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

UNITED STATES OF AMERICA,	§	
	§	
Plaintiff,	§	Civil Action No.
	§	
v.	§	4-07CV-238-A
	§	
PHARMAFAB, INC., a corporation, PFAB LP, d.b.a. PHARMAFAB, a limited partnership, and MARK T. TENGLER and RUSS L. McMAHEN, individuals,	§	
	§	
Defendants.	§	

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, plaintiff, by and through its undersigned counsel, and on behalf of the Food and Drug Administration (FDA), respectfully represents as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 332(a), to permanently enjoin the defendants, PharmaFab, Inc., a corporation, PFab, LP (PFab), doing business as PharmaFab, a limited partnership (collectively, "PharmaFab" unless otherwise noted), and Mark T. Tengler and Russ L. McMahen, individuals (collectively "Defendants"), from: (a) violating 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); (b) 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 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 that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); (d) 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); 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 that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

JURISDICTION

2. This Court has jurisdiction over the subject matter and over all parties to this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

VENUE

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant PharmaFab, Inc. has been incorporated under the laws of the state of Texas since 1994 and conducts business at 2940 North State Highway 360, Suite 100, Grand Prairie, Texas (the "facility"), within the jurisdiction of this Court. PharmaFab is the parent company of two subsidiary companies, which jointly own PFab, LP, as detailed below. All drug manufacturing is conducted by PFab.

5. Defendant PFab, LP d.b.a. PharmaFab, the manufacturing arm of PharmaFab, Inc, is a partnership established in 1999 between two PharmaFab, Inc., subsidiaries. The firm is a contract manufacturer that has manufactured, processed, packed, labeled, held, and distributed

over one hundred different drug products, including cough/cold products, postpartum hemorrhage products, and ulcer treatment products. PFab manufactured drug products for at least thirty-eight customers and was identified as the manufacturer on each customer's labels, but has not conducted any own-label manufacturing. PFab conducts business at the facility, within the jurisdiction of this Court.

6. Defendant Mark T. Tengler, an individual, is the President of PharmaFab, Inc. and Manager of PFab, LP. He is responsible for, and has authority over, all operations of PFab, including quality, manufacturing, purchasing, new product development, facilities, human resources, and finances. Mr. Tengler maintains an office and performs his duties at the facility.

7. Defendant Russ L. McMahen is the Vice President of Scientific Affairs of PFab, LP. He oversees the engineering staff and is responsible for equipment and process validation. His responsibilities include, but are not limited to product formulation and certifying PFab's facility, equipment, and systems for compliance with FDA regulations. Mr. McMahen maintains an office and performs his duties at the facility.

8. Defendants have been, and are now engaged in manufacturing, processing, packing, labeling, holding, and distributing drug products for a variety of uses, in both liquid and solid forms, that are drugs within the meaning of 21 U.S.C. § 321(g).

9. Defendants regularly manufacture drugs using components they receive in interstate commerce and introduce finished drug products into interstate commerce for shipment outside the state of Texas.

Adulterated Drugs

10. FDA's inspections of Defendants' facility beginning in 2004 established that the drug products being manufactured and distributed by Defendants were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that they were drugs, within the meaning of 21 U.S.C. § 321(g) and that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding did not conform to or were not operated or administered in conformity with FDA regulations establishing current good manufacturing practice (CGMP).

11. Compliance with the CGMP regulations, promulgated at 21 C.F.R. Parts 210 and 211, assures that drugs meet the requirements of the Act as to safety and have the identity and strength and meet the quality and purity characteristics that they purport or are represented to possess. Drugs not manufactured, processed, packed, or held in conformance with CGMP regulations are deemed adulterated as a matter of law, without any showing of actual defect.

12. FDA spent more than 20 days inspecting Defendants' facility from March 20 through May 2, 2006 (2006 Inspection). During this most recent inspection, FDA investigators documented 21 significant deviations from the CGMP regulations. These CGMP violations included, but were not limited to, the following:

A. Failure to record and justify deviations from written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, as required by 21 C.F.R. § 211.160(a);

B. Failure to test each batch of controlled-release dosage form drug product to determine conformance to the specifications for the rate of release for each active ingredient, as required by 21 C.F.R. § 211.167(c);

C. Failure to design an adequate written testing program to assess the stability characteristics of drug products to determine the appropriate storage conditions and expiration dates, as required by 21 C.F.R. § 211.166(a);

D. Failure to establish written procedures for reprocessing in-process batches to ensure that the reprocessed batches will conform to all established standards, specifications, and characteristics, as required by 21 C.F.R. § 211.115(a);

E. Failure of the quality control unit (QCU) to review drug product production and control records to determine compliance with all established approved written procedures before a batch is released and distributed, as required by 21 C.F.R. § 211.192; and

F. Failure of the QCU to follow written procedures, as required by 21 C.F.R. § 211.22.

13. The 2006 Inspection was conducted as a follow-up to violative inspections conducted from December 9, 2004, through February 17, 2005 (2004/2005 Inspection), and January 5 through January 14, 2004 (2004 Inspection). Both of these previous inspections showed substantially similar and equally serious CGMP violations as the 2006 Inspection. The failure to follow CGMP regulations also resulted in the submission of unreliable data to FDA as part of a customer's supplemental drug application. During the previous two inspections, FDA investigators made observations of deviations from CGMP including, but not limited to: failure to validate the performance of manufacturing processes; failure to develop and follow a complete written stability program; failure to have an effective quality control unit; failure to have

adequate procedures for, and investigations of, complaints and out-of-specifications (OOS) test results; failure to record and justify deviations from written procedures; failure to establish written procedures for reprocessing in-process batches; failure to thoroughly review a batch, or any of its components, following OOS test results; and failure to record and justify deviations from written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms.

14. Defendants violated the Act, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), as set forth above.

15. Defendants violated the Act, 21 U.S.C. § 331(k), by causing the adulteration (21 U.S.C. § 351(a)(2)(B)) of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Unapproved New Drugs

16. Defendants have been engaged in the manufacture, processing, packing, labeling, holding, and distribution of numerous unapproved new drugs that they have introduced or have caused to be introduced into interstate commerce, in violation of 21 U.S.C. § 331(d). These unapproved new drugs included, but were not limited to:

A. De-Congestine Sustained Release Capsules;
B. GFN 1200/DM 60/PSE 60 Extended-Release Tablets;
C. Rhinacon A Tablets;
D. Sudal 12 Chewable Tablets;
E Histex PD 12 Suspension;
F Atuss HX CIII;
G Ergotrate Tablets; and
H Hyoscyamine Sulfate Time-Release Capsules

17. Defendants' products are drugs within the meaning of 21 U.S.C. § 321(g) because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and/or are intended to affect the structure or any function of the body of man or other animals.

18. Defendants' drug products are "new drugs" within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Many of Defendants' drug products are deemed "new drugs" by regulation, 21 C.F.R. § 310.502(a)(14), in that they are timed release products.

19. Defendants' drug products lack approved new drug applications (NDA) or approved abbreviated new drug applications (ANDA) as required by 21 U.S.C. § 355. These drugs are not exempt under 21 U.S.C. § 355(i) from the Act's pre-market approval requirement. As a result, Defendants' drug products are unapproved new drugs within the meaning of 21 U.S.C. § 355(a).

20. Defendants introduce these unapproved new drugs, or cause them to be introduced, into interstate commerce, in violation of 21 U.S.C. § 331(d).

Misbranded Drugs

21. FDA's 2006 Inspection also revealed that the drugs listed in Paragraph 17 are misbranded. Defendants' prescription drugs are misbranded in that they are unapproved new drugs and in that they lack scientific evidence to demonstrate that these drugs are safe and effective as indicated in their directions for use, thus they cannot bear adequate directions for use

as required by 21 U.S.C. § 352(f)(1) and are not exempt from this requirement pursuant to 21 C.F.R. § 201.115.

Prior Warnings to Defendants

22. Defendants have received many prior warnings about their violative conduct. At the close of each inspection, FDA investigators issued a detailed List of Inspectional Observations (Form 483) to Defendants and discussed the violative conditions with management. During the inspections, the FDA investigators also provided verbal warnings that continued violations of the Act could result in further regulatory action.

23. On June 15, 2004, FDA issued a Warning Letter to Ms. Darlene M. Ryan, then-President of PharmaFab, Inc. and Manager of PFab, LP, emphasizing the serious nature of the CGMP deficiencies enumerated in the Form 483. The Warning Letter stressed that a failure to ensure that all products manufactured by the firm were in compliance with the Act and/or a failure to correct violations could lead to regulatory action, including seizure and/or injunction, without further notice.

24. On October 11, 2002, FDA issued a Warning Letter to Ms. Ryan in reference to unapproved single ingredient guaifenesin extended release products. The letter notified her that timed release drugs required an approved application prior to marketing. The letter also explained that failure to comply with the Act and regulations could lead to regulatory action, including seizure and injunction.

25. Defendants have made many promises to correct their violations of the Act. After FDA's most recent inspection, Defendants once again promised to correct their violations. Despite FDA's repeated warnings and Defendants' promises, FDA has documented little or no

improvement. Each inspection reveals Defendants' continued inability and/or unwillingness to operate in compliance with the Act.

26. The United States is informed and believes that, unless restrained by this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), (d), and (k) in the manner herein alleged.

RELIEF REQUESTED

27. That Defendants PharmaFab, Inc., PFab LP, d. b. a. PharmaFab, Mark T. Tengler, and Russ L. McMahen, 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, be enjoined from manufacturing, processing, packing, labeling, holding, or distributing articles of drug unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute articles of drug are established, operated, and administered in conformity with CGMP and the Act, in a manner that has been found acceptable by FDA; and

28. That 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, be 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(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);

B. 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 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 that are misbranded within the meaning of § 352(f)(1);

D. 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); 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 that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

29. That FDA be authorized pursuant to this injunction to inspect defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by defendants at the rates prevailing at the time the inspections are accomplished; and

30. That the Court award plaintiff United States costs and other such equitable relief as the Court deems just and proper.

Respectfully submitted,

RICHARD B. ROPER
UNITED STATES ATTORNEY

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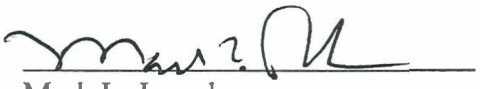
CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing complaint, certificate of interested parties, and consent decree were mailed via regular mail on this 20th day of April, 2007, to the following counsel for defendants:

Philip Katz, Esq.
Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004



Mark L. Josephs
Trial Attorney

COPY

JS 44 (Rev. 10/06)

CIVIL COVER SHEET

RECEIVED
U.S. DISTRICT COURT
NORTHERN DIST. OF TX

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

2007 APR 20 PM 2:04

CLERK OF COURT

I. (a) PLAINTIFFS

United States of America

DEFENDANTS

Pharmafab, Inc., et al.

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Tarrant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)
Mark Josephs, U.S. Dept. of Justice, P.O. Box 386
Washington, DC 20044 (202) 305-3630

Attorneys (If Known)
Philip Katz, Esq., Hogan & Hartson LLP

4-07CV-238-A

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☒ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☒ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881		☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	PROPERTY RIGHTS	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 820 Copyrights	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 830 Patent	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health	☐ 840 Trademark	☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 865 RSI (405(g))	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other			☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**): 21 U.S.C. §332(a)

Brief description of cause: Enjoin defendants from statutory violations in manufacture and distribution of drug products

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) PENDING OR CLOSED (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
4/19/07

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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

PLAINTIFF'S CERTIFICATE OF INTERESTED PARTIES

Pursuant to LR. 3.1(f) plaintiff United States of America represents that the interested parties in this case are: (1) the United States Department of Health and Human Services and its component agency the Food and Drug Administration; and (2) defendants PharmaFab, Inc., PFab LP, d.b.a. PharmaFab, Mark T. Tengler, and Russ McMahen.

Respectfully submitted,

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