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May 20, 1967

Robert A. Kehoe, M.D.
Kettering Laboratories
College of Medicine
Eden Avenue
Cincinnati, Ohio 45219

Dear Dr. Kehoe:

I greatly appreciate the opportunity to renew discussion of the lead sulfur hair dye project with you and enjoyed meeting Drs. Kindel and Pfitzer.

As promised, I am enclosing a copy of our original submission to FDA. You will note that this includes animal toxicity data on R.D. Hair Dressing which was chosen as representative of products in this field. It contains 2% lead acetate together with some fats, oils and emulsifiers and an adequate amount of sulfur.

Although I have related to you in summary my arguments in defence of this submission after it was challenged by FDA, I am also enclosing a copy of a letter, (January 9, 1967), which I wrote Dr. Freeman of FDA confirming my oral arguments and FDA's reactions thereto. Please note, too, his reply (March 27, 1967) which in substance agrees to waive animal data in lieu of the type of human data we are now planning.

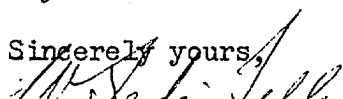
You will also recall that you and I agreed that it would be better to reserve any discussion of the elimination cycle to which Dr. Freeman took exception in his letter of March 27, 1967.

Attached also is a list of the various unfamiliar ingredients which appeared in some of the hair dye formulations. Opposite each is a definition or chemical equivalent.

In addition there is a proposed generic formula carrying the maximum lead content found in the various products sold by members of our group. Included also are exact instructions for use which is typical of those accompanying all trade packages.

I am writing Dr. Freeman that your protocol for this study is now being finalized and that it will be submitted to Dr. Fitzhugh for his review quite soon. This seems in order following my recent letter to him wherein I indicated that this would probably be in May. I presume that we can do this in the next few weeks? Will you do this in person or what will the procedure be?

I'll look forward to receiving the proposal which Dr. Kindel will be sending to me and call you immediately thereafter.

Sincerely yours,


Romex #600 - Could be Atlas Renex 600 - nonionic ethers from ethylene oxide with nonylphenol

DuPont WA paste - sodium lauryl sulfate from DuPont

Lantrol - liquid lanolin oil derived from lanolin, Malmstrom Chemical Corporation

Sulfidal - colloidal sulfur, pharmaceutical grade, Heyden Newport Chemical Company

Sequestrene A.A. - ethylene diamine tetra-acetic acid 99%+ Geigy Chemical Corporation

Arlacel 165 - glyceryl monostearate (acid stable self emulsifying) Atlas

Deltyl Extra - isopropyl myristate, Givauden Delawanna Inc.

Potassium Sorbate - Probably a preservative of Pfizer

Polawax - principally stearyl alcohol with nonionic self emulsifying agent

Methyl Chem. - methyl p-hydroxybenzoate U.S.P. XIV

Cudbear No. 1 powder - a natural lichen derived red coloring

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