FDA Request for info. - Yersinia enterocolitica (3/15/91)

Date: March 15, 1991

From: Gerald V. Quinnan, Jr., M.D., Acting Director,
Center for Biologics Evaluation and Research

Subject: FDA Request for information on blood
storage patterns and red cell
contamination by Yersinia enterocolitica

To: All Registered Blood Establishments

Recent reports to the Centers for Disease Control (CDC) have documented ten cases of shock, including seven deaths, due to red cell transfusions contaminated with Yersinia enterocolitica. These incidents, which occurred between April 1987 and March, 1991, were associated with units older than 25 days of storage at 1-6 C, although other cases reported in Europe have involved units of red cells stored for less than 25 days. Because of the reports, the Food and Drug Administration discussed possible methods to help prevent transfusions contaminated with Y. enterocolitica at the January 17-18, 1991 meeting of the Blood Products Advisory Committee. The possibility of reducing the dating period to 25 days for refrigerator stored red cells was discussed at this meeting, and the FDA now seeks additional information on the expected impact of such a change, as part of its continued consideration of this problem. Also, the agency seeks to determine whether there have been additional cases of red cell contamination by Y. enterocolitica.

The Center for Biologics Evaluation and Research is requesting the cooperation of all blood establishments and transfusion services that collect and store whole blood or red cells to obtain additional information which will be relevant to any decision on modified dating of stored red cells. The attached questions pertain to blood utilization patterns and occurrence of Yersinia infections and other bacterial contaminations.

If possible, please respond by April 12, 1991 so that we may assess the information and summarize the results for discussion at a future meeting of FDA's Blood Products Advisory Committee. If you cannot complete a particular question by that date, please provide the information which is available to you, rather than failing to respond. Also, please provide a best estimate if numbers or percentages are not known with certainty.

Please send completed answers, as soon as possible to:

Cornelius J. Lynch, Ph.D., HFB-250
Division of Biostatistics and Epidemiology
Center For Biologics Evaluation and Research
Food and Drug Administration
8800 Rockville Pike
Bethesda, MD 20892

Questions regarding this request may be directed to Ms. Marty Wells, Division of Transfusion Science, CBER at 301-496-0100.

Thank you very much for your cooperation.

Gerald V. Quinnan, Jr., M.D.

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BLOOD STORAGE PATTERNS AND RED CELL CONTAMINATION
BY YERSINIA ENTEROCOLITICA

1. Responding Facility:

   Name _____

   Address_____

   _____

2. Responsible Person:

   Name _____

   Telephone No. _____

3. Type of Facility: (check most appropriate type)

   Blood Bank _____ Transfusion Service _____

4. Average number of units of whole blood or red cells

   collected per month_____

5. In the following chart, please provide your current daily inventory of whole blood and packed red cells (no. of units). Please report this inventory in categories based on age (days of 1-6 C storage.) The units reported should include all material collected, received from suppliers, stored or released on a single day. If more than one type of product is stored and maximum dating periods differ, please use a separate section for each product dating period, and note the number of days to outdating.

   Date of Reported Inventory _____
   MM/DD/YY

Days of 1-6 C Storage	Number of units with a Maximum dating period of: 42 Days	.....Days
0-7 days	_____	_____
8-14 days	_____	_____
15-21 days	_____	_____
22-28 days	_____	_____

29-35 days	_____	_____
36-42 days	_____	_____
Outdated	_____	_____
Total inventory	_____	_____

6. For the total inventory reported in Question 5., and separately for each dating period of products, please provide the number of units that fall into each listed category of storage or disposition. For starred items, please indicate the percent of units in that category which are released from inventory in order to prevent outdating:

	Number of units with maximum dating period of:			
		42 Days	.....Days	
	No. Units	% Released to Avoid Outdating	No. Units	% Released to Avoid Outdating
Disposition of Units:				
Released for transfusion	_____		_____	
*Shipped to other centers	_____	_____	_____	_____
*Released for further manufacturing use	_____	_____	_____	_____
Retained in inventory	_____		_____	
Discarded due to outdating	_____		_____	
*Other disposition (please explain _____)	_____	_____	_____	_____
Total no. of units stored or released	_____		_____	

(Should agree with total reported in question 5.)

7. In the last five years, how many reports have you received of adverse reactions, including deaths, due to Yersinia enterocolitica contamination of red cells?

No. Reports	Products Transfused (incl. anticoagulant) for each reported case	Days post Collection for whole bld or RBC

1991 _____ _____ _____

1990 _____ _____ _____

1989 _____ _____ _____

1988 _____ _____ _____

1987 _____ _____ _____

1986 _____ _____ _____

8. Please describe any other serious transfusion reactions during the last five years attributed to bacterial contamination of blood products which have not been reported previously to the FDA.

Organism Type of Reaction Year (No. of Reports)

Please send completed questionnaires prior to April 12, 1991 or as soon as possible to:

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Center For Biologics Evaluation and Research
Food and Drug Administration
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Bethesda, MD 20892