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' *EX PARTE* MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION AND SUPPORTING MEMORANDUM OF LAW

In the midst of a viral pandemic and national emergency like nothing seen for more than a century, the above-captioned defendants are exploiting the crisis by marketing a powerful industrial bleach to consumers as a remedy for coronavirus, which includes COVID-19, the novel disease that, in its four months of existence, has infected more than 2 million people worldwide and has claimed the lives of nearly 30,000 Americans. When warned by authorities that their conduct was unlawful, Defendants responded with open defiance, explicitly avowing that they need not—and will "never"—obey the law. As a result, pursuant to Rule 65(b)(1) of the Federal Rules of Civil Procedure and 21 U.S.C. § 332(a), Plaintiff, the United States of America (the "United States"), through undersigned counsel, hereby moves for the entry of a temporary restraining order, preliminary injunction, and other equitable relief to prevent Defendants, Genesis II Church of Health and Healing ("Genesis"), Mark Grenon, Joseph Grenon, Jordan Grenon, and

Jonathan Grenon (collectively, "Defendants"), and any and all persons or entities in active concert or participation with any of them, from directly or indirectly:

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

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

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

INTRODUCTION

In late December 2019, a novel strain of coronavirus began to infect and sicken people in Wuhan, China; the first case in the United States was confirmed weeks later, on January 15, 2020. The virus was dubbed "SARS-CoV-2" for severe adult respiratory syndrome-coronavirus-2, and the disease it caused was named "COVID-19" (short for coronavirus disease – 2019, hereinafter referred to as "COVID-19"). Two weeks later, on January 31, 2020, the Secretary of Health and Human Services, under Section 319 of the Public Health Service Act, 42 U.S.C. § 247d, declared a nationwide public health emergency due to COVID-19. 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.*, by finding and declaring that the COVID-19 outbreak in the United States constituted a national emergency.

As of the date of this filing, there have been over 641,000 confirmed infections across every state in the nation, with more than 2,000 Americans now dying of the disease each day. Unprecedented restrictions on daily living have affected nearly every American, most of whom remain under strict "stay-at-home" orders. Defendants have sought to take advantage of this crisis for their own gain while endangering public health by selling a product they call "Mineral Miracle

Solution" or "MMS" as a remedy. As a result, the United States respectfully requests that the Court, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA" or "the Act"), and the Court's inherent equitable authority, temporarily and preliminarily restrain and enjoin Genesis II Church of Health and Healing, Mark Grenon, Joseph Grenon, Jordan Grenon, and Jonathan Grenon (collectively, "Defendants") from unlawfully distributing their MMS product which, when combined with the included activator, creates an industrial-strength bleach that Defendants intend consumers to ingest to cure, mitigate, treat, or prevent COVID-19, and many other serious diseases.

Despite being warned by the United States Food and Drug Administration ("FDA"), Defendants continue to distribute their product in violation of the FDCA, which Congress enacted to protect the public health by, among other things, ensuring that drugs are safe and effective for their intended uses. 21 U.S.C. § 393(b)(2)(B). In passing the Act, Congress wanted to protect consumers because they cannot adequately protect themselves against unknowable, latent dangers from substances intended to affect the human body. *See United States v. Dotterweich*, 320 U.S. 277, 280 (1943) ("The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.").

Defendants are violating the FDCA—thus endangering public health during this emergency—in at least three ways. First, Defendants are introducing drugs into interstate commerce that have not been approved by FDA and are not generally recognized as safe and effective, in violation of 21 U.S.C. § 331(d). Second, Defendants are introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. § 331(a). Third, Defendants are causing drugs to become misbranded while held for sale after their shipment (or shipment of their components) in interstate commerce, in violation of 21 U.S.C. § 331(k).

Under the FDCA, Defendants' MMS product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease in man. *See* 21 U.S.C. § 321(g) (defining drug). More specifically, MMS is an unapproved new drug because it is not generally recognized as safe and effective for any use, and it is not the subject of an FDA-approved drug application,

nor is it exempt from the approval requirement. Furthermore, Defendants' MMS is a misbranded drug for at least two reasons: (1) its labeling falsely and misleadingly claims it can effectively treat a vast array of serious diseases, including COVID-19, 21 U.S.C. § 352(a); and (2) its labeling fails to bear adequate directions for its use for COVID-19 or any other disease, 21 U.S.C. § 352(f)(1). Defendants ship MMS in interstate commerce to their customers and, upon information and belief, Defendants receive components for their MMS product, or the final product, in interstate commerce.

Congress specifically empowered federal courts to restrain such violations of the FDCA. *See* 21 U.S.C. § 332. Defendants' publicly avowed recalcitrance, even after being advised that their conduct violates federal law, clearly demonstrates that a temporary restraining order and preliminary injunction are essential to protect consumers from Defendants, especially in the context of the current national emergency.

I. FACTUAL BACKGROUND

A. Defendants and Their Operations

1. *Genesis is Not a Religious Organization and Its Leaders Are Not Clergy*

Despite calling itself a "church," Genesis II Church of Health and Healing ("Genesis") is a secular organization[1] that operates a series of websites, by and through the individual Defendants, Mark Grenon, Joseph Grenon, Jordan Grenon, and Jonathan Grenon. *See* Declaration of Tiffany Petty ("Petty Decl."), attached at Exhibit ("Ex.") 1, ¶¶ 9–16, 19–21, Exs. 3–16, 18–20; Declaration

[1] Genesis describes itself on its website as "a non-religious church welcoming people from all walks of life, religions, colors, creeds and belief systems." *Our Church*, GENESIS II CHURCH OF HEALTH & HEALING (OFFICIAL) - MMS, https://genesis2church.ch/our-church (last visited Apr. 12, 2020). Genesis further explains that it employs an uncommon definition of "church" that does not involve a deity: "a church is nothing more than a group of people who have joined together for some common purpose. … Generally, all Churches are formed to serve God … that is not our purpose. We were formed to serve MANKIND directly. We want to bring health to the world." *Id.* The organization further explains, "The Genesis II Church of Health and Healing is a very loose knit organization … we believe that it is each member's private responsibility to form his or her own religious beliefs and thus we remain neutral to all the religious beliefs of our members." *Id.*

of Jason Humbert ("Humbert Decl."), attached at Ex. 2, ¶¶ 12–17, Exs. 1–3, 6–7 (describing Defendants' websites). Genesis is located at 2014 Garden Lane, Bradenton, Florida. Petty Decl. ¶ 7; *id.*, Ex. 1. Although the organization is non-religious, its leaders cloak themselves in clerical titles. Defendant Mark Grenon, a Genesis founder, dubs himself "Archbishop," *id.*, ¶ 11, Ex. 2; Humbert Decl. ¶¶ 11–12, Exs. 2–3, and MMS product labels refer to "Archbishop Mark Grenon," Humbert Decl. ¶ 12, Ex. 3. Defendant Joseph Grenon is a "Bishop" at Genesis, and he also represents himself to be a "Reverend." *Id.* ¶ 13, Ex. 5. Defendants Jordan Grenon and Jonathan Grenon also use the title of "Bishop" at Genesis, and their contact information is provided in written materials accompanying purchases of MMS. *Id.*, ¶¶ 11–13, Ex. 1–2, 5–6.

2. *When Used as Directed, Defendants' MMS is Actually a Powerful Bleach*

Defendants sell and distribute a product they call "MMS." Humbert Decl., ¶ 11, Ex. 2. MMS is also referred to as: "Miracle Mineral Solution;" "Master Mineral Solution;" "Sacramental Cleansing Water;" "MMS1;" "G2Church Sacramental;" "MMS Sodium Chlorite;" "G2Church Sacrament." Defendants also sell MMS to consumers as part of Defendants' "g2sacramentalkit2." *Id*. ¶ 8, Ex. 1; Petty Decl. Ex. 13. Defendants' MMS is comprised of 22.4% sodium chlorite ($NaClO_2$), 5% sodium chloride (NaCl, also known as table salt), 1% "trace minerals," and 71.6% purified water. *See* Humbert Decl., ¶ 11, Ex. 2. MMS is sold with an "activator" that contains 4% hydrochloric acid (HCl). *See id*. When the MMS and activator are combined as directed in the labeling, the sodium chlorite chemically reacts with the acid "activator" to yield chlorine dioxide (ClO_2), a chemical compound that is typically used as an industrial bleach.

3. *Defendants Distribute MMS Through Multiple Websites and Media*

Defendants operate the website genesis2church.ch (the "Genesis Website"), which links to multiple other websites, which, in turn, contain claims that MMS is intended to cure, mitigate, treat, or prevent COVID-19 and other diseases. *See* Humbert Decl. ¶ 17, Ex 7.; Petty Decl. ¶¶ 9–16, 19–20, Exs. 3–16, 18–20. Defendants operate the website newg2sacraments.org (the "Sales Website") from which they sell MMS. Humbert Decl. ¶ 17, Ex. 7; Petty Decl, ¶¶ 11, 16, Exs. 3,

12. The Genesis Website links to the Sales Website. Petty Decl. ¶ 11, Exs. 3, 9. Defendants also operate a news website at g2churchnews.org ("News Website") that can be accessed via a link from the Genesis Website, which, in turn, links to the Sales Website. *Id*. ¶ 13, Exs. 5, 9. In addition, Defendants operate a "G2 Radio station" on g2voice.is (the "Radio Website"), which links to the Sales Website. Humbert Decl. ¶ 17, Ex. 7; Petty Decl. ¶ 14, Exs. 7–9. The Radio Website, along with the Genesis Website and the Sales Website, are referenced in written materials provided with purchases of MMS (Humbert Decl. ¶ 11, Ex. 2), and can be accessed via a link on the Genesis Website. Petty Decl. ¶ 14, Exs. 7–9. Defendants' websites also link to Facebook and Instagram accounts. Petty Decl. ¶ 15, Exs. 10–11.

B. Defendants Sell and Distribute their MMS Products as a Treatment for COVID-19 and Other Serious Diseases

Between March 27 and April 15, 2020, Tiffany Petty, a Program Analyst in FDA's Office of Regulatory Affairs ("ORA"), Division of Enforcement, Health Fraud Branch, reviewed Defendants' websites. Petty Decl., ¶¶ 9–16, 19–21, Exs. 3–12, 14–16, 18–20. During her review, Petty observed that Defendants' websites contained claims that MMS is intended for use in curing, mitigating, treating, or preventing COVID-19, as well as other diseases including, among others, Alzheimer's, autism, brain cancer, HIV/AIDS, and multiple sclerosis. *Id.*, ¶¶ 19–21, Exs. 14–16, 18–20. She, along with her supervisor, Jason Humbert, the Director of ORA's Health Fraud Branch, collected screen shots of the webpages containing coronavirus-related and other disease claims, along with documentation of Defendants' relationship to Genesis, the Genesis Website, the News Website, the Radio Website, and the Sales Website. *See generally* Humbert Decl. and Petty Decl.

Specifically, the websites contained the following claims:

- "**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!"

Petty Decl. ¶ 19, Ex. 18.

The following additional claims were made in a video posted to the Radio Website:

- At or around 1:45 in the video, Mark Grenon says: "The Coronavirus is curable, can you believe it? You better . . ."
- At or around 17:35 in the video, 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 or around 49:57 in the video, Mark Grenon says: "The Coronavirus is curable, you believe that? You better … it's wicked good stuff Joe." Joseph Grenon replies: "MMS will kill it."

Id. ¶ 20, Ex. 14–16, 19.

Genesis also claims on its website https://mmstestimonials.co (which can be accessed via a link on the Genesis Website) that MMS treats or cures a laundry list of other serious diseases including Alzheimer's, autism, brain cancer, HIV/AIDS, and multiple sclerosis. *Id*, ¶¶ 12, 21, Exs. 4, 20. Indeed, the website explicitly states that MMS is a **proven** treatment for the scores of disorders listed: "MMS has proven to restore partial or full health to hundreds of thousands of people suffering from a wide range of diseases … when used properly [MMS] can run through the human body destroying disease pathogens and the poisons they create, while doing no harm to the

body." *Id.* Thus, according to Genesis's interrelated websites, all of which comprise MMS's labeling under the FDCA, MMS is intended for use in curing, mitigating, treating, or preventing coronavirus, which includes COVID-19, and other diseases in people. Declaration of Arthur Simone, M.D., Ph.D. ("Simone Decl."), ¶¶ 16–18.

In addition, Defendants have distributed MMS in interstate commerce via the Sales Website. Working undercover, Petty placed an order on the Sales Website for: one (1) bottle of MMS 2 oz. (Sodium Chlorite); one (1) bottle of Hydrochloric acid 2 oz.; one (1) bottle of MMS2 powder 2.5 oz.; and one (1) pack of clear capsules. Petty Decl., ¶ 16–18, Ex.12–13, 17. On March 27, 2020, she received two e-mails from the account support@newg2sacraments.org to the undercover e-mail account she used to order Defendants' MMS products. *Id.*, ¶ 17, Ex. 17. The e-mails reflect the order totaling $33.00, and the tracking information for the packages sent via the United States Postal Service. *Id.* On March 30, 2020, FDA personnel picked up the package, which was shipped from Florida, in Ashburn, Virginia. Petty Decl. ¶ 18; Humbert Decl. ¶ 11, Ex. 2.

C. FDA Provided Prior Notice to Defendants and Provided Defendants with an Opportunity to Voluntarily Comply with Federal Law

On April 8, 2020, FDA, jointly with the Federal Trade Commission ("FTC"), issued a Warning Letter (the "Warning Letter") to Defendants. *See* Humbert Decl. ¶ 18, Ex 8. The Warning Letter notified Defendants that they were violating the Act by distributing unapproved new drugs and misbranded drugs in interstate commerce, and by misbranding drugs while they were held for sale after shipment of one or more components in interstate commerce—the same violations alleged in this action. *Id.*

The Warning Letter also 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 Warning Letter. *Id.* FDA further warned Defendants that failure to correct the violations within 48 hours of issuance of the Warning Letter may result in legal action, including, without limitation, seizure and injunction. *Id.* 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." *Id.*

D. Defendants Responded to the Government's Warning with Categorical Defiance

On April 9, 2020, Genesis published a response to the Warning Letter, attributed to Defendant Mark Grenon (as "Head Bishop"), on its News Website. Among other things, Genesis's statement included the following:

- "The letter below I received yesterday April 8th, 2020. I immediately prayed and the Lord told me to write back right away to stop this horrible attack from two 'agencies' that are full of corrupt evil players in the decision making positions that effect [sic] many people's lives daily in commerce."

- "Now, they have gone too far! They are attacking a Church Sacrament. This is something that is 'sacred' or 'holy' to us as a Church. Folks, this is THE time to fight and NOT back down and let the whole world know what is happening! You've seen in the last months how the world has changed in regard to control over our lives health wise! The 'virus' has NOT even been identified!"

The website also included a call to action to the organization's members, imploring them to send emails to FDA, FTC, as well as the President. *See* Humbert Decl. ¶ 18, Ex 9.

Shortly after this posting on the Genesis website, on April 9, 2020, FDA received a written response to the Warning Letter from Genesis. *See* Humbert Decl. ¶ 18, Ex 10. Genesis's written response largely duplicated the response on its website and makes clear that Defendants intend to continue to flout federal law. Genesis repeatedly told FDA in its response that it does not believe it is subject to federal law and that the FDCA is "not applicable" to it:

- "[w]e 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?"

- "We can say cure, heal and treat as a Free Church. Don't need you [sic] approval or authorization …"

The response explicitly stated that Genesis plans to continue its recalcitrance in the future:

- "There will be NO corrective actions on our part … You have no authority over us!
- "There will be NO delay [in completing corrective action] because 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!

As of the date of this filing, Defendants have not taken down the Sales Website or the claims that render MMS an unapproved new drug and misbranded drug.

II. ARGUMENT

A. To Obtain Injunctive Relief, the Government Need Only Show That Defendants Violate the Act

Congress enacted the FDCA to protect the American public from "deleterious, adulterated, and misbranded articles" reaching consumers through interstate commerce, *United States v. Walsh*, 331 U.S. 432, 434 (1947); in other words, Congress sought to protect the public from those "products not proven to be safe and effective for their alleged uses[.]" *United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 27–28 (2d Cir. 1972). To that end, Congress empowered federal courts to restrain and enjoin entities and individuals from distributing unapproved new drugs and misbranded drugs and misbranding drugs after shipment of components or finished product in interstate commerce. *See* 21 U.S.C. § 332(a) (authorizing injunctions to restrain violations of 21 U.S.C. § 331(a), (d), and (k)).

Because the FDCA specifically authorizes injunctive relief to enforce Congressional policy, courts use a different injunction standard than is used in private litigation. Specifically, the Supreme Court has held that, unlike a private plaintiff, to obtain an injunction authorized by statute, the government need not show that irreparable harm will result. *United States v. City and County of San Francisco*, 310 U.S. 16, 31 (1940). This is because when it enacted the FDCA, Congress

made "an implied finding that violations will harm the public and ought, if necessary, be restrained." *Diapulse,* 457 F.2d at 28. The Eleventh Circuit Court of Appeals agrees: "Where … an injunction is authorized by statute and the statutory conditions are satisfied … the usual prerequisite of irreparable injury need not be established and the agency to whom the enforcement of the right has been entrusted is not required to show irreparable injury before obtaining an injunction." *Gresham v. Windrush Partners, Ltd.*, 730 F.2d 1417, 1423 (11th Cir. 1984) (quoting *United States v. Hayes Int'l Corp.*, 415 F.2d 1038, 1045 (5th Cir. 1969)). Instead, the government must show only that the defendants have violated the statute and there is some "cognizable danger of recurrent violations" to obtain a statutory injunction. *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *United States v. US Stem Cell Clinic, LLC*, 403 F. Supp. 3d 1279, 1300 (S.D. Fla. 2019) ("FDA need not show that it would suffer irreparable harm if the injunction were not granted."); *United States v. Sene X Eleemosynary Corp.*, 479 F. Supp. 970, 981 (S.D. Fla. 1979) (irreparable harm is presumed).

As this Court has previously observed, "[p]ast behavior is a reliable predictor of future behavior, and injunctive relief is particularly appropriate where a defendant has persisted in violating the law, despite repeated warnings." *United States v. Flu Fighter Corp.*, No-0561940-CIV, 2009 WL 10668958, at *7 (S.D. Fla. Feb. 11, 2009); *see also United States v. Lit Drug Co.*, 333 F. Supp. 990, 999 (D.N.J. 1971) ("The law is also clear that a court must effectively safeguard the public interest against the abuses inflicted by a willful, persistent violator of regulatory legislation who has not shown good faith in compliance."). Here, not only have Defendants persisted in their unlawful conduct after being warned by authorities, but in response to that warning, they have explicitly and unambiguously declared their intention to persist in such violations. There is little doubt, therefore, that there is as at least a "cognizable danger of recurrent violation" necessary for the issuance of the injunction.

There is no difference between temporary restraining orders and preliminary injunctions in the Court's analysis; the standard for obtaining each is the same. *See, e.g., Federal Trade Commission v. Arlington Press, Inc.*, No. 98CV9260, 1999 WL 33562452 at *8 (C.D. Cal. Jan. 18,

1999) (discussing same standard for temporary restraining order or preliminary injunction under Federal Trade Commission Act and noting that "irreparable harm" is presumed under statute); *cf. Morgan Stanley DW, Inc. v. Frisby*, 163 F. Supp. 2d 1371, 1374 (N.D. Ga. 2001) (noting preliminary injunction standard also applies to temporary restraining order); *accord Perdomo v. HSBC Bank USA*, No. 13-22645-CIV, 2013 WL 12101097, at *1 (S.D. Fla. Nov. 13, 2013).

B. Defendants Violate the FDCA

Defendants' MMS Product is a Drug

Under the FDCA, Defendants' MMS is a "drug." *See* 21 U.S.C. § 321(g)(1)(B) (defining "drug" to include products that are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man"). MMS is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of such human diseases as COVID-19, Alzheimer's, autism, brain cancer, HIV/AIDS, multiple sclerosis, and the litany of other diseases listed on Defendants' website. Under the FDCA, the intended use of Defendants MMS may be determined from any relevant source, including product labels, labeling, and circumstances surrounding the distribution of the product. *See United States v. Livdahl*, 459 F. Supp. 2d, 1255, 1260 (S.D. Fla. 2005); *United States v. An Article … Sudden Change*, 409 F.2d 734, 739 (2d Cir. 1969); *see also* 21 C.F.R. § 201.128.

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). "Label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article . . . ." *Id.* § 321(k). If information regarding a drug is provided as part of an integrated distribution system and explains the uses of the drug, that matter "accompanies" the drug and is "labeling;" "[n]o physical attachment one to another is necessary." *Kordel v. United States*, 335 U.S. 345, 350 (1948).

Here, although Defendants' intended use claims are not "physically attached" to their MMS product, Defendants' claims on their websites are labeling under the FDCA and *Kordel* and its

progeny,[2] because they explain MMS's intended uses. Defendants' labeling—including their network of websites—demonstrates that their MMS product is intended for use in curing, mitigating, treating, and/or preventing coronavirus, which includes COVID-19, and a host of other serious medical disorders and diseases. *See* Petty Decl., ¶¶ 19–21; Exs. 14–16, 18–20; Simone Decl., ¶¶ 16–17. As a result, Defendants' MMS is a drug. Simone Decl., ¶ 18.

C. Defendants Distribute an Unapproved "New Drug" in Interstate Commerce Violation of 21 U.S.C. § 331(d)

Under the FDCA, a drug is a "new drug" if 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 use under the condition prescribed, recommended, or suggested in the labeling thereof[.]" 21 U.S.C. § 321(p)(1). A drug is only "generally recognized as safe and effective" ("GRASE"), if there is substantial evidence of its safety and effectiveness. 21 U.S.C. § 355(d); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629 (1973) ("[T]he hurdle of 'general recognition' of effectiveness requires at least 'substantial evidence' of effectiveness for approval of an NDA."). The FDCA prohibits the introduction or delivery for introduction into interstate commerce of an unapproved new drug. 21 U.S.C. § 331(d); 355(a).

FDA has conducted comprehensive searches of publicly available medical and scientific literature for Defendants' MMS and did not identify any published adequate and well-controlled studies demonstrating that MMS is GRASE for any of its intended uses, including for coronavirus, which includes COVID-19. Simone Decl., ¶¶ 22, 29; Exs. 2–5 (detailing searches). There are no adequate and well-controlled studies for MMS to treat any disease; the drug lacks substantial evidence of its effectiveness; and there is no consensus of opinion among qualified experts

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[2] *See United States v. Urbuteit*, 335 U.S. 355, 357–58 (1948); *United States v. Lane Labs USA Inc.*, 427 F.3d 219, 223 (3d Cir. 2005); *United States v. Guardian Chem. Corp.*, 410 F.2d 157, 160–61 (2d Cir. 1969); *United States v. Innovative Biodefense, Inc.*, No. SACV180996DOCJDEX, 2019 WL 2428670, at *3 (C.D. Cal. Feb. 22, 2019); *United States v. BioAnue Labs., Inc.*, No. 5:13-CV-188, 2014 WL 3696662, at *5–6 (M.D. Ga. July 23, 2014); *United States v. Berst*, No. 6:11-CV-6370-TC, 2012 WL 4361408, at *4 (D. Or. Aug. 2, 2012)

concerning its effectiveness. *Id.* ¶ 22. As a result, MMS is not GRASE for its intended uses and is, accordingly, a "new drug" under 21 U.S.C. § 321(p). *See United States v. Loran Med. Sys., Inc.*, 25 F. Supp. 2d 1082, 1087 (C.D. Cal. 1997) (citing *United States v. Articles of Drug (Promise Toothpaste)*, 826 F.2d 564, 569 (7th Cir. 1987)); *see also* Simone Decl., ¶ 29.

After conducting a search of its records for any new drug applications ("NDA"), abbreviated new drug applications ("ANDA"), and investigational new drug applications ("INDs") by Defendants for MMS, FDA determined that Defendants have no such FDA approvals or authorizations. Simone Decl., ¶¶ 32–34. Accordingly, Defendants' MMS is an unapproved new drug within the meaning of 21 U.S.C. § 355(a). *See id.* ¶ 35.

Defendants introduce unapproved new drugs into interstate commerce. Personnel from FDA's Office of Regulatory Affairs's ("ORA") Health Fraud Branch purchased Defendants' MMS product from the Sales Website, and FDA documented that Defendants shipped their MMS product from Florida to Virginia, on or about March 27, 2020. *See* Petty Decl., ¶¶ 16–18; Humbert Decl., ¶¶ 9–11. Such shipment constitutes introduction or delivery for introduction into interstate commerce of an unapproved new drug, in violation of 21 U.S.C. § 331(d).

D. Defendants Distribute Misbranded Drugs in Interstate Commerce in violation of 21 U.S.C. § 331(a)

The Act prohibits introducing or delivering for introduction into interstate commerce misbranded drugs, or the causing thereof. 21 U.S.C. § 331(a). Defendants' MMS is misbranded in at least two different ways, either of which are sufficient to establish a violation of the Act. First, Defendants' MMS is misbranded because its labeling is false and misleading. *See* 21 U.S.C. § 352(a). Also (and separately), Defendant's MMS is misbranded because its labeling fails to bear adequate directions for use. *See* 21 U.S.C. § 352(f)(1). Distributing (or causing the distribution of) misbranded drugs in interstate commerce is prohibited by the FDCA. *See* 21 U.S.C. § 331(a).

1. *Defendants' Drug is Misbranded Because Its Labeling is False and Misleading*

Defendants' labeling for MMS is false and misleading, which causes their MMS products to be misbranded. *See* 21 U.S.C. § 352(a) ("A drug or device shall be deemed to be misbranded … [i]f its labeling is false or misleading in any particular."). Misbranding under 21 U.S.C. § 352(a)(1) requires proof of two elements: (1) a representation in the labeling of the product; and (2) the false or misleading nature of that representation. *United States v. Torigian Labs.*, Inc., 577 F. Supp. 1514, 1525 (E.D.N.Y. 1984), *aff'd*, 754 F.2d 373 (2d Cir. 1984). In determining whether labeling is misleading, not only are representations made or suggested in the labeling taken into account, but also the extent to which the labeling fails to reveal material facts. 21 U.S.C. § 321(n). A curative claim that has little or no expert scientific support is a material fact which, if not revealed, causes a product to be misbranded. H.R. REP. No. 75-2139 (1938); *see generally United States v. Hiland*, 909 F.2d 1114 (8th Cir. 1990) (upholding convictions for false and misleading labeling where defendants made curative claims in labeling despite knowledge that no testing had been done to establish safety or efficacy for such use).

Moreover, a demonstration that a labeling claim is either false or misleading is sufficient to establish misbranding under the Act. *United States v. One Device … The Ellis Micro-Dynameter,* 224 S. Supp. 265, 268 (E.D. Pa. 1963). Only one false or misleading claim need be proven to establish misbranding under 21 U.S.C. § 352(a). *United States v. One Device … Colonic Irrigator*, 160 F.2d 194, 200 (10th Cir. 1947); *Sene X Eleemosynary*, 479 F. Supp. at 980. The labeling is to be evaluated from the point of view of those to whom the literature is addressed, namely "prospective purchasers and actual customers … who cannot be presumed to have special expertness or to be unduly cautious, but who are more likely than not to be persons who are pathetically eager to find some simple cure-all for the diseases with which they are afflicted … ." *V.E. Irons Inc. v. United States*, 244 F.2d 34, 39–40 (1st Cir. 1957).

The curative claims Defendants make in MMS's labeling are false and misleading because they falsely claim that MMS can effectively treat a veritable kitchen sink of serious medical

diseases from autism to multiple sclerosis. And now, while the nation is in the grips of the most serious public health emergency since the Spanish Flu of 1918, Defendants have added coronavirus, which includes COVID-19, to their list of diseases. There are no adequate and well-controlled studies—i.e., no scientific evidence—that MMS can safely or effectively treat COVID-19 or *any* disease. Simone Decl. ¶ 29. Consequently, Defendants' false or misleading curative claims in their labeling causes their MMS to be misbranded under 21 U.S.C. § 352(a)(1).

2. *Defendants' Drug is Misbranded Because It Fails to Bear Adequate Directions for Use*

Under 21 U.S.C. § 352(f)(1), a drug is deemed to be misbranded unless its labeling bears adequate directions for use; that is, "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; *United States v. Articles of Drug … Rucker*, 625 F.2d 665, 671–75 (5th Cir. 1980). If it is a prescription drug however, it is not lawfully possible to create adequate directions for lay use. *See* 21 U.S.C. § 353(b)(1)(A); *see also United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1323–25 (D.C. Cir. 2014); *United States v. Evers*, 643 F.2d 1043, 1050–51 (5th Cir. 1981). 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).

Defendants' MMS is a prescription drug because it is intended for curing, mitigating, treating, or preventing COVID-19, as well as other diseases including, but limited to, Alzheimer's, autism, brain cancer, HIV/AIDS, and multiple sclerosis—all diseases that require diagnosis and management by a physician. Simone Decl., ¶ 37. Consequently, there are no adequate directions under which a layman can safely use MMS, because it is not safe for use except under the supervision of a physician. *See, e.g.*, 21 U.S.C. § 353(b)(1)(A); *Regenerative Scis.*, 741 F.3d at 1323–25. Because Defendants' MMS product does not bear adequate directions for its use—indeed, it bears inadequate directions to treat *any* disease, including COVID-19— it is misbranded

under 21 U.S.C. § 352(f)(1); *Articles of Drug … Rucker*, 625 F.2d at 675; *United States v. Premo Pharm. Labs., Inc.*, 511 F. Supp. 958, 977 n.23 (D.N.J. 1981) ("A drug is misbranded if it is a prescription drug that is an unapproved new drug, because a prescription drug cannot bear the adequate directions for use required by statute... and the lack of an approved NDA means that there is no FDA exemption from the adequate directions for use requirement.") (citations omitted).[3]

3. *Defendants Introduce Their Misbranded Drugs Into Interstate Commerce*

The Act prohibits the introduction or delivery for introduction into interstate commerce of misbranded drugs, or the causing of such introduction or delivery. 21 U.S.C. § 331(a). By shipping MMS, a misbranded drug, from Florida to Virginia, on or about March 27, 2020, Defendants violated 21 U.S.C. § 331(a). *See* § III.C.2, *supra*.

E. Defendants Cause MMS to Become Misbranded While Held for Sale After Shipment in Interstate Commerce in Violation of 21 U.S.C. § 331(k)

The Act prohibits doing an act that causes a drug to become misbranded while such product is held for sale after its shipment, or shipment of its components, in interstate commerce. 21 U.S.C. § 331(k). A product is "held for sale" under section 331(k) if it is used for any purpose other than personal consumption. *United States v. Evers*, 643 F.2d 1043, 1050 (5th Cir. 1981); *see also Torigian Labs.* 577 F. Supp. at 1521; *United States v. Articles of Drug … Hydralazine HCL*, 568 F. Supp. 29, 31 (D.N.J. 1983); *see Diapulse*, 514 F.2d at 1098; *see also United States v. Sullivan*, 332 U.S. 689, 697 (1948) (section 331(k) intended to "extend [FDCA's] coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer").

"[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," 21 U.S.C. § 379a. Defendants' MMS, therefore, is "held for sale … after shipment in interstate

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[3] Although the Act allows for certain exemptions from the adequate directions for use requirement, because Defendants' MMS is a prescription drug, it cannot qualify for such an exemption. 21 C.F.R. §§ 201.100(c)(1), 201.115; *see Rucker*, 625 F.2d at 671–75.

commerce" within the meaning of 21 U.S.C. § 331(k), because Defendants are not the ultimate consumers of the product.

Accordingly, Defendants violate 21 U.S.C. § 331(k) by causing MMS to be misbranded, by offering it for the prevention of diseases with labeling that is false and misleading and fails to bear adequate directions for use, while the MMS is held for sale after shipment of one or more of its components in interstate commerce.

F. Unless Enjoined, Defendants Will Continue to Unlawfully Expose Consumers to Health Risks with their Unapproved New Drug and Misbranded Drug

Defendants have clearly demonstrated their intent to continue to violate the law. In the face of the joint FDA and Federal Trade Commission April 8, 2020, Warning Letter,[4] Defendants claimed that they were going to "fight and NOT back down ... !" *See* § I.D., *supra*. Defendants defiantly rejected FDA's requests for corrective action and professed their intent to continue their violative conduct. Defendants' explicit statements make clear that they will not conform their conduct to the law; there is more than ample basis to expect that, absent this Court's intervention, Defendants' illegal distribution of MMS will continue unabated.

Moreover, Defendants' continued distribution of MMS into interstate commerce poses a risk to consumers' health. MMS is actually chlorine dioxide, a powerful bleach. FDA has received multiple reports of consumers experiencing serious adverse events after drinking chlorine dioxide products, including respiratory failure, cardiac disturbances, life-threatening hypotension, acute liver failure, hemolytic anemia, severe vomiting, and severe diarrhea. *See* Press Release, FDA, *Coronavirus (COVID-19) Update: FDA Warns Seller Marketing Dangerous Chlorine Dioxide Products that Claim to Treat or Prevent COVID-19* (Apr. 8, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-warns-seller-marketing-dangerous-chlorine-dioxide-products-claim. Not only are consumers at risk of these adverse

[4] The Warning Letter was not issued to Defendant Jonathan Grenon specifically, but it was issued to Genesis's email address and subsequently posted on the News Website. As a Bishop at Genesis, Jonathan Grenon is on notice regarding the Warning Letter.

consequences from consuming MMS, but they are also at risk by forgoing appropriate medical care and preventative measures, including for diseases such as Alzheimer's, brain cancer, HIV/AIDS, multiple sclerosis, and COVID-19. Defendants' conduct, especially during the current national emergency and pandemic, presents a clear danger to public health and safety. *See* Simone Decl., ¶¶ 26–28.

Immediate injunctive relief is necessary and proper in this matter. With its motion, the United States has attached a Proposed Temporary Restraining Order providing that Defendants are restrained and enjoined from labeling, holding, and/or distributing any drug, including but not limited to its MMS product, unless and until either: (1) Defendants have an FDA-approved NDA or ANDA, or effective IND for such drug; or (2) Defendants come into compliance with the FDCA to FDA's satisfaction.

Finally, the United States further requests that: (1) Defendants be restrained from disposing of or transferring any assets that might interfere with implementation of restitution payments to consumers in the event the Court orders such restitution; and (2) Defendants be ordered to preserve documents and records that may be relevant to the United States' claims.

CONCLUSION

Under the FDCA and the inherent equitable authority of the Court and to protect the public health from Defendants' violations, Plaintiff respectfully requests that this Court grant a temporary restraining order and a preliminary injunction in favor the United States. A Proposed Temporary Restraining Order is attached.

Dated: April 16, 2020

Respectfully submitted,

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CERTIFICATION UNDER FED. R. CIV. P. 65(b)(1)

Pursuant to Rule 65(b)(1), undersigned counsel hereby certifies and declares that the United States of America's Complaint for Preliminary and Permanent Injunction and United States' *Ex Parte* Motion for Temporary Restraining Order and Preliminary Injunction and Supporting Memorandum of Law will be transmitted by email today to Defendants at the following email addresses:

- contact@genesis2church.is
- mark@genesis2church.is
- jordan@genesis2church.is
- joseph@genesis2church.is
- jonathan@genesis2church.is

and that physical copies of these papers, together with the supporting declarations and exhibits, will be delivered by overnight mail to Defendants at Defendants' last known address of: 2014 Garden Lane, Bradenton, Florida 34205.

The President of the United States has declared that the current COVID-19 pandemic constitutes a national emergency. I am informed and believe that the conduct of Defendants with regard to the distribution of their misbranded drug, MMS, as a treatment for coronavirus infection represents an existing and ongoing serious danger to public health. I am further informed and believe, especially given the existence of the declared national public health emergency, that immediate and irreparable injury to public health may result before Defendants can be heard in opposition to this Motion.

Given the urgent nature of this action and the immediate and continuing irreparable harm at issue, the United States requests immediate *ex parte* relief until such time as Defendants may reasonably be afforded an opportunity to be heard.

Under 28 U.S.C. § 1746, I certify under penalty of perjury that the foregoing Certification is true and correct.

Executed on this 16th day of April, 2020.

Matthew J. Feeley
MATTHEW J. FEELEY
Assistant United States Attorney