UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
CASE NO. 20-21601-CIV-WILLIAMS

UNITED STATES OF AMERICA,

Plaintiff,

vs.

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

Defendants.
_____/

ORDER OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Injunction against Genesis II Church of Health and Healing ("Genesis"), Jordan Grenon, and Jonathan Grenon, individuals (collectively, "Defendants"), and this Court having considered such arguments and supporting evidence filed by Defendants, and it appearing that Defendants are violating the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. § 301 *et seq.*, and, unless restrained by order of this Court, will continue to violate the Act:

After considering the foregoing, it is therefore, **ORDERED AND ADJUDGED** that:

1. This Court has jurisdiction over this action under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

2. The Complaint states a cause of action against Defendants under the FDCA, 21 U.S.C. §§ 301 *et seq*.

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

4. Defendants violate the FDCA, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce and/or causing the introduction or delivery for introduction into interstate commerce drugs, as defined by 21 U.S.C. § 321(g), that are misbranded within the meaning of 21 U.S.C. § 352(a) and (f)(1).

5. Defendants violate the FDCA, 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 such drugs are held for sale after shipment of components or the finished product in interstate commerce.

6. For the purposes of this Order, the following definitions shall apply:

A. "The Facility" means 2014 Garden Lane, Bradenton, Florida 34205-5274.

B. "Current Websites" means the following websites: genesis2church.ch, newg2sacraments.org, g2churchnews.org, g2voice.is, mmstestimonials.co, and g2worldwidemissions.org, as well as any other website(s) and social media account(s) currently in existence that are registered to, owned by, controlled by, or under the direction of any Defendant.

C. "Future Websites" means any future website(s) or social media account(s) that are registered to, owned by, controlled by, or under the direction of any Defendant.

D. "MMS products" refers to Defendants' products called MMS, Sacramental Cleansing Water, Miracle Mineral Solution, MMS1, G2Church Sacramental, G2Church Sacrament, products sold as part of Defendants' "g2kit2," and any other of Defendants' products that, when used as directed, contain chloride dioxide.

7. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them who have received actual notice of this Order by personal service or otherwise are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly labeling, holding, and/or distributing any drug, including but not limited to MMS, unless and until:

A. For all of Defendants' drugs, Defendants have an approved new drug application ("NDA") or an abbreviated new drug application ("ANDA"), pursuant to 21 U.S.C. § 355(b), (j), or an investigational new drug application ("IND") in effect pursuant to 21 U.S.C. § 355(i), for such drugs;

B. Within eight (8) calendar days after the entry of this Order, Defendants shall submit to FDA for its review and approval a recall strategy for all of Defendants' MMS products, including components, raw and in-process materials, and finished products, that were distributed by Defendants from January 1, 2010, through and

including the date of entry of this Order. The recall strategy shall include, but not be limited to, customer notifications, public warning, methods for conducting effectiveness checks, and plans for the disposition of recalled products. Within five (5) calendar days after receiving FDA's approval of the recall strategy, Defendants shall initiate a recall of all MMS distributed product in accordance with such recall strategy. Within thirty (30) calendar days after initiating the recall, Defendants will complete the recall and shall destroy, under FDA's supervision (which may be done by e-mail or other virtual means as FDA determines to be appropriate) and in accordance with the procedures provided in Paragraph 8, all of their MMS products, including components, raw and in-process materials, and finished products that are held and/or were distributed by Defendants from January 1, 2010, through and including the date of entry of this Order. Defendants shall bear the costs of destruction and the costs of FDA's supervision;

C. If FDA determines it to be necessary, FDA representatives inspect the Facility to determine whether the requirements of this Order have been met and whether Defendants are operating in conformity with this Order, the Act, and its implementing regulations;

D. Defendants have reimbursed FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with Paragraph 7, at the rates set forth in Paragraph 15; and

E. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in Paragraphs 7.A – B and 7.D of this Order.

In no circumstance shall FDA's silence be construed as a substitute for written notification.

8. Within fifteen (15) business days after completing the recall of all distributed MMS products as described in Paragraph 7.B, Defendants shall give notice to FDA that, under FDA's supervision (which may be done by e-mail or other virtual means as FDA determines to be appropriate), Defendants are prepared to destroy all MMS products (including components, raw and in-process materials, and finished products) in Defendants' possession, custody, or control. Defendants' notice shall specify the proposed time, place, and method of destruction. Defendants shall not commence or permit any other person to commence destruction until they have received written authorization from FDA to commence the destruction. Within fifteen (15) business days after receiving authorization from FDA to commence destruction, Defendants shall, under FDA supervision (which may be done by e-mail or other virtual means as FDA determines to be appropriate), complete the destruction in compliance with this Order. Defendants shall not dispose of any such products in a manner contrary to the provisions of the Act, any other federal law, or the laws or any state or Territory, as defined in the Act, in which the products are disposed. Defendants shall bear the costs of destruction and FDA's supervision.

9. Defendants shall retain, at their expense, an independent person or persons (the "Auditor") who is qualified by education, training, and experience to determine whether Defendants' labels, labeling, promotional material, Current Websites, and Future Websites cause Defendants' drugs, including but not limited to MMS, to be unapproved

new drugs and misbranded drugs; whether Defendants are directly or indirectly responsible for labeling, holding, or distributing drugs, including but not limited to MMS; and whether Defendants directly or indirectly do any acts that causes drugs to become misbranded while they are held for sale after shipment of one or more of their components in interstate commerce. The Auditor shall be without personal or financial ties (other than a consulting agreement between the parties) to any Defendant or any of Defendants' affiliates (including, but not limited to, any entities that Defendants identify as "chapters"), officers or employees, or immediate families. Defendants shall notify FDA in writing of the identity of the Auditor within ten (10) business days after retaining such Auditor.

A. The Auditor shall conduct audit inspections of Defendants' Current Websites, Future Websites, the Facility, and any other location(s) at which Defendants, now or in the future, directly or indirectly engage in labeling, holding, and/or distributing drugs, no less frequently than once every six (6) months for a period of no less than five (5) years. The first audit shall occur not more than six (6) months after entry of this Order.

B. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with this Order and identifying any deviations from such requirements and shall provide a list of all materials reviewed, including all websites and social media, as well as copies of all such materials ("Audit Report Observations").

C. Each Audit Report shall contain a written certification that the Auditor: (1) has personally reviewed all of Defendants' product labels, labeling, Current Websites, and Future Websites; (2) personally certified whether the product labels, labeling, Current Websites, and Future Websites make claims that cause Defendants' MMS products or other products to be drugs within the meaning of the Act; (3) personally certified whether Defendants are directly or indirectly labeling, holding, or distributing Defendants' MMS products or other products that are drugs within the meaning of the Act; and (4) personally certified whether Defendants are directly or indirectly doing any acts that cause drugs to become misbranded while they are held for sale after shipment of one or more of their components in interstate commerce.

D. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service, overnight delivery service, or e-mail, no later than ten (10) business days after the date the Audit Report is completed. In addition, Defendants shall maintain the Audit Reports in separate files at Defendants' Facility and at any other location(s) at which Defendants, now or in the future, directly or indirectly engage in labeling, holding, and/or distributing drugs, and shall promptly make the Audit Reports available to FDA upon request; and

E. If an Audit Report contains any observations indicating that Defendants are violating any provision of this Order or the Act or its implementing regulations, Defendants shall immediately cease such activity.

10. Upon entry of this Order, Defendants, and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all

persons or entities in active concert or participation with any of them, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

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

C. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of components or finished product in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(a) and/or (f)(1); and

D. Failing to implement and continuously maintain the requirements of the Act, its implementing regulations, and this Order.

11. If, at any time after this Order has been entered, FDA determines, based on the results of an inspection, a review of Defendants' products, product labels, labeling, Current Websites, Future Websites, a report prepared by the Auditor, or any other information, that Defendants have failed to comply with any provision of this Order, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Order, the Act, or its applicable regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but

not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease labeling, holding, and/or distributing any or all drugs;

B. Recall, at Defendants' expense, any drug that is an unapproved new drug, a misbranded drug, or otherwise in violation of this Order, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Order;

D. Submit additional reports or information to FDA as requested;

E. Issue a safety alert; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Order, the Act, or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Order or under the law.

12. Upon receipt of any order issued by FDA pursuant to Paragraph 11, Defendants shall immediately and fully comply with the terms of FDA's order. Any cessation of operations or other action described in Paragraph 11 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Order, the Act, and its implementing regulations, and that Defendants may resume operations. The cost of FDA inspections, sampling, testing,

travel time, and subsistence expenses to implement the remedies set forth in this paragraph shall be borne by Defendants at the rates specified in Paragraph 15.

13. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect the Facility, any other location(s) at which Defendants, now or in the future, directly or indirectly engage in labeling, holding, and/or distributing any drug, and Defendants' operations, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order, the Act, and all applicable regulations. During such inspections, FDA representatives shall be permitted: immediate access to Defendants' Facility and/or other place(s) of business, including but not limited to all buildings or other structures, equipment, raw ingredients, in-process or unfinished and finished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, finished and unfinished materials and products, containers, and labeling; and examine and copy all records relating to the receipt, labeling, holding, and distribution of any and all of Defendants' products and their components. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is separate and apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

14. Defendants shall promptly provide any information or records to FDA upon request regarding the labeling, holding, or distributing (directly or indirectly) of Defendants' drugs, including MMS. Defendants shall submit to FDA, at the street

addresses specified in Paragraph 22 and within ten (10) calendar days after such request, a copy of the materials FDA requests, on CD-ROM or DVD. Such requested materials may include, but are not limited to: a list of all locations where any of Defendants' products, including MMS, are held; a list of all of Defendants' websites and any other media that are registered to, owned by, controlled by, or under the direction of any Defendant; and/or downloaded copies of any and all of Defendants' websites, product labeling and promotional materials, and any other media that are registered to, owned by, controlled by, or under the direction of any Defendant.

15. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Order, including all transportation and associated costs for FDA investigators and experts, at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Order, these rates are: $101.00 per hour or fraction thereof per representative for inspection and investigative work; $121.06 per hour or fraction thereof per representative for analytical or review work; $0.575 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

16. Within five (5) business days after the entry of this Order, Defendants shall post a copy of this Order in a common area at the Facility and at any other location

at which Defendants conduct business and shall ensure that this Order remains posted for as long as this Order remains in effect. Within ten (10) business days after entry of this Order, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

17. Within ten (10) business days after the entry of this Order, Defendants shall provide a copy of this Order by personal service or certified mail (return receipt requested) to each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them ("Associated Persons") and shall post this Order on Current Websites and Future Websites. Within twenty (20) business days after the date of entry of this Order, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, including identifying the names, addresses, and positions of all persons who have received a copy of this Order and websites on which the Order has been posted.

18. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Order, Defendants shall within ten (10) business days after the commencement of such association: (a) provide a copy of this Order, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s); and (b) provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and

positions of all Associated Persons who received a copy of this Order pursuant to this paragraph.

19. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, name, or character of their business that occurs after entry of this Order, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Genesis II Church of Health and Healing, or the sale or assignment of any business assets, such as the Facility, other buildings or structures, equipment, or inventory that may affect obligations arising out of this Order. Defendants shall provide a copy of this Order to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

20. Defendants shall notify FDA in writing, at least ten (10) business days before the creation of a new website or link or reference, direct or indirect, to another website or other source that conveys information about MMS or any other of Defendants' drugs. Defendants shall post a copy of this Order, in accordance with Paragraph 17, on any websites created after entry of this Order that convey information about Defendants' MMS products or other drugs. Within ten (10) calendar days after the creation of any new websites, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this Paragraph.

21. In accordance with the procedures described in subparagraphs A-D of this Paragraph, Defendants shall pay equitable disgorgement to an escrow fund for the purpose of satisfying claims from all purchasers who purchased MMS from or through Defendants since January 1, 2010.

A. Within fifteen (15) business days of the entry of this Order, Defendants shall promptly provide, to a Special Master appointed by the Court (whose services shall be paid by Defendants) and to Plaintiff, a financial statement disclosing the amount of revenue Defendants have obtained from sales or distribution of MMS from January 1, 2010, through the date of this Order, along with all supporting records sufficient to determine: (1) the identities, addresses, and phone numbers of the individuals and entities who purchased MMS by or through Defendants from January 1, 2010 through the date of this Order; (2) the dates and quantities of MMS ordered and the price paid for such products, including any costs of shipping paid by the purchasers (less any refunds already paid by Defendants to such purchasers); and (3) an accounting of gains and expenses related to the manufacturing, packaging, holding, distribution, sales, and promotion of MMS. These records shall include, but not be limited to, state and federal tax returns; bank records; shipping records; sales invoices; accounting records, including certified financial statements; truthful and fully-executed copies of Department of Justice Form OBD-500; and any other records as the Court may request. Within twenty (20) business days after the entry of this Order, Defendants shall each file with the Court an affidavit stating the fact and manner of compliance with this Paragraph. In the event such records cannot be provided by Defendants, an affidavit explaining the inability to

produce some or all of the records shall be filed with Court within twenty (20) business days of the entry of this Order.

B. Within twenty-five (25) business days of entry of this Order, Defendants shall pay to an escrow fund managed and identified by the Special Master, the amount disclosed in subparagraph A., above. The Special Master will administer and effectuate the payment of refunds to purchasers who request them from the escrow fund until October 31, 2020.

C. Within twenty-five (25) business days of entry of this Order, Defendants shall prominently display the following notice on Defendants' Current Websites, and provide it by mail to all persons and entities that have purchased MMS by or through Defendants since January 1, 2010:

NOTICE

You have been identified as an individual who has purchased MMS from Genesis II Church of Health and Healing. The organization and certain individuals associated with it are the defendants in a legal action brought against them by the United States Government to enforce the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et. seq.*) in the United States District Court for the Southern District of Florida.

The Court has found the defendants liable for unlawfully distributing MMS because it is an unapproved new drug and is a misbranded drug. MMS is a misbranded drug, in part, because its labeling and promotional material falsely represented the product as safe and effective for treating various diseases, when in fact there is no substantial evidence that MMS is safe and effective to treat any disease whatsoever.

As a result, the Court has ordered Defendants to provide refunds to those purchasers of MMS who request them. In order to obtain a refund, you must request a refund from the Court-appointed Special Master by email or U.S. mail using the contact information below, no later than October 31, 2020. In your request, you must include the following information:

1. Name
2. Address
3. Phone Number
4. Email
5. Approximate date(s) of your MMS purchase(s)
6. Approximate amount paid for MMS purchases (less any refund received).

CONTACT INFORMATION
XXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXX

You can expect to receive funds once your purchase information is verified.

D. On November 15, 2020, the Special Master shall return the portion of the remaining escrow fund that the Special Master determines represents legitimate business expenses, that is, expenses that Defendants incurred independent of supporting or powering Defendants' unlawful distribution of MMS. On that same date, the Special Master will pay any remaining funds in the escrow fund to the United States Treasury.

E. Upon entry of this Order, Defendants and Associated Persons shall immediately refrain from disposing of or transferring any assets that may interfere with implementation of this disgorgement provision. In addition, Defendants and Associated Persons are prohibited from destroying, discarding, altering, transferring, or otherwise making unavailable any documents and records in electronic format or otherwise within the custody or control of Defendants or Associated Persons.

22. All notifications, correspondence, and communications to FDA required by the terms of this Order shall be addressed to: Director, Office of Pharmaceutical Operations Division II, 4040 North Central Expressway, Suite 300, Mail Code HFR-SW100, Dallas, Texas 75204, and shall also be sent by e-mail to ORAPHARM2_RESPONSES@fda.hhs.gov.

23. Should the United States bring and prevail in a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), investigational and analytical expenses, expert witness fees, and court costs relating to such contempt proceedings.

24. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Order shall be vested in FDA's

discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Order shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

25. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

DONE AND ORDERED in chambers in Miami, Florida, this 9th day of July, 2020.

KATHLEEN M. WILLIAMS
UNITED STATES DISTRICT JUDGE