-of-pocket costs to be our responsibility.

I hope your trip to Europe was thoroughly enjoyable and I look forward to hearing from you at your convenience.

Cordially yours,

COMMITTEE OF THE PROGRESSIVE HAIR DYE INDUSTRY


JULE GORDON
Chairman

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