PhytoCeuticals, Inc. 10/18/16

U.S. FOOD & DRUG ADMINISTRATION

New Jersey District Office
10 Waterview Blvd. 3rd Floor
Parsippany, New Jersey 07054

WARNING LETTER

October 18, 2016

VIA UNITED PARCEL SERVICE

17-NWJ-01

Dr. Mostafa M. Omar
President and Owner
PhytoCeuticals, Inc.
37 Midland Ave.
Elmwood Park, NJ 07407

Dear Dr. Omar:

From March 01, 2016 through March 10, 2016, the United States Food and Drug Administration (FDA) conducted an inspection of your manufacturing facility located at 37 Midland Ave., Elmwood Park, NJ. Based on our inspection and subsequent review of your product labeling, including your firm’s website, we found serious violations of the Federal Food, Drug and Cosmetic Act (the Act). You can find the Act and FDA regulations through links on the FDA’s home page at www.fda.gov (http://www.fda.gov/)

Unapproved New Drugs

During the inspection, FDA collected product labels for products marketed under the brand, "Phyto-C," including product labels for your Phyto-C Signature Cream, Phyto-C Signature Serum, SUPERHEAL O-LIVE Serum, SUPERHEAL O-LIVE Lotion, SUPERHEAL O-LIVE 1 Immune System Revitalizer, SUPERHEAL O-Live 2 Arthritis Formula, Supreme Serum, Selenium in C Serum, Icy Blue, Phyto Gel, PHYTO-C Sunscreen 15 SPF, Vitivera Cream, and Retinol 1% products. In addition, FDA reviewed your website at the Internet address, www.phyto-c.com, in September 2016 and has determined that you take orders on your website for your products, including Phyto-C Signature Cream, Phyto-C Signature Serum, Phyto-C Signature Eye, SUPERHEAL O-LIVE Serum, SUPERHEAL O-LIVE Lotion, SUPERHEAL O-LIVE 1 Immune System Revitalizer, SUPERHEAL O-Live 2 Arthritis Formula, Supreme Serum, Selenium in C Serum, Icy Blue, Phyto Gel, PHYTO-C Sunscreen 15 SPF, Vitivera Cream,
and Retinol 1%. The claims on your product labels and website establish that your products are promoted for uses that cause the products to be drugs under sections 201(g)(1)(B) and/or 201(g)(1)(C) of the Act [21 U.S.C.§ 321(g)(1) (B) and/or 321(g)(1)(C)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease and/or are intended to affect the structure or any function of the human body.

Examples of some of the product label and website claims that provide evidence that your products are intended for use as drugs include:

**Phyto-C Signature Cream**

[Product Label]

- "It stimulates cell-cell interaction, assists in the formation of collagen, and increases skin elasticity..."

[Website]

- "Stimulates cell-cell interactions, and accelerates cell renewal"
- "Helps to preserve cellular energy, assists the formulation of collagen and strengthens in structural proteins"

**Phyto-C Signature Serum**

[Product Label & Website]

- "[R]educe transepidermal waterloss...assists in skin regeneration ...

[Website]

- "Giga White™ is a skin lightener developed by seven Alpine plants with synergistic ratio maximizing the tyrosinase-inhibiting activity."

**Phyto-C Signature Eye**

[Website]

- "Assists in skin regeneration..."
- "Biofactor8000™ A skin respiratory factor that helps skin cells to promote the healing process through the uptake of oxygen. It accelerates the cellular metabolism of sugar, stimulates cell reproduction and collagen."  

**Phyto-C Signature Cream, Phyto-C Signature Serum, and Phyto-CSignature Eye**

[Product insert]

- "[I]nduces signal transduction...reconstructs protein structure...acts as a topical Botox..."
- "[S]timulates cell respiration and increases cell turnover."
- "[A] biosafe alternative to Botox, it relaxes muscle contraction..."
- "Increase Microcirculation"

**Superheal™ O-Live Serum**

[Product Label]
- "Anti-Inflammatory...Anti-Fungal...Rosacea Treatment...Anti-Bacterial...Anti-Viral... Facilitates collagen production...Reduces scar tissue...Promotes wound healing...relieves symptoms of acne and rosacea..."
- "[P]rovides powerful healing...promotes healing and reduces symptoms of acne and rosacea..."

[Website]
- "Anti-Inflammatory • Anti-Fungal • Rosacea Treatment"
- "Provides extraordinary...protection against UV damage"
- "Facilitates collagen production..."
- "Promotes wound healing..."

Superheal™ O-Live Lotion

[Product Label]
- "Powerful Anti-Inflammatory...Provides extraordinary anti-inflammatory and anti-viral properties...Relieves the symptoms of psoriasis..."
- "SUPERHEAL O-live Leaf Extract promotes wound healing, relieves the symptoms of rosacea, eczema, and psoriasis..."

[Website]
- "Powerful Anti-Inflammatory..."
- "Suitable for all types of skin, including psoriasis"
- "Provides extraordinary anti-inflammatory and anti-virus properties"
- "Relieves the symptoms of psoriasis..."
- "Enhances the skin immune system..."

PHYTO-C Supreme Serum

[Product Label]
- "Scar Tissue Reducing...Anti-Cellulite...Facilitates collagen production...Reduces scar tissue...Promotes wound healing..."
- "Anti-Acneic...Protection against harmful UV rays..."
- "Anti-Acne..."

[Website]
- "Provides extraordinary...protection against the damage from UV radiation"
- "Facilitates collagen production..."
- "Reduces scar tissue..."
- "Reduces Scar Tissue• Anti-Cellulite"
- "Provides extraordinary...protection against Photodamage"
- "Promotes wound healing"

Selenium in C Serum

[Product Label]
• "[S]trong anti-cancer effects...Promotes DNA repair...prevents skin cell mutation... Relieves the symptoms of melanoma...reduces the risk of skin cancer...stimulates collagen production...Addresses skin concerns of Photoaging...Melanoma...Skin Cancer..."
• "SELENIUM, an essential trace element that our bodies use to produce glutathione peroxidase, it has been shown to have strong anti-cancer effects, related to its catalytic role in antioxidant enzymes... Facilitates collagen production..."
• "PHYTO-C Selenium in C Serum provides powerful healing antioxidants to restore and protect skin against UV damage..."

[Website]

• "Anti-photoaging..."
• "Provides extraordinary... protection against UV damage"
• "Essential to catalytic role in antioxidant enzymes and protects cells and tissues from oxidation"
• "Promotes DNA repair, prevents skin cell mutation and reduces the risk of skin cancer"
• "Facilitates collagen production and improves signs of photoaging"

**Icy Blue**

[ProductLabel]

• "Anti-Inflammatory...Anti-Allergy...Repairs skin tissue and prevent acne...Promotes tissue healing..."
• "Promotes extraordinary healing capabilities...Essential to help with tissue repair...Controls enzymes, hormones and all chemical biologically reactions inside the body..."
• "The precious Centella Asiatica provides the extraordinary healing capabilities and offers instant relief to dehydrated skin that is damaged by unprotected exposure to the sun's rays..."

[Website]

• "Anti-Inflammatory • Anti-Allergy"
• "Promotes extraordinary healing capabilities..."

**PHYTO-C Phyto Gel**

[ProductLabel]

• "[T]reat acne...Hyperpigmentation Treatment...Anti-Inflammatory...Reduces scar tissue...Anti Cellulite...Anti-Allergic...Active ingredients work synergistically to restrain melanin formation..."
• "Discoloration Treatment...restrain melanin formation...prevents formation of melanin from Tyrosine by deactivating the tyrosinase enzyme...Kojic Acid Inhibits skin melanin formation and educes pigmentation..."
• "Skin Discoloration Treatment"
• "It contains anti-inflammatory and anti-bacterial herbal extracts to smooth and calm irritated skin, at the same time reduces the post-treatment redness..."

[Website]

• "Discoloration Treatment • Lightens"
• "Anti-inflammatory..."
• "[R]estrain melanin formation, and to diminish discoloration and pigmentation"
• "Reduce the post-treatment redness"

_Vitivera Cream_

[Product Label]

• "Stimulates the synthesis of melanocytes...activate melanin production ...restores skin pigment ... Treatment for Vitiligo ...Fungal Infection and Inflammation ..."
• "A natural choice for Vitiligo...Stimulates the synthesis of melanocytes..."
• "A medical prescription line to treat the common dermatological conditions, such as Acne, Rosacea, Dry skin, Vitiligo and Fungal Infections, etc... Vitivera contains apple pectin which helps to utilize the UV rays to initiate the melanin to be active and come back to the normal function ..."

[Website]

• "Treatment for Vitiligo"
• "Stimulates the synthesis of melanocytes"
• "Restores skin pigment. . ."
• "Enhances the immune system ..."

_Retinol 1%_

[Product Label]

• "Acne Treatment"
• "A medical prescription line to treat the common dermatological conditions, such as Acne, Rosacea, Dry skin, Vitiligo and Fungal Infections, etc. . ."

[Website]

• "AcneTreatment"
• "Strengthens the protective skin tissue"

_Superheal™ O-Live Immune System Revitalizer_

[Product Label]

• "[P]rotects day-to-day freedom from sickness...Stimulates phagocytosis, an immune system response in which cells ingest harmful microorganisms and foreign matter*** Helps in the treatment for conditions caused by, or associated with a virus, retrovirus, bacterium, or protozoan. Among such conditions are...digestive problems, the common cold and influenza***Helps control meningitis, Epstein-Barr virus, encephalitis, herpes I & II, shingles, HIV, chronic fatigue, hepatitis B, pneumonia, tuberculosis, malaria, severe diarrhea, blood poisoning, dental, ear, urinary tract and surgical infections****"

• Stimulates phagocytosis, an immune system response in which cells ingest harmful microorganisms and foreign matter *** Helps in the treatment for conditions caused by, or associated with a virus, retrovirus, bacterium, or protozoan. Among such conditions are...digestive problems, the common cold and influenza***Helps control meningitis, Epstein-Barr virus, encephalitis, herpes I & II, shingles, HIV, chronic fatigue, hepatitis B, pneumonia, tuberculosis, malaria, severe diarrhea, blood poisoning, dental, ear, urinary tract, surgical infections***.
Website

- "Stimulates phagocytosis, an immune system response in which cells ingest harmful microorganisms and foreign matter"
- "Helps in the treatment for conditions caused by, or associated with a virus, retrovirus, bacterium, or protozoan. Among such conditions ... digestive problems, the common cold and influenza"
- "Helps control meningitis, Epstein-Barr virus, encephalitis, herpes I & II, shingles, HIV, chronic fatigue, hepatitis B, pneumonia, tuberculosis, malaria, severe diarrhea, blood poisoning, dental, ear, urinary tract, surgical infections"

**Superheal™ O-Live 2 Arthritis Formula**

**ProductLabel**

- "Arthritis Formula...Provides anti-inflammatory properties, reduces joint swelling...Relieves joint pain including rheumatoid arthritis and toothaches..."
- "ARTHRITIS FORMULA ...Provides anti-inflammatory properties, reduces joint swelling...Relieves joint pain including rheumatoid arthritis and toothaches..."
- "ARTHRITIS FORMULA...This arthritis formula contains natural ingredients to help alleviate arthritis symptoms and joint pain..."

Website

- "Provides anti-inflammatory properties, reduce joint swelling"
- "Reinforces joint pain including rheumatoid arthritis and toothaches"

**PHYTO-C Sunscreen SPF 15**

**ProductLabel**

"Sunscreen SPF 15" "Provides hours of highly-effective, broad spectrum UVA/UVB protection."

Website

"Treatment with broad spectrum sun filters technically provides daily protection against damage from UVA/ UVB rays, which are proven to cause signs of premature aging."

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the Act [21 U.S.C. 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. 331(d), 355(a)]. FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

**Application of the OTC Drug Review to PHYTO-C Sunscreen SPF 15**

We note that based on the labeling described above, the PHYTO-C Sunscreen SPF 15 product is intended to help prevent sunburn and other damage caused by the sun. Pending the finalization of the Sunscreen Drug Products for Over-the-Counter Human Use [Stayed Indefinitely] monograph, 21 CFR 352, the Agency does not intend to object to the marketing of sunscreen products without approved applications, so long as the failure to pursue regulatory action

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm525938.htm
does not pose a potential health hazard to the consumer, if they contain only the active ingredients or combinations of active ingredients listed at stayed 21 CFR 352.10 and 352.20; do not make claims addressed at 21 CFR 201.327(c)(3), 201.327(g), and 310.545(a)(29)(ii); comply with the general requirements for OTC drugs at 21 CFR Part 201 and 330.1, the requirements for adverse event reporting for OTC drugs, and provisions of the Act addressing adulteration; and follow the labeling and testing requirements in 21 CFR 201.327.1 As discussed below, your product Sunscreen SPF 15 does not comply with these standards.

First, the claims "waterproof, sweat proof" are found on the backside of the label and on the product website (www.phyto-c.com). As stated in 21 CFR 201.327(g), the claims sweatproof and waterproof are false and/or misleading on sunscreen products. These terms are false and/or misleading when applied to sunscreen products because they are exaggerations of performance that FDA thinks cannot be substantiated (76 FR 35620 at 35643, June 17, 2011).

Second, your PHYTO-C Sunscreen SPF 15 does not contain Drug Facts labeling as required under 21 CFR 201.66.

Third, PHYTO-C Sunscreen SPF 15 does not correctly display the required labeling per 21 CFR 201.327(a)(1)(i)(B). As provided by 21 CFR 201.327(a)(1)(i)(B), the Broad Spectrum SPF statement must appear on the principal display panel (PDP) as "Broad Spectrum SPF [insert numerical SPF value resulting from testing under paragraph (i) of this section]" and this statement must appear as continuous text with the same font style, size, and color. On the PDP for PHYTO-C Sunscreen SPF 15, the SPF value appears separately and in a different font size from the Broad Spectrum statement that appears at the bottom of the label.

Fourth, PHYTO-C Sunscreen SPF 15 is not labeled as required under 21 CFR 201.327(f), because the labeling fails to state "under the heading 'Other Information:' [bullet] protect the product in this container from excessive heat and direct sun."

Fifth, your PHYTO-C Sunscreen SPF 15 product's labeling fails to declare the active and inactive ingredients as required by 21 CFR 201.66(c)(2) and (c)(8) respectively.

Sixth, your PHYTO-C Sunscreen SPF 15 product's labeling fails to bear the warnings required by 21 CFR 201.327(d) (I)(i) and (iii) and by 21 CFR 330.1(g).

**Misbranded Drugs**

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your Superheal™ O-Live System Revitalizer product is intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your product safely for its intended purposes. Accordingly, your Superheal™ O-Live System Revitalizer product fails to bear adequate directions for its intended uses and, therefore, the product is misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of this misbranded drug violates section 301(a) of the Act [21 U.S.C. 331(a)].

Your PHYTO-C Sunscreen SPF 15 product, which, as described above, is a drug intended to help prevent sunburn and other skin damage caused by the sun, is misbranded with the meaning of section 502(a) of the FD&C
Act [21 U.S.C. § 352(a)] because its labeling is false and misleading. Specifically, the claims "waterproof" and "sweat proof" are found on the backside of the label and on the product website (www.phytoc.com). As stated in 21 CFR 201.327(g), the claims sweatproof and waterproof are false and/or misleading on sunscreen products, and will cause the product to be misbranded under section 502 of the FD&C Act. These terms are false and/or misleading when applied to sunscreen products because they are exaggerations of performance that FDA thinks cannot be substantiated (76 FR 35620 at 35643, June 17, 2011).

Your PHYTO-C Sunscreen SPF 15 product is misbranded within the meaning of section 502(c) of the FD&C Act [21 U.S.C. § 352(c)] for several reasons. "PHYTO-C Sunscreen SPF 15" does not have a Drug Facts panel as required under 21 CFR 201.66. Additionally, PHYTO-C Sunscreen SPF 15 does not correctly display the required labeling per 21 CFR 201.327(a)(i)(i)(B). Pursuant to 201.327(a)(i)(i)(B), the Broad Spectrum statement must appear on the principal display panel (PDP) as "Broad Spectrum SPF [insert numerical SPF value resulting from testing]" and the prominence of this statement must appear as continuous text with the same font style, size, and color. On the PDP for "PHYTO-C Sunscreen SPF 15," the SPF value appears separately and in a different font size from the Broad Spectrum statement that appears at the bottom of the label. Finally, "PHYTO-C Sunscreen SPF 15" is not labeled as required under 21 CFR 201.327(f), because the label fails to state under the heading "Other Information: [bullet] protect the product in this container from excessive heat and direct sun."

Your PHYTO-C Sunscreen SPF 15 product is misbranded within the meaning of section 502(e)(1)(A)(ii) and (iii) of the FD&C Act [21 U.S.C § 352(e)(1)(A)(ii) and (iii)] because it fails to declare and distinguish between the active and inactive ingredients as required by 21 CFR 201.66(c)(2) and (c)(8) respectively.

Your PHYTO-C Sunscreen SPF 15 product is further misbranded within the meaning of section 502(f)(2) of the FD&C Act [21 U.S.C. § 352(f)(2)], because the product label fails to bear the warnings as required by 21 CFR 201.327(d)(i) and (iii) and 21 CFR 330.1(g).

**Adulterated Cosmetics**

Even if your Phyto-C Signature Cream, Phyto-C Signature Serum, Phyto-C Signature Eye, SUPERHEAL O LIVE Serum, SUPERHEAL O-LIVE Lotion, Supreme Serum, Selenium in C Serum, Icy Blue, PhytoGel, PHYTO-C Sunscreen 15 SPF,2 Vitivera Cream, and Retinol 1% products did not have claims which make them unapproved new drugs, the products, and any other cosmetic products you manufacture, are adulterated cosmetics within the meaning of section 601(c) of the Act [21 U.S.C. § 361(c)]. The conditions and practices observed and documented during the inspection cause your cosmetic products to be adulterated within the meaning of section 601(c) of the Act in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth, or whereby they may have been rendered injurious to health. It is a violation of section 301(a) of the Act [21 U.S.C. §331(a)] to introduce or deliver for introduction into interstate commerce an adulterated cosmetic. For example, the following observations were made:

1. FDA’s inspection revealed you did not protect ingredients from contamination with foreign materials as observed in the (b)(4) storage area:
   - The (b)(4) used to manufacture Phyto-C products were stored uncovered with their open end facing the ceiling.

2. You did not protect ingredients from contamination with foreign material that was observed in the weighing room:
   - The metal scoops used to weigh raw materials were stored uncovered.
   - Raw materials used to manufacture Phyto-C products including, but not limited to: a) L Glutamine, Product-Velvet gel; b) Caffeine, Product- Velvet gel; and c) Salicylic Acid- Products: Active Serum, Bionic Serum, were