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TO M.M. Sternberg DATE January 4, 1983

FROM M. Mozen COPIES TO R.E. Louie

SUBJECT Chimp testing of hepatitis-safe Koāte®

In the trip report of R.S. Schwartz (12/13/82) it is suggested that the recent data reported by Hyland may cast doubt on the efficacy of pasteurization as a method of hepatitis-B inactivation. The implications of these findings to our own hepatitis-safe Koāte® program deserve some comment.

First off, there is reason to believe that the Hyland process of heating is significantly different from ours, a fact told directly to Dr. Schwartz by Dave Aronson. Further, there are several rumors going about that the Hyland product is heated in the final container in its freeze dried form. Comments made by Dr. J.P. Allain are consistent with this possibility. If this is in fact true, it would not be surprising that hepatitis-B was not inactivated.

The most significant finding of the Hyland study was the late onset of hepatitis-B at 32 and 40 weeks post inoculation. Previous studies of this kind have generally terminated at 6 months at which time experimental conclusions were established.

Our present hepatitis-safe Koāte® study involves 3 chimps; 2 controls and 1 experimental. Each animal received 12,500 chimp infectious units (CID). The experimental chimp has remained non-symptomatic for hepatits for greater than 6 months now and we will continue to follow him for a total of one year. The control chimps have both shown evidence of non-A non-B hepatitis but as yet no serologic markers of hepatitis-B infection. It has been suggested that non-A non-B infection delays the onset of hepatitis-B. This may be so, but we still expect the 2nd control chimp (now about 11 - 12 weeks post inoculation) to contract hepatitis. At this point, the data clearly support that our pasteurization procedure has inactivated non-A non-B hepatitis. Although we will be following our chimpanzees for a longer time than originally projected (1 year vs. 6 months), this need not delay our time-table in so far as filing our PLA ammendment to include heat pasteurization. It is our intention to file in the 2nd quarter of 1983 as planned and hopefully to obtain approval during 1983. This estimate is predicated on satisfactory clinical results and successful introduction of the process into manufacturing.

The recent concern about AIDS and its possible transmission by an infective agent should encourage a rapid review and approval of the submission. Even without hard data, it is certainly logical that a heated product, with no sacrifice of clinical efficacy, should be potentially safer than one not heated. Such a product should be made available to those whose life depends on it in as rapid a time frame as possible even without the final unequivocal demonstration of its freedom from hepatitis and/or AIDS.

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