

Regulatory Guidelines

FDA Title 21 Part 1271

The product(s) you have purchased from Utah Cord Bank, is/are specifically intended by Utah Cord Bank to be regulated under 21 C.F.R. 1271, in its entirety, and, in particular, 21 C.F.R. 1271.10 as *human cells, tissues, and cellular and tissue-based product(s)* (HCT/Ps). The product(s) you have purchased is/are intended by Utah Cord Bank to only be put to a HOMOLOGOUS USE, as that term is defined in 21 C.F.R. 1271.3(c). Under 21 C.F.R. 1271.3(c), HOMOLOGOUS USE is defined to mean “the repair, reconstruction, replacement, or supplementation of the recipient’s cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.”

As the purchaser of Utah Cord Bank HCT/P product(s), it is your obligation to determine and ensure that the product(s) is/are only put to a HOMOLOGOUS USE, as defined in 21 C.F.R. 1271.3(c).

Utah Cord Bank follows the regulations as defined by the FDA in 21 C.F.R.1271. See below.

1271.3 (c)

(c) Homologous use means the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.

1271.3 (f), (1), (2)

(f) Minimal manipulation means: (1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement; and (2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

1271.10 (2)

(2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer’s objective intent.

Section 361 Classification

- The HCT/P does not have a Systemic Effect and is not dependent upon the metabolic activity of living cells for their primary function (21 CFR 1271.10(a)).
- HCT/P cannot be combined with any article, except for water, crystalloids or a sterilizing, preserving or storage agent during the manufacturing process.
- Any agent used must not raise new clinical safety concerns.