

Committee of the Progressive Hair Dye Industry

Room 510-11, 60 East 42nd Street

New York, New York 10017

Members

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

HESS HAIR MILK LABS.
St. Paul, Minn.

HOODS HAIR PRODUCTS, INC.
Madrid, Ia.

LASER LABORATORIES
Minneapolis, Minn.

MAJESTIC DRUG CO.
New York, N. Y.

PEARSON PHARMACAL CO.
Miami, Fla.

RAYMOND RESEARCH CORP.
New York, N. Y.

SUN RAY COMPANY
Bronx, New York

PAUL WESTPHAL, INC.
New York, N. Y.

Kenneth A. Freeman, Ph.D.
Division of Color Certification
and Evaluation
Department of Health, Education
and Welfare
Food and Drug Administration
Washington, D.C. 20204

Dear Dr. Freeman:

We greatly appreciate the attentive and considerate attitude displayed by you and your associates during our visit to your office on December 5th. As a matter of record, our own group consisted of the following:

Ivan Combe, Combe Chemical, Inc., White Plains, N.Y.
Jule Gordon, Hood's Hair Products, Inc., New York, N.Y.
David Garlen, Hazel Bishop Inc., Union, N.J.
W. Kedsie Teller, Combe Chemical, Inc., White Plains, N.Y.

As you requested we confirm our remarks which dealt chiefly with points raised in your letter to us of October 20, 1966. Therein you expressed concern that the animal experiments detailed in our presentation of September 1, 1965 appeared to cast doubt on the safety of lead-containing hair dyes. Apart from the question of comparability of cutaneous absorption, it would seem that a possible misunderstanding resulted in overlooking important factors so that the experiment did not follow human use. Also it did not allow for the elimination cycle following the abnormal exposure.

As explained to your group, these facts are important in judging the relation of the experiment to human use: Directions on all lead hair coloring products sold by our group call for daily application only until the desired hair color is acquired and thereafter once or twice a week to maintain that shade. Such a regimen will require application of about five fluid ounces of product over the first ninety day period and approximately an ounce per month thereafter.

Since the product is applied to the hair, there is probably not more than one half ounce which reaches the skin during the ninety days of first use. That which is applied to the hair becomes insoluble through reaction with carbon dioxide and sulfur compounds. In the lowest dose animal experiment, 0.5 ml./kg. was applied daily to the shaven skin, which area was incidentally

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*extra copy
composite of FDA letter as mailed
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about one fifth of the body area. This is at a rate of one and one-sixth fluid ounces per day, or over two hundred times the amount reaching the skin of a human during the ninety day experiment.

It is an accepted fact that lead acetate may penetrate the skin of certain animals, but it is our position that the animal experiments do not bear on human use.

We are fortunate that a record of the proceedings of the Symposium on Environmental Lead Exposure held in December 1965 received the attention of both your group and ourselves. We know of no more complete a treatise on the subject of lead toxicity and are grateful that we can refer to the many pertinent opinions and facts contained therein.

Of particular importance are the statements of the Deputy Attorney General, Dr. Gehrig 1, and Dr. Ralph G. Smith 10, 12 of Wayne University, both of whom point out that lead is one toxic material about which we know more than any other.

Pertinent to our data on urine lead levels of 105 regular long term users of our products are the many references which show the acceptance of such figures as a basis for judging exposure and healthful status of subjects. 5, 11, 20, 21, 24, 27, 29, 30, 32 and 33.

These proceedings also abound with other remarks on our knowledge of the subject. 3, 4, 10, 12, 13, 16, 17, 18, 19, 20 and 24.

Adequate information on toxicity is presented. 1, 7, 8, 13 and 23.

Vital to our consideration are statements on skin absorption defending our position. 9, 22 and 23.

In our sincere efforts to cooperate further in complying with your wishes to learn more about our products, we told of our conversations with Dr. Robert Kehoe, whom we all recognize as a foremost authority on lead toxicity. He has reviewed your letter of October 20th to us and arranged with Dr. Radford, present director of Kettering Laboratory, College of Medicine, University of Cincinnati, Cincinnati, Ohio, to carry out a human study project on our products.

Dr. Kehoe believes that animal studies are unnecessary. He does not believe that lead acetate is absorbed through skin of humans and that if there is any uptake, it must come by ingestion. Further, he considers that blood and urine lead levels on a dozen individuals who use such an hair dye will be sufficient to reveal the facts. In our preliminary planning with him it was believed that a generic formula would suffice to determine a base line of effects of exposure. Subsequent studies on very few subjects on each brand would reveal whether various wetting agents, emulsifiers and other ingredients vitiated the base results. We anticipate that quantitative compositions of our various products will be needed by him. Herein your Dr. Fitzhugh voiced the opinion that a program which satisfied Dr. Kehoe would seem quite definitive as answering any uncovered questions on safety of hair

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dyes. Dr. Blumenthal also said that human tests would be convincing. Accordingly, it is our intention to ask Dr. Kehoe to meet with your group to discuss the design of a study which Kettering Laboratory would undertake under his direction.

In a recent phone conversation with him, it was learned that he will submit a suggested program to us in January. It is our plan to commission him to meet with such members of your staff as you designate.

The Chairman of our Committee, Mr. Jule Gordon, has asked me to inform you that the member listed on our letterhead as Raymond Research Corp., has been acquired by Hazel Bishop Company, Inc. who will soon determine if they will participate in our group study or carry out a research project of their own. In either event, you will be informed of their decision.

Very truly yours,

W. Kedzie Teller
Technical Consultant

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