IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

United States of America, Plaintiff, v. Smart Women's Choice Incorporated, et al., Defendants.	No. CV-23-02112-PHX-GMS **ORDER AND CONSENT DECREE OF PERMANENT INJUNCTION**

Before the Court is Plaintiff United States of America's Motion to Enter Consent Decree (Doc. 3).

IT IS ORDERED granting Plaintiff's Motion (Doc. 3).

Plaintiff, the United States of America, by its undersigned attorneys, and on behalf of the United States Food and Drug Administration ("FDA"), having filed a Complaint for Permanent Injunction (the "Complaint") against Smart Women's Choice, Inc., an Arizona corporation, and Jennifer A. Richard, an individual (collectively, "Defendants"), and Defendants, solely for the purposes of settlement of this case, and without admitting or denying the allegations in the Complaint, having appeared and consented to the 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 FURTHER 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.

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 *et seq.* (the "Act").

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce a new drug, as defined in 21 U.S.C. § 321(p), that is neither approved under 21 U.S.C. § 355(b) or (j) nor exempt from approval.

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

A. "Days" shall mean calendar days unless otherwise stated.

B. "Defendants' Facilities" shall include:

i. 12805 W. Bloomfield Rd., El Mirage, Arizona 85335;

ii. 12425 W. Bell Rd., Suite 107, Surprise, Arizona 85378; and

iii. Any location at or from which any Defendant now or in the future directly or indirectly manufactures, prepares, processes, packs, repacks, receives, labels, holds, and/or distributes any drug, whether or not such Defendant has an ownership interest in the location.

5. 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 or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, and affiliates), who receive actual notice of this Decree (collectively, "Associated Persons") 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, repacking, receiving, labeling, holding, and/or distributing any drug at or from Defendants' Facilities, unless and until:

A. Defendants demonstrate to FDA that:

i. An approved new drug application or an abbreviated new drug application filed pursuant to 21 U.S.C. §§ 355(b) or 355(j) is in effect with respect to any new drug within the meaning of the Act that Defendants intend to manufacture, prepare, process, pack, repack, receive, label, hold, and/or distribute; or

ii. An exemption from the new drug approval requirement under 21 U.S.C. § 355 applies with respect to any new drug within the meaning of the Act that Defendants intend to manufacture, prepare, process, pack, repack, receive, label, hold, and/or distribute; or

iii. Any nonprescription drug within the meaning of the Act without an approved new drug application under 21 U.S.C. § 355 that Defendants intend to manufacture, prepare, process, pack, repack, label, hold, and/or distribute complies with all applicable provisions of 21 U.S.C. § 355h; or

iv. Defendants have removed from Defendants' product labels, labeling, promotional materials, websites or social media pages owned, created, or controlled by or related to Defendants, including but not limited to www.smartwomenschoice.com, Defendants' Facebook page, Defendants' Instagram page, and any future website(s) or social media page(s) owned, created, or controlled by or related to Defendants, and in any other media over which Defendants have control:

I. All representations that any product that Defendants intend to manufacture, prepare, process, pack, repack, receive, label, hold, and/or distribute is a drug within the meaning of the Act or otherwise cause any such product to be a drug within the meaning of the Act; and

II. All references, direct or indirect, to other sources that contain representations that any product that Defendants intend to manufacture, prepare, process, pack, repack, receive, label, hold, and/or distribute is a drug within the meaning of the Act or otherwise cause any such product to be a drug within the meaning of the Act; and

B. Defendants retain, at Defendants' expense, an independent person or persons (the "Labeling Expert") who is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this provision) to Defendants (or their immediate families) or Associated Persons (or their immediate families), and who, by reason of background, training, education, or experience, is qualified to assess Defendants' compliance with the Act and applicable regulations, to review the claims Defendants make for their product(s) on their product labels, labeling, promotional materials, websites or social media pages owned, created, or controlled by or related to Defendants, including but not limited to www.smartwomenschoice.com, Defendants' Facebook page, Defendants' Instagram page, and any future website(s) or social media page(s) owned, created, or controlled by or related to Defendants, and any other media over which Defendants have control. Defendants shall notify FDA in writing of the identity and qualifications of the Labeling Expert within ten (10) days of retaining such Labeling Expert. If Defendants replace such expert, Defendants shall notify FDA in writing of any such replacement within ten (10) days after such replacement. Any replacement expert shall be qualified as described herein; and

C. The Labeling Expert performs a review of the claims Defendants make in their product labels, labeling, promotional materials, websites or social media pages owned, created, or controlled by or related to Defendants, including but not limited to www.smartwomenschoice.com, Defendants' Facebook page, Defendants' Instagram page, and any future website(s) or social media page(s) owned, created, or controlled by or related to Defendants, and in any other media over which Defendants have control. Specifically, the Labeling Expert shall undertake the following as part of this review:

i. The Labeling Expert shall inspect all of Defendants' Facilities;

ii. The Labeling Expert shall identify all of Defendants' products and personally review, for each product, Defendants' representations on product labels, labeling, promotional materials, websites or social media pages owned, created, or controlled by or related to Defendants, including but not limited to

www.smartwomenschoice.com, Defendants' Facebook page, Defendants' Instagram page, and any future website(s) or social media page(s) owned, created, or controlled by or related to Defendants, and in any other media over which Defendants have control; and

iii. The Labeling Expert shall determine whether Defendants have removed all representations and all references, direct or indirect, to other sources that contain representations that cause any of Defendants' products to be drugs within the meaning of the Act for indications for which they are not approved by FDA or otherwise not lawfully marketed under the Act and applicable regulations; and

D. 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 this Decree, the Act, and applicable regulations. The Labeling Expert's written report shall include the specific results of the inspection and 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 other than the Act and FDA regulations. The report shall be contemporaneously mailed by courier service or overnight delivery service to FDA, as specified in Paragraph 15, and Defendants no later than fifteen (15) days after the conclusion of the Labeling Expert's review. Should the Labeling Expert identify any deficiencies in the report as described in the Decree, Defendants shall submit to FDA and the Labeling Expert in writing within fifteen (15) days of receiving the Labeling Expert's report a document describing in detail the actions Defendants have taken to correct such deficiencies; and

E. The Labeling Expert certifies in writing to FDA and Defendants that:

i. The Labeling Expert has inspected all of Defendants' Facilities;

ii. The Labeling Expert has identified all of Defendants' products and personally reviewed Defendants' representations for each product on product labels, labeling, promotional materials, websites or social media pages owned, created, or controlled by or related to Defendants, including but not limited to

www.smartwomenschoice.com, Defendants' Facebook page, Defendants' Instagram page, and any future website(s) or social media page(s) owned, created, or controlled by or related to Defendants, and in any other media over which Defendants have control; and

iii. Defendants have corrected all deviations, if any, from the requirements of the Decree, the Act, and applicable regulations; and

F. FDA representatives, without prior notice and when FDA deems necessary, inspect Defendants' Facilities to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with this Decree, the Act, and applicable regulations; and

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

6. Upon receipt of written notification from FDA under Paragraph 5.G, Defendants and Associated Persons 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 doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any new drug, as defined in 21 U.S.C. § 321(p), that is neither approved under 21 U.S.C. § 355(b) or (j) nor exempt from approval; or

B. Results in the failure to implement and continuously maintain the requirements of this Decree.

7. Upon resuming operations after having complied with Paragraphs 5.A-F and having received written notification from FDA under Paragraph 5.G of this Decree, Defendants shall retain an independent person(s) who meets the criteria described in Paragraph 5.B, who is qualified to assess Defendants' compliance with this Decree, the Act, and applicable regulations, and who may be the same person(s) as the Labeling Expert

(the "Auditor"), to conduct audit inspections of Defendants' Facilities, including product labels, labeling, promotional materials, websites or social media pages owned, created, or controlled by or related to Defendants, including but not limited to www.smartwomenschoice.com, Defendants' Facebook page, Defendants' Instagram page, and any future website(s) or social media page(s) owned, created, or controlled by or related to Defendants, and in any other media over which Defendants have control. Defendants shall notify FDA in writing of the identity and qualifications of the Auditor within ten (10) days of retaining the Auditor. After Defendants receive written notification from FDA under Paragraph 5.G of this Decree, audit inspections under this Paragraph shall commence no less frequently than once every six (6) months for the next five (5) years. The first audit inspection shall occur not later than six (6) months after Defendants have received FDA's written notification under Paragraph 5.G. Audit inspections shall evaluate, at a minimum, Defendants' compliance with the requirements of this Decree, the Act, and applicable regulations.

A. At the conclusion of each audit inspection described in this Paragraph, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with this Decree, the Act, and applicable regulations. Each Audit Report shall contain:

i. References to the name(s) of the product(s) reviewed and regulations addressed in the process of conducting the review;

ii. A certification that the Auditor has identified all of Defendants' products and personally reviewed all of Defendants' representations for each product on product labels, labeling, promotional materials, websites or social media pages owned, created, or controlled by or related to Defendants, including but not limited to www.smartwomenschoice.com, Defendants' Facebook page, Defendants' Instagram page, and any future website(s) or social media page(s) owned, created, or controlled by or related to Defendants, and in any other media over which Defendants have control;

iii. A detailed description of any deviations from the requirements of this Decree, the Act, and applicable regulations ("Audit Report Observations");

iv. An assessment of the adequacy of corrective actions taken by Defendants to correct any previous Audit Report Observations; and

v. A certification by the Auditor regarding whether Defendants are in compliance with the requirements of this Decree, the Act, and applicable regulations;

B. The Audit Report shall be contemporaneously mailed by courier service or overnight delivery service to FDA, as specified in Paragraph 15, and Defendants no later than fifteen (15) days after the date each audit inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate files at Defendants' Facilities and shall promptly make the Audit Reports available to FDA upon request;

C. If an Audit Report contains any Audit Report Observations, Defendants shall submit to FDA, as specified in Paragraph 15, and the Auditor within five (5) days a document describing in detail the actions Defendants have taken to correct such deviations. Within fifteen (15) days of receiving such documentation, the Auditor shall complete a review of the corrective actions taken by Defendants. Within five (5) days of the Auditor's completion of that review, Defendants shall ensure that the Auditor informs FDA in writing whether each of the Audit Report Observations has been fully corrected and, if not, which Audit Report Observations remain uncorrected; and

D. If an Audit Report identifies Audit Report Observations, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew.

8. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, investigation, analyses of Defendants' product, a report or data prepared or submitted by Defendants, the Labeling Expert, and/or the Auditor, or any other information, that Defendants have failed to comply with the provisions of this Decree, the Act, or applicable regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or applicable regulations, FDA may, as and when it deems necessary, notify Defendants in writing of their noncompliance and order

Defendants in writing to take appropriate corrective action, including, but not limited to, one or more of the following actions:

A. Cease operations to manufacture, prepare, process, pack, repack, receive, label, hold, and/or distribute any or all drugs;

B. Recall, at Defendants' expense, any specified drug manufactured, prepared, processed, packed, repacked, received, labeled, held, and/or distributed by Defendants. Defendants shall initiate the recall(s) within twenty-four (24) hours of receiving notice from FDA that a recall is necessary. Defendants shall, under FDA's supervision and at Defendants' expense, destroy all drugs that are Defendants' possession, custody, or control for which a recall was initiated. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state laws;

C. Destroy any product(s) at Defendants' expense;

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

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

F. Pay liquidated damages as provided in Paragraph 16;

G. Issue a safety alert; and/or

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

The provisions of this Paragraph 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. 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 the requirements of this Decree, the Act, and applicable regulations, and that Defendants may resume operations. In no circumstance shall FDA's silence be construed as a substitute for written notification.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' Facilities and operations, collect samples, and 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 prompt access to Defendants' Facilities and operations, including but not limited to all buildings, equipment, in-process and finished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples, without charge to FDA, of finished and unfinished materials and products, containers, labels, labeling, packaging, and other promotional materials; and to examine and copy all records relating to the receipt, manufacture, processing, packing, receiving, labeling, promoting, holding, and distribution of any and all of Defendant's products in order to ensure continuing compliance with the terms of this Decree. Defendants and Associated Persons are prohibited from destroying, discarding, altering, transferring, or otherwise making unavailable any documents and records in any format, including but not limited to electronic format, or otherwise within the custody or control of Defendants or Associated Persons. 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.

11. Within fifteen (15) days after any FDA written request for Defendants' product labels, labeling, promotional materials, websites or social media pages owned,

created, or controlled by or related to Defendants, including but not limited to www.smartwomenschoice.com, Defendants' Facebook page, Defendants' Instagram page, and any future website(s) or social media page(s) owned, created, or controlled by or related to Defendants, or any other media over which Defendants have control, Defendants shall submit a copy of the requested materials (in hard copy and electronic format) to FDA at the address specified in Paragraph 15.

12. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews specified in this Decree or that FDA deems necessary to evaluate Defendants' compliance with this Decree, including the travel incurred by specialized investigatory and expert personnel, at the standard rates prevailing at the time the costs are incurred. Defendants shall make payment to FDA within twenty (20) business days after receiving an electronic invoice for payment, which shall be sent to Defendants' email address jennifer.ann.richard@gmail.com. Defendants shall make payment through the Pay.gov electronic billing system, subject to all interest, fees, and penalties applicable to delinquent payments, in accordance with 31 U.S.C. § 3717 and 45 C.F.R. § 30. As of the date that this Decree is signed by the parties, these rates are: $110.59 per hour and fraction thereof per representative for inspection and investigative work; $132.56 per hour or fraction thereof per representative for analytical or review work; $0.65 per mile (plus tolls) for travel 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 representative and per day for subsistence expenses, where necessary. If 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. Defendants shall notify FDA within fifteen (15) business days if the email address at which Defendants receive electronic invoices changes.

13. Within ten (10) days after the entry of this Decree, Defendants shall: (1) 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 (2) post the

Decree on all websites and social media owned, created, or controlled by or related to Defendants, including but not limited to www.smartwomenschoice.com, Defendants' Facebook page, Defendants' Instagram page, and any future website(s) or social media page(s) owned, created, or controlled by or related to Defendants, and shall ensure that the Decree remains posted for as long as the Decree remains in effect. Within thirty (30) days of the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance with this Paragraph, stating the fact and manner of compliance and identifying the names, addresses, and positions of all Associated Persons who have received a copy of this Decree. In the event Defendants become associated, at any time after the entry of this Decree, with new Associated Persons, Defendants shall:

A. Within fifteen (15) days of such occasion, provide a copy of this Decree to each such Associated Person by personal service or certified mail (restricted delivery, return receipt requested); and

B. Within thirty (30) days of such occasion, provide to FDA an affidavit of compliance with this Paragraph, stating the fact and manner of compliance and identifying the names, addresses, and positions of all Associated Persons who have received a copy of this Decree.

14. Defendants shall notify FDA in writing at least fifteen (15) days before any change in ownership, character, or name of their business, including incorporation, reorganization, relocation, bankruptcy, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of a subsidiary, franchises, affiliates, or "doing business as" entities, or any other change in the corporate structure of Smart Women's Choice, Inc., or in the sale, lease, 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 potential successor or assignee at least fifteen (15) days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this Paragraph no later than ten (10) days prior to any such assignment or change in ownership.

15. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be prominently marked "Consent Decree Correspondence – Smart Women's Choice, Inc. – [Topic]," shall reference this civil action by case name and civil action number, and shall be addressed to Director, Division of Pharmaceutical Quality Operations IV, FDA Los Angeles District Office, 19701 Fairchild, Irvine, California 92612, and electronically to ORAPHARM4_Responses@fda.hhs.gov, with the email subject "Consent Decree Correspondence – Smart Women's Choice – [Topic]," where the topic is a succinct title describing the correspondence.

16. If Defendants fail to comply with any provision of this Decree, the Act, and/or applicable regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: one thousand dollars ($1,000) in liquidated damages for each day such violation continues; an additional sum of one thousand dollars ($1,000) in liquidated damages for each violation; and further additional sum equal to the retail value of drugs that have been manufactured, prepared, processed, packed, repacked, received, labeled, held, and/or distributed in violation of this Decree, the Act, and/or applicable regulations. Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the Court to impose, civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this Paragraph.

17. 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, to the extent these decisions are subject to review, 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 of the decision. No discovery shall be taken by either party.

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 (including overhead), investigational and analytical expenses, expert witness fees, and any other court costs or fees relating to such contempt proceedings.

19. This Court retains jurisdiction of 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.

Dated this 14th day of November, 2023.

G. Murray Snow
Chief United States District Judge

The undersigned hereby consent to the entry of the foregoing Decree.

FOR DEFENDANTS:

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