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)

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, United States of America, by its undersigned attorneys having filed a Complaint for Permanent Injunction against Iowa Select Herbs, LLC ("Iowa Select Herbs" or the "firm"), a corporation, and Gordon L. Freeman and Lois A. Dotterweich (now known as Lois A. Freeman), individuals (collectively, "Defendants"), and Defendants having appeared and consented to the entry of this Decree without contest and before any testimony has been taken, and Plaintiff having consented to this Decree;

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

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 332. Venue is proper in this district under 21 U.S.C. § 1391(b) and (c).

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. §§ 301–399f (the "Act").

3. Defendants violate 21 U.S.C. § 331(d), by introducing or delivering for introduction, and 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, nor exempt from approval.

4. Defendants violate 21 U.S.C. § 331(a), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce articles of drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use.

5. Defendants violate 21 U.S.C. § 331(k), by causing drugs to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use, while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

6. Defendants violate 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce dietary supplements, as defined by 21 U.S.C. § 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held under conditions that do not comply with the current good manufacturing practice regulations for dietary supplements ("Dietary Supplement CGMP"), see 21 C.F.R. Part 111, and misbranded within the meaning of 21 U.S.C. § 343(s)(2)(C), in that their labeling fails to identify the part of the plant from which each herb or botanical dietary ingredient is derived.

7. Defendants violate 21 U.S.C. § 331(k), by causing dietary supplements, as defined by 21 U.S.C. § 321(ff), to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, and held under conditions that do not

comply with the Dietary Supplement CGMP, see 21 C.F.R. Part 111, and misbranded within the meaning of 21 U.S.C. § 343(s)(2)(C), in that their labeling fails to identify the part of the plant from which each herb or botanical dietary ingredient is derived, while such articles are held for sale after shipment of one or more of their components in interstate commerce.

8. Upon entry of this Decree, Defendants represent to the Court that they are not directly or indirectly engaged in manufacturing, processing, packing, labeling, holding, or distributing any dietary supplement, any product labeled as such, or any drug. If Defendants later intend to resume operations at 2347 Blairs Ferry Road, NE, Suite 2, Cedar Rapids, Iowa 52402, or any other location, Defendants must notify FDA in writing at least sixty (60) business days in advance of resuming operations and must comply with Paragraphs 9(A)-(F) and 9(H) of this Decree. This notice shall identify the type(s) of dietary supplements Defendants intend to manufacture, process, pack, label, hold and/or distribute, and the facility in which Defendants intend to resume operations. Defendants shall not resume operations until Defendants have satisfied all of the conditions in Paragraphs 9(A)-(F), FDA has inspected Defendants' facility and operations pursuant to Paragraph 9(G), Defendants have paid the costs of such inspection(s) pursuant to Paragraph 9(H), and Defendants have received written notice from FDA, as required by Paragraph 9(I), and then Defendants shall resume such dietary supplement operations only to the extent authorized in FDA's written notice.

9. 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 who receive actual notice of this Decree by personal service or otherwise (collectively, "Associated Persons"), are permanently restrained and enjoined under 21 U.S.C. § 332(a) and the equitable authority of this Court, from

introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate commerce any drug or dietary supplement from or at the facility at 2347 Blairs Ferry Road, NE, Suite 2, Cedar Rapids, Iowa and any other locations at which Defendants now, or in the future, directly or indirectly receive, prepare, process, manufacture, label, pack, hold, and/or distribute drugs or dietary supplements (collectively, "Defendants' facility"), unless and until all of the following occur:

A. 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;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "Labeling Expert"), who is without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants and their families, and who by reason of background, experience, education, and training, is qualified to assess Defendants' compliance with the Act and to review the claims Defendants make for each of their products on Defendants' websites, product labeling and promotional materials, and any other media. Defendants shall notify FDA in writing of the identity and qualifications of the Labeling Expert as soon as they retain such expert. At the conclusion of the Labeling Expert's review, the Labeling Expert shall prepare a written report analyzing whether Defendants are operating in compliance with the Act, applicable regulations, and this Decree. The Labeling Expert shall also certify in the report whether (1) Defendants have omitted claims that cause any of Defendants'

products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g), from Defendants' websites, product labeling and promotional materials, and any other media; (2) Defendants have revised their labeling to ensure that the labeling on all dietary supplements is in compliance with the Act, applicable regulations, and this Decree; and (3) if Defendants make any health claims about their products, Defendants only make permitted health claims that comport with the requirements of 21 C.F.R. §§ 101.70–83. The report shall include the specific results of the Labeling Expert's review, including references to product names and regulations addressed in the process of conducting the review. The report shall also include copies of all materials reviewed by the Labeling Expert. The Labeling Expert shall submit this report concurrently to Defendants and FDA no later than twenty (20) calendar days after completing this review;

C. Defendants retain, at Defendants' expense, an independent person or persons (the "Dietary Supplement CGMP Expert"), who is without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants or their families, and who by reason of background, experience, education, and training, is qualified to inspect Defendants' facility to determine whether the facility, methods, processes, and controls are operated and administered in conformity with Dietary Supplement CGMP, 21 C.F.R. Part 111. Defendants, if appropriate, may retain as the Dietary Supplement CGMP Expert the same independent party they retain as the Labeling Expert. Defendants shall notify FDA in writing of the identity and qualifications of the Dietary Supplement CGMP Expert as soon as they retain such expert;

D. The Dietary Supplement CGMP Expert performs a comprehensive inspection of Defendants' facility and the methods and controls used to manufacture, prepare, pack, label, hold, and distribute dietary supplements, and certify in writing to FDA that (1) he or

she has inspected Defendants' facility, methods, processes, and controls; and (2) whether Defendants' operations are, in the Dietary Supplement CGMP Expert's opinion, in compliance with 21 U.S.C. § 342(g)(1), 21 C.F.R. Part 111, and this Decree. The Dietary Supplement CGMP Expert's report of the inspection shall be submitted concurrently to Defendants and FDA no later than twenty (20) calendar days after he or she completes the inspection. This report shall include, but not be limited to, the following:

1. A determination as to whether Defendants prepare and continuously follow a written master manufacturing record for each unique dietary supplement formulation of each product manufactured and for each batch size, as required by 21 C.F.R. § 111.205, and whether Defendants include all required information in the master manufacturing record, as required by 21 C.F.R. § 111.210;

2. An evaluation as to whether Defendants continuously comply with the regulations regarding batch records and batch production, as specified in 21 C.F.R. §§ 111.255 and 111.260;

3. A determination as to whether Defendants have established specifications, as required by 21 C.F.R. § 111.70, and whether those specifications are continuously met as required by 21 C.F.R. § 111.73;

4. A determination as to whether Defendants have established written procedures for calibrating, maintaining, and cleaning equipment and utensils; preventing microbial contamination of dietary supplements; and establishing hygienic practices at the firm, as required by 21 C.F.R. §§ 111.25, 111.8, 111.10(a), and 111.10(b);

5. A determination as to whether Defendants adequately determine and document that the products they receive from their suppliers meet specifications, as required

by 21 C.F.R. § 111.75;

6. A determination as to whether Defendants continuously comply with the procedures and requirements for quality control operations, as required by 21 C.F.R. § 111.123;

7. A determination as to whether Defendants establish and continuously follow written procedures specifying the responsibilities of their quality control operations, as required by 21 C.F.R. § 111.103;

8. A determination as to whether Defendants hold reserve samples in the same container-closure system in which the packaged dietary supplement is distributed, as required by 21 C.F.R. § 111.83(b)(1); and

9. A determination as to whether Defendants have established and follow written procedures for (1) product complaints, see 21 C.F.R. §§ 111.553–111.570; (2) returned dietary supplements, see 21 C.F.R. §§ 111.503–111.535; (3) holding and distributing operations, see 21 C.F.R. §§ 111.453–111.475; and (4) packaging and labeling operations, see 21 C.F.R. §§ 111.403–430.

E. Should the Labeling Expert or Dietary Supplement CGMP Expert (collectively, "Experts") identify any deficiencies in their reports as described in Paragraphs 9(B) and 9(D):

1. Defendants shall report to FDA and the Experts in writing the actions they have taken to correct all such deficiencies; and

2. The Experts shall certify in writing to FDA, based upon the Experts' further review and/or inspection(s), whether (1) Defendants have omitted all claims that cause any of Defendants' products to be drugs within the meaning of the Act, 21 U.S.C.

§ 321(g), from Defendants' websites, product labeling and promotional materials, and any other media; (2) 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); (3) Defendants only make permitted health claims that comport with the requirements of 21 C.F.R. §§ 101.70–83 if Defendants make any health claims about their products; and (4) Defendants' facility and the methods, processes, and controls used to manufacture, prepare, pack, label, hold, distribute, and promote their drug and dietary supplement products appear to be in compliance with the Act, its implementing regulations, and this Decree;

F. Defendants recall and destroy, under FDA's supervision and in accordance with the procedures provided in Paragraph 11, all of Defendants' products that were manufactured, prepared, packed, labeled, held, and/or distributed between January 1, 2015, and the date of entry of this Decree;

G. FDA representatives inspect Defendants' facility 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;

H. Defendants have paid all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews with respect to Paragraph 9, at the rates set forth in Paragraph 17 below; and

I. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 9(A)–(H). In no circumstance shall FDA's silence be construed as a substitute for written notification.

10. Paragraph 9 shall not apply if Defendants have in effect an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355(b) or (j),

and/or an investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for all of Defendants' products, and Defendants are operating in compliance with current good manufacturing practices for drugs. See 21 C.F.R. Parts 210 and 211.

11. Within thirty (30) calendar days after entry of this Decree, Defendants shall recall all drugs and dietary supplements manufactured, prepared, packed, or labeled by Defendants that were held and/or distributed between January 1, 2015, and the date of entry of this Decree. Within seventy-five (75) calendar days after the entry of this Decree, Defendants, under FDA's supervision, shall destroy all of the recalled drugs and dietary supplements and all drugs and dietary supplements that are in Defendants' possession, custody, or control, pursuant to a method approved in advance in writing by FDA. After this destruction, if Defendants receive any drugs or dietary supplements that they manufactured, prepared, packed, labeled, held, and/or distributed between August 25, 2014, and the date of entry of this Decree, Defendants shall destroy such drugs and/or dietary supplements, under FDA's supervision and pursuant to a method approved in advance in writing by FDA, within forty-five (45) calendar days after Defendants receive such products. Defendants shall bear the costs of destruction and, at the rates set forth in Paragraph 17, the costs of FDA's supervision. Defendants shall not dispose of any drugs or dietary supplements in a manner contrary to the provisions of the Act, any other federal law, or the laws of any State or Territory, as defined in the Act, in which the drugs or dietary supplements are disposed.

12. After Defendants have complied with Paragraphs 9(A)-(H) and received FDA's written notification pursuant to Paragraph 9(I), Defendants shall retain an independent person or persons who shall meet the criteria described in Paragraphs 9(B) and 9(C) (hereinafter, the "Auditor") to conduct audit inspections of Defendants' facility no less frequently than once

every six (6) months for a period of no less than three (3) years, and then no less than once a year for the following two (2) years. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to Paragraph 9(I). If Defendants choose, the Auditor may be the same person or persons retained as the Labeling Expert or Dietary Supplement CGMP Expert described in Paragraphs 9(B) and (C).

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with Dietary Supplement CGMP for their dietary supplement operations and identifying any deviations from such requirements ("Audit Report Observations").

B. Each Audit Report shall contain a written certification that the Auditor: (a) has personally reviewed Defendants' websites, product labeling and promotional materials, and any other media containing claims about Defendants' products; and (b) personally certifies whether there are claims that cause any of Defendants' products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g), and whether Defendants are in compliance with the requirements of the Act, its regulations, and this Decree.

C. As a part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA's Kansas City District Office, at the address provided in Paragraph 20 by courier service or overnight delivery service, no later than fifteen (15) business days after the date the Audit Inspection is completed. In addition, Defendants shall maintain their Audit Reports in separate files at Defendants' facility and shall promptly make the Audit Reports available to FDA upon request.

D. If an Audit Report contains any observations indicating that Defendants'

drugs and/or dietary supplements are not in compliance with the Act, its implementing regulations, and/or this Decree, Defendants shall, within fifteen (15) calendar days of receipt of 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 the deviations may take longer than fifteen (15) calendar days, Defendants shall, within ten (10) calendar days of 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 Defendants. In no circumstance, shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule.

E. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within thirty (30) calendar days after the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, 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 Audit Report Observations. Within five (5) business 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.

13. 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 who receive actual notice of this Decree by personal service or otherwise (collectively, "Associated Persons") are permanently restrained and enjoined from directly or indirectly doing or causing 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 new drugs within the meaning of 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, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), dietary supplements that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), and/or dietary supplements that are misbranded within the meaning of 21 U.S.C. § 343(s)(2)(C); or

C. Violating 21 U.S.C. § 331(k), by causing drugs to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), dietary supplements to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), and/or dietary supplements to become 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.

14. If, at any time after this Decree has been entered, FDA determines, based on a review of inspection results, Defendants' websites, product labeling and promotional materials, any other media containing claims about Defendants' products, a report prepared by Defendants' Experts or the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with the Act, applicable regulations, and/or this Decree, 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, processing, packing, labeling, holding, and/or

distributing any or all drugs and/or dietary supplements;

B. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

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

D. Pay liquidated damages as provided in Paragraph 21 below;

E. Recall any article(s) at Defendants' expense; or

F. Take any other corrective action(s) as FDA, in its discretion, deems necessary to bring Defendants and their products into compliance with the Act, applicable regulations, and/or this Decree. 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.

G. Upon receipt of any order issued by FDA pursuant to Paragraph 14, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 14 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. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 14 shall be borne by Defendants at the rates specified in Paragraph 17.

15. Within ten (10) calendar days after FDA's request for Defendants' websites, product labeling and promotional materials, and any other media containing claims about Defendants' products, Defendants shall submit a copy of the requested materials (in hard copy or, if appropriate, on CD-Rom) to FDA at the address specified in Paragraph 20.

16. FDA representatives shall be permitted, without prior notice and as 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. During such inspections, FDA representatives shall be permitted immediate access to buildings, equipment, in-process and finished materials, containers, Defendants' websites, product labeling and promotional materials, and any other media containing claims about Defendants' products, and other materials therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, Defendants' websites, product labeling and promotional materials, and any other media containing claims about Defendants' products; and to examine and copy all labeling and promotional materials and all records relating to the receipt, manufacture, processing, packing, holding, and distribution of any and all 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 conduct inspections under the Act, 21 U.S.C. § 374.

17. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses specified in this Decree or that FDA deems necessary to evaluate Defendants' compliance with this Decree. For the purposes of this Decree, inspections include FDA's review and analysis of Defendants' claims on Defendants' websites, product labeling and promotional materials, and any other media containing claims about Defendants' products. The costs of such inspections shall be borne by Defendants at the prevailing rates in effect 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 and fraction thereof per representative for inspection 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 or the equivalent for the areas in which the inspections are performed per-day, per-representative 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.

18. 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 (restricted delivery, return receipt requested), to each and all of their Associated Persons, and post the Decree on all of Defendants' websites (except for third-party online marketplace websites such as eBay and Amazon). Within thirty (30) 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: (a) within fifteen (15) calendar days of such association, provide a copy of this Decree to each such Associated Person by personal service or certified mail (restricted delivery, return receipt requested), and (b) on a quarterly basis, notify FDA in writing when, how, and to whom the Decree was provided.

19. Defendants shall notify FDA, in writing, at the address specified in Paragraph 20, at least fifteen (15) calendar days before any change in ownership, character, or name of its 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 corporate structure of Iowa Select Herbs 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 of compliance with this Paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

20. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the District Director, Kansas City District Office, United States Food and Drug Administration, 8050 Marshall Drive, Suite 205, Lenexa, Kansas 66214, and shall reference the case name and civil action number.

21. If Defendants fail to comply with the Act, its implementing regulations, and/or any provision of this Decree, including any time frame imposed by this Decree, Defendants shall pay to the United States of America: (a) five thousand dollars ($5,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree; (b) an additional five hundred dollars ($500) in liquidated damages per day, per violation, for each violation of the Act, its implementing regulations, and/or this Decree; and (c) an additional sum in liquidated damages equal to twice the retail value of any distributed drugs or dietary supplements that are adulterated, misbranded, or otherwise 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 the remedy in this Paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

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, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

23. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. If contested, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review 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 for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

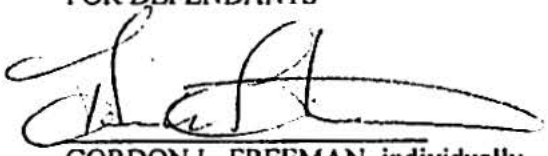
IT IS SO ORDERED.

Dated this 17 day of August, 2015.

Edward J. McManus
UNITED STATES DISTRICT JUDGE

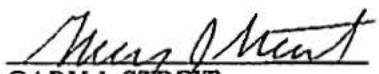
Entry consented to:

FOR DEFENDANTS



GORDON L. FREEMAN, individually
and on behalf of IOWA SELECT
HERBS, LLC

LOIS A. DOTTERWEICH
(now known as LOIS A.
FREEMAN), individually



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