UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
FT. LAUDERDALE DIVISION

CASE NO.: 18-CV-61047

UNITED STATES OF AMERICA,

Plaintiff,

v.

US STEM CELL CLINIC, LLC, a Florida limited liability company,
US STEM CELL, INC., a Florida profit corporation, and
KRISTIN C. COMELLA and
THEODORE GRADEL, individuals,

Defendants.

COMPLAINT

Plaintiff, the United States of America, by and through undersigned counsel, respectfully represents as follows:

1. This statutory injunction proceeding is brought pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 332(a), to enjoin US Stem Cell Clinic, LLC, a Florida limited liability company, US Stem Cell, Inc., a Florida profit corporation, and individuals Kristin C. Comella and Theodore Gradel (collectively, "Defendants"), from violating 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), and misbranded within the meaning of 21 U.S.C. § 352(f)(1) while held for sale after shipment of the drugs or one or more of their components in interstate commerce. An injunction is necessary to prevent Defendants from experimenting on patients with adulterated and misbranded drugs.

Jurisdiction and Venue

2. Jurisdiction to restrain such violations is granted to the district courts of the United States pursuant to 21 U.S.C. § 332(a). This Court also has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

Defendants and their Operations

4. Defendant US Stem Cell Clinic, LLC, ("USSCC") is a Florida limited liability company founded in 2014, with its principal place of business located at 12651 Sunrise Blvd., Suite 104, Sunrise, Florida 33323, within the jurisdiction of this Court. USSCC operates as a division of defendant US Stem Cell, Inc., but is not registered with the United States Food and Drug Administration ("FDA").

5. USSCC manufactures a product containing what is referred to as "stromal vascular fraction" (the "SVF product"), which is manufactured from a patient's adipose (fat) tissue. It then administers the SVF product to the same patient from whom the adipose tissue was removed.

6. USSCC's SVF product is intended for autologous use, which refers to the "implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered." See 21 C.F.R. § 1271.3(a).

7. USSCC's SVF product is used to treat various neurological, autoimmune, orthopedic, and degenerative medical conditions and/or diseases, including, but not limited to, Amyotrophic Lateral Sclerosis ("ALS"), Parkinson's disease, spinal cord injuries, stroke, traumatic brain injury, chronic obstructive pulmonary disease ("COPD"), lung disease, and diabetes.

8. USSC's SVF product is administered to patients using a variety of methods, including intravenously or by injection into specific areas of the body, including the spinal cord. USSCC's products are manufactured and administered at the USSCC facility at 12651 Sunrise Blvd., Suite 104, Sunrise, Florida 33323.

9. Production of USSCC's SVF product is the result of a multi-step manufacturing process. Under Defendants' current procedures, SVF production involves the recovery of adipose tissue from patients in dedicated examination rooms located at USSCC's Sunrise, Florida facility. The tissue recovery is accomplished by a mini-liposuction procedure, whereby a syringe is used to recover adipose tissue.

10. Defendants subject the recovered adipose tissue to numerous processing steps through which many components of the tissue are broken down and discarded. The process involves the addition of a solution containing an enzyme to isolate cell components through enzymatic digestion. It also includes an incubation period, several washing steps, centrifugation, and filtration. Manufacturing employs various types of equipment, including, but not limited to, syringes, cell wash bags, conical tubes, an incubator, a centrifuge, and a filter.

11. USSCC patients are treated with the SVF product on the day that their adipose tissue is recovered.

12. Labeling on USSCC's SVF product identifies only the name of the patient written in permanent marker on a syringe. Among other things, the SVF product's label lacks indications for use, dosages, routes of administration, and side effects.

13. Defendants manufacture the SVF product using one or more components shipped in interstate commerce from places outside the State of Florida.

14. Components received from outside of Florida include, for example, 0.9% Sodium Chloride Injection, USP, which was manufactured in Georgia.

15. USSCC's SVF product has not been licensed or approved by FDA.

16. There are not now, nor have there ever been any approved new drug application ("NDAs") filed with FDA pursuant to 21 U.S.C. § 355(b) or (j) for the SVF product. There are not now, nor have there ever been any approved biologics license applications ("BLAs") filed with FDA pursuant to 42 U.S.C. § 262 for the SVF product. There are not now, nor ever have been, any Investigational New Drug Applications ("INDs") in effect under 21 U.S.C. § 355(i), for the SVF product.

17. Defendant US Stem Cell, Inc., is a Florida profit corporation, founded in 1999, with its principal place of business at 13794 Northwest 4th Street, Suite 212, Sunrise, Florida 33325. US Stem Cell, Inc., is registered with the FDA as a human cells, tissues, and cellular and tissue-based product establishment that recovers, screens, tests, packages, processes, stores, labels and distributes somatic cell therapy products that are regulated as drugs or biological drugs.

18. Under the corporate umbrella of US Stem Cell, Inc., and its subsidiary US Stem Cell Training, Defendants provide training to physicians how to manufacture SVF product. This training is conducted at the USSCC facility in Sunrise, Florida.

19. US Stem Cell, Inc., receives lyophilized vials of Cellase enzyme in interstate commerce. When received by US Stem Cell, Inc., from its supplier, the enzyme is labeled "research use only." US Stem Cell, Inc., applies a label to each vial of Cellase and stores the vials frozen until it later ships the Cellase enzyme to USSCC for the manufacture of SVF product.

20. US Stem Cell, Inc., receives in interstate commerce cell wash solution that USSCC uses to manufacture its SVF product. When received by US Stem Cell, Inc., from its supplier, the solution is in 1-liter bottles that are labeled "not for human therapeutic use." US Stem Cell, Inc., then aseptically divides the solution into 125mL bottles. US Stem Cell, Inc., provides the cell wash solution to USSCC for use in manufacturing USSCC's SVF product by transporting it from US Stem Cell, Inc., to USSCC by car, as needed.

21. US Stem Cell, Inc., assembles adipose extraction kits, which are comprised of, among other things, a plastic beaker, syringes, a conical tube, and a filter. As needed, US Stem Cell, Inc., then transports the adipose extraction kits by car to USSCC for use in manufacturing USSCC's SVF product.

22. Defendant Kristin C. Comella, Ph.D., is the Chief Scientific Officer of both USSCC and US Stem Cell, Inc. She is responsible for overseeing the daily operations at USSCC, including but not limited to overseeing patient scheduling, hiring and firing employees and manufacturing the SVF product. She has stated that she wrote the procedures for the manufacture of the SVF product, and she has trained doctors on the extraction, isolation, and clinical applications of the SVF product. She performs her duties at USSCC's Sunrise facility, within the jurisdiction of this Court.

23. Defendant Theodore Gradel is an officer and co-owner of USSCC. He is a managing officer of USSCC, and he participated in USSCC's refusal of an FDA inspection in 2015. He performs his duties at USSCC's Sunrise facility, within the jurisdiction of this Court.

USSCC's SVF Products Are Drugs Under the FDCA

24. Under the FDCA, a "drug" includes any article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), or that is "intended to affect the structure or any function of the body," 21 U.S.C. § 321(g)(1)(C).

25. The "intended use" of a product refers, in turn, "to the objective intent of the persons legally responsible for the labeling of drugs," and is determined by such persons' expressions or may be shown, for example, by "labeling claims, advertising matter, or oral or written statements by such persons or their representatives. . . ." 21 C.F.R. § 201.128.

26. The USSCC product is a "drug" within the meaning of the FDCA, 21 U.S.C. § 321(g)(1)(B) and (C), because Defendants' records, public statements, and information contained on Defendants' websites and elsewhere establish that the USSCC product is intended to be used in the cure, mitigation, or treatment of diseases in man and/or to affect the structure and function of the body. Examples include, but are not limited to:

a. USSCC's website, http://usstemcellclinic.com, which states the company "offer[s] a variety of therapies" for some of the most common conditions" including "neurological . . . autoimmune . . . degenerative" and other conditions, including but not limited to, ALS, Parkinson's disease, spinal cord injuries, stroke, traumatic brain injury, rheumatoid arthritis, congestive heart failure, kidney disease, and liver disease.

b. Records collected during FDA inspections that document Defendants' manufacture of the SVF product to treat patients with, for example, ALS, Parkinson's disease, COPD, heart disease, and pulmonary fibrosis.

c. A USSCC brochure that markets the SVF product, which provides that "[s]tem cell therapy may promote the regeneration of healthy tissue, bone, or cartilage" and "has proven

to be a better alternative for people facing debilitating conditions such as COPD, Degenerative Disc Disease, Osteoarthritis, and many others where traditional medicine fall short of delivering satisfactory results."

d. A video posted on www.youtube.com ("YouTube") in which Defendant Kristin Comella, representing US Stem Cell, Inc.'s corporate predecessor Bioheart, Inc., said, "At Bioheart, we focused on utilizing . . . fat-derived stem cells, originally focusing on patients with cardiac indications, patients who have had a heart attack or have developed congestive heart failure, and then have moved into other indications, including things like COPD, or lung disease; things like diabetes or limb ischemia; and also injuries, things like spinal cord injuries and orthopedics." U.S. Stem Cell Clinic: Meet Kristin Comella, https://www.youtube.com/watch?v=1sFYmiwbMZM (last accessed April 30, 2018).

27. The SVF product is a "prescription drug" within the meaning of 21 U.S.C. § 353(b)(1)(A) because, due to its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, it is not safe for use except under the supervision of a practitioner licensed by law to administer such drug.

28. There have been no adequate and well-controlled studies performed on the SVF product demonstrating that it is safe or effective for any indication.

29. The SVF product is a "new drug" within the meaning of 21 U.S.C. § 321(p)(1), because it is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling. The SVF product is also a "new drug" within the meaning of 21 U.S.C. § 321(p)(2), because it has not been used to a

material extent or for a material time under the conditions prescribed, recommended, or suggested in its labeling.

Defendants' SVF Product Is a Biological Product Under the PHSA

30. Under the PHSA, a "biological product" includes any "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." 42 U.S.C. § 262(i).

31. Defendants' SVF product is a "biological product" within the meaning of the PHSA, 42 U.S.C. § 262(i), because it is an "analogous product," within the meaning of that section, that is "applicable to the prevention, treatment, or cure of a disease or condition of human beings." As noted above, Defendants claim that the SVF product treats several diseases and conditions, including, but not limited to, ALS, Parkinson's disease, spinal cord injuries, stroke, traumatic brain injury, COPD, lung disease, and diabetes.

32. A product may be both a drug and a biological product. A product that has been licensed under the PHSA is not required to also have an approved NDA under the FDCA. 42 U.S.C. § 262(j). However, the FDCA's adulteration and misbranding provisions, 21 U.S.C. §§ 351 and 352, apply to biological products. 42 U.S.C. § 262(j). As noted above, the Defendants' SVF product has not been licensed or approved by FDA.

Defendants' SVF Product Is Subject to Regulation Under the FDCA

33. In addition to being a drug and biological product, Defendants' SVF product falls within the definition of "human cells, tissues, or cellular or tissue-based products" ("HCT/Ps"). HCT/Ps are defined as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient."

21 C.F.R. § 1271.3(d). Under limited circumstances not applicable here, some HCT/Ps can be regulated effectively solely by controlling the communicable disease risks they present through the regulations set forth in 21 C.F.R. Part 1271, even if such HCT/Ps otherwise would be regulated as drugs and biological products under the FDCA and the PHSA. The criteria found in 21 C.F.R. § 1271.10(a) distinguish those HCT/Ps regulated solely under section 361 of the PHSA (42 U.S.C. § 264) and the regulations in 21 C.F.R. Part 1271 from those HCT/Ps regulated as drugs and biological products under the FDCA and section 351 of the PHSA (42 U.S.C. § 262).

34. FDA has identified other limited circumstances, also not applicable here, under which an establishment is excepted from FDA's regulations set forth at 21 C.F.R. Part 1271. See 21 C.F.R. § 1271.15.

35. HCT/Ps that do not fall within one of the exceptions in 21 C.F.R. § 1271.15, and do not meet all of the criteria in 21 C.F.R. § 1271.10(a) for regulation solely under the PHSA and 21 C.F.R. Part 1271, are regulated as, among other things, drugs and biological products under the provisions of the FDCA and the PHSA, including the adulteration, misbranding, and premarket approval requirements. 21 C.F.R. § 1271.20.

36. The criteria in 21 C.F.R. § 1271.10 include the requirement that the HCT/P be "intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent." 21 C.F.R. § 1271.10(a)(2). "Homologous use" means "the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor." 21 C.F.R. § 1271.3(c).

37. Defendants' SVF product fails to meet 21 C.F.R. § 1271.10(a)(2)'s requirement that the HCT/P be "intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent." As described above in paragraph 26, the SVF product is intended for use in the treatment of various diseases or conditions, including but not limited to, ALS, Parkinson's disease, spinal cord injuries, stroke, traumatic brain injury, COPD, lung disease, and diabetes. Such uses bear no resemblance to any basic function of adipose tissue, which provides cushioning and support to, among other areas, skin and organs. Because Defendants' SVF product does not perform the same basic function or functions of adipose tissue, using the SVF product for the treatment of ALS, Parkinson's disease, spinal cord injuries, stroke, traumatic brain injury, COPD, lung disease, and diabetes is not homologous use.

38. The criteria in 21 C.F.R. § 1271.10(a) also include the requirement that the HCT/P be only "minimally manipulated." 21 C.F.R. § 1271.10(a)(1). For structural tissue, "minimal manipulation" means processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement. 21 C.F.R. § 1271.3(f)(1).

39. Defendants' SVF product fails to meet 21 C.F.R. § 1271.10(a)(1)'s requirement that the HCT/P be only "minimally manipulated." Adipose tissue is structural tissue. Defendants' processing of the SVF product, as described above in paragraph 10, alters the original relevant characteristics of the adipose tissue, including its extracellular matrix and inherent structural properties that contribute to the tissue's utility as, for example, cushioning and support for skin or organs. The production process employed by Defendants includes enzymatic digestion to break down the adipose tissue's extracellular matrix and isolate cellular components. Such processing constitutes more than minimal manipulation of the HCT/P.

40. FDA has also identified certain circumstances under which an establishment is not required to comply with 21 C.F.R. Part 1271. See 21 C.F.R. § 1271.15. One exception from 21 C.F.R. Part 1271 applies to "an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure" ("same surgical procedure exception"). 21 C.F.R. § 1271.15(b). Defendants do not qualify for the same surgical procedure exception because, among other things, the adipose tissue recovered from individuals is subjected to processing rendering Defendants' SVF product no longer "such HCT/Ps," but a collection of cellular components isolated from adipose tissue. Thus, Defendants do not qualify for the same surgical procedure exception in 21 C.F.R. § 1271.15(b), or any other exception from 21 C.F.R. Part 1271.

41. Because Defendants' SVF product does not meet all of the criteria in 21 C.F.R. § 1271.10(a), and does not fall within any of the exceptions in 21 C.F.R. § 1271.15, Defendants' SVF product is regulated as a drug and biological product under the FDCA and section 351 of the PHSA and is subject to the provisions of the FDCA and the PHSA, including the FDCA's adulteration, misbranding, and premarket approval requirements. 21 C.F.R. § 1271.20.

Defendants' SVF Product Is Adulterated

42. Regardless of whether a drug is actually deficient in any respect, a drug is deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice ("CGMP") to assure that such drug meets the requirements of the FDCA as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. 21 U.S.C. § 351(a)(2)(B).

43. FDA investigators inspected USSCC's facility in Sunrise, Florida, from April 10-May 11, 2017. That inspection showed that the methods used in, and the facilities and controls used for, the manufacture, processing, packing, and holding of Defendants' SVF product do not conform to and are not operated or administered in conformity with CGMP. See 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210-211; see also 21 C.F.R. Parts 600-680 (setting forth additional standards and manufacturing requirements applicable to biological products). At the close of the inspection, FDA investigators issued a list of inspectional observations ("Form FDA 483") to Defendant Kristin Comella. The CGMP violations observed during the inspection included, but were not limited to, the following:

a. Failure to establish and follow appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, including validation of all aseptic and sterilization processes, as required by 21 C.F.R. § 211.113(b).

b. Failure to conduct appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms, as required by 21 C.F.R. § 211.165(b).

c. Failure to establish a system for monitoring environmental conditions to prevent contamination during aseptic processing, as required by 21 C.F.R. § 211.42(c)(10)(iv).

d. Failure to establish written procedures for production and process control designed to assure the drug products have the identity, strength, quality and purity they purport or are represented to possess, as required by 21 C.F.R. § 211.100(a).

e. Failure to establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug

products conform to appropriate standards of identity, strength, quality, and purity, as required by 21 C.F.R. § 211.160(b).

f. Failure to establish and follow adequate written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling testing, and approval or rejection of components and drug product containers and closures, as required by 21 C.F.R. § 211.80(a).

g. Failure to establish and follow adequate written procedures describing the handling of all written and oral complaints regarding a drug product, as required by 21 C.F.R. § 211.198(a).

44. Because Defendants do not manufacture their SVF product in a manner that conforms to CGMP, Defendants' SVF product is adulterated within the meaning of the FDCA, 21 U.S.C. § 351(a)(2)(B).

Adverse Events

45. During FDA's inspections at USSCC's Sunrise facility, investigators reviewed numerous records that documented adverse events that occurred after treatment with Defendants' SVF product, including, but not limited to, the following:

a. On June 16, 2015, a patient with macular degeneration experienced eye pain and blurry vision during treatment with Defendants' SVF product. The patient went to the emergency room, where she was diagnosed with intraocular pressure of over 90 mm Hg in her right eye and 73 mm Hg in her left eye. She suffered bilateral detached vitreous with vitreous opacities and was diagnosed with bilateral vitreous hemorrhages, ocular hypertension, and uveitis.

b. On the same day, June 16, 2015, another patient with macular degeneration suffered the loss of sight in both eyes after being treated with Defendants' SVF product. The day after the patient's treatment with Defendants' SVF product, a physician documented multiple hemorrhages in both eyes. On June 29, 2015, a physician determined that the patient had detached retinas and was legally blind at 20/400 in both eyes, even after being corrected with glasses.

c. On May 15, 2016, a patient received intravitreal injections of Defendants' SVF product for treatment of macular degeneration. After the treatment, the patient suffered complete vision loss.

Defendants' SVF Product Is Misbranded

46. Defendants' SVF product is misbranded within the meaning of the FDCA, 21 U.S.C. § 352(f)(1), because it is a drug and its labeling fails to bear adequate directions for use, and because it is not exempt from the requirements of 21 U.S.C. § 352(f)(1).

Defendants Violate the FDCA

47. Defendants violate 21 U.S.C. § 331(k) by causing the adulteration of the SVF product within the meaning of 21 U.S.C. § 351(a)(2)(B), while it is held for sale after shipment of one or more of their components in interstate commerce, as alleged in paragraphs 13-14 and 42-44, above.

48. Defendants violate 21 U.S.C. § 331(k) by causing the misbranding of the SVF product within the meaning of 21 U.S.C. § 352(f)(1), while they are held for sale after shipment of one or more of their components in interstate commerce, as alleged in paragraphs 13-14 and 46, above.

Continuing Noncompliance

49. Defendants are well aware that the SVF product is subject to regulation as a drug and biological product under the FDCA and PHSA, and that their conduct violates the law and could lead to regulatory action.

50. FDA inspected USSCC from October 22, 2015, through December 7, 2015. At the end of that inspection, FDA issued an FDA Form-483, List of Inspectional Observations ("FDA Form-483"), to Defendant Kristin Comella. That FDA Form-483 listed eleven examples of Defendants' noncompliance with FDA's CGMP regulations found by FDA investigators. On December 28, 2015, Defendant Kristin Comella responded to the FDA Form-483 on behalf of USSCC. Ms. Comella's response argued that Defendants' practices are not subject to FDA oversight and offered no indication that Defendants intended to cease producing the SVF product or administering it to patients.

51. FDA again issued an FDA Form-483 to Defendant Kristin Comella after its most recent inspection between April 10 and May 11, 2017. In that document, FDA listed twelve conditions that FDA investigators believed deviated from CGMP requirements. Kristin Comella again responded to the FDA Form-483 on behalf of Defendants on May 16, 2017. Once again, Ms. Comella's response did not promise any corrections, but challenged FDA's authority to regulate USSCC's activities.

52. On August 24, 2017, FDA issued a Warning Letter to USSCC listing again the many deviations from CGMP FDA investigators had observed at USSCC's facility and explaining why USSCC's activities were not exempt from FDA's jurisdiction. Defendants submitted two responses to the Warning Letter: the first signed by Defendant Kristin Comella

and the second signed by counsel to USSCC. In both responses, Defendants continued to deny that FDA had jurisdiction to regulate USSCC's activities.

53. Defendants' conduct demonstrates their persistent refusal to comply with the law. Unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. § 331(k) by causing the adulteration and misbranding of drugs in the manner alleged herein.

WHEREFORE PLAINTIFF PRAYS:

I. That Defendants, USSCC, US Stem Cell, Inc., Kristin C. Comella and Theodore Gradel, and each of their officers, agents, representatives, employees, attorneys, and all persons in active concert or participation with any of them, be permanently restrained and enjoined from directly or indirectly doing any act with respect to a drug (including a biological product) that results in the drug being adulterated or misbranded within the meaning of the FDCA, if such act is done while such drug, or one of its components, is held for sale (whether or not the first sale) after shipment in interstate commerce, in violation of 21 U.S.C. § 331(k).

II. That FDA be authorized pursuant to the injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug and/or drug component to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

III. That the Court award Plaintiff costs and other such relief as the Court deems just and proper, including equitable monetary relief.

DATED: May 9, 2018

Respectfully Submitted,

CHAD A. READLER
Acting Assistant Attorney General
Civil Division

GUSTAV W. EYLER
Acting Director
Consumer Protection Branch

ALAN PHELPS
Assistant Director

By: s/ *Roger J. Gural*
ROGER J. GURAL
Trial Attorney
Consumer Protection Branch
United States Department of Justice
P.O. Box 386
Washington, DC 20044
Tel.: 202.307.0174
Email: **Roger.Gural@usdoj.gov**

Counsel for United States of America

Of Counsel:

ROBERT P. CHARROW
General Counsel

REBECCA K. WOOD
Chief Counsel
Food and Drug Administration

PERHAM GORJI
Deputy Chief Counsel for Litigation

MICHAEL D. HELBING
Associate Chief Counsel for Enforcement
United States Dept.of Health and Human Services
Office of the General Counsel
White Oak 31, Room 4426A
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Telephone: (240) 402-6165

BENJAMIN G. GREENBERG
UNITED STATES ATTORNEY

By: s/ *James A. Weinkle*
JAMES A. WEINKLE
Assistant United States Attorney
Florida Bar No. 0710891
99 N.E. 4th Street, Suite 300
Miami, Florida 33132
Tel.: 305.961.9290
Fax: 305.530.7139
Email: **James.Weinkle@usdoj.gov**

Counsel for United States of America