UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. CARE-TECH LABORATORIES, INC., a corporation; and JOHN C. BRERETON and SHERRY L. BRERETON, individuals, Defendants.	Civil Case No: 4:09CV 1398

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through its undersigned counsel, having filed a Complaint For Permanent Injunction against Care-Tech Laboratories, Inc., a corporation, and John C. Brereton and Sherry L. Brereton, individuals (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without contest, without admitting the allegations referenced herein, and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (the "Act").

3. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

4. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

5. Defendants violate 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1).

6. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that they have been manufactured, processed, packed, and held in violation of current good manufacturing practice ("CGMP") for drugs. 21 C.F.R. pts. 210, 211.

7. Defendants violate 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated

within the meaning of 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210, 211.

8. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(d), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i);

B. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) or adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

C. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded

within the meaning of 21 U.S.C. § 352(f)(1) or adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

9. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any drug at or from the facility located at 3224 South Kingshighway Boulevard, St. Louis, Missouri 63139 ("Defendants' facility"), unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, and hold drugs are established, operated, and administered in compliance with CGMP;

B. Defendants establish and follow scientific product development and manufacturing process design procedures that reflect an understanding of and result in appropriate control over all significant variables, including material attributes and processing parameters, impacting in-process material and final drug product specifications and quality attributes;

C. Defendants establish and follow appropriate laboratory controls, including, but not limited to, properly

validated and otherwise scientifically sound microbiological testing methods that demonstrate the microbial quality of Defendants' in-process material and finished drug products. Such laboratory controls shall be adequate to ensure that all drug products manufactured, processed, packed, held, and distributed by Defendants have the safety, identity, strength, quality, purity, and potency that they purport or are represented to possess, and are in compliance with the provisions of the Act, its implementing regulations, and this Decree;

D. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to inspect Defendants' drug manufacturing operations to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP expert as soon as they retain such expert;

E. The CGMP expert shall perform a comprehensive inspection of Defendants' facility and the methods and controls used to manufacture, process, pack, label, and hold drugs to determine whether they are in compliance with CGMP;

F. The CGMP expert shall evaluate whether Defendants have established and implemented a comprehensive written Quality Assurance ("QA")/Quality Control ("QC") program that is adequate to ensure continuous compliance with the Act, its implementing regulations, and this Decree. The CGMP expert, at a minimum, shall determine whether the QA/QC program:

i. (a) Addresses all facets of compliance monitoring and trend analyses; (b) establishes management systems to track and store records relating to safety, identity, strength, quality, and purity of in-process, bulk, and finished product and internal audit procedures; and (c) confirms that Defendants' Quality Control Unit ("QCU"), as defined by 21 C.F.R. § 210.3(b)(15), is sufficiently trained to evaluate CGMP compliance on an on-going basis and to prevent and promptly correct any future deviations from CGMP;

ii. Includes procedures to ensure that Defendants, in a timely manner, thoroughly investigate: (a) product deviations; (b) reports of complaints regarding Defendants' products; and (c) any unexplained discrepancy or the failure of a batch of drug or any of its components to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same drug and other drugs that may have been associated with the specific failure or discrepancy; and to take required and timely

corrective actions for all products and components that fail to meet their specifications;

iii. Establishes mechanisms to ensure that written standard operating procedures ("SOPs") are periodically re-evaluated so that they remain in continuous compliance with CGMP, and that the SOPs address all facets of CGMP and are reviewed and controlled by an independent QA unit;

iv. Includes written SOPs to ensure that (a) Defendants' QA personnel are promptly notified in writing of deviations and/or problems that could affect the safety, identity, strength, quality, and purity of any drug; (b) Defendants' QA personnel participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations and/or problems; and (c) there are systems to ensure that such written SOPs are continuously followed; and

v. Includes written SOPs that specify the responsibilities and procedures applicable to QA and QC personnel, and establishes mechanisms to ensure such SOPs are followed;

G. The CGMP expert certifies in writing to FDA that:

i. the CGMP expert has inspected Defendants' facility, methods, processes, and controls;

ii. all CGMP deviations brought to Defendants' attention since February 2, 2000, by FDA, the CGMP expert, or any other source have been corrected; and

iii. such facilities, methods, processes, and controls are in compliance with the requirements of CGMP. As part of this certification, the CGMP expert shall include a detailed and complete report of the results of the expert's inspection;

H. Defendants report to FDA in writing the actions they have taken to:

i. correct the CGMP deviations brought to Defendants' attention since February 2, 2000, by FDA, the CGMP expert, and any other source; and

ii. ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP;

I. FDA representatives inspect Defendants' facility to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Decree, which FDA shall commence within ten (10) business days of receipt of both the certification described in paragraph 9(G) and the report described in paragraph 9(H); and

J. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 9(A)-(G) of this Decree. FDA shall notify Defendants in writing within seven (7) business days after completion of the inspection described in paragraph 9(I) whether Defendants appear to be in compliance with the requirements set forth in paragraphs 9(A)-(G). In no circumstance shall FDA's silence be construed as a substitute for written notification.

K. Nothing in paragraph 9 shall preclude Defendants from manufacturing, processing, packing, and holding drug products for the sole purpose of performing equipment qualification, validation of drug manufacturing processes, method validation of microbiological testing methods, or stability studies. Defendants shall maintain in a separate file at Defendants' facility a written log of all lot numbers of drugs manufactured under this provision, and shall promptly make such log available to FDA upon request. None of the drugs produced under paragraph 9(K) may be distributed.

10. Defendants shall not commence, permit any other person to commence, or cause any other person to commence attempting to bring any unapproved, misbranded, and/or adulterated drugs that are in Defendants' possession, custody, or control (the "violative articles") into compliance with the law unless and until Defendants: (a) within 30 calendar days of entry of this

Decree submit a written statement to FDA detailing Defendants' proposed plan to bring the violative articles into compliance with the law (the "Proposal"); (b) receives written approval of the Proposal from FDA; and (c) receives written authorization from FDA to commence attempting to bring the violative articles into compliance with the law. FDA shall provide a written response to the Proposal, and, if approved, a written authorization from FDA to commence attempting to bring the violative articles into compliance, within 30 calendar days of the date of the submission of the Proposal.

11. Defendants shall at all times, until the violative articles have been released in writing by an FDA representative, retain the violative articles intact for examination or inspection by an FDA representative in a place made known to and approved by FDA, and shall maintain the records or other proof necessary to establish the identity of the articles to the satisfaction of the FDA representative.

12. Within 30 calendar days of receiving written authorization to commence attempting to bring the violative articles into compliance with the law, Defendants shall complete their attempt in accordance with the Proposal approved pursuant to paragraph 10, and under the supervision of FDA. Defendants shall destroy any unapproved, misbranded, and adulterated drugs that are in Defendants' possession, custody, or control that has

not been brought into compliance within 90 calendar days of entry of this Decree, at their own expense and under the supervision of FDA.

13. Defendants shall at no time, and under no circumstances whatsoever, directly or indirectly, cause or permit the shipment, sale, offer for sale, or other disposal of the violative articles until:

A. FDA has had free access to the violative articles in order to take any samples or make any tests or examinations that are deemed necessary; and

B. FDA has released, in writing, the violative articles for shipment, sale, or other disposition.

14. Defendants shall not sell, ship, destroy, or dispose of, or permit or cause another person to sell, ship, destroy, or dispose of, the violative articles or any part of them in a manner contrary to the provisions of the Act, or other laws of the United States, or of any State or Territory (as defined in the Act) in which they are disposed of or sold.

15. After Defendants have complied with paragraphs 9(A)-(G) and received FDA's written notification pursuant to paragraph 9(J), Defendants shall retain an independent person or persons (hereinafter, "auditor") who shall meet the criteria described in paragraph 9(D) to conduct audit inspections of Defendants' facility no less frequently than once every six (6) months for a

period of one (1) year, and no less frequently than once every year for four (4) years thereafter, unless otherwise directed by FDA. The first audit shall occur not more than six months after Defendants have received FDA's written notification pursuant to paragraph 9(J). If Defendants choose, the auditor may be the same person or persons retained as the CGMP expert described in paragraph 9(D).

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with CGMP and identifying any deviations from CGMP ("audit report observations"). As a part of every audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) business days after the date the audit inspection is completed. In addition, Defendants shall maintain the audit reports in separate files at Defendants' facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendants are not in compliance with CGMP, Defendants shall, within fifteen (15) calendar days of receipt of

the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than fifteen (15) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Immediately upon correction, Defendants shall submit documentation of their correction to the auditor. Within thirty (30) calendar days of the auditor's receipt of Defendants' documentation of correction, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) business days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

16. Defendants may not commence or resume manufacturing or distributing any drug that purports to be an OTC monograph drug unless and until:

A. Defendants retain, at their expense, an independent person or person(s) (the "monograph expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to review the labeling of Defendants' OTC drug products to determine whether such products conform to an applicable OTC monograph and other labeling requirements of the Act and its implementing regulations. Defendants shall notify FDA in writing of the identity and qualifications of the monograph expert as soon as they retain such expert;

B. For each OTC drug product that Defendants propose to manufacture and distribute, the monograph expert performs a comprehensive review of the proposed labeling of that OTC drug product to determine whether the product strictly conforms to an applicable OTC monograph and all labeling requirements, including 21 C.F.R. § 201, and that the drug product is not otherwise misbranded;

C. For each OTC drug product for which the monograph expert completes the review described in paragraph 16(B), the monograph expert certifies in writing to FDA that:

i. the monograph expert has reviewed the proposed OTC drug product and its labeling;

ii. the proposed OTC drug product conforms to an applicable monograph, and the OTC drug product's labeling conforms to all applicable labeling requirements, including 21 C.F.R. Part 201; and

iii. the drug is not otherwise misbranded. As part of this certification, the monograph expert shall attach the labeling reviewed together with a detailed and complete report of the results of the expert's labeling review, including references to the applicable monograph and labeling regulations consulted by the expert in conducting the review;

D. Defendants have provided FDA any additional information requested by the agency pursuant to the review of the monograph expert's certification; and

E. FDA notifies Defendants in writing that they appear to be in compliance with the terms set forth in paragraphs 16(A)-(D) of this Decree. For submissions concerning the OTC drug products Techni-Care and Satin, FDA will notify Defendants as to whether Defendants appear to be in compliance within 21 days of receipt of the monograph expert's certification as set forth in subparagraph 16(C) and receipt of any information requested by FDA pursuant to subparagraph 16(D). For submissions concerning any other OTC drug product(s), FDA will notify

Defendants as to whether Defendants appear to be in compliance within 75 days of receipt of the monograph expert's certification as set forth in subparagraph 16(C) or any information requested by FDA pursuant to subparagraph 16(D). In no circumstances may FDA's silence be construed as a substitute for written notification.

17. If at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report, or data prepared or submitted by Defendants, the CGMP expert, the auditor, the monograph expert, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, or distributing any or all drugs;

B. Recall, at Defendants' expense, any drug that is unapproved, misbranded, adulterated, or otherwise in violation of this Decree, the Act, or its implementing regulations;

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

D. Submit additional reports or information to FDA as requested; and

E. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

18. The following process and procedures shall apply when FDA issues an order under paragraph 17:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (i) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action(s) taken or proposed to be taken and the proposed schedule for completing the action(s); or (ii) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as

the Agency deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. The Court's decision under this paragraph shall be made in accordance with paragraph 28.

D. The process and procedures set forth in paragraphs 18(A)-(C) shall not apply to any order issued pursuant to paragraph 17 if such order states that, in FDA's judgment, the order must be implemented immediately. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they shall begin compliance with the order while they petition this Court for relief.

19. Any cessation of operations pursuant to paragraph 17 shall continue until FDA notifies Defendants in writing that they appear to be in compliance with the Act, its implementing

regulations, and the requirements of this Decree, and that Defendants may, therefore, resume operations.

20. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' places of business and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During inspections, FDA representatives shall be permitted to: have immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other promotional material therein; take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other promotional material; and examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all drugs and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

21. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants'

compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $85.49 per hour or fraction thereof per representative for inspection and investigative work; $102.49 per hour or fraction thereof per representative for analytical or review work; $0.55 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

22. Within ten (10) calendar days of the entry of this Decree, Defendants shall post a copy of this Decree in a common area at Defendants' facility and at any other location at which Defendants conduct business and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

23. Within ten (10) calendar days of the date of entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them. Within thirty (30) calendar days

of the date of entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

24. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Care-Tech Laboratories, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least thirty (30) calendar days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

25. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be addressed to the District Director, FDA Kansas City District Office, 11630 West 80th Street, Lenexa, Kansas 66214.

26. Should Defendants fail to comply with any provision of the Act or its implementing regulations relating to the

manufacturing, processing, packing, labeling, holding, or distributing of a drug, or any provision of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, such Defendants shall pay to the United States of America: five thousand dollars ($5,000) in liquidated damages for each day such violation continues; an additional sum of one thousand dollars ($1,000) in liquidated damages for each violation of the Act, its implementing regulations, and/or this Decree; and an additional sum in liquidated damages equal to twice the retail value of any shipments of adulterated or misbranded drugs or unapproved new drugs. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

27. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), investigational and analytical expenses, expert witness fees, and court costs relating to such contempt proceedings.

28. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary

and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

29. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this 8th day of September, 2009.

UNITED STATES DISTRICT JUDGE

Entry consented to:

For Defendants

JOHN C. BRERETON
Individually and on behalf of CARE-TECH LABORATORIES, INC., as its President

SHERRY L. BRERETON
Individually and on behalf of CARE-TECH LABORATORIES, INC., as its Vice President and Secretary

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SHERRY L. BRERETON
Individually and on behalf
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