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388-3219

October 31, 1966

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

Dear Dr. Kehoe:

In a phone conversation with Miss Peaslee of your office, I learned that you will be out of town until next Monday, and in consequence promised to write you about my problem in hopes that you might give it some consideration.

I am a consulting chemist and for a number of years operated the Columbus Laboratories in Chicago dealing with foods, drugs and cosmetics, and in part toxicological problems connected therewith. Currently I am semi-retired but because of my past experience in the field have been retained by a group of lead sulfur hair dye manufacturers to advise them in connection with a submission to the FDA concerning the safety of these items.

After about two years laboratory and clinical work done by extremely competent persons, we submitted to the FDA in September 1965 the following data:

1. A carefully controlled study of the effects on rabbits which have been treated with massive doses of one of the widely sold lead sulfur hair dyes which shows nothing alarming. Herein the rabbits have been exposed to many times the amount of product that humans use in normal hair coloring.

2. A compilation of urine lead data from one hundred and five persons who have regularly used the commercial products currently under consideration.

3. A literature survey which shows the opinions of experts regarding the relatively low absorption of lead through the unbroken skin, the levels of blood and urine lead under various conditions, normal and pathological, and other pertinent information.

At this time I won't burden you with details on the rabbit studies excepting to say, as expected there was lead uptake in soft tissues and bones, this because the excessively high dosages caused changes in the normal skin barrier. The human lead data showed urine levels to be within the normal limits expressed by yourself.

We have just received a reply from Mr. Freeman of the Color Division of FDA advising us that the data submitted shows that the products under consideration are unsafe. This despite the fact that the human data is negative and the rabbit uptake is explainably high.

I am fully aware of the literature on this subject and in particular your very valuable contributions thereto and have a copy of the Symposium on Environmental Lead Contamination, December 13-15, 1965. Mr. Freeman refers to this compilation of proceedings as condemning our cause, while my interpretation is exactly to the contrary. He is asking for an enormous amount of work, the cost of which is completely out of keeping with the dollar volume of business done by this industry.

It is my sincere belief that if you could give this problem some study, you could advise me on an approach that might change the attitude of the FDA officials and make it favorable to continuance of this industry.

Accordingly, I shall hope that when I call you the first of next week it will be possible for you to agree to let me visit you in Cincinnati to discuss details surrounding the above, with the hope that you may find it possible to guide us towards a prevailing position.

Yours very truly,

W. Kedzie Teller

WKT/vt