CLOSED

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
JONATHAN F. OLIN
Deputy Assistant Attorney General
Civil Division
U.S. Department of Justice

PAUL J. FISHMAN
United States Attorney
District of New Jersey

By: JACOB ELBERG
LUCY MUZZY
PETER GAETA
Assistant United States Attorneys
970 Broad Street, Suite 700
Newark, New Jersey 07102
Tel: (973) 645-3987
Fax: (973) 297-2094
Jacob.Elberg@usdoj.gov
Lucy.Muzzy@usdoj.gov
Peter.Gaeta@usdoj.gov

MICHAEL S. BLUME, Director
ANDREW CLARK, Assistant Director
Consumer Protection Branch

By: DANIEL K. CRANE-HIRSCH
Trial Attorney, Consumer Protection Branch
U.S. Department of Justice
PO Box 386
Washington, DC 20044-0386
(202) 616-8242 (phone)
(202) 514-8742 (fax)
daniel.crane-hirsch@usdoj.gov

UNITED STATES DISTRICT COURT

DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *Plaintiff,* v. ALL ARTICLES OF OTHER-SONIC GENERIC ULTRASOUND TRANSMISSION GEL . . . , *Defendants in rem.*	Hon. Esther Salas Hon. Joseph A. Dickson Civil Action No. 12-cv-02264-ES-JAD
UNITED STATES OF AMERICA, *Plaintiff,* v. PHARMACEUTICAL INNOVATIONS, INC., a corporation, and CHARLES BUCHALTER, an individual, *Defendants.*	Hon. Esther Salas Hon. Joseph A. Dickson Civil Action No. 14-cv-06139-ES-JAD

CONSENT DECREE OF CONDEMNATION AND PERMANENT INJUNCTION

In *United States v. All Articles of Other-Sonic Generic Ultrasound Transmission Gel . . .*, plaintiff, the United States of America, filed a Verified Complaint for Forfeiture *In Rem* ("Seizure Complaint") against articles of device in the possession of Pharmaceutical Innovations, Inc. ("PII"), a corporation located at 897 Frelinghuysen Avenue, Newark, New Jersey. This Court issued a Warrant for Arrest *In Rem*, and the United States Marshal for this district seized the defendant articles. PII then intervened and filed a claim to the seized articles.

In *United States v. Pharmaceutical Innovations, Inc.*, plaintiff, the United States of America, filed a Complaint for Permanent Injunction ("Injunction Complaint") against PII and Gilbert Buchalter.

On or about September 2014, Charles Buchalter was appointed PII's President and Chief Executive Officer. Defendants represent that prior to September 2014, Charles Buchalter had no involvement with the operations of PII. As the person currently most responsible for PII's operations, Charles Buchalter has consented to be named as a Defendant for the purposes of this Consent Decree of Condemnation and Permanent Injunction ("Decree"). Concurrently with the filing of the parties' joint request for consideration and entry of this Consent Decree of Condemnation and Permanent Injunction, Plaintiff filed a stipulation of dismissal without prejudice of the original individual defendant, Gilbert Buchalter, signed by all parties who had appeared; and an amended complaint, with the consent of the remaining defendant, Pharmaceutical Innovations, naming Charles Buchalter as a Defendant.

PII and Charles Buchalter (hereinafter, collectively, "Defendants") have appeared, have waived formal service of the amended complaint naming Charles Buchalter as a Defendant, and, before any testimony has been taken, voluntarily consent to the entry of this Decree without contest. The United States of America consents to entry of this Decree.

WHEREFORE, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has subject matter jurisdiction over these actions 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 28 U.S.C. §§ 1391(b) and (c).

2. The Seizure Complaint states a cause of action against the seized articles under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. The Injunction Complaint states a cause of action against Defendants under the Act.

4. Defendants agree to entry of this Decree, and do not admit or deny the allegations in the Seizure or Injunction Complaints, except for admitting the jurisdictional facts.

SEIZURE PROVISIONS

5. Claimant PII affirms that it is the sole owner of the seized articles, and that no other person has an interest in the seized articles. PII further affirms that it shall indemnify and hold harmless the United States should any other party or parties hereafter file or seek to file a statement of interest or right to intervene in the Seizure Action, or seek to obtain any part of the seized articles.

6. The Seizure Complaint alleges that the seized articles, which are articles of device as defined by 21 U.S.C. § 321(h), violate the Act as follows:

A. The seized articles are adulterated within the meaning of 21 U.S.C. § 351(c), in that their purity and quality fall below that which they purport or are represented to possess, because they were found to be contaminated with bacterial pathogens, specifically *Pseudomonas aeruginosa* and *Klebsiella oxytoca*;

B. The seized articles are misbranded within the meaning of 21 U.S.C. § 352(a), in that their labeling is false and misleading, as further defined at 21 U.S.C. § 321(n); and

C. The seized articles are misbranded within the meaning of 21 U.S.C. § 352(j), in that they are dangerous to health when used in the manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling, because the product contains *Pseudomonas aeruginosa* and *Klebsiella oxytoca*, bacterial pathogens

that could colonize (or lead to the accumulation of bacteria without any signs of infection) and cause a range of medical conditions, including serious or potentially life-threatening infection.

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

8. Pursuant to 21 U.S.C. § 334(e), PII shall pay to the United States all court costs and fees, storage, and other proper expenses, and any additional costs for which PII is liable with respect to the seized articles. PII shall pay these costs within ten (10) calendar days after receiving written notice from the United States of such costs. FDA will send written notice of any such costs to PII prior to filing this Decree.

9. Pursuant to 21 U.S.C. § 334(d)(1), within twenty (20) calendar days after entry of this Decree, PII shall execute and file with the Clerk of this Court a good and sufficient penal bond with surety in the amount of twenty-five thousand dollars ($25,000) in a form acceptable to the Clerk of this Court and payable to the United States of America, and conditioned on PII's abiding by and performing all of the terms and conditions of this Decree and of such further orders and decrees as may be entered in this proceeding. For the purposes of this Decree, the bond requirement shall be satisfied by PII's deposit of a certified check in the amount of $25,000 in the Court's Registry in accordance with LR 67.1(a)(1), and held as security for the obligations set forth in this Decree.

10. Within twenty-five (25) calendar days after filing the bond with this Court pursuant to paragraph 9 of this Decree, PII shall give written notice to the United States Food and Drug Administration ("FDA") that PII, at its own expense, is prepared to destroy the seized

articles under the supervision of a duly authorized representative of FDA. PII's notice shall specify the proposed time, place, and method of destruction of the seized articles.

11. PII shall not commence or permit any other person to commence destroying the seized articles until FDA has provided PII with written authorization to commence destruction.

12. Following the payment of costs and posting of the bond by PII, as required by paragraphs 8 and 9 of this Decree, and following PII's receipt of written authorization to commence destruction as described in paragraph 11 of this Decree, the United States Marshal for this district, upon receiving notice from FDA, shall release the seized articles to the custody of PII for the sole purpose of destroying the seized articles pursuant to the destruction plan described in paragraph 10 and under FDA supervision.

13. Within thirty (30) calendar days after receiving written authorization to commence destroying the seized articles, PII shall complete the destruction of the seized articles in compliance with this Decree. PII shall pay all costs of FDA's supervising the destruction within ten (10) calendar days after receiving notice of such costs from FDA.

14. PII 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.

15. PII shall at all times, until all of the seized articles have been destroyed pursuant to paragraph 13, retain the seized articles intact for examination or inspection by FDA at the PII facility located at 897 Frelinghuysen Avenue, Newark, New Jersey, or at another place within the United States made known to and approved by FDA, and shall retain all records or other proof

necessary to establish the identity of the seized articles to the satisfaction of an FDA representative.

16. If, within eighty (80) calendar days after the entry of this Decree, PII does not avail itself of the opportunity to repossess and destroy the seized articles in the manner provided in this Decree, or if any portion of the seized articles remain in the United States Marshal's custody after expiration of the thirty (30) day time period described in paragraph 13, the United States Marshal for this district shall destroy the seized articles and make due return to this Court regarding their disposition. PII shall bear the costs of such destruction, and shall pay such costs within ten (10) calendar days after receiving an invoice from the United States.

17. If PII fails to abide by and perform all of the terms and conditions of this Decree or of the bond posted in this proceeding, or any such further order or decree as may be entered in this proceeding relating to the seized articles, the bond described in paragraph 9 shall, on motion of the United States in this proceeding, be forfeited in its entirety to the United States and judgment entered in favor of the United States.

18. If PII breaches any term or condition of this Decree, or any subsequent decree or order in this proceeding, PII 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. Following return of the seized articles, the United States Marshal shall destroy the articles and make due return to this Court regarding their disposition. In the event that return of the articles becomes necessary pursuant to this paragraph, PII shall be responsible for all costs of storage and disposition incurred by the United States.

19. After the United States notifies PII that the seized articles have been destroyed in compliance with this Decree and the law to the United States' satisfaction, and that PII has paid

all costs, PII shall draft a disbursement order in compliance with LR 67.1(b), obtain the United States' consent to entry of the order, and submit the order for approval of the Clerk of this Court or his/her designee.

INJUNCTION PROVISIONS

20. The Injunction Complaint alleges that Defendants violate the Act as follows:

A. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce, articles of device, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of: (1) 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice ("CGMP") requirements in 21 U.S.C. § 360j(f)(1) and the implementing quality system regulation at 21 C.F.R. Part 820; and (2) 21 U.S.C. § 351(f)(1)(B), in that they are Class III devices pursuant to 21 U.S.C. § 360c(f), and there are no approved applications for premarket approval on file with the FDA as required by 21 U.S.C. § 360e(a), and the devices do not have an approved application for investigational device exemption under 21 U.S.C. § 360j(g);

B. Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce, articles of device, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of: (1) 21 U.S.C. § 352(o), in that Defendants fail to provide notice or other information respecting their devices to FDA as required by 21 U.S.C. § 360(k); and (2) 21 U.S.C. § 352(t)(2), in that Defendants

fail to furnish material or information respecting their devices to FDA as required by 21 U.S.C. § 360i and the implementing regulations set forth at 21 C.F.R. Parts 803 and 806;

C. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of device to become adulterated within the meaning of 21 U.S.C. §§ 351(h) and 351(f)(1)(B), as described above, and misbranded within the meaning of 21 U.S.C. §§ 352(o) and 352(t)(2), as described above, while such devices are held for sale after shipment of one or more of their components in interstate commerce;

D. Defendants violate the Act, 21 U.S.C. § 331(p), by failing to provide information required by 21 U.S.C. § 360(k); and

E. Defendants violate the Act, 21 U.S.C. § 331(q)(1)(B), in that Defendants fail to furnish notification or other material or information to FDA as required by 21 U.S.C. § 360i and the implementing regulations set forth in 21 C.F.R. Parts 803 and 806.

21. Prior to the date of the entry of this Decree, Defendants have retained, at their expense, qualified, independent persons (the "Experts"), to conduct inspections of Defendants' operations and to review Defendants' methods, facilities, and controls used to manufacture, design, process, pack, label, hold, and distribute devices, to determine whether their methods, facilities, and controls are operated and administered in conformity with the Act, applicable regulations, and this Decree.

22. Within twenty (20) calendar days after the date of entry of this Decree, Defendants shall submit a written compliance plan to FDA detailing the specific actions Defendants have taken and/or will take to bring Defendants' methods, facilities, and controls used to manufacture, design, process, pack, label, hold, and distribute devices into compliance with 21 U.S.C. § 360j(f)(1) and CGMP requirements for devices as set forth in the QS

regulation, 21 C.F.R. Part 820, and the medical device reporting regulations as set forth at 21 C.F.R. 803 and 806. The compliance plan shall include a comprehensive narrative description of PII's current manufacturing processes and address, but not be limited to, Defendants' process validation procedures; process controls; contamination controls; corrective and preventive action system; maintenance of records; requirements to be met by suppliers, contractors, and consultants; procedures for receiving, reviewing, and evaluating complaints; procedures regarding sampling methods and sampling plans; procedures regarding design changes; and calibration standards. The compliance plan shall include a timetable to be approved by FDA, and FDA will approve or disapprove the proposed compliance plan in writing within forty-five (45) calendar days of receipt. Beginning thirty (30) calendar days after FDA's approval of the compliance plan and every thirty (30) calendar days thereafter until completion of the final step of the compliance plan, Defendants shall submit monthly written status reports to FDA, detailing which step(s) in the compliance plan have been completed. Defendants shall include supporting documentation with each monthly status report, as appropriate or as requested by FDA. All steps of this compliance plan shall be completed no later than October 31, 2016 (other than for validation of the water system, which has an anticipated completion date of May 2017).

23. After the completion of the final step of the compliance plan (other than for validation of the water system referred to in paragraph 22 above), the Experts shall certify in writing to FDA that they have inspected Defendants' methods, facilities, and controls, and state: (1) whether Defendants have corrected all violations set forth in FDA's Inspectional Observations ("Forms FDA 483") from all FDA inspections dated after April 1, 2011, and in FDA's July 29, 2011 Warning Letter issued to Defendants; and (2) whether, based upon this inspection, Defendants' methods, facilities, and controls used to manufacture, design, process,

pack, label, hold, and distribute devices are operated and administered in conformity with the Act, applicable regulations, and this Decree.

24. After receipt of the Experts' certification described in paragraph 23 above, FDA representatives may, without prior notice and as and when FDA deems necessary, inspect Defendants' operations and review Defendants' formulations, methods, facilities, and controls used to manufacture, design, process, pack, label, hold, and distribute devices to determine whether the requirements of this Decree have been met, and whether Defendants are operating in conformity with the Act, applicable regulations, and this Decree. Within sixty (60) calendar days after completion of FDA's inspection, or the receipt of the Expert's certification, if FDA elects not to inspect Defendants' operations, or as soon thereafter as is reasonably practicable, FDA will notify Defendants in writing whether Defendants' methods, facilities, and controls used to manufacture, design, process, pack, label, hold, and distribute devices appear to be in conformity with the Act, applicable regulations, and the Decree. In no circumstances shall FDA's silence be construed as a substitute for written notification.

25. Defendants have affirmed to FDA in writing that they ceased the manufacture and distribution of their Ultra Phonic Ophthalmic Scanning Pad product as of January 11, 2016. Defendants shall submit a 510(k) premarket notification in accordance with 21 U.S.C. § 360(k) and its implementing regulations for each of the following devices no later than October 31, 2016: Other Sonic Generic Ultrasound Transmission Gel; Ultra Phonic Conductivity Gel (20 ml sterile packets); Ultra Phonic Focus Pad; Ultra Phonic Thin Focus Pad (formerly marketed as Ultra Phonic Fontanelle Scanning Pad); Ultra Phonic Free Gel; Ultra Phonic Scanning Gel; and Ultra Phonic Conductivity Gel (non-sterile). Defendants shall thereafter immediately cease manufacturing and distributing any of these devices if: (1) FDA issues an order declaring the

device to not be substantially equivalent to a legally marketed predicate device; (2) Defendants withdraw the 510(k) submission; or (3) FDA notifies Defendants that the agency considers the 510(k) submission withdrawn under 21 C.F.R. § 807.87(*l*). In the event that Defendants fail to submit a 510(k) premarket notification with respect to one of the aforementioned devices prior to October 31, 2016, they shall immediately cease manufacturing and distributing such device until the 510(k) is submitted and cleared.

26. After (a) FDA notifies Defendants, pursuant to paragraph 24, that their methods, facilities, and controls used to manufacture, design, process, pack, hold, and distribute devices appear to be in conformity with the Act, applicable regulations, and the Decree, and (b) Defendants have submitted 510(k) premarket notifications for all of the devices as described in paragraph 25, Defendants may renew their request(s) for Certificate(s) to Foreign Governments and FDA will consider such request(s) as set forth in the Act.

27. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, partnerships, franchisees, and "doing business as" entities), who receive actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce, articles of device, as defined by 21 U.S.C. § 321(h), that are

adulterated within the meaning of 21 U.S.C. §§ 351(c), (f)(1)(B), or (h), or misbranded within the meaning of 21 U.S.C. §§ 352(a), (j), (o), or (t)(2);

B. Violates 21 U.S.C. § 331(k), by causing articles of device, as defined by 21 U.S.C. § 321(h), to become adulterated within the meaning of 21 U.S.C. §§ 351(c), (f)(1)(B), or (h), or misbranded within the meaning of 21 U.S.C. §§ 352(a), (j), (o), or (t)(2) while such devices are held for sale after shipment of one or more of their components in interstate commerce;

C. Violates 21 U.S.C. § 331(p), by failing to provide information respecting articles of devices to FDA as required by 21 U.S.C. § 360(k); or

D. Violates 21 U.S.C. § 331(q)(1)(B), by failing to furnish notification or other material or information to FDA as required by 21 U.S.C. § 360i and the implementing regulations set forth in 21 C.F.R. Parts 803 and 806.

28. After FDA notifies Defendants in writing that they appear to be in compliance with the Act, applicable regulations, and this Decree pursuant to paragraph 24, Defendants shall retain, at their expense, an independent person or persons (the "Auditor"), who is without any personal or financial ties (other than the retention agreement) to Defendants and/or their families, and who, by reason of background, training, education or experience, is qualified to inspect Defendants' operations, review Defendants' methods, facilities, and controls used to manufacture, design, process, pack, label, hold, and distribute devices, and determine whether Defendants' methods, facilities, and controls are operated and administered in conformity with the Act, applicable regulations, and this Decree. The Auditor shall conduct audit inspections of Defendants' operations not less than once every six (6) months for a period of one (1) year, after which the Auditor shall conduct audit inspections annually for an additional two (2) years, for a

total of three (3) years of auditing. The Auditor may be the same person or persons referred to as the Experts in paragraph 21.

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants are operating in compliance with the Act, applicable regulations, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered simultaneously to Defendants and FDA by courier service or overnight delivery service, no later than twenty (20) calendar days after the date the audit inspections are completed. If any Audit Report identifies any deviation from the Act, applicable regulations, and/or this Decree, FDA may, in its discretion, require that the three (3) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at their facilities, including contemporaneous markings to show the date received, and shall promptly make the Audit Reports and underlying data available to FDA upon request.

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty (30) calendar days after receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation may take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days after receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification

for the additional time. That Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. Defendants shall complete all corrections according to the approved Correction Schedule. Within thirty (30) calendar days after Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observation(s). Within five (5) calendar days after beginning that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected.

29. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, an analysis of samples, a report or data prepared or submitted by Defendants, the Experts, or the Auditor pursuant to this Decree, or any other information, that Defendants have failed to comply with any provision of this Decree, or have violated the Act or applicable regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or applicable regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the non-compliance and order Defendants in writing to take appropriate actions, and Defendants shall implement such order immediately upon receipt. Such actions may include, but are not limited to, the following:

A. Cease manufacturing, processing, packing, labeling, holding, and/or distributing devices;

B. Revise, modify, or expand any report(s) prepared pursuant to the Decree;

C. Submit additional notifications, reports, or any other materials or information to FDA;

D. Recall, at Defendants' expense, adulterated, misbranded, unapproved or uncleared devices manufactured, processed, packed, labeled, and/or distributed by Defendants and/or that are under the custody and control of Defendants' agents, distributors, customers, or consumers;

E. Destroy, at Defendants' sole expense and under FDA's supervision, adulterated, misbranded, unapproved, or uncleared devices;

F. Issue a safety alert, public health advisory and/or press release; and/or

G. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health and/or to bring Defendants into compliance with the Act, applicable regulations, and this Decree.

30. The following process and procedures shall apply when FDA issues an order under paragraph 29, except as provided in subparagraph D below:

A. Unless a different time frame is specified by the FDA in its order, Defendants shall, within ten (10) business days after receiving such order, notify FDA in writing that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or

withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for the decision in writing. The written notice of affirmation or modification shall constitute a final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement FDA's order, unless the Court stays, reverses, vacates, 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 18 of this Decree.

D. The process and procedures set forth in paragraph 10.A-C. shall not apply to any order issued under paragraph 29 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while implementing the order.

31. Any cessation of operations described in paragraph 29 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Act, applicable regulations, and this Decree. All costs of recall(s) and corrective actions ordered by FDA pursuant to paragraph 29 shall be borne by Defendants. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in paragraph 29 shall be borne by Defendants at the rates specified in paragraph 33.

This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

32. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' operations and, without prior notice, take any other measures necessary to monitor and to ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted: access to device formulations; access to buildings, equipment, in-process and finished materials, containers, and labeling therein; to take photographs and make video recordings; to take samples of Defendants' materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, manufacture, designing, processing, packing, labeling, holding, and distribution of any and all devices, including without limitation all records relating to device formulations. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

33. Defendant PII shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs of such inspections shall be borne by Defendant PII at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $90.65 per hour and fraction thereof per representative for inspection work; $108.63 per hour or fraction thereof per representative for analytical or review work; $0.54 per mile for travel expenses by automobile; government rate or the 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 applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

34. Within five (5) calendar days after entry of this Decree, Defendants shall post a copy of this Decree in the employee common areas at 897 Frelinghuysen Avenue, Newark, New Jersey and at any other future locations at or from which Defendants manufacture, process, pack, or distribute devices. Defendants shall ensure that the Decree remains posted in its employee common areas for as long as the Decree remains in effect.

35. Within ten (10) calendar days after entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, partnerships, franchisees, and "doing business as" entities) (hereinafter, collectively referred to as "Associated Persons"). Within twenty (20) calendar days after entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who have received a copy of this Decree pursuant to this paragraph and attaching copies of the executed certified mail return receipts.

36. In the event that Defendants become associated, at any time after the entry of this Decree, with new Associated Person(s), Defendants shall within ten (10) calendar days after the commencement of such association: (a) provide a copy of this Decree to each such Associated Person(s) by personal service or certified mail (restricted delivery, return receipt requested); and

(b) provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons or entities who received a copy of this Decree pursuant to this paragraph, and attaching copies of the executed certified mail return receipts.

37. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, character, or name of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, franchisees, affiliates, or "doing business as" entities, or any other change in the corporate structure of Defendant PII or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Decree. Defendants shall provide a copy of this Decree to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

38. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree, with the exception of the Defendants' submission of 510(k) premarket notifications as required by paragraph 25 above, shall be addressed to the District Director, New Jersey District Office, United States Food and Drug Administration, Waterview Corporate Center, 10 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054. Defendants' submission of 510(k) premarket notifications as required by paragraph 25 above should be sent to FDA's Center for Devices and Radiological Health, in accordance with the applicable guidance located on FDA's website.

39. Defendants may at any time petition FDA in writing to extend any deadline provided for herein, and FDA may grant such extension without seeking leave of court. However, any such petitions shall not become effective or stay the imposition of any payments under this Decree unless granted by FDA in writing.

40. If Defendants fail to comply with any of the provisions of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendant PII shall pay to the United States of America seven thousand five hundred dollars ($7,500) in liquidated damages for each day such violation continues; an additional seven thousand five hundred dollars ($7,500) in liquidated damages for each violation of this Decree, the Act and/or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any distributed device that is adulterated or otherwise in violation of this Decree, the Act, and/or its implementing regulations. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for the payment of liquidated damages pursuant to this paragraph.

41. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

42. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. If contested by Defendants, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A).

Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

43. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this 6 day of July, 2016.

UNITED STATES DISTRICT JUDGE
Esther Salas

The undersigned hereby consent to the entry of the foregoing Decree:

For Defendants:

CHARLES BUCHALTER, President and CEO, on behalf of PHARMACEUTICAL INNOVATIONS, INC., and in his individual capacity

ADAM K. DERMAN
Chiesa Shahinian & Giantomasi PC
One Boland Drive
West Orange, NJ 07052
(973) 325-1500
Counsel for Defendants

For Plaintiffs:

PAUL J. FISHMAN
United States Attorney

JACOB ELBERG
LUCY MUZZY
PETER GAETA
Assistant U.S. Attorneys
970 Broad Street, Suite 700
Newark, New Jersey 07102
(973) 645-2733

DANIEL K. CRANE-HIRSCH
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
(202) 616-8242

Of Counsel:

Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

43. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this ___ day of _____, 2016.

_____
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree:

For Defendants:

_____
CHARLES BUCHALTER, President and CEO, on behalf of PHARMACEUTICAL INNOVATIONS, INC., and in his individual capacity

_____
ADAM K. DERMAN
Chiesa Shahinian & Giantomasi PC
One Boland Drive
West Orange, NJ 07052
(973) 325-1500
Counsel for Defendants

For Plaintiffs:

PAUL J. FISHMAN
United States Attorney

Lucy Muzzy/BSC
JACOB ELBERG
LUCY MUZZY
PETER GAETA
Assistant U.S. Attorneys
970 Broad Street, Suite 700
Newark, New Jersey 07102
(973) 645-2733

Daniel K. Crane-Hirsch/BSC
DANIEL K. CRANE-HIRSCH
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
(202) 616-8242

Of Counsel:

MARGARET M. DOTZEL
Acting General Counsel
Food and Drug Division
Office of General Counsel
U.S. Department of Health and Human Services

ELIZABETH H. DICKINSON
Chief Counsel

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

MICHELE LEE SVONKIN
Senior Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
White Oak 32, Room 4308
Silver Spring, MD 20993-0002