Dear Hans,

I have, on behalf of Alan Calderbank and our Registration Section, been following up the queries contained in your telexes of 11 and 12 January. The status of the information you require is as follows.

1. The reports of Broome, Davies and Hepworth and Hepworth referred to in your first telex are not, in themselves, full reports but are summaries of points of information concerning ICI 63197 (PP796) contained in Exploratory Project reports dealing with a wide range of other topics. This information was not submitted to the UK authorities. Because we recognise that this data is of value to our proposed usage of PP796 we have asked Pharmaceuticals Division to re-present it in report format and to include, where possible, as much of the background data as is still available. We hope, therefore, to provide two reports, authenticated by their originators. One will deal with the emetic effects observed in pigs, monkeys and marmosets and the other will deal with the intravenous infusion studies. These reports are currently being drawn together and should be in your hands in advance of the February liaison meeting.

2. There are no individual reports extant relating to the LD₅₀ studies. At the time this information was generated it was not a required part of the protocol. We believe the format as presented should be acceptable to EPA. If you disagree we will have no alternative but to repeat the tests.

3. Individual reports on the cream and ointment irritation and sensitisation studies are available and are currently being typed up.

Yours sincerely,

[Signature]

Date 24th January 1977
4. We are endeavouring to obtain clearer copies of Volume IV - toxicity figures provided the master copy can be found. As I explained when we last met Pharmaceuticals Division have destroyed hard copies of data on compounds which were not developed and much has been transferred to fiche. When this letter reaches you we will have learnt how many copies you require via our telex communication.

5. Figure 13 Volume IV is missing from all copies and the data to provide it is being sought from the records.

6. A clear copy of the C.T.C. for creams and ointments has been obtained and will be forwarded to you. If you have any further queries relating to the original data I will seek to obtain clarification from Pharmaceuticals Division prior to the liaison meeting.

Sincere regards

[D. M. Foulkes]

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