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BIOLOGICAL COORDINATING COMMITTEE
January 3, 1985

1. Those attending were: R. Barden, S. Cullen, M. Duffy, W. Ewald, J. Hink, M. Madsen, C. Patrick, J. Richardson, V. Shalson, C. Turner.
2. FRACTION V - INVENTORY/BACKORDER MANAGEMENT AND ELIMINATION OF LOT-BY-LOT-RELEASE - S. CULLEN/
C. PATRICK

Elimination of OoB release requirements will make available approximately 30,000 Fraction V equivalents. J. Hannon will coordinate a meeting with Domestic and International Sales and Marketing to review the allocation system.

S. Cullen reported that currently International needs are met in the following order:

- 1) Japan
- 2) Sclavo powder
- 3) International foreign label.

Any reduction in International product is made in Domestic label. This prioritization will be used by Production Planning until the BCC decides otherwise.

C. Patrick reported that using Cryosan plasma for Cutter sales is possible. S. Cullen needs to know Cryosan's product mix requirement and how the plasma will be shipped. The first plasma shipment of 7,000 liters will be processed separately. Later shipment may be processed with Cutter plasma. The first product shipment to Cryosan is scheduled for May.

W. Johnson will be requested to report on the status of the Cryosan agreement.

3. NON-HEATED KOATE INVENTORY - C. PATRICK/C. TURNER

C. Patrick reported that sales of non-heated Koate are moving steadily, with 600 vials of 650-20 sold in December, maintaining the November rate.



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C. Patrick will provide an updated analysis at the next BCC meeting of remaining inventories by code, latest sales rates and forecast inventory depletion dates.

C. Turner reported that the 650-30 subpotent lot was released at the request of J. Peterson for the University of Oregon. The university took 80% of the lot and approximately 1300 vials remain. M. Madsen will meet with J. Akers and determine if this can be reserved for 1984 year end.

J. Davis will be requested to report at the next meeting on an update on international non-heated Koate sales.

4. KOATE - NEW MEGA STANDARD - C. TURNER

Lots are being assayed with the new standard, and yields are down. A report will be requested from J. Cherry and S. Ojala on the implementation of the MEGA Standard.

5. KOATE - PKA VALUES - C. TURNER

S. Cullen reported that 2 German lots (50N045 and 50N046) and one domestic lot (50N044) of group specific Koate failed PKA testing. C. Turner will know in 7-10 days if these lots are reworkable and what the cost implication will be.

It will be recommended to the BMC that a task force be formed to study the PKA issue.

6. CORE POSITIVE AHF - C. TURNER

Processing of the "S" plasma AHF has been placed on hold. The filled lots have not been heat treated. V. Shalson will report at the next meeting if we will process this material.

7. HYPRHO-D INVENTORY/SALES PROJECTIONS - R. BARDEN

R. Barden reported that the Rh Institute in Winnipeg is licensed and will send information regarding Anti-D plasma. This institute produces approximately 800 liters per year and claims the plasma has high potency. Procurement will obtain some plasma for evaluation.

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8. BGA REQUIREMENTS - W. EWALD

Dr. Spilles from Tropon will be requested to visit Cutter as soon as the BGA regulations are out and have been studied. Dr. Spilles will explain testing needed for the BGA. The BCC will only get involved after Dr. Spilles has clarified this. W. Ewald and S. Ojala will inform the BCC what requirements are to be implemented.

9. The next meeting is January 17, 1985, 9:00 a.m., CT 2, Room 5.

Agenda

1. Fraction V - Status of Cryosan Agreement - W. Johnson
2. Non-Heated Koate Inventory - J. Davis/M. Madsen/C. Patrick
3. Koate - MEGA Standard Implementation Status - J. Cherry/S. Ojala
4. Koate - High PKA Lots - C. Turner
5. HypRho-D - Rh Institute Plasma - R. Barden
6. Core Positive AHF - V. Shalson
7. BGA Requirements Status - W. Ewald/S. Ojala
8. Potential Write-offs of Unsalable International Material - S. Cullen/J. Davis/C. Turner

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