

Mr J Sloggem MCA/L

FROM: Dr L Tsang MCA/L

DATE: 26 September 1996

COPIES: Dr F Rotblat o/r
Gold File
(MA/3070/0007)

**HYATE:C MULTISTATE APPLICATION
SPEYWOOD PHARMACEUTICALS LTD**

- 1 Your minute of 26 September refers. I have carefully considered the content of that minute regarding the assessment of this application.
2. In order to help you to disentangle yourself out of this allegedly complicated matter, I would suggest the following course of actions.
 - a) Phone the company first to ask them to send in a formal submission of the responses to the remaining quality questions then follow this up with a letter. Remind the company that we cannot proceed with the evaluation unless a formal submission, in the correct format, has been received. I am afraid that we cannot afford the time, nor do we have the resources, to entertain the company with a meeting to discuss the content and format of the summary document. You should tell them what you want on the phone or in writing, whichever is more appropriate.
 - b) the company will have to bear all the consequences for any delay and I do not think that we should concern ourselves too much about these. After all, this is the company's regulatory submission.
 - c) You should not worry about the fate of this application in the European front at this moment in time, i.e. whether it is going to be a mutual recognition application or a centralised list A application.
 - d) It is the company's problem for spending disproportionately long time on answering the questions from the French Authority despite our repeated request, if that is the case, for a formal regulatory submission to the UK.
 - e) regarding Professor Trouvin's suggestion to have a meeting with all concerned member states, I think this will have to be formally initiated by Jean-Hugues through the appropriate channel.
 - f) If you feel that Hyate:C is not ready for assessment, please assess Centeon's human serum albumin, which has been allocated to you by Dr Rotblat.
3. Although I am mindful of your concerns expressed, John, I am afraid that I cannot be more helpful. The assessment of Hyate:C and Centeon's HSA submissions has to be completed by you. It would be helpful to avoid sending lengthy minutes if you can.

LINCOLN TSANG
ROOM 1506/MT EXT

GRO-C

GRO-