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STATE OF TEXAS,
Plaintiff

IN THE DISTRICT COURT OF

v.

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BEXAR COUNTY, TEXAS

ELITE MED, LLC.;
S & B MARKETING, INC., and
BRIAN BAILEY, INDIVIDUALLY,
Defendants.

45th JUDICIAL DISTRICT

**PLAINTIFF'S ORIGINAL PETITION AND APPLICATION FOR EX PARTE
TEMPORARY RESTRAINING ORDER,
TEMPORARY INJUNCTION AND PERMANENT INJUNCTION**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, THE STATE OF TEXAS, Plaintiff, acting by and through its Attorney General GREG ABBOTT ("State"), and at the request of the TEXAS DEPARTMENT OF STATE HEALTH SERVICES ("DSHS") files this Original Petition and Application for Ex Parte Temporary Restraining Order and Temporary and Permanent Injunction against ELITE MED, L.L.C, S & B MARKETING, INC., and Brian Bailey, individually, ("Elite Med") under the authority of the Texas Health and Safety Code (TEX. HEALTH AND SAFETY CODE ANN. §§ 431.001 *et seq.*, also referred to as the Texas Food, Drug and Cosmetic Act) and the TEX. BUS. & COM. CODE ANN. § 17.47 *et seq.*, ("DTPA") and in support thereof would respectfully show the Court the following:

DISCOVERY CONTROL PLAN

1. Discovery shall be conducted under LEVEL 2 in accordance with Rule 190.3 of the Texas Rules of Civil Procedure.

PLAINTIFF

2. This suit is 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 to him by §§ 431.047 and 431.0585 of the Texas Food, Drug and Cosmetic

Act (“TFDCA”) and any regulations promulgated pursuant to this law, upon the grounds that the Commissioner of the Texas Department of State Health Services (“DSHS”) and his authorized agents have found that Defendants have violated and are threatening to violate provisions of the TFDCA.

3. This suit is also brought by Attorney General GREG ABBOTT through his Consumer Protection and Public Health Division in the name of the State of Texas under the authority granted to him by § 17.47 of the Texas Deceptive Trade Act (“DTPA”), upon the grounds that Defendants have engaged in false, misleading and deceptive acts and practices in the conduct of trade or commerce as defined and declared unlawful by § 17.46 (a) and (b) of the DTPA.

DEFENDANTS

4. Defendant Elite Med, LLC. is a limited liability company engaged in business in Texas at 1742 Hunter Road, New Braunfels, Texas 78130. Defendant Elite Med, LLC. may be served with process by serving its registered agent, Brian Bailey, at 1742 Hunter Road, New Braunfels, Texas 78130.

5. Defendant S & B Marketing, Inc. is for-profit corporation engaged in business in Texas at 2211 S. Kirkwood Rd., Apt. 47, Houston, Texas. Defendant S & B Marketing, Inc. may be served with process by serving its registered agent, Brian Bailey, at his business address of 2211 S. Kirkwood Rd., Apt. 47, Houston, Texas or his personal residence at 9600 FM 306, New Braunfels, Texas 78132.

6. Defendant Brian Bailey, Individually, is a resident of the State of Texas and is an owner and/or representative in charge of Elite Med, LLC. and is engaged in business in Texas at 1742 Hunter Road, New Braunfels, Texas 78130. Defendant Brian Bailey may be served with process at his residence at 9600 FM 306, New Braunfels, Texas 78132.

AUTHORITY

7. This action is brought by Attorney General Greg Abbott, through his Consumer Protection & Public Health Division, in the name of the State of Texas and in the public interest under the authority granted to the Attorney General by § 17.47, Texas Deceptive Trade Practices – Consumer Protection Act, Tex. Bus. & Com. Code §§ 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.

8. This action is also brought by the Attorney General Greg Abbott in the name of the State of Texas and in the public interest under the authority granted him by § 431.047 and § 431.0585 of the Texas Food, Drug and Cosmetic Act, Tex. Health & Safety Code Ann. § 431.001 *et seq.* (“TFDCA”). Sections 431.047 of the TFDCA authorizes the Attorney General to seek injunctive relief under certain circumstances and recover any costs and attorney fees incurred in obtaining that relief. In addition, § 431.0585 of the TFDCA 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.

VENUE

9. Venue is proper under TEX. HEALTH & SAFETY CODE § 431.047 (a) - (d) because the violations and threats of violation have occurred in Bexar County, Texas; and

10. Venue is also proper under TEX. BUS. AND COM. CODE § 17.47(b) because the violations occurred in Bexar County, Texas and Defendants do business in Bexar County, Texas.

PUBLIC INTEREST

11. Plaintiff, the STATE OF TEXAS, has reason to believe that the Defendants have engaged in, and will continue to engage in, the unlawful practices set forth below, and unless enjoined from doing so, such continued operations pose a threat to the public health and safety and will also cause adverse effects to legitimate business enterprises which lawfully conduct trade and commerce in this State. Therefore, the Consumer Protection and Public Health Division of the Office of the Attorney General believes, and is of the opinion, that these proceedings are in the public interest.

TRADE AND COMMERCE

12. Defendants are engaged in conduct which constitutes “trade” and “commerce” as those terms are defined by Section 17.45 (6) of the DTPA, in that they were and are engaged in the business of receiving and introducing into commerce prescription devices or more specifically, providing and injecting patients with such prescription devices.

ACTS OF AGENTS

13. Whenever in this petition it is alleged that Defendants Elite Med, LLC., S & B Marketing, Inc. and Brian Bailey, 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 Defendants.

TRIAL BY JURY

14. Plaintiff requests a jury trial and tenders the jury fee to the Bexar County District Clerk’s office pursuant to TEX. R. CIV. P. 216 and TEX. GOV’T CODE ANN § 51.604.

NATURE OF DEFENDANTS’ CONDUCT

Overview of the Regulation of Prescription Devices

15. The United States Food and Drug Administration (“FDA”) is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Federal Food, Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 301 *et seq.*, including but not limited to approving all prescription devices that can legally be used in the United States.

16. Under the FFDCA, the FDA has the sole responsibility for approving prescription devices and also regulates the manufacturing, labeling and distributing of devices in the United States. Federal regulations determine what must be on labels and labeling of prescription devices that can legally be purchased, received, held, possessed, offered for sale or sold in the United States, including, but not limited to the following:

- A. All labels and labeling (all labels and other written, printed, or graphic matter upon any device or any of its containers or wrappers, or accompanying such device) are required to be in the English language, 21 C.F.R. § 801.15(c)(1);
- B. The label or labeling must contain the federal caution statement pursuant to 21 C.F.R. § 801.109(b); and
- C. The label or labeling must contain the FDA-approved product description, indications for use, contraindications, warnings, precautions and patient disclosure information, 21 C.F.R. 801.109 (c) and (d).

Defendants’ Acts

17. On or about April 2006, Defendants began, to purchase, receive, hold, possess, offer for sale or sell prescription devices named Orthovisc, Synvisc, Hyalgan and Eufflexa from a Canadian company M.T.E. Diagnostics. Defendants violated the Texas Food, Drug and Cosmetic Act by being located in Texas and purchasing, receiving, holding, possessing, offering to sell or selling prescription devices, Orthovisc, Synvisc, Hyalgan, and Eufflexa from M.T.E. Diagnostics, without

being licensed with the Texas Department of State Health Services as required by the Act. All prescription devices purchased by Defendants as unlicensed distributors in Texas are misbranded pursuant to the TFDCa and illegal to purchase, receive, hold, possess, offer to sell, or sell.

18. All of the required labeling of the devices purchased, received, held, offered for sale or sold in Texas by Defendants was in languages other than English. Prescription devices that have required labeling not in English are misbranded and illegal to purchase, receive, hold, possess, offer to sell, or sell in the United States under federal law and in Texas under both federal and state law and rules.

19. Despite being told by at least one physician in Texas that some devices purchased from Defendants had labeling that was in entirely in Spanish Defendants persisted in violating the law and purchasing, receiving, possessing, holding, offering for sale or selling such misbranded prescription devices in Texas.

20. The misbranded devices which Defendants Elite Med and S & B Marketing through Defendant Bailey purchased, received, possessed, held, offered for sale and sold were purchased from the Canadian company, M.T.E. Diagnostics, which also is not licensed in Texas as a device distributor (companies located outside Texas are not required to license as device distributors with DSHS) and is not regularly and lawfully engaged in the distribution of such devices in the United States (since such misbranded devices cannot be legally in distribution in the United States). The products purchased and received by Defendants were misbranded when sold and purchased by them as unlicensed distributors or persons not regularly and lawfully engaged in the distribution of such devices in the United States. Additionally, these prescription devices were misbranded because the devices failed to conform with the federal requirements for their labels and labeling to be in English; to bear the federal caution statement required after FDA approval; and to have the approved labeling, including but not limited to the FDA-approved product description, indications for use,

contraindications, warnings, precautions and patient disclosure information. Additionally, some of the prescription devices purchased and received by Defendants from M.T.E. Diagnostics contained labeling with indications for uses that are not approved by FDA for the United States.

FACTUAL ALLEGATIONS

21. Defendants Elite Med, LLC., S & B Marketing, Inc., and Brian Bailey, individually, are in violation of the TFDCA of the Texas Health & Safety Code and Texas Deceptive Trade Practices Act.

22. On January 27, 2009, the Texas Department of State Health Services (“DSHS”) received an anonymous complaint that Defendant Elite Med, LLC. was not licensed as device distributor in Texas and that Elite Med, LLC. imports and distributes medical devices which are not approved by the Food and Drug Administration (“FDA”) for use in the United States. (*See Exhibit 1, attached hereto and incorporated herein*).

23. Brian Bailey is the owner and representative of Elite Med. Elite Med is a Texas firm that is not licensed as a device distributor as required by the TFDCA. Elite Med is in the business of importing and distributing prescription devices which are not labeled for sale in the United States. Elite Med has been in business since 2006 and sells prescription devices to physicians throughout the United States, including Bexar County, Texas.

24. Elite Med distributes Orthovisc, Synvisc, Hyalgan and Euflexxa. All of these devices are cleared for marketing by the FDA as prescription devices, specifically arthritis injections. All of these devices are similar in that they are all injections and are used to provide pain relief suffered by consumers/patients with arthritis of the knee.

25. On April 14, 2009, DSHS responded to the anonymous complaint filed against Elite Med, LLC. by traveling to the address provided by the complainant. The address was the residence of

Defendant Brian Bailey. Once DSHS was at that location, a phone call was made to Brian Bailey. Brian Bailey told the DSHS inspector that he was at his personal residence and requested that the meeting occur the next day at the location of the business on Hunter Road. DSHS requested that Brian Bailey bring receipts and distribution records for any drugs or devices that are distributed by Elite Med, LLC.

26. On April 15, 2009, the DSHS inspector went to the business address of Elite Med, LLC. The location was a small house that Brian Bailey owns and rents to tourists in the area. There were no records or inventory at this location. Brian Bailey brought incorporation documents, tax records and two sets of distribution records. He also provided a physician order form and an Elite Med, LLC. invoice. Brian Bailey stated that he had been told by the FDA that his business was legal as long as he registers as an importer with the FDA. Brian Bailey alleged to have completed the FDA paperwork as an importer. Once purchased from the Canadian supplier, M.T.E., Bailey sells the products to physicians and/or clinics in the United States, including Bexar County, Texas. At the conclusion of this meeting, the inspector requested that Brian Bailey provide more than the two sets of documents that were initially provided in order to fully investigate the complaint that was filed against him. DSHS requested that Brian Bailey provide all receiving and distributing records for the devices for the preceding six months, which would consist of documents from October 2008 through April 2009.

27. On April, 16, 2009, a representative from DSHS met with an FDA import specialist to determine whether or not there were any entries made under the names Elite Med, LLC. or M.T.E. Diagnostics. A consumer safety officer with the FDA was unable to find any entries under either business name in the preceding 12 months. On this date, DSHS also contacted the manufacturer of Orthovisc, which is one of the devices distributed by Elite Med, LLC. DSHS provided the

manufacturer with the lot numbers obtained from the invoices provided to DSHS by Brian Bailey. On a later date, the manufacturer confirmed that those particular lot numbers provided by Elite Med, LLC. had all been shipped to Turkey and would have indications for use that have not been approved for distribution in the United States.

28. On April 17, 2009, the DSHS inspector again met with Brian Bailey and Brian Bailey provided copies of commercial invoices from M.T.E. Diagnostics that were issued in 2008. The invoices reflected that Elite Med, LLC. distributes Orthovisc syringes, Hyalgan kits, and Synvisc. Brian Bailey informed DSHS that Elite Med, LLC. had become a division of M.T.E. Diagnostics since Brian Bailey and Razmik Margoosian, head of M.T.E. Diagnostics had been vendor partners for many years. Elite Med, LLC is listed as a division of M.T.E. Diagnostics on invoices used by Elite Med, LLC. At the conclusion of this meeting, an E-14 was issued to Brian Bailey and Elite Med, LLC. (*See Exhibit 2, attached hereto and incorporated herein*). An E-14 is a list of objectionable conditions issued by the DSHS inspector. This E-14 contained the conditions that Elite Med, LLC. could not provide evidence that its products imported were approved for importation or were declared with United States Customs Service upon entry into the United States. Additionally, Elite Med, LLC. could not provide labeling examples of the products that they distributed. Elite Med, LLC. has not established, maintained, or implemented Medical Device Reporting ("MDR") procedures. Their distribution records failed to show addresses of customers and they are not licensed as a device distributor in Texas. DSHS requested that Brian Bailey provide the last ten transactions that Elite Med, L.L.C has engaged in. To this date, this documentation has never been provided to DSHS.

29. On April 29, 2009, the DSHS inspector again met with Brian Bailey. Bailey stated that he was no longer going to provide billing services for M.T.E. Diagnostics and that he was basically

out of business. At the conclusion of this meeting, Brian Bailey was issued another E-14. (*See Exhibit 3, attached hereto and incorporated herein*). DSHS noted that Elite Med, LLC. provided no evidence that the Class III devices [Hyalgan, Synvisc, and Orthovisc] imported and distributed by Elite Med, LLC. are approved for labeled intended uses of the products and are properly labeled for distribution in the United States. Also, in the course of the investigation, it was discovered that products distributed by Elite Med, LLC. were labeled in and have labeling in a language other than English. Other products distributed by Elite Med, LLC. were for export only and had been shipped by the manufacturer to Turkey. Also, the products shipped to Turkey were labeled with indications for use that were not yet approved by the FDA.

30. Based on observation, interview and records review, DSHS made the determination that Brian Bailey and Elite Med, LLC had purchased Orthovisc, Synvisc and Hyalgan from MTE Diagnostics in Canada for distribution to doctors in Texas.

31. Based on observation, interview and records review, DSHS made the determination that Brian Bailey and Elite Med, LLC were located in Texas and were not licensed as device distributors with DSHS at the time Brian Bailey and Elite Med, LLC. purchased and distributed the devices.

32. Based on observation, interview and records review, DSHS made the determination that Brian Bailey and Elite Med, LLC have distributed devices labeled for use in the treatment of temporomandibular joint dysfunction, a use not approved by the U.S. Food and Drug Administration (FDA).

33. Based on observation, interview and records review, DSHS determined that Brian Bailey and Elite Med, LLC distributed prescription devices to doctors in Texas that were labeled for use in foreign countries in foreign languages and not for distribution in the United States.

34. Based on observation, interview and records review, DSHS made the determination that Brian Bailey and Elite Med, LLC had distributed to doctors in Texas prescription devices that were misbranded because the devices had false or misleading labeling and/or lacked labeling as required by federal and state law, including adequate directions for use, labeling in English, and after FDA approval the federal caution statement, the FDA-approved product description, indications for use, contraindications, warnings, precautions and patient disclosure information.

35. Based on observation, interview and records review, DSHS made the determination that Brian Bailey and Elite Med, LLC failed to develop, maintain and implement written Medical Device Reporting (MDR) procedures.

36. Based on observation, interview and records review, DSHS made the determination that Brian Bailey and Elite Med, LLC violated Section 431.021 of the Texas Food, Drug and Cosmetic Act by receiving, introducing, or delivering for introduction into commerce a misbranded device, by failing to develop, maintain and implement written MDR procedures, and by failing to license as a device distributor.

37. During the course of their investigation, DSHS discovered that Brian Bailey stopped using the name Elite Med LLC and had begun to distribute similar prescription devices that were misbranded under the name of the entity S & B Marketing, Inc. *See Exhibit 4, attached and incorporated herein).*

38. Based on observation, interview and records review, DSHS made the determination that Brian Bailey and S & B Marketing, Inc. were located in Texas and distributed devices to doctors throughout the State of Texas, and that these devices were prescription devices.

39. Based on observation, interview and records review, DSHS made the determination that Brian Bailey and S & B Marketing, Inc. were not licensed as device distributors with DSHS, as required, at the times these products were distributed.

40. Based on observation, interview and records review, DSHS made the determination that Brian Bailey and S & B Marketing, Inc. had distributed to doctors in Texas prescription devices that were misbranded because the devices had false or misleading labeling and/or lacked labeling as required by federal and state law, including adequate directions for use, labeling in English, and after FDA approval the federal caution statement, the FDA-approved product description, indications for use, contraindications, warnings, precautions and patient disclosure information.

41. Based on observation, interview and records review, DSHS made the determination that Brian Bailey and S & B Marketing, Inc. had violated Section 431.021 of the Texas Food, Drug and Cosmetic Act by receiving, introducing, or delivering for the introduction into commerce a misbranded device and by failing to license as a device distributor.

42. Based on observation, interview and records review, DSHS made the determination that Defendants had distributed in Texas a total of 1,291 Orthovisc devices, 1,418 Synvisc devices, 585 Hyalgan devices and 15 Euflexxa devices, all of which were misbranded as discussed above.

APPLICABLE LAWS

TEXAS FOOD, DRUG AND COSMETIC ACT

43. Chapter 431 of the Texas Health & Safety Code authorizes DSHS to regulate and enforce this Act that regulates foods, drugs, and devices and to adopt rules for the efficient enforcement of this chapter. TEX. HEALTH & SAFETY CODE ANN. § 431.241. Those rules are found in 25 TEX. ADMIN. CODE, CHAPTER 229. Additionally, 25 TAC 229.432(a) adopts by reference federal laws and

regulations including (1) the Federal Food, Drug and Cosmetic Act and (2) 21 CFR, Part 801, Labeling, as amended, which governs prescription devices.

44. Section 431.046 of the Texas Health & Safety Code provides that a violation of a rule adopted under this chapter is a violation of this chapter.

45. To enforce these rules and Chapter 431 of the Texas Health & Safety Code, the DSHS Commissioner or authorized agents may inspect the establishment facilities, inspect all product and equipment, obtain necessary samples, and have access to and copy and verify the records required to be maintained. None of the Defendant entities or individuals are licensed to distribute devices in Texas as required by law pursuant to § 431.042 of the Texas Health & Safety Code.

46. Section 431.0585 of the Texas Health & Safety Code provides that a person who violates Section 431.021 is liable for a civil penalty not to exceed \$25,000 a day for each violation. The statute also provides that each day of violation constitutes a separate violation for purposes of penalty assessment.

47. Section 431.047 of the Texas Health & Safety Code provides that where a person has violated, is violating, or is threatening to violate the Chapter or rules adopted thereunder, the Court, upon petition, may grant any injunctive relief warranted by the facts.

48. Section 431.272 (a) of the Texas Health & Safety Code provides that a person may not operate as a distributor or manufacturer of devices in this state unless the person has a license from the commissioner for each place of business; and (b) a distributor or manufacturer of devices in this state must comply with the minimum requirements specified in the federal Act and in this chapter.

49. Section 431.112 of the Texas Health & Safety Code declares, in relevant part, a “drug or device shall be deemed to be misbranded (a) if its labeling is false or misleading in any particular; or (c) if any word, statement, or other information required by or under authority of this chapter

to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; or (e) unless its labeling bears adequate directions for use.

50. Pursuant to § 431.112 (a) of the Texas Health & Safety Code, a device is misbranded if the device has false or misleading labeling and § 431.003 of the Texas Health & Safety Code explains that when determining if labeling is misleading, not only representations made or suggested by statement or word are taken into account, but also the extent to which the labeling fails to reveal material facts to the consumer.

51. Pursuant to § 431.112 (c) of the Texas Health & Safety Code a device is misbranded if it lacked labeling as required by federal and state law, including adequate directions for use, labeling in English, and after FDA approval, the federal caution statement, the FDA-approved product description, indications for use, contraindications, warnings, precautions and patient disclosure information.

52. All devices must have adequate directions for use by a layperson, as required by 21 CFR § 801.5, or comply with one of the exemptions to this requirement in 21 C.F.R. § 801.109(a)(1)(i) the device must be in the possession of a person or his agents or employees regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device or (ii) in the possession of a practitioner, such as physicians, licensed by law to use or order the use of such device and as adopted by the rules in Texas.

53. The exemption to adequate directions for use for a prescription device expires at the beginning of its shipment or delivery to persons in whose possession the prescription device is not exempt under 21 C.F.R. § 801.109(a)(1)(i) pursuant to 21 C.F.R. § 801.127(a). The causing of such

an exemption to expire results in the misbranding of the device under § 431.112(e) of the Texas Health & Safety Code and such misbranding cannot be cured and must result in disposing of the device in such a way that it ceases to be a device.

54. Section 431.021 of the Texas Health and Safety Code declares unlawful and sets forth, in relevant part, as prohibited acts, the following:

(a) the introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic that is adulterated or misbranded;..... or (c) the receipt in commerce of any food, drug, device, or cosmetic in commerce that is adulterated or misbranded; (t)(1) failing to comply with medical device reporting requirements for initial distributor facilities as contained in 21 CFR 803; or (x) engaging in the wholesale distribution of drugs or operating as a distributor or manufacturer of devices in this state without obtaining a license issued by the Department.

TEXAS FOOD, DRUG, AND COSMETIC ACT VIOLATIONS

55. Defendants, as set out in paragraphs 1 through 54 and incorporated herein by reference, have committed or caused to be committed the following acts prohibited and declared to be unlawful by § 431.021 of the Texas Food Drug and Cosmetics Act (TFDCA):

- a. Introducing and delivering into commerce a misbranded device in violation of § 431.021(a);
- b. Receiving into commerce a device that was misbranded and the delivering of that misbranded device for pay or otherwise in violation of § 431.021(c);
- c. Operating as a distributor of devices in the State of Texas without being licensed with the Texas Department of State Health Services as required by TEX. HEALTH & SAFETY CODE § 431.272 in violation of § 431.021(x); and

- d. Failing to develop, maintain, and implement written procedures to comply with medical device reporting (MDR) requirements in 21 CFR Part 803 and Section 519 of the federal Act, in violation of § 431.021(t)(1)(B).

TEXAS DECEPTIVE TRADE PRACTICES ACT

56. The Deceptive Trade Practices Act provides that false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are unlawful and subject to action by the Consumer Protection Division of the Office of the Attorney General. TEX. BUS. & COM. CODE ANN. § 17.46 (b) including:

- a. Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services in violation of § 17.46 (b) (2);
- b. Causing confusion or misunderstanding as to affiliation, connection, or association with, or certification by, another in violation of § 17.46 (b) (3);
- c. Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have or that a person has a sponsorship, approval, status, affiliation, or connection which they not have or that a person has a sponsorship, approval, status, affiliation, or connection which he does not, in violation of § 17.46 (b) (5); and
- d. Representing good or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another, in violation of § 17.46 (7).

57. The Deceptive Trade Practices Act further provides that in addition to a request for injunctive relief, the Consumer Protection Division may request civil penalties be paid to the State in an amount of not more than \$20,000 per violation. TEX. BUS. & COM. CODE ANN. 17.47 (c).

DECEPTIVE TRADE PRACTICES ACT VIOLATIONS

58. As set out in paragraphs 1 through 57 and incorporated herein by reference, Defendants, in the course and conduct of trade and commerce, have directly and indirectly engaged in false, misleading, deceptive and unconscionable acts and practices declared unlawful by § 17.46 (a) and (b) of the Texas Deceptive Trade Practices Act, including but not limited to:

- (b)(2) causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
- (b)(3) causing confusion or misunderstanding as to affiliation, connection, or association with, or certification by another;
- (b)(5) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have; and
- (b)(7) representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another.

**APPLICATION FOR EX PARTE TEMPORARY RESTRAINING ORDER,
TEMPORARY INJUNCTION, AND PERMANENT INJUNCTION**

59. The State alleges that by reason of the foregoing, Defendants should not continue to receive, introduce or deliver into commerce misbranded devices. Because Defendants have engaged in the unlawful acts and practices described above, Defendants have violated and will continue to violate the laws as alleged in this Petition. Unless immediately restrained by this Honorable Court, the Defendants will continue to violate the laws of the State of Texas and cause immediate, irreparable injury, loss and damage to the State of Texas and to the general public. The interests of the State of Texas and the public require immediate action to keep Defendants from illegally distributing misbranded medical devices. Therefore, the State requests an Ex Parte Temporary Restraining Order, Temporary Injunction, and Permanent Injunction, as indicated below.

**REQUEST TO CONDUCT DISCOVERY PRIOR TO TEMPORARY INJUNCTION
HEARING**

60. The State requests leave of this Court to conduct telephone, oral, written, and other depositions of witnesses, including Defendants or employees of Defendants, prior to any scheduled Temporary Injunction Hearing and prior to Defendants' answer date. There could be a number of witnesses who may need to be deposed prior to any scheduled Temporary Injunction hearing. Any depositions, telephonic or otherwise, would be conducted with reasonable shortened notice to the Defendants and their attorneys, if known.

PRAYER

61. Defendants have engaged in the unlawful acts and practices described above, and Defendants have violated and will continue to violate the law as alleged in this Petition. Unless immediately restrained by this Court, Defendants will continue to violate the law and cause immediate, irreparable injury, loss and damage to the State of Texas and to the general public.

62. WHEREFORE, PREMISES CONSIDERED, the STATE OF TEXAS prays that Defendants Elite Med, LLC., S & B Marketing, Inc., and Brian Bailey, individually, be cited according to law and appear and answer herein; that a TEMPORARY RESTRAINING ORDER be issued; that after due notice and hearing a TEMPORARY INJUNCTION be issued; and upon final hearing a PERMANENT INJUNCTION be issued restraining and enjoining Defendants, individually, their successors, assigns, agents, servants, employees, and any other person in active concert or participation with Defendants from engaging in the following acts or practices:

- A. Transferring, concealing, destroying or removing from the jurisdiction of this Court any books, records, documents, invoices, or other written materials relating to these allegations which are in Defendants' possession, custody, or control except in response to further orders or subpoenas in this cause;

- B. Operating as a distributor of devices in the State of Texas without being licensed with the Texas Department of State Health Services;
- C. Purchasing devices from an unlicensed source or source that is not regularly and lawfully engaged in the distribution of devices in the United States or Texas;
- D. Introducing and delivering into commerce a misbranded device that has false or misleading labeling or advertising;
- E. Receiving into commerce a device that was misbranded and the delivering of that misbranded device for pay or otherwise;
- F. Failing to develop, maintain, and implement written procedures to comply with medical device reporting (MDR) requirements in 21 CFR Part 803 and Section 519 of the federal Act;
- G. Refusing inspection at any time by officials of the Texas Department of State Health Services or failing to produce all distribution records for devices;
- H. Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods by distributing unapproved and/or misbranded devices to doctors or medical practices;
- I. Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods by distributing devices that are not labeled in English and that fail to have the required labeling in English to doctors or medical practices;
- J. Representing that goods have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have by distributing devices that are not legal to distribute in the United States to doctors or medical practices;

- K. Representing that goods or services are of a particular standard, quality, or grade if they are of another standard, quality, or grade by distributing devices to doctors or medical practices that are manufactured for import only;
- L. Representing that a person or entity has a sponsorship, approval, status, affiliation, or connection to which the person or entity does not have by representing that the person or entity is licensed by the State of Texas and/or the Texas Department of State Health Services; and
- M. Failing to provide written notice to any agent, servant, employee or representative of the Defendants of the existence and terms of any injunction entered in this case, and of their duty to comply with the terms set for herein.

63. In addition, Plaintiff State of Texas respectfully prays that this Court will:

- A. Order Defendants to pay civil penalties to the State of Texas up to \$25,000.00 per violation per day for each violation of § 431.021 of the TFDCA, as provided in § 431.0585(b) of the TFDCA.
- B. Order Defendants to pay to the State of Texas and to DSHS their reasonable expenses incurred in obtaining injunctive relief, including investigative costs, court costs, and reasonable attorneys' fees pursuant to § 431.047(d) of the TFDCA and/or investigative costs, court costs, reasonable attorneys' fees, expenses, and witness fees pursuant to the laws of the State of Texas including the TEX. GOV'T CODE ANN. §402.006(c).
- C. Order Defendants to pay civil penalties of not more than \$20,000.00 per violation, as provided in § 17.47(c)(1) of the DTPA.

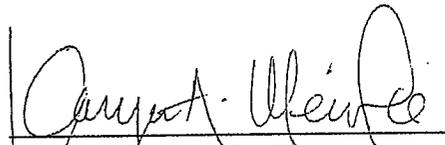
- D. Set this matter for trial and upon final hearing issue a permanent injunction against Defendants.
- E. Grant all other relief to which the State of Texas may be justly entitled.

Respectfully submitted,

GREG ABBOTT
Attorney General of Texas

DANIEL T. HODGE
First Assistant Attorney General

BILL COBB
Deputy Attorney General for Civil Litigation



KARYN A. MEINKE
State Bar No. 24032859

JAMES E. CUSTER
State Bar No. 24004605

Assistant Attorneys General
Consumer Protection and Public Health Division
115 E. Travis, Ste. 925
San Antonio, Texas 78205-1615
Telephone 210-225-4191
Facsimile 210-225-1075

ATTORNEYS FOR PLAINTIFF

EXHIBIT 1

 Food and Drug Groups COMPLAINT AND INJURY REPORT		COMPLAINT NUMBER: 116476 COMPLAINT DATE: 01/27/2009	
COMPLAINT INFORMATION	FORM OF COMPLAINT: LETTER	CFN: 0109322	SOURCE OF COMPLAINT: TRADE SOURCE
COMPLAINANT AND INJURED INFORMATION	INJURED PARTY:		COMPLAINANT: ANONYMOUS
	H:	W:	H: W:
	AGE:	SEX:	REGION: B COUNTY: COMAL
INJURY OR ILLNESS RESULTED	TYPE SYMPTOMS:		
	ATTENDING PHYSICIAN:		HOSPITAL:
PRODUCT AND LABELING	PRODUCTS: UNAPPROVED PRODUCT		
	PRODUCT CODE:		PKG CODE:
	PKG CODE/ SERIAL #:		EXP DATE:
	DATE USED:		DATE PURCHASED:
	AMT REMAINING:		SAMPLE #:
	MANUFACTURER:		DISTRIBUTOR: ELITE MEDICAL 9600 FM 306 NEW BRAUNFELS TX 78132 (830) 832-7595
COMPLAINT OR INJURY	NATURE OF COMPLAINT: DISTRESSED PRODUCT DESCRIPTION OF COMPLAINT/INJURY *** See attached sheet *** VALID:		
NAME	JEFF MANSELL		
TITLE	ES IV		
EVALUATION AND DISPOSITION	GROUP: DRUGS & DEVICES		
	STATUS: OPEN-ASSIGNED		

9. COMPLAINT OR INJURY (CONT.)

THE COMPLAINT WAS FORWARDED TO DSHS BY LETTER WITHOUT RETURN ADDRESS AND INDICATED THE FIRM IS IMPORTING PRODUCTS (LETTER APPEARS TO INDICATE PRODUCT IS AN INJECTION TO TREAT ARTHRITIS) THAT ARE NOT APPROVED FOR USE IN THE U.S. AND NOT LICENSED TO WHOLESALE IN TEXAS.

SEE ATTACHED LETTER SUBMITTED TO DSHS.

INVESTIGATIONS:

INVESTIGATED BY:

DATE INVEST:

INJURY CLASS: 0

REVIEWER:

DATE:

REFERRED TO: DRUG & DEVICE INSP GROUP

DATE: 02/03/2009

FOLLOW-UP: No

NOTICE GIVEN: No

DAYS

DISPOSITION:

JAN 27 2009

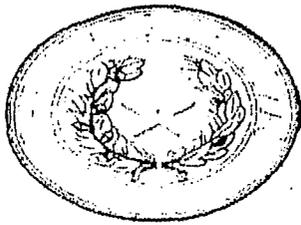
RLU, Food and Drug Licensing Group MC 2835
Texas Department of State Health Services
P. O. Box 149347
Austin, Texas 78714-9347

I am a rep for a major company that sells arthritis injections approved by the FDA.

It has come to my attention that a Bryan Bailey of Elite Medical 9600 FM 306 New Braunfels (830-832-7595) is importing non-approved products into the US.

These products are imported and wholesaled by Elite Medical but I cannot find any listing on your web site for the company. They might not be registered as a Texas wholesaler.

EXHIBIT 2



DEPARTMENT OF STATE HEALTH
SERVICES
1100 West 49th Street
Austin, Texas 78756

No. 08-298

Date 4/17/09

Firm Name Elite Med, LLC Classification Importer
Person Contacted Brian Bailey Title President
City New Braunfels Address 1742 Hunter Road

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE. YOUR ATTENTION IS DIRECTED TO THE CONDITIONS OBSERVED AND NOTED BELOW:

Observation 1

Your firm imports medical devices and could not provide documented evidence of the following:

- a) 510(k) approval or Premarket approval for devices imported;
- b) Documentation that imported devices were declared and authorized by U.S. Customs Service and the Food and Drug Administration;
- c) Copies of labels of imported devices.

Observation 2

Your firm has not developed, maintained, and implemented written Medical Device Reporting (MDR) procedures and has not established a MDR event file.

Observation 3

Distribution records do not show the address of customers. In addition, credential documentation is not maintained as evidence that customers are authorized to possess prescription medical devices.

Observation 4

Firm was unable to present evidence of a current medical device distributor license (start date: 2/15/2006; GAS: \$2,000,000.00). Firm is engaging in the following activity: Elite Med, LLC is registered with the Food and Drug Administration as an Initial Distributor/Importer of medical devices. The firm distributes devices such as

B. Bailey 4/29/09
Signature of Firm Representative

Owner
Title

[Signature]
State Food and Drug Inspector
ROJ WATERS
Sample No. N/A
(If collected)



DEPARTMENT OF STATE HEALTH
 SERVICES
 1100 West 49th Street
 Austin, Texas 78756

No. 08-298

Date 4/17/09

Firm Name Elite Med, LLC Classification Importer
 Person Contacted Brian Bailey Title President
 City New Braunfels Address 1742 Hunter Road

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE. YOUR ATTENTION IS DIRECTED TO THE CONDITIONS OBSERVED AND NOTED BELOW:

Orthovisc and Synvisc, which are Class III medical devices through drop shipment from Canada to customers in the United States. Contact (512) 834-6727 or go to <http://www.dshs.state.tx.us/fdllicense>.

CORRECTION OF ITEMS 1-4 PROMISED
 BY 5/17/09

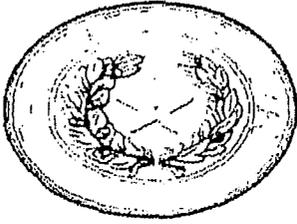
B. C. Bailey
 Signature of Firm Representative

[Signature]
 State Food and Drug Inspector
 POW WATERS

Sample No. n/a
 (If collected)

Title

EXHIBIT 3



DEPARTMENT OF STATE HEALTH
 SERVICES
 1100 West 49th Street
 Austin, Texas 78756

No. 08-298

Date 4/29/09

Firm Name Elite Med, LLC Classification Importer
 Person Contacted Brian Bailey Title President
 City New Braunfels Address 1742 Hunter Road

AN INSPECTION OF YOUR ESTABLISHMENT HAS BEEN MADE. YOUR ATTENTION IS DIRECTED TO THE CONDITIONS OBSERVED AND NOTED BELOW:

Observation 1

No evidence was provided to show that Class III medical devices imported and distributed by your firm are approved for labeled intended uses of the products and are properly labeled for distribution in the United States. In addition, a review of documentation provided by your firm, interviews with customers of your firm, and telephone/Email communications with manufacturers of products distributed by your firm revealed the following:

- a) Packages of Hyalgan, Lot 114800, a product distributed by your firm, was observed during an inspection at a medical clinic, which purchases products from your firm, and the product was found to be labeled, and have labeling, not in English.
- b) Your firm has distributed Orthovisc from several lots including products from Lots N080080B, N080082A, and N080081A. The manufacturer of this product was contacted asked about these three specific lots. The manufacturer verified that these lots were manufactured for Export Only and were shipped to Turkey. The manufacturer stated that the products were labeled with indications for use that were not yet approved by the United States Food and Drug Administration.

B. E. Bailey 4/29/09
 Signature of Firm Representative

D. W. R.
 Title

State Food and Drug Inspector
 Ronald J. Waters

Sample No. N/A
 (If collected)

EXHIBIT 4

STATE OF TEXAS
TRAVIS COUNTY

§
§
§

AFFIDAVIT OF THOMAS BRINCK

Before me, the undersigned notary, on this day personally appeared THOMAS BRINCK, the affiant, a person whose identity is known to me. After I administered an oath to affiant, affiant testified:

“My name is Thomas Brinck. I am over the age of eighteen years, of sound mind, and capable of making this affidavit. The facts stated in this affidavit are within my personal knowledge and are true and correct.

I am employed by the Texas Department of State Health Services (“TDSHS”) as Manager of the Drugs and Medical Devices Group in the Policy, Standards and Quality Assurance Unit. I have been employed in this position since 2004. I have been employed with the Drugs and Medical Devices Group since 1994. I was employed with the Division of Food and Drugs from 1984 to 1994.

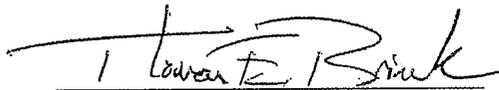
As Manager of the Drugs and Medical Devices Group, I am involved in the development of policies, procedures and quality assurance functions relating to drug, medical device and cosmetic regulatory programs. I have thorough knowledge of the state and federal laws and related rules pertaining to the manufacture, distribution, salvaging and labeling of drugs, medical devices and cosmetics.

As part of my duties, I am familiar with the investigation involving Brian Bailey and Elite Med, L.L.C. in New Braunfels. I reviewed the inspection reports of this individual and business, including the medical devices that were sampled as a result of the investigation. Based on my review and knowledge of the Texas Food, Drug, and Cosmetic Act (“TFDCA”), I determined that Elite Med, L.L.C. has violated the Texas Food, Drug and Cosmetic Act (“TFDCA”) by:

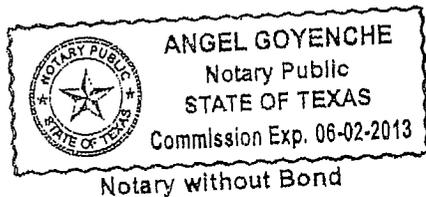
- A. Not being licensed as a device distributor with TDSHS at the time Elite purchased

and distributed prescription medical devices;

- B. Distributing prescription medical devices for use in the treatment of temporomandibular joint dysfunction, a use not approved by the U.S. Food and Drug Administration (FDA);
- C. Distributing prescription medical devices to doctors in Texas which lacked complete English labeling, including adequate directions for use;
- D. Failing to develop, maintain and implement written Medical Device Reporting Requirements;
- E. Receiving, introducing, or delivering for introduction into commerce a misbranded prescription medical device;
- F. Distributing prescription medical devices to doctors in Texas that were labeled for use in foreign countries and not for distribution in the United States;


THOMAS BRINCK

SUBSCRIBED AND SWORN TO BEFORE ME, the undersigned authority, by Thomas Brinck on this 28th day of December 2010.




Notary Public