IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA

UNITED STATES OF AMERICA, Plaintiff, v. MEDISTAT RX, LLC, a limited liability company, and MARK D. ACKER, TIMOTHY L. FICKLING, and V. ELAINE WALLER, individuals, Defendants.	)	Civil Action No. 17-CV-236-C **COMPLAINT FOR PERMANENT INJUNCTION**

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents 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), and this court's inherent equitable authority, to permanently enjoin the defendants, Medistat RX, LLC ("Medistat"), a limited liability company, and Mark D. Acker, Timothy L. Fickling, and V. Elaine Waller, individuals (collectively, "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B), and that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); (b) 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)(A) and 351(a)(2)(B), and to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drugs are held for sale after shipment of one or more of their

components in interstate commerce; and (c) violating 21 U.S.C. § 331(d) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved under 21 U.S.C. § 355, nor exempt from approval.

Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a).

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

Defendants and Their Operations

4. Medistat RX, LLC was an Alabama limited liability company most recently located at 110 East Azalea Avenue, Foley, Alabama, within the jurisdiction of this Court. Medistat obtained a pharmacy license from the Alabama State Board of Pharmacy in 2007, and had retail licenses in several other states. Medistat registered as an outsourcing facility pursuant to 21 U.S.C. § 353b on November 21, 2014.

5. Mark D. Acker was Medistat's Chief Executive Officer and co-owner. Defendant Acker was the person most responsible for Medistat's operations, including, but not limited to, manufacturing and quality operations, and has the authority to prevent, detect, and correct violations. Defendant Acker performed his duties until recently at Medistat, within the jurisdiction of this Court.

6. Timothy L. Fickling was Medistat's Production Manager and co-owner. In Defendant Acker's absence, Defendant Fickling was the person most responsible for Medistat's manufacturing operations, and has the authority to prevent, detect, and correct violations.

Defendant Fickling performed his duties until recently at Medistat, within the jurisdiction of this Court.

7. V. Elaine Waller was Medistat's Quality Manager and Pharmacist-in-Charge from May 2012 until September 2015. Defendant Waller was responsible for Medistat's quality issues, including production oversight, documentation, investigations, and environmental monitoring, and she had the authority to prevent, detect, and correct violations. Defendant Waller performed her duties at Medistat, within the jurisdiction of this Court.

8. During their regular course of business, Defendants manufactured, processed, packed, labeled, held, and distributed articles of drug, within the meaning of 21 U.S.C. § 321(g)(1), including both sterile and non-sterile drugs. Sterile drugs include drugs that are required to be sterile under Federal or state law or drugs that, by nature of their intended use or method of administration, are expected to be sterile ("sterile drugs"). *See* 21 U.S.C. § 353b(d)(5). Defendants' sterile drugs included, for example, injectable vitamins and minerals, amino acids, hormones, steroids, and vasodilators.

9. Defendants distributed their drugs to individual patients, surgery centers, and doctors' offices throughout the United States, including to California, New York, and Texas.

10. Defendants manufactured drugs at Medistat using components that were shipped in interstate commerce, including components from Oklahoma and Texas.

11. During their regular course of business, Defendants distributed certain drugs with labels that omitted the statement "Not for resale."

The Act's Requirements

12. Under the Act, 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).

13. A drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A).

14. The Act requires that drugs be manufactured in accordance with current good manufacturing practice ("CGMP"). 21 U.S.C. § 351(a)(2)(B); *see also* 21 C.F.R. § 210.1(b). 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 CGMP to assure that the drug meets the requirements of the Act as to safety and that it has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess, regardless of whether the drug is actually defective in some way. FDA has promulgated CGMP regulations for drugs at 21 C.F.R. Parts 210 and 211.

15. A drug is deemed to be misbranded "unless its labeling bears adequate directions for use." 21 U.S.C. § 352(f)(1).

16. The Act requires, subject to certain exceptions not applicable here, that drug manufacturers obtain FDA approval of a new drug application ("NDA"), an abbreviated new drug application ("ANDA"), or an investigational new drug exception ("IND") with respect to any new drug they introduce into interstate commerce, 21 U.S.C. §§ 331(d), 355(a). A "new drug" includes any drug "the composition of which is such that such drug 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 the labeling thereof." 21 U.S.C. § 321(p)(1).

17. The label of a drug compounded in an outsourcing facility must contain several specified statements and information, including the statement "not for resale" to be eligible for certain exemptions applicable to outsourcing facilities. 21 U.S.C. § 353b(a)(10).

The Act's Exemptions for Compounded Drugs

18. Under the Act, compounded drugs may be exempt from CGMP, adequate directions for use, and premarket approval requirements (21 U.S.C. §§ 351(a)(2)(B), 352(f)(1), and 355) if the compounded drugs comply with all of the requirements in 21 U.S.C. § 353a. Among other things, 21 U.S.C. § 353a requires that the drug product be "compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient . . . ." 21 U.S.C. § 353a(a). The compounding must be by a licensed pharmacy or physician either "on the prescription order for such individual patient," or "in limited quantities before the receipt of a valid prescription order for such individual patient" and "based on a history of" the pharmacist or physician "receiving valid prescription orders for the compounding of the drug product . . . ." 21 U.S.C. §§ 353a(a)(1) and (2).

19. Under the Act, an "outsourcing facility" is a facility that engages in the compounding of sterile drugs, registers as an outsourcing facility pursuant to 21 U.S.C. § 353b(b) and complies with all of the requirements of 21 U.S.C. § 353b. *See* 21 U.S.C. § 353b(d)(4)(A).

20. Under the Act, drug products compounded in a registered outsourcing facility are exempt from adequate directions for use and premarket approval requirements if the drugs

compounded by the outsourcing facility are compounded in accordance with all of the conditions in 21 U.S.C. § 353b. *See* 21 U.S.C. § 353b(a)(11).

21. The exemption from compliance with CGMP applies under 21 U.S.C. § 353a but does not apply under 21 U.S.C. § 353b. Thus, drugs manufactured in outsourcing facilities must conform to CGMP.

FDA's August-September 2015 Inspection

22. FDA conducted its most recent inspection of Medistat between August 24 and September 23, 2015 ("2015 Inspection") after the Rhode Island Department of Health notified FDA of an outbreak of *Staphylococcus aureus* infections potentially linked to injections of betamethasone manufactured by Medistat.

23. During this inspection, FDA investigators documented that Defendants distributed compounded drugs without receiving a valid prescription for an identified individual patient.

24. FDA investigators observed that Medistat's own documentation revealed that the Defendants recovered several types of microorganisms in the air and on surfaces used for sterile processing, demonstrating that products manufactured in those areas were prepared, packed, or held under insanitary conditions. Microbial contamination recovered by Medistat included, but was not limited to *Bacillus cereus*, *Staphylococcus epidermidis*, and *Penicillium crustosum*. If any of these organisms are present within an injectable product and administered to a patient, serious complications can result.

25. FDA investigators also observed that, upon recovering and identifying the microbial contamination, the Defendants failed to adequately investigate or take sufficient corrective action to alleviate the insanitary conditions that resulted in these microorganisms in the sterile areas of the facility.

26. FDA investigators observed and documented numerous other insanitary conditions, as described further in paragraph 30 below, and violations of CGMP, as described further in paragraph 33 below.

27. FDA investigators documented that Defendants manufactured and introduced into interstate commerce drugs with labels that omitted the statement "Not for resale."

28. At the close of the 2015 Inspection, FDA investigators issued a Form FDA-483, List of Inspectional Observations ("FDA-483") to Defendant Acker and discussed the FDA-483 observations with Defendants Acker, Waller, and Fickling.

29. On September 9, 2015, Medistat announced a voluntary nationwide recall of all lots of unexpired sterile drug products distributed since November 1, 2014, and ceased sterile and non-sterile drug operations.

Adulteration Due to Insanitary Conditions

30. The insanitary conditions that FDA investigators observed at the Medistat facility during FDA's 2015 Inspection establish that drugs manufactured and distributed by Defendants were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A). The insanitary conditions observed by FDA during the 2015 Inspection include, but are not limited to:

a. Continuation of aseptic drug production when significant microbial contamination was present in the aseptic processing areas;

b. Operators moving their hands over open vials, thereby blocking the airflow and increasing risk of contamination;

c. Failure to use sterile wipes to clean critical surfaces of the ISO 5 area; and

d. Poor personnel aseptic practices.

31. Defendants violated 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that they were prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health.

32. Defendants violated 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)(A), while such drugs were held for sale after shipment of one or more of their components in interstate commerce.

Adulteration Due to CGMP Violations

33. During the September 2015 Inspection, FDA investigators documented numerous deviations from CGMP requirements for drugs, including but not limited to Defendants' failure to:

a. Establish an adequate system for maintaining equipment used to control the aseptic conditions, *see* 21 C.F.R. § 211.67(a);

b. Establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, including validation of all aseptic and sterilization processes, *see* 21 C.F.R. § 211.113(b);

c. Establish adequate control systems necessary to prevent contamination during aseptic processing, including but not limited to adequate environmental monitoring, *see* 21 C.F.R. § 211.42(c)(10);

d. Ensure that manufacturing personnel wear appropriate clothing to protect drug products from contamination, *see* 21 C.F.R. § 211.28(a); and

e. Ensure and validate that drug product containers and closures are adequately sterilized and processed to remove pyrogenic properties, *see* 21 C.F.R. § 211.94(c).

34. These observations establish that Defendants' drugs were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

35. Defendants violated 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, and holding did not comply with CGMP to assure that they met the requirements of the Act as to their safety and that they had the identity and strength, and met the quality and purity characteristics, which they purported or were represented to possess.

36. Defendants also violated 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), while such drugs were held for sale after shipment of one or more of their components in interstate commerce.

Misbranding Due to Inadequate Directions for Use

37. Due to their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, Defendants' drugs were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. As such, Defendants' drugs were "prescription drugs" within the meaning of 21 U.S.C. § 353(b)(1)(A).

38. "Adequate directions for use" means directions under which a layperson could use a drug safely and effectively for the purposes for which the drug is intended. 21 C.F.R. § 201.5. A prescription drug, by definition, cannot bear adequate directions for use by a layperson because such drug must be administered under the supervision of a licensed

practitioner. *See* 21 U.S.C. § 353(b)(1). FDA has established exemptions for certain drug products from the requirements that labeling bear adequate directions for use, but because Defendants' drug products were unapproved new drugs, they did not satisfy the conditions for any of these exemptions. *See* 21 C.F.R. §§ 201.115, 201.100.

39. Because at the time of FDA's 2015 Inspection Medistat was registered with FDA as an outsourcing facility, it was required to comply with all of the requirements of 21 U.S.C. § 353b(d)(4)(A) to be able to avail itself of the exemptions in that section. Because a substantial number of Defendants' drugs failed to include labels that stated "Not for Resale" in violation of 21 U.S.C. § 353b(a)(10), these compounded drugs did not qualify for 21 U.S.C. § 353b's exemption from the requirement for adequate directions for use contained in 21 U.S.C. § 352(f)(1) and were thus misbranded. *See* 21 U.S.C. §§ 353b(a), 353b(d)(4)(A).

40. Defendants violated 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that were misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that the labeling of the drugs failed to bear adequate directions for use, and the drugs were not exempt from the requirements of 21 U.S.C. § 352(f)(1).

41. Defendants violated 21 U.S.C. § 331(k) by causing articles of drug that were not exempt from the requirements of 21 U.S.C. § 352(f)(1) to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drugs were held for sale after shipment of one or more of their components in interstate commerce.

Unapproved New Drugs

42. Defendants' compounded drugs, including, but not limited to, injectable methylprednisolone, triamcinolone acetonide, and testosterone cypionate/testosterone

propionate, were not generally recognized as safe and effective because there are no published adequate and well-controlled clinical studies of those drugs upon which qualified experts could conclude that the drugs are safe and effective. Therefore, they are new drugs within the meaning of 21 U.S.C. § 321(p).

43. Defendants' compounded drugs, including, but not limited to injectable methylprednisolone, triamcinolone acetonide, and testosterone cypionate/testosterone propionate, lacked an approved NDA or ANDA, as required by 21 U.S.C. § 355, and were not exempt from approval under 21 U.S.C. § 355(i).

44. At the time of FDA's 2015 Inspection, Medistat was registered with FDA under the outsourcing facility exception of 21 U.S.C. § 353b(d)(4)(A). However, to be entitled to the benefit of that exception, Medistat needed to meet all of the statutory elements of 21 U.S.C. §353b(d)(4)(A). A substantial number of Defendants' drugs failed to include labels that stated "Not for Resale", one of the criteria for qualifying for the exception. 21 U.S.C. § 353b(a)(10)(iii). Thus the drugs were not exempt from the approval requirements. *See* 21 U.S.C. §§ 353b(a), 353b(d)(4)(A).

45. Defendants' distribution into interstate commerce of unapproved new drugs violated 21 U.S.C. § 331(d).

Prior Inspections and Warnings to Defendants

46. FDA previously inspected Medistat between September 9th and 18th, 2014 ("2014 Inspection") and observed similar insanitary conditions and numerous CGMP deficiencies. Defendants' insanitary conditions included, but were not limited to, the failure to adequately investigate the results of environmental monitoring, which recovered numerous microorganisms (including *Penicillum aurantacium, Staphylococcus warnieri, Staphylococcus*

epidermidis, and *Bacillus cereus*) within the aseptic processing area. Defendants continued aseptic operations without taking adequate corrective actions.

47. At the close of the 2014 Inspection, FDA investigators issued a FDA-483 to Individual Defendant Acker and discussed the inspectional observations with Individual Defendants Acker, Fickling, and Waller.

48. Despite promises to correct their deficiencies, Defendants' violations persisted, as evidenced by the violations observed during FDA's 2015 Inspection.

49. During the 2014 and 2015 Inspections, FDA investigators notified Individual Defendants Acker, Fickling, and Waller that FDA may pursue enforcement action against Medistat, including an injunction.

50. Plaintiff believes that, unless restrained by the Court, Defendants will further violate 21 U.S.C. §§ 331(a), (k), and (d), in the manner alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin Defendants and 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, from manufacturing, processing, packing, labeling, holding, or distributing any article of drug, unless and until Defendants bring their manufacturing, processing, packing, labeling, holding, and distribution operations into compliance with the Act and its implementing regulations to the satisfaction of FDA;

II. Permanently restrain and enjoin under 21 U.S.C. § 332(a) Defendants and 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, from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and/or 351(a)(2)(B), and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1);

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

C. Violating 21 U.S.C. § 331(d) by introducing and/or causing the introduction into interstate commerce, and/or delivering and/or causing the delivery for introduction into interstate commerce, of any new drug that is neither approved under 21 U.S.C. § 355, nor exempt from approval;

III. Authorize FDA pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections, including testing and sampling, to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award Plaintiff costs and other such relief as the Court deems just and proper.

DATED this 23rd day of May, 2017.

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