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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,	
Plaintiff,	**Hon. Anne E. Thompson, U.S.D.J.**
v.	**Civil Action No. 10-5143**
ARTICLES OF FINISHED AND IN-PROCESS DRUGS LISTED BELOW, WITH ANY LOT NUMBER, SIZE, OR TYPE CONTAINER, WHETHER LABELED OR UNLABELED:	**CONSENT DECREE OF CONDEMNATION AND DESTRUCTION**
C-PHEN DM DROPS **C-PHEN DM SYRUP** **C-PHEN DROPS** **C-PHEN SYRUP** **CENTERGY DM DROPS** **DEX PC SYRUP** **EXPECTUSS LIQUID** **GUIADRINE DX LIQUID** **HISTACOL DM PEDIATRIC SYRUP** **INTROL** **MINTUSS DR SYRUP** **PBM ALLERGY SYRUP** **P CHLOR GG DROPS** **PDM GG SYRUP** **PHENYLEPHRINE COMPLEX LIQUID** **PSEUDO COUGH** **PSEUDO DM GG SYRUP** **PYRICHLOR PE LIQUID** **QUARTUSS DM DROPS** **QUARTUSS SYRUP** **TENAR DM LIQUID** **TRIPLEX AD LIQUID** **TRIPLEX DM LIQUID**	

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AND

ALL OTHER ARTICLES OF DRUG, INCLUDING FINISHED AND IN-PROCESS PRODUCTS, AND DRUG COMPONENTS, INCLUDING ACTIVE AND INACTIVE INGREDIENTS, OF ANY LOT NUMBER, SIZE OR TYPE CONTAINER, WHETHER LABELED OR UNLABELED, THAT ARE DETERMINED BY THEIR LABELING OR OTHERWISE TO HAVE ORIGINATED FROM OUTSIDE THE STATE OF NEW JERSEY, AND ARE LOCATED ANYWHERE ON THE PREMISES OF TRI-MED LABORATORIES, INC., 68 VERONICA AVENUE, SUITE #1, SOMERSET, NEW JERSEY, OR ELSEWHERE WITHIN THE

JURISDICTION OF THIS COURT,

Defendants *in rem*.

On October 6, 2010, the United States of America ("Plaintiff"), by and through the United States Attorney for the District of New Jersey, filed a Verified Complaint for Forfeiture *In Rem* ("Complaint") in this Court against the above-captioned articles. Pursuant to a Warrant for Arrest *In Rem*, on October 13, 2010, the United States Marshal for this District seized the articles (the "Seized Articles").

The Complaint alleges that the Seized Articles are drugs within the meaning of the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. 321(g)(1). The Complaint further alleges that

the Seized Articles are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with the current good manufacturing practice (hereinafter "GMP") requirements for drugs, 21 C.F.R. Parts 210 - 211. The Complaint also alleges that the Seized Articles may not be introduced or delivered for introduction into interstate commerce pursuant to the Act, 21 U.S.C. § 355(a), in that they are "new drugs" within the meaning of 21 U.S.C. § 321(p), and no approvals of applications filed pursuant to 21 U.S.C. § 355(b) or (j) are in effect with respect to such drugs, nor are there in effect notices of claimed investigational exemptions filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312.

On December 1, 2010, Tri-Med Laboratories, Inc. ("Claimant" or "Tri-Med") intervened and filed a Verified Claim in all of the Seized Articles, signed by Robert E. Caliari, the President and owner, and an Answer. Claimant affirms that it is the sole owner of the Seized Articles, that no other person has an interest in the Seized Articles, and that it will indemnify and hold Plaintiff harmless should any party or parties hereafter file or seek to file a statement of interest, or to intervene in this action and obtain or defend any part of the Seized Articles subject to this Decree. Claimant consents to the entry of this Consent Decree without contest and before any testimony has been taken.

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

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 334 and personal jurisdiction over all parties to this action.

2. FDA shall divide the Seized Articles into two (2) lots designated Lot A and Lot B. Lot A shall consist of all material included in the Seized Articles that is an active or inactive ingredient (whether stored in previously opened or unopened containers), and that a duly authorized representative(s) of the United States Department of Health and Human Services ("FDA representative") determines has not been used in the manufacture of any finished or in-process product (of any kind) or component thereof and remains within its expiration date. Lot B shall consist of any and all of the Seized Articles that remain. Within fifteen (15) days of entry of this Decree, Claimant shall give written notice to FDA, at the address set forth in paragraph 25, identifying specifically the Seized Articles that it contends constitute Lot A. Within thirty (30) days following receipt of such notice, the FDA representative shall inspect the Seized Articles and make a final written determination as to the makeup of Lot A and Lot B. FDA's written determination shall constitute a final decision under paragraph 23 of this Decree.

3. Following receipt of FDA's written determination with respect to the division of the Seized Articles, Claimant may submit a written plan to FDA detailing Claimant's proposal for the disposition of the Seized Articles constituting Lot A. FDA shall either approve or disapprove of such plan in writing, which decision shall be final. Upon being informed by FDA that the plan has been approved, the United States Marshal for this District shall release the Seized Articles in Lot A from its custody to Claimant for disposition in accordance with the approved plan. Any Seized Articles in Lot A that are not released in accordance with the terms and conditions of this paragraph within one hundred eighty (180) days following the entry of this Decree shall be disposed of in accordance with the terms and conditions of this Decree that are applicable to the Condemned Articles.

4. The Seized Articles comprising Lot B (hereinafter the "Condemned Articles") are adulterated while held for sale after shipment of one or more of their components in interstate commerce, within the meaning of the Act, 21 U.S.C. § 351(a)(2)(B), in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, and holding do not conform to and are not operated and administered in conformity with GMP requirements for drugs, 21 C.F.R. Parts 210 - 211.

5. The Condemned Articles may not be introduced or delivered for introduction into interstate commerce pursuant to the Act, 21 U.S.C. § 355(a), in that they are "new drugs" within the meaning of 21 U.S.C. § 321(p), and no approvals of applications filed pursuant to 21 U.S.C. § 355 are in effect with respect to such drugs, nor are there in effect notices of claimed investigational exemptions filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312.

6. Pursuant to 21 U.S.C. § 334(e), Claimant shall pay to the United States all court costs and fees, storage, and other proper expenses of this proceeding incurred to date, and such additional expenses as may hereinafter be incurred and taxed.

7. Within fifteen (15) days of the entry of this Consent Decree, Claimant shall: (a) pay in full the court costs, storage, and other proper expenses of this proceeding to date, as set forth in paragraph 6 of this Decree; and (b) execute and file with the Clerk of this Court a good and sufficient penal bond ("Bond") in the form of an irrevocable stand-by letter of credit in the amount of one-hundred fifty thousand dollars ($150,000), in a form acceptable to the Clerk of this Court and payable to the United States of America, and conditioned on Claimant's abiding by and performing all of the terms and conditions of this Decree with respect to the Seized Articles and such orders and decrees that may be entered in this proceeding with respect to the Seized Articles.

Said Bond shall be obtained from a trust company or commercial bank in good standing, shall be valid for at least one hundred eighty (180) days from the date this Decree is entered, and may be drawn upon by the presentation of a sight draft.

8. The Condemned Articles are hereby condemned pursuant to 21 U.S.C. § 334, and forfeited to Plaintiff.

9. After paying the costs pursuant to paragraph 6 of this Decree, and posting the Bond as specified in paragraph 7 of this Decree, Claimant shall give written notice to FDA, at the address set forth in paragraph 25, that Claimant, at its own expense, is prepared to destroy the Condemned Articles, pursuant to 21 U.S.C. § 334, under the supervision of the FDA representative. Claimant's notice shall specify the proposed time, place, and method of destruction of such articles. Destruction shall be in a manner that complies with all federal, state, and local environmental laws, including, without limitation, the National Environmental Policy Act of 1969.

10. Claimant shall not commence attempting to destroy any of the Condemned Articles until Claimant has received written authorization to commence with the destruction from an FDA representative. The decision of the FDA representative regarding the adequacy of the destruction proposal shall be final. All of the Condemned Articles shall be destroyed at Claimant's expense under the supervision of an FDA representative. Claimant shall pay to the United States all costs incurred in supervising the destruction of the Condemned Articles, at the rates specified in paragraph 22 of this Decree.

11. Following receipt of notice from FDA that Claimant has paid the costs pursuant to paragraph 6 of this Decree, posted the Bond as specified in paragraph 7 of this Decree, and submitted notice to FDA pursuant to paragraph 9 of this Decree, and that FDA has issued the

written authorization pursuant to paragraph 10 of this Decree, the United States Marshal for this District shall release the Condemned Articles from his custody to the custody of Claimant for the sole purpose of destroying such articles pursuant to the FDA-approved destruction proposal.

12. Claimant shall not destroy, dispose of, or permit another person to destroy or dispose of, or cause another person to destroy or dispose of any of the Seized Articles or any part of the Seized Articles 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.

13. Claimant shall at all times, until the Condemned Articles have been destroyed in accordance with this Decree, retain such articles intact for examination or inspection by the FDA representative without prior notice to Claimant. Claimant shall maintain the records or other proof necessary to establish the identity of the Seized Articles to the satisfaction of the FDA representative.

14. Within thirty (30) days following the release of the Condemned Articles by the United States Marshal for this District, Claimant shall complete the destruction of the Condemned Articles under the supervision of the FDA representative. Within fifteen (15) days of Claimant's completion of the destruction of the Condemned Articles, FDA will send Claimant an invoice for the costs of supervising the destruction, and Claimant shall pay those costs within ten (10) days of receiving FDA's invoice.

15. The United States Attorney for this District, upon being advised by an FDA representative that all of the Seized Articles have been destroyed in accordance with this Decree and that Claimant has paid all costs due as of that date, will transmit such information to the Clerk

of this Court, whereupon the Bond given in this proceeding shall be returned, canceled, or discharged.

16. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Claimant's places of business and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted prompt access to Claimant's place(s) of business, including all buildings, equipment, in-process and finished materials and products, containers, labeling and other materials therein; to take photographs and make video recordings; to take samples of Claimant's finished and unfinished materials and products, containers, labels, labeling, and other promotional materials; and to examine and copy all records relating to the receipt, manufacture, processing, packaging, labeling, holding, sale, and distribution of any and all of Claimant's products, including components, in order to ensure continuing compliance with the terms of this Decree. 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 conduct inspections under the Act, 21 U.S.C. § 374.

17. Claimant and Claimant's owner and president, Robert E. Caliari, represent to the Plaintiff and the Court that, as of October 13, 2010, neither they nor any other person with whom they are in active concert or participation (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) ("Person") are engaged in manufacturing, preparing, processing, packing, repacking, labeling, holding, distributing, and/or causing the introduction into interstate commerce of any articles of drug, within the meaning of 21 U.S.C. § 321(g)(1). In the

event that Claimant or Robert E. Caliari, either together, alone, or in active concert or participation with any other Person, intend to begin to manufacture, prepare, process, pack, repack, label, hold, distribute, and/or cause the introduction into interstate commerce of any articles of drug, within the meaning of 21 U.S.C. § 321(g)(1), Claimant and/or Robert E. Caliari shall give thirty (30) days advance notice thereof to FDA at the address set forth in paragraph 25.

18. Upon entry of this Decree, both Claimant and Robert E. Caliari are permanently restrained and enjoined, pursuant to 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(a), by introducing or delivering, or causing to be introduced or delivered into interstate commerce drugs, within the meaning of 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Violating 21 U.S.C. § 331(k), by causing drugs, within the meaning of 21 U.S.C. § 321(g)(1), that are held 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);

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

D. Violating 21 U.S.C. § 331(k), by causing drugs, within the meaning of 21 U.S.C. § 321(g)(1), that are held 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; and

E. Violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs, within the meaning of 21 U.S.C. §

321(p), that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312.

19. Tri-Med's owner and President, Robert E. Caliari, hereby represents that he is divesting all of his interests in Tri-Med, and hereby warrants: (a) that he will not thereafter maintain or obtain any interest in Tri-Med or any subsequent pharmaceutical business located at 68 Veronica Avenue, Somerset, New Jersey; (b) that he will not serve as a consultant or an employee of Tri-Med or any successor entity; and (c) that he will not use any manufacturing equipment, materials, or formulations currently owned or used by Tri-Med in any future enterprise involving the manufacture, preparation, processing, packing, re-packing, labeling, holding, and/or distribution of drugs, within the meaning of 21 U.S.C. § 321(g)(1). Robert E. Caliari shall have a period of one hundred eighty (180) days following the entry of this Decree during which to fully execute such divestment. Within five (5) days following such one hundred eighty (180) day period, Robert E. Caliari shall provide FDA, at the address set forth in paragraph 25, with written confirmation that the full divestment of his interests in Tri-Med is complete and, in addition to and notwithstanding any other relief provided in this Decree, shall be permanently restrained and enjoined from committing any act that violates the warranties set forth above in this paragraph.

20. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, analyses of samples, labeling, promotional materials, or any other information, that Claimant and/or Robert E. Caliari has violated the Act, its implementing regulations, or this Decree, or that additional corrective actions are necessary to achieve compliance with the Act, its implementing regulations, or this Decree, FDA may, as and when it deems necessary in its sole discretion, direct Claimant and/or Robert E. Caliari to cease manufacturing,

processing, packaging, labeling, holding, selling, and/or distributing any or all drugs and/or to take any other corrective action(s) as FDA deems necessary to bring such drugs into compliance with the Act, its implementing regulations, and this Decree.

21. If Claimant fails to abide by and perform all of the terms and conditions of this Decree with respect to the Seized Articles, then the Bond posted pursuant to paragraph 7 of this Decree shall, on motion of Plaintiff in this proceeding, be forfeited in its entirety to Plaintiff and judgment entered in favor of Plaintiff. If Claimant breaches any term or condition of this Decree, then Claimant, at its own expense, shall immediately return the Seized Articles to the United States Marshal for this District or otherwise dispose of them pursuant to an order of this Court. In the event that return of the Seized Articles becomes necessary pursuant to this paragraph, Claimant shall be responsible for all costs of storage and disposition that are incurred by Plaintiff.

22. Claimants shall reimburse the United States for the costs of supervising Claimant's compliance with the terms of this Decree, including all inspections, examinations, reviews, evaluations, and analyses conducted pursuant to this Decree, at the standard rates prevailing at the time the activities are accomplished. As of the date that this Decree is signed by the parties, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour or fraction thereof per representative for analytical or review work; 50 cents per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day 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.

23. Claimant shall abide by the decisions of FDA regarding the destruction or other disposition of the Seized Articles, which 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.

24. Should Plaintiff bring, and prevail in, a contempt action to enforce the terms of this Decree, Claimant agrees to pay all attorney's fees, travel expenses incurred by attorneys and witnesses, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such an action.

25. All notifications, certifications, reports, correspondence, and other communications to FDA required by this Decree shall be addressed to the Director, FDA New Jersey District Office, Waterview Corp. Center, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey, 07054.

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

IT IS SO ORDERED:

Dated this 13th day of April, 2011.

The Hon. Anne E. Thompson, UNITED STATES DISTRICT JUDGE

Entry consented to:

FOR CLAIMANT-INTERVENOR

Robert E Caliari 4-7-11
ROBERT E. CALIARI, individually, and on behalf of TRI-MED LABORATORIES, INC., as its President

THEODORE M. SULLIVAN, attorney for TRI-MED LABORATORIES, INC. and ROBERT E. CALIARI
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