



TITLE:

Adding District Use Codes for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

ORIGINAL EFFECTIVE DATE:
[DATE]

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1. Purpose/Scope

To establish a procedure to be followed by ALL district offices, and the Office of Medical Products and Tobacco Operations (OMPTO)/Division of Medical Products and Tobacco Program Operations (DMPTPO) in updating District Use Codes (DUC) in FMS using information received from the Center for Biological Evaluation and Research (CBER). This procedure summarizes field and headquarter responsibilities and ensures information that is in the Center files and the field's Official Establishment Inventory (OEI) and Registration files are aligned.

Follow FMD-130 for additional instructions, including assigning Establishment Types.

2. Responsibility

A. It is the responsibility of the District OEI Coordinator, District Tissue Program Monitor, or designee to manage assigning district use codes in accordance with this work instruction.

District includes both domestic and foreign areas.

B. The National OEI Coordinator is the point of contact (POC) between CBER and ORA, and will route all communications and questions regarding the data in the spreadsheet/registration documents.

Note: The document refers to District Registration Monitor throughout, but is referring to the above statement.

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3. Background

Previously, firms were identified as tissue firms in Firm Management Services (FMS). CBER requested more granularity in identifying the types of tissue handled by each firm, to assist with work planning and expertise of investigator assigned to each firm. This procedure provides guidance for identifying tissue types handled by each firm in FMS.

4. Procedure

4.1 Dissemination of Information

CBER/ Office of Cellular, Tissue & Gene Therapy (CTGT)/ Division of Human Tissue (DHT)/ Human Tissue Registration Branch (HTRB) emails the Biologics Registration Monitor a PDF file containing a scanned copy of FDA -3356 “Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” which documents information for newly registered firms or annual renewals and change of registration information.

Alternatively, this information may be provided in an EXCEL spreadsheet.

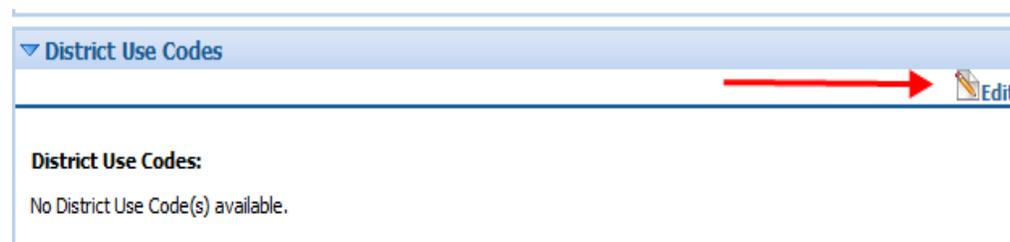
Note: It is anticipated that HCT/Ps that are regulated as medical devices, drugs, and/or biological drugs (e.g. unrelated allogeneic cord blood stem cells, unrelated allogeneic peripheral blood stem cells, unrelated allogeneic somatic cell therapy products, or demineralized bone matrix (DBM) with carrier) may no longer register through HCTERS. These firms will still be assigned District Use Codes, but the procedure will be revised to identify the new source of information.

4.2 Updating Firm Management System (FMS)

Step 1: Review the firm’s registration information as described on the Form FDA-3356 or the EXCEL file

Step 2: Search for the firm being updated in Firm Maintenance Services (FMS) in FACTS.

Step 3: Under “Firm Details”, scroll to the bottom of the page and click “Edit” next to “District Use Codes”.



Step 4: Identify the type of tissue that the firm handles as documented in Section 10 “Establishment Functions and Types of HCT/Ps” of Form FDA 3356 or the “all products” column in the EXCEL spreadsheet.



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Step 5: Identify the appropriate District Use Code (DUC) from the Table in Attachment 1. If there is no District Use Code defined within this procedure, the product is defined solely by establishment type, with no additional granularity needed for inventory breakdown.

District Use Code (DUC)	Explanation
HE	Ocular HCT/Ps: An establishment that engages in recovery, donor screening, donor testing, processing, packaging, labeling, storage, and/or distribution of ocular HCT/Ps (e.g., cornea, sclera) that are intended for implantation, transplantation, infusion, or transfer into a human recipient.
HK	Skin HCT/Ps: An establishment that engages in recovery, donor screening, donor testing, processing, packaging, labeling, storage, and/or distribution of skin HCT/Ps that are intended for implantation, transplantation, infusion, or transfer into a human recipient.
HM	Musculoskeletal (MS), and Cardiovascular HCT/Ps An establishment that engages in recovery, donor screening, donor testing, processing, packaging, labeling, storage, and/or distribution of MS HCT/Ps (e.g., bone, cartilage, ligament, tendon) and/or cardiovascular HCT/Ps (e.g., blood vessels, pericardium, heart valve) that are intended for implantation, transplantation, infusion, or transfer into a human recipient.
HO	Other HCT/Ps: An establishment that engages in recovery, donor screening, donor testing, processing, packaging, labeling, storage, and/or distribution of HCT/Ps not included in district use codes HU, HE, HK, HM, HP, or establishment code HR. Examples include dura mater, tooth pulp, amniotic membrane, autologous pancreatic islets, HPC Marrow, ovarian tissue, parathyroid, somatic cell therapy products, testicular tissue, etc.
HP	Peripheral blood stem / progenitor cells or therapeutic cells (mononuclear cells): An establishment that engages in recovery, donor screening, donor testing, processing, packaging, labeling, storage and/or distribution of human peripheral blood stem / progenitor cells or therapeutic cells (peripheral blood mononuclear cells) that are intended for implantation, transplantation, infusion, or transfer into a human recipient.
HU	Umbilical Cord Blood stem/ progenitor cells: An establishment that engages in recovery, donor screening, donor testing, processing, packaging, labeling, storage and/or distribution of

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	human umbilical cord blood stem/progenitor cells that are intended for implantation, transplantation, infusion, or transfer into a human recipient.
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Step 6: Use the drop down menu and the "Right" Green Arrow to add the District Use Code.

Enter Additional Firm Details

You may enter additional details by clicking on the different tabs below. Once done, press the 'Next' button to continue.

* Denotes required fields
** Denotes conditionally required fields

Required* Cross Ref Contact Program Risk **District Use Codes**

District Use Code:  **No District Use Code(s) available.**

Drop down arrow  "Right" Green arrow

5. Glossary/Definitions

- A. **CBER:** Center for Biological Evaluation and Research
- B. **CFN:** Central File Number
- C. **CTS:** Center Tracking System
- D. **FEI:** Field Establishment identifier
- E. **FACTS:** Field Accomplishment Tracking System
- F. **FMS:** Facility Management Service
- G. **OEI:** Official Establishment Inventory

6. Supporting Documents

- A. 21 CFR 1271

7. Document History

Version #	Status* (D, I, R, C)	Date	Author Name and Title	Approving Official Name and Title
1.0	I		LORI S. LAWLESS, NATIONAL OEI COORDINATOR	Kate Bent, Director OPRM

* - D: Draft, I: Initial, R: Revision, C: Cancel



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8. Change History

Version	Change
1.0	Initial

9. Attachments

Attachment 1: Tissue Type, Associated District Use Code and Associated Establishment Code

Types of HCT/Ps from Form 3356	Tissue Category	District Use Code	Establishment Code
Adipose Tissue	Other	HO	HT
Amniotic Fluid	Other	HO	HT
Amniotic Membrane	Other	HO	HT
Bone	Musculoskeletal or Cardiovascular	HM	HT
Cartilage	Musculoskeletal or Cardiovascular	HM	HT
Cornea	Eye	HE	HT
Dura Mater	Other	HO	HT
Embryo: SIP	Reproductive	N/A	HR
Embryo: Directed	Reproductive	N/A	HR
Embryo: Anonymous	Reproductive	N/A	HR
Fascia	Musculoskeletal or Cardiovascular	HM	HT
Heart Valve	Musculoskeletal or Cardiovascular	HM	HT
Ligament	Musculoskeletal or Cardiovascular	HM	HT
Nerve Tissue	Other	HO	HT
Oocyte: SIP	Reproductive	N/A	HR
Oocyte: Directed	Reproductive	N/A	HR
Oocyte: Anonymous	Reproductive	N/A	HR
Ovarian Tissue	Other	HO	HT
Pancreatic Islet Cells	Other	HO	HT



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Types of HCT/Ps from Form 3356	Tissue Category	District Use Code	Establishment Code
Pericardium	Musculoskeletal or Cardiovascular	HM	HT
Peripheral Blood Stem Cells: Autologous	Hematopoietic Stem Cells	HP	HS
Peripheral Blood Stem Cells: Family Related	Hematopoietic Stem Cells	HP	HS
Peripheral Blood Stem Cells: Allogenic	Hematopoietic Stem Cells	HP	HS
Placenta	Other	HO	HT
Sclera	Eye	HE	HT
Semen: SIP	Reproductive	N/A	HR
Semen: Directed	Reproductive	N/A	HR
Semen: Anonymous	Reproductive	N/A	HR
Skin	Skin	HK	HT
Somatic Cell Therapy Products: Autologous	Other	HO	HT
Somatic Cell Therapy Products: Family Related	Other	HO	HT
Somatic Cell Therapy Products: Allogenic	Other	HO	HT
Tendon	Musculoskeletal or Cardiovascular	HM	HT
Umbilical Cord	Other	HO	HT
Umbilical Cord Blood: Autologous	Hematopoietic Stem Cells	HU	HS
Umbilical Cord Blood: Family Related	Hematopoietic Stem Cells	HU	HS
Umbilical Cord Blood: Allogenic	Hematopoietic Stem Cells	HU	HS
Umbilical Cord Stem Cells	Hematopoietic Stem Cells	HU	HS



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Types of HCT/Ps from Form 3356	Tissue Category	District Use Code	Establishment Code
Vascular Graft	Musculoskeletal or Cardiovascular	HM	HT
Testicular Tissues	Other	HO	HT
Therapeutic Cells	Therapeutic Cells	HP	HS
Tooth Pulp	Other	HO	HT