134865 imuno a
95413 immuno g
134865 imuno a
telex1459 86-02-24 14:21

a copy of this telex will be sent to all four people stated.

attn: dr. eibl, dr. schwarz, mrs. diernhofer, mrs. henninger.

during mr. coombes recent visit, he was clearly informed of your wishes that for one reason or another, you wished us to change over from dry heat to moist heat treatment of concentrates.

we are most anxious to do this, so i am listing the information we are still waiting for vienna to send.

1. general
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agreement that we adopt the scientifically accurate phrase ''moist heat treatment''.

2. [redacted]

(a) we need to know details of the alt test, together with the limit to be applied. we also need to know how many units we can have per annum from alt tested material.

(b) the four additional clinical evidence cases promised by

dr. anderle four weeks after 27th january, 1986. the japanese paper refers to a pressure of 1200 m bar, whereas our submission shows 190 m bar and thus we cannot use the 21 japanese cases.

(c) on p5 of the enclosure on inactivation of factor viii, it is clearly stated that after freeze drying and steam treatment for 1 hour that 10to the power of 2 infectious (htlv iii) units remained.

we are certain that this will be queried.

(d) the rationale on inactivation methods using more than one model virus which was promised by product management tables will be useful in this regard and some were shown to mr. coombes by dr. habison.

once agreement is reached on these points, new packing and pack inserts will be required. if you will prepare, we will edit.

3. feiba

(a) agreement on our hepatitis statement to remain in force until mannucci paper is published. this will definitely hasten the passage of the amendment.

the statement we prefer for the present is:-

''by careful selection of donors and plasma and the moist heat treatment process, the transmission of htlv iii can be excluded.

the above measures will certainly reduce the risk of transmission of viral hepatitis but this cannot be entirely ruled out.''

(b) we need details of the alt test and the limit applied.

as with kryobulin, new packing and pack inserts will be required, which we will edit. this must have regard to the agreed omission of the recent changes in dosage which we will incorporate within 12 months.

4. endobulin
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we are still awaiting the documentation concerning viral inactivation at the 25□ ethanol step and the trypsin step.

this is not only required for our product licence submission but also to get permission to import for sale on a doctor named patient basis.

we also need a comprehensive reply to my letter nb/omc of 11th july, 1985 (reason for animal tests excepted).

5. gammabulin
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can you provide similar inactivation data as for endobulin.

kind regards
n. berry.
134365 imuno a
95413 immuno g