



By fax.

File

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Our Ref: Row412

Miss L R Rowlands
HM Customs and Excise
VAT Policy Branch VAT4A
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4 December 1995

Dear Miss Rowlands

Thank you for your letter of 20 October. We have discussed since then on the telephone and I have discussed with colleagues in the Department. The points we would make are as follows.

We assume that the reason for the exemption in Group 7 of Schedule 9 of the VAT Act of 1994, of Item 6 Human blood and Item 7 Products for therapeutic purposes, derived from human blood is so as not to dissuade voluntary unpaid donors of blood and plasma.

We are all agreed that recombinant Factor VIII does not come under item 6, it is not human blood.

Although the original gene used to produce the Factor VIII came from human cells, the amount used was very small and is now historical since the line is continued by sub culture and additional human cells will only be added rarely if at all. Human Albumin is used as a stabiliser for the recombinant Factor VIII currently licensed in the UK. We are aware that there is another form of recombinant Factor VIII currently being used in clinical trials which does not use human Albumin as a stabiliser. Pharmaceutical manufacturers are now trying to develop products which do not use human Albumin, since although this has a very good safety record, there is always the anxiety that at some stage in the future some unknown virus or other problem may occur because it is derived from human donations.

The Albumin used is only a stabiliser and has no contribution to the therapeutic effect of the recombinant Factor VIII. If one were to extend this to all the other drugs which contain human Albumin, this would also involve Erythropoietin, some of the Interferons, Vaccines and Ceredase.

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M. K. Guinness
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IMPROVING THE HEALTH OF THE NATION

The proportional cost of Albumin in the recombinant Factor VIII product is of the order of 0.08% to 0.2% of the total cost.

I hope these comments are helpful in your decision making. If you require any further details or wish to discuss further, I shall be happy to help.

Yours sincerely

GRO-C

Dr A Rejman MD MRCP MRCPPath
Senior Medical Officer