



UPS EXPRESS MAIL

August 28, 2019

Lynn A. Genet, DC
American Physical Medicine
8417 East McDowell Road, Suite 103
Scottsdale, AZ 85257

Dr. Genet:

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 “stem cell” products to treat a variety of 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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DN: c=US, o=U.S. Government, ou=HHS,
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cn=Mary A. Malarkey -S
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UPS EXPRESS MAIL

August 28, 2019

Kristin Oliver, MD
Bluetail Medical Group, LLC
17300 North Outer 40 Road, Suite 201
Chesterfield, MO 63005

Dr. Oliver:

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Mary A. Malarkey

Director

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UPS EXPRESS MAIL

August 28, 2019

Marion A. Hauser, MS, RD
CEO
Caring Medical Regenerative Medicine Clinics
9738 Commerce Center Ct.
Fort Myers, FL 33908

Dr. Hauser:

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Mary A. Malarkey
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UPS EXPRESS MAIL

August 28, 2019

Jeffrey Donatello, DC
Clinic Director
Center for Functional Medicine and Wellbeing LLC
875 Greenland Road, Suite B3
Portsmouth, NH 3801

Dr. Donatello:

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UPS EXPRESS MAIL

August 28, 2019

Darcey Ladner, DC
Charlotte Stem Cell
10220 Couloak Drive
Charlotte, NC 28216

Dr. Ladner:

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UPS EXPRESS MAIL

August 28, 2019

Patrick D. Devanny, MD
Comprehensive Regenerative Medicine, LLC
2960 N. Circle Drive, Suite 125
Colorado Springs, CO 80909

Dr. Devanny:

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Director

Office of Compliance and Biologics Quality

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UPS EXPRESS MAIL

August 28, 2019

Shelly Sood
Founding Partner
Giostar Chicago
2614 Patriot Boulevard, Unit A
Glenview, IL 60026

Ms. Sood:

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UPS EXPRESS MAIL

August 28, 2019

Timothy Gallagher, DC
Founder & CEO
Michael Marciello, MD
Medical Director & Owner
Maragal Medical
54 William St.
Leominster, MA 1453

Dr. Gallagher and Dr. Marciello:

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Richard Mays, MD
Medical Director
Optimal Health Regenerative Aesthetics Medical
11668 Parkside Drive
Knoxville, TN 37934

Dr. Mays:

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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,
cn=Mary A. Malarkey -S
Date: 2019.08.28 09:27:23 -04'00'

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UPS EXPRESS MAIL

August 28, 2019

Stephanie Jones
Owner
Pain Relief Partners Inc
406 SE 131 st Ave., Suite #203
Vancouver, WA 98683

Ms. Jones:

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Sincerely,

Mary A.
Malarkey -S

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Mary A. Malarkey
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Office of Compliance and Biologics Quality
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UPS EXPRESS MAIL

August 28, 2019

Premier Physical Medicine
2018 E. Broadway Street
Pearland, TX 77581

To Whom it May Concern:

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Sincerely,

Mary A.
Malarkey -S

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
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Date: 2019.08.28 09:09:48 -04'00'

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UPS EXPRESS MAIL

August 28, 2019

Eric Balcavage
Clinic Director, DC, CNS, CFMP, BCIM
Rejuvagen
17 Regency Plaza
Glen Mills, PA 19342

Mr. Balcavage:

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 “stem cell” products to treat a variety of 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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Director

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Center for Biologics Evaluation and Research

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53, cn=Mary A. Malarkey -S
Date: 2019.08.28 09:10:50 -04'00'

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UPS EXPRESS MAIL

August 28, 2019

Richard Ambrozic, MD
Owner & Founder
Southern Stem Cell Institute Atlanta, LLC
240 Pharr Road
Atlanta, GA 30305

Dr. Ambrozic:

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Director

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research

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UPS EXPRESS MAIL

August 28, 2019

Superior Health Centers - Glendale
222 West Eulalia Street, #215
Glendale, CA 91204

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Sincerely,

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

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Date: 2019.08.28 09:15:10 -04'00'

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UPS EXPRESS MAIL

August 28, 2019

Elise Sims, MD
Medical Director
Tennessee Center for Regenerative Medicine, PC
1334 Mackey Branch Drive, Suite 104
Chattanooga, TN 37421-3471

Dr. Sims:

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UPS EXPRESS MAIL

August 28, 2019

Michelle Williams, ND
Medical Director
The Wellness Center PDX
1359 NE 35th Avenue
Portland, OR 97232

Dr. Williams:

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UPS EXPRESS MAIL

August 28, 2019

Michael J. Poss, MD
Virginia Regenerative Medicine, LLC dba Virginia Regenerative Medicine and Spa
8451 West Main Street
Marshall, VA 20115

Dr. Poss:

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 “stem cell” products to treat a variety of 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

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>.

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

¹ For example, 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).

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 2020.²

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

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: 2019.08.28 09:18:21 -04'00'

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

² 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.



UPS EXPRESS MAIL

August 28, 2019

Karen Donaldson, MD
Medical Director
Whole Body Healthcare
3916 Hickory Ave
Baltimore, MD 21211

Dr. Donaldson:

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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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