IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. JAMES R. HILL, an individual d/b/a VIRUXO LLC, Defendant.	NO. 5:15-CV-577-OC-30PRL

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Injunctive Relief against James R. Hill, an individual d/b/a Viruxo LLC ("Defendant"), and Defendant 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.

2. The Complaint states a cause of action against Defendant under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act"), and the civil fraud injunction statute, 18 U.S.C. § 1345 ("Section 1345").

3. Defendant 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 a new drug, as defined by 21 U.S.C. § 321(p), that is neither approved under 21 U.S.C. § 355 nor exempt from approval.

4. Defendant 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 a

drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1) because its labeling fails to bear adequate directions for use.

5. Defendant violates 18 U.S.C. §§ 1341 and 1343 by promoting, selling, and receiving money in exchange for products to cure, mitigate, treat, or prevent a disease despite the absence of well-controlled clinical studies or any other credible scientific substantiation to support those representations, and by (1) doing so using the United States mail and/or a private or commercial interstate carrier and (2) transmitting writings by wire in interstate commerce for the purpose of executing such scheme or artifice.

6. This Court has authority pursuant to 18 U.S.C. § 1345 and 21 U.S.C. § 332(a), and inherent authority, to order injunctive and other equitable relief remedying the unlawful activities described in paragraphs 3, 4, and 5.

7. Defendant is an individual residing in the Middle District of Florida who does business as Viruxo LLC, and sells and distributes products under the brand name Viruxo.

8. The Food and Drug Administration ("FDA") sent a Warning Letter, dated April 28, 2011, to Defendant concerning Viruxo and claims found on Defendant's website. The Warning Letter advised Defendant that Viruxo was a new drug, which may not be legally introduced or delivered for introduction into interstate commerce without prior FDA approval. The Warning Letter further advised Defendant that Viruxo was a misbranded drug, whose introduction or delivery for introduction into interstate commerce also violates the Act.

9. Upon entry of this Decree, Defendant represents to the Court that he is not directly or indirectly engaged in processing, packing, repacking, labeling, holding, or distributing any article of food (including but not limited to dietary supplements and their components) and/or any article of drug.

10. If Defendant later intends to resume marketing or selling Viruxo or to engage in processing, packing, repacking, labeling, holding, or distributing any article of food (including but not limited to dietary supplements and their components) and/or any article of drug, Defendant must notify FDA in writing at least ninety (90) days in advance of resuming operations and must comply with Paragraph 13 of this Decree.

11. Defendant's notice under Paragraph 10 shall identify the type(s) of products that Defendant intends to process, pack, repack, label, hold, and/or distribute, and the location(s) at which Defendant intends to resume operations.

12. Defendant shall not resume operations until the conditions in Paragraphs 13(A)-(B) and 13(D) are satisfied, and Defendant has received written notice from FDA, as required by Paragraph 13(E), and then Defendant shall resume such operations only to the extent authorized in FDA's written notice.

PROHIBITED CONDUCT

13. Upon entry of this Decree, Defendant and each and all of agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, affiliates, franchisees, and "doing business as" entities) (hereinafter, collectively referred to as "Associated Persons") who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined from directly or indirectly introducing and delivering for introduction into interstate commerce, causing to be introduced and delivered for introduction into interstate commerce, and holding for sale after shipment in interstate commerce, any product unless and until:

A. Defendant has in effect with respect to the product a new drug application or abbreviated new drug application approved pursuant to 21 U.S.C. § 355(c) or (j), or an investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i), or the following requirements are met:

1. Defendant's product labels, labeling, promotional material, websites (including but not limited to www.viruxo.com and www.viruxo.net), branded Facebook pages, and any other media do not contain (a) any representations that his products or the ingredients in his products cure, mitigate, treat, or prevent disease, and any representations that otherwise cause any of his products to be a drug within the meaning of the Act, and (b) any links and references, direct or indirect, to other websites or other sources that contain representations that his products or the ingredients in his products cure, mitigate, treat, or prevent disease, and

representations that otherwise cause any of his products to be a drug within the meaning of the Act;

2. Defendant provides notice, by letter or electronic mail, to all persons who are or have been involved in the promotion, sale, distribution, or use of Viruxo informing those persons that, pursuant to an order of this Court, the product should not have been and can no longer be promoted, sold, or distributed for use in the cure, mitigation, treatment, or prevention of disease and that continued promotion, sale, or distribution of the product for the cure, mitigation, treatment, or prevention of disease is a violation of the Act. Prior to distribution, the notification shall be submitted to, and approved in writing by, FDA. After completing distribution of the notification required by this paragraph, Defendant shall provide FDA with an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names and addresses of each recipient who has received a copy of the notification;

3. Defendant retains, at Defendant's expense, an independent person (the "Labeling Expert") who is without any personal or financial ties (other than a retention agreement) to Defendant and/or his family and who, by reason of background, training, education, or experience, is qualified to review Defendant's product labels, labeling, promotional material, websites (including but not limited to www.viruxo.com and www.viruxo.net), branded Facebook pages, and other media to assess compliance with the Act. Defendant shall notify FDA in writing of the identity and qualifications of the Labeling Expert within three (3) business days of retaining such expert; and

4. The Labeling Expert provides to FDA a written certification that, based on a comprehensive review, Defendant's product labels, labeling, promotional material, websites (including but not limited to www.viruxo.com and www.viruxo.net), branded Facebook pages, and other media comply with the Act, and do not contain, or link or refer to other websites or other sources that contain, representations that his products or the ingredients in his products cure, mitigate, treat, or prevent disease, or representations that otherwise cause any product to be a drug within the meaning of the Act. The written certification described in this paragraph shall

include a list of all of Defendant's websites, including social media pages and online marketplace postings. The written certification shall also contain a detailed report of the Labeling Expert's review and include, but not be limited to, a determination that Defendant has implemented procedures that are adequate to ensure that his claims do not cause any of his products to be a drug within the meaning of 21 U.S.C. § 321(g)(1) unless and until the product is the subject of an approved new drug application or abbreviated new drug application, or is exempt from approval under an investigational new drug application, 21 U.S.C. §§ 355(a), (b), (i), (j);

B. Defendant reports to FDA in writing the actions he has taken to ensure that his claims do not cause any of his products to be a drug within the meaning of 21 U.S.C. § 321(g)(1) unless and until the product is the subject of an approved new drug application or abbreviated new drug application, or is exempt from approval under an investigational new drug application, 21 U.S.C. §§ 355(a), (b), (i), and (j);

C. As and when FDA deems necessary, FDA representatives inspect Defendant's operations, including the buildings, equipment, products, labeling, and all relevant records contained therein, to determine whether the requirements of this Decree have been met and whether Defendant is operating in conformity with the Act, its implementing regulations, and this Decree;

D. Defendant has paid all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews with respect to paragraph 13, at the rates set forth in paragraph 20; and

E. FDA notifies Defendant in writing that he appears to be in compliance with the requirements set forth in paragraphs 13(A)-(B) and (D) of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

14. Upon entry of this Decree, and after receiving FDA's written notification pursuant to paragraph 13(E), Defendant and Associated Persons are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 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, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval;

B. Violating 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 that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

C. Failing to implement and continuously maintain the requirements of this Decree.

COMPLIANCE REQUIREMENTS

15. Upon resuming operations after complying with paragraphs 13(A)-(B) and (D), and receiving FDA's written notification pursuant to paragraph 13(E), the following requirements shall be met:

A. Defendant shall notify FDA in writing, at least fourteen (14) days before the creation of a new website or link or reference, direct or indirect, to another website or other source that conveys information about Defendant's products or the ingredients in his products; and

B. Defendant shall retain an independent person or persons (the "Auditor") who shall meet the criteria for, and may be the same person(s) as, the Labeling Expert described in paragraph 13(A)(3), to conduct audits of Defendant's product labels, labeling, promotional material, websites (including but not limited to www.viruxo.com and www.viruxo.net), branded Facebook pages, and other media to assess compliance with the Act. Thereafter:

1. The Auditor shall conduct audit inspections no less frequently than once every six (6) months for a period of no less than five (5) years and then at least once every year thereafter. The first audit shall occur not more than six (6) months after Defendant has received FDA's written notification pursuant to paragraph 13(E);

2. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendant is in

compliance with this Decree, the Act, and its implementing regulations and identifying any deviations from such requirements ("Audit Report Observations"). As a part of every Audit Report (except the first one), the Auditor shall assess the adequacy of actions taken by Defendant to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendant and FDA by courier service or overnight delivery service, no later than seven (7) days after the audit inspection is completed. In addition, Defendant shall maintain the Audit Reports in separate files at Defendant's facility and shall promptly make the Audit Reports available to FDA upon request; and

3. If an Audit Report contains any Audit Report Observations, Defendant shall, within fourteen (14) days after receipt of the Audit Report, correct those observations, unless FDA notifies Defendant that a shorter time period is necessary. If, after receiving the Audit Report, Defendant believes that correction of the Audit Report Observations will take longer than fourteen (14) days, Defendant shall, within seven (7) days after receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendant. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendant shall complete all corrections according to the approved Audit Correction Schedule. Immediately upon completion of all corrections, Defendant shall submit documentation of his corrections to the Auditor. Within twenty-eight (28) days after the Auditor's receipt of Defendant's documentation of corrections, unless FDA notifies Defendant that a shorter time period is necessary, or, if there is an FDA-approved Audit Correction Schedule, within the time period provided therein, the Auditor shall review the actions taken by Defendant to correct the Audit Report Observations. Within seven (7) days after beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

16. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, review, the analysis of a sample, a report, or data prepared or submitted by

Defendant, the Labeling Expert, Auditor, or any other information, that Defendant has failed to comply with any provision of this Decree, Defendant has violated the Act or its implementing regulations, or 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 Defendant in writing of the noncompliance and order Defendant to take appropriate corrective action, including, but not limited to, ordering Defendant to immediately take one or more of the following actions:

A. Cease receiving, processing, packing, repacking, labeling, holding, or distributing any and all products;

B. Recall, at Defendant's expense, any and all products;

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

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

E. Institute or reimplement any of the requirements set forth in this Decree;

F. Issue a safety alert; and/or

G. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendant into compliance with this Decree, the Act, or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

17. Upon receipt of any order issued by FDA pursuant to paragraph 16, Defendant shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 16 shall continue until Defendant receives written notification from FDA that Defendant appears to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendant may resume operations. Defendant shall pay all costs of recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document

preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in paragraph 16, at the rates specified in paragraph 20.

18. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendant's operations and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and all applicable regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to the Defendant's places of business including, but not limited to all buildings, equipment, in-process materials, finished products, containers, packaging material, labeling, and other material therein; take photographs and make video recordings; take samples of the Defendant's in-process materials, finished products, containers, packaging material, labeling, and other material; and examine and copy all records relating to the receipt, processing, packing, repacking, labeling, holding, and distribution of any and all of the Defendant's products and their components. 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.

19. Defendant shall promptly provide any information or records to FDA upon request regarding the receipt, processing, packing, repacking, labeling, holding, and distribution of Defendant's products.

20. Defendant shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, and reviews that FDA deems necessary to evaluate Defendant's compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $89.35 per hour or fraction thereof per representative for inspection and investigative work; $107.09 per hour or fraction thereof per representative for analytical or review work; $0.575 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate 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. Defendant shall make payment in full to FDA within twenty-eight (28) days of receiving written notification from FDA of the costs.

NOTICE REQUIREMENTS

21. Within seven (7) days after entry of this Decree, Defendant shall post a copy of this Decree in a conspicuous location in a common area at Defendant's facility and on all websites under Defendant's control (including but not limited to www.viruxo.com and www.viruxo.net). Defendant shall ensure that the Decree remains posted for as long as the Decree remains in effect. Within fourteen (14) days after entry of this Decree, Defendant shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

22. Within fourteen (14) days after entry of this Decree, Defendant shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree. Within twenty (20) days after entry of this Decree, Defendant shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

23. Within fourteen (14) days after entry of this Decree, Defendant shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all of his Associated Persons. Within twenty-eight (28) days after entry of this Decree, Defendant shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who have received a copy of this Decree, and attaching a copy of the executed certified mail return receipts.

24. In the event that Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendant shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested) to such Associated

Person(s). Within seven (7) days of each time that Defendant becomes associated with any additional Associated Person, Defendant shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

25. Defendant shall notify FDA in writing at least fourteen (14) days before any change in ownership, name, or character of his business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Viruxo LLC, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendant shall provide a copy of this Decree to any prospective successor or assign at least twenty-eight (28) days prior to any sale or assignment. Defendant shall furnish FDA with an affidavit of compliance with this paragraph no later than fourteen (14) days prior to such assignment or change in ownership.

26. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence" and addressed to the Director, Division of Enforcement, Office of Enforcement and Import Operations, Office of Regulatory Affairs, United States Food and Drug Administration, 10903 New Hampshire Avenue, White Oak Building 32 Room 4360, Silver Spring, Maryland 20993, and shall reference this civil action by case name and civil action number.

VIOLATIONS OF THIS DECREE

27. If Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendant shall pay to the United States of America: four thousand dollars ($4,000) in liquidated damages for each day such violation continues; an additional sum of four thousand dollars ($4,000) in liquidated damages per day per violation, for each violation of this Decree, the Act, or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail

value of any product distributed in violation of this Decree, the Act, or its implementing regulations. Defendant understands and agrees 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, or the Court to impose, additional civil or criminal penalties to be paid by Defendant, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

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

OTHER PROVISIONS

29. Defendant 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.

30. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

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

SO ORDERED, this 26 day of Feb., 2016.

HON. JAMES S. MOODY, JR
Senior United States District Judge

Entry consented to:

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Sr.
pro se.
JAMES R. HILL, individually, and on behalf of Viruxo LLC

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