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CC: MR. K.W. FITCH
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21 JUNE 83

ATTN: KAS EGERTON, S/HS19, DHSS

AIDS IN BLOOD PRODUCTS

THANK YOU FOR YOUR TELEX OF 16 JUNE ON THE ABOVE SUBJECT. CERTAIN OF THE SPECIFIC QUESTIONS YOU ASK REQUIRE RESPONSES IN MORE DETAIL THAN THE INFORMATION WE HAVE AVAILABLE AND THESE HAVE BEEN REFERRED TO OUR ASSOCIATE COMPANY IN THE USA FOR MORE COMPREHENSIVE RESPONSES. THESE LATTER WILL BE TRANSMITTED TO YOU AS SOON AS THEY ARE AVAILABLE TO US.

IN THE INTERIM OUR RESPONSES TO THE POINTS YOU RAISE ARE AS FOLLOWS:

1. OUR COMPANY MANUFACTURERS FACTOR VIII CONCENTRATE (TRADE NAMES FACTORATE AND HIGH POTENCY FACTORATE) IN THE USA AND THESE PRODUCTS ARE IMPORTED AND SOLD IN THE UK. APPROXIMATE ANNUAL SALE OF THESE PRODUCTS ARE AS FOLLOWS:

FACTORATE 15 - 20 MILLION IU

HIGH POTENCY FACTORATE 1 - 1.5 MILLION IU

SUPPLIED IN VIALS OF VARYING POTENCIES TO MEET THE NEEDS OF INDIVIDUAL CENTRES.

2. SOURCE PLASMA IS OF USA ORIGIN AND PROCESSING OF THIS TO THE FINISHED PRODUCT ALSO TAKES PLACE IN THE USA.

3. ALL PLASMA IS COLLECTED AT FDA LICENSED CENTRES. ROUTINELY ALL PLASMA USED IS COLLECTED AT PLASMAPHERESIS CENTRES OWNED BY PLASMA ALLIANCE, WHICH AS WITH ARMOUR PHARMACEUTICALS IS A SUBSIDIARY OF THE REVLOX HEALTH CARE GROUP. THESE CENTRES ARE LOCATED AS FOLLOWS:

AKRON (OH), ATLANTA (GA), CHATTANOOGA (TN), CLEVELAND (OH), COLOMBOS (OH), DAYTON (OH), KNOXVILLE (TN), LEXINGTON (KY), LOUISVILLE (KY), NASHVILLE (TN), OKLAHOMA (OK), OMAHA (NE), W.LAFAYETTE (IN), UNIVERSITY OF MINNESOTA (MN), ST. PAUL (MN).

ON OCCASIONS PLASMA HAS ALSO BEEN OBTAINED FROM OTHER FDA-LICENSED CENTRES.

WE ARE SEEKING FURTHER INFORMATION ON THE NAMES AND LOCATIONS OF THESE CENTRES FROM THE USA.

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4. ONLY USA PLASMA IS USED.

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5. WE BELIEVE THAT THE COMPREHENSIVE LABELLING AND RECORD REQUIREMENTS OF THE FDA CODE OF FEDERAL REGULATIONS AND THE ADDITIONAL CORPORATE IN-HOUSE REQUIREMENTS PER MIT IDENTIFICATION OF THE ORIGIN OF PLASMA INCLUDED IN THIS BATCH TO SPECIFIC DONOR LEVEL AS WELL AS CENTRE. CONFIRMATION OF THIS IS AWAITED FROM THE USA.
6. PLASMAPHERISED PLASMA IS COLLECTED FROM THE PLASMA ALLIANCE CENTRES AND PROCESSED AT ARMOUR PHARMACEUTICAL COMPANY, KANKAKEE, ILLINOIS. WE BELIEVE THAT PLASMA FROM SEVERAL CENTRES IS USED IN THE PRODUCTION OF A BATCH OF MATERIAL.
7. NONE OF THE PLASMA ALLIANCE CENTRES ARE LOCATED IN ANY OF THE AREAS ASSOCIATED WITH HIGH RISK OF AIDS TRANSMISSION. WE BELIEVE THIS TO BE ALSO THE CASE WITH OTHER CENTRES USED BY THE COMPANY. THUS OUR FACTORATE PRODUCTS WILL NOT CONTAIN MATERIAL DERIVED FROM PLASMA COLLECTED IN THESE AREAS.
8. WE CONFIRM THAT ALL PLASMA USED IN THE PRODUCTION OF OUR BLOOD PRODUCTS IS NOW COLLECTED IN CONFORMITY WITH THE FDA DIRECTIVE OF MARCH 23, 1983.
9. WE BELIEVE THAT A FULL PROGRAMME OF SPECIAL PRECAUTIONS REGARDING SCREENING PROCEDURES AND DISSEMINATION OF INFORMATION TO DONORS WAS INITIATED IN OUR PLASMA ALLIANCE CENTRES IN FEBRUARY OF THIS YEAR. BEFORE THAT TIME INFORMATION ON THE RISK OF AIDS HAD BEEN RELAYED TO DONORS BY MEANS OF POSTERS DISPLAYED IN THE COLLECTION CENTRES SINCE OCTOBER/NOVEMBER 1982 ALTHOUGH THE REVISED SCREENING PROCEDURES HAD NOT BEEN FINALISED AND IMPLEMENTED. CONFIRMATION OF THIS IS BEING SOUGHT FROM THE USA.
10. WE BELIEVE THAT ALL FUTURE SUPPLIES OF OUR PRODUCTS, FACTORATE AND HIGH POTENCY FACTORATE, SOLD IN THE UK WILL HAVE BEEN PROCESSED FROM PLASMA COLLECTED UNDER THE NEW PROCEDURES.

ANY ADDITIONAL DATA WHICH WE RECEIVE IN RESPONSE TO REFERRAL OF THESE MATTERS TO OUR COLLEAGUES IN THE USA WILL BE TRANSMITTED TO YOU AS SOON AS WE RECEIVE IT. IN THE MEANTIME IF YOU HAVE ANY QUERIES ON THE RESPONSES PRESENTED PLEASE CONTACT US.

REGARDS,

H L SHAW
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