

Bayer



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Your ref

Our ref

JMB/ER/041

Date

22 March 1989

Dear Eli,

Thank you for your telefax of yesterday addressed to Craig which I am replying to in his absence on holiday.

1. KOATE HP

As we discussed several months ago, we intend to apply for a product licence in the UK for Koate HP and you sent us a dossier towards the end of 1988. Since then we have carried out an assessment of the data prior to compiling it into a format for submission to our authorities. We are currently discussing a suitable submission date but this will not be until after the grant of the product licence for Koate HS. If additional data are now available, we should be grateful to receive them as soon as possible.

2. LABELLING

There are basic requirements for the labelling of products to be sold in the UK and, in addition, each product licence can carry specific requirements depending on the type of product involved. The MAL documents to which you refer are booklets summarising the legal requirements but the actual regulations themselves are not included in them. For your information, the latest editions are as follows:

MAL 18 - September 1980
MAL 42 - October 1983
MAL 47 - August 1983
MAL 49 - February 1983

However, it should be noted that these editions do not relate to new regulations but rather to changes in presentation of the books themselves. Finally, I should like to point out that all labelling and packing leaflets have to be approved by the Department of Health.



Directors: M. Schneider, Chairman J.V. Webb, Managing, R. Korn, Lord Walston

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While writing, I should like mention that we now have two telefax machines within the Pharmaceutical Business Group and the first number listed below is actually in the Research and Development Department of which Registration is a part.

0635 39616
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Kind regards.

Yours sincerely,

GRO-C

Mrs. Joyce Boulton
REGISTRATION MANAGER

cc: Craig Simpson