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

Reference: Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry and FDA Staff
Docket No. FDA-2014-D-1696

Dear Sir/Madam,

The Parenteral Drug Association (PDA) commends FDA for addressing and characterizing the important concepts of minimal manipulation and related terms for HCT/P products. These concepts are difficult and undoubtedly will continue to be challenged as new, innovative tools are introduced to process cellular and tissue-based products. The format of questions followed by discussion in this guidance makes it easy to find information and follow the logic of the applicable regulation. Such guidances, with a very directed and limited scope, are a helpful means to communicate FDA's latest thinking in a timely and efficient manner.

To further clarify FDA intentions and enhance the value of this guidance, PDA recommends a more specific example be provided in section 7. It would be very useful to have at least one real-life example of minimal manipulation for readers to wrap their minds around to clarify the phrase "extraction or separation of cells from structural tissue in which the remaining structural tissue's relevant characteristics relating to reconstruction, repair, or replacement remain unchanged" (from the last paragraph of page 5 in the draft guidance). Examples, such as the one presented in Example 10-1 of a separation procedure that is more than minimal manipulation, clarify the meaning of the text. For instance, would extracting muscle tissue and removing surrounding adipose tissue be considered to satisfy the criteria for minimal manipulations being referred to in this section?

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments were prepared by a committee of experts with experience in gene and cell based therapies including members representing our Board

of Directors and our Biotechnology Advisory Board and our Regulatory and Quality Advisory Board.

If there are any questions, please do not hesitate to contact me.

Sincerely,

Richard Johnson
President, PDA

cc: Denyse Baker, PDA