United States District Court

Southern District of Georgia

UNITED STATES OF AMERICA,
Plaintiff,

v.

FUSION HEALTH AND VITALITY LLC, a Limited Liability Company doing business as Pharm Origins; FUSION lONZ LLC, a Limited Liability Company doing business as Pharm Origins; and MATTHEW RYNCARZ, an Individual;

JUDGMENT IN A CIVIL CASE

Case Number: CV420-296

☐ **Jury Verdict.** This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

☒ **Decision by Court.** This action came before the Court. The issues have been considered and a decision has been rendered.

IT IS ORDERED AND ADJUDGED

that in accordance with this Court's Order dated January 7, 2021 granting the Motion to Approve a Consent Decree it is further **ORDERED, ADJUDGED, AND DECREED** as follows:

This Court has jurisdiction over the subject matter and all parties to this action.

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

Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce new drugs, as defined in 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval.

Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce drugs, as defined in 21 U.S.C. § 321(g), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), and food (dietary supplements, as defined in 21 U.S.C. § 321(ff)) that is adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i) and misbranded within the meaning of 21 U.S.C. § 343.

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), and by causing food (dietary supplements, as defined in 21 U.S.C. § 321(ff)) to become adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i) and misbranded within the meaning of 21 U.S.C. § 343, while they are held for sale after shipment of one or more of their components in interstate commerce.

For the purposes of this Decree, the following definitions shall apply:

A. "Facility" means 1360 Union Hill Road, Suite 11B, Alpharetta, Georgia, 30004, or any other location(s) at which Defendants now or in the future directly or indirectly manufacture, process, pack, label, hold, and/or distribute any drug or articles of drugs or food (including but not limited to dietary supplements and their components).

B. "Current Websites" means the following websites: www.pharmorigins.com,www.pharmorigins.co, www.americanraws.net, www.immune-shot.com, www.freecoreoffer.online, www.immune-boost.net, and any other website(s) and social media account(s) currently in existence that are registered to, owned by, controlled by, or under the direction of any Defendant.

C. "Future Websites" means any future website(s) or social media account(s) registered to, owned by, controlled by, or under the direction of any Defendant.

D. "Vitamin D Products" refers to Defendants' products called Immune Shot, Immune Boost, CORE, and any other of Defendants' products that contain vitamin D.

E. "Hordenine HCl Products" refers to any of Defendants' products that contain hordenine HCl, including Defendants' CORE product.

Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them ("Associated Persons") 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, processing, packing, labeling, holding, and/or distributing any drug or articles of drugs or food (including but not limited to dietary supplements and their components), including but not limited to Vitamin D Products and Hordenine HCl Products, unless and until:

A. For all of Defendants' drugs, either:

i. Defendants have an approved new drug application ("NDA") or an abbreviated new drug application ("ANDA"), pursuant to 21 U.S.C. § 355(b), (j), or an investigational new drug application ("IND") in effect pursuant to 21 U.S.C. § 355(i), for such drugs; or

ii. Defendants meet the following requirements:

a. Defendants remove from product labeling (including but not limited to labels, promotional material, Current Websites, and Future Websites) and other promotional/informational material: (1) all representations that Defendants' 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 (2) 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.

b. Defendants retain, at Defendants' expense, an independent person or persons (the "Drug Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who by reason of background, training, education, or experience is qualified to review Defendants' product labeling (including but not limited to labels, promotional material, Current Websites, and Future Websites) and other promotional/informational material to determine whether: (1) Defendants' claims cause any of the products that they manufacture, process, pack, label, hold, and/or distribute, including but not limited to Vitamin D Products, to be a drug within the meaning of 21 U.S.C. § 321(g)(1); and (2) Defendants' product labeling complies with the Act and its implementing regulations. Defendants shall notify FDA in writing of the identity and qualifications of the Drug Expert within three (3) business days after retaining such expert.

c. The Drug Expert shall perform a comprehensive review of Defendants' product labeling (including but not limited to labels, promotional material, Current Websites, and Future Websites) and other promotional/informational material and certifies in writing to FDA that: (1) he or she has identified all of Defendants' products and reviewed Defendants' representations for each product on labeling and other promotional/informational material; (2) Defendants have removed all representations that cause any of Defendants' products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g); and (3) based upon the Drug Expert's inspection and review, Defendants are operating, in compliance with this Decree, the Act, and its implementing regulations. The Drug Expert's written certification

shall include the specific results of his or her inspection and review, including references to product names and copies of all materials reviewed.

d. For all products for which Defendants have removed claims that caused Defendants' products to be drugs within the meaning of the Act, and such products meet the definition of a dietary supplement in 21 U.S.C. § 321(ff), Defendants shall comply with the requirements in Paragraph 7.B of this Decree and the Act's dietary supplement provisions and implementing regulations, before introducing such products into interstate commerce.

B. For all of Defendants' food products (dietary supplements):

i. Defendants retain, at Defendants' expense, an independent person or persons (the "Dietary Supplement Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, except that this person may be the same as the Drug Expert described in Paragraph 7.A, and who, by reason of background, training, education, or experience, is qualified to inspect the Facility and review Defendants' labeling (including but not limited to labels, promotional material, Current Websites, and Future Websites) and other promotional/informational material to determine whether Defendants' methods, processes, and controls, are adequate to ensure that the dietary supplements that they manufacture, process, pack, label, hold, and/or distribute are in compliance with this Decree, the Act, and its implementing regulations, including, but not limited to, whether: (1) Defendants' methods, processes, and controls, are adequate to ensure that none of the dietary supplements that they manufacture, process, pack, label, hold, and/or distribute, including but not limited to Hordenine HCl Products, contain a food additive that is unsafe within the meaning of 21 U.S.C. § 348(a); and (2) Defendants' dietary supplement labeling complies with 21 U.S.C. § 343 and applicable regulations.

ii. Defendants shall notify FDA in writing of the identity and qualifications of the Dietary Supplement Expert within three (3) business days after retaining such expert.

iii. The Dietary Supplement Expert shall perform a comprehensive inspection of the Facility and the methods, processes, and controls used to manufacture, process, pack, label, hold, and/or distribute dietary supplements and a comprehensive review of Defendants' labeling (including but not limited to labels, promotional material, Current Websites, and Future Websites) and other promotional/informational material and certify in writing to FDA that: (1) he or she has inspected the Facility, and the methods, processes, and controls used to manufacture, process, pack, label, hold, and/or distribute dietary supplements; (2) he or she has reviewed Defendants' labeling and other promotional/informational material; (3) Defendants' Facility and the methods, processes, and controls used to manufacture, process, pack, label, hold, and/or distribute dietary supplements are, in the Dietary Supplement Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations; (4) all deviations from the requirements in 21 U.S.C. § 348(a) that have been brought to Defendants' attention by FDA, the Dietary Supplement Expert, and any other source since May 2020, have been corrected; (5) Defendants' products and claims are, in the Dietary Supplement Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations; and (6) Defendants' dietary supplement labeling complies with 21 U.S.C. § 343 and applicable regulations.

iv. The Dietary Supplement Expert shall prepare a detailed report, which shall be submitted to FDA as part of the certification described in Paragraph 7.B.iii, of the Dietary Supplement Expert's inspection that shall include, but not be limited to: (1) a determination that Defendants have implemented corrections to their methods, processes, and controls that are adequate to ensure that none of the dietary supplements that Defendants

manufacture, process, pack, label, hold, and/or distribute contain a food additive that is unsafe within the meaning of 21 U.S.C. § 348(a); (2) Defendants' claims are, in the Dietary Supplement Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations; and (3) Defendants have implemented corrections to ensure that their dietary supplement labeling complies with 21 U.S.C. § 343 and applicable regulations.

C. Should any Expert(s) described in Paragraphs 7.A – 7.B identify any deficiencies as part of their certifications as described in Paragraphs 7.A.ii.c and/or 7.B.iii:

i. Defendants shall report in writing to FDA and the appropriate Expert the actions they have taken to correct all such deficiencies; and

ii. The appropriate Expert shall certify in writing to FDA, based upon his or her further review and/or inspection(s) that Defendants are operating in conformity with this Decree, the Act, and its implementing regulations.

D. If FDA determines it to be necessary, FDA representatives inspect the Facility to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with this Decree, the Act, and its implementing regulations.

E. Defendants recall and destroy, under FDA's supervision and in accordance with the procedures provided in Paragraphs 8 – 9, all of Defendants' Vitamin D Products and Hordenine HCl Products that were manufactured, processed, packed, labeled, held, and/or distributed by Defendants from January 1, 2020, through and including the date of entry of this Decree.

F. Defendants have reimbursed FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with Paragraph 7, at the rates set forth in Paragraph 16; and

G. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in Paragraphs 7.A – 7.C and 7.E – 7.F of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

Within eight (8) calendar days after entry of this Decree, Defendants shall submit to FDA for its review and concurrence a strategy to recall all of the Vitamin D Products and Hordenine HCl Products that were distributed by Defendants from January 1, 2020, through and including the date of entry of this Decree. The recall strategy shall include customer notifications, public warning, methods for conducting effectiveness checks, and plans for product disposition. Within five (5) calendar days after receiving FDA concurrence of the recall strategy, Defendants shall initiate a recall of all distributed Vitamin D Products and Hordenine HCl Products.

Within fifteen (15) business days after completing the recall of all distributed Vitamin D and Hordenine HCl Products as described in Paragraph 8, Defendants shall give notice to FDA that, under FDA's supervision (which may be done by e-mail or other virtual means as FDA determines to be appropriate), Defendants are prepared to destroy all Vitamin D Products and Hordenine HCl Products (including components, raw and in-process materials, and finished products) in Defendants' possession, custody, or control. Defendants' notice shall specify the proposed time, place, and method of destruction. Defendants shall not commence or permit any other person to commence destruction until they have received written authorization from FDA to commence the destruction. Within fifteen (15) business days after receiving authorization from FDA to commence destruction, Defendants shall, under FDA supervision (which may be done by email or other virtual means as FDA determines to be appropriate), complete the destruction in compliance with this Decree. Defendants shall not dispose of any such products in a manner contrary to the provisions of the Act, any other federal law, or the laws or any state or Territory, as defined in the Act, in which the products are disposed. Defendants shall bear the costs of destruction and FDA's supervision.

After Defendants have complied with Paragraphs 7.A – 7.C and 7.E – 7.F and received FDA's written notification pursuant to 7.G, Defendants shall retain an independent person or persons who shall meet the criteria described in Paragraphs 7.A – 7.B (the "Auditor") to conduct audit inspections of the Facility and a comprehensive review of Defendants' labeling (including but not limited to labels, promotional material, Current Websites, and Future Websites) and other promotional/informational material, no less frequently than once every six (6) months for a period of no less than five (5) years. The first audit shall occur not more than six (6) months after Defendants receive FDA's written notification pursuant to Paragraph 7.G. The Auditor may be the same person or persons retained as an Expert described in Paragraphs 7.A – 7.B.

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether or not Defendants are operating in compliance with this Decree, the Act, and its implementing regulations and identifying in detail any deviations from the foregoing ("Audit Report Observations").

B. Each Audit Report shall contain a written certification that the Auditor: (1) has personally inspected Defendants' Facility and operations and reviewed all product labeling (including but not limited to labels, promotional material, Current Websites, and Future Websites) and other promotional/informational material; and (2) personally certifies whether Defendants' food (dietary supplements) and drugs are in compliance with the requirements of this Decree, the Act, and its implementing regulations.

C. As part of every Audit Report, except the first, 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, at the address provided in Paragraph 22, by courier service or overnight delivery service, no later than fifteen (15) days after the date the Audit inspection is completed. In addition, Defendants shall maintain their Audit

Reports and all of their underlying data in separate files at the Facility and shall promptly make the Audit Reports available to FDA upon request.

D. If an Audit Report contains any observations indicating that Defendants' food (dietary supplements) or drugs are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall, within fifteen (15) calendar days after 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 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 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 the Audit 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 have been corrected, and, if not, which Audit Reports Observations remain uncorrected.

11. Upon entry of this Decree and after Defendants receive notification under Paragraph 7.G from FDA that they are permitted to resume operations, Defendants and all 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 into interstate commerce new drugs, as defined in 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 into interstate commerce drugs, as defined in 21 U.S.C. § 321(g), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), and food (dietary supplements, as defined in 21 U.S.C. § 321(ff)) that is adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i) or misbranded within the meaning of 21 U.S.C. § 343.

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), and by causing food (dietary supplements, as defined in 21 U.S.C. § 321(ff)) to become adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i) or misbranded within the meaning of 21 U.S.C. § 343, while they are held for sale after shipment of one or more of their components in interstate commerce.

D. Failing to implement and continuously maintain the requirements of the Act, its implementing regulations, and this Decree.

If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, a review of Defendants' products, labeling, a report prepared by the Drug Expert, the Dietary Supplement Expert, 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 this Decree, the Act, or its applicable 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, processing, packing, labeling, holding, and/or distributing any or all drugs and/or dietary supplements;

B. Recall, at Defendants' expense, any product that in FDA's judgment is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

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

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

E. Issue a safety alert; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants 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.

Upon receipt of any order issued by FDA pursuant to Paragraph 12, Defendants shall immediately and fully comply with the terms of FDA's 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. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph shall be borne by Defendants at the rates specified in Paragraph 16.

Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect the Facility, any other location(s) at which Defendants, now or in the future, directly or indirectly engage in manufacturing, processing, packing, labeling, holding, and/or distributing any drug and/or dietary supplement, and Defendants' operations, collect samples, 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: immediate access to Defendants' Facility and/or other place(s) of business, including but not limited to all buildings or other structures, equipment, raw ingredients, in-process or unfinished and finished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, finished and unfinished materials and products, containers, and labeling; and examine and copy all records relating to the receipt, labeling, holding, and distribution of any and all of Defendants' 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 and apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

Defendants shall promptly provide any information or records to FDA upon request regarding the manufacturing, processing, packing, labeling, holding, and/or distributing of Defendants' drugs and/or dietary supplements, including but not limited to Vitamin D Products and Hordenine HCl Products. Defendants shall submit to FDA, at the street address specified in Paragraph 22 and within ten (10) calendar days after such request, a copy of the materials FDA requests, on CDROM or DVD. Such requested materials may include, but are not limited to: a list of all locations where any of Defendants' drug or dietary supplement products are held, including but not limited to Vitamin D Products and Hordenine HCl Products; a list of all of Defendants' websites and any other media that are registered to, owned by, controlled by, or under the direction of any Defendant; and/or downloaded copies of any and all of Defendants' websites, product labeling and promotional materials, and any other media that are registered to, owned by, controlled by, or under the direction of any Defendant.

Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree, including all transportation and associated costs for FDA investigators and experts,

at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $101.00 per hour or fraction thereof per representative for inspection and investigative work; $121.06 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.

Within five (5) business days after the entry of this Decree, Defendants shall post a copy of this Decree in a common area at the Facility and at any other location at which Defendants conduct business and shall ensure that this Decree remains posted for as long as this Decree remains in effect. Within ten (10) business days after entry of this Decree, Defendants 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.

Within ten (10) business 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 and shall post this Decree on Current Websites and Future Websites. Within twenty (20) business days after the date of entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, including identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall within ten (10) business days after the commencement of such association: (a) provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s); and (b) provide to FDA an affidavit 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.

Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, name, or character of their 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 Fusion Health and Vitality LLC or Fusion Ionz LLC, or the sale or assignment of any business assets, such as the Facility, other buildings or structures, equipment, or inventory. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

Defendants shall notify FDA in writing at least ten (10) business 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 the Vitamin D Products or Hordenine HCl Products or any other of Defendants' drugs or dietary supplements. Defendants shall post a copy of this Decree, in accordance with Paragraph 18, on any websites created after entry of this Decree that convey information about Vitamin D Products or Hordenine HCl Products or other drugs and/or dietary supplements. Within ten (10) calendar days after the creation of any new websites, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this Paragraph.

All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be addressed to: Director, Office of Pharmaceutical Operations Division II, 4040 North Central Expressway, Suite 300, Mail Code HFR-SW100, Dallas, Texas 75204, and shall also be sent by e-mail to ORAPHARM2_RESPONSES@fda.hhs.gov.

If any 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 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, or this Decree; (b) an additional three thousand dollars ($3,000) in liquidated

damages per day, per violation, for each violation of the Decree, the Act, and its implementing regulations; and (c) an additional sum in liquidated damages equal to twice the retail value of any product distributed in violation of the Decree, the Act, and its implementing regulations. 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.

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, and court costs relating to such contempt proceedings.

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, if contested, shall be reviewed by this 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.

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.

January 8, 2021
Date

UNITED STATES COURTS
SOUTHERN DISTRICT OF GEORGIA

John E. Triplett, Acting Clerk
Clerk

James R. Burrell
(By) Deputy Clerk