

Mr. Lowell Crow,
Cutter Laboratories,
International Division,
Fourth & Parker Street,
Berkeley,
California, 94710
USA.

6 Feb. 1976

JE/sb

Dear Mr. Crow,

Product Licence Application for KGATE in the U.K.

Following my telex of to-day, I am sending you a copy of the letter from the DHSS, which I refer to in that telex, together with the comments on it. The number of donations in each pool need only be given approximately, but they would like to have some idea of the size of it. They require as much detail as possible on the assay method and the Standard used so that the National Institute for Biological Standard and Control in London can perform these assays for themselves. In other words, they want to know enough about our methods and results to know how reliable are the Standards which Cutter use and how they relate to the International Standard,

It seems that they are going to insist that our labelling complies with the B.P. requirements as far as possible and it may mean that we shall have to have special labels for the Product in the U.K.. However, we shall send your comments on the B.P. Labelling which you send to us in July to the DHSS for their consideration, but in the meantime I wonder if you have any further comments. I am enclosing a copy of the B.P. Specifications for your reference.

Point 4 of the letter means that in the future, they will require records on this information from the Plasma Collection Centres. However Dr. Andrews mentioned to me on the telephone that if this information is provided on the Protocols which will be looked at by the N.I.B. (National Institute for Biological Standard and Control), that each Batch of the product which we propose to sell in the U.K., this should be sufficient information.

Mr. Lowell Crow

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JB/sb

With regard to Point 5, I am enclosing a copy of the Batch Release Procedure as supplied by the DHSS together with the Guide Protocol so that you can see what this involves.

We should be pleased if you could send us your answer and comments to the five points raised in the letter as soon as possible so that there will be as little delay as necessary in us being granted a Product Licence.

Yours sincerely,

Mrs. J. M. Boulton, B. Pharm., M.P.S.
Registration Officer.

Encs.

cc P.M.G. Cutter, Leverkusen,