

MINISTRY OF HEALTH AND WELFARE

JAPANESE GOVERNMENT

2-2, 1-CHOME, KASUMIGASEKI, CHIYODA-KU, TOKYO

100 JAPAN

June 9, 1989

Dr. Gary C. Schatz
Hepatitis Control Officer
Hepatitis Branch
Division of Viral Diseases
Center for Infectious Diseases
Center for Disease Control
Atlanta GA 30333
the U.S.A.

Dear Dr. Gary C. Schatz,

Thank you for your sending a draft for future control of HBV in the U.S.A.

I would like to collect some informatin concerning hepatitis B in hemophilic patients.

Recently, it turned out that three hemophilic patients who were treated with Fator VIII concentrate produced by Cutter Biological, Miles Inc. had hepatitis B in our country. The details of cases are stated on attached papers. The importer of the products started to recall the products voluntarily in accordance with my direction. So far causes of the accidents have not been made clear and further investigation including inquires of FDA about the situation of GMP in the manufacturer's plant, etc has been continued.

I would like to know information on occurrences of hepatitis B caused by antihemophilic factor. I have special concerns about the occurrences by the products produced since the adoption of inactivatin or elimilation methods of virus such like heating or affinity chromatography in the processing of the products.

I heard that vaccination of hepatitis B vaccine to hemophiliac patients were recommended in the U.S.A., because they were regarded as high risk group of

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hepatitis B. I also would like to know information concerning the
recommendation.

Your kind assistance will be appreciated.

Sincerely yours,

GRO-C

Akio Uno
Director,
Biologics and Antibiotics Division
Pharmaceutical Affairs
Ministry of Health and Welfare