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TO: MILES LABORATORIES LTD

FOR ATTENTION OF DR ELLIOTT
SLOUGH BUCKS

FROM: K A S EBERTON, S/HSIB, DHSS, 14 RUSSELL SQUARE, LONDON WC1E
SEP (883669)

RE TELECON OF 15 JUNE 1983, PLEASE SUPPLY FOLLOWING INFORMATION
URGENTLY BY RETURN TELEX IF POSSIBLE.

1. DOES YOUR COMPANY MANUFACTURE COAGULATION FACTOR CONCENTRATES FOR USE IN THE UK? IF YES, NAME THE PRODUCTS AND STATE HOW MUCH OF EACH IS SUPPLIED ANNUALLY. *Ward*
2. FROM WHICH COUNTRY OR COUNTRIES IS THE SOURCE PLASMA OBTAINED? *Ward*
3. IF FROM THE USA, IS ALL PLASMA COLLECTED AT FDA-LICENSED PLASMA COLLECTION CENTRES? PLEASE GIVE THE NAMES OF THE CENTRES AND THEIR LOCATIONS. *Ward*
4. IF NON-USA PLASMA IS USED, NAME THE COUNTRIES INVOLVED AND STATE WHETHER THE PLASMA COLLECTION CENTRES IN THESE COUNTRIES ARE LICENSED BY THE NATIONAL REGULATORY AUTHORITIES. *Ward*
5. ARE YOU ABLE TO IDENTIFY THE ORIGIN OF THE PLASMA INCLUDED IN EACH BATCH OF FINAL PRODUCT AND THE DATE ON WHICH IT WAS COLLECTED? *Ward*
6. IS THE PLASMA FROM EACH COLLECTION CENTRE FRACTIONATED SEPARATELY OR IS PLASMA FROM SEVERAL COLLECTION CENTRES POOLED PRIOR TO PROCESSING? *Ward*
7. IF THE PLASMA IS OF USA ORIGIN, ARE YOU ABLE TO SUPPLY FINAL PRODUCTS WHICH DO NOT CONTAIN PLASMA FROM THE MAJOR "EPIDEMIC" AREAS FOR AIDS EG NEW YORK, SAN FRANCISCO, LOS ANGELES, MIAMI? *Ward*
8. CAN YOU CONFIRM THAT ALL PLASMA OF USA ORIGIN IN YOUR PRODUCTS IS BEING COLLECTED IN CONFORMITY WITH THE FDA DIRECTIVE OF 23 MARCH 1983? *Ward*
9. DID YOUR COMPANY INSTITUTE, IN ADVANCE OF THE FDA REQUIREMENTS, ANY SPECIAL PRECAUTIONS TO BE TAKEN BY PLASMA COLLECTION CENTRES IN RESPECT OF AIDS? IF SO, WHAT WERE THESE PRECAUTIONS AND WHEN WERE THEY INTRODUCED? *Ward*
10. IF USA PLASMA IS USED, ARE YOU ABLE TO CONFIRM THAT ALL FUTURE SUPPLIES OF COAGULATION FACTOR CONCENTRATES TO BE SOLD IN THE UK WILL BE MANUFACTURED FROM PLASMA COLLECTED IN ACCORDANCE WITH THE FDA DIRECTIVE OF 23 MARCH 1983 (OR IN ACCORDANCE WITH THE SPECIAL PRECAUTIONS, IF ANY, INSTITUTED BY YOUR COMPANY AT AN EARLIER DATE)? *Ward*
11. IF THE ANSWER TO (10) IS NO, FROM WHAT DATE CAN YOU MEET THIS REQUIREMENT? *Ward*

ENQUIRIES TO: 01 636 6811 EXT

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THEIR LOCATIONS. *?*
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WHETHER THE PLASMA COLLECTION CENTRES IN THESE COUNTRIES ARE
LICENSED BY THE NATIONAL REGULATORY AUTHORITIES. *✓*
5. ARE YOU ABLE TO IDENTIFY THE ORIGIN OF THE PLASMA INCLUDED IN
EACH BATCH OF FINAL PRODUCT AND THE DATE ON WHICH IT WAS
COLLECTED? *conf*
6. IS THE PLASMA FROM EACH COLLECTION CENTRE FRACTIONATED SEPARATELY
OR IS PLASMA FROM SEVERAL COLLECTION CENTRES POOLED PRIOR TO
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IN RESPECT OF AIDS? IF SO, WHAT WERE THESE PRECAUTIONS AND WHEN
WERE THEY INTRODUCED? *?*
10. IF USA PLASMA IS USED, ARE YOU ABLE TO CONFIRM THAT ALL FUTURE
SUPPLIES OF COAGULATION FACTOR CONCENTRATES TO BE SOLD IN THE UK
WILL BE MANUFACTURED FROM PLASMA COLLECTED IN ACCORDANCE WITH
THE FDA DIRECTIVE OF 23 MARCH 1983 (OR IN ACCORDANCE WITH THE
SPECIAL PRECAUTIONS, IF ANY, INSTITUTED BY YOUR COMPANY AT AN
EARLIER DATE)? *?*
11. IF THE ANSWER TO (10) IS NO, FROM WHAT DATE CAN YOU MEET THIS
REQUIREMENT? *?*

ENQUIRIES TO: 01 636 6811 EXT GRO-C

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ATTN K.A.S. EGERTON

IN RESPONSE TO YOUR TLX OF 16 JUNE WE ARE PLEASED TO SUPPLY
THE FOLLOWING INFORMATION.

1. YES. KQATE F.VIII CONCENTRATE.
APPROX 8 MILLION I.U.
2. U.S.A.
3. YES. CUTTER-OWNED AND AFFILIATE PLASMA CENTRES ARE LOCATED
AS FOLLOWS:

AUBURN, AL
BIRMINGHAM, AL
MOBILE, AL
MONTGOMERY, AL
TUSCALOOSA, AL
PHOENIX, AZ
SCOTTSDALE, AZ
TEMPE, AZ
BERKELEY, CA
LONG BEACH, CA
OAKLAND, CA
SACRAMENTO, CA
SAN DIEGO, CA
STOCKTON, CA
COLORADO SPRINGS, CO
DENVER, CO
PUEBLO, CO
DAYTONA BEACH, FL
FORT LAUDERDALE, FL
FORT MEYER, FL
GAINESVILLE, FL
JACKSONVILLE, FL
ORLANDO, FL
AUGUSTA, GA
MACON, GA
DAVENPORT, IA
DES MOINES, IA
FORT WAYNE, IN
INDEINAPOLIS, IN
MUNCIE, IN
LOUISVILLE, KY
KANSAS CITY, KS
BATON ROUGE, LA
LAFAYETTE, LA
ANN ARBOR, MI
DETROIT, MI
FLINT, MI
KALAMAZOO, MI
LANSING, MI
YPSILANTI, MI

MINNEAPOLIS, MN
KANSAS CITY, MO
SPRINGFIELD, MO
GREENVILLE, MS
JACKSON, MS
BILLINGS, MT
LINCOLN, NE
ALBUQUERQUE, NM
INDIAN SPRINGS, NV
LAS VEGAS, NV
STEWART, NV
CINCINATTI, OH
COLUMBUS, OH
OKLAHOMA CITY, OK
TULSA, OK
EUGENE, OR
EASTON, PA
PITTSBURGH, PA
SCRANTON, PA
COLUMBIA, SC
RAPID CITY, SD
NASHVILLE, TN
AUSTIN, TX
BROWNSVILLE, TX
CORPUS CHRISTI, TX
DALLAS, TX
DEL RIO, TX
EAGLE PASS, TX
EL PASO, TX
HOUSTON, TX
LAREDO, TX
LUBBOCK, TX
MCALLEN, TX
SAN ANTONIO, TX
OGDEN, UT
SALT LAKE CITY, UT
NORFOLK, VA
ROANOKE, VA
SEATTLE, WA
MILWAUKEE, WI

4. NOT APPLICABLE.
5. YES
6. POOLED FROM SEVERAL CENTRES PRIOR TO PROCESSING.
7. YES THERE ARE NO CUTTER OR AFFILIATED DONOR CENTRES IN
NEW YORK, SAN FRANCISCO, LOS ANGELES OR MIAMI.
8. YES.
9. YES. IMPLEMENTATION OF THE FDA DIRECTIVE OF 24 MARCH
TOOK PLACE BY CUTTER ON 1 MARCH 1983. HOWEVER, FOR
MANY YEARS SOME AIDS RELATED SCREENING PROCEDURES - SUCH
AS ROUTINE CHECKS FOR WEIGHT LOSS AND GENERALISED
LYMPHADENOPATHY HAVE BEEN USED.

10/11. WE EXPECT PRODUCT PRODUCED FROM PLASMA COLLECTED
SINCE MARCH 1983 TO BE AVAILABLE AUGUST 1983.

DR. B.A. ELLIOTT
M.D., F.R.C.PATH.,
MEDICAL DIRECTOR
MILES LABORATORIES LIMITED