U.S. FOOD & DRUG ADMINISTRATION

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER PROTECTION
WASHINGTON, D.C. 20580

WARNING LETTER

Date: May 19, 2021

TO: adl@biocence.com biocence.com@domainprivacygroup.com – BGP, LLC
2118 Wilshire Blvd
#766
Santa Monica, CA 90403

RE: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19)

This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address www.biocence.com on February 9, 2021 and May 11, 2021. We have also reviewed your social media websites at www.facebook.com/Biocence and www.instagram.com/biocence, where you direct consumers to your website, www.biocence.com, to purchase your products. The FDA has observed that your website offers "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug"[1] for sale in the United States and that this product is intended to mitigate, prevent, treat, diagnose, or cure COVID-19[2] and other conditions in people. The FDA also reviewed the ""BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" product label and accompanying pamphlet. Based on our review, this product is an unapproved new drug introduced or delivered for introduction into interstate commerce in violation of section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, this product is a misbranded drug under sections 502(a) and (ee) of the FD&C Act, 21 U.S.C. § 352(a) and (ee). Introduction or delivery for introduction of such a product into interstate commerce is prohibited under sections 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

There is currently a global outbreak of respiratory disease caused by a novel coronavirus that has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2). The disease caused by the virus has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[3] In addition, on March 13, 2020, there was a Presidential declaration of a national emergency in response to COVID-19.[4] Therefore, FDA is taking urgent measures

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[1] "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" is sold in a variety of sizes and package configurations (i.e., 100mL with Sprayer Option; 100ml case of 12; 50ml with Sprayer Option; 50ml case of 16; 10ml with Sprayer Option; 100mL and 50mL with Spray Options and Mask; and 100mL and 50mL with Sprayer Options).

[2] As explained in the next paragraph, there is currently an outbreak of a respiratory disease named "Coronavirus Disease 2019" (COVID-19).

[3] Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

[4] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19)

to protect consumers from certain products that, without approval or authorization by FDA, claim to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. As described below, you sell a product that is intended to mitigate, prevent, treat, diagnose, or cure COVID-19 and other conditions in people. We request that you take immediate action to cease the sale of any unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19 and other conditions.

Examples of claims observed on the "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" product label and labeling that provide evidence of the intended uses (as defined in 21 CFR 201.128) of your product, and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 and other conditions include but may not be limited to, the following:

- "Effective against COVID-19!" [from the "Bio" section of your Instagram account at www.instagram.com/biocence]
- "ALL BOTANICAL FDA approved OTC product…#fightcovid19" [from a March 31, 2020 post on your Social Media webpage www.instagram.com/biocence]
- "Biocence . . . causes a 99.97% reduction of the COVID-19 Virus" [from a July 14, 2020 post on your Social Media webpage www.instagram.com/biocence]
- "Biocence proven effective against Covid-19" [from a July 23, 2020 post on your Social Media webpage www.instagram.com/biocence]
- "A first hand account of how Biocence works to combat Covid-19!" [from a July 27, 2020 post on your Social Media webpage www.instagram.com/biocence]
- "Nurses and doctors and (sic) now using Biocence to stay protected at Covid-19 pre-screenings! Biocence is the best defence(sic)!" [from an August 22, 2020 post on your Social Media webpage www.instagram.com/biocence]
- "Biocence has been proven effective in killing Covid-19!" [from a September 11, 2020 post on your Social Media webpage www.instagram.com/biocence]
- "Proven effective against Covid-19 achieved a 99.97% reduction rate. The highest rating!" [from a November 24, 2020 post on your Social Media webpage www.instagram.com/biocence]
- "Used for both prevention & treatment" [from a December 22, 2020 post on your Social Media webpage www.instagram.com/biocence]
- "Biocence- a preventative and a treatment that really works!" [from a February 5, 2021 post on your Social Media webpage www.instagram.com/biocence]
- "Biocence W.S. Liquid Botanical Human OTC Drug (FDA NDC# 59998), ready to use, demonstrated a >99.97% the highest reduction in viral titer following a 30 second exposure time to SARS-Related Coronavirus 2 (which causes the disease named COVID-19) as compared to the titer of the corresponding virus control." [from your webpage www.biocence.com/biocencestore]
- "Biocence . . . has recently demonstrated . . . 99.97% reduction of the COVID-19 virus" [from a July 9, 2020 post on your Social Media webpage www.facebook.com/Biocence]
- "Biocence has shown . . . its 30 second or less 'kill times' on…current strain of COVID" [from a July 15, 2020 post on your Social Media webpage www.facebook.com/Biocence]
- "BIOCENCE is an advanced wound, anti-viral, anti-bacterial and anti-inflammatory…over the counter drug used in both prevention & treatment." [from an August 1, 2020 post on your Social Media webpage www.facebook.com/Biocence]
- "Stop the spread with the solution that has been proven to kill COVID-19 in 30 seconds or less. Safe for all ages, Biocence is the only FDA registered, Botanical OTC" [from an August 22, 2020 post on your Social Media webpage www.facebook.com/Biocence]

Outbreak (Mar. 13, 2020), *available at* https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

- "Biocence ERADICATES: Pathogen Causing Bacteria 99.99% Pathogen Causing Virus 99.97% Pathogen Causing Fungi 99.99% Pathogen Causing Mold 99.99%" [from a November 9, 2020 post on your Social Media webpage www.facebook.com/Biocence]
- "All the components of the Biocence Botanical Complex have been given a GRAS/E status (Generally Recognized as Safe and Effective) and to date, All Microbes, ie(sic): Gm. Pos/Neg Bacteria (aerobic/anaerobic; cocci/bacilli, vegetative forms and sporiforms); strains of MRSA, VRE, MDRAB; Viruses (including H1N1, Ebola, HIV, HSV, HPV, Pox, enveloped and non- enveloped (sic), RNA/DNA, single and double stranded); Fungi(dermatophytoses, yeasts and molds) have been killed in 30 seconds or less, with the large majority, 'Exploding on Contact.'" (from the brochure that accompanies your product).
- "Biocence can be used as a topical preventative and prophylactic antiseptic; a treatment application for superficial soft-tissue wounds and an inanimate surface wipe-down product; whereas EPA-controlled disinfectants cannot be used, legally, on animate or skin surfaces, human or animal." (from the brochure that accompanies your product).
- "Safely Eradicates 99.9% of Multi-Resistant Organism (MDRO's) that cause majority of HAI's and CAI's in 30 seconds or less.'*' '*In Clinical Studies*'" (from product label)
- "ADVANCE WOUND CARE TECHNOLOGY FOR WOUNDS AND OSTOMY SITES . . . Designed To Give Protection through Prevention with Treatment . . . Apply and Let Dry" (from product label)

Based on the above claims, "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" is a drug as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. § 321(g)(1)(B), because it is intended for the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. § 321(g)(1)(C), because it is intended to affect the structure or any function of the body. Specifically, "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" is intended for use as both a consumer and a health care personnel topical antiseptic.

This topical antiseptic product is a "new drug" within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. § 321(p), because it is not generally recognized as safe and effective (GRASE) for use under the conditions prescribed, recommended, or suggested in its labeling. New drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act, 21 U.S.C. § 355(a), unless they are lawfully marketed under section 505G of the FD&C Act (which is not the case for this product, as further described below) or under other exceptions not applicable here. No FDA-approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. § 355, is in effect for this product, nor are we aware of any adequate and well-controlled clinical studies in the published literature that support a determination that "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" drug product is GRASE for use under the conditions suggested, recommended, or prescribed in its labeling. Accordingly, this product is an unapproved new drug marketed in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C. §§ 355(a) and 331(d).

We note that over-the-counter (OTC) topical antiseptic products had been the subject of rulemaking under the Agency's OTC Drug Review. In particular, such products were addressed in a tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59 FR 31402 (June 17, 1994) (1994 TFM), as further amended by "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016)(Consumer Antiseptic Rubs Proposed Rule) and "Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 80 FR 25166 (May 1, 2015)(Health Care Antiseptic Proposed Rule).Over the course of these rulemakings, three active ingredients (benzalkonium chloride, ethyl alcohol (ethanol), and isopropyl alcohol) were classified as Category III for use in consumer and health care personnel antiseptic rub products, meaning that additional safety and effectiveness data are needed to support a determination that a drug product

containing one of these active ingredients would be GRASE for use as a consumer antiseptic rub.

Section 505G of the FD&C Act addresses nonprescription drugs marketed without an approved application. Under section 505G(a)(3) of the FD&C Act, drugs that were classified as Category III for safety or effectiveness in a TFM that is the most recently applicable proposal or determination for such drug issued under 21 CFR Part 330 – and that were not classified as Category II for safety or effectiveness – are not required to have an approved application under section 505 in order to be marketed, as long as they are in conformity with the relevant conditions of use outlined in the applicable TFM, including the active ingredient, and comply with all other applicable requirements.

"BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" does not conform to the 1994 TFM, as further amended by the 2016 Consumer Antiseptic Rubs Proposed Rule and the 2015 Health Care Antiseptic Proposed Rule, nor any other TFM, proposed rule, or final rule, and does not meet the conditions under section 505G(a)(3) of the FD&C Act for marketing without an approved application under section 505.

First, the active ingredient of your product, "Biocence Botanical Complex," was not a proposed active ingredient in the rulemaking for topical antiseptic drug products for either consumer antiseptic rub products or health care personnel antiseptic rub products. As defined in 21 CFR 201.66(b)(2), an active ingredient is "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans." Although you do not list "Biocence Botanical Complex" as an active ingredient on your product's label, the statements in your product brochure pertaining to "Biocence Botanical Complex," as set forth above, demonstrate that it is intended to furnish pharmacological activity. Because "Biocence Botanical Complex" was not a proposed active ingredient in the rulemaking for topical antiseptic drug products your product is not in conformity with the relevant conditions of use outlined in the 1994 TFM and its subsequent amendments.

Second, the labeling for your product does not conform to the relevant labeling conditions in the 1994 TFM and its subsequent amendments. Specifically, the label and labeling of "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" indicate that it is effective in killing bacteria and viruses such as COVID-19, MRSA, H1N1, Ebola, and HIV and that it can be used for wound care/healing. These labeled intended uses go beyond merely describing the general intended use of a topical antiseptic as set forth in the 1994 TFM as amended by the 2016 Consumer Antiseptic Rubs Proposed Rule and the 2015 Health Care Antiseptic Proposed Rule.

We are unaware of any adequate and well-controlled clinical studies in the published literature that support a determination that "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" is GRASE for the above-described intended uses. Accordingly, your hand sanitizer is a new drug under section 201(p) of the FD&C Act. In addition, there are no FDA-approved applications in effect for the "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" and it is therefore an unapproved new drug sold in violation of sections 505(a) and 301(d) of the FD&C Act, 21 U.S.C §§ 355(a) and 331(d). We note that it also does not conform to any temporary policy FDA has implemented for alcohol-based hand sanitizer products during the public health emergency.[5]

In addition, your webpage and your Instagram social media webpage misleadingly imply that FDA has endorsed or approved your product in some manner. For example, you use such claims as "FDA APPROVED REGISTRY NDC: #59998 MADE IN THE USA" and "ALL BOTANICAL FDA approved OTC

[5] See, e.g., *Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)*. Because "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" is not consistent with the formulations described in these guidances, it does not fall within any temporary Agency policy not to take action against firms manufacturing hand sanitizer products for violations of section 505 of the FD&C Act.

product . . .#fightcovid19." As noted above, your product does not have any FDA approved application on file. Further to state that any drug product is "FDA APPROVED REGISTRY" is inaccurate; drugs are subject to listing with FDA, not registration. Moreover, registration of an establishment or listing of a drug does not denote approval of the establishment, the drug, or any other drugs of the establishment, nor does it mean that a product may be legally marketed, 21 CFR 207.77(a). This language is misleading given that the general public is not likely to be familiar with the details of FDA regulation. Thus, "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" is misbranded under section 502(a) of the FD&C Act, 21 U.S.C. § 352(a), because its labeling is false or misleading in any particular.

Lastly, this product is misbranded under section 502(ee) of the FD&C Act, 21 U.S.C. § 352(ee), because "BIOCENCE WS Multi-use Selective Antibacterial / Antiviral Human OTC Drug" is subject to section 505G of the FD&C Act, 21 U.S.C. § 355h, but does not comply with the requirements for marketing under that section and is not the subject of an application approved under section 505 of the FD&C Act, 21 U.S.C. § 355.

The introduction or delivery for introduction of a misbranded drug into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. § 331(a).

You should take immediate action to address the violations cited in this letter. This letter is not meant to be an all-inclusive list of violations that exist in connection with your products or operations. It is your responsibility to ensure that the products you sell are in compliance with the FD&C Act and FDA's implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as safe and effective for a COVID-19 or other disease related use for which they have not been approved by FDA, and that you do not make claims that misbrand your products in violation of the FD&C Act. **Within 48 hours, please send an email to COVID-19-Task-Force-CDER@fda.hhs.gov** describing the specific steps you have taken to address these violations. Include an explanation of each step being taken to prevent the recurrence of any violations, as well as copies of related documentation. Failure to adequately correct any violations may result in legal action, including, without limitation, seizure and injunction.

FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Your firm will be added to a published list on FDA's website of firms and websites that have received warning letters from FDA concerning the sale or distribution of COVID-19 related products in violation of the FD&C Act. This list can be found at http://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products. Once you have taken corrective actions to cease the sale of your unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19, and any appropriate corrective actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken such corrective actions.

This letter notifies you of our concerns and provides you with an opportunity to address them. If you cannot take action to address this matter completely within 48 hours, state the reason for the delay and the time within which you will do so. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

If you are not located in the United States, please note that products that appear to be misbranded or unapproved new drugs are subject to detention and refusal of admission if they are offered for importation into the United States. We may advise the appropriate regulatory officials in the country from which you operate that FDA considers your product(s) referenced above to be unapproved and misbranded products that cannot be legally sold to consumers in the United States.

Please direct any inquiries to FDA at COVID-19-Task-Force-CDER@fda.hhs.gov.

Lastly, it is unlawful under the FTC Act, 15 U.S.C. 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to $43,792 per violation and may be required to pay refunds to consumers or provide other relief pursuant to Section 19(b) of the FTC Act, 15 U.S.C. § 57b(b). Within 48 hours, please send an email to Richard Cleland, Assistant Director of the FTC's Division of Advertising Practices, via electronic mail at rcleland@ftc.gov describing the specific actions you have taken to address the FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Cleland at 202-326-3088.

Sincerely,

Donald D. Ashley -S

Digitally signed by Donald D. Ashley -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2002198907, cn=Donald D. Ashley -S
Date: 2021.05.19 09:52:13 -04'00'

Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

SERENA VISWANATHAN

Digitally signed by SERENA VISWANATHAN
Date: 2021.05.18 17:37:15 -04'00'

Serena Viswanathan
Associate Director
Division of Advertising Practices
Federal Trade Commission

cc: biocence.com@domainprivacygroup.com