JOYCE R. BRANDA
Acting 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: LUCY MUZZY
Assistant United States Attorney
970 Broad Street, Suite 700
Newark, New Jersey 07102
Tel: (973) 297-2067
Fax: (973) 297-2094
Lucy.Muzzy@usdoj.gov

MICHAEL S. BLUME, Director
RICHARD GOLDBERG, 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.	**Civil Action No.**
PHARMACEUTICAL INNOVATIONS, INC., a corporation, and GILBERT BUCHALTER, an individual, **Defendants.**	

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin Pharmaceutical Innovations, Inc. ("PI"), a corporation, and Gilbert Buchalter, an individual, from violating:

A. 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:

i. 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

ii. 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 ("PMA") on file with the United States Food and Drug Administration ("FDA") as required by 21 U.S.C. § 360e(a), and the devices do not have an approved application for an investigational device exemption under 21 U.S.C. § 360j(g);

B. 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 devices, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of:

i. 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

ii. 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 in 21 C.F.R. Parts 803 and 806;

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

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

E. 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.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant PI is located at 897 Frelinghuysen Avenue, Newark, New Jersey, and is incorporated under the laws of New Jersey. PI manufactures, markets, sells, and distributes medical devices, including ultrasound, mammography, and electrocardiogram gels, scanning pads, and sprays.

5. Defendant Gilbert Buchalter is the founder and owner of PI. For many years, he served as the company's president and sole director and was the most responsible person at the company, with all personnel reporting to him. In September 2014, on information and belief, the company elected two additional Directors; designated Defendant Gilbert Buchalter as Chairman of the Board of Directors; and appointed a new president. As of the date of filing this Complaint, October 2, 2014, the New Jersey Treasury Department certifies that Defendant Gilbert Buchalter was the only officer or director on Pharmaceutical Innovations' most recent annual report, filed August 6, 2014. (Exhibit 1.) On information and belief, Defendant Gilbert Buchalter continues to have responsibility for and authority over the company's operations.

DEFENDANTS' DEVICES

6. Defendants' products are devices, within the meaning of 21 U.S.C. § 321(h), in that Defendants' products are accessories to instruments intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, which do not achieve their primary intended purposes through chemical action or on the body of man and which are not dependent upon being metabolized for the achievement of their primary intended purposes.

7. Examples of Defendants' devices include Ultra Phonic Conductivity Gel (in the 20 mL sterile packet), Ultra Phonic Focus Pad, Ultra Phonic Fontanelle Scanning Pad, Ultra

Phonic Ophthalmic Scanning Pad, Ultra Phonic Free, Ultra Phonic Scanning Gel, Ultra Phonic Conductivity Gel (non-sterile), and Other-Sonic Generic Ultrasound Transmission Gel.

8. Defendants distribute their devices in interstate commerce. In addition, components from states outside New Jersey are shipped to Defendants and used in the manufacture of their devices.

PROHIBITED ACTS

9. It is a violation of the Act to introduce or deliver for introduction into interstate commerce an adulterated or misbranded article of device. 21 U.S.C. § 331(a).

10. It is a violation of the Act to do any act with respect to a device that, while it is held for sale after shipment of one or more of its components in interstate commerce, causes the device to become adulterated or misbranded. 21 U.S.C. § 331(k).

11. It is a violation of the Act to fail to provide any information required by 21 U.S.C. § 360(k). 21 U.S.C. § 331(p).

12. It is a violation of the Act to fail or refuse to furnish any notification or other material or information required under 21 U.S.C. § 360i, and the implementing regulations at 21 C.F.R. Parts 803 and 806. 21 U.S.C. § 331(q)(1)(B).

CGMP VIOLATIONS

13. The Act requires the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation, packing, storage, and installation of a device to conform to CGMP to assure the device's safety and effectiveness. 21 U.S.C. § 360j(f). The statutory CGMP requirements are set out in the quality system regulation for devices, 21 C.F.R. Part 820. Devices that are not manufactured, packed, stored, and installed in conformance with CGMP are deemed to be adulterated. 21 U.S.C. § 351(h).

14. FDA inspected PI's facility from March 22, 2013, through April 3, 2013 ("March–April 2013 Inspection"). During this inspection, the FDA investigators documented Defendants' failures to comply with CGMP in 21 U.S.C. § 360j(f)(1) and the quality system regulation set forth in 21 C.F.R. Part 820, including that:

A. Defendants fail to comply with the process validation requirements set forth at 21 C.F.R. § 820.75(a). For example, Defendants have not shown that they have validated the dry heat sterilization and dry heat treatment processes that they apply to their products;

B. Defendants fail to comply with production and process control requirements set forth at 21 C.F.R. § 820.70(a). For example, Defendants have not shown that they routinely monitor their water systems to ensure that the water is suitable for manufacturing medical devices;

C. Defendants fail to comply with production and process control requirements relating to contamination control set forth at 21 C.F.R. § 820.70(e). For example, Defendants have not shown that they routinely sanitize the tubing and connections of their water systems to ensure objectionable microorganisms do not reside in the inner piping surface;

D. Defendants fail to comply with corrective and preventive action requirements set forth at 21 C.F.R. § 820.100(a). For example, Defendants have not shown that they have validated the heat treatments they instituted as corrective actions in response to a February 2012 hospital report identifying bacterial contamination in their Other-Sonic Generic Ultrasound Transmission Gel; and

E. Defendants fail to comply with purchasing control requirements set forth at 21 C.F.R. § 820.50(a). For example, Defendants have not shown that their microbial testing laboratory uses a validated microbial testing method suitable for testing their medical devices.

15. At the conclusion of the March–April 2013 Inspection, FDA investigators issued Pharmaceutical Innovation's plant manager a form FDA 483, List of Inspectional Observations ("Form FDA 483"), detailing Defendants' deviations from CGMP, and discussed the documented observations with him.

16. FDA also inspected PI from October 2, 2012, through November 6, 2012 ("October–November 2012 Inspection"); from February 13, 2012, through February 27, 2012 ("February 2012 Inspection"); and from April 14, 2011, through May 16, 2011 ("April–May 2011 Inspection"). During each of those inspections, the FDA investigators observed and documented violations of the quality system regulation similar to those described in paragraph 14, including, but not limited to, violations involving the following: process validation (21 C.F.R. § 820.75), production and process controls (21 C.F.R. § 820.70), corrective and preventive action (21 C.F.R. § 820.100), and purchasing controls (21 C.F.R. § 820.50). At the conclusion of each of those inspections, FDA investigators issued a Form FDA 483 to Gilbert Buchalter detailing Defendants' numerous deviations from CGMP and discussed the documented observations with Gilbert Buchalter.

LACK OF PREMARKET APPROVAL AND NOTIFICATION

17. In general, devices introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, are automatically classified as Class III as a matter of law, 21 U.S.C. § 360c(f)(1), unless the sponsor of a device (1) obtains an order

from FDA finding that the device is "substantially equivalent" to a legally-marketed predicate device that does not require premarket approval (commonly known as a "cleared 510(k) premarket notification submission" or "510(k)"), 21 U.S.C. §§ 360c(f)(1), 360c(i), 360e(a)(2) and (b), 360(k), or (2) has the device classified or reclassified in Class I or Class II under 21 U.S.C. §§ 360c(f)(2) or (f)(3). With certain exceptions not applicable here, Class III devices under 21 U.S.C. § 360c(f)(1) must have an approved application for PMA prior to marketing, 21 U.S.C. § 360e(a).

18. A device classified as Class III under 21 U.S.C. § 360c(f) is deemed to be adulterated if: (1) it is required to have in effect an approved application for PMA under 21 U.S.C. § 360e(a); (2) there is no FDA-approved PMA application in effect; and (3) there is not an approved application for an investigational device exemption ("IDE") under 21 U.S.C. § 360j(g). 21 U.S.C. § 351(f)(1)(B).

19. Manufacturers who are required to register with FDA and who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use are required to submit a premarket notification to FDA at least ninety days before making such introduction. 21 U.S.C. § 360(k). An owner or operator of an establishment not exempt under 21 U.S.C. § 360(g) or 21 C.F.R. § 807.65 who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use must register with FDA. 21 C.F.R. § 807.20.

20. Premarket notification is required for any device that is

A. being introduced into commercial distribution for the first time (21 C.F.R. § 807.81(a)(1));

B. currently in commercial distribution, but is significantly changed or modified in design, components, or methods of manufacture such that the change could significantly affect the safety or effectiveness of the device (21 C.F.R. § 807.81(a)(3)(i)); or

C. currently in commercial distribution, but has a major change or modification in its intended use (21 C.F.R. § 807.81(a)(3)(ii)).

21. A device is deemed to be misbranded if a premarket notification was not submitted to FDA as required by 21 U.S.C. § 360(k). 21 U.S.C. § 352(o).

22. A device may be considered "grandfathered," and thus not subject to the premarket review requirements, if it was legally marketed in the United States by a particular firm prior to the enactment of the Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, on May 28, 1976 (commonly known as a "preamendment device") and it has not been significantly changed or modified since that date, and if FDA has not promulgated a regulation requiring an application for PMA for that type of device.

23. Defendants are distributing Class III devices under 21 U.S.C. § 360c(f)(1) for which they do not have an approved application for PMA pursuant to 21 U.S.C. § 360e(a), a cleared 510(k) pursuant to 21 U.S.C.§§ 360(k) and 360c(i), or an approved application for an investigational device exemption ("IDE") under 21 U.S.C. § 360j(g). Defendants' devices are not grandfathered because Defendants have failed to demonstrate that these exact devices were introduced into interstate commerce for commercial distribution prior to May 28, 1976, or that these devices have not been significantly changed or modified from devices Defendants commercially distributed prior to May 28, 1976. The currently marketed devices differ from the devices that the Defendants have claimed to be preamendment devices, and such changes or

modifications could significantly affect the safety and/or effectiveness of the devices. For example,

A. Defendants do not have an approved application for PMA or IDE or a cleared 510(k) for their Ultra Phonic Conductivity Gel (in the 20 mL sterile packet). Defendants have failed to establish that they introduced the Ultra Phonic Conductivity Gel (in the 20 mL sterile packet) into interstate commerce for commercial distribution before May 28, 1976. In addition, the manufacturing process of the Ultra Phonic Conductivity Gel (in the 20 mL sterile packet) differs from that of the devices Defendants have claimed are preamendment devices in a way that could significantly affect the safety or effectiveness of the device. Specifically, the manufacturing process of the Ultra Phonic Conductivity Gel includes a sterilization step, whereas the manufacturing processes of the devices Defendants have claimed are preamendment devices do not include a sterilization step, and sterilization could significantly affect the safety and effectiveness of the device;

B. Defendants do not have an approved application for PMA or IDE or a cleared 510(k) for their Ultra Phonic Focus Pad, Ultra Phonic Fontanelle Scanning Pad, and Ultra Phonic Ophthalmic Scanning Pad ("Pad Devices"). Defendants have failed to establish that they introduced the Pad Devices into interstate commerce for commercial distribution before May 28, 1976. In addition, the design and manufacturing processes of the Pad Devices differ from those of the devices Defendants have claimed are preamendment devices in a way that could significantly affect the safety or effectiveness of the Pad Devices. Specifically, the Pad Devices are solid gel pads, whereas the devices

Defendants have claimed are preamendment devices are liquid gels, and the change from a liquid to solid gel could significantly affect the safety and effectiveness of the devices;

C. Defendants do not have an approved application for PMA or IDE or a cleared 510(k) for their Ultra Phonic Free gel. Defendants have failed to establish that they introduced Ultra Phonic Free into interstate commerce for commercial distribution before May 28, 1976. In addition, the chemical composition and the manufacturing process of the Ultra Phonic Free differ from that of the devices Defendants have claimed are preamendment devices in a way that could significantly affect the safety or effectiveness of the device. Specifically, the Ultra Phonic Free contains a different preservative than the one in the devices Defendants have claimed are preamendment devices, and the change in preservative could significantly affect the safety and effectiveness of the device; and

D. Defendants do not have an approved application for PMA or IDE or a cleared 510(k) for Ultra Phonic Scanning Gel, Ultra Phonic Conductivity Gel (non-sterile), or Other-Sonic Generic Ultrasound Transmission Gel. Defendants have failed to establish that they introduced Ultra Phonic Scanning Gel, Ultra Phonic Conductivity Gel (non-sterile), or Other-Sonic Generic Ultrasound Transmission Gel into interstate commerce for commercial distribution before May 28, 1976. In addition, the manufacturing processes of Ultra Phonic Scanning Gel, Ultra Phonic Conductivity Gel (non-sterile), and Other-Sonic Generic Ultrasound Transmission Gel differ from that of the devices Defendants have claimed are preamendment devices in a way that could significantly affect the safety or effectiveness of the devices. Specifically, the manufacturing processes of Ultra Phonic Scanning Gel, Ultra Phonic Conductivity Gel

(non-sterile), and Other-Sonic Generic Ultrasound Transmission Gel include a dry heat treatment step, whereas the manufacturing processes of the devices Defendants have claimed are preamendment devices do not include a dry heat treatment step, and the dry heat treatment step could significantly affect the safety and effectiveness of the devices.

24. Defendants have introduced into interstate commerce for commercial distribution devices intended for human use without submitting premarket notifications for those devices. Defendants are not exempt from the registration requirements under 21 U.S.C. § 360(g) or 21 C.F.R. § 807.65, and they are engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use. 21 C.F.R. § 807.20.

FAILURE TO COMPLY WITH REPORTING REQUIREMENTS

25. Every manufacturer of a device intended for human use is required to submit certain reports to FDA, as required by regulation, to assure that the device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. 21 U.S.C. § 360i(a).

26. Every manufacturer of a device is required to submit a medical device report ("MDR" or "report") to FDA within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that the marketed device may have caused or contributed to a death or serious injury, and to adequately develop, maintain, and implement written MDR procedures. 21 C.F.R. §§ 803.50(a), 803.17(a).

27. Every manufacturer of a device must submit a written report to FDA of any correction or removal of a device initiated by such manufacturer, within 10 working days of initiating such correction or removal, if the correction or removal was initiated (1) to reduce a risk to health posed by the device; or (2) to remedy a violation of the FDCA caused by the device which may present a risk to health unless the information has already been provided to FDA in

an MDR (21 C.F.R. Part 803) or in a plan for replacement, repair, or refund of electronic products (21 C.F.R. Part 1004) or the corrective or removal action is exempt from the reporting requirements. 21 C.F.R. § 806.10.

28. A device is deemed to be misbranded, pursuant to 21 U.S.C. § 352(t)(2), if its manufacturer fails or refuses to furnish any material or information required by or under 21 U.S.C. § 360i, including if a manufacturer fails to submit reports to FDA as required by 21 C.F.R. Parts 803 and 806.

29. Defendants failed to comply with the reporting requirements set forth at 21 C.F.R. Part 803, including that:

a. Defendants failed to submit an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that their marketed device may have caused or contributed to a serious injury, as required by 21 C.F.R. § 803.50(a)(1). Specifically, Defendants did not submit MDRs to FDA after becoming aware in February 2012 of *Pseudomonas aeruginosa* infections in surgical patients at a hospital in Michigan who had undergone a procedure involving Defendants' Other-Sonic Generic Ultrasound Transmission Gel; and

b. Defendants failed to adequately develop, maintain, and implement written MDR procedures, as required by 21 C.F.R. § 803.17(a). For example, Defendants' MDR procedure does not address how Defendants will submit all information reasonably known to it for each reportable event and the circumstances under which Defendants must submit supplemental or follow-up reports and the requirements for such reports.

30. Defendants failed to comply with the reporting requirements set forth at 21 C.F.R. Part 806 in that Defendants failed to submit a written report to FDA within 10 days of the

correction or removal of devices it initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health, as required by 21 C.F.R. § 806.10(a). Specifically, Defendants have not submitted a report to FDA about its removal of lots of Other-Sonic Generic Ultrasound Transmission Gel that Defendants learned in February 2012 were associated with the *Pseudomonas aeruginosa* infections of surgical patients at the hospital in Michigan.

PRIOR NOTICE OF VIOLATIONS

31. Defendants are well aware that their practices violate the Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with the Act.

32. At the conclusion of the April–May 2011 inspection, FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act, and discussed the documented observations with Gilbert Buchalter.

33. On July 29, 2011, FDA issued a Warning Letter to Defendants, stating that Defendants' devices were adulterated under 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 CGMP requirements under 21 U.S.C. § 360j(f)(1) and the implementing quality system regulation at 21 C.F.R. Part 820.

34. On February 1, 2012, FDA met with Defendants to discuss their CGMP deficiencies.

35. On February 15, 2012, FDA received a report from a hospital in Michigan involving 16 surgical patients infected with *Pseudomonas aeruginosa*. The hospital determined that the most likely source of the bacteria was PI's ultrasound sound transmission gel, Other-

Sonic Generic Ultrasound Transmission Gel. FDA tested samples of PI's Other-Sonic Generic Ultrasound Transmission Gel, and FDA's analysis of the samples confirmed the presence of significant amounts of *Pseudomonas aeruginosa* and *Klebsiella oxytoca*, which pose serious risks of infection to individuals exposed to the product. On April 16, 2012, the United States filed a Verified Complaint for Forfeiture *In Rem* against the relevant lots of PI's Other-Sonic Generic Ultrasound Transmission Gel, and the U.S. Marshal seized the lots on April 17, 2012. *See United States v. All Articles of Other-Sonic Generic Ultrasound Transmission Gel . . . . Manufactured by Pharmaceutical Innovations . . .* , Civil Action No. 12-2264 (ES) (D.N.J.).

36. At the conclusion of FDA's February 2012 inspection, FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act, and discussed the documented observations with Gilbert Buchalter.

37. At the conclusion of FDA's October–November 2012 inspection, FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act, and discussed the documented observations with Gilbert Buchalter.

38. On February 8, 2013, FDA sent a letter to Defendants, stating that many of Defendants' ultrasound devices appear to require premarket notification submissions and requesting that Defendants provide FDA with documentation demonstrating that such submissions are not required.

39. At the conclusion of FDA's March–April 2013 inspection, FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act, and discussed the documented observations with Pharmaceutical Innovations' plant manager. Also, during FDA's March–April 2013 inspection, pursuant to a Court-issued administrative warrant, FDA obtained quality system records, including device formulations, that Defendants had refused to provide to

FDA investigators during prior inspections. *See In the Matter of Establishment Inspection of Pharmaceutical Innovations, Inc. . . . .*, Mag. No. 13-3581 (D.N.J.).

40. On March 27, 2014, at the U.S. Courthouse for the United States District Court for the District of New Jersey, FDA representatives met with Defendants to discuss their CGMP deficiencies and Defendants' marketing of devices without the required approval or clearance.

41. On June 26, 2014, FDA sent a letter to Defendants detailing the deficiencies in Defendants' April 5, 2013 submission to FDA, and April 9, 2014, supplemental submission to FDA and concluding that Defendants had not adequately addressed or corrected the FDA observations from the March–April 2013 inspection.

42. Despite numerous warnings from FDA over the past three years and Defendants' promises to correct the numerous ongoing violations, Defendants continue to violate the Act, as observed in FDA's March–April 2013 inspection; Defendants' April 5, 2013, and April 9, 2014 submissions to the Agency relating to the CGMP deficiencies; and Defendants' March 4, 2013, and June 26, 2014 submissions to FDA relating to their marketing of devices without premarket approval or clearance.

43. Based on Defendants' conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), (k), (p), and (q).

WHEREFORE, Plaintiff prays:

I. That 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, be permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly:

A. violating 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, any article of device that is adulterated within the meaning of 21 U.S.C. §§ 351(h) and 351(f)(1)(B) or misbranded within the meaning of 21 U.S.C. §§ 352(o) and 352(t)(2);

B. violating 21 U.S.C. § 331(k), by causing any article of device to become adulterated within the meaning of §§ 351(h) and 351(f)(1)(B), or misbranded within the meaning of 21 U.S.C. §§ 352(o) and 352(t)(2), while such article is held for sale after shipment of one or more of its components in interstate commerce;

C. violating 21 U.S.C. § 331(p), by failing to provide information required by 21 U.S.C. § 360(k); and

D. violating 21 U.S.C. § 331(q)(1)(B), by failing to provide information required by 21 U.S.C. § 360i.

II. That the Court order 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, to cease directly or indirectly manufacturing, packing, labeling, and distributing (domestically and internationally) any device, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute devices are established, operated, and administered in compliance with CGMP requirements in 21 U.S.C. § 360j(f)(1) and the quality system regulation in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA;

B. Defendants ensure that, for each device requiring premarket approval or 510(k) clearance that the Defendants have introduced into interstate commerce for

commercial distribution or propose to introduce into interstate commerce for commercial distribution, they have obtained the appropriate premarket approval or 510(k) clearance from FDA and that the device is introduced into interstate commerce for commercial distribution in accordance with such clearance or approval; and

C. Defendants comply with the reporting requirements set forth in 21 U.S.C. § 360i and 21 C.F.R. Parts 803 and 806.

III. That the Court authorize FDA, pursuant to this injunction, to inspect Defendants' place of business to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed.

IV. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

Respectfully submitted,

Dated: October 2, 2014

FOR THE UNITED STATES OF AMERICA
STUART F. DELERY
Assistant Attorney General

JONATHAN F. OLIN
Deputy Assistant Attorney General
Civil Division
U.S. DEPARTMENT OF JUSTICE

PAUL J. FISHMAN
United States Attorney

Of Counsel:

WILLIAM B. SCHULTZ
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

JULIE A. DOHM
Associate Chief Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
White Oak 31, Room 4582
Silver Spring, MD 20993-0002

By: /s/ Lucy E. Muzzy
LUCY E. MUZZY
Assistant United States Attorney

MICHAEL S. BLUME, Director
RICHARD GOLDBERG, Assistant Director
Consumer Protection Branch

By: /s/ Daniel K. Crane-Hirsch
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 v. Pharmaceutical Innovations, Inc.

Exhibit 1

New Jersey Treasury Department certification
(October 2, 2014)

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
LONG FORM STANDING WITH OFFICERS AND DIRECTORS

PHARMACEUTICAL INNOVATIONS INC.

6974626000

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Profit Corporation was registered by this office on August 9, 1971.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and registered office are:

Gilbert Buchalter
897 Frelinghuysen Ave.
Newark, NJ 07114

I further certify that the incorporator is:

X
X
X, NJ

I further certify that as of the date of this certificate, the following were listed as officers/directors of this business on the last Annual Report filed in this office on: August 6, 2014.

President	*Gilbert Buchalter* *28 Mountain View Road* *Millburn, NJ 07041*

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
LONG FORM STANDING WITH OFFICERS AND DIRECTORS

PHARMACEUTICAL INNOVATIONS INC.

6974626000

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 2nd day of October, 2014

Andrew P Sidamon-Eristoff
Acting State Treasurer

Certification# 133729328

Verify this certificate at
https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

United States of America

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Daniel K. Crane-Hirsch, U.S. Dep't of Justice, Consumer Protection Branch, PO Box 386, Washington, DC 20044-0386
(202) 616-8242 (phone); (202) 514-8742 (fax)

DEFENDANTS

Pharmaceutical Innovations, Inc., a corporation; and Gilbert Buchalter, an Individual

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

Attorneys *(If Known)*
Adam K. Derman & Mauro G. Tucci, Jr.
Wolff & Samson PC, One Boland Drive, West Orange, NJ 07052
(973) 530-2027 (phone); (973) 530-2227 (fax)

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

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

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

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

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

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☒ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

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

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
Federal Food, Drug & Cosmetic Act (FDCA), 21 U.S.C. § 332(a)

Brief description of cause:
Enforcement action for alleged noncompliance with FDCA; injunction sought

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

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

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. Esther Salas DOCKET NUMBER 12-cv-02264, 14-cv-1156

DATE
10/02/2014

SIGNATURE OF ATTORNEY OF RECORD
/s/ Daniel K. Crane-Hirsch

FOR OFFICE USE ONLY

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

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INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked**.** (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.