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

UNITED STATES OF AMERICA, Plaintiff, v. MYNICNAXS, LLC, a limited liability company, CHEVONNE TORRES, and MICHAEL BANNER, individuals, Defendants.	)	Civil No. 6:18-cv-00389-JA-GJK

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction against MyNicNaxs, LLC, a limited liability company, and Chevonne Torres and Michael Banner, individuals (collectively "Defendants"), and Defendants having appeared and consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and the Court's inherent equitable authority.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. Defendants violate 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce

new drugs within the meaning of 21 U.S.C. § 321(p), that are neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

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

5. Defendants violate 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.

6. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, affiliates, and "doing business as" entities) (collectively, "Associated Persons"), who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly manufacturing, receiving, holding, distributing, or causing the distribution of any drugs or dietary supplements, at or from (i) 1012 Alpine Drive, Deltona, Florida 32725, (ii) 1062 Abagail Drive, Deltona, Florida 32725, (iii) P.O. Box 4214, Enterprise, Florida 32725, or (iv) from any other location at which Defendants now, or in the future, directly or indirectly manufacture, receive, hold, distribute, or cause the distribution of drugs or dietary supplements (the "Facilities"), unless and until all of the following occur:

A. An approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drugs; or

B. All of the following requirements are met:

(1) Defendants retain an independent laboratory (the "Laboratory") that is without any personal or financial ties (other than a service contract) to Defendants and/or their families and that is qualified to analyze products to determine whether the products contain any active pharmaceutical ingredients, including but not limited to sildenafil, sibutramine, and phenolphthalein. Defendants shall notify the U.S. Food and Drug Administration ("FDA") in writing of the identity of the Laboratory within three (3) business days of retaining such laboratory;

(2) The Laboratory analyzes samples from each lot of Defendants' products to determine whether they contain any active pharmaceutical ingredients. Any samples detecting the presence of any active pharmaceutical ingredients shall follow the procedures described in Paragraph 8;

(3) Defendants retain, at Defendants' expense, an independent person or persons (the "Expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, and experience, is qualified (i) to inspect Defendants' Facilities, (ii) to review Defendants' products' labels, labeling, and promotional materials; the websites registered to, owned, controlled by, or under the direction of Defendants now or in the future, including but not limited to www.mynicnaxs.com and www.ruglamourous.com; and any other media owned or controlled by or related to Defendants, their drugs, and/or their dietary supplements (hereinafter,

collectively, "Promotional Materials"), to evaluate Defendants' compliance with the Act, its implementing regulations, and this Decree, and (iii) to review laboratory testing results for the presence of active pharmaceutical ingredients. Defendants shall notify FDA, in writing, of the identity and qualifications of the Expert within three (3) calendar days of retaining such Expert;

(4) Defendants remove from their Promotional Materials and product claims (i) all representations that the products diagnose, cure, mitigate, treat, or prevent disease, and all representations that otherwise cause any of their products to be a drug within the meaning of the Act, and (ii) all references, direct or indirect, to other sources that contain representations that Defendants' products diagnose, cure, mitigate, treat, or prevent disease, and representations that otherwise cause any of Defendants' products to be a drug within the meaning of the Act.

(5) The Expert reviews Defendants' products and the results of the Laboratory analyses and certifies that (i) Defendants have removed from their Promotional Materials and product claims all representations that the products diagnose, cure, mitigate, treat, or prevent disease, and all representations that otherwise cause any of their products to be a drug within the meaning of the Act; (ii) Defendants have removed from their Promotional Materials and product claims all references, direct or indirect, to other sources that contain representations that Defendants' products diagnose, cure, mitigate, treat, or prevent disease, and representations that otherwise cause any of Defendants' products to be a drug within the meaning of the Act; and that (iii) Defendants' products do not contain any active pharmaceutical ingredients, based on his or her review of the analyses conducted on Defendants' products by the Laboratory pursuant to Paragraph 6.B.2. The Expert's written certification shall include a copy of all materials he or she has reviewed, including but not limited to, all Defendants' Promotional Materials, product

claims, and laboratory test results. The Expert shall submit the report concurrently to Defendants and FDA no later than ten (10) calendar days after completing this review; and

(6) After FDA receives the certifications from the Expert pursuant to Paragraph 6.B.5, FDA representatives may inspect some or all of Defendants' Facilities, at FDA's discretion, to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Decree;

C. Defendants have paid all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews with respect to Paragraph 6, at the rates set forth in Paragraph 16; and

D. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in this Paragraph. Under no circumstance shall FDA's silence be construed as a substitute for written notification.

7. Upon resuming operations after complying with Paragraph 6 and receiving written notification from FDA writing pursuant to Paragraph 6.D, Defendants and their Associated Persons are permanently enjoined from commencing distribution of any new product that is a drug or dietary supplement unless and until (i) an approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drugs, or (ii) Defendants receive a certification from the Expert that the new product complies with the requirements in Paragraph 6.B.

8. With respect to the samples and analyses conducted pursuant to Paragraphs 6.B and 7,

A. Defendants shall maintain copies of all records, including records provided to Defendants by the Laboratory, documenting all laboratory analyses.

B. If any laboratory analysis conducted pursuant to Paragraphs 6.B and 7 detects the presence of any active pharmaceutical ingredients, Defendants shall:

(1) Cause the Laboratory to provide to FDA and Defendants contemporaneously the results of that analysis within one (1) business day after the Laboratory obtains such results; and

(2) After FDA has approved, in writing, a written destruction plan from Defendants, Defendants shall, at Defendants' expense and under FDA's supervision, destroy all products from each lot that tested positive for an active pharmaceutical ingredient.

C. If, after notifying FDA of the name of the Laboratory retained to conduct testing pursuant to Paragraph 6.B.1, Defendants terminate their service contract with the Laboratory, Defendants shall notify FDA within three (3) business days of such termination, select another Laboratory that meets the criteria in Paragraph 6.B.1 to conduct the testing described therein, and notify FDA in writing of the identity and qualifications of the newly retained Laboratory within (3) business days of retaining such Laboratory.

9. Within ten (10) calendar days after entry of this Decree, Defendants shall provide an affidavit to FDA listing all locations where Defendants' products are received, held, and/or distributed and listing all websites from which Defendants' products are sold, distributed, or marketed. Within twenty (20) calendar days after entry of this Decree, Defendants shall recall and destroy, under FDA supervision and to FDA's satisfaction, unapproved new drugs and misbranded drugs that Defendants received, held, distributed, or caused to be distributed between February 20, 2015, and the entry of this Decree. Defendants shall, under FDA supervision and to

FDA's satisfaction, notify all affected consumers of the recall. Prior to destruction, Defendants must submit a written destruction plan to FDA, and FDA must approve Defendants' destruction plan in writing before any destruction can take place. Under no circumstance shall FDA's silence be construed as a substitute for written notification. Defendants shall notify FDA in writing within ten (10) calendar days of receiving any additional recalled products. Defendants shall hold the recalled products until FDA is available to supervise destruction. Defendants shall not dispose of any drugs in a manner contrary to the provisions of the Act, any other federal law, or the laws of any state or territory in which the drugs are disposed. Defendants shall bear the cost of the recall, destruction notification, and FDA supervision. The cost of FDA's participation and supervision under this Paragraph shall be borne by Defendants at the rates specified in Paragraph 16.

10. Upon resuming operations after complying with Paragraph 6 and receiving written notification from FDA writing pursuant to Paragraph 6.D, Defendants shall retain an independent person or persons (the "Auditor") at Defendants' expense to conduct audit inspections of Defendants' products and Defendants' Facilities and to review Defendants' Promotional Materials, product claims, and laboratory test results to determine whether Defendants' products are in compliance with the Act, its implementing regulations, and this Decree. The Auditor shall conduct such audit inspections and reviews no less than once every six (6) months for a period of five (5) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections and reviews, and shall be without personal or financial ties (other than a consulting agreement with Defendants) to Defendants' officers or employees or their immediate families. The Auditor may be the same person or persons described as the Expert in Paragraph 6.B.3. Additionally:

A. Defendants shall notify FDA in writing of the identity and qualifications of the Auditor as soon as they retain the Auditor;

B. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") listing all of Defendants' Facilities that the Auditor inspected; listing all materials the Auditor reviewed, including but not limited to, all Defendants' Promotional Materials, product claims, and all laboratory testing results; analyzing whether Defendants' products, product claims, and their Promotional Materials are in compliance with the Act, its implementing regulations, and this Decree; and identifying in detail any deviations from the foregoing ("Audit Report Observations");

C. Each Audit Report shall also contain a written certification that the Auditor:

(1) Has personally reviewed all of Defendants' Promotional Materials and product claims;

(2) Has personally reviewed Defendants' laboratory testing results for each lot of product manufactured, received, held, distributed, or caused to be distributed by Defendants; certified that laboratory testing results detecting the presence of active pharmaceutical ingredients were sent to FDA; and certified that the laboratory testing shows that all lots that contained any active pharmaceutical ingredients were destroyed; and

(3) Has personally certified whether all of Defendants' Promotional Materials, product claims, and their drugs and dietary supplements comply with the requirements of the Act, its implementing regulations, and this Decree;

D. As part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations;

E. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten (10) calendar days after the date the audit inspections are completed;

F. If any Audit Reports identify any deviations from the Act, applicable regulations, and/or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew;

G. Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at Defendants' Facilities and shall promptly make all Audit Reports and underlying data available to FDA upon request; and

H. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within twenty (20) calendar days after receiving the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than twenty (20) calendar days, Defendants shall, within ten (10) calendar days after receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. The Correction Schedule must be reviewed and approved by FDA, in writing, prior to implementation. Under no circumstance shall FDA's silence be construed as a substitute for written notification. Defendants shall complete all corrections according to the approved Correction Schedule. Within ten (10) calendar days after Defendants receive an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observations. Within two (2) calendar days after beginning that review, the Auditor shall report in writing to FDA whether each of the

adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected and their anticipated correction date.

11. Upon entry of this Decree, Defendants and all of their Associated Persons are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any product that is a new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

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

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

D. Fails to implement and continuously maintain the requirements of this Decree.

12. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, a report submitted by Defendants, the Expert, the Auditor, the laboratory, or any other information, that Defendants have failed to comply with any provision of this Decree, the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order

Defendants to take appropriate corrective action, including but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, receiving, holding, distributing, and/or causing the distribution of all drug products or dietary supplement products;

B. Recall and/or destroy, at Defendants' expense, any drug or dietary supplement product that is unapproved, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports, plans, procedures, or other records prepared, or laboratory testing program conducted, pursuant to this Decree;

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

E. Submit additional samples to a qualified laboratory testing program;

F. Issue a safety alert; and/or

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

The provisions of this Paragraph shall be apart from, and in addition to, all other remedies available to FDA.

13. Upon receipt of any order issued by FDA pursuant to Paragraph 12, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 12 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. Under no

circumstance shall FDA's silence be construed as a substitute for written notification. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 12 shall be borne by Defendants at the rates specified in Paragraph 16.

14. FDA shall be permitted, without prior notice and when FDA deems necessary, to make inspections of Defendants' Facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During inspections, FDA shall be permitted to have immediate access to buildings, equipment, products, product labeling and promotional materials, websites, any other media owned or controlled by or related to Defendants and/or their products, and other materials therein; take photographs and make video recordings; take samples of Defendants' products, containers, packaging material, labeling, and other materials; and examine and copy all records relating to manufacturing, receiving, holding, distributing, or causing the distribution of Defendants' products. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

15. Defendants shall promptly provide any information or records to FDA upon request regarding the manufacturing, receiving. holding, distributing, or causing the distribution of Defendants' products.

16. Defendants shall pay all costs of all FDA inspections, investigations. analyses, examinations, sampling, reviews, document preparation, testing, travel, and subsistence expenses that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree, at

the standard rates prevailing at the time costs are incurred, and Defendants shall make payment in full to the United States Treasury within twenty (20) calendar days of receiving written notification from FDA of such costs. For the purposes of this Decree, inspections include, but are not limited to, FDA review and analysis of Defendants' Promotional Materials and product claims. As of the date of this Decree, these rates are: $93.26 per hour and fraction thereof per representative for inspection or investigative work; $111.77 per hour or fraction thereof per representative for analytical or review work; $0.535 per mile for travel by motor vehicle; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day per representative and for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

17. Within ten (10) calendar days after the entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (return receipt requested), to each and all Associated Persons; post the Decree in a common area of all of Defendants' Facilities; and post the Decree on websites under Defendants' control, including but not limited to www.mynicnaxs.com and www.ruglamorous.com. Defendants shall ensure that the Decree remains posted in the common area of all of Defendants' Facilities and on websites under Defendants' control for as long as the Decree remains in effect. Within twenty (20) calendar days after the entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this Paragraph and identifying the names and positions of all Associated Persons who have received a copy of this Decree and the manner of notification. In the event that Defendants become associated, at any time after the

entry of this Decree, with new Associated Persons, Defendants shall: (i) within five (5) calendar days of such association, provide a copy of this Decree to each such Associated Person by personal service or certified mail (return receipt requested), and (ii) within ten (10) calendar days of such association, provide FDA an affidavit stating the fact and manner of their compliance with the provisions of this Paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this Paragraph and the manner of such notification.

18. Defendants shall notify FDA in writing at the addresses specified in Paragraph 20, at least fifteen (15) calendar days before any change in ownership, character, or name of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchises, affiliates, or "doing business as" entities, or any other change in the organizational structure of MyNicNaxs, LLC or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit stating the fact and manner of their compliance with this Paragraph no later than ten (10) calendar days before such assignment or change in ownership.

19. Defendants shall notify FDA, in writing, no later than ten (10) business days after the creation of a new website or link or reference, direct or indirect, to another website or other source that conveys information about Defendants' drugs and/or dietary supplements.

20. All notifications, certifications, reports, correspondence, and other communications to FDA required under this Decree shall be addressed to the District

Director/Program Division Director, Florida District Office, United States Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, and shall prominently reference this Consent Decree, the case name, and civil action number.

21. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, Defendants shall pay to the United States of America one thousand dollars ($1,000.00) in liquidated damages for each violation of this Decree, the Act, and/or its implementing regulations; an additional one thousand dollars ($1,000.00) in liquidated damages per day, per violation, for each violation of this Decree, the Act, and/or its implementing regulations; and an amount equal to twice the retail value of any drugs or dietary supplements distributed in violation of the Act, its implementing regulations, and/or this Decree. Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this Paragraph.

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

23. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the

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

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

SO ORDERED, this 27th day of March, 2018.

UNITED STATES DISTRICT JUDGE

Entry consented to:

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