

COALITION FOR REGULATORY REFORM

American Association of Blood Banks - America's Blood Centers -
American Blood Resources Association

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STATEMENT

By
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Regarding FDAMA Objectives
(August 14, 1998)

Good morning, my name is Roger Brinser. I am the Director of Regulatory Affairs for Sera-Tec Biologicals, LP, a Source Plasma collection company. Today I am speaking to you as a Co-Chair of the Coalition for Regulatory Reform (CFRR). CFRR was formed in 1994 at the request of FDA, to bring the blood and plasma industries together to jointly explore ideas for a more efficient regulatory system for blood and plasma products. The CFRR is composed of the American Association of Blood Banks (AABB), (which includes the American Red Cross and the Armed Services Blood Program Office), America's Blood Centers (ABC), and the American Blood Resources Association (ABRA). This organization represents the entire spectrum of blood and plasma collection and transfusion interests. We appreciate the opportunity to comment on the important topics outlined in Section 406(b) of the Food and Drug Administration Modernization Act (FDAMA).

Agency Communication

Recently, FDA's communication with industry has improved greatly. The agency has published proposed rules in a timely fashion, given industry an adequate opportunity to comment, disseminated draft guidance early in the process, and conducted more frequent agency workshops to address important regulatory changes. CFRR applauds FDA's improved communication and encourages further steps in this regard. Foremost, CFRR encourages FDA to strictly adhere to its Good Guidance Practices (GGP) document and broaden the document's scope of application. The greatest effect in terms of regulatory efficiency is seen when industry is given an opportunity to meaningfully participate in the regulatory process. Groups like CFRR and others stand ready to work with FDA in developing even initial drafts of agency guidance.

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Improve the Review Process

In the last year the Center for Biologics Evaluation and Research (CBER) has made great strides toward improving the licensure process. The proposed rule to replace the Product License Application and Establishment License Application (PLA/ELA) has been published and the Biologics License Application (BLA) process shows great promise. The guidance document that implements the BLA, the so-called CMC Guidance, also was recently published. CFRR strongly encourages CBER to ensure that the paperwork reduction and regulatory efficiency goals of the BLA are maximized with its implementation.

In addition, FDA has a host of new tools for effecting modifications or changes to approved applications. These include the prior approval supplement (PAS), the Changes Being Effected (CBE30), and Annual Report (AR) submissions. These are important milestones; however, much work remains to be done in the area of biologics applications. FDA should utilize these tools to the greatest possible extent; the onerous PAS process should be used only for novel products or for a first-time request to license an establishment or product.

Areas where the agency has promised guidance and which industry desperately needs, include guidance specific to blood and plasma for CBE30 and, in particular, annual reports and comparability protocols. These are tools that may yield the greatest regulatory efficiencies but remain untapped. Many companies already have been required to submit annual reports without clear guidance on what the reports are supposed to contain or how the agency will use this information. Comparability protocols offer the promise of a standardized method for effecting certain application changes without the need for prior agency approval, but the scope of eligible changes and protocol contents remain undefined. These tools and others if used as intended, can relieve the agency's application review burdens for non-user fee industries.

Blood Action Plan

The Blood Action Plan holds promise for better communication of agency product quality expectations to industry. Based on FDA's public statements, the Blood Action Plan calls for a rewrite of the blood and plasma regulations. This includes formalizing requirements published through guidance and memoranda into regulations. CFRR applauds these efforts and hopes to work with the agency in achieving these goals.

It is important to note, however, that no publicly available documents currently exist to describe the Blood Action Plan, time frames for achieving the plan objectives have not been publicly announced and industry input has not been sought. One initiative of the plan is to develop a pilot program for approval of certain blood and plasma products through a monograph system. While this program holds promise for both FDA and industry in terms of the application process, without an industry-FDA dialogue this program may never get off the ground and an important opportunity may be lost.

Product Quality

Although GMPs are the cornerstone of quality products, the blood and plasma industries have lacked clear GMPs. Instead, the current GMPs contain many references to biologics that often do not directly bear on the blood and plasma industries. The current GMPs applicable to blood and plasma products span three sections of the Code of Federal Regulations – 21 C.F.R. §200, §600 and §800. A comprehensive rewrite of the GMPs is needed to incorporate these important requirements into one set of unified regulations for blood and plasma products.

Other regulatory requirements that bear on product quality include error and accident reporting, adverse event reporting, and product recalls and withdrawals. These tools are underutilized. Although industry expends vast resources submitting error and accident reports, FDA has failed to use this information as a quality assurance tool. Quarterly reports of errors and accidents are published but no meaningful analysis or trend reporting of submitted errors and accidents has ever been made publicly available. This is a missed opportunity. FDA can help industry better itself by making this kind of information available. Furthermore, error and accident reporting should not be extended to other industry segments without careful consideration.

Recalls and withdrawals are intended to help ensure that only quality products reach patients. However, the current recall regulations are not appropriate for blood and plasma products. Many if not most blood and plasma recalls involve only hypothetical risks, expired products or already transfused products. Other tools such as recipient notification may be more appropriate in such circumstances. A more rational recall and withdrawal policy would save agency resources and permit industry to concentrate its resources on delivering high quality products.

Closing

In closing, I would like to say that CFRR recognizes the magnitude of FDA's task – ensuring that only safe and effective products are made available to consumers. Without adequate funding CBER cannot carry out this mandate. Furthermore, this important mandate requires that the agency retain individuals with extensive skills and technical expertise. As such, CFRR fully supports CBER-based research needed to maintain an appropriate scientific infrastructure.

Thank you for the opportunity to comment. CFRR looks forward to working with the agency on current and future regulatory initiatives.