Dear Reporting Official,

This letter notifies you that the annual registration period has begun and describes how to update your annual establishment registration for Human Cells, Tissues, or Cellular or Tissue-based Products (HCT/Ps). The annual update period for 2023 begins November 15, 2022 and ends December 31, 2022 (see 21 CFR 1271.21). You may access a searchable link to the regulations in 21 CFR part 1271 here.

According to 21 CFR 1271.1(b), you are required to list HCT/Ps that are regulated solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271 (361 HCT/Ps). HCT/P establishment registration and product listing information must be submitted electronically (see 21 CFR 1271.22) using the electronic Human Cell and Tissue Establishment Registration System (eHCTERS).

Manufacturers of HCT/Ps regulated as drugs, devices, and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug and Cosmetic Act must register and list their products and submit annual registration updates in accordance with 21 CFR parts 207 or 807, as applicable. eHCTERS is not for registration and listing of these products. Please refer to Drug Establishment Registration and Listing or Device Registration and Listing websites for additional information.

FDA does not require establishments that manufacture HCT/Ps regulated as drugs, devices, and/or biological products that are the subject of an investigational new drug application (IND) (21 CFR part 312) or an investigational device exemption (IDE) (21 CFR part 812) to register and list those HCT/Ps in accordance with 21 CFR part 207 or 807 until the products receive marketing authorization. Therefore, establishments that only manufacture HCT/Ps currently under an IND or IDE may inactivate or change their registration in eHCTERS as indicated.

Please note, you should only list 361 HCT/Ps that are intended for implantation, transplantation, infusion, or transfer into a human recipient (see HCT/P definition at 21 CFR 1271.3 (d)). For example, whole heart, whole eye, or placenta are source material for HCT/Ps and are not included on the list of HCT/P Types. Instead, the list includes heart valves, cornea, sclera, or amniotic membrane.

For your convenience, your Registration Summary Report is attached to this email that includes your FDA Establishment Identifier (FEI) number and the Last Registration Receipt Date of your registration. **Please carefully review all the information in the Registration Summary Report, including the HCT/P Types listed and their Proprietary Names, and update the registration accordingly.**

The following instructions describe how to submit your annual registration update electronically. Refer to the "Instructions for Using the eHCTERS" for more information.

1) Access eHCTERS at CBER On-Line through a secure web page here.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

2) If you have forgotten your user name or password, click the link “Forgot your User Name or Password?” and follow the instructions. Once you receive your user name and/or password information, return to the CBER On-Line Login Screen.

3) Enter your User Name and Password, select the application “eHCTERS Tissue Establishment Registration” from the drop-down list, then press the “LOGIN” button.

4) On the Activity Selection screen, select “Edit Registration Information” and select “Annual Registration/Listing” as “Reason for Submission”. Select your establishment from the drop-down list, then press the “Continue” button. If you do not see your establishment in the drop-down list, click the “User Establishments” button to add your establishment to your account.

5) Verify that all registration information is accurate on each screen and update the information where applicable. When your review and update is complete press the “Submit to FDA” button.

6) When prompted, sign the form by entering your Reporting Official E-Mail address then press “Continue”.

After receipt of your annual registration update, an email from FDA will provide the Reporting Official with an updated copy of the Registration Summary Report, which will reflect a new “Last Registration Receipt Date” and “Last Annual Registration Year” in the upper right-hand corner of the report. Please note it may take a few weeks until you receive the updated Registration Summary Report from the FDA. Please keep this copy at the establishment’s location for inspection purposes.

Please note the “Last Annual Registration Year” on the upper right-hand corner of the Registration Summary Report indicates that your establishment registration is current through December 31st of that year. The FDA Information Collection OMB control number and the expiration date listed at the bottom of the Registration Summary Report is not the expiration date of your registration.

As a reminder, according to 21 CFR 1271.27(b), FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA.

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

Regards,

Tissue Registration Coordinator