THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

UNITED STATES OF AMERICA, Plaintiff, v. GRANDMA'S HERBS, INC., a corporation; KEVIN PARR, and TRACY PARR, individuals, Defendants.	**CONSENT DECREE OF PERMANENT INJUNCTION** Case No. 4:21-cv-00106-DN District Judge David Nuffer

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction (the "Complaint")[1] against Grandma's Herbs, Inc. ("Grandma's Herbs" or "the company"), a corporation, and Kevin Parr and Tracey Parr, individuals (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Consent Decree of Permanent Injunction (the "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 over all parties to this action.

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

[1] Docket no. 2, filed Oct. 18, 2021.

3. The Complaint alleges that Defendants violate 21 U.S.C. § 33l(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355(b) or (j), nor exempt from approval under 21 U.S.C. § 355(i).

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drugs, as defined in 21 U.S.C. § 321(g), 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. 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 in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any drug at or from 221 W. 200 S, Saint George, Utah 84770, or at or from any other location(s) at which Defendants, now or in the future, directly or indirectly manufacture, prepare, process, pack, label, hold, and/or distribute any drug ("Defendants' establishment"), unless and until:

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

B. Defendants retain, at their expense, an independent person or persons (the "Labeling Expert"), who is without personal or financial ties (other than the retention agreement)

to Defendants and/or their families, and who by reason of background, training, education, or experience, is qualified to inspect Defendants' establishment and to review the representations Defendants make for each of their products on product labels; labeling; leaflets; websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, grandmasherbs.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants); promotional materials; and any other media over which Defendants have control. Defendants have notified the United States Food and Drug Administration ("FDA") in writing that they have retained a Labeling Expert, prior to signing this Decree, and shall provide in writing the identity and qualifications of the Labeling Expert within fifteen (15) business days after entry of this Decree. In addition, Defendants shall notify FDA in writing of the identity and qualifications of any other Labeling Expert retained in the future within fifteen (15) business days of retaining such expert; and

C. The Labeling Expert shall submit a written report certifying to FDA:

(1) that he or she has inspected Defendants' establishment;

(2) that he or she has identified all of Defendants' products and reviewed Defendants' representations for each product on product labels; labeling; leaflets; websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, grandmasherbs.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants); promotional materials; and any other media over which Defendants have control;

(3) whether 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), for indications for which they do not have FDA approval; and

(4) based upon the Labeling Expert's inspection and review, whether Defendants are causing any of their products to be drugs within the meaning of the Act for indications for which they do not have FDA approval. The Labeling 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 and specific recommendations to achieve compliance;

D. Should the Labeling Expert identify any deficiencies in his or her report as described in Paragraph 5.C:

(1) Defendants shall report to FDA and the Labeling Expert in writing the actions they have taken to correct such deficiencies; and

(2) The Labeling Expert shall certify in writing to FDA, based upon the Expert's further review and/or inspections(s) that (a) Defendants have removed all representations from each of their product labels; labeling; leaflets; websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, grandmasherbs.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants); promotional materials; and any other media over which Defendants have control, that cause any of Defendants' products to be drugs within the meaning of the Act for indications for which they do not have FDA approval and (b) Defendants are no longer causing any of their products to be drugs within the meaning of the Act for indications for which they do not have FDA approval;

E. Defendants have reimbursed FDA within fifteen (15) days of the receipt of any invoice for the costs of all FDA inspections, investigations, supervision, analyses,

examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with Paragraph 5, at the rates set forth in Paragraph 12;

F. FDA representatives inspect Defendants' establishment 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; and

G. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in Paragraphs 5.A-E of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

6. Upon resuming operations after complying with the requirements of Paragraph 5 and receiving FDA's written notification pursuant to Paragraph 5.G, Defendants shall retain an independent person or persons who shall meet the criteria for, and may be the same person as, the Labeling Expert, described in Paragraph 5.B (hereinafter, the "Auditor"), to conduct audit inspections of Defendants' establishment-including product labels; labeling; leaflets; websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, grandmasherbs.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants); promotional materials; and any other media over which Defendants have control- no less frequently than once every six months for a period of no less than five years. The first audit shall occur not more than six months after Defendants have received FDA's written notification pursuant to Paragraph 5.G.

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 this Decree, the Act, and its implementing regulations, 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 all of Defendants' product labels, labeling, leaflets, websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, grandmasherbs.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants), promotional materials, and any other media over which Defendants have control; and (b) personally certifies whether they make claims that cause Defendants' products to be drugs within the meaning of the Act for indications for which they do not have FDA approval;

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 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 the Audit Reports in separate files at Defendants' establishment and shall promptly make the Audit Reports available to FDA upon request; and

D. If an Audit Report contains any observations indicating that Defendants' drugs are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall, within twenty (20) business 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 will take longer than twenty (20) business days, Defendants shall, within fifteen (15) business 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. Within five (5) days of correction, Defendants shall submit documentation of their corrections to the Auditor. Within thirty (30) business days of 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 an Audit Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within seven (7) business days of 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.

7. Upon entry of this Decree, Defendants, 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, 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, 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, within the meaning of 21 U.S.C. § 32l(g), 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, the Act, and its implementing regulations.

8. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection; a review of product labels, labeling, leaflets, websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, grandmasherbs.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants), promotional materials, and any other media over which Defendants have control; a report prepared by the Labeling 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 implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of their noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to take one or more of the following actions:

A. Cease manufacturing, preparing, processing, packing, labeling, holding, and/or distributing any or all drugs;

B. Recall, at Defendants ' expense, any drug that is 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 or required 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 bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor recalls and other corrective actions, at the rates specified in Paragraph 12.

9. Upon receipt of any order issued by FDA pursuant to Paragraph 8, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 8 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.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' 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 Defendants' establishment, including, but not limited to, all buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material therein; take photographs and make video recordings; take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material , labeling, and other material; and examine and copy all records relating to the receipt, manufacture, preparing, processing, packing, repacking, 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 from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

11. Within fifteen (15) business days after FDA's request for Defendants' product labels; labeling; leaflets; websites or social media pages owned, created by, controlled by, or related to Defendants (including, but not limited to, grandmasherbs.com, and any future website(s) or social media page(s) owned by, created by, controlled by, or related to Defendants); promotional materials; and any other media over which Defendants have control, Defendants shall submit a copy of the requested materials (in electronic format unless otherwise specified) to FDA at the address specified in Paragraph 17.

12. 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 the travel incurred by specialized investigatory and expert personnel, 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: $102.39 per hour and fraction thereof per representative for inspection or investigative work; $122.71 per hour or fraction thereof per representative for analytical or review work; $0.56 per mile (plus tolls) 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.

13. Within seven (7) business days after the entry of this Decree, Defendants shall post a copy of this Decree in a common area at Defendants' establishment, at any other location at which Defendants conduct business, and on all websites under Defendants' control (including, but not limited to, grandmasherbs.com, and any future website(s) under Defendants' control), and shall ensure that the Decree remains posted for as long as it remains in effect. Within fifteen (15) 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.

14. Within fifteen (15) business days after the entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to 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 (collectively, "Associated Person(s)"). Within thirty (30) 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, identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

15. In the event that any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall, within fifteen (15) business days after the commencement of such association, provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s), and provide to FDA an affidavit stating the fact and manner of compliance

with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who received a copy of this Decree pursuant to this paragraph.

16. 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 the company, or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Decree. 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.

17. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence" and reference this civil action by case name and civil action number, and shall be addressed to: District Director, U.S. Food and Drug Administration, Denver District Office, 1 Denver Federal Center, 6th Avenue & Kipling Street, Building 20, P.O. Box 25087, Denver, Colorado 80225-0087. Additionally, materials submitted in electronic format shall be emailed to: ORAHAFWEST4FirmResponses@fda.hhs.gov.

18. 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 and analytical expenses, expert witness fees, court costs, and any other costs and fees relating to such contempt proceedings.

19. 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.

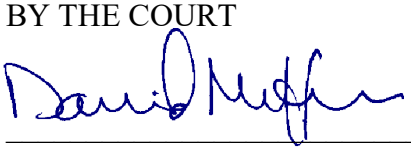
20. This court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

21. The clerk is directed to close the case.

SO ORDERED:

Dated this 20th day of October, 2021.

BY THE COURT



David Nuffer
United States District Judge