



FDA U.S. FOOD & DRUG
ADMINISTRATION



WARNING LETTER

Date: April 8, 2020

TO: Genesis II Church of Health and Healing, Mark Grenon, Joseph Grenon,
Jordan Grenon, and Jim Humble

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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 websites at the Internet addresses <https://genesis2church.is> (which auto redirects to <https://genesis2church.ch>), <https://g2churchnews.org>, <https://g2voice.is>, and <https://jimhumble.co>, between March 27 and 31, 2020.¹ Your website <https://genesis2church.ch> includes a link to <http://jimhumble.is> (which auto redirects to <https://jimhumble.co>), which it describes as “Jim’s Blog.” On the website <https://jimhumble.co>, it states that “the protocols described on this site are official sacraments of the Genesis II Church of Health and Healing.”

FDA has observed that the website <https://newg2sacraments.org> offers Miracle Mineral Solution (MMS) (chlorine dioxide)² for sale in the United States and that this product is intended to cure, mitigate, treat, prevent, or diagnose Coronavirus and/or COVID-19 in people. Your website <https://jimhumble.co> directs consumers to <https://genesis2church.ch>, which in turn directs consumers to <https://G2Sacraments.org>, which auto redirects to <https://newg2sacraments.org>, where MMS may be purchased. Additionally, your websites <https://g2churchnews.org> and <https://g2voice.is> direct consumers to <https://G2Sacraments.org>, which auto redirects to <https://newg2sacraments.org>, where MMS may be purchased.

Based on our review, MMS is an unapproved new drug sold 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 section 502(f)(1) of the FD&C Act, 21 U.S.C. § 352(f)(1). The introduction or delivery for introduction of this 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). It is also a prohibited act under section 301(k) of the FD&C Act, 21 U.S.C. § 331(k), to misbrand a product

¹ These websites state that Jordan and Joseph Grenon are “Bishops,” Mark Grenon is an “Archbishop” and founder of Genesis II Church of Health and Healing (Genesis), and Jim Humble is an “Archbishop” and founder of Genesis.

² You also refer to your MMS product as: “Chlorine Dioxide”; “G2Sacrament”; “Miracle Mineral Solution”; “Sacramental Cleansing Water”; “G2 Sacramental”; “MMS1”; and “MMS Sodium Chlorite.”

while it is held for sale after shipment of a component or finished product in interstate commerce.

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, the President declared a national emergency in response to COVID-19.⁴ Therefore, FDA is taking urgent measures to protect consumers from certain products that, without approval or authorization by FDA, claim to diagnose, cure, mitigate, treat, or prevent COVID-19 in people. As described below, you sell products that are intended to cure, mitigate, treat, or prevent COVID-19 in people. We request that you take immediate action to cease the sale of such unapproved and unauthorized products for the cure, mitigation, treatment, or prevention of COVID-19. Further, FDA has previously warned consumers about the dangerous and potentially life threatening side effects of MMS, see <https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-about-dangerous-and-potentially-life-threatening-side-effects-miracle-mineral>.

Some examples of the claims on your websites that establish the intended use of your product and misleadingly represent it as safe and/or effective to cure, mitigate, treat, or prevent COVID-19 include:

On your page titled, “Coronavirus Update (COVID-19),” from your website <https://jimhumble.co/blog/coronavirus-update-covid-19>:

- “14 people who were confirmed cases of COVID-19 (in Europe), took MMS and have recovered their health. All of these tested positive and when re-tested after taking MMS, they came out negative for COVID-19.”
- “Those of us who have used chlorine dioxide (MMS) over the years certainly expected it to also work with this virus, but we wanted to be sure and now with this data we are confident that the proper mixture of chlorine dioxide (MMS) has every hope of eradicating COVID-19.”
- “If you have COVID-19: --Take Protocol 6 and 6 to start. This is one 6-drop dose of MMS, then one hour later take another 6-drop dose of MMS. --After two 6-drop doses of MMS, go on hourly doses of 3 activated drops in 4 ounces of water hourly . . . --For children, follow the same instructions as above and cut the amounts in half.”
- “Here is the testimony of a man who was experiencing very serious symptoms of Coronavirus: The man is 85 years old and was confirmed to have coronavirus. He was quarantined at home, all of his relatives at home were also infected, but the elderly man

³ Secretary of Health and Human Services Alex M Azar II, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>).

⁴ President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>).

was in very serious condition and on oxygen—by far he was the most worst off. He was given a 1 liter bottle of water which had 20 activated drops of MMS added to it. He was instructed to take a sip from the bottle every five minutes, but not to let it go past 10 minutes. So every 5 to 10 minutes the man took a sip (not a big gulp, just a sip) from the bottle—that’s all, but he did this faithfully, every 5 to 10 minutes throughout the day until the bottle was finished, just a sip each time. After three days he was noticeably improved and off of the oxygen, so his dose was reduced to 12 activated drops in the 1 liter bottle of water and he drank from it, just sipping it, every half hour. He is recovering quickly—90% improved, has just a slight remnant of cough occasionally. The rest of the family who also took MMS are now fully recovered.”

On your page titled, “A Word on Coronavirus,” from your website <https://jimhumble.co/blog/a-word-on-coronavirus>:

- “Again, I have reason to believe, MMS (chlorine dioxide) can be very effective in both preventing and eradicating the coronavirus . . . let MMS be your first line of defense.”
- “Regarding the coronavirus, at this point in time if you have it, I would suggest trying MMS first as MMS has eradicated a wide range of maladies . . . I have to say there have been positive results at least 95% of the time.”

On your page titled, “G2Voice Broadcast #182 The Coronavirus is curable! Do you believe it? You better!” from your website <https://g2churchnews.org/577-gvoice-182>:

- “G2Church Sacramental Dosing for Coronavirus!
For Adults: 6 drops activated MMS in 4 ounces of water every two hours 5 times first day, Repeat 2nd day. If all symptoms are gone then continue with 3 drops and [sic] hour for 8 hours for another 3 days!
For Small Children: same a [sic] above but with only 3 drops. 1 drop instead of 3 drops for the 3 days after the first two days of strong dosing!
NOTE: This should wipe it out this flu-like virus that many are being scared with its presence in this world!”
“For Sacramental Guidance and products please contact us at:
support@genesis2church.is”

On your video titled, “G2Voice Broadcast #182 The Coronavirus is curable! Do you believe it? You better! (3-8-2020),” on your website <https://g2voice.is/broadcast/182>:

- At around minute 1:45, Mark Grenon says, “The Coronavirus is curable, do you believe it? You better . . .”
- At around minute 17:35, Mark Grenon says, “Every week I am putting in the G2Sacramental dosing for Coronavirus, why . . . we have a family on it, we have a couple of other people . . . 6 drops MMS activated 4oz of water every two hours four or five times the first day, it should, it might even kick it out the first day, but depends on how long you’ve had it, if it’s in your lungs, do it the second day again, then I’d go to three drops eight hours a day for three or four days, then just to keep going, kick it out of you. Small children, we can cut everything in half, three drops every two hours versus a couple days, three hours then a drop really, not three.”

- At around minute 49:57, Mark Grenon says “The Coronavirus is curable, you believe that? You better . . . it’s wicked good stuff Joe,” and Joseph Grenon replies, “MMS will kill it.”

You should take immediate action to correct 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 its 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-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-CDER@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 <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 cure, mitigation, treatment, or prevention of COVID-19, and such actions have been confirmed by 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 unapproved new drugs and misbranded 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.

In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 *et seq.*, to advertise that a product can 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 product identified above. Thus, any coronavirus-related treatment or cure claims regarding such product 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 and an order may require that you pay back money to consumers. Within 48 hours, please send an e-mail 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
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Sincerely,

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