RICHSOURCE FLOWABLE ALLOGRAFT RICHGEN IS EXEMPT FROM FDA 351 AND 361 STATUS PER THEIR DEFINITIONS.

IMPORTANT FDA DEFINITIONS

FDA exempts parties who do not come in contact with the HCT/Ps.

RichSource does not come in contact with the HCT/Ps and therefore, has exempt status. The manufacturer processes and ships directly to the physician supporting this exemption.

FDA definitions:

1271.3 (e) *Manufacture means*, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor.

The human tissue processing laboratory is the manufacturer.

1271.3 (2) (bb) *Distribution* means any conveyance or shipment (including importation and exportation) of an HCT/P that has been determined to meet all release criteria, whether or not such conveyance or shipment is entirely intrastate. If an entity does not take physical possession of an HCT/P, the entity is not considered a distributor.

RichSource is exempt from FDA regulations for 351 and 361 status as not defined as a distributor. The manufacturer is required to support status for being in contact with the HCT/Ps.

Sec. 1271 (3)The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P;

The manufacturer does not involve another article because it is manufactured from single donor material. Post birth materials are from one birth so there is no combining.

Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use. Guidance for Industry and Food and Drug Adminstration Staff page 21, V. B.

V. B. Compliance and Enforcement Policy Regarding Certain Regulatory Requirements

To give manufacturers time to determine if they need to submit an IND or marketing application in light of this guidance and, if such an application is needed, to prepare the IND or marketing application, for the first 36 months following issuance of this guidance FDA generally intends to exercise enforcement discretion with respect to the IND and the premarket approval requirements for HCT/Ps that do not meet one or more of the 21 CFR 1271.10(a) criteria, provided that use of the HCT/P does not raise reported safety concerns or potential significant safety concerns.

The first 36 months ends December 2020 to operate as 361 status. Lab manufacturers have until the end of November 2020 to file their Investigational Drug Application (IND) for 351 status.