CONFIDENTIAL

BIOLOGICAL COORDINATING COMMITTEE

14 November 1983

1. REVIEW OF MINUTES - J. RYAN

The minutes were approved as corrected by those attending:

R. Barden, J. Richardson, M. Duffy, D. Aston, J. Hannon, S. Cullen, J. Ryan, T. Johnson, C. Turner, J. Hink.

Corrections:

The budget price for outdate plasma is $39.60, not $37.56 as reported in item 2 of the analysis. The balancing figure used in conclusion 4 of 1,398,000 liters for Factor VIII is clarified to show that this figure includes 1,273,000 liters of source plasma, 90,000 liters of outdate and prison plasma, and 11,800 liters for RhoD and HBIG.

2. HT PRODUCT BREAKDOWN BY CODE - S. CULLEN

A. International product is in shortest supply, with inventory sufficient to 1 February, 1984 only in a number of codes.

Since the last BCC, meetings have been held between representatives of marketing and production planning to determine what product will be available after the recent withdrawal. A hand-out which was discussed at one such meeting, entitled "KOATE (includes replacement)", dated November 7, 1983, was distributed. It showed that, for Domestic inventories, a four months' supply exists of each product size. For International, inventories sufficient to at least February 1 are reported. Export material using Domestic labelling is included as Domestic material in the hand-out.

B. Production planning for the balance of 1984 is directed to GP product.

Approval for the GP process is expected by mid-January. Any delay beyond mid-January of GP approval would result in sporadic backorders, particularly in the 500 i.u. size, for non-GP material. Two lots of 500 i.u. size GP material will be submitted to the OB in December, so that sales of GP product may commence immediately upon approval.

The submission for the dry heat process is still on track for November 23. Language is now being reviewed to ensure that the submittal covers the currently planned product which includes 5 mg of albumin.

As to future production for markets other than the U.S., some ultrafiltered product will still be required. Japan will require the ultrafiltration process. The U.K. and Italy may be switched to the GP process when further information regarding the regulatory status of our product in these countries is obtained. German alcohol/ultrafiltered production is scheduled to produce product sufficient last through mid-1984.

As to inventory status and production planning of GP product, 2 - 2.5 months' worth of product has been filled. Three lots of GP product in Clayton could be submitted to the OB for approval for sale as non-HT product. This would make additional non-HT product available to cover possible short term inventory shortages due to the withdrawal. It would, however, also make less HT product immediately available. A decision will be reached between production planning and marketing.

C. Labelling must be developed which is specific for each process.

Beginning in early 1984, we will have three basic types of products: 1. GP non-heated; 2. GP heated; and 3. ARC material. Labelling for each of these needs to be developed. The statements needed for GP labelling are known, but we must wait for instruction from the OB as to what statement can

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be made with regard to our heated product. The statement "contains dextrose" will be absent on GP non-HT carton.
The product code appears on bottle labels and cartons.

Each process should have a different product code used. This is essential in order that the plants are certain which process they should be using for a particular run, and so that accounting costs can be allocated for each particular process. Thus, if the modified process or the wet heat process is ever implemented, different product codes would be necessary for these processes as well. Labelling must therefore be developed around this need for different product codes for each process.

Certain labelling components for HT products have already been ordered and should be used if possible. For example, the bottle label developed for the wet HT process could be used for the dry HT process, if that product code were adopted for dry HT. The carton from the wet heat process, however, cannot be used due to a statement contained thereon regarding hepatitis.

In addition, separate codes (such as the addition of a prefix) are necessary in situations where non-HT product is different for a particular international market place, such as a different labelling language or statement.

Thus, it is necessary that a complete directory to codes be published.

David Soules will be invited to attend the next BCC, so that an overall strategy for labelling and assignment of product codes may be developed.

D. AIDS material

With regard to the AIDS work in process material planned for GP production, it was decided that two lots of this material would be heat-treated for possible submission to the OB. This would result in an indication from the OB as to what their

policy would be with regard to approval of heat-treated product obtained from possibly contaminated sources. Recommendations for disposition of the remainder of the product will be promolgated.

E. Modified process material

As a follow-up to a previous meeting in which it was decided that the testing of the modified process in Berkeley would continue, it was reported that two lots of "modified" product were DR'ed. This material contained excessive particles. Two more lots will be completed in the next several weeks. A PLA has been submitted so that any saleable product which results from these trials could be released under the current labelling.

3. REWORKING OF 20 ML ALBUMIN - C. TURNER

As shown in Attachment 1, an analysis was done on the cost effect of reworking approximately 100,000 vials of 20 ml albumin into a 50 ml presentation for Japan.

We currently have about 1.5 years of inventory of 20 ml albumin. This includes about the product currently in Japan, as well as material already manufactured and in inventory in the U.S.

The calculated cost for letting the 100,000 vials in question remain in inventory for about 1.5 years is approximately $194,000. The 100,000 vials in question represent about three months' inventory. The product can remain in house for up to three years without losing any dating. It would cost about $265,000 to rework the material. Thus, there appears to be justification for not reworking the material, except for the following factors:

1. The 20 ml size is rapidly losing its marketability in Japan. It does not appear that it will be anymore saleable one year from now than it is today;

2. Current production scheduling allows for time to rework this material this coming December,

but may not allow for such time in the future;

3. Since we sell through a distributor (OTSUKA) in Japan, we cannot dictate which product size will be sold or force sales of the 20 ml size.

4. The preference of the International Division is that the product be reworked. This subject can be brought up at the next BMC meeting.

4. FRACTION V / AHF MIX - S. CULLEN

A review of the Fraction V / AHF mix discussed at the special meeting of the BCC of 28 October was in order due to the recent product withdrawal, and a hand-out explaining the new mix status was distributed. If no revision is made in the plan adopted at that special meeting, there would be an excess of product in Japan in the amount of 15,000 liters of shipments of Fraction V over committed forecasts. This is much less excess than was expected. If the assumed NIH approval time was lowered from 75 days to 65 days, 43,000 extra liters worth of Fraction V would be available. Willi Ewald and Jack Ryan will meet to discuss this proposal.

With regard to procurement of AHF to make up for any deficit brought about by the product withdrawal, it appears that this deficit of about 169,000 liters can be made up entirely out of inventory, if we expect to carry about 4.8 weeks worth of inventory instead of the projected 10 weeks. The 4.8 weeks figure may be higher if yields improve during the year. It may also be possible to produce AHF-HT from prison plasma. It is therefore recommended by the BCC that the inventory figure be lowered.

5. AGENDA

The next meeting will be Monday, November 28, 9 ~~am, Room~~ 5, CT-2.

1. Review of Minutes - J. Ryan
2. Labelling - D. Soules

3. Procurement, sales, and inventory - graphs and charts - S. Cullen

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November 15, 1982