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BIOLOGICAL COORDINATING COMMITTEE
January 17, 1984

Copy	Biological Management Committee Members	BCC Members
1.	J. D. Ryan - Chairman	
2.	J. A. Akers	
3.	S. Bhonsle	S. Bhonsle
4.	J. H. Cherry	
5.	R. L. Cole	
6.	W. Ewald	W. Ewald
7.	K. H. Fischer	
8.	J. V. Hjorth	
9.	W. G. Johnson	
10.	R. J. Modersbach - Recording Secretary	
11.	M. M. Mozen	
12.	S. J. Ojala	
13.	V. H. J. Shalson	V. H. J. Shalson, Chairman
14.	M. M. Sternberg	
15.	C. F. Treppa	
16.	C. K. Turner	C. K. Turner
17.		S. A. Cullen
18.		J. M. Davis
19.		M. H. Duffy
20.		M. Madsen
21.		C. Patrick
22.		J. P. Richardson

Copies

23.	[redacted] Barden
24.	J. E. Benninger
25.	M. T. Boyce
26.	W. P. DeHart
27.	W. F. Schaeffler
28.	L. J. Wood

Minutes issued by M. Duffy January 31, 1985.

MIL 064343

EXHIBIT 30

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BIOLOGICAL COORDINATING COMMITTEE
January 17, 1985

1. Those attending were: B. Barden, S. Cullen, J. Davis, M. Duffy, J. Hink, M. Madsen, C. Patrick, J. Richardson, V. Shalson. Attending for specific agenda items were: B. Cole, W. Johnson, S. Ojala.

2. CRYOSAN - W. JOHNSON (Attachment I)

The details of the Cryosan agreement were presented. The plasma will be shipped to Cutter from Interstate Blood Bank, which is a current Cutter supplier. The importance of verifying delivery volume was stressed. According to B. Barden the arrangement with Interstate Blood Bank is that any shipment that has a discrepancy between reported and actual volume will be returned to Interstate Blood Bank.

New product codes will be required and special handling of raw plasma and work-in-process inventory accounts will be necessary. M. Duffy will initiate new product codes. M. Madsen will develop inventory accounting procedure.

3. MEGA STANDARD - S. OJALA

The December FDA pronouncement made the new AHF standard, 1.25, effective January 1, 1985. QA is thought to still be using "lot A", which is a 1.35 standard, and has scheduled the change-over at the end of January. B. Cole will discuss with Dr. Fischer and J. Cherry to clarify.

4. BGA REQUIREMENTS - S. OJALA

Currently the new BGA requirements include HTLV-III, or TPHA and core antibody testing, ALT testing, and labeling changes including number of donations and number of liters of each lot. Suit has been filed against the BGA by the industry, but the outcome is expected to be unfavorable. According to S. Ojala, our competitors are already preparing to meet the requirements, and are interpreting the implementation date of July 1 to mean shipments to Germany after that date must be

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in compliance. Dr. Spilles from Tropon will be here for meetings regarding the requirements the week of January 21. J. Hink, J. Cherry and C. Turner will meet in conjunction with the meetings with Dr. Spilles, and report back to the BCC with plans for implementation.

5. TURBIDITY STATEMENT/MILES INC. LABELING REQUIREMENTS - V. SHALSON

In January 1984 the FDA announced a new requirement of a turbidity statement on direction sheets, cartons and labels. The effective date was January 19, 1985. Two years ago when Cutter was merged with Miles the FDA directed that all labels indicate Miles Inc. instead of Cutter Inc. As of this month these regulations have not been fully met.

Packaging materials for 5% albumin, PPF, ARC and CRC products are out of compliance for lack of turbidity statement. All tetanus packaging is out of compliance for "Miles Inc." requirement. S. Cullen will review inventories for other products that do not meet regulations. An analysis of inventory status will be sent to V. Shalson, S. Ojala and J. Ryan. Artwork for new materials is due over the next 3 days, then 30-45 days is required for printing. B. Cole will discuss the problem with Dr. Fischer and J. Cherry to develop an action plan with S. Cullen to minimize product shortages.

6. CHANGE IN RELEASE REQUIREMENT - S. OJALA (Attachment II)

The FDA has notified Cutter of the elimination of the requirement for lot-by-lot releases for Fraction V products. C. Turner will tell S. Ojala the first lot number to be released without samples going to the OoB. J. Davis will get from E. Greene a list of countries that will continue to require OoB release.

7. ALBUMIN VERSUS ALPHA 1 PRIORITY - S. CULLEN

Clayton has a 2 week fractionation shutdown this month for refrigeration repairs, and Berkeley is scheduling an upgrade shutdown in the near future. To minimize production delays S. Cullen has discussed product development priorities with M.

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Boyce. He agreed that Alpha 1 could be delayed in favor of albumin production, but scheduled AT-III production is required. B. Cole reported that the PMT plan included the addition of 4 people which have not yet been approved. Delays in Alpha 1 and AT-III production cause further delays to PMT development work.

B. Cole expects a Berkeley upgrade/shutdown schedule by January 23 and will give it to S. Cullen. It was agreed that Berkeley will do 3 albumin pools and one AT-III lot for clinicals the week of January 21, delaying one Alpha 1 lot.

8. FRACTION V AVAILABILITY - S. CULLEN (Attachment III and IV)

The latest projections from Procurement indicate a shortfall for production year 1985 of 58,000 liters. S. Cullen commented that the budgeted 26,000 equivalent units Fraction V for PMT may not be available this year. B. Barden reported that currently raw plasma price per liter is averaging $48.00 versus a budget price of $46.00. Oklahoma Blood Institute has approximately 20,000 L/year available at $50/L liquid and $52/L fresh frozen.

The BCC recommended we pursue this plasma purchase. W. Johnson will confirm J. Ryan's concurrence and will contact OBI.

The BCC will consider a recommendation to increase Procurement's authorized plasma price. J. Davis will provide M. Madsen with updated price projections for a cost and profit analysis. The U.S. price projection is $36.50.

9. NON-HEATED KOATE - C. PATRICK (Attachment V)

All uncommitted domestic inventory will be sold to New York Blood Center in February, with the exception of remaining low unitage material from University of Oregon lot. The NYBC may also take some ultrafiltered material.

J. Davis reported all G.P. non-heated product for International is committed for sale. Five non-heated ultrafiltered lots remain in inventory with questionable status, with a value of $497,977. Additionally, approximately 5 million i.u. ultrafiltered product for U.K. is now

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unsalable since the U.K. will no longer take non-heated product.

S. Cullen and C. Patrick will determine which lots can be reworked and completed in time to meet the February NYBC schedule. M. Madsen confirmed with production representatives that ultrafiltered cannot be reworked to glycine precipitate by any licensed process, and reworking does not allow new dating to be assigned.

10. CORE POSITIVE AHF - V. SHALSON

The final decision on lots 50N023 and 50N024, and all other concentrates made from "S" plasma, is that they will not be completed or distributed for sale, but may be used internally for development work.

11. IGIV - S. CULLEN (Attachment VI)

Remaining inventory of 6.8 IGIV, produced in anticipation of Japan product introduction, is valued at $174,713. J. Davis will consider using this material in European promotion before the product is outdated during 1985.

12. RHO-D - B. BARDEN

Procurement has obtained a new supply of 150 liters anti-D plasma per month. Rh Institute samples are in route. NABI has not yet shipped committed plasma. Current projections indicate the 12,000 liter plan will be met, but we will not meet the 18,000 level needed to accommodate lower yields and higher sales.

13. KOATE - HIGH PKA LOTS - C. TURNER

Deferred to next meeting.

14. The next meeting is February 7, 1985, 9:00 a.m., CT 2, Room 5.

Agenda

1. Cryosan Product Codes - M. Duffy
2. BGA Requirements - E. Greene/J. Cherry

3. Turbidity Statement/Miles Inc. Labeling Requirements - J. Cherry/S. Cullen

4. Elimination of OoB Release Requirement - J. Davis/ C. Turner

5. Fraction V Production at Berkeley - S. Cullen

6. Fraction V Procurement Status - S. Bhonsle/ J. Davis

7. Non-Heated Koate - C. Patrick

8. pH 6.8 IGIV - J. Davis

9. Rho-D - B. Barden

10. Koate - High PKA Lots - C. Turner

11. IGIV - CMV Requirements - J. Davis

MD:lm