UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO.: 1:20CV21601

UNITED STATES OF AMERICA,

Plaintiff,
vs.

GENESIS II CHURCH OF HEALTH
AND HEALING,
MARK GRENON,
JOSEPH GRENON,
JORDAN GRENON, and
JONATHAN GRENON,

Defendants.
_____/

**UNITED STATES OF AMERICA'S COMPLAINT FOR PRELIMINARY AND PERMANENT INJUNCTION**

Plaintiff, the United States of America, through its undersigned attorneys, and on behalf of the United States Food and Drug Administration ("FDA"), alleges that:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. § 332(a), to halt the sale of an unproven and unapproved treatment for coronavirus, which includes coronavirus disease 2019 ("COVID-19") and any other disease. Specifically, Plaintiff seeks a permanent injunction to restrain and enjoin Genesis II Church of Health and Healing, an entity based in the state of Florida, and Mark Grenon, Joseph Grenon, Jordan Grenon, and Jonathan Grenon, individuals, (collectively "Defendants") from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction into interstate commerce unapproved new drugs;

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(a) and (f)(1); and

C. Violating 21 U.S.C. § 331(k), by causing drugs to become misbranded within the meaning of 21 U.S.C. § 352(a) and (f)(1), while they are held for sale after shipment of one or more of their components in interstate commerce.

**JURISDICTION AND VENUE**

2. This Court has jurisdiction over the parties and this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391.

**DEFENDANTS**

4. Genesis II Church of Health and Healing ("Genesis") is a secular entity based in the State of Florida that sells and distributes a product called Miracle Mineral Solution, also referred to as "MMS." Genesis operates a website, https://newg2sacraments.org ("Sales Website"), which offers MMS for sale in the United States. Genesis describes itself on its website as "a non-religious church … focus[ing] on 'restoring health' to the world" that "was formed for the purpose of serving mankind and not for the purpose of worship." *Our Church*, GENESIS II CHURCH OF HEALTH & HEALING (OFFICIAL) – MMS, https://genesis2church.ch/our-church (last visited Apr. 12, 2020). Genesis operates another website, https://g2churchnews.org ("News Website"), that contains claims that MMS is intended to cure, mitigate, treat, or prevent coronavirus, which includes COVID-19, and links to testimonials claiming that MMS cures a litany of other diseases including, among others, Alzheimer's, autism, brain cancer, HIV/AIDS, and multiple sclerosis. The Sales Website is available through links from Defendants' websites genesis2church.ch and

g2voice.is, both of which contain or link to claims regarding MMS's use to cure diseases. Genesis is located at 2014 Garden Lane, Bradenton, Florida, and does business within the jurisdiction of this Court.

5. Mark Grenon holds the title of "Archbishop" at Genesis and is one of its founders. Mark Grenon is responsible for Genesis's operations including, but not limited to, labeling, holding, and/or distributing MMS. Mark Grenon performs his duties at 2014 Garden Lane, Bradenton, Florida.

6. Joseph Grenon holds the title of "Bishop" at Genesis, and he also represents himself to be a "Reverend." Joseph Grenon is responsible for Genesis's operations, including but not limited to, labeling, holding, and/or distributing MMS. Joseph Grenon performs his duties at 2014 Garden Lane, Bradenton, Florida.

7. Jordan Grenon holds the title of "Bishop" at Genesis. Jordan Grenon is responsible for Genesis's operations including, but not limited to, labeling, holding, and/or distributing MMS. Jordan Grenon performs his duties at 2014 Garden Lane, Bradenton, Florida.

8. Jonathan Grenon holds the title of "Bishop" at Genesis. Jonathan Grenon is responsible for Genesis's operations including, but not limited to, labeling, holding, and/or distributing MMS. Jonathan Grenon performs his duties at 2014 Garden Lane, Bradenton, Florida.

**DEFENDANTS UNLAWFULLY DISTRIBUTE UNAPPROVED NEW DRUGS**

9. It is a violation of the Act to introduce or deliver for introduction into interstate commerce a "new drug" that is neither approved by FDA nor exempt from approval. 21 U.S.C. §§ 331(d) and 355(a). Specifically, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is

exempt from approval pursuant to an effective investigational new drug application ("IND"). 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j).

**MMS is a Drug**

10. Under the FDCA, the definition of "drug" includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 21 U.S.C. §§ 321(g)(1)(B).

11. The intended use of a product may be determined from any relevant source, including labeling. *See* 21 C.F.R. § 201.128.

12. The Act defines "label" as, among other things, "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). The Act defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The labeling includes anything that explains the uses of the drug, such as marketing material, whether or not it is physically attached to the product itself. *See Kordel v. United States*, 335 U.S. 350 (1948).

13. MMS is a drug within the meaning of the Act because it is intended for use in the cure, mitigation, treatment, or prevention of disease in man. According to MMS's labeling, including but not limited to materials and links on Defendants' News Website and on Defendants', https://g2voice.is website ("Radio Website"), MMS is intended to cure, mitigate, treat, or prevent Coronavirus, which includes COVID-19, among other diseases.

14. Defendants' News Website contains claims that MMS cures, mitigates, or treats coronavirus. For example, the News Website states:

- "**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 of 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"

- "**The Coronavirus is curable!**"

*G2Voice Broadcast # 182: The Coronavirus Is Curable! Do You Believe It? You Better!*, G2CHURCHNEWS (Mar. 3, 2020), https://g2churchnews.org/577-gvoice-182.

15. In a video available on Defendants' Radio Website, Defendant Mark Grenon makes the following claims concerning the use of MMS to cure, mitigate, or treat coronavirus:

- "The Coronavirus is curable, do you believe it? You better . . . "
- "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."

*Id.*

16. In the video referenced in paragraph 15, Defendant Mark Grenon also says: "The Coronavirus is curable, you believe that? You better. . . it's wicked good stuff Joe." Defendant Joseph Grenon then replies: "MMS will kill it." *Id.*

17. COVID-19 is a disease caused by a novel coronavirus dubbed "severe adult respiratory syndrome coronavirus 2" (SARS-CoV-2), which was first detected in December, 2019.

Reported illnesses for confirmed COVID-19 cases have ranged from mild to severe, many resulting in death. The Centers for Disease Control and Prevention has stated that the COVID-19 pandemic "poses a serious public health risk." https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html (visited March 26, 2020).

18. Moreover, as the World Health Organization has explained, "there is no evidence that current medicine can prevent or cure the disease." World Health Organization, *Q&A on Coronaviruses (COVID-19)*, (Apr. 8, 2020), https//www.who.int/new-room/q-a-detail/q-a-coronaviruses; *see also* U.S. Centers for Disease Control and Prevention, *Therapeutic Options for COVID-19 Patients* (Apr. 13, 2020), https://www.cdc.gov/coronavirus/2019-ncov/hcp/therapeutic-options.html ("There are no drugs or other therapeutics approved by [FDA] to prevent or treat COVID-19. Current clinical management includes infection prevention and control measures and supportive care …").

19. On January 31, 2020, the Secretary of Health and Human Services declared a public health emergency, under 42 U.S.C. § 247d, for the entire United States in response to SARS-CoV-2.

20. On March 11, 2020, the World Health Organization announced that the COVID-19 outbreak was properly characterized as a worldwide pandemic.

21. On March 13, 2020, the President of the United States exercised his authority under the National Emergencies Act (50 U.S.C. § 1601 *et seq.*) and officially declared that the COVID-19 outbreak in the United States constituted a national emergency.

**Defendants' Product is a New Drug**

22. Under the Act, a "new drug" is "[a]ny drug . . . the composition of which is such that" (1) "such drug is not generally recognized, among experts qualified by scientific training and

experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . .” or (2) “such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.” 21 U.S.C. § 321(p)(1) and (2).

23. For a new drug to be “generally recognized as safe and effective” (“GRASE”) within the meaning of 21 U.S.C. § 321(p)(1), three conditions must be satisfied. First, there must be substantial evidence of its effectiveness. The Act defines “substantial evidence” as “evidence consisting of adequate and well-controlled investigations, including clinical investigations . . . on the basis of which it could fairly and responsibly be concluded by . . . [qualified] experts that the drug will have the effect it purports or is represented to have . . . ” 21 U.S.C. § 355(d). Second, the investigations must be published in the scientific literature so that they are made generally available to the community of qualified experts and thereby subject to peer evaluation, criticism, and review. *Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 652 (1973). Third, there must be a consensus among the experts, based on those published investigations, that the product is safe and effective under the conditions prescribed, recommended, or suggested in its labeling. *Id.*

24. FDA conducted comprehensive searches of the publicly-available medical and scientific literature for MMS, including searching the following aliases under which Defendants sell MMS: Sacramental Cleansing Water, Miracle Mineral Solution, MMS1, G2Church Sacramental, G2Church Sacrament, and as part of their “g2kit2,” and determined that there are no published, adequate and well-controlled studies demonstrating that Defendants’ MMS is safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. Because there are no published adequate and well-controlled studies for the intended uses of MMS

to cure, mitigate, treat, or prevent coronavirus, or any other disease, qualified experts cannot have come to a consensus of opinion concerning its effectiveness for such uses. Therefore, Defendants' MMS is not GRASE and is a new drug under 21 U.S.C. § 321(p)(1).

25. Defendants' MMS is also a "new drug" within the meaning of 21 U.S.C. § 321(p)(2). COVID-19 is an infectious disease caused by a newly discovered coronavirus, SARS-CoV-2. The "new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019." *See* https://www.who.int/news-room/q-a-detail/q-a-coronaviruses. Therefore, as a matter of law, Defendant's MMS cannot have been marketed for a material time or to a material extent and, accordingly, is a "new drug."

**Defendants' MMS is an Unapproved New Drug**

26. After searching its records for NDA, ANDA, and IND submissions by Defendants, FDA determined that there are no approved NDAs or ANDAs and no INDs in effect for MMS.

27. Therefore, MMS is an unapproved new drug within the meaning of 21 U.S.C. § 355(a).

**Defendants Distribute Unapproved New Drugs in Interstate Commerce**

28. "Interstate commerce," under 21 U.S.C. § 321(b)(1), means commerce between any State and any place outside of it. On or about March 27, 2020, Defendants shipped MMS from Florida to Virginia, which constitutes distribution in "interstate commerce" within the meaning of 21 U.S.C. § 321(b)(1).

29. Therefore, Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, unapproved new drugs.

## DEFENDANTS UNLAWFULLY DISTRIBUTE MISBRANDED DRUGS IN INTERSTATE COMMERCE

### Defendants' MMS Has False or Misleading Labeling (21 U.S.C. § 352(a))

30. Under the FDCA, a drug is deemed misbranded "[i]f its labeling is false or misleading in any particular." 21 U.S.C. § 352(a)(1).

31. Defendants' labeling for MMS, including its internet websites, contains numerous claims that are false and misleading, including that MMS can safely and effectively treat Coronavirus, which includes COVID-19, and a litany of other serious diseases.

32. The curative claims in Defendants' labeling lack expert scientific support; there are no published, adequate, and well-controlled studies that demonstrate that MMS is safe and effective at treating coronavirus or *any* disease, including the litany of diseases identified in the labeling.

33. As a result, the labeling for Defendants' MMS is false and misleading, and therefore, is a misbranded drug under 21 U.S.C. § 352(a).

### Defendants Distribute Drugs that Fail to Bear Adequate Directions for Use

34. Under the FDCA, a drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use" and it is not exempt from this requirement. FDA has defined "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5.

35. A prescription drug is "[a] drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A). By law, adequate directions for lay use cannot be written for prescription drugs.

36. Defendants' MMS is a prescription drug because it is intended for curing, mitigating, treating, or preventing coronavirus, which includes COVID-19, a disease that requires diagnosis and management by a physician. Consequently, there are no adequate directions under which a layman can safely use this drug, because it is not safe for use except under the supervision of a physician.

37. Because Defendants' drug labeling does not bear adequate directions for use, MMS is misbranded under 21 U.S.C. § 352(f)(1), unless it qualifies for an exemption.

38. FDA has promulgated regulations establishing exemptions from the adequate directions for use requirement in 21 U.S.C. § 352(f)(1), but each exemption requires the drug to bear the labeling approved by FDA in an NDA. 21 C.F.R. §§ 201.100, 201.115. Because MMS is not the subject of an approved NDA or ANDA, Defendants' MMS does not qualify for any exemption from the requirement that its labeling bear adequate directions for use. *See* 21 C.F.R. §§ 201.100(c)(2), 201.115.

**Defendants Distribute Their Misbranded Drugs in Interstate Commerce**

39. Defendants shipped MMS from Florida to Virginia, which constitutes a distribution in interstate commerce within the meaning of 21 U.S.C. § 321(b)(1).

40. Defendants violate 21 US.C. § 331(a) by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, drugs that are misbranded within the meaning of 21 U.S.C. § 352(a) and 352(f)(1).

41. Under 21 U.S.C. § 379a, "[i]n action to enforce the requirements of this Act respecting a . . . drug . . . the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist." Upon information and belief, Defendants receive MMS components or the finished MMS product from outside of Florida.

**DEFENDANTS CAUSE MISBRANDING OF DRUGS WHILE HELD FOR SALE**

42. By labeling MMS with claims that it cures, mitigates, treats, or prevents coronavirus, which includes COVID-19, and a litany of other serious diseases, Defendants cause MMS to become a misbranded drug within the meaning of 21 U.S.C. § 352(a) and 352(f)(1), while it is held for sale after shipment of one or more of its components in interstate commerce, in violation of 21 U.S.C. § 331(k).

**FDA WARNED DEFENDANTS THAT THEIR CONDUCT IS UNLAWFUL**

43. On April 8, 2020, FDA issued a Warning Letter (the "Warning Letter") to Defendants, warning them that they are violating the Act by distributing unapproved new drugs and misbranded drugs in interstate commerce. The Warning Letter requested that Defendants respond within 48 hours by e-mail and describe the specific steps they have taken to correct the violations described in the letter. FDA further warned Defendants that failure to immediately correct their violative conduct may result in legal action, including an injunction. The Warning Letter also stated: "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 [FDCA], include your reasoning and any supporting information for our consideration."

44. On April 9, 2020, the Warning Letter was posted to Defendants' News Website, along with Genesis's statement in reaction to it. Specifically, Defendants claimed that FDA did not have jurisdiction over their activities or products and that they would fight the Warning Letter and to continue to distribute MMS.

45. FDA also received a written response to the Warning Letter from Genesis on April 10, 2020. Genesis's response made clear that it had no intention of taking corrective action, stating:

"**We can say cure, heal and treat as a Free Church. Don't need you [sic] approval or authorization for a Church Sacrament."** (emphasis in original.) Genesis's letter to FDA, signed by Defendant Mark Grenon, further stated that: "**There will be NO corrective actions on our part … You have no authority over us! … Never going to happen."** (emphasis in original). ***See*** https://g2churchnews.org/584-fda-and-ftc-attack.

46. Unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Issue an injunction restraining and enjoining Genesis II Church of Health and Healing, Mark Grenon, Joseph Grenon, Jordan Grenon, Jonathan Grenon, and each and all of their directors, officers, agents, employees, representatives, attorneys, successors, and assigns, and all persons in active concert or participation with any of them ("Associated Persons"), pursuant to 21 U.S.C. § 332(a) and the inherent equity of the Court, from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction into interstate commerce new drugs, as defined in 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval;

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce drugs, as defined in 21 U.S.C. § 321(g), that are misbranded within the meaning of 21 U.S.C. § 352(a) and/or 352(f)(1); and

C. Violating 21 U.S.C. § 331(k), by causing drugs to become misbranded within the meaning of 21 U.S.C. § 352(a) and/or 352(f)(1) while they are held for sale after shipment of one or more of their components in interstate commerce.

II. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished;

III. Order that Defendants make restitution to all purchasers of Defendants' MMS products of the full amount paid by the purchaser, and that Defendants and Associated Persons immediately refrain from disposing of or transferring any assets that may interfere with implementation of such restitution payments;

IV. Order that Defendants and Associated Persons be immediately prohibited from destroying, discarding, altering, transferring, or otherwise making unavailable any documents, data, or records related to MMS, within the custody or control of Defendants and Associated Persons.

V. Order that Plaintiff be awarded costs and such other equitable relief as the Court deems just and proper.

Dated: April 16, 2020

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General
U.S. Department of Justice

GUSTAV W. EYLER
Director
Consumer Protection Branch

Ross S. Goldstein
Senior Litigation Counsel
D.C. Bar No. 480280
Ross.Goldstein@usdoj.gov

ARIANA FAJARDO ORSHAN
United States Attorney

Matthew J. Feeley
MATTHEW J. FEELEY
Florida Bar No. 12908
Assistant United States Attorney
99 N.E. 4th Street, Suite 300
Miami, FL 33132
(305_961-9235 (office)
(305) 530-7139 (facsimile)
Matthew.Feeley@usdoj.gov

(202) 353-4218 (office)
(202) 514-8742 (facsimile)

David A. Frank
DAVID A. FRANK
Court ID No. A5500486
Senior Litigation Counsel
U.S. Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, D.C. 20044
(202) 307-0061 (office)
(202) 514-8742 (facsimile)
David.Frank@usdoj.gov
Counsel for the United States of America

OF COUNSEL:

ROBERT P. CHARROW
General Counsel

STACY CLINE AMIN
Chief Counsel
Food and Drug Administration
Deputy General Counsel
U.S. Department of Health and Human Services

ANNAMARIE KEMPIC
Deputy Chief Counsel, Litigation

JOSHUA A. DAVENPORT
Associate Chief Counsel for Enforcement
U.S. Department of Health and Human Services
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002