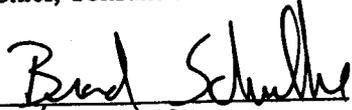




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Attorneys for Respondents



- markets and sells CCTMs through its company-owned stores and independent retail distributors (“IRDs”);

- provides CCTMs as inventory for its company-owned stores and IRDs; and
- provides promotional information, including brochures and flyers, to its company-owned stores and IRDs to facilitate the sale of CCTMs.

1.3. At present, CERAGEM conducts business in Texas, and markets and sells CCTMs, through company-owned stores in North Dallas (“CERAGEM DALLAS NORTH”), South Dallas (“CERAGEM DALLAS SOUTH”), Garland (“CERAGEM GARLAND”), Pasadena (“CERAGEM PASADENA”) and San Antonio (“CERAGEM SAN ANTONIO”).

1.4. At present, the following IRDs market and sell CCTMs in Texas:

- CHARLES KIM d/b/a CERAGEM HOUSTON GESSNER,
- J&P COMPANY d/b/a CERAGEM HOUSTON LITTLE YORK,
- CAPITAL LOGISTICS MEDICAL L.P. d/b/a CERAGEM LEWISVILLE,
- PLATAWN INC. d/b/a CERAGEM EL PASO and EL PASO WEST,
- DELMO CASAREZ and DIANA CASAREZ d/b/a CERAGEM CORPUS CHRISTI, and
- GOOD FAITH HEALTH CARE INC. d/b/a CERAGEM MCALLEN.

1.5 The CCTM has been cleared for marketing as an over-the-counter, non-prescription, class II medical device identified by the United States Food and Drug Administration (“USFDA”) as “a multi-function physical therapy table ... intended for medical purposes that consists of a motorized table equipped to provide patients with heat, traction, and muscle relaxation therapy” as set out in 21 CFR 890.5880 (2004).

1.6 The USFDA issued a Substantial Equivalence letter dated July 28, 2004,

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<sup>1</sup> The use by Ceragem of the term “retail distributor” is not intended to satisfy the definition of “distributor” found at TEX. HEALTH & SAFETY CODE § 431.271(1).  
ASSURANCE OF VOLUNTARY COMPLIANCE  
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identified as 510(k) Number K040031 (hereinafter the "SE510(k) letter"), setting forth the following indications for use of the CCTM for which it is authorized for sale in the United States:

The intended use of the CERAGEM-C Thermal Massager is to provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the CERAGEM-C Thermal Massager provides radiant infrared heat for:

- > temporary relief of minor muscle and joint pain, and stiffness
- > temporary relief of minor joint pain associated with arthritis
- > temporary increase in local circulation where applied, and
- > relaxation of muscles.

1.7 CERAGEM began marketing the CCTM several months before the SE510(k) letter was issued by the USFDA.

## II. Allegations by the State

2.1. The STATE OF TEXAS, the TEXAS DEPARTMENT OF STATE HEALTH SERVICES, and DR. EDUARDO J. SANCHEZ, COMMISSIONER, allege that, in Texas, CERAGEM (including CERAGEM company-owned stores in Pasadena and San Antonio) and IRDs, including Charles Kim, many of which market substantially in the Spanish language and directly effect the Spanish-speaking population of Texas, have violated the Texas Food, Drug and Cosmetic Act ("TFDCA"), found at Texas Health and Safety Code §§ 431 *et seq.*, and have engaged in false, deceptive and misleading acts and practices in the course of trade and commerce in the State of Texas as defined in, and declared unlawful by, the Texas Deceptive Trade Practices-Consumer Protection Act ("DTPA") at §§ 17.41 *et seq.* by making misrepresentations, either directly or indirectly, to the public of the State of Texas in violation of § 17.46 of the DTPA concerning the CCTM's ability to treat, cure, and mitigate a wide range of

diseases, as well as the labeling and promotion of the CCTM as a "Thermal Acupressure Massager," causing the CCTM to become, at law, a class III unapproved medical device.

2.2. In July and September, 2004, investigators from the Office of the Attorney General of the State of Texas visited four different stores, three of which market substantially in the Spanish language. Investigators at all four stores observed spokespersons overstating the intended and cleared use of the CCTM, representing to prospective customers that the CCTM would not only alleviate pain, but would also cure certain medical conditions and diseases. The Office of the Attorney General of the State of Texas recently became aware of a complaint filed with the USFDA by a patron of a fifth store alleging that brochures being used by the store advertise the CCTM as a "cure all." Such statements and representations are outside the scope of the intended usage cleared by the USFDA and recognized in the labeling.

2.3. With respect to the marketing, advertising and promotion of the CCTM, the STATE OF TEXAS, the TEXAS DEPARTMENT OF STATE HEALTH SERVICES, and DR. EDUARDO J. SANCHEZ, COMMISSIONER, specifically allege that:

A) despite the fine print disclaimer on the brochures that the product is not intended to diagnose, cure, or prevent any disease, certain spokespersons misrepresented the therapeutic value of the therapy from the devices by stating that the CCTM will help cure, prevent, or mitigate a long list of diseases and physical conditions. Such representations would indicate an intended usage which is beyond the scope of the usage cleared by the USFDA;

B) because the CCTM has been advertised under the label "Ceragem Thermal Acupressure Massager" rather than its cleared name of "Ceragem-C Thermal Massager," CERAGEM and the IRDs implied that the CCTM makes use of acupressure medical procedures for which further approvals or clearances are

necessary but which have not been obtained; and

C) because of the reputedly large number of consumers who use the CCTM on any given day, there may exist the possibility of spreading communicable diseases such as skin infections caused by Community Associated Methicillin Resistant Staphylococcus Aureus (CA-MRSA), of which CERAGEM and the IRDs have not adopted appropriate sanitary procedures.

### III. Denials of CERAGEM and the IRDs

3.1. CERAGEM and the IRDs (a) deny that any state or federal statutes or regulations have been violated, (b) deny that any injury or harm has occurred, (c) believe that the State's allegations, even if true, are generally not representative of the marketing, advertising, promotion and sales activities of CERAGEM and the IRDs, and (d) believe that any perceived violations of state or federal statutes or regulations were aberrational and not intentional, and have nevertheless been cured.

### IV. Assurances

4.1. For the purpose of resolving all issues and controversies between them with respect to the marketing, advertising, promotion and sale of CERAGEM products including the CCTM in Texas, CERAGEM and Charles Kim hereby agree and voluntarily assure the STATE OF TEXAS, the TEXAS DEPARTMENT OF STATE HEALTH SERVICES and DR. EDUARDO J. SANCHEZ, COMMISSIONER, acting by and through the ATTORNEY GENERAL of the STATE of TEXAS, that effective with the date of signing hereof, CERAGEM and the IRDs, including Charles Kim, and their officers, directors, employees, agents and representatives:

A) will not market, advertise, promote, represent or claim that the CCTM can provide anything more than radiant infrared heat and massage therapy for the temporary relief of

minor muscle and joint pain, stiffness; the temporary relief of minor joint pain associated with arthritis, the temporary increase in local blood circulation where applied, and the relaxation of muscles, unless otherwise approved, cleared, precleared, or exempted by the USFDA;

B) will not market, advertise, promote, represent or claim that any of CERAGEM's products, including but not limited to the CCTM, can cure, treat, or mitigate any disease or physical condition other than those approved, cleared, precleared, or exempted by the USFDA;

C) will not use the word "Acupressure" or "Acupuncture" in naming, identifying, labeling (as defined in Attachment A herein), or advertising the CCTM;

D) will employ sanitary practices designed to reduce the potential for the transmission of disease in accordance with practices enumerated in the "Guidelines for the Reduction of the Spread of Staphylococcal Infections in Health and Fitness Centers," published by the San Antonio Metro Health Department;

E) will prominently display signs in both English and Spanish at Texas-based CERAGEM and IRD locations at the entrance and in both the presentation areas and the demonstration areas indicating: (1) the cleared usage of the CCTM as per the SE510(k) letter, as may be subsequently amended, (2) the cleared name of the CCTM as per the SE510(k) letter, as may be subsequently amended, and (3) that the CCTM is not intended to cure, treat, mitigate, or diagnose any physical disease or condition other than those diseases or conditions indicated in the SE510(k) letter, as may be subsequently amended;

F) will not sell, offer for sale, promote, advertise, distribute into trade and commerce, or deliver for distribution into trade and commerce, any device which requires pre-market approval or clearance from the USFDA and which has not been approved or cleared pursuant to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §301 et. seq.;

G) will not represent, directly or by implication, that goods or services have

sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities which they do not have, and will not represent in any way that the CCTM has premarket approval, clearance, or preclearance from the USFDA or any other federal or state agency, for any use which has not been actually approved, cleared, or precleared;

H) will not misbrand (as defined in Attachment A herein) the CCTM, or introduce, deliver or distribute misbranded CCTMs into commerce;

I) will not adulterate (as defined in Attachment A herein) the CCTM, or introduce, deliver or distribute adulterated CCTMs into commerce;

J) will implement a plan (as set forth in Attachment B herein) by which CERAGEM will monitor the marketing, advertising and promotional activity of CERAGEM and Texas-based IRDs;

K) will implement a plan (as set forth in Attachment C herein) for the approval of advertising proposed by CERAGEM and Texas-based IRDs;

L) will implement a plan (as set forth in Attachment D herein) in which CERAGEM will conduct training sessions for owners and managers at CERAGEM company-owned and IRD locations in Texas designed to review CERAGEM's monitoring and advertising approval policies;

M) will implement a plan (as set forth in Attachment E herein) in which CERAGEM will provide pro rated restitution to every Texas consumer who indicates that they purchased the CCTM because of their belief, based upon representations made at CERAGEM company-owned stores or IRD stores in Texas, that the CCTM would cure, treat, or mitigate any disease or physical condition not covered within the scope of the 510k letter issued for preclearance of the CCTM;

N) will not represent, directly or by implication, that the ATTORNEY GENERAL of

the STATE OF TEXAS has approved or cleared any good or service sold or offered for sale by CERAGEM through its CERAGEM company-owned stores or IRD stores in Texas, or has approved or cleared any business practice of CERAGEM through its CERAGEM company-owned stores or IRD stores in Texas;

O) will not interfere with, prevent, or in any way obstruct agents of the TEXAS DEPARTMENT OF STATE HEALTH SERVICES (formerly the Texas Department of Health) from reasonably inspecting, copying, or photographing all business records and business premises of CERAGEM company-owned stores or IRD stores in Texas and all devices found therein, pursuant to TEX. HEALTH & SAFETY CODE §431.042, 431.043, and 431.044; said agents to be allowed access to all such records or devices;

P) will provide copies of this AVC to all present and future owners and managers of CERAGEM company-owned stores and IRD stores in Texas, and will require present and future owners and managers of CERAGEM company-owned stores and IRD stores in Texas to comply with the assurances contained within the AVC and to the applicable requirements of Texas law as a condition of continued operation of an authorized Ceragem store; and

Q) will reimburse the State of Texas for attorney fees, expenses and costs of investigation incurred by the STATE OF TEXAS, the TEXAS DEPARTMENT OF STATE HEALTH SERVICES and DR. EDUARDO J. SANCHEZ, COMMISSIONER, acting by and through the ATTORNEY GENERAL of the STATE of TEXAS.

#### V. Conditions

5.1 The acceptance of this Assurance of Voluntary Compliance is conditioned upon the stipulation that CERAGEM reimburse the STATE OF TEXAS in the amount for the attorney fees, expenses and costs of investigation incurred by the STATE OF TEXAS, the TEXAS

DEPARTMENT OF STATE HEALTH SERVICES and DR. EDUARDO J. SANCHEZ, COMMISSIONER, acting by and through the ATTORNEY GENERAL of the STATE of TEXAS, and that a receipt for the payment of attorney fees, expenses and costs of investigation will be signed and acknowledged by the STATE OF TEXAS.

5.2 In order to comply with TEX. BUS. & COM. CODE § 17.58(c), this AVC shall not be considered an admission of prior violation of the DTPA. However, unless this AVC has been rescinded by agreement of the parties or voided by a court for good cause, subsequent failure to comply with the terms of this AVC will constitute prima facie evidence of a violation of the DTPA.

5.3 This AVC in no way affects individual rights or action under the DTPA.

5.4 While the parties to this AVC presently intend to cooperate in securing and obtaining compliance with the terms herein, the matters settled by the filing of this AVC may be reopened at any time by the OFFICE of the ATTORNEY GENERAL of the STATE OF TEXAS for further proceedings in the public interest.

5.5 When signed, this AVC will be filed and placed in the public record with all costs herein assessed against CERAGEM and Charles Kim.

Signed this 22<sup>nd</sup> day of ~~October~~<sup>November</sup>, 2005.

Respectfully submitted,

GREG ABBOTT  
Attorney General of Texas

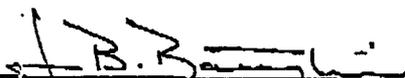
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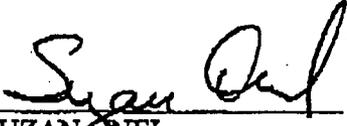
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d/b/a Ceragem San Antonio

By: \_\_\_\_\_  
Kyung Hwan Huh, President

CHARLES KIM  
d/b/a Ceragem Houston Gessner

By: \_\_\_\_\_  
Charles Kim

Having considered the agreement of the parties as shown by the signatures affixed hereto, the court is of the opinion that pursuant to the Texas Deceptive Trade Practices-Consumer Protection Act § 17.58, this Assurance of Voluntary Compliance should be, and the same is hereby, approved.

ENTERED AND FILED OF RECORD

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

\_\_\_\_\_  
Presiding Judge

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 Presiding Judge

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CERAGEM INTL INC  
CERAGEM HOUSTON

PAGE 03  
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Presiding Judge

ASSURANCE OF VOLUNTARY COMPLIANCE  
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PAGE 11

## **Attachment A**

### **Definitions**

In connection with the Assurance of Voluntary Compliance, it is stipulated that the following definitions shall apply:

#### **1. Advertising**

“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.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.002(1).

#### **2. Device**

“Device,” except when used in Sections 431.003, 431.021(l), 431.082(g), 431.112(c) and 431.142(c), means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is:

(A) recognized in the official United States Pharmacopoeia National Formulary or any supplement to it;

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or

(C) intended to affect the structure or any function of the body of man or other animals and that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and is not dependent on metabolization for the achievement of any of its principal intended purposes.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.002(13).

#### **3. Federal Act**

“Federal Act” means the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.002(15).

#### **4. Label**

“Label” means a display of written, printed or graphic matter upon the immediate container of any article, and a requirement made by or under authority of this chapter that any word, statement or other information that appears on the label shall not be considered to be complied with unless the word, statement or other information also appears on the

outside container or wrapper, if any, of the retail package of the article, or is easily legible through the outside container or wrapper.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.002(21).

#### 5. Labeling

“Labeling” means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.002(22).

#### 6. Adulterated Device

A device shall be deemed to be “adulterated” if it is, or purports to be or is represented as, a device that is subject to a performance standard established under Section 514 of the Federal Act, unless the device is in all respects in conformity with the standard.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.111(e).

A device shall be deemed to be “adulterated” if it is a class III device that is required by a regulation adopted under Section 515(b) of the Federal Act to have an approval under that section of an application for premarket approval and that is not exempt from Section 515 as provided by Section 520(g) of the Federal Act, and

for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the United States Food and Drug Administration by the 90th day after the date of adoption of the regulation, or

for which that application was filed and approval was denied or withdrawn, for which that notice was filed and was declared incomplete, or for which approval of the device under the protocol was withdrawn.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.111(f)(1)(A).

A device shall be deemed to be “adulterated” if it is a class III device that was classified under Section 513(f) of the Federal Act into class III, which under Section 515(a) of the Federal Act is required to have in effect an approved application for premarket approval, that is not exempt from Section 515 as provided by Section 520(g) of the Federal Act, and that does not have the application in effect.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.111(f)(1)(B).

A device shall be deemed to be “adulterated” if it is a class III device that was classified under Section 520(l) of the Federal Act into class III, which under that section is required to have in effect an approved application under Section 515 of the Federal Act, and that does not have the application in effect, except that:

in the case of a device classified under Section 513(f) of the Federal Act into class III and intended solely for investigational use, Subdivision (1)(B) does not apply to the device during the period ending on the 90th day after the date of adoption of the regulations prescribing the procedures and conditions required by Section 520(g)(2) of the Federal Act; and

in the case of a device subject to a regulation adopted under Section 515(b) of the Federal Act, Subdivision (1) does not apply to the device during the period ending on whichever of the following dates occurs later:

(i) the last day of the 30-day calendar month beginning after the month in which the classification of the device into class III became effective under Section 513 of the Federal Act; or

(ii) the 90th day after the date of adoption of the regulation.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.111(f)(1)(C).

#### **7. Misbranded Device**

A device shall be deemed to be misbranded if its labeling is false or misleading in any particular, or if its labeling or packaging fails to conform with the requirements of Section 431.181.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.112(a).

A device shall be deemed to be misbranded if in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, provided that under Subdivision (2) reasonable variations shall be permitted, and exemptions as to small packages shall be allowed in accordance with regulations prescribed by the secretary under the Federal Act.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.112(b).

A device shall be deemed to be misbranded 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 (as compared with other words, statements, designs, or devices in the labeling) 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.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.112(c).

A device shall be deemed to be misbranded unless its labeling bears adequate directions for use and such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or durations of administration or application, in such manner and form, as are necessary

for the protection of users unless the drug or device has been exempted from those requirements by the regulations adopted by the secretary.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.112(f).

A device shall be deemed to be misbranded in the case of any restricted device distributed or offered for sale in this state if its advertising is false or misleading in any particular or if it is sold, distributed or used in violation of regulations prescribed under Section 520(e) of the Federal Act.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.112(r).

**8. False Advertisement**

An advertisement of a food, drug, device or cosmetic shall be deemed to be false if it is false or misleading in any particular.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.182(a).

**9. False Advertisement of Drug or Device**

An advertisement of a drug or device is false if the advertisement represents that the drug or device affects:

- (1) infectious and parasitic diseases;
- (2) neoplasms;
- (3) endocrine, nutritional, and metabolic diseases and immunity disorders;
- (4) diseases of blood and blood-forming organs;
- (5) mental disorders;
- (6) diseases of the nervous system and sense organs;
- (7) diseases of the circulatory system;
- (8) diseases of the respiratory system;
- (9) diseases of the digestive system;
- (10) diseases of the genitourinary system;
- (11) complications of pregnancy, childbirth, and the puerperium;
- (12) diseases of the skin and subcutaneous tissue;
- (13) diseases of the musculoskeletal system and connective tissue;
- (14) congenital anomalies;
- (15) certain conditions originating in the perinatal period;
- (16) symptoms, signs, and ill-defined conditions; or
- (17) injury and poisoning.

Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE § 431.183(a).

## Attachment B

### Plan for Monitoring Marketing, Advertising and Promotional Activities in Texas

The following plan has been developed and implemented by Ceragem to monitor the marketing, advertising and promotional activities in Texas of Ceragem products including the Ceragem-C Thermal Massager. It is intended that such plan will assure compliance with Ceragem's policies, with relevant Texas and federal statutes and regulations, and with the Assurance of Voluntary Compliance and all attachments thereto (hereafter "the AVC"). The plan, the terms of which are set forth below, is effective immediately and shall apply to all Ceragem company-owned and Independent Retail Distributor stores in Texas.

1. Marketers, sellers and distributors of Ceragem products shall, in conjunction with the reporting of unit sales, regularly report and represent to Ceragem that products were marketed, advertised, promoted and sold in compliance with Ceragem policies, state and federal law, and the AVC. Failure of Texas-based Independent Retail Distributors to comply with Ceragem policies, relevant Texas and federal statutes and regulations, and with the AVC, in the marketing, advertising, promotion and sale of Ceragem products will constitute sufficient cause to terminate the distributorship and licensing agreement.

2. In supplement to, and in conjunction with, the above self-reporting requirements of Texas-based Independent Retail Distributors, Ceragem shall conduct periodic scheduled and unscheduled on-site visitations (the "Visitations") of Texas-based Independent Retail Distributor locations to monitor for compliance. Ceragem shall prepare, keep and maintain a report of each Visitation, to be called a Visitation Report. The Visitation Report shall include the date, time and location of each visit. Ceragem shall compile and maintain all Visitation Reports.

3. Ceragem shall promptly address and resolve any reports reflecting non-compliance. In this regard, Ceragem shall promptly communicate with the Independent Retail Distributor regarding any alleged violation, shall request immediate compliance, and shall require immediate cessation of non-compliant practices.

4. Non-compliant practices are defined as those which violate (a) state or federal law, (b) Ceragem's policies and procedures, and (c) the terms of the AVC.

5. Should a Texas-based Independent Retail Distributor fail to stop or remedy any non-compliant practice within 15 days, Ceragem shall place such Independent Retail Distributor under suspension, and shall discontinue the shipment of Ceragem products to that distributor. Such distributor shall remain under suspension until appropriate remedial actions have been taken by such distributor to ensure compliance. Should a distributor fail to stop or remedy non-compliant practices within 30 days after notice by Ceragem to the distributor of non-complaint practices, Ceragem shall terminate the distributorship and licensing agreement and shall prohibit the distributor from marketing, advertising, promoting or selling Ceragem products.

6. Should the provisions of this plan conflict with any existing contractual provisions between Ceragem and any Texas-based Independent Retail Distributor, the provisions of this plan will prevail and will serve to alter or amend any existing contractual provisions.

## Attachment C

### Plan for Review and Approval of Proposed Advertising

The following plan has been developed and implemented by Ceragem to review and approve proposed advertising by owners and managers of Ceragem company-owned and Independent Retail Distributor stores in Texas of Ceragem products including the Ceragem-C Thermal Massager. It is intended that such plan will assure compliance with Ceragem's policies, with relevant Texas and federal statutes and regulations, and with the Assurance of Voluntary Compliance and all attachments thereto (hereafter "the AVC"). The plan, the terms of which are set forth below, is effective immediately and shall apply to all Ceragem company-owned and Independent Retail Distributor stores in Texas.

1. Prior to the usage of any advertising or promotional material, Texas-based Independent Retail Distributors of Ceragem products shall submit to Ceragem for its approval, drafts of any and all proposed written advertising materials and promotional programs developed or produced by such distributor to be used for the purpose of marketing, advertising, promoting or selling Ceragem products.
2. Ceragem shall review such advertising materials and promotional programs for compliance prior to approving any use, display, publication or dissemination of any such advertising materials or promotional programs. Any non-compliant advertising materials or promotional programs shall not be used unless revised as appropriate for compliance and until approval by Ceragem is given.
3. Should the provisions of this plan conflict with any existing contractual provisions between Ceragem and any Texas-based Independent Retail Distributor, the provisions of this plan will prevail and will serve to alter or amend any existing contractual provisions.

## **Attachment D**

### **Plan for IRD Information and Training Sessions**

The following plan has been developed and implemented by Ceragem to inform and train Texas-based Independent Retail Distributors of Ceragem products. It is intended that such plan will assure compliance with Ceragem's policies, with relevant Texas and federal statutes and regulations, and with the Assurance of Voluntary Compliance and all attachments thereto (hereafter "the AVC"). The plan, the terms of which are set forth below, is effective immediately and shall apply to all Ceragem company-owned and Independent Retail Distributor stores in Texas.

1. Ceragem shall conduct informational meetings with all Texas-based Independent Retail Distributors at their facilities to review Ceragem's policies and procedures, including Ceragem's monitoring and advertising approval policies. In conjunction with such meetings, Ceragem shall discuss the contents of the AVC and shall obtain a confirmation from each Texas-based Independent Retail Distributor that the contents of the AVC are understood. Where necessary, Ceragem will provide a Spanish-language translation of the AVC.
2. Ceragem shall conduct training sessions with all Texas-based Independent Retail Distributors. The training sessions will include product and speaking demonstrations designed to assure compliance with Ceragem's policies, with relevant Texas and federal statutes and regulations, and with the AVC.
3. Should the provisions of this plan conflict with any existing contractual provisions between Ceragem and any Texas-based Independent Retail Distributor, the provisions of this plan will prevail and will serve to alter or amend any existing contractual provisions.

## Attachment E

### Plan for Restitution

The following plan has been developed and shall be implemented by Ceragem to compensate Texas consumers who purchased the CCTM because of their belief, based upon representations made at a Texas-based Ceragem location, that the CCTM would cure, treat, or mitigate any disease or physical condition not covered within the scope of the 510k letter issued for preclearance of the CCTM. It is intended that such plan will assure compliance with Ceragem's policies, with relevant Texas and federal statutes and regulations, and with the Assurance of Voluntary Compliance and all attachments thereto (hereafter "the AVC"). The plan, the terms of which are set forth below, is effective immediately and shall apply to all Ceragem company-owned and Independent Retail Distributor stores in Texas.

1. Ceragem shall send a letter, the form of which is subject to the approval of the Office of Attorney General, within 10 days of the date of the filing of this AVC to every Texas consumer who purchased a CCTM in Texas.
2. Ceragem shall accept responses to the letter for a period of sixty days from the date of the mailing of the letter to the consumer.
3. Ceragem shall collect and compile the responses to the letter and send copies of the responses to the letter to the Office of Attorney General within ninety days from the date of the mailing of the letter to the consumer.
4. Ceragem shall evaluate the responses and communicate with consumers for the purpose of validating and resolving claims for restitution. Ceragem shall provide a pro rated refund of the purchase price plus financing charges paid by the consumer, if any, for a CCTM to every consumer who indicates that they purchased the CCTM because of their belief, based upon representations made at Texas-based Ceragem locations, that the CCTM would cure, treat, or mitigate any disease or physical condition not covered within the scope of the 510k letter issued for preclearance of the CCTM.
5. Ceragem shall compile a list of names of all consumers responding to the letter along with the amount of any refund paid to the consumer and tender this list to the Office of Attorney General within one hundred twenty days from the date of the mailing of the letter to the consumer.
6. The Office of the Attorney General reserves the right to challenge the amount of restitution paid to any consumer. If the Office of the Attorney General and Ceragem are not able to agree to the appropriate amount of restitution, the parties will submit the dispute to the Court or an impartial arbitrator.