

CHRISTOPHER J. CHRISTIE
United States Attorney
By: PETER W. GAETA
Assistant United States Attorney
970 Broad Street, Suite 700
Newark, New Jersey 07102
(973) 645-2927

U.S. DISTRICT COURT
NEW JERSEY
P. 119

JOEL SCHWARTZ
Trial Attorney
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
(202) 514-0514

ERIC M. BLUMBERG
Special Assistant United States Attorney
U.S. Food and Drug Administration
5600 Fishers Lane, Room 6-13
Rockville, MD 20857
(301) 827-1138

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,)
)
Plaintiff,)
)
v.)
)
UNDETERMINED QUANTITIES)
OF BOXES OF ARTICLES OF)
DEVICE * * *)
)
and)
)
SHELHIGH, INC.,)
and SHLOMO GABBAY, M.D.,)
and LEA GABBAY, individuals,)
)
Defendants.)

Hon. William J. Martini
Civil Action No. 07 CV 1769 WJM

CONSENT ORDER

On April 16, 2007, plaintiff, the United States of America, by and through its attorneys, filed a Verified Complaint for Forfeiture *In Rem* (Complaint) against articles of device in the possession of Shelhigh, Inc. (Shelhigh), a business entity that was incorporated under the laws of New Jersey but is doing business as "Shelhigh, Inc.," located at 650 Liberty Avenue, Union, New Jersey. The Complaint alleges that the defendant articles of device are adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 351(h), because the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice (CGMP) requirements for devices as set forth in the Quality System (QS) regulation, 21 C.F.R. Part 820.

Pursuant to a Warrant for Arrest *In Rem* issued by this Court, the United States Marshal for this district seized the defendant articles on April 17, 2007. On April 24, 2007, Shelhigh intervened and filed a claim to the seized articles. Shelhigh filed an Answer to the Complaint on May 14, 2007.

Claimant Shelhigh and Defendants Shelhigh, Shlormo Gabbay, M.D., and Lea Gabbay (hereafter, collectively, defendants) having appeared and voluntarily consented to the entry of this Order without contest, before any testimony has been taken, without admitting the violations alleged in the Complaint, and waiving the filing and service of an amended complaint seeking injunctive relief, and the United States having consented to this Order:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

1. This Court has subject matter jurisdiction over this action and personal jurisdiction over all parties pursuant to 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. §§ 332 and 334. Venue is proper in this district under 21 U.S.C. § 1391(b) and (c).

2. The Complaint states a claim for relief against defendants under the Act, 21 U.S.C. §§ 301-397.

3. Defendant Shelhigh affirms that it is the sole owner of the seized articles, and that no other person has an interest in the seized articles. Defendant Shelhigh further affirms that it shall indemnify and hold the United States harmless should any other party or parties hereafter file or seek to file a statement of interest or right to intervene in this action, or seek to defend or obtain any part of the seized articles.

SECTION 334 PROVISIONS

4. The seized articles are devices that are in violation of 21 U.S.C. § 351(h).

5. The seized articles are hereby condemned pursuant to 21 U.S.C. § 334 and forfeited to the United States.

6. Pursuant to 21 U.S.C. § 334(e), Shelhigh shall pay to the United States all court costs and fees, storage and other proper expenses of this proceeding incurred to date, and such additional expenses as may hereinafter be incurred and taxed. Defendant Shelhigh shall pay these costs within ten (10) days of receiving written notice from the United States of such costs.

7. Pursuant to 21 U.S.C. § 334(d)(1), within three hundred and sixty (360) days of the entry of this Order, Shelhigh shall execute and file with the Clerk of this Court a good and sufficient penal bond with surety in the amount of one and one half million dollars (\$1,500,000.00) in a form acceptable to the Clerk of this Court and payable to the United States of America, and conditioned on Shelhigh's abiding by and performing all of the terms and conditions of this Order and of such further orders and decrees as may be entered in this proceeding.

The penal bond shall be applied initially to all components that have not been sterilized ("Phase I" articles) and subsequently and sequentially applied to succeeding lots as described in subparagraphs A-D of this paragraph. However, at no time may Shelhigh have seized articles released to it articles whose total retail value exceeds one million dollars (\$1,000,000.00).

The schedule for release of the devices and components is as follows:

A. The Phase I articles, which will be further designated by the FDA representative and which are stored at the Shelhigh facility located at 650 Liberty Avenue, Union, New Jersey 07083, shall be released to Shelhigh for the sole purpose of attempting to bring the Phase I articles into compliance with the law up to but not including the sterilization and subsequent manufacturing steps.

B. If, and only if, Shelhigh complies with all of the terms of this Order with respect to the Phase I articles, and Phase I articles have been released in writing by FDA for sterilization and subsequent processing (i.e., conversion to "Phase II" articles), a portion of the Phase I seized articles with a total value not to exceed one million dollars (\$1,000,000.00) retail shall be designated by the FDA representative for re-release to Shelhigh for the purpose of attempting to bring said articles into compliance with the law.

C. If, and only if, Shelhigh complies with all of the terms of this Order with respect to the release of the articles in subparagraph A and B of this paragraph, and those articles have been released in writing by FDA for distribution, additional Phase II seized articles with a total value not to exceed one million dollars (\$1,000,000.00) retail shall be further designated by the FDA representative for release to Shelhigh for the purpose of attempting to bring said articles into compliance with the law.

D. The terms of subparagraphs B and C of this paragraph shall apply to the sequential release of seized articles, each consisting of a lot whose value does not exceed one million dollars (\$1,000,000.00) retail.

E. Shelhigh may at any time, with prior notice and written consent of an FDA representative, increase the value of penal bond to obtain a greater amount of seized articles for attempted reconditioning.

8. After filing the bond with this Court pursuant to paragraph 7 of this Order, Shelhigh shall give written notice to the United States Food and Drug Administration (FDA) at the addresses specified in paragraph 30 of this Order that Shelhigh, at its own expense, is prepared to attempt to bring the seized articles into compliance with the law under the supervision of a duly authorized representative of FDA.

9. Shelhigh shall submit to FDA a detailed written plan describing its proposal to attempt to bring the seized articles into compliance with the law ("reconditioning plan"). Shelhigh shall not attempt to bring the seized articles into compliance until it has submitted to FDA a reconditioning plan (with accompanying protocols, validation data, expert reports, and standard operating procedures (SOPs)) as FDA deems necessary and FDA has provided Shelhigh with written authorization to commence reconditioning. The reconditioning plan may be done in stages acceptable to FDA; defendants shall consult with FDA before developing and submitting a reconditioning plan. FDA's decision regarding the adequacy of the reconditioning plan shall be final. The reconditioning plan described in this paragraph shall also be applicable to any components and finished devices manufactured or returned to Shelhigh between April 17, 2007 and the date on which this Order is entered.

10. FDA shall notify Shelhigh in writing within thirty (30) business days of FDA's receipt of each Shelhigh reconditioning plan whether the proposed reconditioning plan is acceptable and provides a potential opportunity to recondition the goods. Shelhigh understands that FDA makes no assurance that the attempted reconditioning will be successful.

11. Following the payment of costs and posting of the bond by Shelhigh, as required by paragraphs 6 and 7 of this Order, and following Shelhigh's receipt of written authorization to commence attempted reconditioning, as described in paragraph 9 of this Order, the United States Marshal for this district shall, upon receiving notice from FDA, release the seized articles to the custody of Shelhigh for the sole purpose of attempting to bring the articles into compliance with the law pursuant to the reconditioning plan described in paragraph 9.

12. Shelhigh shall not, directly or indirectly, cause the seized articles or any part thereof to be shipped, sold, or disposed of in a manner contrary to the provisions of the Act, any other federal law, or the laws of any State or Territory (as defined in the Act) in which the articles are shipped, sold, or disposed. All seized articles that are not brought into compliance under a reconditioning plan accepted in writing by FDA pursuant to paragraph 9 shall be destroyed at Shelhigh's expense under the supervision of an FDA representative, and Shelhigh shall pay to the United States all costs incurred in supervising the destruction of such articles, at rates specified in paragraph 27 of this Order.

13. Shelhigh shall at all times, until the seized articles have been released in writing by an FDA representative for shipment, sale, or other disposition, retain the seized articles intact for examination or inspection by FDA at the Shelhigh facility located at 650 Liberty Avenue, Union NJ 07083, and shall retain all records or other proof necessary to establish the identity of the

seized articles to the satisfaction of an FDA representative.

14. Shelhigh shall at no time and under no circumstances, directly or indirectly, cause or permit the shipment, sale, or other disposal of the seized articles, or any part thereof, unless and until an FDA representative has had free access to the articles to take any samples or make any examinations that are deemed necessary, and an FDA representative has released, in writing, such seized articles for shipment, sale, or other disposition.

15. If requested by an FDA representative, Shelhigh shall furnish duplicate copies of invoices of sale of the released articles, or other evidence of disposition as requested by an FDA representative.

16. Within one hundred and fifty (150) days of the United States Marshal's release of the seized articles to the custody of Shelhigh for reconditioning pursuant to paragraph 11, or such further time as FDA may allow, Shelhigh shall complete its attempt to bring the seized articles into compliance with the law under the supervision of an FDA representative and in a manner acceptable to FDA. Within ten (10) days after this one hundred and fifty (150) day period, Shelhigh shall destroy, at its sole expense and under the supervision of an FDA representative, any seized article that has not been brought into compliance within such one hundred and fifty (150) day period.

17. The United States Attorney for this district, upon being advised by FDA that the seized articles have been brought into compliance with the law and the requirements of this Order or destroyed in compliance with this Order and the law, and that Shelhigh has paid all costs to date, will transmit such information to the Clerk of this Court, whereupon the penal bond given in this proceeding shall be canceled and discharged.

18. If, within sixty (60) days of filing the bond pursuant to ¶ 7, Shelhigh does not submit a reconditioning plan as set forth in paragraph 9 of this Decree, the United States Marshal for this district shall destroy the seized articles and make due return to this Court regarding their disposition. Shelhigh shall bear the costs of such destruction.

19. If Shelhigh fails to abide by and perform all of the terms and conditions of this Order or of the bond posted in this proceeding, then that bond shall, on motion of the United States in this proceeding, be forfeited in its entirety and judgment entered in favor of the United States. In addition, if Shelhigh breaches any term or condition of this Order, then Shelhigh shall, at its own expense, immediately return the seized articles to the United States Marshal for this district or otherwise dispose of them pursuant to an order of this Court. In the event that return of the articles becomes necessary pursuant to this paragraph, Shelhigh shall be responsible for all costs of storage and disposition that are incurred by the United States.

SECTION 332 PROVISIONS

20. Upon entry of this Order, defendants and each of their officers, directors, agents, employees, representatives, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them who have received actual notice of this Order by personal service or otherwise are, except as provided in paragraph 21 below, permanently enjoined from manufacturing, processing, packing, labeling, and distributing any seized device or component or any component or device received or processed by defendants after seizure, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack,

label, and distribute devices are established, operated, and administered in compliance with the requirements of CGMP and the QS regulation, 21 C.F.R. Part 820, the Medical Device Reporting (MDR) requirements set forth at 21C.F.R. Part 803, and this Order, including, but not limited to, the following:

1) Establishing and implementing adequate written procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria;

2) Establishing and implementing adequate written procedures to control product that does not conform to specified requirements;

3) Establishing and implementing adequate quality requirements that must be met by contractors, suppliers, and consultants, and adequate written procedures to ensure that all purchased or otherwise received products and services conform to specified requirements;

4) Developing, conducting, controlling, and monitoring production processes to ensure that devices conform to their specifications;

5) Adequately validating processes whose results cannot be fully verified by subsequent inspection and testing, and establishing and implementing adequate written procedures for monitoring and controlling process parameters for validated processes to ensure that specified requirements continue to be met;

6) Establishing and implementing adequate written procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality;

7) Establishing and implementing adequate written procedures to control environmental

conditions that could reasonably be expected to have an adverse effect on product quality;

8) Establishing and implementing adequate requirements for the health, cleanliness, personal practices, and clothing of personnel;

9) Establishing and implementing adequate written procedures for identifying, documenting, validating or, when appropriate, verifying, reviewing, and approving design changes prior to their implementation;

10) Establishing and implementing adequate design validation requirements to ensure that devices conform to defined user needs and intended uses;

11) Establishing and implementing adequate written procedures for identifying employee training needs, for ensuring that all personnel are trained to adequately perform their assigned responsibilities, and for documenting such training;

12) Establishing and implementing procedures for corrective and preventive actions (CAPA);

13) Maintaining complaint files and establishing and implementing adequate written procedures for receiving, reviewing, and evaluating complaints; and

14) With respect to any components and finished devices manufactured or returned to Shelhigh between April 17, 2007 and the date on which this Order is entered, satisfactory completion of the reconditioning plan described in paragraph 9.

B. Defendants have corrected all of the items listed in FDA's December 20, 2006 List of Observations (FDA-483).

C. Defendants develop and implement adequate written MDR procedures in compliance with 21 C.F.R. Part 803, and ensure that employees are trained on and understand MDR

requirements.

D. Defendants select and retain, at defendants' expense, independent persons (the "experts"), who are qualified by education, training, and experience in the CGMP/QS regulation, microbiology, aseptic processing of medical devices, and the MDR reporting requirements to evaluate whether defendants are in compliance with CGMP/QS regulation requirements as set forth at 21 C.F.R. Part 820, the MDR reporting requirements set forth at 21 C.F.R. Part 803, and this Order. The expert(s) shall be without personal or financial ties (other than the consulting agreement between the parties) to any officer or employee of defendants or their immediate families. Defendants shall notify FDA in writing of the identity of the experts as soon as they retain such experts, and each expert shall:

- 1) Inspect defendants' facilities, validation protocols, validation data, processes, controls, SOPs, and employee qualifications and training, and training records;
- 2) Determine whether defendants are in compliance with the CGMP/QS regulation requirements as set forth at 21 C.F.R. Part 820, the MDR requirements set forth at 21 C.F.R. Part 803, and this Order; and
- 3) Provide FDA with complete and detailed written report identifying in detail which processes, controls, SOPs, and FDA-483 observations they inspected and their detailed evaluations as to whether each such SOPs, systems, and observations have been corrected and whether, in their professional opinions, defendants are in compliance with CGMP and 21 C.F.R. Parts 820, the MDR requirements set forth at 21 C.F.R. Part 803, and this Order.

E. Defendants submit a detailed written report of all corrections defendants have made to come in to compliance with the requirements of the Act and 21 C.F.R. Parts 820, the MDR

requirements set forth at 21 C.F.R. Part 803, and this Order. The written report shall document what steps they have taken to: correct each of the observations listed on FDA's December 20, 2006 List of Observations (FDA-483), to ensure that defendants' employees and managers are adequately trained in the CGMP/QS regulation and MDR requirements applicable to their assigned responsibilities and positions, and to ensure that defendants will continuously remain in compliance with this Order.

F. The experts have certified to FDA in writing that defendants are in compliance with the Act, 21 C.F.R. Part 820, the MDR requirements set forth at 21 C.F.R. Part 803, and this Order.

G. Duly authorized FDA representatives have made inspections, as and when FDA deems necessary and without prior notice, of defendants' facilities, including buildings, equipment, personnel, finished and unfinished materials, containers and labeling, and all records relating to the manufacture, packing, labeling, and distribution of devices to determine whether the requirements of paragraph 20 A through F of this Order have been met. Such inspection shall commence no later than twenty (20) days after receipt of the reports and certifications that meet the requirements of paragraph 20 A through F above; and

H. FDA notifies defendants in writing that they appear to be in compliance with the Act 21 C.F.R. Parts 820, the MDR requirements set forth at 21 C.F.R. Part 803, and this Order, and may commence manufacturing, packing, labeling, and distributing medical devices. FDA shall notify defendants within thirty (30) days following the conclusion of this inspection whether defendants may resume manufacturing, packing, labeling, and distributing medical devices.

21. Notwithstanding the prohibition in the preceding paragraph, defendants may, at their

own risk and with the understanding that any products manufactured pursuant to this paragraph, including components and devices that have been satisfactorily reconditioned pursuant to paragraph 9, may not later be approved by FDA for distribution, resume manufacturing – but not distributing for any purpose – components and devices, under the following conditions:

A. For all components and devices that have been processed up to but not including the sterilization step, defendants may resume manufacturing after all of the following conditions have been met:

(1) defendants' experts have complied with paragraphs 20 B and D - F for all CGMP requirements that may affect components and processes prior to sterilization;

(2) defendants have complied with paragraph 20 E and have submitted to FDA all test protocols, validation data, validation reports, and SOPs that FDA deems necessary to substantiate the foregoing CGMP requirements; and

(3) FDA has reviewed the test protocols, validation data, validation reports, SOPs, and defendants' assurances and has authorized in writing the resumption of manufacture of components and devices up to but not including sterilization (hereafter, collectively, "Phase I").

B. For all components and devices that have been sterilized and completed any manufacturing step subsequent to Phase I, defendants may resume manufacturing after all of the following conditions have been met:

(1) defendants have satisfactorily completed all requirements of Phase I;

(2) defendants' experts have complied with paragraphs 20 A-F for all CGMP requirements that may affect the sterilization of components and all steps subsequent to sterilization;

(3) defendants have complied with paragraph 20 E and have submitted to FDA all test protocols, validation data, validation reports, SOPs and other data that FDA deems necessary to substantiate the foregoing CGMP requirements; and

(4) FDA has reviewed the test protocols, validation data, validation reports, expert reports, SOPs, and defendants' assurances and has authorized in writing the resumption of manufacture of components and devices for the sterilization step and all subsequent manufacturing steps (hereafter, collectively, "Phase II").

C. Upon receipt of any data package described in paragraph 21, FDA will provide defendants with its written evaluations within thirty (30) business days, and will exercise its best efforts to do so sooner.

D. No Phase I components or devices may be sterilized (i.e, begin Phase II) until FDA, if it elects to do so, has inspected defendants' facility and Phase I processes and has advised defendants in writing that Phase I appears to be in compliance with the Act, 21 C.F.R. Part 820, and this Order. No Phase II products may be released for distribution under this paragraph until FDA has inspected defendants' facility, if it elects to do so, and advised defendants in writing that defendants' facilities and processes are in compliance with the requirements of the Act and 21 C.F.R. Part 820, the MDR requirements set forth at 21 C.F.R. Part 803, and this Order.

E. If it elects to do so, FDA will initiate the inspections described in this paragraph within ten (10) days after FDA, as provided in subparagraph C of this paragraph, approves the data submitted by defendants pursuant to subparagraphs A and B of this paragraph, and will exercise its best efforts to do so sooner. FDA will advise defendants of the results of its inspections within twenty (20) days after completing its inspections, and will exercise its best

efforts to do so sooner.

22. After defendants resume manufacturing, packing, labeling, and distributing devices pursuant to paragraph 20 or 21 above, defendants and each 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 have received actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined from directly or indirectly doing or causing to be done any act that:

A. violates 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce any article of device, within the meaning of 21 U.S.C. § 321(h), that is adulterated within the meaning of 21 U.S.C. § 351(h), or that is misbranded within the meaning of 21 U.S.C. § 352(t)(2);

B. violates 21 U.S.C. § 331(k), by causing any article of device to become adulterated within the meaning of 21 U.S.C. § 351(h) or misbranded within the meaning of 352(t)(2), while such article is held for sale after shipment of one or more of its components in interstate commerce; and

C. violates 21 U.S.C. section 382(g), by failing to provide the notifications set forth in that section.

23. If, at any time after entry of this Order, FDA determines, based on the results of an inspection, a sample analysis, a report or data prepared or submitted pursuant to this Order, or any other information, that defendants have failed to comply with any provision of this Order, or have violated the Act or any applicable regulation, or that additional corrective actions are necessary to achieve compliance with this Order, the Act, or any applicable regulation, FDA

may, as and when it deems necessary, order defendants in writing to take appropriate action, including, but not limited to, ordering defendants immediately to take one or more of the following actions:

- A. Cease manufacturing, packing, labeling, and distributing devices (including components);
- B. Revise, modify, or expand any reports or plans prepared pursuant to this Decree;
- C. Submit additional reports or information to FDA;
- D. Recall devices released or distributed by defendants or under the custody and control of defendants' agents, distributors, customers, or consumers. Defendants shall bear the costs of any such recalls; or
- E. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring defendants into compliance with the Act, the applicable regulations, and the terms of this Order.

24. Any decision issued by FDA pursuant to paragraph 23 shall specify the alleged violations giving rise to the order. Within seven (7) days after receiving such decision from FDA during the term of this Order, the defendants shall notify FDA in writing that:

A. The defendants are undertaking or have undertaken the requested action(s), in which event the defendants shall also describe the action taken or to be taken and specify the time frame in which the action will be completed; or

B. The defendants disagree with FDA's decision, in which case the defendants shall state in writing the reasons for the disagreement. In so doing, the defendants may propose specific alternative actions and specific time frames for achieving FDA's objectives.

C. If the defendants notify FDA that they do not agree with FDA's decision, FDA will review the defendants' objections, and thereafter, in writing, affirm, modify, or withdraw its decision, as FDA deems appropriate;

D. If FDA affirms or modifies its decision, defendants shall, within ten (10) business days of receipt of the decision, begin to implement the decision (as modified, if applicable) and, if they so choose, bring the matter before this Court for review. Defendants shall continue to diligently implement FDA's decision unless and until the Court reverses or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 33; and

E. Any cessation of operations or other action described in paragraph 23 shall continue until defendants receive written notice from FDA that defendants appear to be in compliance with this Order, the Act, and its implementing regulations. All costs of recall(s) and corrective actions ordered by FDA pursuant to paragraph 23 shall be borne by the defendants. The costs of FDA inspections, sampling, testing, document preparation and review time, travel time, and subsistence expenses to implement the remedies set forth in this paragraph shall be borne by the defendants at the rates specified in paragraph 27. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

25. After defendants resume manufacturing pursuant to paragraph 20 or 21 above, they shall retain independent experts ("auditors") who shall meet the criteria set forth in paragraph 20 D above to conduct audits of their manufacturing operations no less frequently than once every year. The auditors may be the same persons retained as experts pursuant to paragraph 20 D above.

A. At the conclusion of each audit inspection, the auditors shall prepare written reports ("audit reports") evaluating whether defendants are in compliance with requirements of the Act and 21 C.F.R. Part 820, the MDR requirements set forth at 21 C.F.R. Part 803, and this Order. As part of every audit report, the auditors shall assess whether defendants have adequately corrected observations made by auditors in previous reports and any observations that FDA may have made in an FDA-483 or written correspondence. The audit reports shall be delivered contemporaneously to defendants and to FDA no later than ten (10) days after conclusion of the audits. Defendants shall also retain the audit reports in separate files at their facility and shall immediately make them available to FDA investigators upon request.

B. If an audit report contains any observation indicating that defendants are not in compliance with requirements of the Act and 21 C.F.R. Parts 820, the MDR requirements set forth at 21 C.F.R. Part 803, and this Order, defendants shall correct the observation(s) within thirty (30) days of receipt of the audit report, unless FDA and defendants agree in writing on a different time frame. The auditors shall review defendants' corrections within sixty (60) days of the issuance of the audit report and within ten (10) days of said review shall notify defendants and FDA in writing whether, in the auditor's opinion, the observation has been corrected.

26. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect defendants' facilities and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order. During such inspections, FDA investigators shall be permitted to make inspections of all of Shelhigh's equipment, finished and unfinished materials and products, containers, and labeling; to take photographs; to collect samples of any articles of device; and to examine and copy all records

relating to the manufacture, packing, labeling, and distribution of any Shelhigh medical device. Such inspections shall be authorized upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

27. Defendants shall reimburse the United States for the costs of supervising its compliance with the terms of this Order, including all inspections, examinations, reviews, evaluations, analyses (and the supervision of any of the foregoing) conducted pursuant to this Order, at the standard rates prevailing at the time the activities are accomplished. As of the date this Order is signed by the parties, these rates are: \$78.09 per hour and fraction thereof per representative for inspection work; \$93.61 per hour or fraction thereof per representative for analytical work; \$0.445 per mile for travel expenses by automobile; the government rate or equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day, per representative for subsistence expenses, where necessary. In the event that the standard rates generally applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

28. Within ten (10) calendar days after entry of this Order, defendants shall provide a copy of this Order, by personal service or registered mail, to each 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. Defendants shall also post a copy of this Order in the employee common areas at all of their manufacturing facilities. Within thirty (30) calendar days of the date of entry of this Order, defendants shall provide to FDA an affidavit of

compliance, based upon personal knowledge of the affiant, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names and positions of all persons who have received a copy of this Order.

29. Defendants shall notify FDA at least fifteen (15) calendar days before change in ownership or character of their business, such as reorganization, relocation, dissolution, assignment, or sale resulting in the emergence of a successor entity, the creation or dissolution of subsidiaries, or any other change in the corporate structure of Shelhigh, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance obligations arising out of this Order. Defendants shall provide a copy of this Order to any potential successor or assignee at least fifteen (15) 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 before any change in ownership or character of their business.

30. Defendants and defendants' expert(s) shall address all communications with FDA required under this Order to the Director, Division of Enforcement B, 2098 Gaither Road, Rockville, MD 20850 and the Director, New Jersey District Office, U.S. Food and Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey 07054.

31. If any defendant fails to comply with any of the provisions of this Order, upon motion of the United States, that defendant shall pay to the United States of America the sum of four thousand dollars (\$4,000) in liquidated damages for each day of the violation and, in addition, four thousand dollars (\$4,000) for each violation. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and that they do not

in any way limit the ability of the United States to seek, and the Court to impose, additional civil and criminal contempt penalties based on conduct that may also form the basis for the payment of liquidated damages.

32. Should the United States bring and prevail in a contempt action to enforce the terms of this Order, defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, court costs, expert witness fees, and investigational and analytical expenses incurred in bringing such an action.

33. All decisions specified in this Order shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by a Court of any FDA decision rendered pursuant to this Order shall be conducted without discovery and shall be based exclusively upon the written record that was before FDA at the time the decision was made.

34. If defendants maintain a continuous state of compliance with the CGMP/QS regulation requirements as set forth at 21 C.F.R. Part 820, the MDR reporting requirements set forth at 21 C.F.R. Part 803, and this Order, for a period of five (5) years after the date of entry of this Order and the FDA has not notified defendants that there has been a significant violation of this Order, the CGMP/QS regulation requirements as set forth at 21 C.F.R. Part 820, and the MDR reporting requirements set forth at 21 C.F.R. Part 803, the government will not oppose defendants' motion to dissolve this Order.

35. Defendants and defendants' counsel represent that they have been advised by food and drug counsel regarding the terms of this Order and that they understand and agree with its

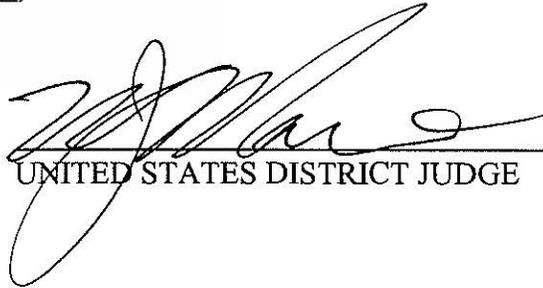
provisions.

36. All agreements between the parties are set forth in this Order and there are no other understandings, written or verbal, not contained herein. The parties further agree that any change to this Order must be in writing, signed by both parties, and agreed to by the Court.

37. This Court retains jurisdiction to issue such further decrees and orders as may be necessary to enforce or modify this Order and for granting such other relief as may be necessary to appropriate for the proper disposition of this proceeding.

SO ORDERED:

Dated this 22nd day of June, 2007.


UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree.

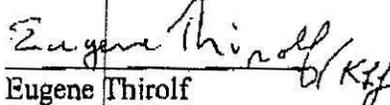
SHELHIGH, INC.

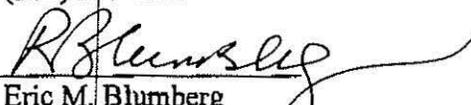
By: 
Shlomo Gabbay, M.D.,
Individually and as President
of Shelhigh, Inc.


Lea Gabbay, Individually


Carmel E. Gabbay
Counsel for Shelhigh, Inc.,
Shlomo Gabbay, M.D., and
Lea Gabbay
650 Liberty Ave..
Union, New Jersey
(908) 206-8706

CHRISTOPHER J. CHRISTIE
United States Attorney


Eugene Thirolf
Director,
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
(202) 307-3009


Eric M. Blumberg
Special Assistant U.S. Attorney
5600 Fishers Lane, Room 6-13
Rockville, MD 20857
(301) 827-1138

OF COUNSEL:

DANIEL MERON
General Counsel

SHELDON BRADSHAW
Associate General Counsel
Food and Drug Division

JENNIFER E. CARUSO
MARC B. NORTON
Associate Chief Counsels

United States Department of
Health and Human Services
Office of the General Counsel
Food and Drug Administration
5600 Fishers Lane,
Rockville, Maryland 20857

RECEIVED-CLERK
U.S. DISTRICT COURT
JUN 19 11:21