0 2. März 1988

REGISTRIERUNG

⊕mai d-

1muno /a GRO-C 1mmuno gm 1muno a 0934 88-03-01 16:59

543/2,3:28 Rep./801

to: mrs. henninger

re: krýobulin eiré

the following amendments are proposed for the pack insert used for our last uk variation.

1. page 1 delete everything under composition and properties that follows ... 'not more that 64 mg fibrinogen per 100 iu factor viii'.

replace with your new standard text as given to mr. coombes in relation to plasminogen./ please however substitute austria\ and germany for central europe.

 page 5 under precautions and warnings delete last two sentences ie 'the careful selection of donors . . . transmission of hepatitis cannot be entirely ruled out.''

we propose to replace this with:-

''the risk of transmission of viral infection cannot be excluded with absolute certainty following the use of human blood or blood products.''

note

this is a new proposal under 2. we believe this best describes the current situation in view of all matters including current regulatory requirements.

we therefore suggest this be used on the following data:-

feiba - u.k. prothromplex - u.k.

if you approve we will also notify the ndab that we wish to use this wording for the two albumin products in ireland.

regards, r. nicholson

examp • •

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