

BloodCenter of Wisconsin, Inc.

Response to FDA Federal Register Notice 21 CFR Parts 203 and 205

(Docket No. 2005N-0428)

Distribution of Blood Derivatives by Registered Blood Establishments that Qualify as Health Care Entities; Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures

Dear Ladies and Gentlemen:

This statement is in response to the proposed amendments to the Prescription Drug Marketing Act of 1987 and is made by BloodCenter of Wisconsin, Inc., a registered blood establishment serving patients and their healthcare providers in south and central Wisconsin. BloodCenter of Wisconsin is in favor of the proposed amendments to the final rule to allow registered blood establishments that provide related healthcare services to also distribute blood derivatives.

We believe, however, that the proposed amendments as written are overly restrictive in limiting the exceptions to only the sale and distribution of blood derivatives. We believe the exception should be expanded to include both blood-derived and blood-related biologics used in the treatment of patients with bleeding and clotting disorders. We believe that this is what Congress intended, and it makes sense in the context of allowing blood centers to fulfill their mission to patients.

As a registered blood establishment, BloodCenter of Wisconsin collects blood and manufactures blood components, and also recovers plasma used in the production of therapeutic proteins. In addition, we distribute blood, blood products and therapeutic proteins derived from plasma as well as other related biologics used to treat patients, including: IVIG, Albumin, Rh Immune Globulin, and Coagulation Proteins – both plasma derived and recombinant. Treatment of patients with bleeding disorders is not limited to blood or plasma-derived products. For example, since the original PDMA was passed in 1987, the market has seen the introduction and acceptance of recombinant forms of antihemophilic clotting factor. We believe that the final rule should be modified to include these products. We also believe the final rule must anticipate and make provisions to include the future introduction of biologically modified blood-derived products. For example, hemoglobin solutions and infusible platelet membrane preparations are expected to enter the market and should be accommodated in the final rule.

The current system whereby blood centers offer community hospitals the full range of blood-related products (as well as trained personnel and expertise in handling those products) is cost-effective and makes economic sense. If individual community hospitals were required to maintain their own inventories of these specialized products, duplication of costs and inefficiencies would result. Also, because these are relatively low-use products for hospitals, blood centers and buying groups can negotiate better prices. Blood centers can also offer utilization reviews to hospitals. The current system has

emerged in the marketplace because it is sensible, and it should be preserved for the same reason.

The proposed final rule as written would also provide an exclusion from the sales restrictions in 21 CFR 203.20 for a registered blood establishment that qualifies as a health care entity as long as the health care services it provides are related to its activities as a registered blood establishment. We have concerns about language in the Proposed Rule that would make the exclusion unavailable if the blood center performs *any* health care services not related to blood. From time to time, blood centers (including BloodCenter of Wisconsin) may provide incidental services, such as offering flu shots, that in the broader sense further their interest in a healthy blood donor community but may not be strictly related to their activities as a registered blood establishment. We believe that any hypothetical concern about “encourag[ing] hospitals and other health care entities to register as blood establishments” to take advantage of the exclusion can be easily addressed by requiring the health care services to be *predominantly* blood-related. Unless the health care is predominantly blood-related, the registered blood establishment would not qualify for the exception.

Blood centers, including BloodCenter of Wisconsin have been a stable and reliable source of biological proteins, both human-derived and recombinant, to hospitals with which they have long-established relationships for providing life-saving blood and blood components. The ability of registered blood establishments to provide blood-derived and blood-related biologics and related healthcare services for the treatment of bleeding disorders is an important and cost effective part of the health care delivery system, and we believe is consistent with and would not be detrimental to the intent of the final rule.

Respectfully submitted for consideration, April 27, 2006.

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