



American Red Cross

National Headquarters

August 31, 2000

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Docket Officer
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair [Docket No. 00N-1380, 65 FR 44485 (July 18, 2000)]

Dear Docket Officer:

The American Red Cross (ARC or Red Cross) appreciates the opportunity to submit comments in response to the public meeting regarding Human Bone Allograft that took place on August 2, 2000. At this meeting, The Food and Drug Administration (FDA) solicited input regarding their plans to clarify the regulation of Human Bone Allograft.

As a provider of human tissue, including allograft bone, ARC is pleased to be able to participate in the development of the FDA policy, and would like to make a few brief points for FDA's consideration as they continue their efforts to regulate tissue.

Our main points are with regard to FDA's consideration of the definitions for "minimal manipulation" and for "homologous use", and for the decision as to whether to regulate allograft bone as devices or as tissue.

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Minimal Manipulation

Minimal manipulation is defined in 21 CFR 1271.1 as: "processing that does not alter the original relevant characteristics for the tissue relating to the tissue's utility for reconstruction, repair or replacement."

ARC believes that allograft bone dowels should be considered as meeting this definition. Once the tissue is collected, its basic structure is cut using the same equipment and techniques as those used by surgeons. Indeed, the bone is frequently cut to meet the surgeon's specifications in order to save time during the surgery. The tissue recovery and processing techniques remain the same as for other uses of allograft bone, and the original characteristics, as well as bone function, remain the same.

Thus, ARC believes that allograft bone dowels should be considered "minimally manipulated".

Homologous Use

FDA has also asked about the appropriate application of the definition of "homologous use" to bone which they define as: "... for structural tissue-based products, occurs when the tissue is used for the same basic function that it fulfills in its native state, in a location where such structural function normally occurs..."

Allograft bone is used as a structure to provide support, which is the use of bone while in its native state. Additionally, the support is needed so that the patient's "basic function" is maintained and can continue in a "location where such structural function normally occurs..." while the body remodels the bone. Thus, we believe that "homologous use" is an appropriate interpretation for bone that is used in spinal or other reconstructive surgery.

Regulation of Bone as Tissue

ARC believes that allograft bone should be regulated as tissue, not as devices. One considerable safety concern with such materials is the potential for transmission of disease. Device regulations do not specify that the materials must be tested for such diseases, and thus, an important safety step will not be adequately regulated.

Further, there are other device regulatory requirements, such as design specifications and 510(k) requirements, that do not easily fit the circumstances under which processors and others handle tissue, including allograft bone. Additional time and resources will be

expended to attempt to meet such requirements with no additional health benefit. Indeed PMA or 510(k) requirements are likely to result in delays or in decreases in availability of these products.

Thus, ARC urges FDA to continue to regulate allograft bone as tissue, not as devices.

Additional Points

Finally, ARC would like to point out to FDA that pre-shaped bone products actually increase the safety of the surgery. The length of time the patient is under anesthesia is shortened, and by using pre-cut bone, the patient will be sure to receive allograft bone that exactly matches their needs.

Thank you for the opportunity to provide public comments. We look forward to and actively support the additional actions under FDA consideration including the development of regulations for Current Good Tissue Practices. If you have any questions, please contact Anita Ducca, Director, Regulatory Relations at 703-312-5601.

Sincerely,

A handwritten signature in black ink, appearing to read 'Glenn M. Mattei', with a long, sweeping horizontal line extending to the right.

Glenn M. Mattei, Esq.
Interim Vice President
Quality Assurance/
Regulatory Affairs