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Reg./ Sen.

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telex2965 84-12-21 11:24

attn: mrs. diernhofer/mrs. henninger.

re your tlx 6271. point 2.

can you please let me know if you are referring to feiba or to all three heat treated products?

in principal our view is the same - if there is evidence to show that there is a reduction in post transfusion hepatitis rates with kryobulin tim 2 prothromplex tim 4 and feiba tim 4 then the statement concerning hepatitis transmission is acceptable without amendment. however because we thought this evidence was not present in the data for submission to the dhss we suggested the phrase should be amended and dr. schwarz agreed.

we realise that initially leaflets were prepared including the reduced hepatitis with claims were however done before we had a chance to evaluate the data and discuss modifications with you.

whether or not the product is licensed is we feel irrelevant. all claims for products whether licenced or not should be capable of full substantiation as otherwise the company is open to criticism for making incorrect claims and possibly even legal action in serious cases

we therefore would prefer u.k. leaflets not to claim reduction in hepatitis risk.

regards and best wishes for christmas and new year.

r. nicholson.

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