



**UPS EXPRESS MAIL**

April 3, 2019

Rejuvenate Health HHI  
1544 Fording Island Road  
Hilton Head Island, SC 29926

**To Whom It May Concern:**

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.<sup>1</sup>

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 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.

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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.<sup>2</sup>

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,

/s/

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

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**U.S. FOOD & DRUG  
ADMINISTRATION**

**UPS EXPRESS MAIL**

April 3, 2019

Christopher Schroeder, DC  
Stem Cell Regeneration, LLC  
421 E 30th Avenue  
Hutchinson, KS 67502

Dear 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 "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.<sup>1</sup>

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Sincerely,

/s/

Mary A. Malarkey  
Director  
Office of Compliance and Biologics Quality  
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**FDA U.S. FOOD & DRUG  
ADMINISTRATION**

**UPS EXPRESS MAIL**

April 3, 2019

Mike Van Thielen, PhD  
President and CEO  
Neo Matrix, Inc., dba Neo Matrix Medical  
290 Clyde Morris Blvd, Suite D-1  
Ormond Beach, FL 32174

Dear Dr. Van Thielen:

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.<sup>1</sup>

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Mary A. Malarkey  
Director  
Office of Compliance and Biologics Quality  
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U.S. FOOD & DRUG  
ADMINISTRATION

**UPS EXPRESS MAIL**

April 3, 2019

Guadalupe Nuno, DC  
Tyrone Isquirdo, DC  
East Bay Health and Wellness  
2255 Ygnacio Valley Road #W  
Walnut Creek, CA 94598

Dear Drs. Nuno and Isquirdo:

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.<sup>1</sup>

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Sincerely,

A stylized handwritten signature, likely of Mary A. Malarkey, is displayed within a grey rectangular box. The signature is written in a dark ink and appears to be a cursive or semi-cursive script.

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

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U.S. FOOD & DRUG  
ADMINISTRATION

UPS EXPRESS MAIL

April 3, 2019

Melissa Golden, MBA, Director  
Stemcellix LLC  
4401 West Kennedy Boulevard, Suite 101  
Tampa, FL 33609

Dear Ms. Golden:

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.<sup>1</sup>

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U.S. FOOD & DRUG  
ADMINISTRATION

**UPS EXPRESS MAIL**

April 3, 2019

Scott Sneller, DC, Clinic Director  
Garry Clark, DO, ACOFP, Medical Director  
Multi Care Health Clinic, PC  
3930 Stadium Drive  
Sioux City, IA 51106

Dear Drs. Sneller and Clark:

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.<sup>1</sup>

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## UPS EXPRESS MAIL

April 3, 2019

Christopher R. Sforzo, MD  
Christopher L. Dillingham, MD  
Charles E. Stewart, MD  
Philip Meinhardt, MD  
Sforzo | Dillingham | Stewart Orthopedics + Sports Medicine  
5831 Bee Ridge Road, Suite 200  
Sarasota, FL 34233

Dear Drs. Sforzo, Dillingham, Stewart, and Meinhardt:

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.<sup>1</sup>

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/s/

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Director  
Office of Compliance and Biologics Quality  
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**UPS EXPRESS MAIL**

April 3, 2019

Regan J. Archibald, Founder  
East West Health Solutions, Inc.  
34 S 500 E #203  
Salt Lake City, UT 84102

Dear Mr. Archibald:

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.<sup>1</sup>

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U.S. FOOD & DRUG  
ADMINISTRATION

**UPS EXPRESS MAIL**

April 3, 2019

Brian Roadhouse, DC  
Regeneration Nation LLC  
6565 S. Yale Avenue, Suite 106  
Tulsa, OK 74136

Dear Dr. Roadhouse:

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Sincerely,

/s/

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

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U.S. FOOD & DRUG  
ADMINISTRATION

**UPS EXPRESS MAIL**

April 3, 2019

Lindsay Carmody, MSN, FNP-BC, APNP  
Forward Healthy Lifestyles, LLC  
N112 W15568 Mequon Road, Suite 6  
Germantown, WI 53022

Dear Ms. Carmody:

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.<sup>1</sup>

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

April 3, 2019

Jason Y. Hui, NMD, DC, DACBN, President and Secretary  
Progressive Health & Rehabilitation, Ltd.  
1283 West Dundee Road  
Buffalo Grove, IL 60089

Dear Dr. Hui:

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.<sup>1</sup>

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Mary A. Malarkey  
Director  
Office of Compliance and Biologics Quality  
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**FDA U.S. FOOD & DRUG  
ADMINISTRATION**

**UPS EXPRESS MAIL**

April 3, 2019

Thomas A. Santucci, DC  
Advanced Regen Medical, Inc.  
471 Division Street  
Campbell, CA 95008

Dear Dr. Santucci:

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.<sup>1</sup>

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Mary A. Malarkey  
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U.S. FOOD & DRUG  
ADMINISTRATION

**UPS EXPRESS MAIL**

April 3, 2019

Orca Biotech LLC  
126 West Sego Lily Drive, Suite 195  
Sandy, UT 84070

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U.S. FOOD & DRUG  
ADMINISTRATION

UPS EXPRESS MAIL

April 3, 2019

James P. Dickens, MD, Medical Director  
Natural Foundations Medical Group, Inc.  
4450 Capitola Road, Suite 105  
Capitola, CA 95010

Dear Dr. Dickens:

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.<sup>1</sup>

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

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## UPS EXPRESS MAIL

April 3, 2019

Wisconsin Stem Cell LLC  
1370 Pabst Farms Circle, #340  
Oconomowoc, WI 53066

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**FDA U.S. FOOD & DRUG  
ADMINISTRATION**

**UPS EXPRESS MAIL**

April 3, 2019

Joshua LeBlanc, DC  
Alpha Spine and Wellness, LLC  
3648 Pontchartrain Dr., Suite 100  
Slidell, LA 70458

Dear Dr. LeBlanc:

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**UPS EXPRESS MAIL**

April 3, 2019

Active Integrated Medical Centers PC  
797 East Lancaster Ave., Suite 7  
Downingtown, PA 19335

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Mary A. Malarkey  
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Center for Biologics Evaluation and Research

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<sup>2</sup> 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.





U.S. FOOD & DRUG  
ADMINISTRATION

UPS EXPRESS MAIL

April 3, 2019

Darcy E. Brunk, DC  
Achieve Vitality LLC  
1606 Wynn Joyce Road  
Garland, TX 75043

Dear Dr. Brunk:

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.<sup>1</sup>

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

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<sup>1</sup> 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.<sup>2</sup>

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,

A grey rectangular box redacting the signature, with the handwritten text "/s/" visible in the center.

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

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**UPS EXPRESS MAIL**

April 3, 2019

Anand Srivastava, MS, PhD  
Chairman, Cofounder and Chief Scientific Officer  
Global Institute of Stem Cell Therapy and Research, Inc. (GIOSTAR)  
4660 La Jolla Village Drive  
Suite 100 & 200  
San Diego, CA 92122

Dear Dr. Srivastava:

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.<sup>1</sup>

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Sincerely,

/s/

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

cc: GIOSTAR, Inc.  
13278 Birch Tree Lane  
Poway, CA 92064

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**UPS EXPRESS MAIL**

April 3, 2019

Charles Roger Carroll, President  
Body Garage LLC  
123 Webster Street  
Dayton, OH 45402

Dear Mr. Carroll:

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.<sup>1</sup>

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Sincerely,

/s/

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

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