

July 3, 1967

O. G. Fitzhugh, Ph.D.
Toxicological Advisor
Division of Toxicological Evaluation
Department of Health, Education, and Welfare
Food and Drug Administration
Washington, D.C. 20204

Dear Doctor Fitzhugh:

I enclose herewith the information promised to you in my letter of June 13. I'm sorry we slipped up on its enclosure in the earlier letter. The memo was being prepared at the time the letter was written, and in my preoccupation with other matters, I neglected to see that it was enclosed.

I enclose three items of information:

- (1) The brief protocol indicating the number and sex of the subjects and the bare description of the general procedure;
- (2) The details of the formulation that is to be used, and the type of instructions that are given to the subjects orally, and handed to them in written form. These items of information are as they were presented to us in writing by the representative of the sponsors, on our request for his advice. The proposed formulation seemed to us to be quite in order, after we had reviewed the various formulations that are marketed. We shall obtain the ingredients and make our own preparation, and, of course we shall use our own ethyl alcohol instead of any denatured product. We shall not add perfume, but we believe a wetting agent should be used, if for no other reason than that some such agent as that suggested is used in most of the commercial preparations. We shall use Tween #20 in the suggested concentration;
- (3) A memo prepared by me, for the purpose of recording certain details and procedures which seem to be appropriate, so as to make sure that no matter of significance is overlooked.

I believe that this letter and these enclosures will acquaint you with what we have in mind, but if you require any other information, please let me know.

Cordially yours,

Robert A. Kehoe, M.D.
Professor Emeritus of