

CAUSE NO. \_\_\_\_\_

|                                |   |                          |
|--------------------------------|---|--------------------------|
| STATE OF TEXAS,                | § | IN THE DISTRICT COURT OF |
| Plaintiff                      | § |                          |
|                                | § |                          |
|                                | § |                          |
| VS.                            | § |                          |
|                                | § |                          |
| JANICE JACKSON d/b/a INSIDEOUT | § | TRAVIS COUNTY            |
| AND WITHIN                     | § |                          |
| Defendants.                    | § | ____ JUDICIAL DISTRICT   |

**FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION**

Plaintiff, the STATE OF TEXAS, acting by and through Attorney General Greg Abbott (“State”), and JANICE JACKSON d/b/a INSIDEOUT AND WITHIN, Defendant, having consented to the entry of this Final Judgment and Permanent Injunction, and before any testimony is taken in this case and without Defendant admitting to any violations of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. §431.001 *et seq.* (“TFDCA”) or the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.21 *et seq.* (“DTPA”); or any other law, have jointly moved that the Court enter this Judgment.

JANICE JACKSON d/b/a INSIDEOUT AND WITHIN consents and agrees to the entry of this Judgment and that the terms of said agreement are fair, just and equitable. Defendant further agrees that Plaintiff’s execution of this Judgment does not constitute an approval by the Plaintiff of her business practices.

JANICE JACKSON d/b/a INSIDEOUT AND WITHIN stipulates that the LIBBE Colon Irrigation Devices, owned and operated by Defendant and manufactured by Tiller Mind Body, Inc. and the Tiller rectal tubes are colon irrigation systems and prescription medical devices as

cleared for marketing by the Federal Food and Drug Administration, pursuant to 21 C.F.R. § 876.5220, and are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations.

JANICE JACKSON d/b/a INSIDEOUT AND WITHIN also stipulates that the term “colon irrigation system” used in this Final Judgment and Agreed Permanent Injunction includes all accessories and parts, such as rectal nozzles or tubes, even if not explicitly stated in each term.

Defendant JANICE JACKSON d/b/a INSIDEOUT AND WITHIN stipulates to the amount of civil penalties, attorneys fees, and investigative costs listed in paragraphs 12, 13, and 14 below, if Defendant fails to comply with paragraph below.

Defendant JANICE JACKSON d/b/a INSIDEOUT AND WITHIN stipulates that the State of Texas’ agreement to and the Court’s approval of this Final Judgment are expressly premised upon Defendant’s compliance with Defendant’s stipulation to pay the amounts required in paragraph 12 below, and to comply with the terms of this injunction regarding the marketing, advertising, and provision of colon irrigation services and using prescription colon irrigation systems, including nozzles and tubes; and that these stipulations are specifically relied upon by the State of Texas in negotiating and agreeing to the terms of this Final Judgment.

JANICE JACKSON d/b/a INSIDEOUT AND WITHIN also stipulates that Defendant’s indebtedness to the State of Texas for civil penalties, identified in paragraph 9 below, for violations of the TDPTA and TFDCA, having been found by this court to constitute a civil fine or penalty to and for a governmental unit and not compensation for actual pecuniary loss, would be a debt that would be nondischargeable in a subsequently filed bankruptcy proceeding under either Chapter 7 or Chapter 11 and that, in the event a voluntary or involuntary chapter 7 or chapter 11 bankruptcy proceeding is commenced against debtor, the debtor stipulates that she

shall not contest either directly or indirectly future attempts, if any, by the State of Texas to have such debt declared nondischargeable in accordance with 11 U.S.C. § 523(a)(7).

The Court, after reading the pleadings and stipulations of the parties and it appearing to the Court that all parties agree to and have approved its entry of this Judgment, makes the following orders under the provisions of the TFDCA and the DTPA. The Court is of the opinion that, in view of these findings, said agreement should be and is hereby in all things approved, and accordingly that this Judgment should be entered.

**IT IS THEREFORE ORDERED, ADJUDGED and DECREED THAT:**

1. This Court has jurisdiction, through the TFDCA and the DTPA, over the subject matter and over all parties to this action.
2. Plaintiff's Original Petition states a claim for relief against JANICE JACKSON d/b/a INSIDEOUT AND WITHIN.
3. Venue of this matter is proper in Travis County by virtue of the fact that Defendant is engaged in the business of advertising and marketing prescription colon irrigation systems in Texas and the Texas Food, Drug and Cosmetic Act allows for any action alleging violations of this act by the State of Texas to be filed in Travis County.
4. By entering into this Judgment, Defendant admits no wrongdoing and this Judgment does not constitute any evidence or admission of any kind regarding any issues set forth herein, nor does it acknowledge that Defendant has engaged in any unlawful activity, nor shall it be construed as evidence that Defendant has engaged in any methods, acts, practices, uses or solicitations declared to be unlawful under the TFDCA and the DTPA. Defendant does not admit the truth of any alleged facts, any of the characterizations of Defendant's alleged conduct, or any of the conclusions in Plaintiff's Original Petition, or any amended pleadings pertaining to

this matter.

5. The following definitions shall be used in construing this Judgment:
  - A. “Advertising” means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics.
  - B. “Adulterate” a device means to use a device in violation of § 431.111 of the Texas Health and Safety Code, including but not limited to, using a colon irrigation system for a use not approved by FDA or using a colon irrigation system for general well being.
  - C. “Colon irrigation systems”, as used in this injunction, shall mean any colon irrigation system, rectal nozzles or tubes, or any part of the system as defined in 21 CFR § 876.5220.
  - D. “Dangerous drug” means a device or drug that is unsafe for self-medication that bears or is required to bear a federal legend such as: Caution: federal law prohibits dispensing without prescription as defined by Section 483, Dangerous Drug Act, of the Health and Safety Code.
  - E. “False advertising” of a food, drug, device, or cosmetic means advertising that is false, deceptive, or misleading in any particular.
  - F. “FDA” means the Federal Food and Drug Administration.
  - G. “Federal Act” means the Federal Food, Drug and Cosmetic Act.
  - H. “Labeling” means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.
  - I. “Medical device reporting requirements” means reporting requirements in Section 519 of the Federal Act.
  - J. “Misbrand” a device means any violation of §431.112 of the Texas Health and Safety Code, including but not limited to, labeling for a device if it is false or misleading in any particular; labeling of a device without adequate directions for use; advertising of a restricted device if the advertising is false or misleading in any particular; or if a restricted device is sold, distributed, or used in violation of federal regulations.
  - K. “Physician” means a person licensed to practice medicine in this state as defined in § 151.002 (a)(12) of the TEXAS OCCUPATIONS CODE ANN.

- L. “Practitioner” means a person as defined in §483.001 (12), Texas Dangerous Drug Act, TEX. HEALTH AND SAFETY CODE ANN.
- M. “Prescription device(s)” means device(s) which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which adequate directions for use cannot be prepared; and therefore are required to bear a federal legend that states: “Caution: Federal law restricts this device to sale by or on the order of a \_\_\_\_\_” with the blank filled in with the designation of a practitioner licensed by the law of the State in which he practices to use or order the use of the device, as required by 21 CFR § 801.109.

6. **IT IS FURTHER ORDERED THAT** Defendant and her officers, agents, servants, employees, subsidiaries, assigns and any other person acting in concert or participation with or on behalf of JANICE JACKSON d/b/a INSIDEOUT AND WITHIN and all such persons or entities shall not in the future:

- a. Purchase and possess prescription colon irrigation systems, including rectal tubes, without a practitioner licensed under Texas law to purchase and possess such devices;
- b. Use prescription colon irrigation systems, including rectal tubes, without the supervision of a practitioner licensed by Texas law to use such devices;
- c. Use prescription colon irrigation systems, including rectal tubes, without a written order for each use from a practitioner licensed under Texas law to order the use of such prescription devices;
- d. Use prescription colon irrigation systems, including rectal tubes, for treating diseases of the body or for uses, including general well being for which FDA has not approved these devices;
- e. Falsely advertise or falsely represent that prescription colon irrigation systems, including rectal tubes, can be self-administered;
- f. Falsely advertise or falsely represent that prescription colon irrigation systems, including rectal tubes, are effective for treating diseases of the body, such as, constipation, pounding headaches, weight gain, bloating, heavy menstrual bleeding, heart disease, high blood pressure, chronic fatigue, yeast, and swollen ankles and feet, for which FDA has not approved these devices;

- g. Falsely advertise or falsely represent that prescription colon irrigation systems, including rectal tubes, are effective for general well being if FDA has not approved these devices for such use;
- h. Fail to disclose that Defendants' prescription colon irrigation systems are approved only for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations;
- i. Fail to comply with federal medical device reporting requirements, as required by 21 CFR § 803 and Section 519 of the federal Act;
- j. Fail to disclose that the prescription colon irrigation systems used for colon irrigation are only to be used under the written order and supervision of a practitioner licensed in Texas;
- k. Advertise that prescription colon irrigation systems can be self-administered when FDA has cleared these systems only for use by a practitioner or under the supervision of a practitioner;
- l. Misbrand or adulterate prescription colon irrigation systems, including rectal tubes in commerce;
- m. Fail to comply with any requirement prescribed under Section 520(g) of the Federal Act and furnishing any notification or information required by or under Section 519 or 520(g) of the Federal Act;
- n. Cause confusion as to the approval of a good by allowing consumers to use prescription colon irrigation systems, including rectal tubes, for self-use or without order of practitioner; and
- o. Fail to provide written notice to any agent, servant, employee or representative of the existence and terms of any injunction entered in this case, and of their duty to comply with the terms set forth herein.

7. **IT IS FURTHER ORDERED THAT** Defendant JANICE JACKSON d/b/a INSIDEOUT AND WITHIN shall develop, adopt, and implement protocols, in conjunction with a licensed practitioner who is the medical director for JANICE JACKSON d/b/a INSIDEOUT AND WITHIN for the purposes of supervision of and delegation of health care tasks in compliance with Chapter 151 of the TEXAS OCCUPATIONS CODE ANN regulating the practice of medicine in Texas, concerning the purchasing, holding, possessing, and using of prescription

colon irrigation systems, including rectal tubes.

8. **IT IS FURTHER ORDERED THAT** Defendant JANICE JACKSON d/b/a INSIDEOUT AND WITHIN shall not promote or allow the use of any colon irrigation system, that is a prescription device and defined as a dangerous drug under Texas law, except on the order of and under the direction and supervision of a licensed practitioner acting in compliance with Chapter 151 of the TEXAS OCCUPATIONS CODE ANN regulating the practice of medicine in Texas.

9. **IT IS FURTHER ORDERED THAT** JANICE JACKSON d/b/a INSIDEOUT AND WITHIN shall pay and deliver Fifteen Thousand Dollars (\$15,000.00) to the Office of the Attorney General as civil penalties pursuant to § 431.0585 of the TFDCA and to DTPA §17.47(c)(1) A. **THIS ORDER** shall further constitute a judicial determination that these civil penalties shall constitute a civil fine or penalty to and for a governmental unit and are not compensation for actual pecuniary loss, subject to paragraphs 12-13 below.

10. **IT IS FURTHER ORDERED THAT** JANICE JACKSON d/b/a INSIDEOUT AND WITHIN, shall pay and deliver to the Office of the Attorney General Two Thousand Dollars (\$2,000.00) as attorneys fees and investigative costs under § 431.047 of the TFDCA and the TEX. GOVT. CODE § 402.006(c), subject to paragraphs 12-13 below.

11. **IT IS FURTHER ORDERED THAT** JANICE JACKSON d/b/a INSIDEOUT AND WITHIN shall pay and deliver Three Thousand Dollars (\$3,000.00) to the Texas Department State Health Services, formerly the Texas Department of Health, to cover their investigative costs pursuant to § 431.047 of the TFDCA, subject to paragraphs 12-13 below.

12. **IT IS FURTHER ORDERED THAT** ninety-one (91) days following receipt by the State of Texas from Defendant JANICE JACKSON d/b/a INSIDEOUT AND WITHIN of the

total sum of Seven Thousand Dollars (\$7,000.00) to the Office of the Attorney General, with Two Thousand Dollars (\$2,000.00) designated as civil penalties; Two Thousand Dollars (\$2,000.00) designated as attorneys fees under §431.047 of the TFDCA and the TEX. GOVT. CODE §402.006( c); and Three Thousand Dollars (\$3,000.00) to Texas Department of State Health Services to cover the investigative costs pursuant to §431.047 of the TFDCA, the State of Texas shall consider the monetary portion of the Final Judgment, as ordered in paragraphs 9, 10, and 11 above, satisfied in full unless the State has evidence that this Final Judgment should be reopened as outlined in paragraph 14 below. The State of Texas then may reopen this Final Judgment for the sole purpose of allowing the State of Texas to modify the monetary liability of the Defendant.

13. **IT IS FURTHER ORDERED THAT** Defendant JANICE JACKSON d/b/a INSIDEOUT AND WITHIN's agreement to and the Court's approval of this Final Judgment are expressly premised upon the above stipulations, as relied upon by the State of Texas in negotiating and agreeing to the terms of this Final Judgment.

14. **IT IS FURTHER ORDERED** that if the State of Texas has evidence that the Defendant JANICE JACKSON d/b/a INSIDEOUT AND WITHIN fails to comply with Defendant's stipulations listed above, the State of Texas may reopen this Final Judgment for the sole purpose of allowing the State of Texas to modify the monetary liability of the Defendant. If the Court finds that Defendant failed to comply with the above stipulations relating to payment of the amounts required in paragraph 12 above, or to comply with the terms of this injunction regarding the marketing, advertising, and provision of colon irrigation services and using prescription colon irrigation systems, including nozzles and tubes, the Court shall reinstate the suspended judgment against Defendant JANICE JACKSON d/b/a INSIDEOUT AND WITHIN,

in favor of the State of Texas, in the amounts listed in paragraphs 9, 10, and 11 above. All other terms of this Final Judgment shall remain in full force and effect unless otherwise ordered by the Court. For the purposes of reopening or enforcing this Final Judgment, Defendant JANICE JACKSON d/b/a INSIDEOUT AND WITHIN waives any right to contest any of the allegations set forth in **Plaintiff's Original Petition filed in this matter.**

15. **IT IS FURTHER ORDERED** that JANICE JACKSON d/b/a INSIDEOUT AND WITHIN's agreement to and the Court's approval of this Final Judgment are expressly premised upon the above stipulations, as relied upon by the State of Texas in negotiating and agreeing to the terms of this Final Judgment.

16. **IT IS FURTHER ORDERED** that Defendant shall pay all costs of the Court.

17. The clerk of the Court is authorized to issue such writs of execution or other process necessary to collect and enforce this Judgment.

18. The Court retains jurisdiction to enforce this Judgment.

19. It is agreed and understood that this Judgment shall in no way affect the rights of individual citizens.

20. All relief not granted herein is hereby denied.

Signed this \_\_\_\_\_ day of \_\_\_\_\_, 2005.

---

DISTRICT JUDGE

THE UNDERSIGNED, WHO HAVE THE AUTHORITY TO CONSENT AND SIGN ON BEHALF OF THE PARTIES IN THIS ACTION, HEREBY CONSENT TO THE FORM AND CONTENTS OF THE FOREGOING FINAL JUDGMENT AND AGREED PERMANENT INJUNCTION AND TO ITS ENTRY:

Signed this \_\_\_\_\_ day of \_\_\_\_\_, 2005.

**DEFENDANT JANICE JACKSON d/b/a INSIDEOUT AND WITHIN**

By: \_\_\_\_\_  
**JANICE JACKSON**

**Attorney for Defendant**

\_\_\_\_\_  
Nikelle S. Meade  
State Bar No.:  
Brown McCarroll, L.L.P.  
111 Congress Avenue, Suite 1400  
Austin, Texas 78701  
(512) 472-5456  
(512) 479-1101 (fax)

Date: \_\_\_\_\_

**Plaintiff State of Texas**

GREG ABBOTT  
Attorney General of Texas

BARRY MCBEE  
First Assistant Attorney General

ED D. BURBACK  
Deputy Attorney General for Litigation

PAUL D. CARMONA  
Assistant Attorney General  
Chief, Consumer Protection and Public Health Division

---

JOYCE WEIN ILIYA  
Assistant Attorney General  
Consumer Protection and Public Health Division  
State Bar No. 00784319  
1600 Pacific Avenue, Suite 1700  
Dallas, Texas 75201-3513  
(214) 969-7639, ext. 111  
Facsimile: (214) 969-7615

Attorneys for the State