

December 21, 1973

Henk van Riezen, M.D.
Scientific Development Group
N.V. Organon
Oss, Holland

Dear Henk,

When I received the letter describing the placebo vehicle, I read the available regulations. I found none that applied to IND formulations. Nevertheless, I called the men at the Division of Neuropharmacology of the F.D.A., reached Dr. Edward Tocus and discussed the problem with him. He sent me on to two young associates, Drs. Kum Kumian and Thomas Hayes. None of the three believed the question presented a problem.

I believe that the formulation is acceptable.

Should you send the supplies to us in the present form, I will file an amendment to the IND, stating that the formulations used for the ongoing studies consist of the type you make available to me. There will be no objection.

It is probable, however, that should OI-63 come to an NDA, and you then submit the formulation with a coloring substance, that the marketing reviewers may object.

WE have had severe winter storms here, but it is clear and cold today. The warm sunshine of Palm Springs seems so far away. Our best wishes for a happy New Year !

Sincerely yours,

Max Fink, M.D.