FDA Publishes Draft Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufactures of HCT-Ps, January 16, 2009

The FDA announced on January 16, 2009, the availability of a draft document, "Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). The draft guidance document provides establishments that manufacture HCT/Ps with recommendations for complying with CGTP requirements.

View/download the January 16, 2009, Federal Register Notice - http://edocket.access.gpo.gov/2009/pdf/E9-919.pdf and FDA Guidance Document - http://www.fda.gov/cber/gdlns/tissuehctps.htm (scroll down to table of contents).

In the draft guidance, It appears that the regulation has not changed as to what parts of Subpart D apply to ART laboratories, including 1271.150(c) {establishment agreements} and 1271.155 {exemptions}.

The FDA further clarifies in the guidance document what should be done in an audit of a testing facility. Examples for this are included in Section III CGTP REQUIREMENTS; C; Example 2.

In Section IV "Exemptions and Alternatives," the FDA gives examples and clarifies the exemption process.

The remainder of the document addresses areas of Subpart D that do not currently apply to ART laboratories.