

Section 431.060 of the TFDCA specifically provides that the Attorney General, to whom the Commissioner of the Texas Department of State Health Services (“TDSHS”) reports a violation of the TFDCA, shall initiate and prosecute appropriate proceedings. In addition, §431.047 of the TFDCA authorizes the Attorney General to seek injunctive relief and recover any costs and attorney fees incurred thereby. This action is also brought pursuant to §431.0585 of the TFDCA, which authorizes the Commissioner of Health to refer persons who violate §431.021 of the TFDCA and its associated regulations to the Attorney General for civil penalties against such violators.

2.2 This action is further brought by Attorney General Greg Abbott, through his Consumer Protection and Public Health Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §17.47 of the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.* (“DTPA”) upon the grounds that Defendants have engaged in false, misleading or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§17.46(a) and (b) of the DTPA.

3. PARTY DEFENDANTS

3.1 Defendant APOTHECURE, INC., is a domestic corporation doing business in Dallas, Texas at 4001 McEwen Road, Suite 100, 75244, and may be served with process at this address.

3.2 Defendant SPECTRA PHARM, INC., is a domestic corporation doing business in Dallas, Texas at 4001 McEwen Road, Suite 100, 75244, and may be served with process at this address.

3.3 Defendant GARY OSBORN, individually, is the registered agent, President, sole director, and sole shareholder of both Defendants APOTHECURE, INC., and SPECTRA PHARM, INC. Defendant GARY OSBORN is also designated as the pharmacist-in-charge of Defendant APOTHECURE, INC., and actively directs and participates in all business activities of APOTHECURE, INC., and SPECTRA PHARM, INC. OSBORN is in charge of conducting business at 4001 McEwen Road, Suite 100, Dallas, Texas 75244 and may be served with process at this address, or alternatively, he can be served at the following address: 40 Kennington Court, Dallas, Texas 75248.

4. VENUE

4.1 Venue of this action lies in Dallas County on the basis of TFDCA §§431.047(c) and 431.0585(d) by virtue of the fact that Defendants were engaged in the business of manufacturing, offering to sell, and selling adulterated and misbranded drugs, unapproved new drugs, and/or misbranded or adulterated foods in Texas. Venue of this action also lies in Dallas County on the basis of §17.47(b) of the DTPA by virtue of the fact that Defendants have their principal place of business in Dallas County and the transactions giving rise to this suit occurred in Dallas County.

5. PUBLIC INTEREST

5.1 Because Plaintiff STATE OF TEXAS has reason to believe that APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, have engaged in, and will continue to engage in, the unlawful practices set forth below, Plaintiff STATE OF TEXAS has reason to believe that APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, will continue to violate the DTPA and the TFDCA to the detriment of the STATE

OF TEXAS and its citizens, and will also cause adverse effects to legitimate business enterprises which conduct their trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the STATE OF TEXAS believes and is of the opinion that these proceedings are in the public interest.

6. ACTS OF AGENTS

6.1 Whenever in this petition it is alleged that Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, did any act or thing, it is meant that Defendants performed or participated in such act or thing or that such act was performed by agents or employees of Defendants and in each instance, the agents or employees of Defendants were then authorized to and did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually.

7. TRADE AND COMMERCE

7.1 Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, have, at all times described below, engaged in conduct which constitutes "trade" and "commerce" as those terms are defined by §17.45(6) of the DTPA.

8. NOTICE BEFORE SUIT

8.1 Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, were informed in general of the alleged unlawful conduct described below and as may be required by §17.47(a) of the DTPA by certified and regular mail on November 28, 2007.

9. DEFENDANTS' CONDUCT

9.1 Defendant GARY DOUGLAS OSBORN ("OSBORN") is a Texas-licensed pharmacist, who is engaged in various business enterprises. In particular, Defendant OSBORN is the President, sole director, and sole shareholder of both Defendants APOTHECURE, INC. ("APOTHECURE") and SPECTRA PHARM, INC., ("SPECTRA PHARM") and actively directs and participates in the operation of both corporations. Defendant OSBORN is also the pharmacist-in-charge of APOTHECURE. Defendant OSBORN as a licensed pharmacist in Texas has to comply with the federal compounding laws and the TFDCA and can be disciplined if the Board of Pharmacy finds that OSBORN has "...violated any pharmacy or drug statute or rule of this state, another state, or the United States" pursuant to §565.001(12) of the Occupations Code. Defendant OSBORN as Pharmacist-in-Charge of Apothecure has the authority or responsibility for the pharmacy's compliance with statutes and rules relating to the practice of pharmacy, pursuant to §551.003(29) of the Occupations Code.

A. APOTHECURE, INC. and OSBORN

9.2 Defendants APOTHECURE and GARY OSBORN, as President, sole-director, and pharmacist-in-charge, conduct business in a facility located in Dallas, Texas. From that facility, APOTHECURE and OSBORN manufacture, advertise, and sell over-the-counter drugs and dietary supplements. Defendants APOTHECURE and GARY OSBORN operate a pharmacy that purports primarily to compound injectable prescription drugs although much of this compounding is actually a guise for manufacturing, as Defendants do not have prescription drug orders from a practitioner for an identified individual patient and do not meet most of the other requirements for compounding in Texas for the majority of the drugs compounded.

9.3 Since July 18, 2008, Defendants APOTHECURE and OSBORN fail to comply with the federal requirements for compounding, discussed in paragraphs 9.14, 9.15, and 9.16 below, for the majority of drugs compounded, and therefore are manufacturing under the guise of compounding. Defendants must comply with current good manufacturing practices to assure that such drugs meet the requirements of safety, have the identity and strength, and meet the quality and purity characteristics which they purport or are represented to possess. Also, beginning July 18, 2008, Defendants APOTHECURE and OSBORN do not meet the exemption for compounding in the definition of “manufacture”¹ in §431.002(23) of the TFDCA as they are not compounding pursuant to a prescription drug order or initiative from a practitioner for a patient.

9.4 APOTHECURE is licensed in Texas by the Texas State Board of Pharmacy as a community or “Class A” pharmacy and OSBORN is designated as the pharmacist-in-charge. APOTHECURE is also licensed by TDSHS as a food manufacturer (dietary supplements are foods under Texas law) and as a drug manufacturer/distributor for over-the-counter drugs.

9.5 In addition to compounding and manufacturing drugs and foods, APOTHECURE also operates a walk-in retail store where its own dietary supplements, privately labeled dietary supplements, homeopathic drugs, and over-the-counter drugs are available for sale. Product handouts and promotional brochures are available on a turnstile display rack inside the storefront. APOTHECURE and OSBORN provide similar promotional materials and sell the same products on their website (www.apothecure.com) and in their newsletter, as well as the retail website for

¹“Manufacture” of a drug means: ...(B) the process of preparing, propagating, compounding, processing, packaging, repackaging, labeling, testing, or quality control of a drug or drug product, but does not include compounding that is done within the practice of pharmacy and pursuant to a prescription drug order or initiative from a practitioner for a patient or prepackaging that is done in accordance with Section 562.154, Occupations Code; ...” §431.002(23) of the TFDCA. (Emphasis added.)

SPECTRA PHARM (www.ruhealthy.com) and the website for one of Defendant OSBORN's other companies, the Texas Institute of Functional Medicine ("TIFM") (www.tifm.com).

(a). Three Deaths After Use of Adulterated and/or Misbranded Colchicine Intravenous Drugs Compounded by APOTHECURE and OSBORN

9.6 APOTHECURE and OSBORN compounded an intravenous form of the potentially toxic drug, Colchicine. Colchicine in intravenous form is not approved by the Food and Drug Administration ("FDA") (only combination colchicine/probenecid tablets are approved by FDA in tablet form for the treatment of gout). On February 7, 2007, APOTHECURE and OSBORN sold to the Center for Integrative Medicine ("CIM"), in Portland, Oregon, seventy (70) 4-milliliter vials from three batches of Colchicine (APOTHECURE lot numbers 20070122@26 (31 vials of 34 compounded), 20061214@28 (39 vials of 87 compounded) that APOTHECURE and OSBORN compounded. Additionally, Defendants also sold the remaining 45 vials of 20061214@28 on or about January 3 and 8, 2007 and kept 3 vials of each of these two compounded batches for testing and hold-back.

9.7 Defendants APOTHECURE and OSBORN compounded and sold adulterated intravenous Colchicine in at least two of the batches from which CIM's order was filled. Specifically, batch 20070122@26 contained vials of injectable Colchicine that were far more potent than their labels indicated. Defendants APOTHECURE and OSBORN also misbranded these drugs when the actual amount of Colchicine's active ingredient was incorrectly listed on the label of the drugs. These vials of injectable Colchicine were both adulterated under §431.111(c) of the TFDCa and misbranded under §431.112 (e) of the TFDCa by APOTHECURE and OSBORN prior to the introduction of these drugs into commerce.

9.9 Approximately one month after selling the adulterated and misbranded injectable Colchicine (batch 20070122@26) to CIM, three deaths were reported as being associated with the use of this batch of misbranded and adulterated drugs. Two Portland residents who were treated at the CIM in Portland, Oregon and a Yakima, Washington woman who was treated at her local clinic with Colchicine sold to CIM died after being administered this super-potent, intravenous Colchicine that was compounded and sold by APOTHECURE and OSBORN.

9.10 In response to these deaths, the Oregon Medical Examiner detained the remaining unused vials sold to CIM, and conducted potency testing. According to the Oregon deputy state medical examiner, remaining vials from lot 20070122@26 were found to have a potency of 4 milligrams per milliliter, rather than the 0.5 milligrams per milliliter stated on labels. Further, the deputy medical examiner reported that one injection of the mislabeled, super-potent Colchicine would be potent enough to cause death.²

9.11 The FDA also tested the Colchicine lots associated with these three deaths and also determined the super-potency of lot number 20070122@26.

9.12 APOTHECURE and OSBORN conducted an internal investigation of the Colchicine lots associated with the three deaths. As a result, the super-potency of lot number 20070122@26 was confirmed through third-party testing commissioned by APOTHECURE and OSBORN. Further, OSBORN has admitted that APOTHECURE's staff had determined that "human error" likely caused the "mis-weighing" of the Colchicine active ingredient, which resulted in the super-potent lot. APOTHECURE and OSBORN did not require the testing of the

²See http://www.portlandtribune.com/news/story.php?story_id=117762598274410600.

potency of any of the compounded batches of Colchicine at the time of compounding.

9.13 Additionally, APOTHECURE and OSBORN compounded intravenous Colchicine labeled as 1mg/2ml (lot# 20061214@28) that was tested and found to have an actual strength of 0.38mg Colchicine/ml. This 84 vials of Colchicine, lot# 20061214@28, compounded by Defendants are also misbranded under §431.111(c) of the TFDCA, as these drugs do not contain the amounts of Colchicine as listed on their labels.

(b). APOTHECURE under the Direction of OSBORN fails to comply with the Compounding Requirements found in the Federal Food, Drug and Cosmetic Act.

9.14 On July 18, 2008, the Fifth Circuit issued its opinion in the *Medical Ctr. Pharm. v. Mukasey*, 536 F.3d 383 (5th Cir. 2008), case holding that provisions of 21 U.S.C. §353a, §503a of the Federal Food, Drug and Cosmetic Act (“FFDCA”) (hereinafter, “21 U.S.C. §353a”); could be severed from the unconstitutional advertising provision and were the law in effect that regulate compounding in the states in its circuit.³ These provisions, 21 U.S.C. §353a, set forth an exemption from an adulteration finding based on the failure to follow good manufacturing practices, a misbranding finding based on the lack of adequate directions for use, and an unapproved new drug finding if compounding is done in compliance with this provision. If a drug is adulterated, misbranded, and an unapproved new drug under 21 U.S.C. §353a, the drug is also adulterated pursuant to §431.111(a)(2)(B) of the TFDCA, misbranded pursuant to §431.111(c) of the TFDCA, and an unapproved new drug pursuant to §431.114(a)(1) of the

³ Section (c) of 21 U.S.C. § 353a, was affirmed as unconstitutional in *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61 (2002). All references to 21 U.S.C., §353a in this petition acknowledge that 21 U.S.C. § 353a (c) is unconstitutional and the State is making no attempts to enforce or allegations related to this unconstitutional advertising provision that prohibited any advertising of a compounded drug.

TFDCA.

9.15 In order for the compounding exemption from unapproved new drugs and misbranded and adulterated drugs in 21 U.S.C. §353a to apply, Defendants must meet all of the following criteria, after July 18, 2008:

- A. First, a drug must be compounded for an “identified individual patient” based on the receipt of a prescription from a practitioner or before the receipt of a prescription if done in limited quantities based on a history of receiving prescriptions within an established pharmacist-practitioner-patient relationship⁴. 21 U.S.C., §353a (a)(1) and (2).
- B. Second, the bulk drug substances used in the compounding must 1) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the compounding chapter found in the U.S. Pharmacopoeia; or 2) be drug substances that are components of drugs approved by the FDA, if a monograph does not exist; or 3) if neither 1) nor 2) apply, appear on an FDA list of approved compounded drugs.⁵ 21 U.S.C. §353a(b)(1)(A)(i).
- C. Third, the bulk drug substance must be manufactured in a facility registered under section 510 of the FFDCA. 21 U.S.C. §353a(b)(1)(A)(ii).
- D. Fourth, the bulk drug substances must have valid certificates of analysis. 21 U.S.C. §353a(b)(1)(A)(iii).
- E. Fifth, ingredients, other than bulk drug substances, must comply with the

⁴The provision allows for compounding by a licensed pharmacist or a licensed physician.

⁵FDA has not compiled such a list.

standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the compounding chapter found in the U.S. Pharmacopoeia. 21 U.S.C. §353a(b)(1)(B).

F. Additionally, a pharmacy cannot compound a drug which appears on an FDA list as a drug which has been withdrawn from the marketplace because the drug or its components have been found to be unsafe or ineffective, or, regularly or in inordinate amounts, a drug that is basically a copy of a commercially available drug. 21 U.S.C. §353a(b)(1)(C) and (D).

G. Finally, a drug product cannot be compounded if it has been identified by the FDA in a regulation as a drug product which is difficult to compound without affecting the safety or effectiveness of the product. 21 U.S.C. §353a(b)(3)(A).

9.16 Despite the Fifth Circuit's ruling on July 18, 2008, Defendants APOTHECURE and OSBORN failed to comply with each of the requirements of 21 U.S.C. §353a for compounding drugs and continue to compound the majority of their drugs without compliance. The failure to follow the requirements of 21 U.S.C. §353a for compounding after July 18, 2008, causes these drugs to be adulterated because of the failure to comply with good manufacturing practices, misbranded because of the lack of adequate directions for use, and unapproved new drugs under the FFDCA and the TFDCA. This adulteration, misbranding, and manufacture of unapproved new drugs includes, but is not limited to, the following:

A. APOTHECURE and OSBORN, as the pharmacist-in-charge, continues after July 18, 2008, to compound drugs by creating finished drug products before receiving a prescription order for an identified individual patient from a practitioner and without a

history of receiving prescription orders for the drug products within an established pharmacist-practitioner-patient relationship as required by 21 U.S.C.; §353a (a)(1) and (2). In fact, the vast majority of the drugs compounded by APOTHECURE and OSBORN fail to meet this standard. For example, Defendants have no practitioners' prescriptions for an identified individual patient for Artichoke or Cobalt Chloride injections, nor for any drugs compounded for office use since each such order acknowledges that no individual prescriptions exist for the ordered drugs. Each drug compounded by Defendants, after July 18, 2008, in violation of this requirement is adulterated, misbranded, and an unapproved drug and each such compounded drug in Texas is a separate violation of the TFDCFA.

B. APOTHECURE and OSBORN, as the pharmacist-in-charge, compound numerous drugs for injection after July 18, 2008, and fail to use bulk drug substances that 1) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the compounding chapter found in the U.S. Pharmacopoeia; or 2) are drug substances that are components of drugs approved by the FDA, if a monograph does not exist; or 3) if neither 1) nor 2) apply, appear on an FDA list of approved compounded drugs, as required by §503a(b)(1)(A)(I) of the FFDCFA, 21 U.S.C. §353a(b)(1)(A)(i). Some examples of such illegally compounded drugs that do not meet any of these three requirements for the bulk drug substances include the use of bulk drug substances of DMPS, Artichoke Extract, Liver Extract, Sulfoxime, Beta Glucan, L-Glutathione, Copper Chloride, Pituitary Powder (Anterior) Powder, Pancreas Substance Powder, Germanium Sesquioxide Powder, Grape Seed Extract Powder,

Thymus Freeze-dried Powder, N-acetyl-Carnosine, Melatonin, Melilotus, s-adenyl-methionine, Methylsufonylmethane, Silymarin, Alpha Lipoic Acid, a.k.a. Thiocctic Acid, a.k.a. Thiocctic (alpha). Each drug compounded by APOTHECURE and OSBORN, as the pharmacist-in-charge, that uses bulk drug substances that do not meet any of these three requirements for the bulk drug substances, after July 18, 2008, is adulterated, misbranded, and an unapproved new drug under the TFDCA.

C. APOTHECURE and OSBORN, as the pharmacist-in-charge, compound numerous drugs for injection and fail to use bulk drug substances that are manufactured in a facility registered under section 510 of the FFDCA as required by §503a(b)(1)(A)(ii) of the FFDCA, 21 U.S.C. §353a(b)(1)(A)(ii), after July 18, 2008. Many of the bulk drug substances used by Defendants are actually food grade substances and are not manufactured in a facility registered under section 510 of the FFDCA since this section deals with registration as a drug manufacturer. Each drug compounded by APOTHECURE and OSBORN, as the pharmacist-in-charge, after July 18, 2008, that uses bulk drug substances that are not manufactured in a facility registered under section 510 of the FFDCA is adulterated, misbranded, and an unapproved new drug under the TFDCA. Several examples of manufacturers not registered under section 510 of the FFDCA whose bulk drug substances are illegally used in compounded drugs after July 18, 2008,, include but are not limited to DNP International Co., Marcor Development Corporation, Richman Chemical Inc., and Stryka Botanics. Some of Defendants' use of bulk drug substances that are not manufactured in a facility registered under section 510 of the FFDCA include Meso-2,3-dimercaptosuccinic acid (DMSA) substance

manufactured by DNP International Co., 2,3-dimercaptopropanesulfonic acid sodium salt (DMPS) substance manufactured by Richman Chemical, and deoxycholic acid substance manufactured by Marcor Development Corporation.

D. APOTHECURE and OSBORN, as the pharmacist-in-charge, compound numerous drugs, both before and after July 18, 2008, using bulk drug substances requiring **only** certificates of analysis, rather than complying with the additional requirements of 21 U.S.C. §353a, in violation of federal compounding law. Each drug compounded by APOTHECURE and OSBORN, after July 18, 2008, that only meets the requirement of having a valid certificate of analysis is adulterated, misbranded, and an unapproved new drug in violation of the TFDCA.

E. The ingredients, other than bulk drug substances, used by APOTHECURE and OSBORN, as the pharmacist-in-charge, in their compounded drugs, after July 18, 2008, must comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the compounding chapter found in the U.S. Pharmacopoeia, pursuant to 21 U.S.C. §353a(b)(1)(B).

1. APOTHECURE and OSBORN fail to meet this requirement for other ingredients, after July 18, 2008, by combining bulk drug substances in their injectable drugs with United States Pharmacopoeia (“USP”) Sterile Water for Irrigation. Particularly, APOTHECURE and OSBORN use USP Sterile Water for Irrigation in the vast majority of the prescription drug products that they compound as injections/intravenous drugs, including but not limited to DMPS, EDTA Disodium, Polidocanol, Colchicine, Liver, Sulfoxime, Beta Glucan, L-

Glutathione, DL-Thioctic Acid, Thioctic Acid, Copper Chloride, and Grape Seed Extract Powder. Defendants' use of USP Sterile Water for Irrigation in injections, after July 18, 2008, fails to comply with the standards of the applicable United States Pharmacopoeia or National Formulary monograph which state that USP Sterile Water for Irrigation is not for use in injections and these compounded drugs are unapproved new drugs and misbranded and adulterated. Rather, it is indicated for use as an irrigating fluid, and is generally less expensive than USP water for injection.⁶ Additionally, the label of the USP Sterile Water for Irrigation used by APOTHECURE and OSBORN bears the following warning:

“Contradictions: Not for injection” which tracks the United States Pharmacopoeia or National Formulary monograph.

2. APOTHECURE and OSBORN also fail to meet the requirements of 21 U.S.C. §353a(b)(1)(B) for ingredients, after July 18, 2008, by combining some bulk drug substances in their injectable drugs with either Sodium Chloride for Irrigation Solution or Normal Saline for Irrigation Solution. For example, Defendants use Sodium Chloride for Irrigation Solution in injections with the following bulk drug substances: Artichoke, Pituitary Powder (Anterior) Powder, and Germanium Sesquioxide Powder. Additionally, an example of Defendants' use of Normal Saline for Irrigation Solution in injections is in combination with the following bulk drug substance: Pancreas Substance Powder. Defendants' use

⁶USP Water for Injection is designed solely for use in combination with drugs that require dilution or must be dissolved in an aqueous vehicle prior to injection. USP Sterile Water for Injection is purified using distillation or double pass reverse osmosis, and is supplied in small single-dose containers to dilute or dissolve drugs for injection.

of Sodium Chloride for Irrigation Solution and Normal Saline for Irrigation Solution in injections, after July 18, 2008, fails to comply with the standards of the applicable United States Pharmacopoeia or National Formulary monograph that state that these ingredients are not for use in injections and therefore, also fail to comply with 21 U.S.C. §353a(b)(1)(B) making these drugs unapproved new drugs and misbranded and adulterated. The indicated uses for Sodium Chloride for Irrigation Solution and Normal Saline for Irrigation Solution are as irrigating fluids.

F. APOTHECURE and OSBORN, as the pharmacist-in-charge, compound drugs, after and before July 18, 2008, which appear on an FDA list as drugs which have been withdrawn from the marketplace because the drugs or their components have been found to be unsafe or ineffective and fail to comply with 21 U.S.C. §353a(b)(1)(C) and (D) as follows:

1. APOTHECURE and OSBORN compounded Adrenal Cortex injections, Adrenal Cortex sublingual drops, and Adrenal Cortex Kits although all drug products containing Adrenal Cortex are on the Food and Drug Administration's list of drugs removed from the market for safety reasons. In addition to illegally compounding Adrenal Cortex injections and sublingual drops, Defendants APOTHECURE and OSBORN engaged in deception and tried to circumvent the banning of Adrenal Cortex in a drug by manufacturing, advertising, offering for sale, and selling "Adrenal Cortex Kits" and then instructing the purchaser how to make an injectable drug when such drugs are against the law. APOTHECURE and

OSBORN advertised in their catalog that “Although it is illegal to sell ACE for injection use, it is perfectly legal to filter sublingual ACE with a 0.22 micron barrel filter, which renders it sterile. For more information on this technique, call 1-800-969-6601.” Also, APOTHECURE and OSBORN manufacture or compound sublingual Adrenal Cortex drops. Any product that employs a sublingual method of administration is a drug, not a dietary supplement.⁷ Therefore, APOTHECURE and OSBORN’s sublingual Adrenal Cortex drops are classified as a drug and cannot be legally compounded or manufactured. Each drug compounded or manufactured by Defendants, after July 18, 2008, containing Adrenal Cortex is adulterated, misbranded, and an unapproved drug in violation of the TFDCA. Additionally, Defendants offer for sale and sell drugs containing Adrenal Cortex, whether in injections, sublingual drops, or tablets, which violate federal prohibitions and are therefore, unapproved new drugs that cannot be sold without FDA approval.

2. In addition, APOTHECURE and OSBORN compound, without complying with 21 U.S.C. §353a(b)(1)(B), Cobalt Chloride injections, and drugs containing Cobalt have also been withdrawn or removed from the market for safety reasons and are specifically prohibited from being compounded or

⁷ 21 USC 321(ff) The term “dietary supplement”... (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); (2) means a product that—(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or (ii) complies with section 411(c)(1)(B)(ii); (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and (C) is labeled as a dietary supplement;...

manufactured. Each drug compounded or manufactured by Defendants containing Cobalt Chloride is adulterated, misbranded, and an unapproved drug in violation of the TFDCa.

Defendant APOTHECURE and OSBORN's failure to meet any of the requirements of 21 U.S.C. §353a for a compounded drug, after July 18, 2008, causes all of such compounded drugs to be adulterated because of the failure to comply with current good manufacturing practices, misbranded because of the lack of adequate directions for use, and unapproved new drugs under the FDCA and the TFDCa.

(c). APOTHECURE under the Direction of OSBORN Manufacture Adulterated Drugs

9.17 Defendants APOTHECURE and OSBORN adulterate, pursuant to §431.111(a)(2)(B) of the TFDCa, all of the drugs that they manufacture under the guise of compounding, after July 18, 2008, since they fail to meet the requirements for the exemption for compounding in 21 U.S.C. §353a, as described in paragraphs 9.14 through 9.16 above. Additionally, after July 18, 2008, since Defendants APOTHECURE and OSBORN do not meet the exemption for compounding in the definition of "manufacture" in §431.002(23) of the TFDCa for drugs compounded without a prescription order for a patient, Defendants are manufacturing drugs as described in paragraphs 9.14 through 9.16. Defendants' failure to comply with current good manufacturing practices to assure that such drugs meet the requirements of safety and have the identity and strength and meet the quality and purity characteristics, which they purport or are represented to possess, adulterates all drugs that are manufactured pursuant to §431.111(a)(2)(B) of the TFDCa.

9.18 Defendants APOTHECURE and OSBORN adulterated, pursuant to §431.111(c)

of the FDCA, all of the Colchicine injections that they compounded as described in paragraphs 9.6 through 9.13 whose strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

9.19 APOTHECURE and OSBORN's use of USP Sterile Water for Irrigation in compounding intravenous prescription drugs also adulterates each such drug pursuant to §431.111(a)(2)(B) of the FDCA of the FDCA as alleged in paragraphs 9.16 E., contrary to both the USP or National Formulary monograph and the labeling for such ingredient that has a warning: **"Contraindications: Not for injection."**

9.20 APOTHECURE and OSBORN's use of Sodium Chloride for Irrigation Solution and Normal Saline for Irrigation Solution in compounding injections/intravenous prescription drugs, after July 18, 2008, also adulterates each such drug pursuant to §431.111(a)(2)(B) of the FDCA of the FDCA as alleged in paragraph 9.16 E., contrary to both the USP or National Formulary monograph, as required by the federal compounding law cited above.

9.21 In addition, APOTHECURE and OSBORN use bottles of USP Water for Irrigation labeled as "Single-dose Container" to manufacture multiple batches of what is purported to be sterile, intravenous prescription drugs. APOTHECURE and OSBORN do this even though they do not have validation data demonstrating the propriety of using single-dose containers of USP Water for Irrigation for multiple batches and also adulterate each such drug pursuant to §431.111(a)(2)(B) of the FDCA.

9.22 APOTHECURE and OSBORN adulterate, pursuant to §431.111(c) of the FDCA, drugs when they use the USP Sterile Water for Irrigation, Sodium Chloride for Irrigation Solution, and Normal Saline for Irrigation Solution in their compounded intravenous

drugs, after July 18, 2008, by failing to list these ingredients accurately on the label.

(d). APOTHECURE and OSBORN's Manufacture Unapproved New Drugs

9.23 All of the drugs that Defendants APOTHECURE and OSBORN, as the pharmacist-in-charge, compound, after July 18, 2008, that fail to meet the requirements for the exemption for compounding in 21 U.S.C. §353a as described in paragraphs 9.1-9.5 and 9.14-9.16. above, are unapproved new drugs pursuant to §431.114 of the TFDCa. Additionally, each drug compounded by Defendants APOTHECURE and OSBORN that does not meet the exemption for compounding in the definition of "manufacture" in §431.002(23) of the TFDCa, is an unapproved new drug pursuant to §431.114 of the TFDCa.

9.24 All of the Colchicine injections that Defendants APOTHECURE and OSBORN compounded, as described in paragraphs 9.6 through 9.13, are also unapproved new drugs pursuant to §431.114 of the TFDCa as Colchicine is only approved in tablet form for gout and it violates the TFDCa to manufacture, offer to sell, and sell Colchicine injections and Colchicine for the indicted use of pain, as advertised by Defendants.

9.25 In addition, Defendants APOTHECURE and SPECTRA PHARM, under the direction of OSBORN, manufacture and advertise unapproved new drugs pursuant to §431.114 of the TFDCa when they advertise and promote products labeled as dietary supplements to cure, treat, prevent, or mitigate diseases since these products have not been approved by the FDA for these intended uses since they are labeled as dietary supplements as identified below in paragraphs 9.32 through 9.40.

9.26 APOTHECURE and SPECTRA PHARM, under the direction of OSBORN, market an OTC product called "Relieve Blue Pain Gel," which does not comply with the

over-the-counter federal monograph for topical analgesics and does not have an FDA approved product-specific new drug application (“NDA”). Particularly, the active drug ingredients in Defendants’ OTC drug Relieve Blue Pain Gel (i.e., MSM, Aloe Vera and Emu Oil) are not approved for the indicated uses advertised, such as: pain relief, arthritis, reducing joint degeneration and inflammation of tissue. Nevertheless, the following claims were found on the websites www.ApotheCure.com and www.ruhealthy.com regarding the product Relieve Blue Pain gel:

“...for just about any persistent or chronic pain.”

“...MSM...highly useful in targeting certain types of arthritis pain and stiffness...”

Because Defendants make such drug claims, while not complying with the federal monograph and not having an FDA approved NDA, they are illegally manufacturing and marketing an unapproved OTC drug product pursuant to §431.114 of the FDCA.

(e.) Defendants Misbrand Drugs

9.27 Defendants APOTHECURE and OSBORN misbrand all of the drugs that they manufacture under the guise of compounding that fail to meet the requirements for the exemption for compounding in 21 U.S.C. §353a, after July 18, 2008, as described in paragraphs 9.1-9.5 and 9.14-9.16 pursuant to §431.112(e) of the FDCA as these drugs fail to have adequate directions for use for the layperson as required by federal law since they are not exempt from such directions. Additionally, each drug compounded by Defendants APOTHECURE and OSBORN that does not meet the exemption for compounding in the definition of “manufacture” in §431.002(23) of the FDCA is a misbranded drug pursuant to §431.112 (e) of the FDCA.

9.28 Defendants APOTHECURE and OSBORN misbrand, all of the Colchicine

injections that they compounded, as described in paragraphs 9.6 through 9.13 above, as the labeling (the amount of Colchicine in each vial) is false or misleading in any particular pursuant to §431.112(a)(1) and/or (e) of the TFDCA.

9.29 APOTHECURE and OSBORN misbrand all drugs in which they use USP Sterile Water for Irrigation, Sodium Chloride for Irrigation Solution, and Normal Saline for Irrigation Solution in injectable/ intravenous drugs because the list of ingredients on the labeling is false or misleading as the labeling does not identify these actual ingredients and because the labeling does not contain adequate directions for use pursuant to §431.112(a)(1) and/or (e) of the TFDCA.

9.30 Defendants APOTHECURE and OSBORN misbrand and false advertise drugs by advertising some drugs for uses not approved by the FDA, including, but not limited to, oxytocin, hCG, and naltrexone. For example, APOTHECURE and OSBORN advertise Naltrexone which is approved by FDA for reversing the effects of opioids for the following unapproved uses: treating multiple sclerosis, Crohn's disease, HIV/AIDS, chronic fatigue syndrome, psoriasis, fibromyalgia, ALS, autism, and cancer. Also, another example is APOTHECURE and OSBORN's advertising of human chorionic gonadotropin (hCG) for weight loss. HCG has only been approved by the Federal Food and Drug Administration for prepubertal cryptorchidism (undescended testicles), hypogonadotropic hypogonadism in males (decreased function of testes due to a pituitary deficiency), and ovulation induction and is specifically labeled as not being approved for weight loss.

9.31 These advertisements of FDA-approved drugs for unapproved uses misbrands these drugs pursuant to §431.112(a)(1) and/or (e) of the TFDCA. The claims and offers for sale contained in Defendants APOTHECURE and OSBORN's websites and newsletters for drugs

compounded without complying, after July 18, 2008, with 21 U.S.C. 353a,⁸ for unapproved new drugs, and for FDA-approved drugs for uses not approved by FDA are deemed to be false because the advertising is false or misleading in any particular, pursuant to §431.182 of the TFDCa. Additionally, §431.021(f) of the TFDCa prohibits the dissemination of any false advertisements by Defendants.

(f.) Defendants Misbrand and Falsely Advertise Foods

9.32 In addition, Defendants APOTHECURE and SPECTRA PHARM, under the direction of OSBORN, manufacture and advertise misbranded drugs pursuant to §431.112(a)(1) and/or (e) of the TFDCa when they advertise and promote products labeled as dietary supplements to cure, treat, prevent, or mitigate diseases since these products have not been approved by the FDA for these intended uses since they are labeled as dietary supplements as identified below in paragraphs 9.33 through 9.42. Alternatively, Defendants APOTHECURE and SPECTRA PHARM, under the direction of OSBORN, misbrand foods, pursuant to §431.082(a) of the TFDCa, when they manufacture and advertise dietary supplements, which are foods as defined in §431.002(16) of the TFDCa, to cure, treat, prevent, or mitigate diseases since these products have not been approved by the FDA for these intended uses as shown below in paragraphs 9.32 through 9.40. Additionally, the advertising of foods, including dietary supplements, to cure, treat, prevent, or mitigate disease is false or misleading in any particular, pursuant to §431.182 of the TFDCa. Additionally, §431.021(f) of the TFDCa prohibits the

⁸ As previously indicated in footnote 2, provision (c) of 21 U.S.C. §353a was affirmed as unconstitutional in *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61 (2002). The State is not seeking to enforce this provision or to prohibit advertising of legally compounded drugs or FDA-approved drugs for approved uses.

dissemination of any false advertisements by Defendants.

B. TDSHS INSPECTIONS

2007 - 2009 Inspections

9.33 On April 26, 2007, the Texas Department of State Health Services (“TDSHS”) received a complaint alleging that the three people in Oregon and Washington died after receiving an intravenous Colchicine drug product manufactured by APOTHECURE and OSBORN. In response, TDSHS conducted an inspection of APOTHECURE. More specifically, TDSHS inspected the APOTHECURE facility, on May 17, 2007 and June 12, 2007, and also made investigative observations of APOTHECURE’s website (www.apothecure.com). During its investigations, TDSHS identified numerous unlawful conditions. Particularly, TDSHS found numerous violations which generally relate to the following: (1) manufacturing, offering to sale, and sale of a super and sub-potent drug product (i.e., Colchicine), which both adulterates and misbrands this drug; (2) compounding without prescription drug orders for a specific patient as documented on numerous forms; (3) numerous deficient manufacturing practices for prescription and over-the-counter drugs; (4) dietary supplement advertising and labeling violations related to unlawful disease and/or drug claims; and (5) various other violations of the Texas Food, Drug and Cosmetic Act.

9.34 Specifically, TDSHS found the following violations on May 17, 2007 and June 12, 2007, related to the manufacturing and sale of a super and sub-potent prescription drug product:

- A. Colchicine labeled as 1mg/2ml (lot# 20070122@26) was tested and found to have an actual strength of 4mg Cochicine/ml.
- B. Colchicine labeled as 1mg/2ml (lot#20070122@26) and determined to have an

actual strength of 4 mg Colchicine/ml was sold and shipped to Geoffrey Wiss, M.D. at the Center for Integrative Medicine, 5125 S.W. Macadam Ave., Suite 200, Portland, Oregon, on February 2, 2007 (31 vials).

- C. Colchicine labeled as 1mg/2ml (lot# 20061214@28) was tested and found to have an actual strength of 0.38mg Colchicine/ml.
- D. Colchicine labeled as 1mg/2ml (lot#20061214@28) and determined to have an actual strength of 0.38 mg Colchicine/ml was sold and shipped to:
 - i. Geoffrey Wiss, M.D. at the Center for Integrative Medicine, 5125 S.W. Macadam Ave., Suite 200, Portland, Oregon, on January 2, 2007 (35vials);
 - ii. Paul Stallone, NMD at the Arizona Integrative Med. Center, 8144 E. Cactus Rd., Ste. 820, Scottsdale, Arizona on January 8, 2007 (10 vials); and
 - iii. Geoffrey Wiss, M.D. at the Center for Integrative Medicine, 5125 S.W. Macadam Ave., Suite 200, Portland, Oregon, on February 7, 2007 (39 vials).

9.35 TDSHS further found on May 17, 2007 and June 12, 2007, the following violations related to various deficient manufacturing practices for prescription and over-the-counter drug products:

- A. The firm lacked prescription drug orders for the Colchicine that it claimed to be compounding and refused to allow TDSHS to review distribution and production records for any other of the drugs that Defendants claimed to compound.
- B. The firm generally lacked laboratory records and specifically laboratory records which assure compliance with established specifications and standards. For example, Defendants lacked data establishing compliance with specifications and standard for the following two drug products: SDA 1600 Alcohol Gel; and SDA 1600 Mouthwash with Xylitol.
- C. The firm lacked written procedures for the equipment calibration. Particularly, the firm lacked written procedures for the calibration of the scales used in drug manufacturing.
- D. The firm lacked documentation of validation of their cleaning procedures. For instance, the firm lacked documentation validating the cleaning procedures used for utensils and equipment used in drug manufacturing.
- E. The firm failed to package drugs in tamper resistant packaging. For example, the

firm's SDA 1600 Mouthwash with Xylitol (lot#20070604@12) was not sealed with tamper-resistant packaging.

- F. The firm failed to adequately test, approve or reject prescription drug components during manufacture. For example, the firm accepts reports of analysis from suppliers, without performing at least one specific identity test on each component.
- G. The firm failed to adequately document the weight and measure of prescription drug components during manufacture.
- H. The firm failed to adequately document each batch of a prescription drug component (i.e., no lot number identification). Particularly, sixteen (16) bottles of SDA 1600 Alcohol Gel, 2oz., and eleven (11) bottles of SDA 1600 Alcohol Gel, 8oz., did not have lot numbers.
- I. The firm failed to calculate or state an actual yield in determining satisfactory conformance to specifications for prescription drug products. For instance, the firm does not test each batch of drug products, whether injectables, capsules, creams, or any other product, to verify the product quality specifications such as potency and identity.
- J. The firm failed to adequately document in-process and laboratory control results. For instance, the firm's master production and control records do not describe the specific equipment and mixing instructions, sampling and testing procedures, nor do they include the specifications of components used in manufacturing.
- K. The firm lacks sterilization procedures designed to prevent microbiological contamination of drug products. For instance, the firm does not have written procedures or validation data to demonstrate the multiple use of USP sterile water for irrigation as a component in sterile, injectable drugs. Yet, the label for sterile water for irrigation read in part, "Contraindications: Not for injection. ***Single-dose container."
- L. The firm failed to validate the sterilization process for prescription drugs. For instance, the firm failed to have adequate evidence showing the effectiveness of using a 0.2 micro-filter for the sterile filling of all injectable drug products, including but not limited to, Calcium-Disodium EDTA, Disodium EDTA, DMPS, Lidocaine, Polidocanol, Procaine, and Colchicine.
- M. The firm manufactured over-the-counter drug products with active ingredients that are not approved for their indicated uses. For example, the firm manufactured SDA 1600 Mouthwash with Xylitol (lot#20070604@12) and labeled it as a "spectracidal disinfectant agent," however that product does not contain an active drug ingredient approved for the indicated use.

9.36 The Department additionally found on May 17, 2007 and June 12, 2007, the following violations related to dietary supplements advertising and misbranding violations related to unlawful disease and/or drug claims which also makes these products unapproved drugs. Some of these violations were also found during inspections on or about February 21, 2008 and March 5, 2009 as indicated below:

- A. **D-Mannose USP 650mg** : The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"D-Mannose is a new product on the market for urinary tract infections."
"D-mannose . . . can cure more than 90 percent of all UTIs within 1 to 2 days."
"...because it gets rid of UTI-causing bacteria without committing 'bacteriacide,' people who use it suffer none of the unwanted side effects of antibiotics."
"...women (even pregnant women) who are susceptible to recurrent UTIs can safely take D-Mannose as a preventive measure to head off future attacks. D-Mannose is also ideally suited for children with UTIs."
"...have demonstrated its mode of action and effectiveness against E.coli the microorganism that causes most UTIs."
"...it is just about as effective at curing UTIs as antibiotic drugs.”;
- B. **Arginine 500mg**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"...when combine with Lysine, ...reduce the risk of cardiovascular disease..."
"...helpful with alcoholism."
"...helpful with hepatitis"
"...may help some cases of high blood pressure”;
- C. **Pregnenolone**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"...precursor to other hormones, including dehydroepiandrosterone (DHEA) and progesterone." (Also found on February 21, 2008);
- D. **Oregacillin**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Oregacillin products are for anti-fungal, anti-viral, anti-bacterial, anti-parasitic and anti-spasmodic uses." (Also found on February 21, 2008);
- E. **HCI Plus**: The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"...acidify systemically (bursitis, tendonitis and environmental sensitivity), symptoms of hypochlorhydria (gas, bloating, bad breath, body odor, loss of taste

for meat, anemia, pregnancy, low mineral values as seen on a hair-mineral analysis).";

- F. **Super EPA:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Supplementation with fish oils might benefit some of these conditions: Allergies, Chronic diarrhea, Cancer, Aging, Autoimmune diseases, Heart disease, Lupus, Arthritis, Rashes, and Anti-inflammation"(Also, similar violation, "help heal a large number of conditions," found on February 21, 2008);
- G. **Absorb Aid:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"... eliminate the symptoms of indigestion, heartburn and reflux naturally, through better digestion."(Also found on February 21, 2008);
- H. **Pro Biotic Live 12 Plus:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
Decreases incidents of digestive ailments
Decreases incidents of stomach ailments
Decreases incidents of bloating/heartburn
Decreases incidents of constipation/diarrhea
Decreases presence of yeast infection
Decreases incidents of certain infections
Decreases incidents of oral cavity infections (Similar violations also found on February 21, 2008 and March 5, 2009);
- I. **Essential Daily Defense:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Formulated to help the body excrete undesirable toxins, heavy metals and lipids, while helping to control excessive blood clotting tendencies (blood clots are believed to cause 85% of the deaths from heart attacks and strokes)...";
- J. **Endozyme:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
Specifically, Endozyme Medicine contains:
-Nattokinase - to enhance the body's ability to fight blood clots and reduce blood pressure
-Bromelain - an anti-inflammatory to balance the immune system
-Papain - to degrade accumulation of age-related proteins
-Rutin - a powerful anti-inflammatory to help promote a healthier environment for joint mobility
-White Willow Bark - a herbal extract to help normalize inflammation (Similar violations also found on February 21, 2008);

- K. **DHEA 25mg:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
Health Benefits of DHEA: Fights Osteoporosis and Fights Auto-immune Diseases;
- L. **Chromium Polynicotinate:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"A recent study on antidepressant pharmacotherapy for dysthymic disorder (depression) in 5 patients showed that chromium polynicotinate supplementation led to remission of dysthymic symptoms and concluded that "preliminary observations suggest that chromium may potentate antidepressant pharmacotherapy for dysthymic disorder."
"For many with diabetes, chromium enhances the ability of insulin to lower serum glucose levels.";
- M. **Biotin with Horsetail:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Uses:
-Cradle cap (seborrheic dermatitis)
-Diabetes
-Biotin deficiency is a rare nutritional disorder caused by a deficiency of biotin. Biotin deficiency can have a very serious, even fatal, outcome if it is allowed to progress without treatment;

"Initial symptoms of biotin deficiency include:
-Dry skin
-Seborrheic dermatitis
-Fungal infections
-Rashes including erythematous periorofacial macular rash
-Hair loss or total alopecia;

-If left untreated, neurological symptoms can develop, including: Mild depression
-Changes in mental status
-Generalized muscular pains (myalgias)
-Hyperesthesias and paresthesias;
- N. **Liquid Health Attention:** The website www.apothecure.com and www.ruhealthy.com had the following labeling:
"...for ADD/ADHD."(Also found on February 21, 2008);
- O. **Adrenal Cortex Support:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"We have found this particular blend to be very effective in supporting adrenal dysfunction and chronic fatigue syndrome.

"Adrenal dysfunction is one of the major underlying cause and/or result of most chronic illnesses.

Indicated for use with allergies (All violations also found on February 21, 2008);

- P. **Adrenal Cortex Sublingual:** The website www.apothecure.com, www.ruhealthy.com and promotional literature had the following labeling claims:
"... helps in resistance to infections and stress of all types, increases blood lymphocytes, and decreases serum gamma globulin content."
"Adrenal Cortex Extract has shown to be effective for hypoglycemia, inflammation, drug and alcohol withdrawal, stress management, trauma, allergies, and of course Addison's Disease."
"...indicated for stress, renal insufficiencies, inflammation, trauma, and toxic infections."
"Although it is illegal to sell ACE for injection use, it is perfectly legal to filter sublingual ACE with a 0.22 micron barrel filter, which renders it sterile."
Indicated for use with allergies, (Violations similar to above found on February 21, 2008)
In addition, the product is a sublingual delivery system bypassing the digestive tract (This violation also found on March 5, 2009);
- Q. **Youth Reborn** (topical Vitamin C): The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
Protects against or lessens the severity of sunburns.
Wound healing as it aids in stabilizing collagen(Similar violations found on February 21, 2008 on a promotional display and on March 5, 2009 on product labeling);
- R. **Bumble Bar:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims for the product:
"...help protect against heart disease, cancer, arthritis..."
"...protect against breast, colon and prostate cancers.";
- S. **Free Radical Quenchers:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Free radicals are associated with both the initiation & promotion of cancer, all types of inflammation, arthritis, circulatory disorders, Parkinson's disease & many other health problems.";
- T. **Complete Prostate Formula:** The pamphlet had the following labeling claims:
"...most common problems are prostatitis, benign prostatic hyperplasia, and prostate cancer.";

"How can you prevent any of the above conditions? Taking the unique combination of supplements can help prevent inflammation and cancer (saw

palmetto extract, red clover extract, nettle, pygeum extract, lycopene, pumpkin seed extract, beta sitosterol, zinc, and copper- all ingredients found in Complete Prostate Formula).”;

- U. **Liquid Health, Women's Multi:** The pamphlet for this product had the following labeling claims:
"...improve circulation for the reduction of spider and varicose veins.";
- V. **Collagen/Hyaluronic Acid Anti-Aging Powder Drink Mix:** The pamphlet for this product had the following labeling claims:
"...can rid the body of cellulite, eliminate hemorrhoids..."
"...connective tissue disorders, such as mitral valve prolapse, TMJ, osteoarthritis, and keratoconus.";
- W. **Ascorbic Acid (Ascorbate) #8:** The pamphlet for this product had the following labeling claims:
"...such as healing of wounds and burns. It assists in the prevention of blood clotting and bruising..."
"...help reduce cholesterol levels, high blood pressure and preventing arteriosclerosis."
Indicated for use with allergies;
- X. **FYI:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims: "...control and prevent inflammation, they have no side effects whatsoever and may, oftentimes, prevent the occurrence of unwanted side effects caused by prescription medications."(Similar violations also found on February 21, 2008);
- Y. **5-Hydroxytryptophane:** Website indications include: Anxiety and Depression:
- Z. **Magnesium Glycinate 750 mg.:**
Website indication is for high blood pressure(Also found on February 21, 2008);
- AA. **Relieve Blue Pain Gel:** The product does not comply with the over-the-counter federal monograph for topical analgesics, in that the active drug ingredients (MSM, Aloe Vera and Emu Oil) are not approved for the indicated uses advertised, such as: pain relief, arthritis, reducing joint degeneration and inflammation of tissue. Some of the following claims were found on the website www.apothecure.com and www.ruhealthy.com for the product Relieve Blue Pain gel:
"...for just about any persistent or chronic pain."
"...MSM...highly useful in targeting certain types of arthritis pain and stiffness..."(All violations also found on February 21, 2008 and similar violations found on March 5, 2009 on www.TIFM.com);

BB. **Choles/TIFM:** The use of the phrase "For Blood Fat Disorders" implies that the product treats disease condition; and

CC. **Insulin Support:** Website indication is for diabetes.

9.37 Furthermore, TDSHS found on May 17, 2007 and June 12, 2007, additional violations of the Texas Food, Drug and Cosmetic Act, including several related to false or misleading advertising and misbranding violations. Some of these violations were also found on or about February 21, 2008 and March 5, 2009 as indicated below:

- A. **SDA 1600 Mouthwash with Xylitol and SDA 1600 Alcohol Gel:** do not have a Drug Facts Panel;
- B. **SDA 1600 Alcohol Gel, 8oz:** Eleven (11) bottles did not have a Drug Facts Panel;
- C. **Relieve Blue Pain Gel:** The product does not comply with the over-the-counter federal monograph for topical analgesics, in that the active drug ingredients (MSM, Aloe Vera and Emu Oil) are not approved for the indicated uses advertised, such as: pain relief, arthritis, reducing joint degeneration and inflammation of tissue. Some of the following claims were found on the website www.apothecure.com and www.ruhealthy.com for the product Relieve Blue Pain gel:
"...for just about any persistent or chronic pain."
"...MSM...highly useful in targeting certain types of arthritis pain and stiffness..."(All violations also found on February 21, 2008 and similar violations found on www.TIFM.com on March 5, 2009);
- D. **Progesterone Cream 16mg/ml:** The website www.apothecure.com advertises the availability of the topical drug product- "One product we have available for over the counter is Progesterone Cream."(Also found on February 21, 2008);
- E. **Dermaheal Nourishing Hair Solution:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Increase the follicle size and stop hair from falling out by reducing DHT."
"Help form new blood vessels, stimulate follicles to produce stronger, healthier hair."
"Increase synthesis of Collagen & Elastin, increase blood flow, restrains hair depigmentation."
"Increase stem cell release from bulge into matrix of hair follicle."
"Play important role in the control perifollicular vascularization during hair

cycling."(All violations also found on February 21, 2008 and March 5, 2009);

- F. **A'LIVE Gel:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
"Tests by leading medical researchers have shown that A'LIVE 5% Hydrogen Peroxide Gel provides effective therapeutic relief from a variety of irritating skin conditions including: wounds, burns & sunburn, insect bites, aging spots, chronic allergic dermatitis, rosacea & vulgaris acnes, psoriasis lotricum, atopic dermatitis, fine wrinkles, periodontal disorders."
"Improved formula A'LIVE, with active ingredient methyl sulfonyl methane (MSM), is quickly absorbed deep into the skin where it combines with certain enzymes to produce oxygen thus restoring the skin's health, beauty, and natural vitality." (claim shows that the product is delivered transdermally)(All violations also found on February 21, 2008 and similar claim found on www.TIFM.com on March 5, 2009);
- G. **EDTA Calcium Disodium Magnesium:** The website www.apothecure.com, www.ruhealthy.com and promotional literature had the following labeling claims:
"...it removes plaque and returns the arterial system to a smooth, healthy, pre-atherosclerotic state."
A better metaphor might be "Liquid-Plumr®," because, where Roto-Rooter violently scrapes deposits off the interior surfaces of your plumbing with a rapidly rotating blade, Liquid-Plumr simply dissolves them away;
- H. **Apothe Cure Nutritionals MSM Plus:**
Product label lacks Supplement Facts Panel.
Product label lacks an approved FDA disclaimer statement.
The components of the capsule are not provided in the ingredients statement
The product label lacks a proper serving size in that it uses the term "recommended dosage." The term "recommended dosage" implies a therapeutic use for the product.
The statement that appears on the label "and all other medicines" appears to be false and misleading in that the product is being sold as a dietary supplement;
- I. **Adrenal Cortex Support:**
The proper name for Pantothenic acid is not being used in that the term Vitamin B-5 is provided as a dietary ingredient in the Supplement Facts panel and is not a recognized synonym. In addition, the calcium source is declared in Supplement Facts panel as originating from B-5;
- J. **DHEA 25 mg.:**
The common or usual name of the product does not accurately describe product in that the term is an abbreviation;

- K. MSN Metal Detox II:**
The common or usual name of the product does not accurately describe product in that the term is an abbreviation. The word "Detox" is an unapproved drug claim. The Supplement Facts panel does not state serving size of the product. The Supplement Facts panel does not state the servings per container. The product ingredients are not listed in the Supplement Facts panel in the correct format in that the ingredients without %DV's are listed with the ingredients that have established %DV's. The warnings, uses, and directions act as intervening material between the dietary ingredients and other ingredients in the Supplement Facts panel. The term "active ingredients" appears to be false and misleading in that the product is being sold as a dietary supplement. The label fails to identify the ingredients that do not have a %DV established. The components of the capsule are not provided in the ingredient statement;
- L. Trace Mineral #1 with Iron:**
The common or usual name of the product does not adequately describe the product. The term "Vitamin K1" is not the proper nomenclature for Vitamin K (All violations also found on February 21, 2008);
- M. Trace Mineral #1:**
The common or usual name of the product does not adequately describe the product. The term "Vitamin K1" is not the proper nomenclature for Vitamin K (All violations also found on February 21, 2008);
- N. Trace Mineral # 2 with Iron:**
The common or usual name of the product does not adequately describe the product. (This violation also found on February 21, 2008)
The % DV of Manganese contained in product does not coincide with amount per serving provided in Supplement Facts panel;
- O. Trace Mineral # 2 Iron Free:**
The common or usual name of the product does not adequately describe the product (Also found on February 21, 2008);
- P. Electrolyte #1:**
The common or usual name of the product does not adequately describe the product. (This violation also found on February 21, 2008)
The term "Vitamin K1" is not the proper nomenclature for Vitamin K;
- Q. Electrolyte #2:**
The common or usual name of the product does not adequately describe the

product. (Also found on February 21, 2008)

The term "Vitamin K1" is not the proper nomenclature for Vitamin K.

The dietary ingredients are not listed in the Supplement Facts panel in the proper order. (Also found on February 21, 2008)

The weight of the compound, Potassium Phosphate, is provided in the Supplement Facts panel rather than the weight of the elemental Potassium (Also found on February 21, 2008);

R. Electrolyte #3:

The common or usual name of the product does not adequately describe the product.

The term "Vitamin K1" is not the proper nomenclature for Vitamin K.

The dietary ingredients are not listed in the Supplement Facts panel in the proper order.

The weight of the compounds, Sodium Carbonate, Potassium Chloride, Potassium Iodate, and Potassium Phosphate, are misleading in that the weight of the entire compound is listed in the Supplement Facts panel rather than the individual weight of the Sodium and Potassium;

S. Apothe Cal Calcium Supplement with Boron:

The components of the capsule are not provided in the ingredients statement.

The common or usual name does not accurately describe the product.

Calcium is not declared properly in the Supplement Facts panel;

T. Ascorbate #8:

The components of the capsule are not provided in the ingredients statement.

The common or usual name does not accurately describe the product. (Also, found on February 21, 2008)

Dietary ingredients are not declared properly in the Supplement Facts panel.

The order of predominance of the ingredients statement on bulk (12 Bottles-200 capsules each) Ascorbate #8 does not match the order of predominance provided in the Supplement Facts panel;

U. EDTA (calcium powder) with Magnesium Malate (Repeat violation from 10/13/04 & 1/25/06 DSHS Inspection of Spectrapharm):

The common or usual name of product does not adequately describe the product in that the proper nomenclature for EDTA is not provided.

The Supplement Facts panel provides an incorrect %DV for Magnesium.

The Magnesium is not declared properly in the Supplement Facts panel.

The components of the capsule is not declared in the ingredients statement (Also found on February 21, 2008 and on March 5, 2009);

V. Vitamin C 100mg/tsp.:

The product label does not provide a Supplement Facts Panel.
The common or usual name of the product does not adequately describe the product.
The components of OraSweet are not provided in the Supplement Facts panel.
Artificial cherry flavorings are not identified in the ingredient statement.
Artificial colorings are not identified in the ingredients statement.
The substance in which the product is suspended is not identified in the ingredients statement;

W. Magnesium Glycinate 750 mg.:

The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel.
The entire weight of Magnesium Glycinate is listed in the Supplement Facts panel rather than the actual weight of the elemental magnesium. (This violation also found on February 21, 2008 and March 5, 2009)
Website indication is for high blood pressure (Last violation also found on February 21, 2008);

X. Glucosamine Sulfate Complex with Chondroitin & MSM:

The common or usual name of the product does not adequately describe the product.(Also found on February 21, 2008)
The servings per container are not provided in the Supplemental Facts panel.
The proper nomenclature is not provided for MSM.
The components of the capsule are not provided in the ingredients statement;

Y. 5-Hydroxytryptophane 50mg.:

The term "pharmaceutical grade ingredients" is false and misleading in that there are no pharmaceutical grade ingredients recognized for foods.
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement facts panel.
The hypoallergenic filler ingredients are not provided in the ingredients statement.
Website indications include: Anxiety and Depression (Last violation also found on February 21, 2008);

Z. 5-Hydroxytryptophane 25mg.:

The term "pharmaceutical grade ingredients" is false and misleading in that there are no pharmaceutical grade ingredients recognized for foods.
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement facts panel.
The hypoallergenic filler ingredients are not provided in the ingredients statement.
Website indications include: Anxiety and Depression (Last violation also found on February 21, 2008);

AA. Malic Acid Triple Plus with AKG:

The servings per container are not provided in the Supplement Facts panel.
The common or usual name does not adequately describe the product. (This violation also found on February 21, 2008)
The components of the capsule are not provided in the ingredients statement;

BB. 1-Melthionine 500 mg.:

The components of the capsule are not provided in the ingredients statement.
The common or usual name does not adequately describe the product.
The servings per container is not provided in the Supplement Facts panel;

CC. Chromium Polynicotinate 400 mcgm:

The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

DD. Growth Hormone Releaser Beginner Formula

No Supplement Facts panel is provided on product label.
The components of the capsule are not provided in the ingredients statement;

EE. D Mannose USP 650mg.:

The components of the capsule are not provided in the ingredients statement;

FF. Choles/TIFM

The common or usual name does not adequately describe the product. (This violation also found on February 21, 2008)
The use of the phrase "For Blood Fat Disorders" implies that the product treats disease condition.(similar violation found on www.ruhealthy.com on March 5, 2009)
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

GG. Immune Enhancer Formula:

The common or usual name does not adequately describe the product.
The servings per container are not provided in the Supplement Facts panel.
The components of the capsule are not provided in the ingredients statement;

HH. Liquid Iodine:

The servings per container are not provided in the Supplement Facts panel.
The suspension liquid is not provided in the ingredients statement.
The established % DV for Iodine is not provided in the Supplement Facts panel;

II. Insulin Support:

The common or usual name does not adequately describe the product.
The dietary ingredients are not provided in the proper format in the Supplement Facts panel.

The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel.
The %DV is not provided in the Supplement Facts panel for the dietary ingredients with established daily values.
Website indication is for diabetes;

JJ. L-Glutamine 500 mg.:

The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

KK. Biotin 15 mg Capsules with Horsetail:

The components of the capsule are not provided in the ingredients statement.
The established %DV for Biotin is not provided in the Supplement Facts panel.
The dietary ingredients with established %DV's are not separated with a bar from the dietary ingredients that do not have established %DV;

LL. Pregnenolone 30 mg.:

The components of the hypoallergenic filler are not provided in the ingredients statement.
The term "pharmaceutical grade" may be false and misleading in that there are no pharmaceutical grade ingredients used for food.
The components of the capsule are not provided in the ingredients statement.
The directions for use do not coincide with the mg contained in the capsules;

MM. Zinc Complex:

The components of the capsule are not provided in the ingredients statement.
The weight of the zinc compounds is provided in the Supplement Facts panel rather than the weight of the elemental zinc. (This violation also found on February 21, 2008 and on March 5, 2009 along with incorrect % of daily value.)
The dietary ingredients with %DV's are not separated from those that do not (Last violation also found on February 21, 2008);

NN. Asparagine 500 mg.:

The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

OO. Carnitine 500 mg.:

The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

PP. I-Histidine 500 mg.:

The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;

- QQ. **Arginine 500 mg.:**
The components of the capsule are not provided in the ingredients statement.
The servings per container are not provided in the Supplement Facts panel;
- RR. **Bulk Ascorbate #8:**
No Supplement Facts panel is provided on product label;
- SS. **Celtic Sea Salt:**
The product label does not contain the statement, "This salt does not supply iodine, a necessary nutrient."

2010 Inspections

9.38 On January 14, 2010 and January 15, 2010, TDSHS inspected APOTHECURE's business premises and found that APOTHECURE was distributing prescription drugs wholesale without a wholesale distributor's license, and that it was distributing prescription drugs to an entity (Spectra Pharm, Inc.) which is not authorized to possess prescription drugs. TDSHS also found that APOTHECURE failed to have standard operating procedures in place for the wholesale distribution of prescription drugs, failed to have a temperature log for the storage of prescription drugs, and could not provide a list of the names, duties and qualifications of the personnel in charge of the wholesale distribution of prescription drugs.

C. SPECTRA PHARM, INC.

2007-2009 Inspections

9.39 Defendant OSBORN operates SPECTRA PHARM as a retail establishment, which offers the following food and drug products: dietary supplements, SPECTRA PHARM's private label dietary supplements, homeopathic drugs, and over-the-counter drugs. SPECTRA PHARM maintains a retail storefront, adjacent to APOTHECURE's Dallas, Texas facility, where SPECTRA PHARM sells these products. Also, SPECTRA PHARM advertises and sells its products via its website, www.ruhealthy.com.

9.40 Coinciding with its inspection of APOTHECURE on May 17, 2007 and June 12, 2007, the TDSHS also inspected the SPECTRA PHARM facility. Further, TDSHS made investigative observations of SPECTRA PHARM's website during its investigations, and identified numerous unlawful conditions. Additionally, TDSHS inspected SPECTRA PHARM on February 21, 2008 and March 5, 2009 and found some of the following violations were continuing. Particularly, TDSHS found the following false advertising and/or misbranding violations, which generally relate to SPECTRA PHARM's unlawful and misleading labeling of dietary supplements:

- A. **DHEA 25mg.:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims:
Health Benefits of DHEA
 - a. Fights Osteoporosis
 - b. Fights Auto-immune Diseases;

- B. **Adrenal Cortex Support:** The website www.apothecure.com and www.ruhealthy.com had the following labeling claims for the product:
We have found this particular blend to be very effective in supporting adrenal dysfunction and chronic fatigue syndrome. (This violation also found on February 21, 2008)
Adrenal dysfunction is one of the major underlying cause and/or result of most chronic illnesses. (This violation also found on February 21, 2008)
Indicated for use with allergies.
Calcium source is declared in supplement Facts panel as originating from B-5 (This violation found on February 21, 2008);

- C. **Adrenal Cortex Sublingual:** The website www.apothecure.com, www.ruhealthy.com and promotional literature had the following labeling claims:
"... helps in resistance to infections and stress of all types, increases blood lymphocytes, and decreases serum gamma globulin content."(This violation also found on February 21, 2008)
"Adrenal Cortex Extract has shown to be effective for hypoglycemia, inflammation, drug and alcohol withdrawal, stress management, trauma, allergies, and of course Addison's Disease."
"...indicated for stress, renal insufficiencies, inflammation, trauma, and toxic infections."(This violation also found on February 21, 2008)
"Although it is illegal to sell ACE for injection use, it is perfectly legal to filter

sublingual ACE with a 0.22 micron barrel filter, which renders it sterile."

Indicated for use with allergies.

In addition, the product is a sublingual delivery system bypassing the digestive tract (This violation also found on February 21, 2008);

- D. **Complete Prostate Formula:** The pamphlet for this product had the following labeling claims:
"...most common problems are prostatitis, benign prostatic hyperplasia, and prostate cancer."
How can you prevent any of the above conditions? Taking the unique combination of supplements can help prevent inflammation and cancer (saw palmetto extract, red clover extract, nettle, pygeum extract, lycopene, pumpkin seed extract, beta sitosterol, zinc, and copper- all ingredients found in Complete Prostate Formula);
- E. **Ascorbic Acid (Ascorbate) #8:** The pamphlet for this product had the following labeling claims:
"...such as healing of wounds and burns. It assists in the prevention of blood clotting and bruising..."
"...help reduce cholesterol levels, high blood pressure and preventing arteriosclerosis."
Indicated for use with allergies, colds, flu, and asthma;
- F. **EDTA Calcium Disodium Magnesium:** The website www.apothecure.com, www.ruhealthy.com and promotional literature had the following labeling claims:
"...it removes plaque and returns the arterial system to a smooth, healthy, pre-atherosclerotic state."
A better metaphor might be "Liquid-Plumr®," because, where Roto-Rooter violently scrapes deposits off the interior surfaces of your plumbing with a rapidly rotating blade, Liquid-Plumr simply dissolves them away;
- G. **Apothe Cure Nutritionals MSM Plus:**
Product label lacks Supplement Facts Panel
Product label lacks an approved FDA disclaimer statement
The components of the capsule are not provided in the ingredients statement
The product label lacks a proper serving size in that it uses the term "recommended dosage." The term "recommended dosage" implies a therapeutic use for the product.
The statement that appears on the label "and all other medicines" appears to be false and misleading in that the product is being sold as a dietary supplement;
- H. **Adrenal Cortex Support:**
The proper name for Pantothenic acid is not being used in that the term Vitamin B-5 is provided as a dietary ingredient in the Supplement Facts panel and is not a

recognized synonym. In addition, the calcium source is declared in Supplement Facts panel as originating from B-5;

- I. **DHEA 25 mg.:**
The common or usual name of the product does not accurately describe product in that the term is an abbreviation;
- J. **MSN Metal Detox II:**
The common or usual name of the product does not accurately describe product in that the term is an abbreviation. The word "Detox" is an unapproved drug claim. The Supplement Facts panel does not state serving size of the product. The Supplement Facts panel does not state the servings per container. The product ingredients are not listed in the Supplement Facts panel in the correct format in that the ingredients without %DV's are listed with the ingredients that have established %DV's. The warnings, uses, and directions act as intervening material between the dietary ingredients and other ingredients in the Supplement Facts panel. The term "active ingredients" appears to be false and misleading in that the product is being sold as a dietary supplement. The label fails to identify the ingredients that do not have a %DV established. The components of the capsule are not provided in the ingredient statement;
- K. **Trace Mineral #1 with Iron:**
The common or usual name of the product does not adequately describe the product. The term "Vitamin K1" is not the proper nomenclature for Vitamin K (All violations also found on February 21, 2008);
- L. **Trace Mineral #1:**
The common or usual name of the product does not adequately describe the product. The term "Vitamin K1" is not the proper nomenclature for Vitamin K (All violations also found on February 21, 2008);
- M. **Trace Mineral # 2 with Iron:**
The common or usual name of the product does not adequately describe the product.(This violation also found on February 21, 2008);
The %DV of Manganese contained in the product does not coincide with the amount per serving provided in Supplement Facts Panel;
- N. **Trace Mineral # 2 Iron Free:**
The common or usual name of the product does not adequately describe the product (This violation also found on February 21, 2008);

- O. **Electrolyte #1:**
The common or usual name of the product does not adequately describe the product. (This violation also found on February 21, 2008)
The term "Vitamin K1" is not the proper nomenclature for Vitamin K;
- P. **Electrolyte #2:**
The common or usual name of the product does not adequately describe the product. (This violation also found on February 21, 2008)
The term "Vitamin K1" is not the proper nomenclature for Vitamin K.
The dietary ingredients are not listed in the Supplement Facts panel in the proper order. (This violation also found on February 21, 2008)
The weight of the compound, Potassium Phosphate, is provided in the Supplement Facts panel rather than the weight of the elemental Potassium (This violation also found on February 21, 2008);
- Q. **Electrolyte #3:**
The common or usual name of the product does not adequately describe the product.
The term "Vitamin K1" is not the proper nomenclature for Vitamin K.
The dietary ingredients are not listed in the Supplement Facts panel in the proper order.
The weight of the compounds, Sodium Carbonate, Potassium Chloride, Potassium Iodate, and Potassium Phosphate, are misleading in that the weight of the entire compound is listed in the Supplement Facts panel rather than the individual weight of the Sodium and Potassium;
- R. **Apothe Cal Calcium Supplement with Boron:**
The components of the capsule are not provided in the ingredients statement.
The common or usual name does not accurately describe the product.
Calcium is not declared properly in the Supplement Facts panel;
- S. **Ascorbate #8:**
The components of the capsule are not provided in the ingredients statement.
The common or usual name does not accurately describe the product. (This violation also found on February 21, 2008)
Dietary ingredients are not declared properly in the Supplement Facts panel.
The order of predominance of the ingredients statement on bulk (12 Bottles-200 capsules each) Ascorbate #8 does not match the order of predominance provided in the Supplement Facts panel; and
- T. **EDTA (calcium powder) with Magnesium Malate** (Repeat violation from 10/13/04 & 1/25/06 DSHS Inspection of Spectrapharm)
The common or usual name of product does not adequately describe the product in that the proper nomenclature for EDTA is not provided. (This violation also

found on February 21, 2008 and March 5, 2009)
The Supplement Facts panel provides an incorrect %DV for Magnesium. (This violation also found on February 21, 2008 and March 5, 2009)
The Magnesium is not declared properly in the Supplement Facts panel.
The components of the capsule are not declared in the ingredients statement.

2010 Inspection

9.41 On January 14, 2010 and January 15, 2010, TDSHS inspected SPECTRA PHARM'S business premises and found that SPECTRA PHARM was distributing prescription drugs without a valid wholesale distributor's license, that SPECTRA PHARM received prescription drugs from an unlicensed wholesaler (Apothecure), and that SPECTRA PHARM did not have records showing the source of non-prescription drugs. TDSHS also found that SPECTRA PHARM lacked standard operating procedures for the wholesale distribution of prescription drugs, a temperature log for the storage of prescription drugs, and a list of the names, duties and qualifications of the people in charge of prescription drug wholesale distribution.

D. REFERRAL

9.42 Based upon its investigations of APOTHECURE and SPECTRA PHARM as directed by Defendant OSBORN, TDSHS identified numerous TFDA violations, which pose a threat to the public health and safety. As a result, TDSHS referred Defendants APOTHECURE, SPECTRA PHARM, and OSBORN to the Texas Attorney General requesting that his office seek appropriate remedies.

10. VIOLATIONS OF THE TEXAS FOOD, DRUG AND COSMETIC ACT

10.1 Based on paragraphs 1.1 through 9.42 above, Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, have manufactured or compounded and/or introduced into commerce adulterated drugs, misbranded drugs, and

unapproved new drugs; introduced misbranded foods (i.e., dietary supplements) into commerce; and falsely represented that these unapproved new drugs and misbranded foods are intended to cure, mitigate, treat, or prevent human diseases. Defendants have also false advertised approved drugs for unapproved uses.

A. Unapproved New Drugs

10.2 Defendants APOTHECURE and SPECTRA PHARM are manufacturing under the guise of compounding or manufacturing drugs and Defendant OSBORN is the pharmacist-in-charge of APOTHECURE and owns, directs, and participates in the manufacture of drugs by both entities. Many of the products Defendants manufacture and/or compound constitute drugs, as defined in §431.002(14) of the TFDCa, because these products are intended to cure, mitigate, treat, or prevent disease in man. The drugs Defendants manufacture without having FDA approval of a New Drug Application, including but not limited to Apothelash and Biocean, are “new drugs” pursuant to §431.002(25) of the TFDCa.

10.3 Paragraphs 9.14 through 9.23 generally identify unapproved new drugs manufactured under the guise of compounding by Defendants APOTHECURE AND OSBORN after July 18, 2008. If Defendants compound without complying with federal compounding law, 21 U.S.C. §353a and all such compounded drugs are unapproved new drugs pursuant to §431.114 of the TFDCa. Additionally, Defendants are manufacturing drugs rather than compounding when they fail to meet the exemption for compounding in the definition of “manufacture” in §431.002(23) of the TFDCa after July 18, 2008,.

10.4 Another example of Defendants manufacturing of drugs involves its manufacture

of products labeled as dietary supplements generally identified in paragraphs 9.26 and 9.33 through 9.41. Dietary supplements are foods as defined in §431.002(16) of the TFDCa, but Defendants SPECTRA PHARM and OSBORN advertise and promote these products to cure, mitigate, treat, or prevent human diseases. Therefore these products are drugs as defined in §431.002(14) of the TFDCa based upon their claims. Moreover, these drugs are also new drugs as defined in §431.002(25) of the TFDCa because they are not recognized in the official United States Pharmacopoeia or National Formulary and are neither approved by the FDA, nor generally recognized among experts as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof.

10.5 Defendants APOTHECURE, SPECTRA PHARM, and OSBORN also manufacture and/or sell unapproved new drugs, which they improperly market as over-the-counter drugs generally identified in paragraphs 9.27 and 9.33 through 9.41. Over-the-counter (“OTC”) drugs are drugs that are available to consumers without a prescription. Federal monographs specify the active ingredients that can be contained within OTC drug products. Only OTC drug products containing ingredients that comply with standards established in an applicable monograph are considered to be “generally recognized as safe and effective” (“GRASE”) and do not require specific FDA approval before marketing.

10.6 OTC drug products with active ingredients, dosage forms, dosage strengths, or routes of administration that differ from the federal monographs are regulated under the new drug application (“NDA”) process. Under the NDA process, legal marketing is under the authority of an approved product-specific new drug application. The FDA must approve the NDA for an OTC drug product before that product can be marketed OTC. In order to be approved, a drug

manufacturer must submit data in an NDA demonstrating that the drug product is safe and effective for use by consumers without the assistance of a healthcare professional. The drug manufacturer can only market the product with the specific formulation and exact labeling approved by the FDA. To make a change, the manufacturer must submit an NDA supplement and the FDA must approve that supplement.⁹

10.7 Section 431.114(a)(1) of the TFDCa provides that a person shall not sell, deliver, offer for sale, hold for sale or give away any new drug without an FDA approved new drug application. Further, the introduction or delivery for introduction into commerce of any article violating § 431.114 of the TFDCa is prohibited under § 431.021(e) of the TFDCa.

B. Adulterated Drugs

10.8 Defendants APOTHECURE and OSBORN compounded adulterated drugs and then introduced those products into commerce as described in paragraphs 1.1 through 10.7 above. This adulteration occurred in the following ways:

- A. The manufacture and selling of super and sub-potent drugs, including 31 vials from a batch of intravenous Colchicine (Apothecure lot number 20070122@26) that was more potent than their labels indicated (a potency of 4 milligrams per milliliter, rather than the 0.5 milligrams per milliliter stated on labels); and
- B. The manufacture and selling of 81 vials of intravenous Colchicine labeled as having a potency of 1 milligram per 2 milliliter (Apothecure lot number 20061214@28), which was tested and found to have an actual strength of 0.38mg Colchicine per milliliter.

Section 431.111(c) of the TFDCa provides that a drug is deemed to be adulterated if its strength differs from, or its purity or quality falls below, that which it purports to be or is represented to possess. Therefore, APOTHECURE and OSBORN's super and sub-potent lots of a prescription

⁹See http://www.fda.gov/cder/Offices/OTC/reg_mechanisms.htm.

drug were adulterated because their strengths differed from that which they purported to possess.

10.9 Defendants APOTHECURE and OSBORN adulterate by failing to comply with current good manufacturing practices, pursuant to §431.111(a)(2)(B) of the TFDCa, all of the drugs that they manufacture under the guise of compounding, since they fail to meet the requirements for the exemption for compounding in 21 U.S.C. §353a after July 18, 2008, and, fail to meet the exemption for compounding in the definition of “manufacture” in §431.002(23) of the TFDCa, after July 18, 2008, as described in paragraphs 9.14 through 9.16 and 9.17 through 9.23.

10.10 APOTHECURE and OSBORN’s use of USP Sterile Water for Irrigation in compounding intravenous prescription drugs also adulterates each such drug pursuant to §431.111(a)(2)(B) of the TFDCa and/or §431.111(c) of the TFDCa as alleged in paragraphs 9.16 E., 9.19, 9.21 and 9.22, contrary to both the USP or National Formulary monograph and the labeling for such ingredient that has a warning: “**Contraindications: Not for injection.**”

10.11 APOTHECURE and OSBORN’s use of Sodium Chloride for Irrigation Solution and Normal Saline for Irrigation Solution in compounding intravenous prescription drugs also adulterates each such drug pursuant to §431.111(a)(2)(B) of the TFDCa and/or §431.111(c) of the TFDCa as alleged in paragraphs 9.16 E., 9.20, and 9.21 contrary to both the USP or National Formulary monograph.

10.12 Since Defendants APOTHECURE and OSBORN, do not have prescription drug orders from a practitioner for a identified individual patient for the majority of the drugs that they claim to compound, Defendants APOTHECURE and OSBORN are manufacturing and must comply with current good manufacturing practices to assure that such drug meets the

requirements of safety and has the identity and strength and meets the quality and purity characteristics, which it purports or is represented to possess. Because Defendants failed to comply with the current good manufacturing practices, Defendants adulterated numerous drug products, as identified above in paragraphs 1.1 through 10.11. For example, during its inspection of APOTHECURE's facility, TDSHS's representatives determined that APOTHECURE failed to adequately test, approve, or reject prescription drug components. Further, they found that APOTHECURE failed to document the weight and measure of prescription drug components during manufacture. Defendants' practices fail to comply with the federal regulations that prescribe the current good manufacturing practices for pharmaceuticals. *See* 21 C.F.R. §§ 211.84, 211.113(b), 211.188(b)(4).¹⁰ Section 431.111(a)(2)(B) of the TFDCA provides that a drug is deemed adulterated if the methods used in its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practice. Defendants' other deficient manufacturing practices are described above and further elaborate the extent of

¹⁰Section 211.84 of the good manufacturing practices provides: "[e]ach lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit." 21 C.F.R. § 211.84(a)

Section 211.113(b) of the good manufacturing practices provides: "[a]ppropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of any sterilization process." 21 C.F.R. § 211.113(b)

Section 211.188 of the good manufacturing practices provides: "Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include: (b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including: (4) Weights and measures of components used in the course of processing." 21 C.F.R. § 211.188(b)(4)

Defendants' adulteration of drug products.

10.13 Section 431.021(a) of the TFDCa prohibits the introduction into commerce (or delivery for introduction into commerce, or causing the introduction or delivery for introduction into commerce), within the State of Texas, of any adulterated drug. Section 431.021(h) of the TFDCa prohibits the manufacturing of adulterated drugs in this state. Nevertheless, Defendants manufactured and sold adulterated drug products in Texas whether to Texas customers or to out-of-state customers, and thereby introduced them into commerce, in violation of §§431.021(a) and (h) of the TFDCa.

C. Misbranded Drugs

10.14 Defendants APOTHECURE, SPECTRA PHARM, and OSBORN manufacture misbranded drug products and introduce those products into commerce. This misbranding occurred in numerous ways as identified in paragraphs 1.1 through 10.13 above.

10.15 Defendants APOTHECURE and OSBORN misbrand, pursuant to §431.112(a)(1) of the TFDCa, all of the Colchicine injections that they compounded as described in paragraphs 9.6 through 9.13 and 9.29 above as the labeling of the super-potent and sub-potent Colchicine is false or misleading in any particular (the amount of Colchicine in each vial).

10.16 APOTHECURE and OSBORN misbrand, pursuant to §431.112(a)(1) and (e) of the TFDCa, all injectable/ intravenous drugs in which they use USP Sterile Water for Irrigation, Sodium Chloride for Irrigation Solution, and Normal Saline for Irrigation Solution as indicated in paragraphs 9.16 E. and 9.30.

10.17 SPECTRA PHARM and OSBORN's labeling and packaging of OTC drugs without accurate information on the label misbrands these drugs. Section 431.112(c) of the

TFDCA provides that a drug shall be deemed to be misbranded if information required to appear on the label or labeling is not prominently placed thereon. For example, all OTC drugs are required to provide a drug facts panel on their labeling pursuant to 21 CFR § 201.66; 25 TAC §§ 229.242, 229.251(a) and (g). Defendants manufacture and/or market and sell the following two OTC drugs: SDA 1600 Alcohol Gel and SDA 1600 Mouthwash with Xylitol.

Nevertheless, the labeling for these drugs omits the requisite fact panels. These specific drugs are misbranded, in addition to the other OTC drugs as indicated in paragraphs 9.33 through 9.41 above.

10.18 Some of Defendants' drugs are also misbranded, under the terms of the TFDCA, because their labeling fails to provide adequate directions regarding the uses for which these drugs are intended and are being promoted in Texas, as alleged above in paragraphs 1.1 through 10.17. Section 431.112(e)(1) of the TFDCA provides that a drug is deemed to be misbranded if its labeling fails to provide adequate directions for use, unless the drug has been exempted from those requirements by regulations adopted by the Secretary of the United States Department of Health and Human Services.

10.19 Per federal regulation, "adequate directions for use" means "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 CFR § 201.5. The drugs promoted and sold by Defendants fail to provide adequate directions for their intended use, because adequate directions cannot be written providing for the use of an unapproved drug by a layperson. Therefore, all unapproved drugs found by TDSHS in paragraphs 1.1 through 10.18 and all drugs advertised for unapproved uses are misbranded under the terms of § 431.112(e)(1) of the TFDCA.

10.20 Defendants APOTHECURE and OSBORN misbrand all of the drugs that they manufacture under the guise of compounding that fail to meet the requirements for the exemption for compounding in 21 U.S.C. §353a after July 18, 2008. Defendants also fail to meet the exemption for compounding in the definition of “manufacture” in §431.002(23) of the TFDCa, as described in paragraphs 9.1-9.5, 9.14-9.23, and 9.28 pursuant to §431.112(e) of the TFDCa as these drugs fail to have adequate directions for use for the layperson as required by federal law since they are not exempt from such directions.

10.21 Defendants APOTHECURE and OSBORN misbrand drugs by advertising unapproved drugs since they have not been approved by FDA (includes all drugs manufactured under guise of compounding by failing to comply with 21 U.S.C. §353a after July 18, 2008) and some FDA-approved drugs for uses not approved by the FDA, as indicated in paragraphs _____ above. These advertisements of FDA-approved drugs for unapproved uses misbrands these drugs pursuant to §431.112(a)(1) and/or (e) of the TFDCa. Similarly, advertising of products labeled as dietary supplements to prevent, treat, cure, mitigate, or diagnose diseases by all Defendants misbrands these dietary supplements as drugs pursuant to §431.112(a)(1) and/or (e) of the TFDCa as indicated in paragraphs 9.32 and 9.33 through 9.41.

10.22 Sections 431.021(h) and (a) of the TFDCa respectively prohibit the manufacturing of misbranded drugs and the introduction into commerce (or delivery for introduction into commerce, or causing the introduction or delivery for introduction into commerce) of any misbranded drug, including Defendants’ unapproved new drugs, FDA approved drugs for unapproved uses, and drug products with labels and/or labeling that do not conform with state and federal standards. Since Defendants’ drugs are misbranded under Texas

law, Defendants are in violation of §§ 431.021(a) and/or (h) of the TFDCAs as indicated in paragraphs 1.1 through 10.21 above.

D. Misbranded Foods

10.23 Defendants manufacture, advertise, offer for sale, and sell dietary supplements, which the TFDCAs defines as “food” in § 431.002(16) of the TFDCAs. The TFDCAs further provides that food shall be deemed to be misbranded if: (1) the food’s labeling is false or misleading in any particular; (2) fails to prominently display information and statements required by regulations in such a manner to render it likely to be read and understood by the ordinary individual under customary conditions; or (3) the food labels do not bear the common or usual name of the foods and/or ingredients. *See* § 431.082(a), (f), (g), and (j) of the TFDCAs.

10.24 Therefore, Defendants’ foods, including the products it markets as dietary supplements, are misbranded under the terms of the TFDCAs based upon the claims made for these foods and by virtue of labeling that is misleading or otherwise inadequate.

10.25 Thus, many of Defendants’ foods, as indicated in paragraphs 1.1 through 10.24 above, are deemed misbranded because their labeling: (1) is false or misleading; (2) fails to bear the common or usual names of the foods and their underlying ingredients; and/or (3) fails to prominently display information and statements required by regulations in such a manner to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

10.26 The TFDCAs prohibits the misbranding of foods in commerce pursuant to §431.021(b) of the TFDCAs and the introduction into commerce (or the delivery for introduction into commerce or causing the introduction or delivery for introduction into commerce) within

the State of Texas of any misbranded food, such as Defendants' dietary supplements with labels and/or labeling that make drug/disease claims and/or otherwise do not conform with state and federal standards, pursuant to § 431.021(a) of the TFDCa. The TFDCa prohibits the manufacture of misbranded food pursuant to §431.021(h) of the TFDCa. Since Defendants' foods are misbranded under Texas law, Defendants are violating §§ 431.021(a) and/or (b) and (h) of the TFDCa, as indicated in paragraphs 1.1 through 10.26 above.

E. False Advertisement

10.27 Based on the conduct alleged above, including paragraphs 9.1 through 9.41 and 10.1 through 10.26 above, Defendants APOTHECURE, SPECTRA PHARM, and OSBORN have falsely advertised their drugs and foods, and thereby violated § 431.021(f) of the TFDCa. Particularly, Defendants have engaged in false advertisement through their promotion of unapproved new drugs, adulterated and misbranded drugs, and misbranded food.

10.29 Defendants' Internet websites, labeling, and promotional materials, including their newsletter, constitute advertising within the definition set out in § 431.002(1) of the TFDCa¹¹ because they contain representations disseminated for the purpose of inducing consumers to purchase Defendants' drugs or foods.

10.30 Defendants' advertising of unapproved new drugs and adulterated or misbranded drugs is false within the meaning of § 431.182 of the TFDCa because it is misleading in numerous particulars as set out above in paragraphs 1.1 through 10.29. For instance,

¹¹"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. TEX. HEALTH & SAFETY CODE § 431.002(1)

Defendants' advertisements for unapproved new drugs are false because the FDA has not approved these drugs, and they therefore it is illegal to market such drugs. Similarly, Defendants' advertising of FDA drugs for unapproved uses and advertising of adulterated or misbranded drugs, as alleged above is false within the meaning of §431.182 of the TFDCa because it is misleading in numerous particulars as set out above in paragraphs 1.1 through 10.29. Additionally, any such advertisement by Defendants for unapproved new drugs, FDA drugs for unapproved uses, and misbranded and/or adulterated drugs is false because it is directed toward the public and is not consistent with labeling claims permitted by the FDA in §431.183 of the TFDCa.

10.31 Defendants' advertising of foods (i.e., dietary supplements) is also false within the meaning of § 431.182 of the TFDCa because it is misleading in numerous particulars, as set out above. For instance, Defendants' advertisements of many dietary supplements are false because the advertisements make disease claims that cannot be made for foods, and it is illegal to market these foods with such claims.

10.32 Section 431.021(f) of the TFDCa prohibits the dissemination of any false advertisements. Defendants have disseminated false advertisements through their promotion of unapproved new drugs, FDA approved drugs for unapproved uses, adulterated and/or misbranded drugs, and misbranded food. Therefore, Defendants have violated § 431.021(f) of the TFDCa.

11. PROHIBITED ACTS UNDER THE TEXAS FOOD, DRUG AND COSMETIC ACT

11.1 Based on the conduct alleged above in paragraphs 9.1 through 10.32 above, Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN,

individually, have committed or caused to be committed the following acts prohibited and declared to be unlawful by the TFDCCA:

- A. Introducing or delivering for introduction into commerce adulterated drugs in violation of § 431.021(a) of the TFDCCA;
- B. Introducing or delivering for introduction into commerce misbranded drugs in violation of § 431.021(a) of the TFDCCA;
- C. Introducing or delivering for introduction into commerce misbranded foods in violation of § 431.021(a) of the TFDCCA;
- D. Adulterating drugs in commerce in violation § 431.021(b) of the TFDCCA;
- E. Misbranding drugs in commerce in violation § 431.021(b) of the TFDCCA;
- F. Misbranding foods in commerce in violation § 431.021(b) of the TFDCCA;
- G. Disseminating false advertisements in violation § 431.021(f) of the TFDCCA;
- H. Failing to package drug products in tamper resistant packaging pursuant to 25 T.A.C. § 229.251(c) and 21 C.F.R. § 211.132 that results in manufacturing adulterated drugs, in violation of § 431.021(h) of the TFDCCA;
- I. Manufacturing within this state drugs that are adulterated in violation of § 431.021(h) of the TFDCCA;
- J. Manufacturing within this state drugs that are misbranded in violation of § 431.021(h) of the TFDCCA;
- K. Manufacturing within this state foods that are misbranded in violation of § 431.021(h) of the TFDCCA;
- L. Introducing an unapproved new drug into commerce in violation of § 431.021(e) of the TFDCCA;
- N. Refusing to permit access to or copying of any record as authorized by §§ 431.042 through 431.044 of the TFDCCA, including records associated with compounding to determine if Defendants are in compliance with compounding law under the FFDCA and the TFDCCA or if Defendants are manufacturing prescription drugs in violation of § 431.021(g) of the TFDCCA; and
- O. Engaging in the wholesale distribution of drugs in this state without obtaining a

license in violation of § 431.021(x) of the TFDCA.

12. VIOLATIONS OF THE TEXAS DECEPTIVE TRADE PRACTICES ACT

12.1 Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, as alleged above in paragraphs 9.1 through 11.1 above, have in the course of trade and commerce engaged in false, misleading and deceptive acts and practices declared unlawful in § 17.46(a) of the DTPA. Additionally, Defendants have violated § 17.46(b) of the DTPA as follows:

- A. Causing confusion or misunderstanding as to the approval of the drugs manufactured, advertised, or sold by Defendants, in violation of § 17.46(b)(2) of the DTPA;
- B. Causing confusion or misunderstanding as to the approval of the foods manufactured, advertised, or sold by Defendants, in violation of § 17.46(b)(2) of the DTPA;
- C. Representing that Defendants' drugs have benefits which they do not have, in violation of § 17.46(b)(5) of the DTPA;
- D. Representing that Defendants' foods have benefits which they do not have, in violation of § 17.46(b)(5) of the DTPA;
- E. Representing that Defendant APOTHECURE has the status of a compounding pharmacy, when it is compounding without a prescription drug order from a physician for an individual identified patient, in violation of § 17.46(b)(5) of the DTPA;
- F. Representing that Defendants' drugs are of a particular standard, quality, or grade, if they are of another, in violation of § 17.46(b)(7) of the DTPA;
- G. Representing that Defendants' foods are of a particular standard, quality, or grade, if they are of another, in violation of § 17.46(b)(7) of the DTPA; and
- H. Failing to disclose that it is illegal to make claims to cure, prevent, treat, diagnose, or mitigate diseases unless a product has been approved by FDA as a drug, when the failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of § 17.46(b)(24) of the DTPA.

13. INJURY TO CONSUMERS

13.1 By means of the foregoing unlawful acts and practices, Defendants have acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

14. TEMPORARY AND PERMANENT INJUNCTION

14.1 The State alleges that by reason of the foregoing, Defendants should not continue to operate as food and drug manufacturing establishments or as a pharmacy that manufactures, compounds, advertises, or sells their products in violation of the laws of Texas. The interests of the State of Texas require a temporary and permanent injunction to prohibit Defendants from continuing to unlawfully operate food and drug manufacturing establishments and the pharmacy and to advertise and sell their drug and food products, unless and until their food and drug manufacturing establishments and pharmacy are determined upon inspection by TDSHS to be free of violations of the TFDCA. The interests of the State of Texas also require a temporary and permanent injunction to prohibit Defendants from advertising and selling their products unless Defendants are in compliance with the DTPA and to prohibit past violative conduct from re-occurring.

14.2 Unless injunctive relief is granted, Defendants will continue to violate the laws of the State of Texas to the detriment of the State of Texas and to the general public.

15. PRAYER

15.1 WHEREFORE, Plaintiff prays that Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, be cited according to law to appear and answer herein; that after due notice and hearing, a TEMPORARY INJUNCTION be

issued, and upon final hearing a PERMANENT INJUNCTION be issued, restraining and enjoining Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, their successors, assigns, officers, agents, servants, employees, and any other person in active concert or participation with Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, from engaging in the following acts or practices:

- A. Manufacture an adulterated or misbranded drug;
- B. Manufacture any drug without a new drug application having been submitted to and approved by the FDA for each drug manufactured;
- C. Manufacture drugs within this state, unless Defendants comply with the current good manufacturing practices and are appropriately licensed;
- D. Sell, deliver, advertise, offer for sale, hold for sale, or give away any drug unless the drug has been approved by the FDA or compounded in compliance with all of the requirements of 21 U.S.C. §353a;
- E. Introduce into commerce an adulterated drug by manufacturing, advertising, offering to sell, or selling a drug that has not been approved by the FDA or compounded in compliance with the requirements of 21 U.S.C. §353a;
- F. Introduce into commerce a misbranded drug by manufacturing, advertising, offering to sell, or selling a drug that has not been approved by the FDA or compounded in compliance with the requirements of 21 U.S.C. §353a;
- G. Compound a drug before receiving a prescription order for an individually identified patient from a practitioner and without a history of receiving prescription orders for the drug products within an established pharmacist-practitioner-patient relationship;
- H. Use a bulk drug substance in compounding that 1) fails to comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the compounding chapter found in the U.S. Pharmacopoeia; or 2) is not a drug substance that is a component of drugs approved by the FDA, if a monograph does not exist; or 3) if neither 1) nor 2) apply, does not appear on an FDA list of approved compounded drugs;

- I. Compound a drug by using a bulk drug substance that is not manufactured in a facility registered under section 510 of the FFDCa;
- J. Compound a drug by using bulk drug substances that fail to have valid certificates of analysis;
- K. Compound a drug by using bulk drug substances that only have valid certificates of analysis and fail to meet the other requirements of 21 U.S.C. §353a;
- L. Compound a drug by using ingredients, other than bulk drug substances, that fail to comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the compounding chapter found in the U.S. Pharmacopoeia;
- M. Compound a drug for injection that uses ingredients that are not for use in injections, including but not limited to USP Water for Irrigation, Sodium Chloride for Irrigation Solution, and Normal Saline for Irrigation Solution;
- N. Compound a drug which appears on an FDA list as a drug which has been withdrawn from the marketplace because the drug or its components have been found to be unsafe or ineffective;
- O. Compound Colchicine injections or any drug containing Cobalt Chloride;
- P. Manufacture, compound, advertise, hold, offer for sale, and/or sell any product incorporating Adrenal Cortex as a component, except for food products that are orally ingested into the gastrointestinal tract (i.e., eating or drinking);
- Q. Manufacture, compound, advertise, hold, offer for sale, and/or sell any product incorporating Adrenal Cortex as a component that is advertised or indicated for use via a route of drug administration, including but not limited to sublingual and injections, except for oral ingestion into the gastrointestinal tract for a food product;
- R. Disseminate any marketing materials, instructions, or protocols for a product incorporating Adrenal Cortex as a component or packaging a product incorporating Adrenal Cortex as a component in a manner to subvert the federal prohibition of Adrenal Cortex in a drug product;
- S. Compound a drug product if it has been identified by the FDA as a drug product which is difficult to compound without affecting the safety or effectiveness of the product;
- T. Falsely advertise or falsely represent that a drug, whether manufactured or

compounded in compliance with 21 U.S.C. §353a , is effective for treating diseases of the body, when the FDA has not approved the drug for the advertised use;

- U. Distribute any drugs that have been compounded;
- V. Manufacture, compound, advertise, hold, offer for sale, and/or sell any product incorporating DMPS as a component unless FDA includes this bulk drug substance in a final list of drugs that can be compounded under 21 U.S.C. §353a (b)(1)(A)(i)(III);
- W. Compound an adulterated or misbranded drug;
- X. Manufacture, advertise, offer to sell, or sell any manufactured drug unless the drug has been approved by the FDA and the advertisement or offer promotes the drug only for the intended uses that were the basis for FDA approval;
- Y. Advertise or offer to sell a drug compounded by Defendants unless the advertisement or offer promotes the drug only for the intended uses that were the basis for FDA approval of the components or the designated use in the USP;
- Z. Represent that Defendants' drugs have benefits which they do not have;
- AA. Cause confusion or misunderstanding as to FDA's approval of drugs compounded or manufactured by Defendants;
- BB. Introduce into commerce, or cause the introduction into commerce of, a misbranded or adulterated drug or misbrand or adulterate a drug in commerce;
- CC. Distribute drugs wholesale without a wholesale distributor's license or to an entity that is not authorized to possess prescription drugs;
- DD. Fail to have standard operating procedures, a temperature log for the storage of prescription drugs, and a list of the names, duties and qualifications of the personnel in charge for the wholesale distribution of drugs;
- EE. Falsely advertise or cause the false advertising of drugs in Texas;
- FF. Use testimonials to make claims about a drug that Defendants could not lawfully make themselves;
- GG. Compound drugs in anticipation of future prescriptions unless such anticipated orders are based upon a history of receiving valid prescriptions issued within an established pharmacist/patient/prescriber relationship;

- HH. Fail to package drugs in tamper resistant packaging;
- II. Introduce into commerce any over-the-counter drug which does not comply with the over-the-counter federal monograph for such drug;
- JJ. Introduce into commerce any drug lacking adequate directions for use, unless the drug has been exempted from the requirement for adequate directions for use by regulations adopted by the Secretary of the United States Department of Health and Human Services;
- KK. Introduce into commerce any over-the-counter drug whose label does not have a drug facts panel;
- LL. Make any express or implied claim in the labeling, marketing, or advertising of a dietary supplement that the dietary supplement may be used in the diagnosis, cure, mitigation, treatment or prevention of disease in humans;
- MM. Make any express or implied structure/function claim in the labeling, marketing, or advertising of a dietary supplement, unless at the time the claim is made, competent and reliable scientific evidence exists substantiating such claim, and the claim does not make the product a drug;
- NN. Make any express or implied claim in the labeling, marketing, or advertising of a dietary supplement concerning the health benefit, performance, efficacy or safety of a food marketed as a dietary supplement, unless at the time the claim is made, competent and reliable scientific evidence exists substantiating such claim, and the claim does not make the product a drug;
- OO. Introduce into commerce a misbranded food or misbrand a food in commerce;
- PP. Cause confusion or misunderstanding by claiming that a dietary supplement can diagnose, prevent, treat, cure or mitigate any disease;
- QQ. Represent that a dietary supplement has benefits which it does not have;
- RR. Introduce into commerce a dietary supplement that does not provide consumers with a common or usual name that is appropriately descriptive of the nature of the product;
- SS. Use testimonials to make claims about a dietary supplement that Defendants could not lawfully make themselves;
- TT. Introduce into commerce a dietary supplement whose label fails to prominently

display, in such a manner to render it likely to be read and understood by the ordinary individual under customary conditions, information and statements required by regulations, including but not limited to:

- (1) a supplement facts panel;
 - (2) an approved FDA disclaimer;
 - (3) a proper serving size;
 - (4) a statement in the supplement fact panel, describing all of the ingredients, including the components of any capsules; and
 - (5) a statement enumerating the servings per container, in the supplement facts panel;
- UU. Manufacture foods within this state, unless Defendants comply with the current good manufacturing practices and are appropriately licensed;
- VV. Refuse to permit access to or copying of any record as authorized by TFDC §§ 431.042 through 431.044, including records associated with the manufacture of drugs and foods, including dietary supplements;
- WW. Fail to develop and implement a plan for monitoring and regulating all of Defendants' Internet sites and all advertising and promotional materials for dietary supplements to insure that they do not include claims that said foods treat, cure, mitigate, or prevent diseases and serious illnesses;
- XX. Fail to develop and implement a plan for the monitoring and regulation of all of Defendants' Internet sites and all advertising and promotional materials for drugs to insure that they do not include claims that promote unapproved drugs or FDA-approved drugs for unapproved uses;
- YY. Conduct potency and identity testing on all drugs compounded by Defendants;
- ZZ. Fail to keep each prescription order for an individually identified patient from a practitioner for a drug to be compounded by Defendants and make these prescription orders available for inspecting and copying by TDSHS within 72 hours, if requested by an authorized agent of the TDSHS;
- AAA. Fail to compile and maintain records for all drugs compounded by Defendants, electronically or manually, that show compliance with all of the requirements of §353a and make these records available for inspecting and copying by TDSHS within 5 business days, if requested by an authorized agent of the TDSHS;
- BBB. Fail to allow TDSHS to inventory all the stocks of drugs compounded by Defendants as part of any inspection conducted by TDSHS; and

CCC. Fail to allow TDSHS to conduct an inspection of all aspects of Defendants' facilities to determine whether Defendants are in compliance with the terms of this Final Judgment and Agreed Permanent Injunction and to cooperate with TDSHS inspectors during said inspection.

15.2 Plaintiff further prays that this court upon final hearing order Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, to pay civil penalties in favor of the STATE OF TEXAS in the amount of \$25,000.00 per day per violation of §431.021 of the TFDCA pursuant to §431.0585 of the TFDCA.

15.3 Plaintiff further prays that this court, upon final hearing, order Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, to destroy all products that are unapproved new drugs or adulterated or misbranded drugs or dietary supplements in violation of §431.021 of the TFDCA pursuant to of §431.051 of the TFDCA.

15.4 Plaintiff further prays that, upon final hearing, this Court will order Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, to pay civil penalties in favor of the STATE OF TEXAS in the amount of \$20,000.00 per violation of the DTPA pursuant to of §17.47(c)(1) of the DTPA.

15.5 Plaintiff further prays that upon final hearing that this Court order Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, to pay to the STATE OF TEXAS attorney fees and costs of court pursuant to the TEX. GOVT. CODE §402.006(c) (Vernon 2005, Supp. 2007).

15.6 Plaintiff further prays that upon final hearing that this court order Defendants APOTHECURE, INC., SPECTRA PHARM, INC., and GARY OSBORN, individually, to pay to the Office of the Attorney General and to the Texas Commissioner of Health their reasonable

expenses incurred in obtaining injunctive relief under §431.047 of the TFDCa, including investigative costs, court costs, reasonable attorneys' fees, witness fees, and deposition expenses pursuant to §431.047(d) of the TFDCa.

15.7 Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may show itself entitled.

Respectfully submitted,

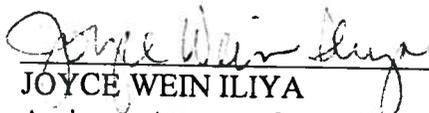
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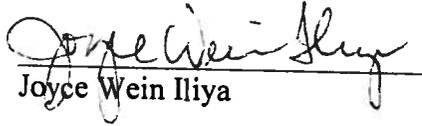
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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing *State's Third Amended Original Petition* was served on all Defendants by and through their attorney Ryan Lurich, by certified mail return receipt requested on this 11th day of July, 2011.


Joyce Wein Iliya

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