HYLAND
DIVISION TRAVENOL LABORATORIES, INC.

Interoffice correspondence

to: D. L. Castaldi

from: A. J. Lazos

subject: Hepatitis Removal
Monthly Summary

date: April 26, 1978

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Attached is the subject Priority "A" report for the period March 7, 1978, through April 21, 1978.

GRO-C

AJL:bb

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HEPATITIS REMOVAL MONTHLY SUMMARY

I. Progress Since March 1978 — Responsibility

A. Isolation, identification and/or removal of hepatitis from Therapeutic products. — G. Dolana

1. Non-A, Non-B hepatitis studies are continuing at the CDC Hepatitis Laboratory. The four chimpanzees infused with Hyland product the week of 2/12/78 have all demonstrated enzymatic and histological evidence of hepatitis. These animals will continue to be monitored to further characterize the disease. In addition, each animal has been plasmapheresed at selected intervals and the plasma held at -50°C for future evaluation.

   A study designed to show that the agent can be transmitted has been initiated. It is designed to demonstrate that an "agent" is responsible for the changes noted in the first four chimps. If successful, the study data would strongly suggest an infectious disease, probably viral in origin.

   Preliminary electron microscopy studies conducted with ultracentrifuge concentrated and purified material obtained from the implicated Hyland product have demonstrated the presence of virus-like particles. The reaction of these particles with serum suspected of containing non-A, non-B antibody will be investigated.

2. Methods of propagation of phage for determination of pore size in molecular exclusion filters and assay bacteriophage R17 have been completed. The stability of this phage in solutions which will be passed through molecular exclusion filters will be investigated.

B. CDC proposal for Non-A, Non B Hepatitis CDC/Hyland joint effort received. Based on the approach and scope of the information submitted, it is quite apparent that a good opportunity may exist for Baxter/Travenol to realize benefits for its hepatitis strategy program. — G. Dolana

Progress Since March 1978 (cont'd)	Responsibility
C. No progress on the studies on removal of Hepatitis infectivity either through heat treatment of Hemofil or molecular filtration of proplex.	T. Andary/ D. Edgell

II. Problems or Delays Encountered and Solutions

	Problem	Responsibility	Solution
A.	Manpower Restraints. Phase I of hepatitis removal proposal was funded for $63,165. On January 19, 1978, additional funding of $78,000 was requested to fund (1) a collaborative non-A, non-B hepatitis study with the CDC, and (2) the services of Dr. Dolana and a Senior Research Associate. A Decision Package was submitted in February, 1978, to hire the Senior Research Associate. To date, no decision has been made on funding for the latter two parts of the proposal.	A. Lazos	As mentioned in last month's report, in order to continue with a viable Hepatitis Removal program, the proposal above for additional funds and manpower should be approved.

III. Key Milestones and Responsibilities Next Three Months

	Milestone	Responsibility	Date
A.	Investigation of other potential F-VIII stabilizers which have been proven safe and effective in other therapeutic products.	D. Edgell	Dependent on availability of funds and manpower.
B.	Continued evaluation of the efficacy of ion exchange resins and/or molecular filtration in removal of hepatitis infectivity from Proplex and other therapeutic products.	T. Andary	Dependent on availability of funds and manpower.
C.	Outline plan for removal of hepatitis virus from therapeutic products by Monsanto's polyelectrolyte process.	T. Andary	As soon as S. Holst provides literature from Corporate.