



March 13, 2020

UPS EXPRESS MAIL

Sam L. McGough, DC
Discovery Medical Center, LLC
502 Pratt Avenue NE
Huntsville, AL 35801

Dr. McGough:

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In order to lawfully market an HCT/P that is also a biological product and a drug, a valid biologics license must be in effect. Such licenses are issued only after a showing of safety and efficacy for the product's intended use. While in the development stage, such products intended for clinical use in humans, generally require an investigational new drug application (IND).²

FDA's November 2017 comprehensive regenerative medicine policy framework is intended to spur innovation and efficient access to safe and effective regenerative medicine products, including HCT/Ps. An overview of the framework is outlined in a suite of four guidance documents that are available on FDA's website at <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm585218.htm>.

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FDA is currently applying a risk-based approach to enforcement, accounting for how products are being administered and the diseases and conditions for their use, and reminds you that the 36-month period during which FDA intends to exercise enforcement discretion will end in November 2020.³

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Sincerely,

Mary A.
Malarkey -S

Digitally signed by Mary A. Malarkey -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300054353,
cn=Mary A. Malarkey -S
Date: 2020.03.13 08:41:29 -04'00'

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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UPS EXPRESS MAIL

Roger Kasendorf, DO
Medical Director
StemX Regenerative Medicine
9834 Genesee Ave., Suite 221
La Jolla, CA 92037

Dr. Kasendorf:

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March 13, 2020

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Eric Codner, DC
Columbus Physical Medicine Center
118 Enterprise Ct., Ste B
Columbus, GA 31904

Dr. Codner:

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UPS EXPRESS MAIL

Ann Marie Giedd, NP
Concierge Care, NP
P.O. Box 183
Eaton, NH 3832

Ms. Giedd:

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March 13, 2020

UPS EXPRESS MAIL

Gabor A. Farkas, BS, DC, CKTP
Creekside Integrative Medical Center
3344 E FM 528 Rd., Suite A
Friendswood, TX 77546

Dr. Farkas:

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Director

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research

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March 13, 2020

UPS EXPRESS MAIL

Marc Darrow, MD, JD
Darrow Stem Cell Institute
11645 Wilshire Blvd., Suite 120
Los Angeles, CA 90025

Dr. Darrow:

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March 13, 2020

UPS EXPRESS MAIL

Xerxez Calilung, DDS
Owner
Dental Arts of Irvine
4330 Barranca Parkway, Suite 200
Irvine, CA 92604

Dr. Calilung:

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March 13, 2020

UPS EXPRESS MAIL

Daniel L. Johnson, MD
Medical Director
Desert Longevity Institute
74-075 El Paso, Suite B2
Palm Desert, CA 92260

Dr. Johnson:

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In order to lawfully market an HCT/P that is also a biological product and a drug, a valid biologics license must be in effect. Such licenses are issued only after a showing of safety and efficacy for the product's intended use. While in the development stage, such products intended for clinical use in humans, generally require an investigational new drug application (IND).²

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Sincerely,

Mary A.

Malarkey -S

Mary A. Malarkey

Director

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research

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DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300054353
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Date: 2020.03.13 10:50:34 -04'00'

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March 13, 2020

UPS EXPRESS MAIL

Dennis Harper, MD
Owner
Diversified Biological Signaling Solutions, Inc
2005 SE 192nd Avenue, Suite 200
Camas, WA 98607

Dr. Harper:

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Sincerely,
**Mary A.
Malarkey -S**

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ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=130005435
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Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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March 13, 2020

UPS EXPRESS MAIL

Iris P. Ko, MD
President
Dling Medical Aesthetic Center
9525 E Las Tunas Dr.
Temple City, CA 91780

Dr. Ko:

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Sincerely,

Mary A.
Malarkey -S

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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March 13, 2020

UPS EXPRESS MAIL

Gill Kentof, DC
Dr Gil Center for Back, Neck, and Chronic Pain Relief
209 S Royal Oaks Blvd, Suite 222
Franklin, TN 37064

Dr. Kentof:

It has come to the attention of the United States Food and Drug Administration (FDA or the Agency), Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) that you appear to be offering regenerative medicine products to treat certain diseases or conditions. FDA generally regulates such products under the Public Health Service Act (PHS Act) as human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR 1271.3(d). Although generally regulated as HCT/Ps, such products may also be regulated under the PHS Act and the Federal Food, Drug, and Cosmetic Act (FD&C Act), as biological products, drugs, and/or devices, and may require pre-market review.¹

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Sincerely,

Mary A.
Malarkey -S

Mary A. Malarkey
Director

Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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March 13, 2020

UPS EXPRESS MAIL

William D. Yates, MD
Dr Yates Hair Science Group, LLC
213 N. Stetson Ave
Chicago, IL 60601

Dr. Yates:

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Sincerely,

Mary A.
Malarkey -S

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0.9.2342.19200300.100.1.1=1300054353,
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Date: 2020.03.13 09:36:04 -04'00'

Mary A. Malarkey
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March 13, 2020

UPS EXPRESS MAIL

Junli Zha, MD
Dr Zha Medical
4980 Barranca Parkway, Suite 110
Irvine, CA 92604

Dr. Zha:

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Sincerely,

Mary A.
Malarkey -S

Mary A. Malarkey

Director

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research

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March 13, 2020

UPS EXPRESS MAIL

Mark Dudley, DC, QNCP
Dudley Medical & Wellness
2505 E 3300 S, Suite 201
Salt Lake City, UT 84109

Dr. Dudley:

It has come to the attention of the United States Food and Drug Administration (FDA or the Agency), Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) that you appear to be offering regenerative medicine products to treat certain diseases or conditions. FDA generally regulates such products under the Public Health Service Act (PHS Act) as human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR 1271.3(d). Although generally regulated as HCT/Ps, such products may also be regulated under the PHS Act and the Federal Food, Drug, and Cosmetic Act (FD&C Act), as biological products, drugs, and/or devices, and may require pre-market review.¹

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Sincerely,

Mary A.
Malarkey -S

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
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cn=Mary A. Malarkey -S
Date: 2020.03.13 09:38:01 -04'00'

³ Please be advised that FDA has not evaluated the application of the compliance and enforcement policy to your firm or its products. You and your firm are responsible for ensuring full compliance with the PHS and FD&C Acts and all applicable regulations.



March 13, 2020

UPS EXPRESS MAIL

David M. Ellison, MD
Medical Director, Chief Scientific Officer
Ellison Medical Group
900 Adams Crossing
Cincinnati, OH 45202

Dr. Ellison:

It has come to the attention of the United States Food and Drug Administration (FDA or the Agency), Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) that you appear to be offering regenerative medicine products to treat certain diseases or conditions. FDA generally regulates such products under the Public Health Service Act (PHS Act) as human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR 1271.3(d). Although generally regulated as HCT/Ps, such products may also be regulated under the PHS Act and the Federal Food, Drug, and Cosmetic Act (FD&C Act), as biological products, drugs, and/or devices, and may require pre-market review.¹

In order to lawfully market an HCT/P that is also a biological product and a drug, a valid biologics license must be in effect. Such licenses are issued only after a showing of safety and efficacy for the product's intended use. While in the development stage, such products intended for clinical use in humans, generally require an investigational new drug application (IND).²

FDA's November 2017 comprehensive regenerative medicine policy framework is intended to spur innovation and efficient access to safe and effective regenerative medicine products, including HCT/Ps. An overview of the framework is outlined in a suite of four guidance documents that are available on FDA's website at

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<https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm585218.htm>.

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FDA is currently applying a risk-based approach to enforcement, accounting for how products are being administered and the diseases and conditions for their use, and reminds you that the 36-month period during which FDA intends to exercise enforcement discretion will end in November 2020.³

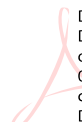
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Sincerely,

Mary A.
Malarkey -S

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

 Digitally signed by Mary A. Malarkey -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300054353,
cn=Mary A. Malarkey -S
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March 13, 2020

UPS EXPRESS MAIL

Salvador Renteria, DO
Escalon Physical Medicine
1631 4th St.
Escalon, CA 95320

Dr. Renteria:

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Sincerely,

Mary A.
Malarkey -S

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
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March 13, 2020

UPS EXPRESS MAIL

Dale Leibert
Essential Biologics, Inc
530 Los Angeles Ave., Suite 115-255
Moorpark, CA 93021

Mr. Leibert:

It has come to the attention of the United States Food and Drug Administration (FDA or the Agency), Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) that you appear to be offering regenerative medicine products to treat certain diseases or conditions. FDA generally regulates such products under the Public Health Service Act (PHS Act) as human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR 1271.3(d). Although generally regulated as HCT/Ps, such products may also be regulated under the PHS Act and the Federal Food, Drug, and Cosmetic Act (FD&C Act), as biological products, drugs, and/or devices, and may require pre-market review.¹

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Sincerely,

Mary A.
Malarkey -S

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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March 13, 2020

UPS EXPRESS MAIL

Thang Tran, DC
Co-Founder
Essential Stem Cell
3715 West Azeele St.
Tampa, FL 33609

Dr. Tran:

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Malarkey -S

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0.9.2342.19200300.100.1.1=1300054353,
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Mary A. Malarkey
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March 13, 2020

UPS EXPRESS MAIL

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Sincerely,

Mary A.
Malarkey -S

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

 Digitally signed by Mary A. Malarkey -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=1300054353,
cn=Mary A. Malarkey -S
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March 13, 2020

UPS EXPRESS MAIL

Jonathan Walker
CEO
Ethos Health Group
625 Commerce Dr., Suite 104
Lakeland, FL 33813

Mr. Walker:

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Sincerely,

Mary A.
Malarkey -S

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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March 13, 2020

UPS EXPRESS MAIL

Nick Koinoglou, DC, DIPL. AC. (IAMA)
Family Health Physical Medicine LLC
641 E. State St.
Alliance, OH 44601

Dr. Koinoglou:

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Digitally signed by Mary A. Malarkey -S
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Date: 2020.03.13 10:20:03 -04'00'

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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March 13, 2020

UPS EXPRESS MAIL

Brad Fraum, DC
Fraum Center for Restorative Health
1403 Main Street Village
Hilton Head Island, SC 29926

Dr. Fraum:

It has come to the attention of the United States Food and Drug Administration (FDA or the Agency), Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) that you appear to be offering regenerative medicine products to treat certain diseases or conditions. FDA generally regulates such products under the Public Health Service Act (PHS Act) as human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR 1271.3(d). Although generally regulated as HCT/Ps, such products may also be regulated under the PHS Act and the Federal Food, Drug, and Cosmetic Act (FD&C Act), as biological products, drugs, and/or devices, and may require pre-market review.¹

In order to lawfully market an HCT/P that is also a biological product and a drug, a valid biologics license must be in effect. Such licenses are issued only after a showing of safety and efficacy for the product's intended use. While in the development stage, such products intended for clinical use in humans, generally require an investigational new drug application (IND).²

FDA's November 2017 comprehensive regenerative medicine policy framework is intended to spur innovation and efficient access to safe and effective regenerative medicine products, including HCT/Ps. An overview of the framework is outlined in a suite of four guidance documents that are available on FDA's website at <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm585218.htm>.

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Sincerely,

Mary A.
Malarkey -S

Mary A. Malarkey

Director

Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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March 13, 2020

UPS EXPRESS MAIL

Todd Molski, DC
Founder
Freedom Health Centers
2709 Virginia Pkwy
McKinney, TX 75071

Dr. Molski:

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Sincerely,

Mary A.
Malarkey -S

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March 13, 2020

UPS EXPRESS MAIL

Mira Mirhashemi, DO
Harbor Medical Clinic and Wellness Center
33 Creek Rd #310
Irvine, CA 92604

Dr. Mirhashemi:

It has come to the attention of the United States Food and Drug Administration (FDA or the Agency), Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) that you appear to be offering regenerative medicine products to treat certain diseases or conditions. FDA generally regulates such products under the Public Health Service Act (PHS Act) as human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR 1271.3(d). Although generally regulated as HCT/Ps, such products may also be regulated under the PHS Act and the Federal Food, Drug, and Cosmetic Act (FD&C Act), as biological products, drugs, and/or devices, and may require pre-market review.¹

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March 13, 2020

UPS EXPRESS MAIL

Clifford Fetters, MD
Health & Wellness of Carmel
11900 N. Pennsylvania St., Suite 200
Carmel, IN 46032

Dr. Fetters:

It has come to the attention of the United States Food and Drug Administration (FDA or the Agency), Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) that you appear to be offering regenerative medicine products to treat certain diseases or conditions. FDA generally regulates such products under the Public Health Service Act (PHS Act) as human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR 1271.3(d). Although generally regulated as HCT/Ps, such products may also be regulated under the PHS Act and the Federal Food, Drug, and Cosmetic Act (FD&C Act), as biological products, drugs, and/or devices, and may require pre-market review.¹

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Sincerely,

Mary A.
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Mary A. Malarkey
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March 13, 2020

UPS EXPRESS MAIL

Christopher Drew, DC
Clinic Director
HealthMax Progressive Medicine
7060 Valley Creek Plaza, Ste. 121
Woodbury, MN 55125

Dr. Drew:

It has come to the attention of the United States Food and Drug Administration (FDA or the Agency), Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) that you appear to be offering regenerative medicine products to treat certain diseases or conditions. FDA generally regulates such products under the Public Health Service Act (PHS Act) as human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR 1271.3(d). Although generally regulated as HCT/Ps, such products may also be regulated under the PHS Act and the Federal Food, Drug, and Cosmetic Act (FD&C Act), as biological products, drugs, and/or devices, and may require pre-market review.¹

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