



May 7, 2020

UPS EXPRESS MAIL

Al Sears, MD
Owner
Sears Institute for Anti-Aging Medicine
11905 Southern Blvd.
Royal Palm Beach, FL 33411

Dr. Sears:

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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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


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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,
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cn=Mary A. Malarkey -S
Date: 2020.05.07 10:34:50 -04'00'

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May 7, 2020

UPS EXPRESS MAIL

Christopher D.. Schroeder, DC
Central Kansas Regeneration
421 E. 30th Avenue
Hutchinson, KS 67502

Dr. Schroeder:

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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Director

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May 7, 2020

UPS EXPRESS MAIL

J. Scott Clark, DC
Owner
Clark Integrated Medical Clinics, LLC
130 Rue Beauregard, Suite A
Lafayette, LA 70508

Dr. Clark:

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

Mary A. Malarkey
Director
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UPS EXPRESS MAIL

Sonny Rubin, MD
Founder, Medical Director
Newport Regenerative Medicine (Orange County Pain Specialist)
455 Old Newport Blvd., Suite 101
Newport Beach, CA 92663

Dr. Rubin:

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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May 7, 2020

UPS EXPRESS MAIL

Luis Dominguez, DO
Medical Director
NuLife Institute
1040 Biscayne Blvd., 8th Floor
Miami, FL 33132

Dr. Dominguez:

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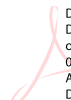
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UPS EXPRESS MAIL

Yoshi Rahm, DO
Oasis Family Medicine
3541 Ocean View Blvd.
Glendale, CA 91208

Dr. Rahm:

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May 7, 2020

UPS EXPRESS MAIL

Clement Lee, NMD
Founder
Optimal Health & Wellness
202 S. Lake Ave. Suite 298
Pasadena, CA 91101

Dr. Lee:

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0.9.2342.19200300.100.1.1=1300054353,
cn=Mary A. Malarkey -S
Date: 2020.05.07 11:03:30 -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.



May 7, 2020

UPS EXPRESS MAIL

Hasan Badday, MD
Pacific Pain and Regenerative Medicine
16405 Sand Canyon Ave, Suite 215
Irvine, CA 92618

Dr. Badday:

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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

Mary A. Malarkey

Director

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research

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May 7, 2020

UPS EXPRESS MAIL

Brian Paris, DC
CEO
Pain Arthritis Relief Center
50 West Gude Dr., Suite 46B
Rockville, MD 20850

Dr. Paris:

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Mary A. Malarkey
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May 7, 2020

UPS EXPRESS MAIL

Kenneth J. Vinton, DC
Director
Pain Relief and Wellness Strategies Center
190 George Junior Rd.
Grove City, PA 16127

Dr. Vinton:

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,
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Malarkey -S**

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Mary A. Malarkey
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May 7, 2020

UPS EXPRESS MAIL

Robert Birch, DC, CCEP, BCIM, CFMP
Owner
Parker Integrative Health
18801 E Mainstreet, Suite 190
Parker, CO 80134

Dr. Birch:

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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May 7, 2020

UPS EXPRESS MAIL

Luis Del Rio, DC
Director of Regenerative Medicine
Peak Health
820 Palmway St.
Kissimmee, FL 34744

Dr. Del Rio:

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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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May 7, 2020

UPS EXPRESS MAIL

William F. Rodriguez, MD, CAQSM
Medical Director
Peak Health
820 Palmway St.
Kissimmee, FL 34744

Dr. Rodriguez:

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May 7, 2020

UPS EXPRESS MAIL

Doug Minton, MD
Medical Director
Peak Vitality
8101 E Prentice Ave.
Greenwood Village, CO 80111

Dr. Minton:

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Date: 2020.05.07 10:40:33 -04'00'

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

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May 7, 2020

UPS EXPRESS MAIL

Brant T. Koenig, DC
Founder, Owner
Physical Medicine of Oklahoma
800 W 18th St., Suite 100
Edmond, OK 73013

Dr. Koenig:

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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,

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Director
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Center for Biologics Evaluation and Research

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May 7, 2020

UPS EXPRESS MAIL

Diana Hashaw, MSN, FNP-C
Medical Director
Physicians Wellness
2551 Drew Street, Suite 206
Clearwater, FL 33765

Ms. Hashaw:

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May 7, 2020

UPS EXPRESS MAIL

Daniel Rasmussen, EAMP, Dipl. OM, FMP
Owner
Pinnacle Integrative Health
509 Olive Way, Suite 803
Seattle, WA 98101

Mr. Rasmussen:

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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May 7, 2020

UPS EXPRESS MAIL

Amish Patel, MD, MBA
Managing Partner
Premier Pain and Spine LLC
1365 Wiley Rd., Suite 153
Schaumburg, IL 60173

Dr. Patel:

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

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May 7, 2020

UPS EXPRESS MAIL

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Founding Partner
Premier Pain and Spine LLC
1365 Wiley Rd., Suite 153
Schaumburg, IL 60173

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May 7, 2020

UPS EXPRESS MAIL

Sham M. Vengurlekar, MD, PC
Premier Pain Institute
7010 E Chauncey Ln, Suite 215
Phoenix, AZ 85054

Dr. Vengurlekar:

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May 7, 2020

UPS EXPRESS MAIL

Iren Prober, MD
Prestige Medical Group
6924 Professional Parkway East, Suite B
Lakewood Ranch, FL 34240

Dr. Prober:

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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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cn=Mary A. Malarkey -S
Date: 2020.05.07 10:54:18 -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.



May 7, 2020

UPS EXPRESS MAIL

Larry Vigilia, MD
Refresh
1141 E. Colorado St.
Glendale, CA 91205

Dr. Vigilia:

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>.

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>.

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

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Director

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