

Eingegangen am:

17. Mai 1989

REGISTRIERUNG

132813 imuno a
95413 immuno g
132813 imuno a
0943 89-05-16 16:50

attn:mrs henninger

re - change from lyophilisation to ultrafiltration in albumin.

as you know we have not yet submitted these documents. we have now considered the position further and think it would be helpful to also submit details of the testing methods used for sds, limules, aluminium and o.d.

as a reason for this variation we propose stating
"to further reduce the level of aluminium in the final product"

one final point - can you please let us know if anyone has considered the safety implications of replacing the lyophilisation step? as you know with ivig the loss of a lyophilisation step had a marked impact on the transmission of nanb with the british product. we realise that the terminal pasteurisation is probably felt adequate but would welcome any comments on this.

could we also please have a two further sets of originals for submission in ireland.

many thanks
r.nicholson
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95413 immuno g

1729/17.5.89
Reg. 15

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