IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

UNITED STATES OF AMERICA,
Plaintiff,

v.

MYNICNAXS, LLC, a limited liability company, and CHEVONNE TORRES and MICHAEL BANNER, individuals,

Defendants.

Civil No. 6:18-CV-389-ORL-28-GJK

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 332(a), to permanently enjoin and restrain MyNicNaxs, LLC, Chevonne Torres, and Michael Banner (collectively, "Defendants") from:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved under 21 U.S.C. § 355 (b) or (j), nor exempt from approval under 21 U.S.C. § 355(i);

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

C. Violating 21 U.S.C. § 331(c), by receiving in interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(a), 352(f)(1), and 352(j), and delivering or proffering for delivery such drugs for pay or otherwise.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a), 28 U.S.C. §§ 1331, 1337, and 1345, and its inherent equitable authority.

3. Venue in this District is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant MyNicNaxs, LLC ("MyNicNaxs") is a Florida limited liability company and operates from 1012 Alpine Drive, Deltona, Florida 32725 ("Defendants' facility"), within the jurisdiction of this Court. The company has also distributed and/or received its products from the following addresses: (1) P.O. Box 4214, Enterprise, Florida 32725. and (2) 1062 Abagail Drive, Deltona, Florida 32725, both within the jurisdiction of this Court.

5. Defendant Chevonne Torres is the owner of MyNicNaxs. Ms. Torres receives and ships products, manages the company's website and social media platforms, and responds to customer orders and questions. She performs her duties at 1012 Alpine Drive, Deltona, Florida 32725, within the jurisdiction of this Court.

6. Defendant Michael Banner is an officer at MyNicNaxs. Mr. Banner also receives products, helps manage the company's website, and responds to customer questions. He performs his duties at 1012 Alpine Drive, Deltona, Florida 32725, within the jurisdiction of this Court.

LEGAL FRAMEWORK

Unapproved New Drugs

7. A product is a drug within the meaning of the Act if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," or "intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(B), (C).

8. The intended use of a product may be determined from any relevant source, including the product's labeling. *See* 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). The term "accompanying" in the second clause of 21 U.S.C. § 321(m) is not restricted to labels that are on or in the article at issue; physical attachment to the article is not necessary. *See Kordel v. United States*, 335 U.S. 345, 349-50 (1948). It is the textual relationship and integrated nature of the transaction that is significant. *See id.* at 350.

9. A "new drug" is defined as any drug "the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1).

10. For a product to be deemed "generally recognized as safe and effective" ("GRAS/E"), (1) the drug must have substantial evidence of effectiveness as demonstrated through adequate and well-controlled 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.

11. The U.S. Food and Drug Administration ("FDA") has established and published regulations, called "monographs," that describe certain categories of over-the-counter ("OTC") drugs. OTC drugs manufactured and labeled in strict conformance with final monographs are deemed to be GRAS/E, 21 C.F.R. § 330.1, and can be marketed without FDA's premarket approval. Drugs that do not strictly conform to each of the conditions contained in an applicable final monograph, however, are subject to the new drug provisions of the Act. *See* 21 C.F.R. § 330.10(b).

12. A "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. §§ 331(d), 355(a), (b), (i), and (j).

Misbranded Drugs

13. The Act, 21 U.S.C. § 352, sets forth circumstances in which a drug is deemed to be misbranded. A drug is misbranded, for example, if its "labeling is false or misleading in any particular." 21 U.S.C. § 352(a). "[I]n determining whether the labeling . . . is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling . . . fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling." 21 U.S.C. § 321(n).

14. A drug is misbranded within the meaning of 21 U.S.C. § 352(j), if "it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

15. A drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1), if its labeling fails to bear "adequate directions for use" and the drug does not fall within a regulatory exemption to this requirement. Under 21 C.F.R. § 201.5, "adequate directions for use" are defined as "directions under which the layman can use a drug safely and for the purpose for which it is intended." Unapproved new drugs are not exempt from the requirement for adequate directions for use. *See* 21 C.F.R. §§ 201.100(c)(2), 201.115.

16. The introduction or delivery of misbranded drugs, or causing the introduction or delivery, into interstate commerce violates the Act. 21 U.S.C. § 331(a).

17. The receipt in interstate commerce of misbranded drugs and the delivery or proffered delivery of such drugs for pay or otherwise also violates the Act. 21 U.S.C. § 331(c).

FACTUAL BACKGROUND

18. Defendants sell weight loss and sexual enhancement drugs in interstate commerce directly to consumers through their websites, www.mynicnaxs.com and www.ruglamourous.com.

19. The following of Defendants' products are drugs under the Act because they are "intended to cure, mitigate, treat or prevent disease." 21 U.S.C. § 321(g)(1)(B).

	Product	Disease Claim	Citation
a.	African Superman (also known as African Superstud)	"[I]mproves the kidney function, splves [*sic*] impotence"	Product label

	Product	Disease Claim	Citation
b.	Ginseng For Reinforcing Kidney	"Applicable group: ED [erectile dysfunction] . . . myasthenia of limbs . . . prostatitis and other caused by kidney deficiency"	Product label
c.	African Viagra (also known as USA African V)	"[R]emedy for problems such as sexual dysfunction"	Website
d.	Purists Choice Colon Cleanse	"Fennel . . . limits cholesterol build-up" "Buck thorn . . . has also been used to treat gallstones and intestinal parasites" "Pomegranate extract . . . inhibits abnormal cell growth" "Golden seal . . . has been used to treat respiratory, digestive and genitourinary tract inflammation" "Ginger root . . . can lower blood pressure" "Apple Fiber . . . is beneficial for constipation, heart disease and high cholesterol"	Website
e.	Advanced Super Colon Cleanse 1800 Strength	"Licorice extracts . . . cures gastritis, breathing diseases, ulcers"	Website
f.	Garcinia Cambogia Extract – NEW 2016	"[R]educing blood lipids levels and lowering cholesterol and in turn offering support for cardiovascular health"	Website
g.	Garcinia Cambogia 1300 or 3000		
h.	Green Coffee Bean Extract 800 mg	"Chlorogenic acid has also been shown beneficial for treating hypertension. . . . [I]nhibits oxidation of the low-density lipoprotein (LDL) . . . that can damage the arteries and accelerate atherosclerosis. Limiting this process is thought to help prevent cardiovascular disease. . . . A number of population studies identified Chlorogenic acid users as being substantially less likely to get Type 2 diabetes"	Website
i.	Green Coffee Bean & Garcinia Cambogia 1300 (combo pack)		
j.	Raspberry Ketone Lean	"Fight and prevent disease and obesity"	Website
k.	Raspberry Ketone Lean & Super African Mango 1200 (combo pack)		
l.	Body Beauty Slimming Capsules – 2015	"Theophylline . . . relaxes smooth muscles of the bronchi and used to treat asthma"	Website

	Product	Disease Claim	Citation
m.	New 2 Day Diet - COCOA Polyphenols	"Poly phenol which . . . has been shown to lower the risk of cancer and heart diseases"	Website
n.	Vitalize Pro 3000 Hair Growth and Anti Loss Capsules	"[H]elping both men and women suffering from hair growth disorders"	Website
o.	Tyrannosaurus Sex Pill	"[U]sed for men with sexual dysfunction such as low libido, premature ejaculation and erectile problems"	Website
p.	Moneysteel Sex Pill Supplement	"Help[s] with erectile dysfunction"	Website
q.	Enjoy Your Time Sex Pills	"Whether or not you suffer from erectile dysfunction ENJOY sex capsules work together to increase the blood flow during arousal, promoting a firmer and more sustained erection"	Website

20. Additionally, the following of Defendants' products are drugs under the Act because they are "intended to affect the structure or function of the body." 21 U.S.C. § 321(g)(1)(C).

	Product	Structure/Function Claim	Citation
a.	Old Chinese	"[M]akes the penis erect more quickly while shortening the interval for a second intercourse and reduce fatigue"	Website
b.	Lean Extreme Max	"Promotes Weight Loss. Boosts Energy. Helps Burn Fat . . . [I]ncreas[es] your metabolism with little or no side effects"	Product label
c.	X-treme Beauty Slim	"Increasing rate of metabolism up to 18 times. Quick effect & Fast weight lose [*sic*] from the first capsule"	Product label
d.	Platinum Max Strength Blue Pill	"The active ingredient tightens Muscles and Boosts Serotonin levels"	Product label
e.	Slimming Plus Advanced Weight Loss	"Restrain the appetite naturally . . . can help reduce sugar cravings"	Product label

	Product	Structure/Function Claim	Citation
f.	Platinum Weight Loss Solution	"Koncing Nut . . . breaks down accumulated fat in the body and increases the body's natural ability to burn fat. Konjac is a fat fighter and helps decompose fat immediately. Apple and Kiwi can inhibit the body's ability to produce fat"	Product label

21. In December 2016, FDA tested several of Defendants' products and detected the following undeclared active pharmaceutical ingredients:

	Product	Undeclared Active Pharmaceutical Ingredient(s)	Average Amount of Active Pharmaceutical Ingredient
a.	African Superman (also known as African Superstud)	Sildenafil	30.7 mg per tablet
b.	African Viagra (also known as USA African V)	Sildenafil	0.24 mg per capsule
c.	Ginseng For Reinforcing Kidney	Sildenafil	17.8 mg per tablet
d.	Old Chinese	Sildenafil	44.4 mg per capsule
e.	Lean Extreme Max	Sibutramine	10.0 mg per capsule
f.	X-treme Beauty Slim	Sibutramine	18.8 mg per capsule
g.	Platinum Weight Loss Solution	Sibutramine Phenolphthalein	12.39 mg per capsule 30.59 mg per capsule
h.	Platinum Maximum Strength Blue Pill Version	Sibutramine Phenolphthalein	14.10 mg per capsule 28.87 mg per capsule
i.	Slimming Plus Advanced Formula	Sibutramine Phenolphthalein	15.26 mg per capsule 29.89 mg per capsule

22. Sildenafil is a phosphodiesterase type-5 ("PDE-5") inhibitor and the active pharmaceutical ingredient in Viagra, an FDA-approved prescription drug for the treatment of erectile dysfunction. The use of PDE-5 inhibitors may pose serious health risks to consumers with underlying medical issues, such as heart disease and high blood pressure.

23. Sibutramine is the active pharmaceutical ingredient in Meridia, an FDA-approved prescription drug for the treatment of obesity. In 2010, following FDA's request, the manufacturer of Meridia voluntarily removed the drug from the U.S. market because the drug was associated with an increased risk of serious adverse cardiovascular events, including heart attack and stroke.

24. Phenolphthalein was an ingredient in some over-the-counter laxative drugs until it was re-classified by FDA as "not generally recognized as safe and effective" after studies indicated it posed a potential carcinogenic risk. *See* 21 C.F.R. § 310.545(a)(12)(iv)(B); 64 Fed. Reg. 4535 (Jan. 29, 1999), 62 Fed. Reg. 46,223 (Sept. 2, 1997).

25. Although some of the products listed in Paragraph 21 purport to be dietary supplements, none of them meet the definition of dietary supplement in 21 U.S.C. § 321(ff), because they each contain an article that is "approved as a new drug under [21 U.S.C. § 355]" or "authorized for investigation as a new drug . . . for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public," if the article "was not before such approval . . . or authorization marketed as a dietary supplement or as a food." 21 U.S.C. § 321(ff)(3).

26. As described in Paragraph 21, FDA conducted laboratory analyses and determined that Old Chinese contains sildenafil. FDA approved the new drug application for Viagra (sildenafil) in March 1998. Sildenafil was not marketed as a dietary supplement or as a food before FDA's approval of Viagra. Therefore, under 21 U.S.C. § 321(ff)(3)(B)(i), Old Chinese is excluded from the dietary supplement definition.

27. As described in Paragraph 21, FDA conducted laboratory analyses and determined that Lean Extreme Max, X-treme Beauty Slim, Platinum Weight Loss Solution,

Platinum Maximum Strength Blue Pill Version, and Slimming Plus Advanced Formula contain sibutramine. FDA authorized Meridia (sibutramine) for investigation as a new drug under an investigational new drug application in January 1986, and clinical investigations were instituted thereafter. The existence of substantial clinical investigations of sibutramine became public no later than Meridia's FDA-approval date in 1997. Sibutramine was not marketed as a dietary supplement or as a food before Meridia was authorized for investigation as a new drug in January 1986. Therefore, under 21 U.S.C. § 321(ff)(3)(B)(ii), Lean Extreme Max, X-treme Beauty Slim, Platinum Weight Loss Solution, Platinum Maximum Strength Blue Pill Version, and Slimming Plus Advanced Formula are excluded from the dietary supplement definition.

DEFENDANTS DISTRIBUTE UNAPPROVED NEW DRUGS

28. Defendants violate 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval under 21 U.S.C. § 355(i).

29. FDA searched the literature and found no adequate and well-controlled studies demonstrating substantial evidence of safety and effectiveness for the drugs listed in Paragraphs 19 and 20. These drugs are, therefore, "new drugs" within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized among qualified experts as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

30. The drugs listed in Paragraphs 19 and 20 do not conform to any OTC drug monograph.

31. FDA searched its records and determined that Defendants do not have approved NDAs, ANDAs, or effective INDs for the drugs listed in Paragraphs 19 and 20.

32. Accordingly, Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce unapproved new drugs.

DEFENDANTS RECEIVE AND DISTRIBUTE MISBRANDED DRUGS

Certain of Defendants' Drugs Are Misbranded Because Their Labeling Is False and Misleading

33. A drug is misbranded if its "labeling is false or misleading in any particular." 21 U.S.C. § 352(a).

34. Defendants' drugs are misbranded because their labeling is false and misleading in that they do not declare certain active pharmaceutical ingredients or reveal the consequences that may result from using products containing those active pharmaceutical ingredients. Specifically, as described in Paragraph 21, certain of Defendants' drugs do not declare that they contain sildenafil, sibutramine, and/or phenolphthalein.

35. Accordingly, drugs listed in in Paragraph 21 are misbranded within the meaning of 21 U.S.C. § 352(a).

Certain of Defendants' Drugs Are Misbranded Because They Are Dangerous to Health As Labeled

36. A drug is misbranded within the meaning of 21 U.S.C. § 352(j), if "it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

37. Sibutramine is no longer on the market because of the increased risk in cardiovascular events. Defendants' sibutramine-containing products—Lean Extreme Max, X-treme Beauty Slim, Platinum Weight Loss Solution, Platinum Maximum Strength Blue Pill Version, and Slimming Plus Advanced Formula—are therefore dangerous to health when used as prescribed, recommended, or suggested in their labeling, and are misbranded within the meaning of 21 U.S.C. § 352(j).

38. Phenolphthalein is no longer on the market because of its potential carcinogenic risk. Defendants' phenolphthalein-containing products—Platinum Weight Loss Solution, Platinum Maximum Strength Blue Pill Version, and Slimming Plus Advanced Formula—are therefore dangerous to health when used as prescribed, recommended, or suggested in their labeling, and are misbranded within the meaning of 21 U.S.C. § 352(j).

39. Accordingly, African Superman, Ginseng For Reinforcing Kidney, Old Chinese, Lean Extreme Max, X-treme Beauty Slim, Platinum Weight Loss Solution, Platinum Maximum Strength Blue Pill Version, and Slimming Plus Advanced Formula are misbranded within the meaning of 21 U.S.C. § 352(j).

Defendants' Drugs Are Misbranded Because
Their Labeling Fails to Bear Adequate Directions for Use

40. A drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1), if its labeling fails to bear "adequate directions for use" and the drug does not fall within a regulatory exemption to that requirement.

41. By definition, the labeling for a drug that is a prescription drug cannot bear adequate instructions for lay use. 21 U.S.C. § 353(b)(1)(A) (requiring a drug to be dispensed by prescription that, "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 C.F.R. § 201.5 (defining "adequate directions for use" as "directions under which the layman can use a drug safely and for the purpose for which it is intended").

42. The drugs listed in Paragraph 19 are prescription drugs because medical expertise and special clinical assessments are needed to diagnose and determine appropriate therapeutic interventions for many of their intended uses, including erectile dysfunction, impotence, and

prostatitis. The drugs listed in Paragraph 20 are prescription drugs because of the toxicity or other potentiality for harmful effect associated with the presence of sildenafil, sibutramine, and/or phenolphthalein in those drugs. Thus, as a matter of law, "adequate directions for use" cannot be written for Defendants' drugs. *See* 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5.

43. Moreover, adequate directions for use must be based on animal and clinical data derived from extensive, scientifically controlled testing. It would be impossible to write such directions for use for Defendants' drugs, because adequate directions for drug use, including indications, contraindications, dosages, routes of administration, warnings, side effects, and necessary collateral measures, are necessarily premised on animal and clinical data derived from extensive, scientifically controlled testing, which Defendants' products do not have.

44. Because Defendants' drugs are unapproved new drugs, as described above, they are not exempt from the requirement for adequate directions for use. *See* 21 C.F.R. §§ 201.100(c)(2), 201.115.

45. Defendants' drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1), because they fail to bear adequate directions for use and do not qualify for a regulatory exemption from that requirement.

DEFENDANTS DISTRIBUTE UNAPPROVED NEW DRUGS AND MISBRANDED DRUGS IN INTERSTATE COMMERCE

46. Defendants distribute their drugs outside Florida through the company's websites, including www.mynicnaxs.com. In December 2016, Defendants shipped their drugs to undercover FDA employees in Maryland and Virginia. These shipments constitute the introduction or delivery for introduction of unapproved new drugs and misbranded drugs into interstate commerce under 21 U.S.C. § 331(a) and (d).

47. Defendants receive the drugs they sell from outside Florida. For example, the Ginseng For Reinforcing Kidney product label notes that the product was "[m]anufactured by Hong Kong Weixin Biotechnology Co., Ltd. Address: 1169-6, New East District, Hong Kong." The African Superman product label describes itself as manufactured in "Neimenggu City, Tibet." Defendants received these drugs in interstate commerce, and delivered or proffered for delivery these drugs for pay or otherwise within the meaning of 21 U.S.C. § 331(c).

INJUNCTIVE RELIEF IS NECESSARY

48. Defendants have a history of distributing unapproved new drugs and misbranded drugs. For example, between October 2012 and September 2016, U.S. Customs and Border Protection ("CBP") detained shipments addressed to Defendants on at least nine different occasions because the shipments contained, or were suspected of containing, drugs with undeclared active pharmaceutical ingredients. Defendants were given notice of each detention, and these drugs were either refused entry or referred to CBP for seizure and destruction.

49. In November 2013, FDA inspected Defendants' facility and sampled ten of Defendants' products. FDA confirmed the presence of at least one undeclared active pharmaceutical ingredient (sibutramine, desmethylsibutramine, benzylsibutramine, and/or phenolphthalein) in each of the ten samples. FDA notified Defendants of the findings, and explained that it is unlawful to sell unapproved drugs labeled as dietary supplements. FDA also explained that it is unlawful for Defendants' products, which purport to be dietary supplements, to include claims that the products treat, cure, or mitigate disease. In February 2014, Defendants voluntarily recalled the ten products containing undeclared active pharmaceutical ingredients.

50. In February 2015, FDA sent Defendants a warning letter for "distribut[ing] unapproved and misbranded drugs." FDA stated that Defendants' products that contain

undeclared active pharmaceutical ingredients are unapproved new drugs and misbranded drugs. FDA also explained that Defendants are responsible for ensuring that their products do not contain undeclared ingredients and for complying with all requirements of the Act and its implementing regulations. In response, Defendants removed 35 products from the company's website.

51. Despite ample notice and warnings, Defendants continue to distribute unapproved new drugs and misbranded drugs in interstate commerce. Most recently, as alleged in Paragraph 23, in December 2016, FDA tested nine of Defendants' products and detected undeclared active pharmaceutical ingredients in all of the tested products.

52. Unless restrained by this Court, Defendants will likely continue to distribute unapproved new drugs and misbranded drugs.

WHEREFORE, the United States respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce unapproved new drugs;

B. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(a), 352(f)(1), and/or 352(j); or

C. Violating 21 U.S.C. § 331(c), by receiving in interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(a), 352(f)(1), and/or 352(j),

and delivering or proffering for delivery such drugs for pay or otherwise.

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any new drug unless and until an approved NDA, ANDA, or IND filed pursuant to 21 U.S.C. § 355(a), (b), (j), or (i) is in effect for each such drug.

III. Order that Defendants destroy, under FDA's supervision and at Defendants' expense, all unapproved new drugs and misbranded drugs in their custody, control, or possession, and that the costs of FDA's supervision be borne by Defendants at the rates prevailing at the time the destruction is accomplished.

IV. Order that FDA be authorized to inspect all locations where Defendants operate and all records relating to receipt, holding, and distributing of any of Defendants' products to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

V. Order that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 14th day of March, 2018.

Respectfully submitted,

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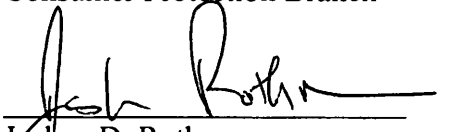

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JS 44 (Rev 09/10)

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA

CIVIL COVER SHEET

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law.

Plaintiff(s):

First Listed Plaintiff:
United States of America ;
County of Residence: Outside This District

Defendant(s):

First Listed Defendant:
MyNicNaxs, LLC ;
County of Residence: Volusia County

Additional Defendants(s):
Chevonne Torres ;
Michael Banner ;

County Where Claim For Relief Arose: Volusia County

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Basis of Jurisdiction: 1. U.S. Government Plaintiff

Citizenship of Principal Parties (Diversity Cases Only)

Plaintiff: N/A

Defendant: N/A

Origin: 1. Original Proceeding

Nature of Suit: 890 Other Statutory Actions

Cause of Action: 21 U.S.C. 331(d) (introducing unapproved new drugs in interstate commerce); 21 U.S.C. 331(a)(introducing misbranded drugs in interstate commerce); 21 U.S.C. 331(c) (receiving misbranded drugs in interstate commerce and delivering or proffering those drugs for sale).

Requested in Complaint

Class Action: Not filed as a Class Action

Monetary Demand (in Thousands):

Jury Demand: Yes

Related Cases: Is NOT a refiling of a previously dismissed action

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Signature: Joshua David Rothman

Date: 3/8/2018

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