IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF IOWA

UNITED STATES OF AMERICA, Plaintiff, v. IOWA SELECT HERBS, LLC, a corporation, and GORDON L. FREEMAN and LOIS A. DOTTERWEICH, individuals, Defendants.	CIVIL NO. 15-cv-60 (EJM)

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 (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Iowa Select Herbs, LLC ("Iowa Select Herbs" or the "firm"), a corporation, and Gordon L. Freeman and Lois A. Dotterweich, individuals (collectively, "Defendants"), from violating:

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

b. 21 U.S.C. § 331(a), by introducing or delivering, and/or causing to be introduced or delivered, into interstate commerce any article of drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1);

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

d. 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce articles of food (dietary supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), and misbranded within the meaning of 21 U.S.C. § 343(s)(2)(C); and

e. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), and misbranded within the meaning of 21 U.S.C. § 343(s)(2)(C), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

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

DEFENDANTS

4. Defendant Iowa Select Herbs is a limited liability company located at 2347 Blairs Ferry Road, NE, Suite 2, Cedar Rapids, Iowa 52402. The facility serves as both the firm's manufacturing establishment and retail distribution location. Iowa Select Herbs manufactures, labels, and distributes dietary supplements under its own brand name: Iowa Select Herbs.

5. Defendant Gordon L. Freeman is Iowa Select Herbs' President and CEO, and he is also one of its owners. He is responsible for developing product formulas, establishing the content of the firm's website, developing the product postings he places on online marketplace websites, approving all product labels, and writing all product brochures. During FDA's August

2013 and August 2014 inspections, Mr. Freeman identified himself to the FDA investigators as the most responsible person at the firm.

6. Defendant Lois A. Dotterweich co-owns Iowa Select Herbs with Mr. Freeman and serves as the firm's Product Manager. She is responsible for quality control at the firm and is involved in the firm's manufacturing by personally mixing the herbs and preparing the firm's extracts.

7. Defendants promote and distribute many products, including, but not limited to: Cold BeGone, Papaya Leaf Extract, Echinacea Angustifolia Extract, Elderberry Extract, Feverfew Extract, Graviola Leaf Extract "Soursop," Holy Basil Extract, Lemon Balm Leaf Extract, Nettle Leaf Extract, Pygeum Bark Extract, Cinnamon Bark Extract, Hawthorn Berries Extract, Hops Extract, Milk Thistle Seed Extract, Oatstraw Extract, Passion Flower Leaf Extract, Valerian Root Extract, Chaparral Leaf Extract, Echinacea Purpurea Extract, Gymnema Sylvestre Extract, Plantain Extract, and Black Currant Extract. During FDA's most recent inspection, Defendants told the investigators that Defendants distribute 197 different dietary supplements.

8. Defendants sell their products directly to consumers and to wholesalers.

9. Defendants sell the majority of their products online through Iowa Select Herbs' website (www.stores.iowaselectherbs.com) or through online marketplace websites, such as eBay, Amazon, and buy.com.

DEFENDANTS' PRODUCTS ARE DRUGS UNDER THE ACT

10. Under the Act, a product is a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B).

11. The intended use of a product may be determined from any relevant source, including labeling and other promotional materials. 21 C.F.R. § 201.128.

12. 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).

13. Defendants promote some of their products for the cure, mitigation, treatment, and prevention of various diseases (e.g., cancer, malaria, and heart disease) in product labeling, on flyers that accompany their products, through videos posted on Iowa Select Herbs' Facebook page, and through their postings on online marketplace websites, like Amazon and eBay. For example, Defendants' promotional materials include the following disease treatment claims:

a. Cold BeGone: "It acts as a[n] immunostimulator [sic], fever reducer, antibiotic, decongestant, expectorant, body ache reliever, antifungal, detoxifier, neutralizer, antioxidant, antihistamine, antibacterial, healing accelerator, sooths [sic] sore throats, antiinflamatory [sic], astrigent [sic] properties, hydrator."

b. Papaya Leaf Extract: "Papaya may also aid in the fight against cancer."

c. Echinacea Angustifolia Extract: "Echinacea . . . offers some protection against herpes simplex viruses."

d. Elderberry Extract: "Used for the treatment of bronchitis, colds, congestion, cough, eyes/vision, flu, sinus, sore throat."

e. Feverfew Extract: "Feverfew inhibits platelet aggregating in the bloodstream, thus preventing blockage of small capillaries. This action is one of the reasons behind feverfew's popularity in treatment of migraines. It has also been used for inflammation, arthritis, . . . fever, and other aches and pains."

f. Graviola Leaf Extract "Soursop:" "Graviola contains many properties that may be active against cancer, as well as disease-causing agents such as bacteria, viruses, and parasites."

g. Holy Basil Extract: "Holy Basil is used for common colds, headaches, stomach disorders, inflammation, heart disease, various forms of poisoning, and malaria."

h. Lemon Balm Leaf Extract: "Lemon balm leaf extract can be used for the treatment of cold sores, shingles, and herpes."

i. Nettle Leaf Extract: "Stinging nettle . . . has been shown effective in treatment of BPH [Benign Prostatic Hyperplasia] in clinical trials when combined with saw palmetto."

j. Pygeum Bark Extract: "Use internally for enlarged prostate gland, chronic prostate inflammation, reverse male sterility, urinary disorders."

DEFENDANTS DISTRIBUTE PRODUCTS THAT ARE UNAPPROVED NEW DRUGS

14. 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). For a product to be deemed "generally recognized as safe and effective" ("GRAS/GRAE"), it must have substantial evidence of safety and effectiveness. 21 U.S.C. § 355(d).

15. Under the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval. 21 U.S.C. §§ 355(a), (b), (j); 331(d). A drug may be exempt from the Act's new drug approval requirements, 21 U.S.C. § 355(a), if it is the subject of an investigational new drug application ("IND"). 21 U.S.C. § 355(i).

16. Defendants' drugs are "new drugs" as defined by 21 U.S.C. § 321(p)(1), because they are 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 their labeling.

17. None of Defendants' drugs are the subject of an approved NDA or ANDA, or an effective IND. Defendants have no such approvals on file from FDA.

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

DEFENDANTS' PRODUCTS ARE MISBRANDED DRUGS

19. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded violates the Act. 21 U.S.C. § 331(a).

20. It is also a violation of the Act, 21 U.S.C. § 331(k), to do or cause to be done an act that results in a drug being misbranded while it is held for sale after shipment of one or more of its components in interstate commerce.

21. Defendants drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because their labeling fails to bear "adequate directions for use" and the drugs do not fall within a regulatory exemption from that requirement. See, e.g., 21 C.F.R. § 201.115.

22. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce misbranded drugs.

23. Defendants violate 21 U.S.C. § 331(k) by causing drugs to become misbranded while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS DISTRIBUTE ADULTERATED DIETARY SUPPLEMENTS

24. The Act prohibits doing or causing "the introduction or delivery for introduction into interstate commerce . . . any food [including any dietary supplement] that is adulterated." 21 U.S.C. §§ 331(a), 321(ff).

25. It is also a violation of the Act to do or cause to be done an act that results in a dietary supplement being adulterated while it is held for sale after shipment of one or more of its components in interstate commerce. 21 U.S.C. §§ 331(k), 321(ff).

26. The Act defines "dietary supplement" as "a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of [any of them]." 21 U.S.C. § 321(ff). In addition, a dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." Id.

27. Many of Defendants' products fall within the Act's definition of a dietary supplement in that they contain at least one of the dietary ingredients specified in 21 U.S.C. § 321(ff) and are labeled as dietary supplements on their principal display panels as defined in 21 C.F.R. § 101.1.

28. Although dietary supplements are deemed to be "food" under the Act, 21 U.S.C. § 321(ff), the Act expressly provides that a product that is a dietary supplement may also be a drug if it meets the definition of a "drug" under 21 U.S.C. § 321(g).

29. The Act requires manufacturers of dietary supplements to operate in compliance with current good manufacturing practice regulations for dietary supplements set forth at 21 C.F.R. Part 111 ("Dietary Supplement CGMP"). 21 U.S.C. § 342(g)(1). Manufacturing

according to Dietary Supplement CGMP means that the manufacturing process incorporates a set of controls in the design and production processes to assure a quality finished product. Dietary supplements not manufactured, prepared, packed, or held in conformance with Dietary Supplement CGMP are deemed to be adulterated. 21 U.S.C. § 342(g)(1).

30. The FDA investigators inspected Defendants' facility on August 25–28, 2014 (the "August 2014 inspection"). The August 2014 inspection revealed significant deviations from Dietary Supplement CGMP, including, but not limited to, the following:

a. Defendants failed to establish written records and procedures. For example, Dietary Supplement CGMP requires Defendants to prepare a written master manufacturing record for each unique dietary supplement formulation and each batch size. 21 C.F.R. § 111.205(a). Additionally, Dietary Supplement CGMP requires Defendants to prepare a batch production record every time they manufacture a batch of a dietary supplement. See 21 C.F.R. § 111.255(a). The batch production record must include complete information relating to the production and control of each batch. See 21 C.F.R. § 111.255(b). Defendants failed to prepare written master manufacturing records or batch production records.

b. Defendants failed to establish specifications "for any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and [to ensure] that the dietary supplement is packaged and labeled as specified in the master manufacturing record." 21 C.F.R. § 111.70(a). Defendants have failed to establish any specifications for any of their products.

c. Defendants failed to test the dietary ingredient components, non-dietary ingredient components, or their finished product dietary supplements. See 21 C.F.R. §§ 111.73, 111.75(a)(1)(i), 111.75(a)(2). During the August 2014 inspection, Mr. Freeman told the FDA

investigators that unless the firm resells a particular ingredient to a wholesale customer who requires it, the firm does not conduct identity testing on any of the dietary ingredients Defendants use. Mr. Freeman also told the FDA investigators that he does not conduct any testing nor does he obtain certificates of analysis for any non-dietary ingredient components. The firm conducts no tests or examinations of any kind on any of the 197 dietary supplements it makes.

d. Defendants failed to establish and implement written quality control operations. Dietary Supplement CGMP requires Defendants "to establish and follow written procedures for the responsibilities of the quality control operations." 21 C.F.R. § 111.103. The regulations require that the responsible quality control personnel perform a variety of quality control procedures including: approving or rejecting all processes, specifications, written procedures, controls, tests, and examinations, and deviations from or modifications to them, that may affect the identity, purity, strength, or composition of a dietary supplement; ensuring that the required representative samples are collected; and determining whether all specifications are met. 21 C.F.R. § 111.105(a), (f), (h). The firm failed to have written quality control procedures for any of the dietary supplements it manufactures. The firm also did not have a written record of any type of quality control operations ever taking place.

31. As a result of the Dietary Supplement CGMP violations, the dietary supplements manufactured by Defendants are adulterated within the meaning of 21 U.S.C. § 342(g)(1).

32. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce dietary supplements that are adulterated.

33. Defendants violate 21 U.S.C. § 331(k) by causing dietary supplements to become adulterated while such dietary supplements are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS DISTRIBUTE MISBRANDED DIETARY SUPPLEMENTS

34. The Act prohibits doing or causing "the introduction or delivery for introduction into interstate commerce . . . any food [including any dietary supplement] . . . that is . . . misbranded." 21 U.S.C. §§ 331(a), 321(ff).

35. It is also a violation of the Act to do or cause to be done an act that results in a dietary supplement being misbranded while it is held for sale after shipment of one or more of its components in interstate commerce. 21 U.S.C. §§ 331(k), 321(ff).

36. Dietary supplements that contain an herb or other botanical are misbranded if they "fail to identify [on the label or in the labeling] any part of the plant from which the ingredient is derived." 21 U.S.C. § 343(s)(2)(C); see 21 C.F.R. § 101.4(h)(1).

37. Many of Defendants' dietary supplements (including, Echinacea Purpurea Extract, Gymnema Sylvestre Extract, Plantain Extract, Black Currant Extract, and Oatstraw Extract) fail to identify on their labels or in their labeling the part of the plant from which their botanical dietary ingredients are derived.

38. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce dietary supplements that are misbranded.

39. Defendants violate 21 U.S.C. § 331(k) by causing dietary supplements to become misbranded while such dietary supplements are held for sale after shipment of one or more of their components in interstate commerce.

DEFENDANTS ENGAGE IN INTERSTATE COMMERCE

40. Defendants ship their finished drug and dietary supplement products in interstate commerce to locations outside of Iowa, including Maryland, Michigan, California, New Jersey, Florida, and North Carolina. In addition, Defendants manufacture their drug and dietary supplement products using components that are shipped in interstate commerce from places

outside of the state of Iowa. For example, during the August 2014 inspection, the FDA investigators collected records that documented Defendants' receipt of papaya leaves from an out-of-state supplier in California and Solomon's seal root from a supplier in Oregon.

PRIOR NOTICE

41. Defendants are well aware that their conduct violates the law and that continued violations could lead to regulatory action.

42. FDA first inspected Defendants' facility in August 2013. FDA issued Iowa Select Herbs and Mr. Freeman an 11-item List of Inspectional Observations ("Form FDA 483") that listed the Dietary Supplement CGMP violations the FDA investigators observed during the inspection. The FDA investigators discussed these violations with Mr. Freeman at the conclusion of the inspection and warned him that failure to comply with the law could result in regulatory action, including a seizure or injunction.

43. Based on the observations FDA noted during the August 2013 inspection, and a subsequent review of the firm's website in March 2014, FDA issued a Warning Letter to Iowa Select Herbs and Mr. Freeman on April 18, 2014. The Warning Letter notified the firm and Mr. Freeman that their practices violated the Act and its regulations. Specifically, FDA warned that Iowa Select Herbs was distributing unapproved new drugs and misbranded drugs, as well as adulterated and misbranded dietary supplements. FDA also warned that the violations contained in the Warning Letter were not an all-inclusive list of violations and reminded Iowa Select Herbs and Mr. Freeman that it was their responsibility to ensure that all of their products were in compliance with the law.

44. Iowa Select Herbs and Mr. Freeman responded to FDA's Warning Letter on April 28, 2014. In the response, Mr. Freeman promised that the firm had made many corrections, but provided few details on the exact improvements made. When FDA returned to the firm four

months later, for the August 2014 inspection, the FDA investigators again found significant violations. The August 2014 inspection culminated in FDA issuing a 13-item Form FDA 483. The FDA investigators discussed the violations with Mr. Freeman at the conclusion of the inspection.

45. As of the date of this Complaint, Defendants have not responded to the August 2014 Form FDA 483.

46. Additionally, FDA conducted an online search in November 2014, three months after FDA inspected Defendants' facility, and found multiple postings by Defendants on eBay and Amazon in which Defendants continued to make disease-treatment claims about Iowa Select Herbs' products.

47. Defendants' history of promoting products to cure, mitigate, treat, and/or prevent diseases, including, but not limited to, such serious health problems as cancer, malaria, and heart disease demonstrates their unwillingness to comply with the Act. Based on Defendants' conduct, it is evident that, unless restrained by order of this Court, Defendants will continue to violate the Act, 21 U.S.C. § 331(a), (d), and (k).

WHEREFORE, Plaintiff 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, 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 distributing unapproved new drugs in interstate commerce;

B. Violating 21 U.S.C. § 331(a), by distributing misbranded drugs in interstate commerce;

C. Violating 21 U.S.C. § 331(k), by causing drugs to become misbranded, which such drugs are held for sale after shipment of one or more of their components in interstate commerce;

D. Violating 21 U.S.C. § 331(a), by distributing adulterated and misbranded dietary supplements in interstate commerce; and

E. Violating 21 U.S.C. § 331(k), by causing dietary supplements to become adulterated and misbranded, while such articles are held for sale after shipment of one or more of their components in interstate commerce;

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, assigns, and any and all persons in active concert or participation with any of them, from promoting and distributing any drug or dietary supplement unless and until:

A. A new drug application or abbreviated new drug application is approved and in effect for the product pursuant to 21 U.S.C. § 355; or

B. An investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or

C. Defendants have removed all claims from (1) websites owned, controlled by, or related to Defendants, including the firm's website (www.stores.iowaselectherbs.com), Defendants' Facebook page(s), any future website created by Defendants, and Defendants' postings on eBay, Amazon, and other online marketplace websites (collectively, "Defendants' websites"); (2) other product labeling and promotional materials, including videos; and (3) any

other media that cause Defendants' products to be drugs as defined by the Act;

III. 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 manufacturing, processing, packing, labeling, holding, or distributing dietary supplements, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and hold dietary supplements are established, operated, and administered in conformity with the Act and Dietary Supplement CGMP, 21 C.F.R. Part 111, in a manner that has been found acceptable by FDA;

B. Defendants have updated their labeling to ensure that the labeling on all dietary supplements is in compliance with 21 U.S.C. § 343(s)(2)(C);

IV. Order that FDA be authorized pursuant to this injunction to inspect Defendants' facility and all records relating to receiving, manufacturing, processing, packing, labeling, holding, and distributing any drug or dietary supplement 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; and

V. 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 10th day of July, 2015

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