UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. CUSTOM ULTRASONICS, INC., a corporation, and FRANK J. WEBER, an individual Defendants.	)	NO. COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by Patrick L. Meehan, United States Attorney for the Eastern District of Pennsylvania, respectfully represents to this Court as follows:

1. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c).

2. The United States brings this statutory injunction proceeding under the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a) and the Court's inherent equity authority to enjoin Custom Ultrasonics, Inc. ("CUI"), a corporation, and Frank J. Weber, an individual (collectively, "Defendants") from violating:

A. 21 U.S.C. § 331(a), by introducing or delivering 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, or installation are not in conformity with current good manufacturing practice as set forth in the Quality System Regulation (collectively, "CGMP/QS Regulation"), 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)(1) that do not have approved premarket approval applications ("PMA") on file with FDA as required by 21 U.S.C. § 360e, and the devices are not within the scope of an effective investigational device exemption ("IDE") pursuant to 21 U.S.C. § 360j(g);

B. 21 U.S.C. § 331(a), by introducing or delivering 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 notice or other information regarding the devices was not provided to FDA as required by 21 U.S.C. § 360(k); and

(2) 21 U.S.C. § 352 (t)(2), in that Defendants failed

to furnish material or information to FDA required by or under 21 U.S.C. § 360i regarding the devices; and

C. 21 U.S.C. § 331(e), by failing to establish, maintain, and implement written procedures required by 21 U.S.C. § 360i.

3. Defendant CUI is incorporated under the laws of the Commonwealth of Pennsylvania. CUI is engaged in the manufacture and distribution of articles of device, within the meaning of 21 U.S.C. § 321(h), at its facility located at 144 Railroad Drive, Ivyland, Pennsylvania, within the jurisdiction of this Court.

4. Defendant Frank J. Weber, an individual, is the President and Chief Executive Officer of CUI, and is responsible for and has authority over all operations including manufacturing procedures, quality assurance, and compliance with the CGMP/QS Regulation requirements, as well as with other requirements for devices under the Act. Defendant Weber performs his duties at 144 Railroad Drive, Ivyland, Pennsylvania, within the jurisdiction of this Court.

5. Defendants have been, and are now, engaged in the manufacture, packing, storage, or installation of various articles of device, as defined by 21 U.S.C. § 321(h). These articles of device include cleaning and disinfecting systems for rigid surgical instruments and flexible endoscopes.

December 2005-January 2006 Inspection

6. FDA investigators conducted a comprehensive inspection of Defendants' facility between December 6, 2005, and January 3, 2006.

7. The December-January inspection revealed that Defendants' methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation are not in conformity with FDA's CGMP/QS Regulation requirements for medical devices, which are set forth at 21 C.F.R. Part 820. FDA documented the following violations of Part 820, including, but not limited to:

A. Failure to establish and maintain adequate written procedures for implementing corrective and preventive actions to detect and correct quality system deficiencies (21 C.F.R. § 820.100);

B. Failure to establish and maintain adequate written procedures to identify the action needed to correct and prevent recurrence of nonconforming product and other quality problems (21 C.F.R. § 820.100(a)(3));

C. Failure to establish and maintain adequate written procedures for receiving, reviewing, and evaluating complaints by a formally designated unit (21 C.F.R. § 820.198);

D. Failure to review and evaluate all complaints to

determine whether an investigation is necessary (21 C.F.R. § 820.198(b));

E. Failure to establish and maintain adequate written procedures for identifying, documenting, evaluating, segregating, and disposing product that does not meet its specifications (21 C.F.R. § 820.90(a));

F. Failure to establish and maintain adequate written procedures to control the design of devices in order to ensure that specified design requirements are met. (21 C.F.R. § 820.30);

G. Failure to establish, define, and document written procedures for identifying, documenting, validating or verifying, reviewing, and approving design changes prior to their implementation (21 C.F.R. § 820.30(i));

H. Failure to develop written standard operating procedures (SOPs) that define and control the manner of production (21 C.F.R. § 820.70(a)(1));

I. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to adequately established procedures to ensure that the quality system is in compliance with CGMP/QS Regulation requirements. (21 C.F.R. § 820.20(c));

J. Failure to conduct quality audits to ensure that the quality system is in compliance with the established quality system requirements and to determine its effectiveness. (21 C.F.R. § 820.22); and

K. Failure to establish written procedures for identifying training needs to ensure that all personnel are trained to adequately perform their assigned responsibilities including, but not limited to, employees who do not speak or understand English (21 C.F.R. § 820.25(b)).

8. During the inspection, the FDA investigators also documented that Defendants shipped units of their System 83 Plus Mini-Flex device in interstate commerce to Southwood Specialties, Kaiser Permanente, Jonesboro, Georgia on May 13, 2005; to Sequoia Health Services, Redwood City, California on June 17, 2005; and to the Naval Medical Center, Portsmouth, Virginia on September 17, 2005, without complying with the premarket notification requirements of 21 U.S.C. § 360(k), or, alternatively, obtaining an approved PMA or IDE.

9. During the January-February 2005 inspection, the FDA investigators found that Defendants were not in compliance with Medical Device Reporting ("MDR") requirements set forth at 21 C.F.R. Part 803. These regulations require device manufacturers to submit an MDR within thirty days of receiving information that

reasonably suggests that one of their devices caused or contributed to a death or serious injury. Defendants had received information in a MedWatch report dated September 29, 2004, which suggested that Defendants' System 83 Plus device caused or contributed to a serious injury. Specifically, thirteen patients who were exposed to endoscopes cleaned and sanitized by Defendants' System 83 Plus device on separate occasions later tested positive for Hepatitis C. Defendants did not report this event to FDA until the most recent inspection, over 2 years later.

Prior Inspections and Prior Warnings

10. The FDA investigators previously conducted a comprehensive CGMP/QS Regulation inspection of Defendants' facility between January 18, 2005, and February 15, 2005. During this inspection, the FDA investigators observed and documented the same or similar violations to those described in Paragraphs 7 and 9 above.

11. At the conclusion of the January - February 2005 inspection, the FDA investigator presented a Form FDA483 Inspectional Observations ("FDA483"), to Defendant Frank J. Weber and discussed the observations with him. Defendant Weber responded to the FD483 in a letter dated February 21, 2005. In that letter, Defendant Weber promised to take corrective action

and requested an extension of 60 days to provide a detailed response. FDA granted the extension; however, FDA never received a response from Defendants.

12. Following the January - February 2005 inspection, FDA issued a Warning Letter to Defendants dated June 22, 2005. The Warning Letter identified violations of the CGMP/QS Regulation and MDR requirements observed during the inspection and warned Defendants that failure to correct the violations may result in an enforcement action, including seizure and/or an injunction. In addition, the letter requested that Defendant Weber meet with representatives of FDA's Philadelphia District Office and enforcement officials from FDA's Center for Devices and Radiological Health to discuss the regulatory status of CUI. Defendant Weber met with FDA officials on June 30, 2005. During the meeting, FDA officials discussed Defendants' violative inspectional history with Defendant Weber and emphasized the importance of responding to the FDA483 and Warning Letter. Defendants responded to the Warning Letter on July 19, 2005, promising corrective action.

13. In addition to the December 2005-January 2006 and the January-February 2005 inspections described above, FDA inspected CUI in 1995, 1992, and 1991. All of the inspections revealed significant violations of the CGMP/QS Regulation and MDR

requirements similar to those found during the last two inspections.

14. FDA sent Warning Letters to Defendants following the 1991 and 1992 inspections advising Defendants that their devices were adulterated under 21 U.S.C. §§ 351(f)(1) and 351(h) and misbranded under 21 U.S.C. §§ 352(o) and 352(t)(2). Following the 1995 inspection, FDA sent a letter to Defendants concerning Defendants' failure to submit an MDR for a reportable event.

15. FDA also warned defendants in letters dated June 2, 2005, August 12, 2005, and September 1, 2005, that their 21 U.S.C. § 360(k) premarket notification submission for their System 83 Plus Mini-Flex device was incomplete and that they may not market the device until they submitted complete information sufficient for FDA to determine whether the device is substantially equivalent to an approved predicate device. Despite these warnings, Defendants shipped units of their System 83 Plus Mini-Flex device in interstate commerce on June 17, 2005, and September 17, 2005.

16. Defendants' long history of violative inspections, failure to correct continuing violations of CGMP/QS Regulation and MDR requirements despite promises to do so, and failure to comply with the Act's premarket notification requirements despite two FDA warnings that they must do so before shipping their

devices in interstate commerce demonstrates Defendants' inability or unwillingness to make comprehensive changes to their manufacturing operations in order to comply with CGMP/QS Regulation and MDR requirements, and the statutory premarket notification and device approval requirements.

17. Plaintiff is informed and believes that, unless enjoined by this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), 331(p), 331 (q)(1)(B), and 331(e) in the manner herein alleged.

WHEREFORE, Plaintiff prays that:

I. The Defendants, Custom Ultrasonics, Inc., a corporation, and Frank J. Weber, an individual, and each and all of their officers, directors, agents, employees, attorneys, representatives, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) be perpetually restrained and enjoined from committing or performing, or doing or causing to be done, directly or indirectly, any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of device that are adulterated within the meaning of 21 U.S.C. §§ 351(h) or 351(f)(1)(B);

B. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of device that are misbranded within the meaning of 21 U.S.C. §§ 352(o) or 352(t)(2); and

C. Violating 21 U.S.C. § 331(e) by failing to establish, maintain, and implement written procedures required by or under 21 U.S.C. § 360i.

II. That the Court order Defendants and each and all of their officers, directors, agents, employees, representatives, attorneys, successors, and assigns, and any and all persons in active concert or participation with them (including individuals directors, corporations, subsidiaries, affiliates, and partnerships) to cease manufacturing, assembling, packing, repacking, labeling, installing, storing, and distributing all articles of device unless and until Defendants demonstrate to FDA's satisfaction that they are in compliance with CGMP/QS Regulation requirements set forth at 21 C.F.R. Part 820, the MDR requirements set forth at 21 C.F.R. Part 803, that they have developed adequate written MDR procedures in compliance with 21 C.F.R. Part 807 Subpart E., and, with respect to their System 83 Plus Mini-Flex device or any other device, have submitted an adequate and complete premarket notification to FDA and received an order finding that the device is substantially equivalent to

an approved predicate device, or, alternatively, have obtained an approved PMA or IDE for the device.

III. That this Court award Plaintiff costs and such other relief as the Court deems proper.

DATED this _____ day of_____, 2006.

Respectfully submitted,

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