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Baxter

12th June, 1989

Department of Health,
Medicines Control Agency,
Brittania House,
7 Trinity Street,
London, SE1 7DA.

Dear Sir,

RE: PL.0116/0201: HEMOFIL^{R} M,
Antihaemophilic Factor (Human), Method M,
Monoclonal Purified

Please find enclosed three copies of the Product Licence application for the above referenced product.

In order to aid your processing of this application I give below notes that should be of assistance to you.

A) The file is constructed as follows:-

PART I (Two Volumes)

1) MLA201 and Data Sheet
2) Expert Reports

PART II (Six Volumes)

1) PART I
2) Chemistry and Pharmacy Documentation
3) Appendices
4) Appendices - continued
5) Appendices - continued
6) PART V

PART III (Three Volumes)

1) PART I
2) Toxicological and Pharmacological Documentation
3) PART V

PART IV (Three Volumes)

1) PART I
2) Clinical Documentation
3) PART V

Registered Office as above
Registered in England No. 461365

PART V 1) Labelling and Packaging

B) The number of pages given in Point 9 of the MLA.201 forms relate only to the relevant scientific evidence and do not include the PART I or PART V pages.

C) In this application we reference CellTech DMF 6989-A7374. A copy of the letter of access is provided with each MLA.201 form.

D) Two additional small sections are provided, containing photographs not included in the three copies.

i) SDS - PAGE Immunoblots (Pages 2 - 106 to 2 - 115.
ii) ELISA prints (Pages 4 - 113 to 4 - 114)

E) I apologise for the poor quality of some of the photographs in Appendix 37 (BioResponse Report). Originals of these photographs will be included in the BioResponse DMF when submitted.

Should you have any queries concerning this package, do not hesitate to contact me on the above referenced telephone number (Ext. GRO-C).

Yours faithfully,

GRO-C

Ivan Bryant
Senior Regulatory Officer

IJB/MES