

CONFIDENTIAL

BIOLOGICAL MANAGEMENT COMMITTEE

February, 15, 1983

Meeting # 2

1. Quality is Free

L. Franke, L. Hal, C. Orelli and P. Pender reviewed their very constructive analysis of HyperHep® quality standards and presented their recommendations. Copies of the presentation were distributed and form a part of these minutes. Recommendations to obtain higher-potency plasma, to maximize filling bulk size, and to raise the in-house standard to 1.35 with 3-year dating while setting target of 1.50 for diluting bulk concentrate have already been implemented.

Two further recommended options, 3b and 3c, provide for 2-year dating for some or all lots, rather than our present 3-year dating. U.S. competition has 2-year dating, but 3-year dating may be necessary for Japan, due to testing requirements, and perhaps other overseas markets. International will look at competition and consider feasibility of 2-year dating. J. Ryan and J. Wood will give J. Hjorth data and recommendations on this point.

The group was applauded and commended for its very successful project.

Dr. Sternberg suggested we consider possible yield-improvement methods for very expensive hyperimmunes. J. Hink pointed out that such methods could affect other important product characteristics, e.g. molecular weight, IgM, etc. Dr. Schaeffler asked that this dialogue be pursued, and the outcome reported at the next meeting.

2. Financial Update, U.S. - T. Johnson

January sales were 97% of Budget and 38% ahead of last year. Koāte sales, 31% below Budget and 18% below 1982, may reflect AIDS impact. The pattern, which continues into February, is one of generally lower Koāte volume; no major accounts have been lost. Hemophiliacs have been advised to avoid elective surgery. Whether the sales slowdown reflects less usage or hospital inventory reduction, or both, remains to be seen. Gamimune sales were 18% over Budget. ARC revenues were under Budget but are expected to catch up later in the year. PBT for January is estimated at \$300,000 vs. Budget of \$589,000, due mainly to higher sales in low-margin products - blood bags and Fraction V.

022000 07 07 07

104 5760

Koate® Product Improvements (Cont'd)

For the intermediate term we will develop the process shown as # 7 in the table AHF Processing alternatives: dilute fill, glycine precipitation, as recommended. Since no additional biochemist will be hired, timing to completion is projected to be nine months instead of seven.

For the longer term we will evaluate the feasibility of # 10, controlled-pore glass without $Al(OH)_3$. This will require a concept M.A. once feasibility is confirmed, followed by an A.R.

9. AIDS - S. Ojala, N. Ashworth

There have been no new AIDS cases reported among hemophiliacs since the last meeting. AIDS has now been reported in Germany, Spain and Denmark. We are now voluntarily screening donors. Hill & Knowlton has been retained as PR adviser on this issue. A draft press release and text for plasma-center poster are circulated; look OK with certain corrections. R. Modersbach is Cutter's official media spokesman; outside inquiries should be referred to him. Initial cost estimate for this program is \$15,000 plus printing costs.

A position statement has been prepared and sent to our distributors overseas.

J. Hink stressed that while a company position and press release are important, it is in the plasma centers where most of the hard questions will be asked and answered. The center operators must be oriented and trained ASAP.

Gross Townsend Frank is drafting an issue of ECHO devoted to AIDS; if it looks good we will use it.

10. Plasma from Prison - S. Ojala

It was decided that we will no longer release Koate® from prison plasma as commercial product, thus forestalling regulatory action. Instead this plasma will be processed separately and the AHF produced will be used internally in R & D and technology programs.

11. Koate® H-S - S. Ojala

O.B. believes heat treatment reduces but does not eliminate hepatitis B risk, but is very effective in preventing non-A, non-B hepatitis. The yield reduction of the process may turn out to be critically important: the Hyland process is reported to involve heating the final container to 60°C for 72 hours, with yield loss on the order of 10-20%. If so, the Hyland process would be much simpler than ours, require very little investment and result in a considerably lower yield loss.

026000

000000

104 5761