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, *et al*.,

Defendants.

_____/

ORDER

THIS MATTER is before the Court on Plaintiff's, United States of America ("Government"), motion for final default judgment against Genesis II Church of Health and Healing, Jonathan Grenon, and Jordan Grenon (collectively, "Defendants"). (DE 49.) Defendants have not responded to the motion and the time to do has now passed. For the reasons below, Plaintiff's motion (DE 49) is **GRANTED**.

I. BACKGROUND

This action arises out of Defendants' violation of the Food, Drug, and Cosmetic Act ("FDCA") by marketing and distributing a product called Miracle Mineral Solutions ("MMS"), a drug Defendants claim is a cure for COVID-19 and other serious diseases. MMS is comprised of 22.4% sodium chlorite ($NaClO_2$), 5% sodium chloride (NaCl), 1% "trace minerals," and 71.6% purified water. (DE 3 at 5.) It is sold with an "activator" that contains 4% hydrochloric acid (HCl). (*Id.*) When the MMS and the activator are combined, as directed by the product labeling, a chemical reaction occurs yielding chlorine dioxide (ClO_2), a chemical commonly used as an industrial bleach. (*Id*.)

Genesis II Church of Health and Healing ("Genesis") is a secular entity based in Bradenton, Florida that describes itself as a "non-religious church," that is focused on "restoring health to the world." (DE 1 ("Complaint") at ¶ 4.) While the organization is non-religious, its leaders hold clerical titles. Defendants Jonathan Grenon and Jordan Grenon are known as "Bishops," and are responsible for Genesis' operations, including the labeling, holding, and distribution of MMS. (*Id.* at ¶¶ 7-8.)

Defendants operate several websites on which they market and sell MMS, including www.newg2sacraments.org ("Sales Website"), g2churchnews.org ("News Website"), g2voice.is ("Radio Website"), genesis2church.ch, mmstestimonials.co, and others. (*Id.* at ¶ 4.) On these websites, Defendants explain—and link to testimonials that claim—that MMS is a treatment and cure for COVID-19, Alzheimer's, autism, brain cancer, HIV/AIDS, multiple sclerosis, and other illnesses. (*Id.*) For instance, on March 3, 2020, Defendants posted the following claims on their News Website:

> **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!**

(Complaint at ¶ 14.) Defendants also distribute MMS in interstate commerce to customers who have made purchases on the Sales Website.[1] (DE 3 at 8.) On March 27, 2020, an undercover Food Drug Administration ("FDA") employee visited the Sales Website and ordered various MMS products. (DE 3-1 at ¶ 16.) On March 30, 2020, the FDA received Defendants' package containing the purchased products in Ashburg, Virginia, with a return address in Bradenton, Florida. (DE 3-2 at ¶ 11.)

On April 8, 2020, the FDA issued a warning letter to Defendants informing them that their marketing and distribution of MMS violated the FDCA. (DE 3-2 at ex. 8.) The letter requested Defendants to respond within 48 hours by describing the steps they have taken to correct the violations and warned them that the failure to comply may result in legal action. (*Id.*) A day later, Defendants posted the letter on its News Website, stating that the FDA did not have jurisdiction over their activities or products, and that they would not be taking any corrective action. (*Id.* at ex. 9.) The post also included a call to action to the organization's members, imploring them to send emails to the FDA, FTC, and the President. (*Id*.) The FDA also received a written response from Defendants that included the following statements:

> We are NOT under your authority in regard to your agencies
>
> We DO NOT need your approval for [MMS] or for anything we do in our Church.
>
> You have NO authority over us so why would we even consider your Act?

[1] After this lawsuit was filed, Defendants altered the Sales Website and MMS can no longer be purchased directly from the website. Instead, the Sales Website directs customers to send questions to an email address. (DE 23-1.) Defendant Jordan Grenon responded to emails regarding the availability of MMS by directing customers to alternate sources. (*Id.*) After the Court had entered its preliminary injunction order, the Government emailed the provided email address undercover, and was able to obtain MMS through an alternative source. (DE 39-1.)

> We can say cure, heal, and treat as a Free Church. Don't need you [sic] approval or authorization . . . .
>
> There will be NO corrective actions on our part . . . You have no authority over us!
>
> We will NOT stop our Church Sacraments! . . . we will NOT comply!"
>
> We don't have to cease anything in regard to our Church Sacraments [MMS]! You cease and desist and harassing us!

(*Id*. at ex. 10.) Because Defendants did not comply with the warning letter, on April 16, 2020, the Government filed a Complaint against them, seeking a permanent injunction under 21 U.S.C. § 332(a) to enjoin them from violating the following sections of the FDCA: 21 U.S.C. § 331(d) for introducing into interstate commerce unapproved new drugs; 21 U.S.C. § 331(a) for introducing into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) and (a); and 21 U.S.C. § 331(k) for causing drugs to become misbranded while they are held for sale after shipment of one or more of their components in interstate commerce. (Complaint at ¶¶ 9-13.)

Genesis and Jonathan Grenon were served with the Complaint on April 27, 2020 and Jordan Grenon was served on April 29, 2020. (DE 19-10, 19-11, 19-14.) Pursuant to Rule 12(a)(4)(A) of the Federal Rules of Civil Procedure, the applicable time for Genesis and Jonathan Grenon to respond to the Complaint expired on May 19, 2020, and on May 20, 2020 for Jordan Grenon. None of the Defendants have responded to the Complaint. Accordingly, on May 29, 2020, the Government obtained a clerk's entry of default against them. (DE 46.) The Government now moves for the final entry of default judgment. (DE 49.)

II. LEGAL STANDARD

Under Rule 55 of the Federal Rules of Civil Procedure, if a defendant fails to plead or otherwise defend against a complaint, the Clerk of the Court may enter a default against that defendant. Fed. R. Civ. P. 55(a). Where a default occurs, the plaintiff's well-pleaded allegations are deemed admitted. *Buchanan v. Bowman*, 820 F.2d 359, 361 (11th Cir. 1987). Once a default is entered, a plaintiff may seek entry of a default judgment against the defaulting defendant. Fed. R. Civ. P. 55(b). A default judgment, however, is a matter of discretion for the court, not a matter of right to the moving party. *See Pitts ex rel. Pitts v. Seneca Sports, Inc.*, 321 F.Supp.2d 1353, 1356 (S.D. Ga. 2004). Before entering a default judgment, the court must ensure that the well-pleaded allegations in the complaint, taken as true by virtue of the default, actually state a substantive cause of action, and that there is a substantive, sufficient basis in the pleadings for the particular relief sought. *Tyco Fire & Sec., LLC v. Alcocer*, 218 F. App'x 860, 863 (11th Cir. 2007). While a defaulted defendant cannot challenge the sufficiency of the evidence, "[it] is entitled to contest the sufficiency of the complaint and its allegations to support the judgment." *Cotton v. Mass. Mut. Life Ins. Co.*, 402 F.3d 1267, 1278 (11th Cir. 2005).

"Entry of default judgment is only warranted when there is 'a sufficient basis in the pleadings for the judgment entered.'" *Surtain v. Hamlin Terrace Found*, 789 F.3d 1239, 1245 (11th Cir. 2015) (citation omitted). The Eleventh Circuit has explained that the standard for assessing entitlement to default judgment is "akin to that necessary to survive a motion to dismiss for failure to state a claim." *Id.* (citing *Chudasama v. Mazda Corp.*, 123 F.3d 1353, 1370 n.41 (11th Cir. 1997)).

III. DISCUSSION

In its motion, the Government seeks final default judgment on the three FDCA claims asserted in its Complaint: 21 U.S.C. § 331(d), distribution of unapproved new drugs into interstate commerce; 21 U.S.C. § 331(a), introduction of a misbranded drug into interstate commerce; and 21 U.S.C. § 331(k), causing the misbranding of drug while held for sale after shipment of its components in interstate commerce. The Government also urges the Court to enter a permanent injunction under 21 U.S.C. § 332 (a) to restrain Defendants from continued violations of the FDCA. The Court first considers Plaintiff's entitlement to default judgment and then its request for a permanent injunction.

A. Plaintiff's Entitlement to Default Judgment

1. **21 U.S.C. § 331(d)**

The FDCA defines a "drug" as a substance that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 21 U.S.C. § 321(g)(1)(B). "The intended use of a product may be determined from any relevant source, including labeling." 21 C.F.R. § 201.128. "Labeling" is defined 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 need not be physically attached to the product and includes anything that explains the uses of the drug, such as marketing materials and websites. *See Kordel v. United States*, 335 U.S. 350 (1948); *United States v. Flu Fighter Corp*, 2009 WL 10668958, at *4 n.2 (S.D. Fla. Feb. 11, 2009) (finding the products' websites to constitute "labeling" under the FDCA); *United States v. Innovative Biodefense, Inc*., 2019 WL 2428670, at *4 (C.D. Cal. Feb. 22, 2019) ("statements on a drug product's website generally constitute part of the product's labeling.").

Under the FDCA, a "new drug" is any drug "the composition of which is such that 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[2] for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). To introduce a "new drug" into interstate commerce, the FDA must approve a new drug application ("NDA") or an abbreviated new drug application ("ANDA"), or the new drug must be exempt from the approval process pursuant to an investigational new drug application ("IND"). *See* 21 U.S.C. §§ (a), (b), (j), and (i). Otherwise, a person who introduces or delivers for introduction into interstate commerce an unapproved new drug violates 21 U.S.C. § 331(d). The FDCA defines "interstate commerce" as commerce between any state and any place outside of it. 21 U.S.C. § 321(b)(1).

Here, upon a review of the Complaint, the Court finds the Government has sufficiently pled the elements of 21 U.S.C. § 331(d) for the introduction of an unapproved new drug into interstate commerce.

a. **MMS is a "Drug" under the FDCA**

Plaintiff alleges—with specific examples—that Defendants' "labeling" shows that MMS is intended to cure, mitigate, treat, or prevent COVID-19 and other diseases. (Complaint at ¶ 13.) For instance, the Government claims that on March 3, 2020, Defendants posted on its News Website instructions for the use of MMS as a

[2] For a drug to be "generally recognized as safe and effective" ("GRAS/E"), it must (1) have substantial evidence of safety and effectiveness as demonstrated through adequate and well-controlled clinical studies; (2) the studies on which a claim of GRAS/E is based must be published in the scientific literature so that they are made generally available to the community of qualified experts; and (3) there must be a consensus of opinion among qualified experts, which is based on the published studies, that the drug is safe and effective for its labeled indications. *See United States v. S Hackett Mktg. LLC*, 2018 WL 4146606, at *3 n.4 (D.N.J. Aug. 30, 2018) (citing 21 U.S.C. § 355(d)).

treatment for COVID-19 for adults and children. (*Id.* at ¶ 14.) The post claimed "[t]he Coronavirus is curable!" and that following the instructions would "wipe out this flu-like virus . . . ." (*Id.*) Defendants also posted a video on the Radio Website, in which the following statements were made regarding MMS' potential to treat COVID-19:

> 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, 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.
>
> The Coronavirus is curable, you believe that? You better . . . it's wicked good stuff Joe.
>
> MMS will kill it.

(*Id.* at ¶ 15.) In light of these particularized allegations, the Court finds that the Government has plausibly alleged that MMS is a "drug" within the meaning of the FDCA. *See S Hackett Marketing*, 2018 WL 4146606, at *3 (finding that plaintiff sufficiently alleged that products were "drugs," based on allegations that the labeling made "at least thirty-two structure and function claims."); *United States v. BioAnue Labs., Inc*., 2014 WL 3696662, at *6 (M.D. Ga. July 23, 2014) (finding products to be "drugs" at the summary judgment stage because the defendant's websites were "replete with claims that [ ] products are intended to cure, mitigate, treat, or prevent disease in man."); *United States v. Berst*, No. 6:11-CV-6370-TC, 2012 WL 4361408, at *4 (D. Or. Aug. 2, 2012), *report and recommendation adopted*, 2012 WL 4361559 (D. Or. Sept. 20, 2012) (same).

b. **MMS is an Unapproved "New Drug" under the FDCA**

The Complaint alleges that MMS is a "new drug" because it 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 treating COVID-19 and other illnesses. (*Id.* at ¶ 24.) Specifically, Plaintiff claims that:

> [The] FDA conducted comprehensive searches of the publicly-available medical and scientific literature for MMS . . . 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.

(*Id.* at ¶ 25.) The Government also explains that "[a]fter 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." (*Id.* at ¶ 26.) With these allegations, the Government has properly pled that MMS is an unapproved "new drug" within the meaning of the FDCA. *See S Hackett Marketing*, 2018 WL 4146606 at *3 (finding that plaintiff sufficiently alleged that products were unapproved "new drugs," based on allegations that the FDA found "no adequate and well-controlled studies" demonstrating the effectiveness of the products for their intended use, and that the defendants lacked an approved "NDA or ANDA, or effective IND for any of their drugs."); *BioAnue Labs*., Inc., 2014 WL 3696662 at *7 (finding that products were unapproved new drugs at the summary judgment stage, based on evidence that the Government's search "found no published studies of any kind on the Defendants' products" and "no approved new drug

applications for any of the Defendants' products."); *United States v. Hakim*, 2020 WL 2751020, at *8 (S.D.N.Y. May 26, 2020) (same).

c. **Defendants Distributed MMS into Interstate Commerce**

Finally, Plaintiff has plausibly alleged that Defendants distributed MMS into interstate commerce by pleading that "[o]n or about March 27, 2020, Defendants shipped MMS from Florida to Virginia." (*Id.* at ¶ 28.) *See S Hackett Marketing*, 2018 WL 4146606 at *4 (finding that plaintiff sufficiently pled interstate commerce by alleging, *inter alia*, that the defendants had shipped "various Illicit Drugs from New Jersey to Maryland."); *Hakim*, 2020 WL 2751020 at *8 (finding that plaintiffs established this element at the summary judgment stage, based on evidence that the defendants had shipped products from New York to North Carolina).

Because Plaintiff has sufficiently alleged that Defendants distributed MMS, an unapproved "new drug," into interstate commerce, the Complaint states a cause of action under 21 U.S.C. § 331(d). Accordingly, the Government is entitled to default judgment as to this claim.

2. 21 U.S.C. § 331(a)

The FDCA prohibits "[t]he introduction or delivery for introduction into interstate commerce" a drug that is "misbranded." 21 U.S.C. § 331(a). There are several provisions in the FDCA that explain the circumstances under which a drug is "misbranded." A drug is "misbranded" under 21 U.S.C. § 352(a) if "its labeling is false or misleading in any particular." Misbranding under this provision requires the Government to establish two elements: "(1) a representation in the labeling of the device; and (2) the false or misleading nature of that representation." *United States v. Torigian Labs., Inc.*, 577 F.

sSupp. 1514, 1525 (E.D.N.Y.), *aff'd sub nom. United States v. Torigian Labs*., 751 F.2d 373 (2d Cir. 1984). A drug is "misbranded" under 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use" and is not exempt from this requirement. "[A]dequate directions for use" are those "under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. Prescription drugs, by their definition, cannot have adequate directions for layperson use. *See* 21 U.S.C. § 353 (b)(1)(A). The FDCA defines a "prescription drug" as a product that "because of its toxicity or other potentiality for harmful effects . . . is not safe for use except under the supervision of a practitioner licensed by law to administer such a drug." *Id.*

Plaintiff has adequately pled that MMS is "misbranded" within the meaning of 21 U.S.C. § 352(a). As previously discussed, the Government alleges that Defendants' labeling claims that MMS can effectively treat COVID-19 and "a litany of other serious diseases." (Complaint at ¶ 31; *supra* at SectionIII.A1a.) Plaintiff contends that these claims are false and misleading because "[t]he 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 disease identified in the labeling." These pleadings sufficiently state the elements of "misbranding" under 21 U.S.C. § 352(a). *See United States v. Undetermined Quantities of Articles of Drug*, 145 F. Supp. 2d 692, 702 (D. Md. 2001) ("in the absence of clinical proof, in the form of adequately controlled clinical studies, which establishes that the product is effective for any indicated use, any representation as to its proven efficacy is false and misleading, and therefore, the product

is misbranded.") (quoting *United States v. Sene X Eleemosynary Corp., Inc.*, 479 F. Supp. 970, 980 (S.D. Fla. 1979)) (internal brackets and ellipses omitted).

The Complaint also contains well-pled allegations demonstrating that MMS is *per se* "misbranded" under 21 U.S.C. § 352(f)(1) for lacking "adequate directions for use," because it is a "prescription drug." Plaintiff alleges that "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." (Complaint at ¶ 36.) It contends that "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." (*Id*.) The Government further explains that the exemptions from the adequate directions for use requirement in § 352(f)(1) do not apply to MMS because "each exemption requires the drug to bear the labeling approved by FDA in an NDA." (*Id.*) Finally, it alleges that "[b]ecause MMS is not the subject of an approved NDA or ANDA, Defendants' MMS does not qualify" for an exemption. (*Id*.) These allegations sufficiently plead "misbranding" under 21 U.S.C. § 352(f)(1). *See United States v. Hakim*, 2020 WL 2751020 at *8 ("the record shows that many of Defendants' drugs are intended for treating serious diseases or conditions such as HIV, cancer, and Ebola, all of which require diagnosis and management by a physician. As such, they are *only* safe for use under the supervision of a physician, which brings them within the definition of prescription drugs. . . they are presumptively misbranded unless they qualify for [an exemption], none of which apply here."); *See S Hackett Marketing*, 2018 WL 4146606 at *3 (finding plaintiff sufficiently alleged misbranding under 21 U.S.C. § 352(f)(1) based on pleadings that "medical expertise and special clinical

assessments are needed to diagnose and determine the appropriate therapeutic interventions for many of [the products'] intended uses, including erectile dysfunction, impotence, and prostatitis. . . .").

Because the Complaint contains well-pled allegations showing that MMS is a "misbranded" drug within the meaning of 21 U.S.C. §§ 352(a) and (f)(1), and that Defendants distributed MMS into interstate commerce, *see supra* at SectionIII.A1c, the Complaint states a cause of action under 21 U.S.C. § 331(d). Accordingly, the Government is also entitled to default judgment as to this claim.

3. **21 U.S.C. § 331(k)**

The FDCA prohibits causing a drug to become misbranded while it is "held for sale (whether or not the first sale) after shipment in interstate commerce. . . ." 21 U.S.C. § 331(k). To establish a violation of § 331(k), the Government must prove that (1) the relevant product is a drug, (2) defendants received the drug or its components after shipment into interstate commerce, (3) the product is being "held for sale," and (4) defendants have misbranded, or caused the misbranding of, the drug. The second element, "interstate commerce," is met even if a single ingredient or component of that drug is shipped interstate. *See United States v. Regenerative Scis., LLC*, 878 F. Supp. 2d 248, 259 (D.D.C. 2012), *aff'd*, 741 F.3d 1314 (D.C. Cir. 2014). The third element, "held for sale," is satisfied when the product is used for purposes other than personal consumption. *See United States v. US Stem Cell Clinic, LLC*, 403 F. Supp. 3d 1279, 1298 n.11 (S.D. Fla. 2019) ("Courts have interpreted 'held for sale' as meaning any use beyond personal consumption.").

Here, the Government has plausibly alleged a 21 U.S.C. § 331(k) violation. As previously explained, the Complaint provides well-pled allegations showing that MMS is a "drug" and that it is "misbranded" within the meaning of the FDCA. *See supra* at Section III.A.1.a and Section III.B. Because Plaintiff alleges that Defendants "sell and distribute" MMS to consumers, the Complaint also sufficiently states that MMS is "held for sale." (Complaint at ¶ 4.) Finally, Plaintiff has pled the "interstate commerce" element by alleging that Defendants received one or more MMS ingredients or components from outside of Florida. (*Id.* at ¶ 41.) *See United States v. Dianovin Pharm., Inc*., 475 F.2d 100, 103 (1st Cir. 1973) ("The appellants' use of components shipped in interstate commerce to make [the subject product] brought their activities within § 331(k)."); *Baker v. United States*, 932 F.2d 813, 815 (9th Cir. 1991). Accordingly, the Court finds that the Complaint also states a claim under 21 U.S.C. § 331(k).

B. Plaintiff's Entitlement to a Permanent Injunction

Having determined that Plaintiff is entitled to default judgment as to its claims under 21 U.S.C. §§ 331(d), (a), and (k), the Court turns to the Government's requested relief for a permanent injunction under 21 U.S.C. § 332(a), which authorizes the Court to restrain violations of Section 331 of the FDCA.

To obtain a permanent injunction under the FDCA, the Government "need not show that it would suffer irreparable harm if the injunction were not granted." *United States v. US Stem Cell Clinic, LLC*, 403 F. Supp. 3d 1279, 1300 (S.D. Fla. 2019) (citing *Gresham v. Windrush Partners, Ltd.,* 730 F. 2d 1417, 1423 (11th Cir. 1984)). Instead, a permanent injunction is appropriate when the Government has demonstrated that Defendants have violated the applicable statute and that there is some reasonable

likelihood that violations may reoccur. *Id*.; *United States v. Hakim*, 2020 WL 2751020, at *9 (S.D.N.Y. May 26, 2020). In making this determination, courts review: (1) "whether a defendant's violation was isolated or part of a pattern, (2) whether the violation was flagrant and deliberate or merely technical in nature, and (3) whether the defendant's business will present opportunities to violate the law in the future." *US Stem Cell Clinic*, 403 F. Supp. 3d at 1300 (alterations made).

Here, because the Government is entitled to default judgment as to each of its claims, its well-pled allegations regarding Defendants' violations of 21 U.S.C. §§ 331(d), (a), and (k) are deemed admitted. *See Perez v. Wells Fargo N.A.*, 774 F.3d 1329, 1339 (11th Cir. 2014). Accordingly, Plaintiff has established that Defendants violated various provisions of section 331 of the FDCA. *See S Hackett Marketing*, 2018 WL 4146606 at *4. Moreover, the Government has also demonstrated that unless enjoined, there is a reasonable likelihood that Defendants will continue to violate the FDCA.

First, Defendants' distribution and misbranding of MMS are not isolated. After the Court entered its temporary restraining order and preliminary injunction order—both containing provisions that prohibited Defendants from distributing and misbranding MMS[3]—Defendants continued to distribute MMS by directing customers to alternate sources, and misbrand MMS by refusing to remove claims regarding its curative potential

[3] Both orders state "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. . . ." and "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." (DE 4; DE 26) (emphasis added.)

on its websites. (DE 39-1; DE 23-1.) Second, Defendants' violations are not merely technical, but deliberate. When confronted with the warning letter, Defendants did not take measures to comply. Instead, they declared that the FDA did not have jurisdiction over their activities, and that they would not be taking any corrective measures, stating in their written response, "[t]here will be NO corrective action on our part. . . You have no authority over us!" and "We don't have to cease anything in regard to our Church Sacraments [MMS]! You cease and desist and harassing us!" (DE 3-2 at exs. 9, 10.)

In addition, the week after the Court had entered its temporary restraining order, Defendants posted a video on its Radio Website that explained, "[j]ust because the FDA submits a TRO and the DOJ . . . signs the order, it doesn't mean it has to be obeyed or even given attention," and "[w]ell, we're not going to be under compliance to them because they're not over us." (DE 23-4; DE 33-1.) The week following the Court's entry of the preliminary injunction order, Defendants posted another video on its Radio Website, in which the following statements were made:

> We're going to obey God rather than men. Well, what about if you go to jail? Ha ha ha ha . . . You think we're afraid of some Obama-appointed judge that broke their oath? You're no judge.
>
> We're not going to stop anything.
>
> We're not obeying it [the preliminary injunction order]. Don't care what you do . . . we're going to carry on anyways, so it's not going to stop us. But we're going to carry on directly, directly, whatever you say.

(DE 33-1.) In light of these remarks, it is also evident that Defendants' business will present opportunities to violate the FDCA in the future; Defendants have used their

websites to market and sell MMS in violation of the FDCA, and have openly declared their intent to persist in such violations, notwithstanding the Court's orders. (DE 3, DE 33.)

For these reasons, the Court finds that the entry of a permanent injunction in this case is appropriate. *See US Stem Cell Clinic*, 403 F. Supp. 3d at 1300 (finding entry of permanent injunction appropriate because, *inter alia*, the defendant did not comply with the FDCA after receiving a warning letter); *S Hackett Marketing*, 2018 WL 4146606 at *8 (same).

IV. CONCLUSION

For the foregoing reasons, it is **ORDERED AND ADJUDGED** that Plaintiff's motion for final default judgment against Genesis II Church of Health and Healing, Jonathan Grenon, and Jordan Grenon (DE 49) is **GRANTED**. The Court will enter judgment against Defendants in a separate order.

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

KATHLEEN M. WILLIAMS
UNITED STATES DISTRICT JUDGE