

## SETTLEMENT AGREEMENT

This Settlement Agreement is entered into this 23<sup>rd</sup> day of June, 2004, by and between the United States of America, Department of Justice ("United States") acting through its United States Attorney's Office for the District of Connecticut and The P.F. Laboratories, Inc. of Totowa, New Jersey ("Laboratories").

### Recitals

1. As a result of an investigation of Laboratories that began in or around June, 2001, conducted by the United States Drug Enforcement Administration, Office of Diversion Control ("DEA"), the United States contends that Laboratories failed to keep accurate records concerning the manufacture of Oxycontin in Totowa, New Jersey. The United States also alleged that facilities related to Laboratories in Ardsley, New York and Wilson, North Carolina failed in certain instances to keep accurate records regarding the manufacture of the same substance.
2. The violations of as alleged by the United States fall into the following categories at the specified locations:
  - a. At Totowa, New Jersey there was a failure to:

maintain narcotic quality control logs and other readily retrievable records regarding controlled substances utilized in manufacturing or awaiting destruction or export; properly execute DEA 222 order forms; conduct complete and accurate inventories of controlled substances.
  - b. At Ardsley, New York, there was a failure to:

maintain acceptable and readily retrievable records regarding controlled substances utilized in manufacturing, and conduct a complete and accurate inventory and biennial inventory.

- c. At Wilson, North Carolina, there was a failure to:  
conduct a current, complete and accurate inventory.
3. The United States alleges that the above record keeping and reporting deficiencies violated provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et seq. ( the “Act”), and regulations promulgated under the Act.
4. Laboratories is a pharmaceutical company which in the ordinary course of business manufactures, stores and distributes controlled substances as defined by the Act, thereby requiring Laboratories to comply with the provisions set out in the Act and its implementing regulations.
5. Laboratories is registered with the Attorney General of the United States under the provisions of 21 U.S.C. § 822.
6. Pursuant to 21 U.S.C. § 842(c)(1), Laboratories is subject to a civil penalty of up to \$10,000 for each alleged violation.
7. The United States acknowledges that since the inspection of Laboratories’s facility in Totowa, New Jersey, and its related facilities in Ardsley, New York and Wilson, North Carolina, substantial steps have been taken to bring said facilities into full compliance with the Act and that said facilities have substantially remediated the alleged violations.
8. The parties have agreed to settle and compromise and resolve all existing claims under § 842(c)(1) of the Act that directly arise out of DEA’s investigation of Laboratories conducted from June 3, 2001 through June 28, 2002; and the DEA’s investigation of its related facility in Ardsley, New York from June 3, 2002 through July 29, 2002; and the DEA’s investigation of its related facility in Wilson, North Carolina from July 25, 2002

through November 4, 2002.

**Terms and Conditions of this Agreement**

In consideration of the mutual promises, covenants, and obligations set forth in this Settlement Agreement and for other good and valuable consideration as stated herein, the parties have agreed as follows:

9. Laboratories shall pay to the United States the sum of Two Million Dollars (\$2,000,000.00) (the "Settlement Amount") pursuant to this Settlement Agreement. The payment shall be made within ten business days of the signing of this Settlement Agreement by all of the parties. Payment shall be made by electronic funds transfer, in accordance with written instructions to be provided by the United States Attorneys Office, Financial Litigation Unit, New Haven, Connecticut. The costs of such electronic funds transfer shall be the responsibility of Laboratories. Laboratories shall send a copy of the electronic funds transfer transaction record, and the transmittal letter to Paralegal Specialist Rose Oren, Financial Litigation Unit, United States Attorneys Office, P.O. Box 1824, New Haven, Connecticut, 06508.
10. Notwithstanding any other provision of this Settlement Agreement, the settling parties understand that this Settlement Agreement expressly does ***not*** release Laboratories from:
  - (a) any criminal liability;
  - (b) any criminal, civil or administrative claims arising under Title 26 of the U.S. Code (Internal Revenue provisions);
  - (c) any claims for suspension or debarment that may be brought by an agency of the United States; and
  - (d) any other liability to the United States (or its agencies) for any violations of federal

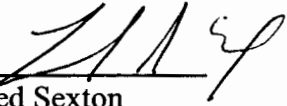
law other than those violations described in paragraph 2.

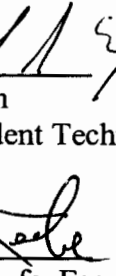
11. Except as provided in paragraph 10, the United States, in exchange for and in consideration of Laboratories's compliance with this Settlement Agreement, agrees to settle and relinquish all civil penalty claims arising under the Act or the regulations promulgated thereunder which were discovered during the course of DEA's investigation described in paragraph 1. The United States does not release Laboratories from any potential claims for personal injury, property damage or for other consequential damages other than those claims which are specifically released above. This release only binds the United States Attorney's Office for the District of Connecticut.
12. By entering into this Settlement Agreement, Laboratories does not admit to the conclusions reached as a result of the DEA investigation, at its facility in Totowa, New Jersey or its related facilities in Ardsley, New York and Wilson, North Carolina, or to any violation of law, liability, fault, misconduct, or wrongdoing. Laboratories has further alleged that it has defenses to the violations alleged by the United States.
13. Laboratories fully and finally releases the United States, its agencies, employees, servants, and agents from any claims(including attorneys fees, costs, and expenses of every kind and however denominated) which Laboratories could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the conduct that was the subject of DEA's investigation specifically described in paragraph #1 and the violations referred in paragraph 2.
14. Each party to this Settlement Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Settlement Agreement.

15. This Settlement Agreement, and the conditions contained herein, in no way prevents, precludes, or prejudices the United States' right to enforce the Act and the regulations promulgated thereunder by commencing a civil, criminal, or administrative action against Laboratories for any violations of the Act which occur at Laboratories after the date of execution of this Agreement, or which have previously occurred at Laboratories but are not presently known to the United States.
16. By this Settlement Agreement the United States agrees not to take action, through the DEA to suspend or revoke the DEA registration of Laboratories, pursuant to 21 U.S.C. § 824 and related statutory and regulatory provisions, on the basis of acts alleged in the Recitals above. However, in the event that the United States decides to initiate administrative proceedings to suspend or revoke the registration of Laboratories based on conduct occurring after the date of the execution of this Settlement Agreement, or for acts that have occurred but which the United States is presently unaware of, the United States shall not be precluded from relying upon this Settlement Agreement, the Recitals above, or the alleged violations giving rise to this Settlement Agreement, as evidence of Laboratories' history of compliance vel non with the Act and implementing regulations, or as substantive evidence to support revocation or suspension of Laboratories registration pursuant to 21 U.S.C. §§ 823 and 824. Nothing herein shall preclude Laboratories from raising any objections to such evidence. Similarly, Laboratories shall not be precluded from seeking to rely upon evidence of its substantial compliance enhancements at its facility in Totowa, New Jersey and its related facilities both prior to and subsequent to the execution of the Settlement Agreement as a basis for why such a revocation or suspension is unwarranted.

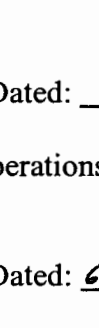
17. This Agreement shall be governed by the laws of the United States. The parties agree that the exclusive jurisdiction and venue for any dispute arising under this Agreement shall be the United States District Court for the District of Connecticut.
18. This document contains the complete agreement between the parties, and cannot be amended, except in writing and signed by all parties to this Agreement.
19. Laboratories hereby waives any defense it may have, based in whole or in part on the Double Jeopardy Clause of the Constitution to any criminal prosecutions or to any prosecutions, or civil or administrative proceedings based upon allegations unrelated to the subject matter of DEA's inspection of Laboratories and its related facilities in 2001 and 2002.
20. Laboratories acknowledges that a representative of its management has read this Agreement and understands that as of the date of its execution, it will be a matter of public record.
21. Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is duly authorized to do so.
22. The Parties to this Agreement acknowledge that the provisions and language of this Agreement have been negotiated, and agree that no provision of this Agreement shall be construed against any party by reason of such party having drafted such provision of this Agreement.
23. This Settlement Agreement shall become final and binding only upon signature by each party hereto.

**THE P.F. LABORATORIES, INC.**


By:  Dated: 6/17/04  
Fred Sexton  
Vice-President Technical Operations

By:  Dated: 6/16/04  
Hugh F. Keefe, Esq.  
Lynch, Traub, Keefe & Errante  
Attorney for The P.F. Laboratories, Inc.

**UNITED STATES OF AMERICA**

By:  Dated: 6/23/04  
Kevin J. O'Connor  
United States Attorney  
District of Connecticut

John B. Hughes, AUSA, Chief Civil Division  
District of Connecticut

By:  Dated: 6/23/04  
Alan Marc Soloway, Esq.  
Assistant U.S. Attorney  
District of Connecticut