Bethesda Towers
4350 East West Highway
Suite 150
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
www.pda.org

February 23, 2015

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

Reference: Human Cells, Tissues, and Cellular and Tissue-Based Products from Adipose Tissue: Regulatory Considerations; Draft Guidance for Industry
Docket No. FDA-2014-D-1856

The Parenteral Drug Association congratulates FDA for preparing a clear guideline with the content presented in a logical and helpful fashion. The document is largely well written and the content of guideline is necessary to provide clarification to manufacturers working with adipose tissue. PDA recommends adding a couple of additional clarifications which are noted in the attachment.

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, 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
Attachment

Attachment: Food and Drug Administration Draft Guidance Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations

PDA Specific Comments to the Text

Line No.	Current Text	Proposed Change	Rationale
217-219	Therefore, the HCT/P would generally be considered not to meet the criteria in 21 CFR 1271.10(a) for regulation solely under section 361 of the PHS Act and the regulations in Part 1271.	**In addition, the process of removing the stem cells from the tissue involves more than minimal manipulation (see Example A-1 above).** Therefore, the HCT/P would generally be considered not to meet….	PDA recommends adding this additional text to clarify how the example discussed fails on the basis of more than one criteria.
259-260 and 344 - 348 and 403-404	Lines 259-260 (and lines 403-404) suggest a facility engaged in contract mfg (e.g. preparing cells as a subcontractor) for a Section 361 product would need to register the establishment but lines 344-348 indicate a facility (an individual) engaged in preparing cells as a subcontractor would be *excepted* from registering its facility.	Please clarify this apparent conflicting recommendation in the document regarding which facilities need to register. Specifically what is the difference between "individual" and a "facility"	As written, it is not clear when a facility must register.