CONFIDENTIAL

BIOLOGICAL COORDINATING COMMITTEE
April 4, 1985

1. Those attending were: R. Barden, S. Bhonsle, R. Cole, S. Cullen, J. Davis, M. Duffy, K. Fischer, M. Madsen, S. Ojala, C. Patrick, J. Richardson, V. Shalson. Attending for specific agenda items were: P. DeHart, J. Hannon.

2. RAW PLASMA TESTING REQUIREMENTS - S. BHONSLE/ P. DEHART

S. Bhonsle reported that the Special Testing Laboratory is ready and enough samples should arrive by tomorrow to begin HTLV-III and ALT testing. HTLV-III testing will be done on every donor; ALT testing will be done on type A and type B plasma. Germany will accept ALT test results up to 2X normal. Over 3% of plasma is expected to be over 2X normal. S. Ojala reported that up to 5X normal is acceptable and we will use anything up to that for markets other than Germany. S. Ojala will approach the FDA on April 24 on this matter.

S. Ojala reported on labeling requirements. We will have to have specific wording on all labeling but these changes will not be required immediately. We will have information on the time table for these changes by 3rd quarter.

3. UPDATE ON PLASMA PROCUREMENT - S. BHONSLE

Receipts were 125,000 liters during March, slightly ahead of plan. April receipts are expected to be 120,000-121,000 liters. Receipts may drop May and June due to implementation of testing. We expect 4,000 liters per month more of prison plasma by 3rd quarter. S. Ojala and other manufacturers will be meeting with the FDA regarding using prison plasma for AHF.

R. Barden reported he will have to go up $5-10 per liter of anti-D plasma to keep current supply. We will end the year at 1,000 liters per month average. There is some high titer material coming from Canada this summer. Columbia Biologicals would like Cutter to fund a donor-stimulated study

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in order to get more anti-D plasma. S. Ojala will approach the FDA on this matter.

We are currently bringing in 4,000 liters per month of pertussis plasma. We expect to procure the total 1985 budget in the first 6 months.

4. STATUS OF ALPHA CRYO - S. CULLEN/S. OJALA

S. Cullen reported the 30 kg of cryo from Alpha arrived last week. The product will be filled on April 9. By April 15 we will have finished samples and will have the assay by the end of that week. S. Ojala reported that the product licenses of each company will apply to the appropriate manufacturing steps. Our license will cover the second portion, from cryo to finished product. Special joint labeling is required (license number and address only). A 6-8 week minimum lead time is required to get labeling approval from the FDA. Bottle labels and direction sheets must be changed for U.S. product; stickers may be used on cartons to meet requirement. It was agreed that the only label change to be implemented for this product is to add required Alpha information. P. DeHart will initiate the label development.

5. FRACTION V SHIPMENTS TO JAPAN - J. HANNON

J. Hannon reported the assumptions have not changed for shipments to Japan and we are working with Option I (see item 7 in March 21 BCC minutes), but discussions are on-going to see if further reductions are needed.

6. CLAYTON VALIDATION OF ULTRAFILTRATION OF 5% ALBUMIN - R. COLE/J. HANNON

R. Cole reported a single lot is needed. The BCC approved his request to begin immediately.

7. CMV AND PSEUDOMONAS PLASMA SUPPLY SITUATION - R. BARDEN/V. SHALSON (Attachment 1)

V. Shalson reported that M. Boyce informed him that the planned increase in testing staff has been delayed due to personnel problems. S. Bhonsle will look at alternatives for testing (e.g. do testing in San Diego or Clayton). R. Barden reported there would not be any advantage at this time to Federal Express the

material back and forth for screening. He presented a chart showing CMV plasma as a percentage of average center's total production and CMV liters produced.

8. FACTOR VIII SUPPLY SITUATION - P. DEHART

U.S. Koate sales are 138.7% of budget at the end of March. This equates to 39.3 million i.u. HT and 2 million i.u. non-HT. Inventory of 655-20 in the U.S. is at less than two weeks sales; next releases are expected in May.

The 4 million i.u. Koate promised to Canada will go out by May 1. The U.K. has back-orders for March with no inventory. We have backordered Sclavo 3,000 vials of 655-77. W. Johnson, V. Shalson, C. Patrick and P. DeHart will meet to review the allocation system currently used by U.S. Marketing.

9. KOATE ULTRAFILTERED LOTS - P. DEHART (Attachments 2 and 3)

Recent telexes from Cutter Japan were reviewed by P. DeHart. The MHW is expected to approve HT products by the end of June rather than end of year as earlier projected. Cutter Japan is requesting immediate shipment of Koate HT in order to be able to supply present customers when the HT products are approved. Existing inventory of non-HT ultrafiltered Koate will not be saleable after approval. That inventory is estimated to be 5 million i.u. in the U.S. and 5.3 million i.u. in Japan at the end of June.

10. KOATE RESERVES - M. MADSEN (Attachment 4)

M. Madsen presented a chart which shows $943,000 of ultrafiltered product in inventory with a $50,000 reserve. This amount together with the approximately 10 million i.u. that Cutter Japan won't be able to sell will result in over 20 million i.u. of unsaleable ultrafiltered Koate.

11. The next meeting is April 18, CT 2, room 5.

Agenda:

1. Update on Plasma Procurement and Testing Program - S. Bhonsle

2. Fraction V Shipments to Japan - J. Hannon

3. Factor VIII Supply Situation - P. DeHart

4. Status of Alpha Cryo - C. Patrick

5. Koate Ultrafiltered Lots - R. Cole/C. Patrick

6. CMV and Pseudomonas Plasma Supply Situation - S. Bhonsle

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