Sandeep Chiplonkar

From: CDRH Registration and Listing <reglist@CDRH.FDA.GOV>
Sent: Sunday, November 11, 2018 7:29 AM
To: RA_Licenses
Subject: Registration Number 3008812241: Successful 2019 Medical Device Establishment Registration
Attachments: Header.jpg; SignatureBlockLogo.png

Follow Up Flag: Follow up
Flag Status: Flagged

Dear JOEL OSBORNE:

This e-mail provides confirmation that the annual registration for the following medical device establishment has been successfully completed for 2019:

Registration Number: 3008812241
Owner Operator Number: 9032400
MTF Jessup Distribution Center
1175 Mid Valley Dr
Olyphant, PA 18447
UNITED STATES

If you do not see a registration number assigned to the establishment and your establishment previously had one, please send an email to reglist@cdrh.fda.gov and include the registration number you believe is assigned to your establishment. We will review and determine if a duplicate registration has been created for your establishment.

Your registration is valid until December 31, 2019. Registration for 2020 will be conducted between October 1 and December 31, 2019.

Please note that registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to the CDRH Registration and Listing Helpdesk at reglist@cdrh.fda.gov.

CDRH Registration and Listing Helpdesk
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 301-796-7400, Option 1
Email: reglist@cdrh.fda.gov

Dear Reporting Official:

This letter describes how to update your annual establishment registration for human cells, tissues, and cellular and tissue-based products (HCT/Ps). The annual update period begins November 15, 2017 and ends December 31, 2017 (see 21 CFR 1271.21). For this year, a few expectations have changed for the annual registration update using the electronic Human Cell and Tissue Establishment Registration System (eHCTERS). Note that 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 HCT/Ps. Access the final rule here.

1) You are only required to list HCT/Ps that are regulated solely under Section 361 of the Public Health Service Act and 21 CFR Part 1271 of the regulations (361 HCT/Ps). Annual registration using an appropriate FDA electronic registration system is also required for HCT/Ps regulated as drugs, devices, and/or biological products under 21 CFR Parts 207 or 807, as applicable; however, eHCTERS should no longer be used for these products, and you may inactivate the existing registrations in eHCTERS if you are not manufacturing any 361 HCT/Ps. Please refer to Drug Establishment Registration and Listing or Device Registration and Listing websites for additional information.

   Note: FDA does not require establishments that manufacture drugs and devices under an investigational new drug application (IND) (21 CFR Part 312) or an investigational device exemption (IDE) (21 CFR Part 812) to register and list their HCT/Ps until the HCT/P is approved through a biologics license application (BLA), a new drug application (NDA), or a premarket approval application (PMA); or cleared through a premarket notification submission (510(k)). Therefore, establishments that only manufacture HCT/Ps currently under an IND or IDE may inactivate or change their registration in eHCTERS as indicated. [1]

2) Beginning November 29, 2017, HCT/P establishment and product listing information required under §1271.22 (including the annual update) must be submitted electronically, unless waived in certain circumstances. Establishments may request a waiver from the electronic submission requirement as described in §1271.23.

The following instructions describe how to submit your annual registration update electronically. For your convenience, your current registration information is attached to this email that includes your FDA Establishment Identifier (FEI) # and the validated date of your current registration.

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

2) If you have forgotten your 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 both "Edit Validated Form", 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, follow the instructions for adding 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".

Please do not submit your registration update too early as the change will not be reflected in the annual update if submitted prior to November 15, 2017.

After receipt of your annual registration update, we will provide the Reporting Official with an updated copy of the registration form, which will reflect a new validation date in the upper right-hand corner of the form. Please keep this copy at the establishment location for inspection purposes.

If you have questions or need assistance in updating the registration, please contact us at 240-402-8369. You may also submit questions about registration to tissuereg@fda.hhs.gov.

Sincerely yours,

Aletha Davis-Knight
Human Tissue Establishment Registration Coordinator
Division of Human Tissues
Office of Tissues and Advanced Therapies

[1] Guidance for Industry: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide

Help (./help/index.html)

DRLM Home (mainMenu.htm)

✔ Facility

✔ Products Listing

Annual Registration Successful

Facility: MTF Jessup Distribution Center, Olyphant, Pennsylvania, UNITED STATES

You have successfully updated your registration and listing information for 2019.

Your registration will be valid through Dec 31, 2019.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2019.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 9032400.

Facility Information

Registration Number:
3008812241

Initial Importer:
N

Facility Name:
MTF Jessup Distribution Center

Address:
1175 Mid Valley Dr,
Olyphant, Pennsylvania, 18447, UNITED STATES

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Owner/Operator Information

Owner/Operator Number:
9032400

Contact Name:
JOEL - OSBORNE

Company:
MUSCULOSKELETAL TRANSPLANT FOUNDATION

Address: 125 MAY ST., SUITE 300 , --
Edison, NEW JERSEY, 08837, UNITED STATES

Telephone:
732 - 6610202

Fax:
732 - 6612189

E-mail: RA_Licenses@MTF.org

DUNS Number:

Official Correspondent Information

Contact Name:
JOEL - OSBORNE

Company:
MUSCULOSKELETAL TRANSPLANT FOUNDATION

Address: 125 MAY ST., SUITE 300 , --
Edison, NEW JERSEY, 08837, UNITED STATES

Telephone:
732 - 6610202

Fax:
732 - 6612189

E-mail: RA_Licenses@MTF.org

DUNS Number:

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities
D209124	K091218	MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
		MBP	Filler, bone void, osteoinduction (w/o human growth factor)	
D097840	Exempt	HTO	REAMER	Remanufacturer Specification Developer
A978688	Exempt	LXH	ORTHOPEDIC MANUAL SURGICAL INSTRUMENT	Repackager/Relabeler
D209115	K042125	MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
E381064	K042829	MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Repackager/Relabeler
		MBP	Filler, bone void, osteoinduction (w/o human growth factor)	

D327564	K110771	FMF	Syringe, piston	Repackager/Relabeler
D227434	K980987	FMF	Syringe, piston	Repackager/Relabeler
D227432	K100754	FMF	Syringe, piston	Repackager/Relabeler
D095116	Exempt	HXL	MALLET	Specification Developer Remanufacturer
D227435	K921520	JKA	Tubes, vials, systems, serum separators, blood collection	Repackager/Relabeler
D227436	K931367	JKA	Tubes, vials, systems, serum separators, blood collection	Repackager/Relabeler
D142438	BK060006	KSS	SUPPLIES, BLOOD-BANK	Manufacturer
D142437	BK020051	KSS	SUPPLIES, BLOOD-BANK	Manufacturer
E606507	Exempt	HTJ	GAUGE, DEPTH	Repackager/Relabeler
E606506	Exempt	GFG	BIT, SURGICAL	Repackager/Relabeler
E606505	Exempt	HTD	FORCEPS	Repackager/Relabeler
E606504	Exempt	GFF	BUR, SURGICAL, GENERAL & PLASTIC SURGERY	Repackager/Relabeler
E606503	Exempt	HTE	ELEVATOR	Repackager/Relabeler
D095120	Exempt	HXG	TAMP	Remanufacturer
E606509	Exempt	HXP	INSTRUMENT, BENDING OR CONTOURING	Repackager/Relabeler
D324237	K050797	KYZ	SYRINGE, IRRIGATING (NON DENTAL)	Manufacturer
D208635	K040262	MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
		GXP	METHYL METHACRYLATE FOR CRANIOPLASTY	
D209127	K040501	NUN	BONE GRAFTING MATERIAL, HUMAN SOURCE	Manufacturer

Date of Initial Registration: 2010-12-03 09:29:58.0

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

November 27, 2017

RE: Removal of HCT/Ps Regulated as Medical Devices from FDA Annual Registration

To Whom It May Concern:

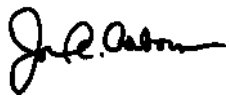
2017 Annual Registration for 2018; FDA has provided a letter (attached), which states that only HCT/Ps solely regulated under Section 361 of the Public Health Service Act and 21 CFR Part 1271 of the regulations (361 HCT/Ps), should be listed on FDA HCT/P Registrations; and any HCT/Ps regulated as Medical Devices should be removed. The following MTF products which are HCT/Ps that are regulated as Medical Devices, all of which have associated 510ks (attached); have been/will be removed.

- DBX Mix
- DBX Paste
- DBX Putty
- DBX
- DBX Strip
- DBX Inject
- AFT

Please note that these products now fall under MTFs FDA Medical Device Registration, and no changes have been made with regards to status; these products are FDA approved.

If you have any questions, please do not hesitate to contact me at (732)-661-0202, extension 2209 or email MTF Regulatory Affairs at Regulatory_Customer_Inquiry@mtf.org.

Sincerely,



Joel C. Osborne
Vice President, Regulatory Affairs