

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:

LEINER HEALTH PRODUCTS INC., et al.,¹

Debtors.

)
) Chapter 11

)
) Case No. 08-10446 (KJC)

)
) Jointly Administered

)
) Hearing Date: May 30, 2008 at 11:00 a.m. (EDT)

)
) Objection Deadline: May 23, 2008 at 4:00 p.m. (EDT)

**DEBTORS' *AMENDED*² MOTION FOR ENTRY OF AN
ORDER APPROVING SETTLEMENT WITH
UNITED STATES DEPARTMENT OF JUSTICE**

The above-captioned debtors and debtors in possession (collectively, the "Debtors") file this amended motion (the "Amended Motion") seeking entry of an order, substantially in the form attached hereto as Exhibit A (the "Order"), approving a proposed plea agreement with the United States Department of Justice (the "DOJ"), substantially in the form attached hereto as Exhibit B. In further support of this Amended Motion, the Debtors respectfully state as follows:

Preliminary Statement

1. The Debtors seek authority to enter into a proposed plea agreement (the "Plea Agreement") that would resolve the investigations by the Food and Drug Administration (the "FDA") and the DOJ (the "DOJ Investigation") into over-the-counter ("OTC") pharmaceutical

¹ The Debtors in these cases, along with the last four digits of each Debtor's federal tax identification number, are: Leiner Health Products Inc. (1709), LHP Holding Corp. (7947), Leiner Health Products, LLC (6283) and Leiner Health Services Corp. (4464). The address for all Debtors is: 901 E. 233rd Street, Carson, California 90745.

² A blackline comparing this amended motion against the *Debtors' Motion for Entry of an Order Approving Settlement With United States Department of Justice* [Docket No. 288] (the "Original Settlement Motion"), filed May 9, 2008 is attached hereto Exhibit D.

manufacturing practices at the Debtors' Fort Mill, South Carolina facility. More specifically, the Debtors have determined, in their business judgment, that the proposed Plea Agreement (which is subject to possible revision and approval by the United States Attorney's Office for the District of South Carolina) is fair and reasonable. Accordingly, and as set forth more fully below, the Debtors submit that the proposed Plea Agreement is in the best interests of the estates and should be approved.

2. The DOJ Investigation has been one of the Debtors' biggest obstacles prior to and during these chapter 11 cases. Although the Debtors are confident in the quality and safety of their products, there is always risk and expense associated with regulatory investigations and resolving disputes through litigation. At this stage of the Chapter 11 Cases, the timely and efficient resolution of the DOJ Investigation is particularly important to the Debtors, as it provides greater comfort in the sale process to prospective purchasers. Moreover, the resolution of the ongoing DOJ Investigation would minimize the need to reserve for contingent DOJ claims under a chapter 11 plan. Indeed, without a settlement, the Debtors may be embroiled in costly litigation with the government that could hinder the success of these chapter 11 cases.

Jurisdiction

3. The Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 157 and 1334. This matter is a core proceeding within the meaning of 28 U.S.C. § 157(b)(2). Venue in this Court is proper pursuant to 28 U.S.C. §§ 1408 and 1409.

4. The statutory bases for the relief requested herein are sections 105(a), and 363(b) of title 11 of the United States Code, 11 U.S.C. §§ 101-1532 (the "Bankruptcy Code"), and Rule 9019 of the Federal Rules of Bankruptcy Procedure (the "Bankruptcy Rules").

Background

A. The DOJ Investigation

5. On March 16, 2007, the Debtors' principal operating subsidiary, Leiner Health Products, LLC ("Leiner") received a list of Inspection Observations on Form 483 from FDA inspectors. The Form 483 contained inspection observations relating to product quality and deficiencies in the Debtor's compliance with good manufacturing practices for OTC drug products manufactured, packaged or tested at its Fort Mill facility. In response to the Form 483 notice from the FDA, on March 20, 2007, Leiner immediately and voluntarily suspended the production and distribution of all OTC products manufactured, packaged or tested at its facilities in the United States, and subsequently hired an outside consulting firm to review all testing procedures.

6. Notwithstanding these drastic actions, on September 5, 2007, the United States District Court for the District of South Carolina (the "District Court") issued a search warrant upon the application of the United States Attorney's Office for the District of South Carolina and the FDA Office of Criminal Investigations. Pursuant to the warrant, the DOJ copied electronic servers containing all of the email accounts and electronic documents maintained by personnel at the Fort Mill facility, as well as numerous manufacturing, production, distribution, laboratory testing and personnel records.

7. The DOJ also served Leiner with grand jury subpoenas issued by the District Court requiring the production of documents (including all email correspondence and other correspondence, in whatever form) relating to the production, control and distribution of all OTC products maintained at the Fort Mill facility for the period of January 1, 2004 through September 5, 2007.

8. The Debtors immediately announced they would cooperate fully with the investigation and, to date, have done so in all respects. The Debtors negotiated with the United States Attorney's Office regarding the process of responding to the grand jury subpoenas, and the government agreed to an extension of the deadline for doing so. Under this arrangement, the Debtors began producing documents on a rolling basis. The Debtors then conducted an internal investigation that included interviewing witnesses, collecting and reviewing documents and producing responsive, non-privileged material to the United States Attorney's Office and to the FDA Office of Criminal Investigations.

B. The Effect of the DOJ Investigation on the Debtors' Businesses

9. The Debtors' customers are obviously concerned about the ongoing DOJ Investigation. On October 17, 2007, the FDA informed the Debtors they could distribute previously manufactured OTC products that have been verified by independent third-party product quality assessments. However, the FDA's qualified approval of the Debtors' re-entry into the OTC market did not resolve the DOJ's inquiry into certain practices at the Debtors' Fort Mill facility. Although the Debtors are ready, willing and able to resume sales of their OTC products, customers' concerns over the DOJ Investigation have rendered the Debtors virtually unable to do so.

10. The pending DOJ Investigation has also caused many of the Debtors' biggest customers to begin dual-sourcing their vitamins, minerals and nutritional supplements ("VMS") products, notwithstanding the fact that the DOJ Investigation was related only to OTC production. Indeed, the impact of the OTC issues on the VMS business has been significant, including lost market share in the amount of \$50 million, lost profits in the amount of \$10 million and pricing adjustments in the amount of \$40 million as a result of competitors' efforts to displace the Debtors' products.

11. In light of this commercial reality, the Debtors expedited their efforts to bring the DOJ Investigation to a conclusion. On numerous occasions, counsel for the Debtors spoke with the Office of the United States Attorney for the District of South Carolina about the facts of the case and on February 19, 2008, the Debtors' counsel, Chairman of the Board of Directors and President and Chief Executive Officer met with the United States Attorney to provide detailed information about the Debtors' deteriorating financial situation and their impending bankruptcy filing, in an endeavor to negotiate a resolution of the DOJ Investigation. On March 10, 2008 (the "Petition Date"), each of the Debtors filed a petition with the Court under chapter 11 of the Bankruptcy Code (collectively, the "Chapter 11 Cases").

C. The Proposed Plea Agreement

12. The DOJ Investigation relates to Leiner's alleged failure to comply with certain federal regulations setting forth manufacturing specifications for pharmaceutical products, known as Current Good Manufacturing Practices ("cGMPs"). One cGMP requirement involves stability testing, which measures the shelf-life of a drug or the length of time during which the drug will have the appropriate identity, strength, quality and purity. The DOJ concluded that certain stability testing at the Ft. Mill facility demonstrated that a number of the OTC products being manufactured by Leiner failed to meet required specifications at the expiration date in violation of cGMPs. In particular, the DOJ alleges that on or about December 13, 2006, Leiner's Quality Control department gave the false appearance that certain drugs had passed stability testing, and allowed the nonconforming drugs to be shipped to a customer.³ The DOJ's

³ Importantly, the Debtors hired a new head of Quality Control in July 2007. See Declaration of Robert K. Reynolds, President, Chief Executive Officer and Director of Leiner Health Products Inc. in Support of First Day Pleadings, filed on March 10, 2008 [Docket No. 14] ¶ 52.

allegations are set forth in greater detail in the proposed Information, which is substantially in the form attached hereto as Exhibit C.

13. Following extensive negotiations between the Debtors and the United States Attorney's Office for the District of South Carolina, the parties reached a tentative agreement under which Leiner would plead to one count of mail fraud pursuant to 18 U.S.C. § 1341 and forfeit a total of \$10 million in cash. The obligations and privileges of the proposed Plea Agreement would bind and inure to all of the Debtor entities, including Leiner Health Products Inc. and LHP Holding Corp. The DOJ would retain the right to void all of its obligations under the Plea Agreement, and Leiner would not have the right to withdraw its plea, if Leiner were to fail to comply with any provision of the Plea Agreement.

14. Under the proposed Plea Agreement, Leiner would consent to:

- a. the entry of a money judgment in the amount of \$10 million, payable on the date of sentencing;
- b. forfeit its interests in and not contest the money judgment, or prevent the disbursement and encumbrance of the money judgment;
- c. forego any objection to civil forfeiture proceedings or any other steps taken by the DOJ to collect the judgment; and
- d. pay a \$400 special assessment.

15. The Government would agree to recommend that the District Court impose the \$10 million forfeiture in lieu of a fine as a sentence. However, the District Court may require the Debtors to make full restitution in an amount to be determined at sentencing. While the DOJ would not recommend that restitution be imposed, it would not take a position against the District Court's doing so.

16. In addition, the DOJ would agree not to prosecute any of the Debtor entities for conduct which (a) falls within the scope of the DOJ Investigation or (b) was known by the DOJ

prior to the date of execution of the Plea Agreement. The DOJ acknowledges that it is aware of the allegations in the Form 483 dated March 16, 2007, the Warning Letter dated August 28, 2007, and the affidavit in support of the search warrant executed on September 5, 2007, and that the number of lots identified in the investigation is a reasonable approximation of the extent of the affected lots. The DOJ would not further prosecute the Debtors for other lots with respect to the allegations in the Form 483, the Warning Letter, and the search warrant affidavit concerning the production, testing, and distribution of OTC products at the Ft. Mill facility. The DOJ would agree not to prosecute because it is not aware of any allegations of adverse health effects relating to the matters alleged in the Form 483, the Warning Letter, and the search warrant affidavit. However, the DOJ's non-prosecution obligation would not apply should adverse health effects resulting from the alleged wrongful conduct arise in the future. This non-prosecution obligation would be expressly contingent on (a) Leiner's guilty plea being accepted by the Court and not withdrawn; and (b) Leiner's performance of all of its material obligations as set forth in the Plea Agreement.

17. The DOJ would expressly reserve the right to prosecute any individual in connection with the conduct encompassed by the Plea Agreement, and the Debtors would agree to cooperate with the DOJ, including the DOJ's possible prosecution of any individuals, by providing full, complete and truthful information about any criminal activities about which they had knowledge. The Debtors would also agree to provide any documents or other evidence to the DOJ and to testify, through their authorized agents, before grand juries or at trials and other proceedings if called upon to do so by the DOJ.

Relief Requested

18. By this Amended Motion, the Debtors respectfully request entry of the proposed order: (a) authorizing the Debtors to enter into and implement the proposed Plea Agreement in

accordance with the intent of the parties, and (b) approving the forfeiture of \$10 million in accordance with the terms of the proposed Plea Agreement.

Basis for Relief

19. The proposed Plea Agreement between the Debtors and the DOJ represents a compromise and settlement of the DOJ Investigation and is, therefore, subject to approval by the Court under Bankruptcy Rule 9019(a). See In re Adelpia Communications Corp., Case No. 02-41729 (REG) (Bankr. S.D.N.Y. May 26, 2005) (approving settlement agreement between the debtors and the DOJ); In re Aerovias Nacionales de Columbia S.A. Avianca, Case No. 03-11678 (ALG) (Bankr. S.D.N.Y. Nov. 8, 2004) (approving a settlement between the debtors and the U.S. Attorney for the Southern District of New York); In re Precision Specialty Metals, Inc., Case No. 01-2411 (MFW) (Bankr. D. Del. June 23, 2004) (approving a plea agreement with the State of California); In re WorldCom, Inc., Case No. 02-13533 (AJG) (Bankr. S.D.N.Y. May 4, 2004) (approving a settlement agreement between the debtors and the DOJ).

20. Settlements and compromises are “a normal part” of the chapter 11 process. Protective Comm. for Indep. Stockholders of TMT Trailer Ferry, Inc. v. Anderson, 390 U.S. 414, 424 (1968) (citations omitted). Indeed, “compromises are favored in bankruptcy” because they minimize litigation and expedite the administration of a bankruptcy estate. See In re Martin, 91 F.3d 389, 393 (3d Cir. 1996); see also In re Key3Media Group, Inc., 2006 WL 2842462, at *3 (D. Del. 2006).

21. In exercising its discretion to approve a particular settlement, a bankruptcy court must determine that the proposed settlement is fair, reasonable and in the best interests of the debtor’s estate. See Martin, 91 F.3d at 394; In re Marvel Entm’t Group, Inc., 222 B.R. 243, 249 (D. Del. 1998) (“[T]he ultimate inquiry [is] whether ‘the compromise is fair, reasonable, and in the interest of the estate.’”) (citation omitted).

22. The proposed settlement need not be the best result that the debtor could have achieved, but only must fall “within the reasonable range of litigation possibilities.” Key3Media Group, 2006 WL 2842462, at *3; In re World Health Alternatives, Inc., 344 B.R. 291, 296 (Bankr. D. Del. 2006) (citing In re Penn Cent. Transp. Co., 596 F.2d 1102, 1114 (3d Cir. 1979)). A proposed settlement falls within the reasonable range of litigation possibilities if a proponent can demonstrate that the settlement does not fall “below the lowest point in the range of reasonableness.” World Health Alternatives, 344 B.R. at 296 (citations omitted); see also In re Neshaminy Office Bldg. Assocs., 62 B.R. 798, 803 (E.D. Pa. 1986).

23. The standard by which bankruptcy courts evaluate the reasonableness of a proposed compromise and settlement is well established. This standard includes consideration of the following four factors: “(1) the probability of success in litigation; (2) the likely difficulties in collection; (3) the complexity of the litigation involved, and the expense, inconvenience and delay necessarily attending it; and (4) the paramount interest of the creditors.” Martin, 91 F.3d at 393; see also In re Nutraquest, Inc., 434 F.3d 639, 644-45 (3d Cir. 2006). Under these factors, the Debtors submit that the proposed Plea Agreement represents a fair and reasonable compromise that falls well within the range of reasonableness. Because the proposed Plea Agreement with the DOJ satisfies the Third Circuit’s standard for approval of a settlement, the Debtors should be authorized to enter into the Plea Agreement pursuant to Bankruptcy Rule 9019.

A. The Probability of Success in Litigation

24. The failure to resolve the pending DOJ Investigation could jeopardize the success of these Chapter 11 Cases. As an initial matter, a criminal indictment:

- a. could cause customers to immediately discontinue purchasing products (including VMS) from the Debtors;

- b. may constitute an "Event of Default" under their debtor-in-possession ("DIP") financing, providing the lenders with the right to accelerate repayment of the borrowings thereunder; and
- c. could severely diminish the quality of bids received by the Debtors in the proposed sale.

25. Even if the DOJ continued its investigation rather than immediately seeking an indictment, the success of these Chapter 11 Cases would be jeopardized, as there is no question that the pendency of a criminal investigation would hamper the Debtors' sale efforts and severely chill bidding. Because either scenario would be detrimental to all parties in interest, the Debtors believe a settlement of the DOJ's claims is in the best interests of the estates.

26. Furthermore, if the Debtors were found guilty, they would face the prospect of significantly greater governmental fines. Generally, the maximum statutory fine per felony is the greater of \$500,000 or twice the defendant's gross gain or gross loss to others. See 18 U.S.C. § 3571. Under the U.S. Sentencing Guidelines, the calculation of a criminal fine is based upon a consideration of numerous factors. Here, after lengthy negotiations between the Debtors and the DOJ concerning an appropriate settlement amount, the government agreed to take into account, among other things, the Debtors' current ability to pay and the Debtors' acceptance of responsibility. One factor impacting the government's assessment of the Debtors' acceptance of responsibility is the Debtors' entry of a plea of guilty. If the proposed Plea Agreement is not approved, the Debtors may lose the benefit of the government's current favorable position regarding its ability to pay and its acceptance of responsibility.

27. Moreover, any criminal fine assessed by a court against the Debtors may not be dischargeable in these Chapter 11 Cases, because section 3613(e) of title 18 of the United States

Code (the "Criminal Code") provides that a bankruptcy discharge does not affect a debtor's liability for criminal fines.⁴ Since a criminal fine may not be dischargeable, the DOJ could argue that the Debtors' proposed sale under section 363(f) of the Bankruptcy Code is inappropriate under the circumstances.

28. Given the serious nature of the DOJ's claims and the potential consequences an indictment or conviction would have in these Chapter 11 Cases, the Debtors aver that settlement in these circumstances is appropriate.

B. The Difficulties Encountered in Collection

29. The Debtors intend to file a proposed plan and disclosure statement by the end of May 2008. If resolution of the DOJ's claims is delayed past confirmation of a plan in these Chapter 11 Cases, the Debtors may have to reserve for such claims for an unknown period of time. These reserves would reduce initial distributions to holders of allowed claims and potentially delay the effective date of a confirmed plan. To avoid such a delay, the Debtors believe entry into the proposed Plea Agreement is appropriate.

C. The Complexity, Expense and Inconvenience of Litigation and the Attendant Delay

30. Any continuation of the DOJ proceedings necessarily will be complex, given the breadth of the subpoena. Even if the Debtors were ultimately successful in defending against the DOJ's claims, they could expend substantial resources in the process. It could take months, if not years, for the DOJ to complete its investigation and prosecution of the Debtors, requiring the Debtors to dedicate significant resources to their defense. Indeed, the Debtors have already spent

⁴ Pursuant to section 3613 of the Criminal Code, "[n]o discharge of debts in a proceeding pursuant to any chapter of title 11, United States Code, shall discharge liability to pay a fine pursuant to this section, and a lien filed as prescribed by this section shall not be voided in a bankruptcy proceeding." See 18 U.S.C. § 3613(e).

many hours conducting an internal investigation, interviewing witnesses and producing over 41,000 pages of material in response to the grand jury subpoenas.

31. Moreover, if the Debtors are convicted, the financial consequences could be dire. If the Plea Agreement is not approved, the DOJ may seek a fine significantly higher than the money judgment provided for in the proposed Plea Agreement. Pursuant to section 3613(c) of the Criminal Code, “a fine imposed pursuant to the provisions . . . of this title . . . is a lien in favor of the United States on all property and rights to property of the person fined as if the liability of the person fined were a liability for a tax assessed under the Internal Revenue Code of 1986. . . .” In other words, without a settlement, the Debtors risk the imposition of a substantial fine, secured by all the Debtors’ assets. But under the proposed Plea Agreement, the Debtors will achieve certainty with respect to the amount of the judgment (\$10 million) and the source of payment. Depending on the timing of the Debtors’ sentencing, the money judgment will either be assumed by the purchaser (as required by the Debtors’ bidding procedures) or paid in full directly out of sale proceeds or DIP proceeds (as reflected in the revised DIP budget). This certainty ultimately benefits the Debtors’ unsecured creditors, who would be junior to any liens imposed under section 3613 of the Criminal Code. Accordingly, the Debtors submit that the proposed Plea Agreement is fair and reasonable.

D. The Paramount Interests of Creditors

32. If the proposed Plea Agreement is not approved by the Court, the Debtors’ creditors would be negatively affected in several ways. First, without the Plea Agreement, it will be more difficult for the Debtors to determine creditors’ distributions under a proposed chapter 11 plan. If the Debtors are assessed a hefty criminal fine, the Debtors’ payments under a plan will increase significantly, which will reduce distributions to unsecured creditors. Second, with the DOJ Investigation pending, the Debtors’ ability to realize value in the sale process is limited.

Not surprisingly, prospective purchasers have expressed concern over the DOJ Investigation and the Debtors' potential criminal liability. The proposed Plea Agreement, if approved, would not only motivate prospective purchasers to submit a bid, but it would also encourage higher quality bids in terms of both price and terms. Finally, the Debtors' creditors necessarily will incur much of the negative consequences of any ongoing investigation by the DOJ, including shouldering their share of the burdensome costs and expenses to the estates. The proposed Plea Agreement is therefore in the best interests of the Debtors' creditors.

33. In sum, the Debtors have determined, exercising their business judgment, that the proposed Plea Agreement is fair, equitable and reasonable. Moreover, the timely resolution of the DOJ claims is in the best interests of the Debtors' estates and their creditors. Accordingly, the Debtors respectfully request that the Court authorize their entry into the proposed Plea Agreement pursuant to Bankruptcy Rule 9019.

Notice

34. The Debtors have provided notice of this Amended Motion by Federal Express, overnight mail or overnight courier service to: (a) the Office of the United States Trustee for the District of Delaware; (b) counsel to the official committee of unsecured creditors; (c) counsel to the agent for the Debtors' postpetition secured lenders; (d) counsel to the agent for the Debtors' prepetition secured lenders; (e) the Internal Revenue Service; (f) the Securities and Exchange Commission; (g) the United States Department of Justice; (h) the Food and Drug Administration; (i) the Federal Trade Commission; (j) the indenture trustee for each of the Debtors' outstanding bond issuances; (k) counsel to the ad hoc group of the Debtors' senior subordinated bondholders; (l) counsel to the Debtors' equity sponsors; and (m) any persons who have filed a request for

notice in the above-captioned cases pursuant to Bankruptcy Rule 2002. In light of the nature of the relief requested, the Debtors respectfully submit that no further notice is necessary.⁵

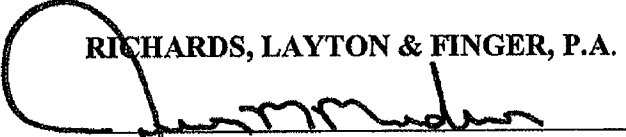
No Prior Request

35. Except to the extent of the relief sought in the Original Settlement Motion, no prior motion for the relief requested herein has been made to this or any other court.

WHEREFORE, for the reasons set forth herein, the Debtors respectfully request that the Court enter the order, substantially in the form annexed hereto as **Exhibit A**.

Dated: May 16, 2008
Wilmington, Delaware

RICHARDS, LAYTON & FINGER, P.A.



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Possession

⁵ Pursuant to Bankruptcy Rule 2002(a)(2), the Debtors provided 20 days' notice of the Original Settlement Motion and, consequently, submit that notice of the Original Settlement Motion and this Amended Motion is sufficient and appropriate.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ROCK HILL DIVISION

UNITED STATES OF AMERICA)	CRIMINAL NO. _____
)	
v.)	
)	
LEINER HEALTH PRODUCTS, LLC)	INFORMATION

THE UNITED STATES ATTORNEY CHARGES:

COUNT 1
(MAIL FRAUD)

At times relevant to this Information:

1. Leiner Health Products, LLC (hereinafter "Leiner") is a company that, along with its corporate parent, affiliates, and subsidiaries, manufactured and distributed over-the-counter (OTC) drugs, as well as vitamins, minerals, and nutritional supplements, and was headquartered in Carson, California. Leiner had a manufacturing and testing facility in Ft. Mill, South Carolina.

2. Leiner manufactured various over-the-counter (OTC) drugs, including Ibuprofen, APAP allergy medication, Diphenhydramine, Diphenhydramine HCl, Bisacodyl, Naproxen Sodium, and Loratadine. These drugs were sold to retailers throughout the United States, who predominantly marketed them under private, store-brand labels, and also under Leiner's own brand, Pharmacist Formula.

3. Pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 301 *et seq.*, drugs are deemed adulterated if they are not manufactured in

conformity with Current Good Manufacturing Practice (cGMP). 21 U.S.C. § 351(a)(2)(B). The cGMP regulations, set out in parts 210 and 211 of Title 21 of the Code of Federal Regulations, outline requirements for all aspects of drug manufacture, including, among other things, for laboratory controls, testing, and keeping records and making reports. Minimum current good manufacturing practice for drugs required, among other things, that manufacturers follow a written testing program designed to assess the stability characteristics of drug products. The results of this testing were required to be used in determining appropriate storage conditions and expiration dates. 21 C.F.R. § 211.166.

4. As part of the production process, Leiner tested drugs to verify conformance with final specifications for the drug product, as is required by cGMP. The results of the tests were then evaluated, and each shipment of drugs from Leiner was required to meet the requisite standards for identity, strength, quality, and purity as described in the specifications.

5. Tests for Leiner's OTC drugs were conducted at the Ft. Mill facility. The tests included stability testing. Stability testing demonstrates the shelf-life of a drug, that is, the length of time during which the drug will have the appropriate identity, strength, quality, and purity. Stability testing is conducted on groups of drugs (commonly referred to as "lots") pulled during the production process as representative samples of a particular drug line.

6. For certain of the OTC drugs, tests conducted at the Leiner Ft. Mill facility yielded failing results with respect to required specifications for identity, strength,

quality, and purity during the time of possible use by the consumer, that is, the time between the distribution and the labeled expiration date. However, the Leiner Quality Control (QC) department manipulated or falsified test data to give the appearance that the drugs actually had passed the tests. Leiner failed to disclose the accurate test data to its customers, and as a result, it distributed OTC drugs to retailers when, in fact, Leiner knew they were adulterated and not produced in accordance with cGMP.

7. Between 2004 and 2007, at least 33 stability lots failed. These stability lots were representative samples of seven different product lines manufactured and distributed by Leiner. These stability lots corresponded to approximately 1,275 batches of drugs that were placed into commerce by Leiner.

8. On or about December 13, 2006, in the District of South Carolina, Leiner, for the purpose of executing, and attempting to execute, the above-described scheme and artifice to defraud, knowingly caused to be sent by a commercial interstate carrier, from the Leiner facility in Ft. Mill, South Carolina, to an Eckerd Drugs facility in Liverpool, New York, Ibuprofen 200 mg. Tablets, listed in Leiner invoice #545960 and required to have been produced in accordance with cGMP, when in fact, as Leiner then well knew, the drugs had failed testing administered at the Ft. Mill facility, and the test results had been deliberately falsified and manipulated by Leiner.

In violation of Title 18, United States Code, Section 1341.

FORFEITURE ALLEGATIONS

1. MAIL FRAUD

As a result of the foregoing violation of 18 U.S.C. § 1341 (Mail Fraud), as charged in Count 1 of this Information, upon conviction, the Defendant, Leiner, shall forfeit to the United States any property, real or personal, which constitutes or is derived from any proceeds the Defendant obtained, directly or indirectly, as a result of such violation, and any property traceable to such property.

2. Pursuant to 18 U.S.C. §§ 981(a)(1)(C), 982(a)(2)(A), 982(b)(1), and 28 U.S.C. § 2461(c), the property which is subject to forfeiture upon conviction of the Defendant for the violation charged in Count 1 of this Information includes, but is not limited to, the following:

Cash/Money Judgment:

The sum of \$10,000,000 (ten million dollars) in United States currency, and all interest and proceeds traceable thereto, in that such sum in the aggregate constitutes proceeds the Defendant obtained, directly or indirectly, as a result of its violation of 18 U.S.C. § 1341 as charged in Count 1;

3. Substitute Assets

If any of the property described above, as a result of any act or omission of the Defendant - -

- (1) cannot be located upon the exercise of due diligence;
- (2) has been transferred or sold to, or deposited with, a third party;
- (3) has been placed beyond the jurisdiction of the court;
- (4) has been substantially diminished in value; or

(5) has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to 21 U.S.C. § 853(p) as incorporated by 18 U.S.C. § 982(b)(1) and 28 U. S. C. 2461(c), to seek forfeiture of any other property of the said Defendant up to the value of the forfeitable property described above.

All pursuant to Title 18, United States Code, Sections 981(a)(1)(C), 982(a)(2)(A) and 982(b)(1); and Title 28, United States Code, Section 2461(c).

KEVIN F. McDONALD (WDHjr)
ACTING UNITED STATES ATTORNEY

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ROCK HILL DIVISION

UNITED STATES OF AMERICA)
) Criminal No.:
 v.)
)
 LEINER HEALTH PRODUCTS, LLC) **PLEA AGREEMENT**

General Provisions

This PLEA AGREEMENT is made this _____ day of _____,
2008, between the United States of America, as represented by Acting United States
Attorney KEVIN F. McDONALD, Assistant United States Attorney WINSTON D.
HOLLIDAY, JR., the Defendant, **LEINER HEALTH PRODUCTS, LLC (hereinafter**
"LEINER"), and Defendants' Attorneys, J. PRESTON STROM, JR., Esquire, and
STEPHEN P. ANTHONY, Esquire. IN CONSIDERATION of the mutual promises made
herein, the parties hereto agree as follows:

1. The Defendant, **LEINER**, agrees to waive Indictment and arraignment, and plead
guilty to a one-count Information, charging MAIL FRAUD, in violation of Title 18, United
States Code, § 1341.

In order to sustain its burden of proof as to this offense, the Government is
required to prove the following:

On or about December 13, 2006, in the District of South Carolina, the Defendant

- (A) Knowingly devised or knowingly participated in a scheme or artifice to
defraud or to obtain money or property by means of false or fraudulent
pretenses, representations, or promises as detailed in the Information; and
- (B) In advancing, or furthering, or carrying out this scheme to defraud or to

obtain property by means of false or fraudulent pretenses, representations, or promises, the defendant used the mails, or a private or commercial interstate carrier, or caused them to be used; and

(C) The defendant acted with intent to defraud.

Possible Penalties for 18 U.S.C. § 1341

\$500,000 fine, or twice the gross gain or loss
\$400 special assessment

2. The Defendant agrees to provide detailed financial information to the United States Probation Office prior to sentencing. The Defendant further understands and agrees that any monetary penalty imposed is not dischargeable in bankruptcy.

(A) Fines: The Defendant understands and agrees that the Court may impose a fine pursuant to 18 U.S.C. §§ 3571 and 3572, which fine may be due and payable immediately after sentencing regardless of whether the Defendant has the money to pay the fine. In the event the Defendant does not have the money, the Defendant understands and agrees that the Court may establish a payment schedule, taking into account the Defendant's present and future means of earning money, or of obtaining money to pay the fine.

(B) Restitution: The Defendant agrees to make full restitution under 18 U.S.C. § 3556 in an amount to be determined by the Court at the time of sentencing, which amount is not limited to the count(s) to which the Defendant pled guilty, but will include restitution to each and every identifiable victim who may have been harmed by its scheme or pattern of

criminal activity, pursuant to 18 U.S.C. § 3663. The Defendant agrees to cooperate fully with the government in identifying all victims. The Defendant understands and agrees that full payment of restitution is due immediately after sentencing unless the Court provides, in the interest of justice, for payment on a date certain or in installments over the shortest time in which full payment can be reasonably made. The Defendant further understands and agrees that the government will seek enforcement of any order of restitution, and reserves the right to petition the Court at a later date to increase the amount of any installment payments toward restitution in the interest of justice. Recognizing the Court's statutory obligation to provide restitution to the victims of the Defendant's conduct, the parties agree that fashioning an order of restitution in this case would unduly prolong and complicate the sentencing process, as noted 18 U.S.C. § 3556(a)(1)(B)(ii). This is largely due to the difficulty of identifying and verifying a definable list of victims; that is, those who can demonstrate they purchased over-the-counter drugs manufactured by the Defendant that fall within the problem batches covered by this Agreement. As such, the parties agree that forfeiture is a more appropriate remedy in this instance than restitution.

- (C) Special Assessment: Pursuant to 18 U.S.C. § 3013, the Defendant must pay a special assessment of \$400 for each felony count for which it is

convicted. This special assessment must be paid at or before the time of the guilty plea hearing.

3. The Defendant understands that the matter of sentencing is within the sole discretion of the Court and that the sentence applicable to Defendant's case will be imposed after the Court considers as advisory the United States Sentencing Commission Guidelines, Application Notes and Policy Statements, as well as the factors set forth in Title 18, United States Code, Section 3553(a). The Defendant also understands that Defendant's sentence has not yet been determined by the Court, and that any estimate of a probable sentencing range Defendant may have received from Defendant's attorneys, the Government, or the United States Probation Office is only a prediction, not a promise, and is not binding on the Government, the Probation Office or the Court. The Defendant further understands that the Government retains the right to inform the Court of any relevant facts, to address the Court with respect to the nature of the offense, to respond to questions raised by the Court, to correct any inaccuracies or inadequacies in the presentence report, to respond to any statements made to the Court by or on behalf of the Defendant, and to summarize all evidence which would have been presented at trial to establish a factual basis for the plea.

4. The Defendant agrees that all facts that determine its offense level under the Guidelines and pursuant to any mandatory minimum (including facts that support any specific offense characteristic or other enhancement or adjustment) can be found by the Court at sentencing by a preponderance of the evidence standard and the Court may

consider any reliable evidence, including hearsay. By executing this Agreement, the Defendant understands that it waives any argument that facts that determine its offense level under the Guidelines and pursuant to any mandatory minimum should be alleged in an indictment and found by a jury beyond a reasonable doubt.

5. The Defendant understands that the obligations of the Government within the Plea Agreement are expressly contingent upon the Defendant's abiding by federal and state laws.

6. In the event that the Defendant fails to comply with any of the provisions of this Agreement, either expressed or implied, it is understood that the Government will have the right, at its sole election, to void all of its obligations under this Agreement and the Defendant will not have any right to withdraw its plea of guilty to the offense enumerated herein.

Cooperation and Forfeiture

7. The Defendant agrees to be fully truthful and forthright with federal, state and local law enforcement agencies by providing full, complete and truthful information about all criminal activities about which it has knowledge. The Defendant must provide full, complete and truthful debriefings about these unlawful activities and must fully disclose and provide truthful information to the Government including any books, papers, or documents or any other items of evidentiary value to the investigation. The Defendant through its duly authorized agents must also testify fully and truthfully before any grand juries and at any trials or other proceedings if called upon to do so by the

Government, subject to prosecution for perjury for not testifying truthfully. The failure of the Defendant to be fully truthful and forthright at any stage will, at the sole election of the Government, cause the obligations of the Government within this Agreement to become null and void. Further, it is expressly agreed that if the obligations of the Government within this Agreement become null and void due to the lack of truthfulness on the part of any duly authorized agent of the Defendant, the Defendant understands that:

- (A) the Defendant will not be permitted to withdraw its plea of guilty to the offenses described above;
- (B) all additional charges known to the Government may be filed in the appropriate district;
- (C) the Government will argue for a maximum sentence for the offense to which the Defendant has pleaded guilty; and
- (D) the Government will use any and all information and testimony provided by the Defendant in the prosecution of the Defendant of all charges.

8. The Government agrees that any self-incriminating information provided by the Defendant as a result of the cooperation required by the terms of this Agreement, although available to the Court, will not be used against the Defendant in determining the Defendant's applicable guideline range for sentencing pursuant to the U.S. Sentencing Commission Guidelines. The provisions of this paragraph shall not be applied to restrict any such information:

- (A) known to the Government prior to the date of this Agreement;
- (B) concerning the existence of prior convictions and sentences;
- (C) in a prosecution for perjury or giving a false statement; or
- (D) in the event the Defendant breaches any of the terms of the Plea Agreement.

9. The Defendant consents to the entry of a personal money judgment against the Defendant and in favor of the United States in the amount of ten million dollars (\$10,000,000) in United States currency, as of the date of entry of judgment. The full amount of the money judgment is payable on or before the date of sentencing.

The Defendant agrees to forfeit all interests in and not to contest the \$10,000,000 forfeiture by the United States of America. The Defendant further agrees to prevent the disbursement, relocation or encumbrance of this money and agrees to fully assist the government in the recovery and return to the United States of the money, or portions thereof, as described above, wherever located. The Defendant further agrees to make a full and complete disclosure of all assets over which Defendant exercises control and those which are held or controlled by nominees. The Defendant further agrees to submit appropriate documentation, sworn to under penalty of perjury, on the issue of assets if it is deemed necessary by the United States.

Should it become necessary to collect on the money judgment, the Defendant agrees to take whatever steps are necessary to convey to the United States of America title to other assets and property up to the value of the unpaid judgment. These steps

include, but are not limited to, the surrender of title and the signing of any other documents necessary to effectuate such transfers. The Defendant agrees not to object to any civil forfeiture proceedings brought against any assets or properties pursuant to any provision of law and the Defendant further understands that any such civil proceedings may properly be brought if the agreed-upon installment payments are not timely made. Defendant also agrees to waive any double jeopardy claims it may have as a result of the forfeiture of such assets or properties as provided for by this Agreement.

No Further Prosecution: Government's Recommendation Regarding Sentencing

10. Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(A), the Government agrees that, other than the charge in the Information, it shall not further prosecute Leiner Health Products LLC or any corporate parent, subsidiary, or affiliate thereof for conduct which (a) falls within the scope of the Information or (b) was known to the U.S. Attorney's Office prior to the date of execution of this Agreement. The parties agree that the U.S. Attorney's Office is aware of the allegations in the FDA Form 483 dated March 16, 2007, the FDA Warning Letter dated August 28, 2007, and the affidavit in support of the search warrant executed on September 5, 2007. The parties agree that the number of lots identified in the Information is a reasonable approximation of the extent of the affected lots, and the Government will not further prosecute Leiner for other lots with respect to the allegations in the FDA Form 483, the FDA Warning Letter, and the search warrant affidavit concerning the production, testing, and distribution of

OTC products at the Ft. Mill facility. The U.S. Attorney's Office is not aware of any allegations of adverse health effects relating to the matters alleged in the FDA Form 483, the FDA Warning Letter, and the search warrant affidavit, and the Government's non-prosecution obligation shall not apply to any such allegations in the event such allegations should arise in the future. The Government's non-prosecution obligation in this paragraph is expressly contingent on: (1) the guilty plea of Leiner Health Products LLC being accepted by the Court and not withdrawn; and (2) Leiner Health Products LLC's performance of all of its material obligations as set forth in this Agreement. The Government expressly reserves the right to prosecute any individual in connection with the conduct encompassed by this Agreement.

11. Pursuant to Federal Rule of Criminal Procedure 11(c)(1)(B), the Government agrees that it will recommend to the Court that (a) the Defendant be sentenced to pay the sum of ten million dollars (\$10,000,000) as a forfeiture in lieu of a fine; and (b) that the Defendant be required to pay a special assessment of \$400.

Corporate Authorization

12. The Defendant's acknowledgment of this Agreement and execution of this Agreement is evidenced by the signature of its corporate officer below. The Defendant shall provide to the Government and to the Court a resolution of the Board of Directors of Leiner, affirming that the Board of Directors has authority to enter into this Agreement and has (1) reviewed the Information in this case and this Agreement or has been advised of the contents thereof; (2) consulted with the Defendant's legal counsel in

connection with the matter; (3) voted to enter into the proposed Plea Agreement; (4) voted to authorize Leiner to plead guilty to the charge specified in the Information; and (5) voted to authorize the corporate officer identified below to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement.

Merger and Other Provisions

13. The Defendant represents to the Court that it has met with its attorneys on a sufficient number of occasions and for a sufficient period of time to discuss the Defendant's case and receive advice; that the Defendant has provided truthful information to its attorney and related all information of which the Defendant is aware pertaining to the case; that the Defendant and its attorney have discussed possible defenses, if any, to the charges in the Information, including the existence of any exculpatory or favorable evidence or witness, discussed the Defendant's right to a public trial by jury or by the Court, the right to the assistance of counsel throughout the proceedings, the right to confront and cross-examine the government's witnesses, the Defendant's right to provide testimony on its own behalf, or to remain silent and have no adverse inferences drawn from his silence; and that the Defendant, with the advice of counsel, has weighed the relative benefits of a trial by jury or by the Court versus a plea of guilty pursuant to its Agreement, and has entered this Agreement as a matter of the Defendant's free and voluntary choice, and not as a result of pressure or intimidation by any person.

14. The Defendant is aware that 18 U.S.C. § 3742 and 28 U.S.C. § 2255 afford every defendant certain rights to contest a conviction and/or sentence. Acknowledging those rights, the Defendant, in exchange for the concessions made by the Government in this Plea Agreement, waives the right to contest either the conviction or the sentence in any direct appeal or other post-conviction action, including any proceedings under 28 U.S.C. § 2255. This waiver does not apply to claims of ineffective assistance of counsel or prosecutorial misconduct. This Agreement does not affect the rights or obligations of the Government as set forth in 18 U.S.C. § 3742(b). Nor does it limit the Government in its comments in or responses to any post-sentencing matters.

15. The Defendant waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a.

16. This plea agreement is binding upon Leiner, its corporate parent, affiliates, and subsidiaries, including LHP Holding Corp. and Leiner Health Products.

17. The parties hereby agree that this Plea Agreement contains the entire agreement of the parties; that this Agreement supersedes all prior promises, representations and statements of the parties; that this Agreement shall not be binding on any party until the Defendant tenders a plea of guilty to the Court having jurisdiction over this matter; that this Agreement may be modified only in writing signed by all parties; and that any and

all other promises, representations and statements, whether made prior to, contemporaneous with or after this Agreement, are null and void.

DATE

Duly authorized agent, on behalf of
LEINER HEALTH PRODUCTS, LLC,
Defendant

DATE

J. PRESTON STROM, JR.
Attorney for the Defendant

DATE

STEPHEN P. ANTHONY
Attorney for the Defendant

KEVIN F. McDONALD
ACTING UNITED STATES
ATTORNEY

DATE

BY: _____
WINSTON D. HOLLIDAY, JR.
Assistant U. S. Attorney