WARNING LETTER

The Jim Bakker Show

MARCS-CMS 604820 — MARCH 06, 2020

Product:

Drugs

Recipient:

The Jim Bakker Show

180 Grace Chapel Rd.
Blue Eye, MO 65611
United States

partner.services@jimbakkershow.com (mailto:partner.services@jimbakkershow.com)

website@jimbakkershow.com (mailto:website@jimbakkershow.com)

Issuing Office:

Center for Food Safety and Applied Nutrition (CFSAN)

United States

Federal Trade Commission (Federal Trade Commission)

WARNING LETTER

Date: March 6, 2020

TO: partner.services@jimbakkershow.com, website@jimbakkershow.com – James Bakker, The Jim Bakker Show
180 Grace Chapel Rd.
Blue Eye, MO 65611

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.jimbakkershow.com on February 21, 2020 and February 13, 2020, respectively. We have also reviewed your social media page at https://www.facebook.com/jimbakkershow/, where you provide a link to your website www.store.jimbakkershow.com to purchase your products. The FDA has determined that your website offers products labeled to contain silver, such as "Silver Sol Liquid," for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] in people. FDA has determined that these products are unapproved new drugs sold in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 355(a). Furthermore, these products are misbranded drugs under section 502 of the FD&C Act, 21 U.S.C. § 352. The introduction or delivery for introduction of these products into interstate commerce is prohibited under section 301(a) and (d) of the FD&C Act, 21 U.S.C. § 331(a) and (d).

The Secretary of Health and Human Services, under section 319 of the Public Health Service Act, 42 U.S.C. § 247d, has determined that a public health emergency exists nationwide as a result of confirmed cases of COVID-19. Therefore, FDA is taking urgent measures 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. We request that you take prompt action to cease the sale of such unapproved and unauthorized products for mitigation, prevention, treatment, diagnosis, or cure of COVID-19.

Some examples of the claims on your website that establish the intended use of your products and misleadingly represent them as safe and/or effective for the treatment or prevention of COVID-19 include:

• "But this influenza [sic] that is now circling the globe, you're saying that Silver Solution would be effective? Well let's say it hasn't been tested on this strain of the coronavirus, but it's been tested on other strains of the coronavirus, and has been able to eliminate it within 12 hours, totally eliminate it, kills it, deactivates it" [from your video entitled "A Close Look At What's Not Being Said About the Coronavirus (Day 1)" at [44:48], https://jimbakkershow.com/watch/?guid=3861]

• “Silver Solution has been proven … to kill every pathogen it has ever been tested on … and it can kill any of these known viruses …”

• “So the virus, like the coronavirus that we’re talking about … affects the lung tissue so what you can do … put it straight … in a nebulizer which then creates a steam and you breathe it in and it will go directly into your lungs where that virus is and any other infection”

“You should take immediate action to correct the violations cited in this letter. The violations cited in this letter are not meant to be an all-inclusive list. 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 representing your products for a COVID-19 related use for which they have not been approved by FDA, and that you do not make claims that misbrand the products in violation of the FD&C Act. **Within 48 hours, please send an email to** COVID-19-Task-Force-CFSAN@fda.hhs.gov (COVID-19-Task-Force-CFSAN@fda.hhs.gov) describing the specific steps you have taken to correct these violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. Failure to immediately correct the violations cited in this letter 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 www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products (www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-covid-19-products). Once you have taken corrective actions and such actions have been confirmed by the FDA, the published list will be updated to indicate that your firm has taken appropriate corrective action.

If you cannot complete corrective action within 48 hours, state the reason for the delay and the time within which you will complete the corrections. 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) listed 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-CFSAN@fda.hhs.gov (COVID-19-Task-Force-CFSAN@fda.hhs.gov).

In addition, 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. To make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act.

There currently are no vaccines, pills, potions, lotions, lozenges or other prescription or over-the-counter products available to treat or cure coronavirus disease 2019 (COVID-19). Thus, the claims cited above are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. In addition, you are advised to review all claims for your products and immediately cease making claims that are not supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. 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,
/S/

William A. Correll
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

Sincerely,
/S/

Richard A. Quaresima
Acting Associate Director Division of Advertising Practices
Federal Trade Commission

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1 COVID-19 is the official name for the disease that is causing the 2019 novel coronavirus outbreak, first identified in Wuhan, China.

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