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REF: K-2-230

TO: Merrill Boyce
FROM: Steve Klein
SUBJECT: Commentary on Hepatitis-Free Koate, MA

DATE: May 5, 1982
COPIES TO: Jack Wood
Jan Peterson

Merrill,

As per your request, the following comments may be applicable to your Hepatitis free Koate MA statement:

- 1) Page 2: Although the Miller Study indicated that 58% of the physicians in the U.S. would always use a hepatitis free product on their current patient population, such a number (initially, at any rate) is almost certainly too high. During the first 1 to 3 years of product availability, the conversion to hepatitis safe Koate would probably not exceed 35% of total concentrate usage. Granted that my estimate is quite subjective; the Behring product, however, is still used primarily in neonates rather than having gained widespread acceptance (this, of course, is due at least partially to its high price). Hence, a commitment of 25% of our production to hepatitis safe material during the first year of market entry may be optimistic.
- 2) According to John Lundblad, Paul Ng, and Duane Schroeder, the yield loss across the pasteurization process is roughly 30% (at present). Scale up to manufacturing levels may reduce the pasteurization loss to 25%. These yield reductions as balanced against promised future yield increases (probably a little overstated-not by you, though) indicate that your estimates may be low. Again, however, all the estimates rendered by the involved parties probably have a large element of subjectivity present in them.
- 3) Pasteurized AHF is, in truth, hepatitis safe rather than hepatitis free. Since there is no current market for non-A, non-B hepatitis, complete freedom from hepatitis can't be proved. Anecdotal information states that the Behring product is 15-20 times as hepatitis safe as a nonpasteurized product but not totally free. This is probably the basis for Behring's "hepatitis safe" terminology for the product.

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Merrill Boyce
Hepatitis-Free Koate
Page Two

- 4) The Behringwerke hepatitis safe product is approximately 50% more expensive than standard concentrate. Behringwerke has recently lowered the prices substantially.
- 5) Will our "greatest advantage" be gained by being able to convert 100% of our AHF production to hepatitis safe product? This is an extremely difficult question to answer. Ultimately, this is the direction to go in. In the interim, a carefully determined mix of standard product and "HS" product would be more advantageous. (Don't ask me how long the interim period would be).

Hope these comments are of some help.

Regards,

GRO-C

SK/cfk

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