



April 7, 2020

UPS EXPRESS MAIL

Patrick Gorman, DC, CCEP
Independent Physical Medicine
3469 W Elm St., Suite B
Lima, OH 45807

Dr. Gorman:

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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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
Date: 2020.04.07 10:01:34 -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.



April 7, 2020

UPS EXPRESS MAIL

Jeremy Girmann, DO
Inertia Medical
6200 Union Centre Blvd
Fairfield, OH 45014

Dr. Girmann:

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Mary A.
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April 7, 2020

UPS EXPRESS MAIL

Travis Whitney, NMD, MSc, MSAc
Innate Healthcare Phoenix
4840 E. Indian School Rd., Suite 104
Phoenix, AZ 85018

Dr. Whitney:

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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April 7, 2020

UPS EXPRESS MAIL

Anthony Pirritano, DC
President
Integrated Medical Center of Corona, LLC
2250 S. Main St., Suite 203
Corona, CA 92882

Dr. Pirritano:

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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April 7, 2020

UPS EXPRESS MAIL

Keith S. Ungar, DC
Integrated Medicine of Ohio
2800 S. Arlington Rd., Suite 100
Akron, OH 44312

Dr. Ungar:

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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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April 7, 2020

UPS EXPRESS MAIL

Cory Frogley, DC, CCEP
Co-Owner
Integrated Wellness - Bountiful
458 North 500 West
Bountiful, UT 84010

Dr. Frogley:

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April 7, 2020

UPS EXPRESS MAIL

Kirk Wersland, DC, CCEP
Co-Owner, Clinic Director
Integrated Wellness - Bountiful
458 North 500 West
Bountiful, UT 84010

Dr. Wersland:

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

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April 7, 2020

UPS EXPRESS MAIL

Scott Frogley, DC, CCEP
Co-Owner
Integrated Wellness - South Jordan
10376 S Jordan Gateway
South Jordan , UT 84095

Dr. Frogley:

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Sincerely,

Mary A. Malarkey
-S

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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,
cn=Mary A. Malarkey -S
Date: 2020.04.07 11:07:33 -04'00'

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
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April 7, 2020

UPS EXPRESS MAIL

Randy Woodward, DC, CCEP
Co-Owner
Integrated Wellness - South Jordan
10376 S Jordan Gateway
South Jordan , UT 84095

Dr. Woodward:

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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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April 7, 2020

UPS EXPRESS MAIL

George Graff, MD
Intelligent Pain & Regenerative Medicine Solutions
8929 Wilshire Blvd., Suite 200
Beverly Hills, CA 90211

Dr. Graff:

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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April 7, 2020

UPS EXPRESS MAIL

Dan Joseph, DC
Director
Joseph Health Group
5001 N University St.
Peoria, IL 61614

Dr. Joseph:

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Sincerely,

Mary A.
Malarkey -S

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

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April 7, 2020

UPS EXPRESS MAIL

Sunny Gill, DC
Kingston Crossing Wellness Clinic, PS
8202 NE State Hwy 104 #105
Kingston, WA 98346

Dr. Gill:

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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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April 7, 2020

UPS EXPRESS MAIL

Philip Lenoue, III, DO, RMSK
Lenoue Integrative Medicine
301 East Sharp Ave.
Spokane, WA 99202

Dr. Lenoue, III:

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Malarkey -S

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Office of Compliance and Biologics Quality
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April 7, 2020

UPS EXPRESS MAIL

Kevin R. Kemp, DC
Lifestyle Medical Solutions
3998 Indianola Avenue
Columbus, OH 43214

Dr. Kemp:

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Date: 2020.04.07 10:12:04 -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.



April 7, 2020

UPS EXPRESS MAIL

Matthew Gianforte, DC
LifeWorks Integrative Health
22742 Midland Dr.
Shawnee, KS 66226

Dr. Gianforte:

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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: 2020.04.07 10:13:55 -04'00'

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

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April 7, 2020

UPS EXPRESS MAIL

Sonja Fung, ND
Owner, Medical Director
Live Well Clinic
78900 Avenue 47, Ste 102
La Quinta, CA 92253

Dr. Fung:

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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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April 7, 2020

UPS EXPRESS MAIL

M. Brandon Pettke, DC
Clinic Director
Lone Star Progressive Medicine
1320 NW John Jones Dr.
Burleson, TX 76028

Dr. Pettke:

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Sincerely,

Mary A.
Malarkey -S

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Date: 2020.04.07 10:17:21 -04'00'

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
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April 7, 2020

UPS EXPRESS MAIL

Drew DeMann, DC, MA, FNP, RMSK, GCSRT
Managing Director
Manhattan Medicine
300 E. 56th Street
New York, NY 10022

Dr. DeMann:

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

Digitally signed by Mary A. Malarkey -S
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ou=HHS, ou=FDA, ou=People,
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April 7, 2020

UPS EXPRESS MAIL

Victor Mattos, MD
Founder, Clinical Director, CEO
Mattos Medical Group
8315 N. Saulray St.
Tampa, FL 33604

Dr. Mattos:

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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: 2020.04.07 10:26:31 -04'00'

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April 7, 2020

UPS EXPRESS MAIL

Manouchehr T. Shabab, MD
Director
MedWell, LLC
33 Central Ave.
Midland Park, NJ 7432

Dr. Shabab:

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Sincerely,

Mary A. Malarke

-S

Mary A. Malarkey

Director

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research

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April 7, 2020

UPS EXPRESS MAIL

Rosa M. Navarro, MD
Navarro Pain Control Group Inc
2452 Fenton Street, Suite 101
Chula Vista, CA 91914

Dr. Navarro:

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Mary A.
Malarkey -S

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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.



April 7, 2020

UPS EXPRESS MAIL

A. Elliot Hirshorn, DC, DACNB
CEO
New Life Medical Center
227 N Main St.
Simpsonville, NC 29681

Dr. Hirshorn:

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

¹ Secreted body fluids (e.g., amniotic fluid) are generally not considered HCT/Ps; see 21 CFR 1271.3(d), however, such products are subject to premarket review and approval as drugs and biological products when they are intended to treat diseases or conditions in humans.

² Please be advised that, as a general matter, exosomes for clinical use in humans are regulated as drugs and biological products under section 351 of the PHS Act and the FD&C Act, and are subject to premarket review and approval requirements. We also direct your attention to FDA's Public Safety Notification on Exosome Products, issued on December 6, 2019, and available at <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/public-safety-notification-exosome-products>.

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

FDA's final guidance, *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use*, issued in November 2017, informed manufacturers, health care providers, and other interested parties about the Agency's compliance and enforcement policy for these products. The guidance outlined FDA's intent to exercise enforcement discretion for the first 36 months following issuance of the guidance for certain products with respect to FDA's IND and premarket approval requirements when the use of the product does not raise reported safety concerns or potential significant safety concerns. This period provides manufacturers time to comply with the IND and premarket approval requirements and engage with FDA to determine whether they need to submit an IND or marketing authorization application, and if so, to submit their application to FDA.

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

Manufacturers, health care providers, and other interested parties who have any uncertainty regarding the regulatory status of their products, and who have not already done so, are encouraged to contact FDA well in advance of November 2020, to determine whether their products are subject to the agency's premarket approval requirements.

For more information on how to contact FDA to obtain a recommendation or decision regarding the classification of an HCT/P, or for further information about IND requirements for biological products, please see pages 23 and 24 of the guidance entitled *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use*, available at <https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm585218.htm>.

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
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