SGB/MB

2nd February, 1976

G.H.T. Deveney, Esq.,
Department of Health and Social Security,
Finsbury Square House,
33-37a Finsbury Square,
LONDON, EC2A 1PP.

REGULATORY COMPLIANCE
JUL 1 1980
J. J. BONA

Dear Sir,

PL 0231/0038

With reference to your letter of 27th January, 1976, I shall answer your questions in the sequence in which they were posed:-

1. (a) Details on the method of assay, the standard used and the method of calibration has been arranged with Dr. Bangham. Our method of assay is in AHF units. We intend to calibrate our House Standard against the present International Standard. Dr. Bangham is aware that the current standard is contaminated with hepatitis antigen and Armour do not wish to introduce this risk into their laboratories. Dr. Bangham has suggested this work is carried out in the U.K. Calibration is to be carried out with sufficient assays to give a cumulative precision with fiducial limits 90-110%. The statistical design has been discussed and is to be carried out with Armour's concentrate House Standard at the Oxford Haemophilia Centre.

(b) Batch reproducibility has been shown in our submission (Vol. I, pages 64-74) for five batches. Do you require additional evidence of batch to batch consistency of our product?

2. (a) The number of donations is approximately 1,540 per batch to give a pooled plasma of approximately 1,000 litres. The rejection rate at blood collection centres is below 1% for accepted donors. The only data available concerns those rejected for blood pressure, temperature and other illnesses on the day of the donation. No data is available on rejections caused by other medical examinations.

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(b) The potency of the product will be expressed in international units as soon as assays can be arranged in the U.K. (see item 1 (a)).

(c) The stability data at 4-6°C is satisfactory. We have indicated storage at 2-8°C on our product leaflet because of refrigerator variabilities. We agree to store at 6°C or below.

(d) Product labelling which at present conforms to U.S.A. requirements can be amended to show B.P. requirements, (page 65 BP, 1973).

(e) We agree to the inclusion in the product licence the three provisions of batch release.

(f) We confirm that the plasma will be only from donor centres in the U.S.A., and from U.S.A. sources.

From various telephone conversations, I understand that our application has progressed to the point of being acceptable in principle and trust the above answers clarify what has already been discussed. Please let me know if additional batch analyses are required.

Yours faithfully,
ARMOUR PHARMACEUTICAL COMPANY LTD.

S.G. Brooks, B.Sc.
Head of Regulatory Affairs