



America's Blood Centers®  
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Division of Dockets Management (HFA 305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: FDA Docket 2004N-0366, From Concept to Consumer: CBER Working with Stakeholders on Scientific Opportunities for Facilitating Development of Vaccines, Blood and Blood Products, and Cellular, Tissue and Gene Therapies; Public Workshop; Reopening of the Comment Period.

Dear Docket Officer:

America's Blood Centers thanks the Food and Drug Administration for re-opening this docket. We applaud FDA and the Center for Biologics Evaluation and Research for addressing the critical need to apply scientific knowledge and tools to facilitate the development of new biological products. With respect to the area of blood and blood products, there remains a great need for expediting the availability of new technology that will result in increased transfusion safety.

We appreciated the opportunity to participate in the October 7, 2004 public workshop. Although much useful information was presented, FDA's approach in the critical path document focused primarily on current challenges and specific issues facing FDA and the regulated industry. ABC believes that this is shortsighted. Major changes in FDA's processes and infrastructure and a focU.S. on the path ahead are urgently needed.

To achieve FDA's stated goals of applying scientific knowledge and tools to facilitate the development of new biological products, ABC recommends a focU.S. on three major areas: improving scientific dialogue between FDA and industry; developing a database of information on blood components within CBER; and better application of the scientific approach to expeditiously investigate potential threats to the blood supply.

**1. Improved and More Frequent Dialogue with Industry on Guidances, Regulations and Memoranda.** The FDA modernization act created an impetU.S. for the agency to undertake this essential task, but for many important blood initiatives, follow-through has been slow. A good example is the HIV and HCV lookback guidance and donor re-entry algorithms, which were in development for several years before being issued for comment this week. There are no timelines requiring the publication of the summary or results of a workshop. For

example, it took several years for the guidance based on the workshop on hemoglobin based oxygen carriers to be published.

- **ABC recommends the introduction of a method for publishing workshop summaries quickly** – even though a subsequent guidance or regulation may take a lot longer. The brief summaries provided to the Blood Products Advisory Committee or the Advisory Committee for Blood Safety and Availability BPAC or the ACBSA by FDA staff are insufficient.

We are aware that a number of rules restrict FDA's ability to engage in dialogue with industry after the internal decision is made to develop guidance. But we need a mechanism that allows open dialog.

- **We suggest that CBER hold an annual workshop to discuss the guidance/regulations that it intends to publish during the upcoming year.** This might eventually evolve into a review of priorities and an open discussion with stakeholders about what is needed to meet patient needs first, industry needs second, and regulatory and compliance needs as required.
  - **We also recommend that BPAC have at least one meeting per year devoted to strategic planning and advising FDA on the needs of both patients and the regulated industry.**
  - **Finally, workshops and public meetings sponsored by industry could be geared to providing the needed data in an open forum fostering discussion and providing FDA with the solid, evidence-based information it needs for decision making.**
2. **Creating the Necessary Infrastructure for Basic Research and Evaluation of Currently-Licensed Blood Components.** It is evident from incidents such as the discovery of white particular matter (WPM) in red cells that CBER lacks the infra-structure for basic research and evaluation of currently used blood components. For example, during the recent CBER discussions regarding the quality of lyophilized plasma products and products such as anti-coagulants and collection bags or devices, it became obvious that FDA does not have the ability to characterize these products as far as their basic chemical and molecular content. Nor does it appear that there is a requirement for the manufacturer to submit such data as part of the QC of each lot that is released.
- **ABC recommends that FDA create a master profile of data provided by each manufacturer of either, gas chromatograph, atomic adsorption spectrophotometry or even Scanning EM emission tomography as appropriate.** Other chemical, molecular or biologic methods should be used to profile each product from each manufacturer. Lot release would include a comparison of the past lot and current lot profiles to detect changes on contaminants. Future incidents like WPM on the hemolysis attributed to Pall LP filters could be investigated in a scientific Manner. Lyophilized plasma products could be screened and past and current spectra compared for contaminants and/or through protein analysis the inadvertent addition of a high or low MW component that might result in inhibitor formation in the patient or affect the efficacy of the product.

We are aware that FDA needs funding and resources to accomplish this. However, it would not all have to be done in house but could be accomplished by contracting with private or academic laboratories.

- 3. Greater Use of Scientific Approach to Investigate Threats to the Blood Supply.** FDA and CBER need to have the ability to rapidly investigate threats to the blood supply such as WPM. The academic and private labs we recommended to improve FDA's infrastructure could make up a core infra-structure of labs and scientists capable of evaluating red cells, platelet, plasma and other basic blood components as they become licensed products.

The closure of most departments at the American Red Cross' Holland Laboratory, the reduced capabilities of the Army Blood Research lab, the closure of Dr. Valeri's Naval Blood Research Laboratory and the aging of the primary investigators should be sending signals to FDA and this country that future regulatory decisions and the available data about collection devices, blood components and modifications to current components will rely solely on data from manufacturers and institutions supported by manufacturers. To prevent this, independent labs must be available for rapid analysis and unimpaired by contractual obligation from revealing that analysis and free from apparent conflicts of interest.

- We recommend that FDA have its own granting mechanism or through NHLBI have a method of reserving funding each year for regulatory or compliance required research.** If these are multi-year funds a grant cycle could be developed that would guarantee funds are not wasted but that they would always be available.

In conclusion, ABC believes that and CBER does not have the necessary scientific resources to perform its core functions. Of course, industry needs to be inspected and be responsible to the compliance arm for meeting regulation. But at the same time, the agency must respond rapidly to changes and advances in technology without tying the hands of industry.

We need to re-define the relationships and provide a framework that enhances patient care, product advancement and availability and patient safety. We could legitimately claim that U.S. patients are at risk because clear safety enhancements that have been put in place outside of the U.S. (e.g., PRISM, pre-pooled platelets, frozen platelets) others are unavailable because of what manufacturers see as insurmountable roadblocks at CBER. Innovation in the U.S. is being stifled by a bureaucratic quagmire at FDA and CBER. We need to work together to find a way through this morass.

Thank you for the opportunity to comment. We would be pleased to answer any questions you might have.



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