INSPECTION ACTION GROUP

AGENDA ITEM 5

Manufacturer: Alpha Therapeutic corporation
5555 Valley Boulevard
Los Angeles
California
USA

Product Licence Holder: Alpha Therapeutic UK Ltd

Product Licence Number: 4447/0005 Profilate (Factor VIII)

Alpha Therapeutics is a subsidiary of the Green Cross Corporation of Japan and a comprehensive range of blood products are made at the Los Angeles site.

The site was inspected on 6-10th October 1989, where it was found that the company had failed to carry out agreed upgradings in order to ensure safe production i.e. viral free Factor VIII ("Profilate").

This situation is now regarded as critical and removal of the licence is therefore recommended by the Inspectorate.

Factor VIII produced by this methodology is not supplied to the USA but the company is preparing a UK PL variation so that the product presently supplied in the USA can be licenced for the UK.

A copy of the inspector's report and the list of deficiencies are at Appendix A.

The company's response to the Inspectors' observations at the final discussion is at Appendix B.

The variation to the UK Product Licence mentioned in Appendix B was submitted to the Licensing Authority on 25th October 1989.

The Group will be aware of the political implication of this case in either allowing the licence to continue or removing it as a source of supply.

The Group is invited to consider Section 28 to revoke the product licence. The grounds are Section 28 3(b) and (e).

MB6B

01189-1-LVK

DEPT. OF HEALTH - MEDICINES INSPECTORATE

INSPECTOR'S SUMMARY

APPENDIX A

SITE: OVERSEAS MANUFACTURER COMMERCIAL IN CONFIDENCE

FILE REF: 285/IN/4966	MB5B Report No. 1989/14/49
TITLE: Alpha Therapeutics Corp. 5555 Valley Boulevard Los Angeles California	CO. TELE: (213) 225-2221
DATE OF INSPECTION: 6-10 October 1989	INSPECTOR(S): D R S Warburton M L Kavanagh

REGION/AREA 4.0 GMP _ _ NO. EMPLOYEES _ _ PROCESS CODE _ _ _ _ _ _ _ _ _ _ _ _
CAT _ _ _ _ _ ACTIVITY _ _ PD INTEREST _ _ VOLUME _ _ COMMENT _ _ _ _ _ _ _ _

COPIES TO :			
MISG	For routine distribution		
MB5B	K J Ayling		

DATE OF LAST INSPECTION: 22-24 February 1988

PREVIOUS INSPECTIONS (YEARS): 1983

PURPOSE OF VISIT: Routine re-inspection of the site's Production and Quality Control facilities.

LICENCES HELD OR APPLIED FOR: Albutein ~~0447~~ 0447/7-9. Plasmatein ~~0447~~ 0447/10. Bulk Cryo Paste 4029/002. Profilate ~~0447~~ 0447/005. Venoglobulin ~~0447~~ 0447/0014 (Application)

LICENSING CHANGES: ACTUAL:

IMMINENT:

RECOMMENDATIONS/ACTION:

1. The PL for Profilate (Heat Treated) ~~0047/005~~ 0447 ccs should be withdrawn.
2. An Inspectorate letter, listing the remaining non critical deficiencies noted during the visit (see Appendix), should be sent to the company.
3. Provided a satisfactory reply is received to the Inspectorate letter, no administrative action is required on the remaining PLs.
4. Re-inspect within ~~24~~ 6 months GRO-C

PROPOSED DATE OF NEXT VISIT (YEAR): DAYS NEEDED:

COMPILED BY: D R S WARBURTON (SPMI) M L KAVANAGH (PMI) GRO-C DATE SIGNED: 7 November 1989	COUNTER SIGNATURE: REGIONAL PMI SMI / GRO-C: KJ Ayling 8/11/89

The factual matter contained in this report relates only to those things that the Inspector(s) saw and heard on the occasion of the visit. This report is not to be taken as implying a satisfactory state of affairs in premises, equipment, personnel or procedures not examined on this occasion.

FSO.