CTJ/RMT

ORIGINAL

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

PHARMAFAB, INC., a corporation, PFAB LP, d.b.a. PHARMAFAB, a limited partnership, and MARK T. TENGLER, and RUSS L. McMAHEN, individuals,

Defendants.

Civil Action No. 4-07CV-238-A

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for permanent injunction ("Complaint") against PharmaFab, Inc., a corporation, PFab LP, d.b.a. PharmaFAB, a limited partnership, and Mark T. Tengler, and Russ L. McMahen, individuals (hereinafter, collectively, "Defendants"), and Defendants solely for the purposes of settlement of this case, and without admitting or denying the allegations in the Complaint, having appeared and having consented to entry of this Decree without contest 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 of this action and has personal jurisdiction over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (the "Act").

3. Except as provided in paragraph 6 below, 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 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 articles of drug unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in compliance with CGMP, 21 C.F.R. Parts 210 and 211. These methods, facilities, and controls shall specifically include, but not be limited to, the following:

(1) Establishing adequate control procedures, including written procedures, to verify the validity, accuracy, and reliability of test methods and results used by Defendants to determine the identity, strength, purity, and stability of drugs prior to release;

(2) Establishing adequate control procedures, including written procedures, to verify the validity of manufacturing processes that may cause variability in the characteristics of both in-process material and over-the-counter ("OTC") and prescription drugs;

(3) Establishing procedures and implementing methods for assessing the stability characteristics of drugs and establishing reliable expiration dates for products based on properly developed stability data prior to release;

(4) Establishing and following procedures to ensure proper investigations of product complaints and batch failures, including a written record of the steps taken to correct

the problem or an explanation of why an investigation was not done and the recommended corrective action plan; and

(5) Establishing an adequately trained quality control unit and adequate written procedures governing its authority, responsibilities, and procedures;

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

C. The CGMP expert performs a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, pack, label, hold, and distribute drugs to determine whether they are in compliance with subparagraph 3(A) and CGMP;

D. The CGMP expert certifies in writing to FDA that: (1) he or she has inspected Defendants' facilities, methods, processes, and controls; (2) all CGMP deviations brought to Defendants' attention by FDA since 2004 or the CGMP expert have been corrected or rendered moot by subsequent manufacturing changes; and (3) such facilities, methods, processes, and

controls are in compliance with the requirements of subparagraph 3(A) and CGMP. As part of this certification, the CGMP expert shall include a full and complete detailed report of the results of his or her inspection;

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

(1) correct the CGMP deviations brought to Defendants' attention by FDA, the CGMP expert, and any other source;

(2) 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;

(3) bring their products into compliance with the drug approval provisions of the Act; and

(4) ensure their products have adequate directions for use as required by the Act;

F. FDA inspects Defendants' facilities to determine whether the requirements of this Decree have been met, and whether Defendants' facilities are operating in conformity with CGMP, the Act, and its implementing regulations. This inspection shall occur within sixty (60) calendar days of FDA's receipt of Defendants' report under subparagraph 3(E) or the CGMP expert's report under subparagraph 3(D), whichever is later; and

G. FDA notifies Defendants in writing within thirty (30) calendar days from the conclusion of the inspection in subparagraph 3(F), that Defendants appear to be in compliance with the requirements set forth in subparagraphs 3(A) - (E). In no circumstance will FDA's silence be construed as a substitute for written notification.

4. Except as provided in paragraph 6 below, upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons 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 doing or causing to be done any of the following acts:

A. Introducing or delivering for introduction into interstate commerce, holding for sale after shipment in interstate commerce, manufacturing, processing, packing, labeling, holding, or distributing any drug, unless and until:

(1) an approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. § 355 is in effect for such drug;

(2) an investigational new drug application filed pursuant to 21 U.S.C. § 355(i) and 21 C.F.R. Part 312 is in effect for such drug and the drug is distributed and used solely for the purpose of conducting clinical investigations in strict accordance with the investigational new drug application; or

(3) such drug conforms strictly to all of the requirements set forth in any of the FDA OTC drug monographs, 21 C.F.R. Part 330;

B. Introducing or delivering for introduction into interstate commerce; holding for sale after shipment in interstate commerce; manufacturing, processing, packing, labeling, holding, or distributing any adulterated drug, within the meaning of 21 U.S.C. § 351(a)(2)(B); or the causing the adulteration of any drug within the meaning of 21 U.S.C. § 351(a)(2)(B); while such drug is held for sale after shipment of one or more components in interstate commerce; and

C. Introducing or delivering for introduction into interstate commerce; holding for sale after shipment in interstate commerce; manufacturing, processing, packing, labeling, holding, or distributing any misbranded drug, within the meaning of 21 U.S.C. § 352; or the misbranding of any drug within the meaning of 21 U.S.C. § 352, while such drug is held for sale after shipment of one or more components in interstate commerce.

5. Before Defendants may commence distributing any new drug, or continue the distribution of any previously distributed drug that is a new drug within the meaning of 21 U.S.C. § 321(p), Defendants shall first notify FDA in writing of their intention to do so, and shall also do the following:

A. For any drug not manufactured and labeled in strict conformance with an FDA OTC monograph under the terms of subparagraph 5(B), Defendants shall demonstrate to FDA that the drug is the subject of: 1) an approved application under 21 U.S.C. § 355(a) or § 355(j) by submitting to FDA a copy of FDA's approval letter for such application or 2) an investigational new drug application under 21 U.S.C. § 355(i) by submitting a copy of the submissions made to FDA and an affidavit that a period of 30 days has lapsed since submission and FDA has not implemented a clinical hold or otherwise prevented the application from going into effect. In no event may Defendants distribute a drug product that is not the subject of an approved application under 21 U.S.C. §§ 355(a) or (j), or the subject of an investigational new drug application under 21 U.S.C. § 355(i), which application must explicitly authorize manufacture of the drug at Defendants' facility;

B. If the product purports to be an OTC monograph drug, as described in subparagraph 4(A)(3), Defendants may not distribute such drug unless and until:

(1) Defendants retain, at Defendants' expense, an independent person or persons (the "drug monograph expert"), who is without any personal or financial ties (other than the 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(s) to determine whether such product complies with the applicable OTC drug monograph and other labeling requirements of the Act and FDA regulations. Defendants shall notify FDA in writing of the identity and qualifications of the drug monograph expert as soon as they retain such expert;

(2) The drug monograph expert performs a comprehensive review of the OTC drug's proposed labeling to determine whether the product strictly conforms to an applicable FDA OTC monograph and all labeling requirements, including 21 C.F.R. Part 201, and that the OTC drug is not otherwise misbranded;

(3) The drug monograph expert certifies in writing to FDA that: (1) he or she has reviewed the OTC drug and its labeling; (2) the OTC drug labeling conforms to the requirements of an OTC drug monograph and all applicable labeling requirements, including 21 C.F.R. Part 201; and (3) the OTC drug is not otherwise misbranded. As part of this certification, the drug monograph expert shall include a full and complete detailed report of the results of his or her labeling review, including references to the OTC monograph and labeling regulations addressed in the process of conducting the labeling review;

(4) Defendants have provided to FDA any additional information requested by FDA after FDA's review of the drug monograph expert's certification pursuant to subparagraph 5(B)(3); and

(5) FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in subparagraphs 5(B)(1) - (4). FDA shall provide notification to Defendants as to whether Defendants appear to be in compliance within 60 calendar days of receipt of the drug monograph expert's certification as set forth in subparagraph 5(B)(3). In no circumstance may FDA's silence be construed as a substitute for written notification. In no event may Defendants distribute a drug product that does not strictly conform to an applicable OTC drug monograph.

6. Paragraphs 3 and 4 of this Decree shall not apply to the following:

A. Processing or holding any article of drug solely for purposes of conducting stability studies, 21 C.F.R. § 211.166 or maintaining reserve samples, 21 C.F.R. § 211.170; however, in no event shall such drugs be distributed for commercial marketing; or

B. Performing research and development activities that do not involve human subjects; however, in no event shall such drugs be distributed for commercial marketing or administered to human subjects.

7. If, after Defendants have received written notice from FDA pursuant to paragraph 3(G) and Defendants' auditor, as set forth in paragraph 9, 1) has not documented significant deviations from CGMP or 2) has documented significant deviations from CGMP which Defendants have sufficiently corrected, to FDA's satisfaction, Defendants may undertake research and development involving human subjects, including, but not limited to bioavailability or bioequivalence studies, if Defendants first notify FDA in writing of their intention to do so and FDA authorizes such studies in writing.

8. Within fifteen (15) calendar days of entry of this Decree, Defendants shall, under FDA supervision, destroy all drugs in Defendants' possession, custody, and/or control which are adulterated because they were not manufactured, processed, packed, labeled, held, and/or distributed in accordance with CGMP except that Defendants may retain quantities necessary to meet regulatory obligations regarding products that were distributed before the date of entry of this Decree, as provided in paragraph 6(A), above. In no event shall any retained drugs be distributed for commercial marketing. Defendants shall reimburse FDA for the supervision of the destruction at the rates set forth in paragraph 11 of this Decree. Defendants shall not dispose of any drugs in a manner contrary to any federal, state, or local laws, including but not limited to, the National Environmental Policy Act of 1969.

9. After Defendants have complied with subparagraphs 3(A)-(E) and FDA has notified them pursuant to subparagraph 3(G), Defendants shall retain an independent person or persons who shall meet the criteria described in subparagraph 3(B) ("auditor") to conduct audit inspections of their drug manufacturing operations not less than once every six (6) months for a period of no less than three (3) years and not less than once every twelve (12) months for a period of two (2) years thereafter. If Defendants choose, the auditor may be the same person or persons retained as the CGMP expert in subparagraph 3(B).

A. At the conclusion of each audit inspection, the auditor shall prepare a 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, except the first 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 inspections are completed. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any audit report observations indicating that Defendants are not in compliance with CGMP, Defendants shall, within thirty (30) 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 thirty (30) 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 will FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) calendar days of Defendants' receipt of an audit report, 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.

10. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' place(s) of business and 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 ready access to Defendants' place(s) of business including, but not limited to, all buildings, equipment, finished and unfinished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples of Defendants' finished and unfinished materials and products, containers, labeling, and other promotional material; and to examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all of Defendants' drugs, 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 make inspections under the Act, 21 U.S.C. § 374

11. 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 activities are accomplished. As of the date of entry of this Decree, these rates are: $78.09 per hour or fraction thereof per representative for inspection and investigative work; $93.61 per hour or fraction thereof per representative for laboratory and analytical work; $0.485 per mile for travel expenses by automobile, government rate or the equivalent for travel by air; 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. In addition, should

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

12. Within ten (10) calendar days of the entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in a common area at 2940 North State Highway 360, Suite 100, Grand Prairie, Texas, and at any other location at which Defendants conduct business, and shall ensure that the Decree remains posted for a period of twelve (12) months at each location.

13. 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 (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, customers, and any and all persons in active concert or participation with any of them (collectively referred to as Associated Persons). 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 received a copy of this Decree pursuant to this paragraph.

14. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within ten (10) calendar days of each time any of the

Defendants becomes associated with any such additional Associated Person, Defendants shall provide to the District Director, FDA Dallas District Office, an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

15. For purposes of this Decree, a licensee of Defendant PFAB LP's proprietary technology who engages in activities with Defendants solely pursuant to a license agreement, is not, by virtue of those activities alone, a person in active concert or participation with Defendants or their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and customers, so long as those activities are with regard to product that will not be manufactured, distributed or marketed by Defendants, and will be marketed only pursuant to an approved application under 21 U.S.C. § 355 or in conformity with all of the requirements set forth in any of the FDA OTC drug monographs, 21 C.F.R. Part 330.

16. Defendants shall notify the District Director, FDA Dallas District Office, in writing at least fifteen (15) calendar days before any change in majority ownership, character, or name of any of their businesses, including incorporation, reorganization, bankruptcy, assignment, sale resulting in the emergence of a successor business or corporation, or any other change in the structure or identity of PharmaFab, Inc. or PFab, LP (or any of their subsidiaries), 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 ten (10) 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.

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 drug monograph expert, the auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, 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 all manufacturing, processing, packing, labeling, holding, and/or distributing any or all drug(s);

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

C. Revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Discontinue any or all studies involving human subjects;

F. Issue a safety alert; and/or

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

18. Any order issued pursuant to paragraph 17 shall issue from the District Director, FDA Dallas District Office, and shall specify the deficiencies or violations giving rise to the order.

A. Unless a different time frame is specified by FDA in its order, within five (5) business days after receiving an order pursuant to paragraph 17, Defendants shall notify FDA in writing either that (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific action taken or to be taken and the schedule for completing the action; or (2) Defendants do not agree with FDA's order.

B. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for the disagreement; in so doing, Defendants may also propose specific alternative actions and specific time frames for achieving FDA's objectives.

C. If Defendants advise FDA in writing that they do not agree with FDA's order, FDA will review Defendants' written notification and thereafter, in writing, affirm, modify, or withdraw its order, as the Agency deems appropriate. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable)

19. Any corrective action ordered pursuant to paragraph 17 shall continue until FDA notifies Defendants in writing that Defendants appear to be in compliance with the Act, its

implementing regulations, and the requirements of this Decree, and that the corrective action is no longer necessary. Defendants shall pay all costs of such corrective actions, including the costs of FDA supervision, inspections, investigations, analyses, examinations, reviews, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in paragraph 11 of this Decree. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

20. If Defendants fail to comply with any of the provisions of this Decree, including any time frame imposed by this Decree, then, on motion of the United States in this proceeding, Defendant PharmaFab, Inc., 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 equal to twice the retail value of each shipment of an unapproved or misbranded drug, in liquidated damages for each such unlawful shipment. The amount of liquidated damages in this paragraph shall not exceed five million dollars ($5,000,000) in any one calendar year. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

21. 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.

22. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be addressed to the District Director, FDA Dallas District Office, 4040 North Central Expressway, Suite 300, Dallas, Texas 75204.

23. If Defendants petition the Court for relief from this Decree and, at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with the Act, its implementing regulations, and this Decree for the sixty (60) months preceding the petition, Plaintiff will not oppose such petition.

24. 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.

and signed

SO ORDERED this 24 day of April, 2007.

UNITED STATES DISTRICT JUDGE

Entry consented to:

For Defendants

Mark T. Tengler
Individually and on behalf of
PharmaFab, Inc., as its President, and
PFab, LP, as its Manager

Russ L. McMahen
Individually and on behalf of
PFab, LP, as its Vice President of
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