125 MAY STREET | EDISON, NJ 08837 | MTFBIOLOGICS.ORG

December 10, 2018

RE: 2019 FDA HCT/P Registrations and Discontinuation of FDA Form-3356

Dear MTF Customer:

The purpose of this letter is to address questions verification of annual HCT/P Registrations. Starting January 2019, FDA will discontinue the HCT/P registration Form 3356 and replace this form with a Registration Summary Report. (**NOTE:** for reference, the notification from FDA is attached to this letter).

Copies of these Registration Summary Reports may be downloaded directly from the FDA Human Cell & Tissue Registration (HCTERS) Public Query data base website:
https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/index.cfm

HCT/P Registration and The Joint Commission (TJC) Standards:

TJC Standards for Transplantation are used by TJC Accredited Hospitals that receive and store tissues for transplantation. For many years, TJC Accredited hospitals have required a copy of FDA HCT/P annual registration forms to verify that the tissue processor is appropriately registered. Please note that the TJC Standards (TS.03.01.01) do NOT require or mention FDA Form 3356.

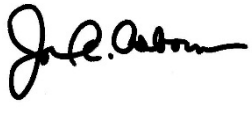
Excerpt from TJC Elements of Performance for TS.03.01.01

3. *The hospital confirms that tissue suppliers are registered with the U.S. Food and Drug Administration (FDA) as a tissue establishment and maintain a state license when required.**
   ** For U.S. Food and Drug Administration (FDA) registration, the supplier registration status may also be checked annually by using the FDA's online database*

Please note copies of all MTF's current licenses, registrations and certification, including FDA registrations, are also available for download through MTF's website at:
https://www.mtfbiologics.org/licenses-certifications

If you have any questions, please feel free to contact me at 732-661-2209, or email MTF Regulatory Affairs at Regulatory_Customer_Inquiry@mtf.org

Sincerely,



Joel C. Osborne
Vice President, Regulatory Affairs

Dear Reporting Official,

This letter is to inform you regarding the new version of the electronic Human Cell and Tissue Establishment Registration System (eHCTERS) released on November 9, 2018.

As background, FDA published in the Federal Register of August 31, 2016 (81 FR 60170) a final rule that amended FDA's regulations governing drug establishment registration and drug listing, including establishment registration and listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). In accordance with the final rule, beginning November 29, 2017, HCT/P establishment registration and product listing information must be submitted electronically. Establishments may request a waiver from the electronic submission requirement as described in §1271.23.

Under this final rule, only establishments that manufacture HCT/Ps regulated solely under Section 361 of the Public Health Service (PHS) Act (361 HCT/Ps) are required to register and list their HCT/Ps in accordance with 21 CFR Part 1271 (§1271.1(a)-(b)(1)). Manufacturers of HCT/Ps that are regulated as drugs, devices, and/or biological products under Section 351 of the PHS Act and/or under the Food, Drug, and Cosmetic Act, must register and list their products in accordance with 21 CFR Part 207 or 807, as applicable, rather than 21 CFR Part 1271 (§1271.1(b)(2)). You may access a searchable link to the regulations in 21 CFR Part 1271 here.

FDA has modified eHCTERS to meet all the HCT/P registration and listing requirements in the final rule referenced above. Major changes in the system version released on November 9, 2018 include:

1) The "HCT/Ps Regulated as Medical Devices" and "HCT/Ps Regulated as Drugs or Biological Drugs" regulatory categories have been removed because eHCTERS can no longer be used for registering and listing such products.
2) For foreign HCT/P establishments that import 361 HCT/Ps into the United States (U.S.), fields were added to provide information about the importer(s) that is(are) known to the establishment at the time of initial registration or when submitting the annual registration update.
3) The system allows foreign HCT/P establishments to provide information on more than one U.S. agent.
4) References to FDA Form 3356 were removed.
5) The list of HCT/P Types was updated.
6) The "Allogeneic" (unrelated) Donor Type was removed.
7) Fields were added for entering the "Date of Discontinuance" and "Date of Resumption," as applicable, for HCT/Ps listed.

Form FDA 3356 has been replaced by a Registration Summary Report of your establishment's registration and HCT/P listing information. Please note the following:

- Your previous listings for HCT/Ps regulated as drugs, devices, and/or biological products have been removed from eHCTERS and will not be listed on the Registration Summary Report.

- Some product names have changed, and others were deleted:

  For example, if you previously listed "Therapeutic Cells" the new version of eHCTERS converted it to "Peripheral Blood Mononuclear Cells" which are HCT/Ps collected from the peripheral

blood by leukapheresis or venipuncture (other than HPC Apheresis). If this does not meet the description of your HCT/P, please review other available HCT/P Types and update your HCT/P listing accordingly.

For another example, "Somatic Cell Therapy Product" is no longer included on the HCT/P list because such products are generally not regulated solely under Section 361 of the PHS Act (see the Federal Register Notice (Vol. 58 No 197, 10/14/1993, p53248): Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products).

If you were an eHCTERS user previously, you should still use the same User Name and Password to log into your account to review your registration and listing (access eHCTERS at CBER On-Line through a secure webpage here).

We recommend all Reporting Officials carefully review their establishment's registration and HCT/P listing in the new version of eHCTERS and update information accordingly. You may include your updated information when submitting your annual registration update between November 15 and December 31, 2018.

Note: If you submit changes to your registration before November 15, 2018, you are still required to submit your annual registration update during the update timeframe even if you have no additional changes to report.

If you determine you do not manufacture any 361 HCT/Ps, please inactivate your registration in eHCTERS.

If your establishment has at least one HCT/P that was listed as an HCT/P described in 21 CFR 1271.10, you will receive another email from us on November 15 to remind you that the annual registration update timeframe has begun, and you will receive as an attachment your establishment's Registration Summary Report.

The "Instructions for Using eHCTERS" has been revised to match the updates to eHCTERS. A PDF of the revised instructions accompanies this letter.

If you have questions or need assistance, please submit questions about registration to tissuereg@fda.hhs.gov.

Regards,

Tissue Registration Coordinator