May 7, 2020

EXEMPTION FROM FDA TISSUE ESTABLISHMENT LICENSURE

Per the Code of Federal Regulations (CFR) Title 21 Part 1271.1 (b)(1), the FDA requires registration and listing of establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under the authority of section 361 of the Public Health Service Act.

As outlined in 21 CFR Part 1271.3(e) 'manufacture' is defined as "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".

TheraCell does not perform any of the aforementioned activities.

All HCT/Ps marketed by TheraCell are manufactured by licensed tissue banks. The fully manufactured HCT/Ps are supplied to a third-party logistics supplier who manages the storage and distribution of Theracell HCT/Ps. Our third-party logistics supplier is also a registered tissue establishment.

TheraCell handles orders for sales of HCT/Ps by hospitals and other medical facilities; however, TheraCell is expressly excluded from the specific regulatory definition of distributor in the context of the regulation, 21 CFR part 1271.3(bb) which states: "if an entity does not take physical possession of an HCT/P the entity is not considered a distributor".

TheraCell does not take physical possession of any HCT/Ps at any time. Accordingly, TheraCell is not required to register with the FDA as a tissue establishment.

Establishment registrations for TheraCell suppliers who manufactured or distribute HCT/Ps may be found in the following FTA tissue establishment registration database:

https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/index.cfm

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