UNIVERSITY of IOWA HEALTH CARE

University of Iowa College of Medicine
Annette J. Schlueter, M.D., Ph.D.
Department of Pathology
1167 Medical Lab
Iowa City, Iowa 52242-1181
*319-335-8329 **Tel***
*319-335-6555 **Fax***
annette-schlueter@uiowa.edu

May 2, 2001

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

To Whom it May Concern:

This letter is in response to the request for comments on the proposed rule 21CFR 1271, Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement. The comments reflect the concerns of myself, the staff of the DeGowin Blood Center and the Blood and Marrow Transplantation Program at University of Iowa Health Care.

In general, we applaud the efforts of the FDA to design reasonable rules for the manufacture of human cellular and tissue-based products, and agree that this area deserves to be regulated similarly to the manufacture of blood components. We specifically offer comments on the following sections.

1271.150(b): We are concerned about the decision to assign ultimate responsibility for the product to the establishment that is responsible for making the product available for distribution. Among the options considered, it appears to be the most reasonable. However, it is unclear what sort of documentation would be sufficient to assure that the establishments that handled the product prior to receipt by the distributor were in compliance with these standards. This is particularly concerning with respect to international donor centers, some of which are not affiliated with the NMDP in any way, but may be the only source of HLA-matched hematopoietic progenitor cells (HPC) for a given patient. These international registries have no incentive to comply with FDA regulations, yet the ability to access their donors may be the only chance of survival that our patients have. Perhaps consideration could be given to allowing harvest of HPC to proceed without documentation of GTP, with the understanding that the distributing institution test the product for infectious disease transmission, sterility and viability.

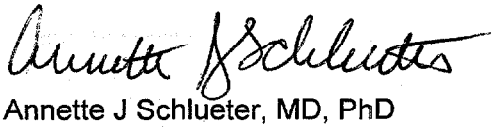
1271.160(d); 1271.225(b): These are examples of regulations that seem to be more stringent for institutions that process tissue based products (like HPC) than for institutions that process blood components. For regulations that could reasonably apply in either situation, we would anticipate the same stringency of regulation be applied to both establishments. Particularly in the case of HPC, processing of these cells often takes place in the same facility as blood component preparation and it will be very difficult to apply

different sets of regulations in a highly integrated unit. Additionally, if the requirement for a comprehensive audit truly means an audit of all processes on an annual basis, this would require a huge increase in annual expenditures primarily in order to hire the personnel necessary to perform the audits. This is a much more stringent requirement than is presently imposed on blood component processing facilities, and the reason for this increased stringency in the setting of HPC is unclear. We submit that this level of regulation is no more critical in the processing of HPC than it is in blood component processing, and should be revised to the level of audits required for the latter.

1271.420: What is the relationship of this proposed FDA inspection to the current inspections of HPC products that are performed by the Department of Public Health or the USDA upon entry into the United States? It is unclear to us whether both processes would occur, whether the FDA inspection would supersede the current inspections, or whether they apply to different products.

Thank you for the opportunity to comment on the proposed regulations.

Sincerely yours,



Annette J Schlueter, MD, PhD
Laboratory Director
Hematopoietic Progenitor Cell Laboratory
DeGowin Blood Center

Annette J Schlueter, MD, PhD (1167 ML)

UNIVERSITY of IOWA HEALTH CARE

University of Iowa College of Medicine
Department of Pathology
Iowa City, Iowa 52242

Changing Medicine. Changing Lives.™

P534

PRESORTED FIRST CLASS

IOWA CITY IOWA MAY-3'01 P B METER 6741692

U.S.POSTAGE ≈ 0.27 8

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

1 AUNB 20857