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## Department of Health and Social Security

Medicines Inspectorate 55 High Street, Lymington, Hants

Telephone 0590-76471

eyt

Mrs M Tatt Registration Manager Cutter Laboratories Stoke Poges

Your reference

Our reference

Date 28 March 1988

Dear Mrs Tatt

Following the recent inspection of your Company site at Clayton North Carolina USA in February 1988, I have attached a list of the deficiencies found for you to circulate to the site. I would like to have any comments together with the proposed action programme for these items.

In addition the UK product licenses should be **veried** where appropriate to cover the following additional activities carried out

- (a) BSI should be included as a plasma source for use in Factor Eight, Factor Nine and Immuno globulin.
- (b) Alpha Theraputics should be named as a source of Fraction Two and Fraction Three.
- (c) The usage of Sourced Salvaged Plasma should be named.

Yours sincerely

GRO-C

D WARBURTON