CONFIDENTIAL

BIOLOGICAL COORDINATING COMMITTEE November 15, 1984

Сору	Biological Management Committee Members	BCC Members
1. 2. 3. 4. 5.	J. D. Ryan - Chairman J. A. Akers J. N. Ashworth J. H. Cherry R. L. Cole W. Ewald	<u>bec members</u>
7. 8. 9. 10.	K. H. Fischer J. H. Hink J. V. Hjorth W. G. Johnson R. J. Modersbach - Recording Secretary	W. Ewald J. H. Hink
12. 13. 14. 15. 16.	M. M. Mozen S. J. Ojala V. H. J. Shalson M. M. Sternberg C. F. Treppa C. K. Turner	V. H. J. Shalson C. K. Turner
18. 19. 20. 21. 22. 23.		S. A. Cullen M. Madsen C. Patrick M. H. Duffy J. Davis J. P. Richardson
	Copies	J. I. Kichardson
24. 25. 26. 27. 28. 29.	R. E. Barden J. E. Benninger S. Bhonsle M. T. Boyce W. P. DeHart W. F. Schaeffler L. J. Wood	5
Minutes	issued by M. Duffy December 6, 1984.	5

EXHIBIT 34

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BIOLOGICAL COORDINATING COMMITTEE November 15, 1984

 Those attending were: B. Barden, S. Cullen, J. Davis, M. Duffy, J. Hink, M. Madsen, C. Patrick, J. Richardson, V. Shalson.

Core Testing

A question of International commitments to supply AHF only from core-tested material was raised at the last meeting. J. Davis confirmed that there are no such commitments.

3. Fraction II Blending: Core Positive and Negative

Blending of Fraction II powder from core-tested material will continue until all tested material has been used. S. Cullen will verify that all core-negative Fraction II will be blended, so that no shortage will occur.

4.. Non-Heated Koate Inventory

Non-heated Koate inventory is being reviewed to determine which lots would be worthwhile to heat. Many of the lots in inventory are relatively low unitage; heating and subsequent assay with new standard will result in lower unitage. It was suggested that two lots with over 280 units/vial that are currently reserved for Canada be heated. Then lots with lower, but still acceptable, AHF units will be sent to Canada. There is excess non-heated inventory, especially 650-20. J. Davis will review International markets again to determine if more of this product can be sold. At this time the decision is to heat the 650-60 lots, and to wait for response from International and information from Regulatory Affairs regarding standard changes before determining which other lots will be heated.

Two lots of core positive AHF were filled due to concentrate storage constraints. While preliminary data indicate the heating process inactivates the suspected AIDS virus, the OoB has not established policy regarding AIDS donors and product withdrawals. Each AIDS donor case will be decided separately, including heated product. C. Patrick will get opinions from M. Mozen and

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S. Ojala regarding the heating and selling of this material.

5. Heat-Treated Konyne

Qualifying lots of heat-treated Konyne were released this week. S. Cullen needs confirmation of forecast of heated and non-heated Konyne.

6. HypRho-D

Current backorder situation developed from increasing sales and decreasing yields due to pH adjustment required to correct monomer/polymer levels. Procurement will increase 300 liters/month starting January. J. Davis will check on availability of anti-D plasma from Canada. B. Barden will work with P. Forester to project anti-D receipts for January-March.

7. AB Plasma Premium

B. Barden reported that 3 centers are paying an additional \$1/donation for AB plasma. Results of this trial will be evaluated in January.

8. AIDS Prodrome Donor

Plasma from an AIDS prodrome donor has been used in 3 "Special" (core positive or untested plasma) lots. S. Cullen will verify this plasma has not been used in Koate.

9. 1985 Schedule (Attachment)

BCC meetings in 1985 will continue to be held twice a month on Thursdays. Exceptions to this are when the monthly BMC meeting is not a Monday, then the prior BCC meetings will be adjusted to two days before the BMC date.

MD:lm

1985 SCHEDULE

BCC		ВМС
January 3 - Thursday January 17 - Thursday		January 22 - Tuesday
February 7 - Thursday February 19 - Tuesday	e de la companya de La companya de la co	February 21 - Thursday
March 7 - Thursday March 21 - Thursday		March 25 - Monday
April 4 - Thursday April 18 - Thursday		April 22 - Monday
May 9 - Thursday May 22 - Wednesday		May 24 - Friday
June 6 - Thursday June 20 - Thursday		June 24 - Monday
July 3 - Wednesday July 18 - Thursday		July 22 - Monday
August 1 - Thursday August 15 - Thursday		August 19 - Monday
September 5 - Thursday September 19 - Thursday		September 23 - Monday
October 10 - Thursday October 24 - Thursday		October 28 - Monday
November 14 - Thursday		November 18 - Monday
December 5 - Thursday December 19 - Thursday		To be determined

All BCC meetings will start at 9:00 a.m.