



January 7, 2020

UPS EXPRESS MAIL

Gene S. Elliot
CEO
Stratus BioSystems, LLC
913 S Main St., Ste 215
Grapevine, TX 76051

Mr. Elliot:

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

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.

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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=13000543
53, cn=Mary A. Malarkey -S
Date: 2020.01.07 09:04:40 -05'00'

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UPS EXPRESS MAIL

Louis E. Barnes
President, COO
Vivex Biologics
1951 NW 7th Ave., Ste. 200
Miami, FL 33136

Mr. Barnes:

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Robert J. Palmisano
President, CEO
Wright Medical Group
1023 Cherry Road
Memphis, TN 38117

Mr. Palmisano:

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Christopher M.B. Sharp
President, CEO
Human Regenerative Technologies, LLC
2255 Campus Drive
El Segundo, CA 90245

Mr. Sharp:

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Oliver Burckhardt
President
Flower Orthopedics
100 Witmer Road, Suite 280
Horsham, PA 19044

Mr. Burckhardt:

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UPS EXPRESS MAIL

Neil Riordan, PA, PhD
Founder
Signature Biologics
11496 Luna Rd., Ste 800
Dallas, TX 75234

Dr. Riordan:

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Robert D. Maguire
CEO
Axolotl Biologix
1637 W Knudsen Dr.
Phoenix, AZ 85027

Mr. Maguire:

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Andy Barlow
Manager
Regenerative Medicine of Mississippi, LLC
398 N Eason Blvd
Tupelo, MS 38804

Mr. Barlow:

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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

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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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DN: c=US, o=U.S. Government, ou=HHS,
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cn=Mary A. Malarkey -S
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January 7, 2020

UPS EXPRESS MAIL

Tyler Barrett
Regenerative Labs, LLC
1700 West Main Street
Pensacola, FL 32503

Mr. Barrett:

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January 7, 2020

UPS EXPRESS MAIL

Richard S. Schaffer, Jr., MD
Medical Director
QC Kinetix, PC
309 S. Sharon Amity Road, Suite 302
Charlotte, NC 28211

Dr. Schaffer, Jr.:

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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January 7, 2020

UPS EXPRESS MAIL

Tyler Vail, MMS, PA-C
Director of Regenerative Medicine
QC Kinetix, PC
309 S. Sharon Amity Road, Suite 302
Charlotte, NC 28211

Mr. Vail:

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Director

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January 7, 2020

UPS EXPRESS MAIL

Adrienne Stewart, NMD
Owner & Medical Director
Nourish Naturopathic Medicine, Inc
10505 Sorrento Valley Road #225
San Diego, CA 92121

Dr. Stewart:

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Office of Compliance and Biologics Quality
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January 7, 2020

UPS EXPRESS MAIL

Korianne Haas, MD
Owner
Flourish MD Acupuncture
227 North El Camino Real #106
Encinitas, CA 92024

Dr. Haas:

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January 7, 2020

UPS EXPRESS MAIL

Michael Crescenzo
CEO
Evologics, LLC
4766 Research Drive
San Antonio, TX 78240

Mr. Crescenzo:

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January 7, 2020

UPS EXPRESS MAIL

C. Randall Harrell, MD
Chairman, CEO, CMO
Regenerative Processing Plant, LLC
Fountain of Youth Building, 34176 US Highway 19 N
Palm Harbor, FL 34684

Dr. Harrell:

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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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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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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January 7, 2020

UPS EXPRESS MAIL

Dan Crane, MBA
President
Apex Biologix
5646 South Green St.
Murray, UT 84123

Mr. Crane:

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Sincerely,

Mary A.
Malarkey -S

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

UPS EXPRESS MAIL

Katherine Brooks, MD
Med Cell Regenerate
7373 Kirkwood Court North Suite 110B
Maple Grove, MN 55369

Dr. Brooks:

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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Mary A.
Malarkey -S

Mary A. Malarkey
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Center for Biologics Evaluation and Research

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January 7, 2020

UPS EXPRESS MAIL

Vicki Mansavage
President, CEO
New Life Regenerative Medicine
244 Crystal Grove Blvd
Lutz, FL 33548

Ms. Mansavage:

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January 7, 2020

UPS EXPRESS MAIL

Bryan T. Drain, ND
Regenerative Wellness
1060 University Ave., Suite A211
San Diego, CA 92103

Dr. Drain:

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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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January 7, 2020

UPS EXPRESS MAIL

Kanon Oswald, DC
Co-Founder
Vanguard Spine & Sport, PLLC
8800 Katy Fwy, #105
Houston, TX 77024

Dr. Oswald:

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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Mary A.
Malarkey -S

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Director
Office of Compliance and Biologics Quality
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January 7, 2020

UPS EXPRESS MAIL

Lance Iguess, DC
Co-Founder
Vanguard Spine & Sport, PLLC
8800 Katy Fwy, #105
Houston, TX 77024

Dr. Iguess:

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

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.



January 7, 2020

UPS EXPRESS MAIL

Anna Stahl
Founder, CEO
XLmedica
6900 Daniels Pkwy, Suite 29 - PMB 197
Ft. Myers, FL 33912

Ms. Stahl:

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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