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.

SEALED TEMPORARY RESTRAINING ORDER

1. Plaintiff has filed a Complaint for Injunction against Genesis II Church of Health and Healing ("Genesis"), and Mark Grenon, Joseph Grenon, Jordan Grenon, and Jonathan Grenon, individuals (collectively, "Defendants"), pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, alleging that Defendants directly or indirectly do or cause the following acts:

A. Violate 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. Violate 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 (f)(1); and

C. Violate 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.

2. This Court has jurisdiction over the subject matter and Defendants.

3. The Complaint for Injunction alleges a cause of action against Defendants under the FDCA.

4. The United States has demonstrated that Defendants are violating the FDCA, 21 U.S.C. § 301, *et seq.* and that there is a cognizable danger that Defendants will continue so in the future unless a temporary restraining order is issued.

5. Because the United States' motion is based upon 21 U.S.C. § 332(a), which expressly authorizes injunctive relief to protect the public interest, no specific finding of irreparable harm is necessary, no showing of any inadequacy of other remedies at law is necessary and no balancing of interests of the parties is required prior to the issuance of a temporary restraining order in this case.

6. The provision of advance notice to Defendants is not required because the immediate and irreparable injury to public health may result before Defendants may be heard.

7. The conditions for granting a temporary restraining order under Rule 65(b) of the Federal Rules of Civil Procedure and 21 U.S.C. § 332(a) having thus been met.

After considering the foregoing, it is therefore,

ORDERED, ADJUDGED AND DECREED that:

1. The United States' Motion for a Temporary Restraining Order is **GRANTED** without notice to Defendants. Pursuant to Federal Rule of Civil Procedure 65(b)(2), this Temporary Restraining Order was issued on <u>April 17th, 2020</u>, at <u>10:00AM</u>. This Temporary Restraining Order shall expire on <u>May 1, 2020 at 10:00 AM</u>, unless it is extended by the Court for good cause shown or the Defendants consent to a longer extension.

2. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, representatives, employees, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (hereinafter, "Associated Persons") who receive actual notice of this Order, shall not, during the pendency of this action, directly or indirectly, label, hold, and/or distribute any drug, including but not limited to MMS, that does not have an approved new drug application pursuant to 21 U.S.C. § 355(b) or abbreviated new drug application pursuant to 21 U.S.C. § 355(j), or an investigational new drug application in effect for its use pursuant to 21 U.S.C. § 355(i), or any drug that is misbranded within the meaning of 21 U.S.C. § 352.

3. Upon entry of this Order, Defendants and Associated Persons, shall not, directly or indirectly, violate 21 U.S.C. § 331(k) by causing any drug, including but not limited to MMS, to become misbranded within the meaning of 21 U.S.C. § 352(a) and/or (f)(1) after shipment of one or more of its components in interstate commerce.

4. 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 payment of restitution to consumers who purchased Defendants' drugs, should the Court ultimately order such restitution payments in its final judgment in this matter.

5. Upon entry of this Order, Defendants and Associated Persons are prohibited from destroying, discarding, altering, transferring or otherwise making unavailable any document or record in electronic format or otherwise within their custody or control that are related to (a) MMS; (b) misbranded drugs; and/or (c) unapproved new drugs.

6. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' places of business and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order. During such inspections, FDA representatives shall be permitted to: have immediate access to buildings, including but not limited to 2014 Garden Ln, Bradenton, FL 34205-5274 (the "Facility"), equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling,

and other promotional material therein; take photographs and make video recordings; take samples of Defendants' in-process or unfinished and finished products, containers, packaging material, labeling, and other promotional material; and examine and copy all records relating to the labeling, holding, and distribution of any and all drugs 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 FDCA, 21 U.S.C. § 374.

7. Defendants shall bear the cost of any inspections, analytical work, and supervisory activities that FDA deems necessary to evaluate Defendants' compliance with any of the terms of this Order.

8. 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 the Order remains posted for as long as the Order remains in effect.

 IT IS FURTHER ORDERED that the United States shall promptly provide notice of this action and this Order to Defendants by, to the extent necessary, attempting service at last known email addresses and physical addresses.
Pursuant Rule 65(c) of the Federal Rules of Civil Procedure, Plaintiff United States of America shall not be required to post security for the instant action.
This matter is set for a preliminary injunction hearing on <u>Friday, May 1,</u> 2020, at 10:00AM.

DONE AND ORDERED in chambers in Miami, Florida, this <u>17th</u> day of <u>April</u>, 2020.

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KATHLEEN M. WILLIAMS UNITED STATES DISTRICT JUDGE