IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

CANTRELL DRUG COMPANY, a corporation, and JAMES L. McCARLEY, JR., an individual,

Defendants.

Civil Action No. 4:18-cv-159-BRW

This case assigned to District Judge Wilson and to Magistrate Judge Deere

COMPLAINT FOR 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"), alleges:

1. This action relates to the nationwide distribution of injectable drug products manufactured under conditions that fall short of the minimal legal requirements necessary to ensure the safety and quality of such drugs. The majority of drugs manufactured by Cantrell Drug Company ("Cantrell"), a corporation, and James L. McCarley, Jr., an individual, (collectively, "Defendants") purport to be or are expected to be sterile. Such drugs include injectable Sodium Bicarbonate, which is used in the treatment of metabolic acidosis, which may occur in patients with severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, or cardiac arrest. FDA's inspections revealed that Defendants' injectable drugs were being manufactured under insanitary conditions and using deficient manufacturing practices, which Defendants were made aware of on repeated occasions.

Notwithstanding FDA's 2015 Warning Letter informing Defendants to their ongoing current good manufacturing practice violations, and subsequent FDA efforts to get Defendants to cease manufacturing drugs until necessary remedial actions are fully implemented, Defendants continue to manufacture purportedly sterile drugs and distribute such drugs in interstate commerce.

2. This action is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301, *et seq*. Defendants' manufacturing and distribution in interstate commerce of adulterated drugs is prohibited by two provisions of the Act:

A. Defendants violate 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or 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) (relating to insanitary conditions) and 21 U.S.C. § 351(a)(2)(B) (relating to current good manufacturing practices).

B. Defendants violate 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) (relating to insanitary conditions) and 21 U.S.C. § 351(a)(2)(B)) (relating to current good manufacturing practices), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

3. The United States, pursuant to 21 U.S.C. § 332(a), and this Court's inherent equitable authority, is seeking a preliminary injunction and permanent injunctive relief to enjoin Defendants from: (a) violating 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or 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

(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), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Jurisdiction and Venue

4. 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).

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

Defendants and Their Operations

6. Cantrell Drug Company is a corporation located at 7321 Cantrell Road, Little Rock, Arkansas, 72207, within the jurisdiction of this Court. Cantrell obtained a pharmacy license from the Arkansas Board of Pharmacy for retail and manufacturing and distribution operations.

7. James L. "Dell" McCarley, Jr. is Cantrell's Chief Executive Officer and has co-owned the company since January 1992. Defendant McCarley is the person most responsible for Cantrell's operations. Defendant McCarley retains financial and operational authority over the business, including the ability to prevent, detect, and correct violations. Defendant McCarley performs his duties at Cantrell, within the jurisdiction of this Court.

8. During their regular course of business, Defendants manufacture, process, pack, label, hold, and distribute articles of drug, within the meaning of 21 U.S.C. § 321(g)(1). The majority (97%) of Defendants' drug products, by virtue of their labeling and/or route of administration, purport to be or are expected to be sterile. 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 are administered and/or injected into patients via the following methods: intravenous (into a vein), intramuscular (into a muscle), subcutaneous (under the skin), and epidural (into the space outside the spinal cord's dura mater).

9. Most of Defendants' sterile injectable drug products are intended to be aseptically processed, which involves filling drug products that have been rendered sterile by filtration, into their final containers in a manner that maintains sterility.

10. Defendants' facility contains "cleanrooms" where it produces purportedly sterile drugs. The cleanrooms contain "ISO 5" and "ISO 7" processing areas (referring to International Standards Organization classifications for clean rooms). ISO 5 processing areas are critical zones that, by designation, have the highest level of cleanliness within Defendants' facility. Defendants' ISO 5 areas purport to have sufficient protection from contamination during the aseptic processing of sterile drugs.

11. Defendants distribute most of their drugs directly to hospitals and other health care entities throughout the United States, including to North Carolina, Pennsylvania, Colorado, and Virginia.

12. Defendants manufacture drugs at Cantrell using components that were shipped in interstate commerce, including components from New York and Illinois.

Requirements of the Act

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

14. 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).

15. The Act requires that drugs be manufactured in accordance with the current good manufacturing practice ("CGMP") requirements. 21 U.S.C. § 351(a)(2)(B); 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 it 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 finished pharmaceuticals at 21 C.F.R. Parts 210 and 211.

Requirements for Outsourcing Facilities

16. Compounding generally refers to the practice in which a licensed pharmacist or physician (or, in the case of an "outsourcing facility," a person under the direct supervision of a licensed pharmacist) combines, mixes, or alters ingredients to create a drug. Outsourcing facilities are not required to obtain prescriptions for identified individual patients.

17. 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).

18. On December 16, 2013, Cantrell registered with FDA as an outsourcing facility and, thereafter, its operations were subject to the requirements of 21 U.S.C. § 353b. Cantrell

continues to be subject to 21 U.S.C. § 353b, and most recently re-registered as an outsourcing facility on October 12, 2016.

19. Cantrell's operations are subject to the Act's provisions which deems drugs to be adulterated if they are prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health. 21 U.S.C. § 351(a)(2)(A).

20. As an outsourcing facility, Cantrell's operations are subject to the Act's adulteration provisions regarding CGMP. 21 U.S.C. § 351(a)(2)(B).

FDA's 2017 Inspection of Cantrell

21. FDA conducted its most recent inspection at Cantrell between June 12 and 29, 2017 ("2017 Inspection"), which was initiated to determine whether Defendants corrected the deficiencies observed and discussed with Defendant McCarley during the previous FDA inspection conducted in 2016.

22. During the 2017 Inspection, FDA investigators documented that Defendants manufacture drug products under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health, and in a manner that does not conform to CGMP. The FDA investigators' inspectional observations were listed in a Form FDA-483, List of Inspectional Observations ("FDA 483"), which was provided to Defendant McCarley at the conclusion of the inspection. The FDA investigators discussed each of the inspectional observations with Defendant McCarley.

Adulteration Based on Insanitary Conditions

23. During the 2017 Inspection, FDA investigators observed that Defendants' own documentation revealed that Cantrell repeatedly 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. On at least twelve (12) different occasions between January and May 2017, Defendants' environmental monitoring in its ISO 5 areas detected microbes in excess of their "action limit" (i.e., a level of contamination high enough to trigger a response, such as an investigation and corrective action). The microbial contamination identified by Cantrell consisted of bacteria, including but not limited to, *Bacillus oleivorans*, *Staphylococcus epidermidis*, *Micrococcus luteus*, and *Bipolaris spicifera*. If any of these organisms are present in an injectable product and administered to a patient, they are capable of causing serious adverse effects.

24. FDA investigators also observed that Defendants' employees did not accurately record data on microbial growth that had been detected in air and on surfaces used for sterile processing, as well as on equipment used and personnel engaged in drug product manufacturing. On at least nine (9) occasions in June 2017, Defendants' documentation logged that no "colony forming units" (i.e., visible microorganisms) were present in environmental and personnel monitoring plates; however, on those same occasions, FDA investigators observed a range of one (1) to twenty-six (26) colony forming units in the same plates. Some of the microorganisms had been detected in the critical processing areas (inside the ISO 5 processing hoods) or on personnel in the immediate vicinity of the ISO 5 areas.

25. FDA investigators also observed that Defendants' own records also documented that its contract laboratory detected spore-forming bacteria on contact surfaces inside and adjacent to Defendants' aseptic processing rooms and on personnel gloves. The spore-forming bacteria identified by Defendants' contract laboratory included, but was not limited to, *Bacillus cereus*, *Paenibacillus taiwanensis*, *Kroppenstedtia eburnean*, and *Sporosarcina luteola*.

26. FDA investigators also observed that Cantrell disregarded the potential adverse impact of the microbial contamination on patients. For example, on May 12, 2017, after detecting *Staphylococcus epidermidis* on surfaces in the ISO 5 area used for aseptically processing Sodium Bicarbonate 8.4% Injection Solution (50 mL) Syringe (Lot 10204), Cantrell released the product for distribution.

27. FDA investigators observed and documented other evidence of insanitary conditions during the 2017 Inspection, including:

A. Failure to ensure air quality in aseptic processing areas. Maintaining positive airflow and pressure differentials (i.e., zero or negative pressure) from areas of higher air quality (e.g., ISO 5 cleanrooms) to areas of lower air quality (e.g., anterooms adjacent to cleanrooms) is necessary to prevent microbial contamination of sterile drug products during processing. Without proper airflow, there is no assurance that the air quality in the aseptic processing areas is tightly controlled and continuously maintained, which, in turn, can cause microbial contamination in drug products being processed in those areas; and

B. Failure to ensure adequate high-efficiency particulate air (HEPA) filters in aseptic processing areas. Air entering cleanrooms must be HEPA filtered to remove airborne particles. HEPA filter leaks and gaps around HEPA filters have an impact on the unidirectional airflow that is necessary to protect sterile components and products from microbial contamination within the hood during aseptic processing. If HEPA filters are not sealed, air that is not HEPA filtered could enter the cleanroom, with the potential to introduce microorganisms. Cantrell's failure to seal gaps around the HEPA filters was an issue that was brought to its attention by FDA in 2016.

28. The insanitary conditions that FDA investigators identified at Defendants' facility during the 2017 Inspection establish that drugs manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that they are prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health.

Adulteration Based on CGMP Violations

29. During the 2017 Inspection, FDA investigators documented significant deviations from the CGMP requirements in Defendants' sterile drug manufacturing operations, including the following:

A. Failure to establish and follow appropriate written procedures, including validation of all aseptic and sterilization processes designed to prevent microbiological contamination of drug products purporting to be sterile (*see* 21 C.F.R. § 211.113(b)). Cantrell detected microbial contamination at actionable levels in ISO 5 processing areas during environmental and personnel monitoring. In addition, Cantrell recorded zero (0) microbial growth on environmental and personnel monitoring plates when, on the same day, FDA investigators observed a range of one (1) to twenty-six (26) colonies on the same plates;

B. Failure to establish adequate control systems necessary to prevent contamination during aseptic processing, including but not limited to an air supply filtered through HEPA filters under positive pressure (*see* 21 C.F.R. § 211.42(c)(10)(iii)), and a system for cleaning and disinfecting the room and equipment to produce aseptic conditions (*see* 21 C.F.R. § 211.42(c)(10)(v)). During routine re-qualification in 2016, Cantrell learned that eight (8) of the hoods it used for aseptic processing had leaks in the HEPA filters. FDA investigators observed that these leaks persisted during the 2017 Inspection. Gaps around the HEPA filters

also have been repeatedly observed during the 2017 and an earlier 2016 inspection. In addition, Defendants' operators placed their heads and parts of their bodies inside an ISO 5 classified hood during cleaning operations prior to the start of production. Subsequently, an environmental sample taken from that same hood determined the presence of a microorganism;

C. Failure to establish and follow written procedures for cleaning equipment used in the manufacture, processing, packing, or holding of a drug product (*see* 21 C.F.R. § 211.67(b)). Cantrell's routine cleaning and disinfectant procedures have not been scientifically evaluated to ensure their effectiveness. According to manufacturer instructions, a cleaning solution used at Cantrell's facility requires a certain amount of contact time to be effective against spore-forming bacteria. Cantrell routinely used the product with only one-third of that contact time. Cantrell routinely used another cleaning solution with only half the contact time that the manufacturer instructed was required for effectiveness against spore-forming bacteria. Defendants' own records indicate that spore-forming bacteria were found on surfaces throughout the facility on multiple occasions, including on operator gloves, in an ISO 5 hood, and on a keyboard used in an ISO 7 room;

D. Failure to thoroughly review and investigate unexplained discrepancies and the failure of a batch or any of its components to meet any of its specification, whether or not the batch has already been distributed (*see* 21 C.F.R. § 211.192). Cantrell failed to conduct adequate investigations of microbial contamination found in aseptic processing areas (on surfaces, in the air, and on personnel), as well as spore-forming bacteria detected in ISO 5 rooms, ISO 7 rooms, and on operator gloves. Cantrell also aborted sterility test results derived from a rapid microbial detection system, and retested and released products without establishing whether the aborted tests were valid;

E. Failure to have adequate training for each person engaged in aseptic processing (*see* 21 C.F.R. § 211.25(a)). Defendants' employees were observed placing their heads and parts of their bodies inside the ISO 5 hood during aseptic cleaning operations prior to production, and Defendants' employees did not sanitize their gloves after touching non-sterile product prior to entering the ISO 5 hood. Defendants repeatedly have identified training as the root cause of these failures; and

F. Failure to have an adequate quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling, and drug products, and the authority to review production records to assure that errors have not occurred or, if errors have occurred, that they have been fully investigated (*see* 21 C.F.R. §§ 211.22(a), (d)). Defendants' quality control unit not only failed to review and record accurate environmental excursions, but it also failed to ensure that adequate investigations were conducted. Cantrell recorded zero (0) colonies on nine (9) different environmental and personnel plates without review and signature of the results from its quality control unit as required, and on the same day, FDA observed a range of one (1) to twenty-six (26) colonies on those exact plates. Defendants' quality control unit also released a batch of Sodium Bicarbonate 8.4% Injection Solution (50 mL) Syringe (Lot 10204), even though Cantrell was aware of and documented bacterial growth in the aseptic processing areas on the date that batch was produced.

30. These observations establish that Defendants' drugs are 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, or holding do not comply with CGMP to assure that they meet the requirements of the Act as to their safety and that they have the identity

and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

Defendants' 2017 Recall of Sterile Drug Products

31. Shortly after the conclusion of FDA's 2017 Inspection, on July 25, 2017, Defendants voluntarily recalled all lots of non-expired purportedly sterile drug products that it compounded and distributed nationwide between February 16 and July 19, 2017, based in part on several of the issues raised during FDA's 2017 Inspection.

32. The recall involved drugs packaged in a syringe or IV Bag. The recall notice stated that "Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening."

Defendants' Operations

33. Despite being aware that their injectable drug products may present a risk to patient health, Defendants represented to FDA that they intended to cease aseptic operations only on a temporary basis and did not commit to waiting for FDA to confirm compliance with the Act and its implementing regulations. Defendant McCarley gave FDA less than 24 hours' notice before Defendants resumed aseptic processing operations.

34. FDA informed Defendants on multiple occasions that it had no assurance of Defendants' products' sterility, and urged the company to not resume sterile compounding. Defendants proceeded to manufacture and distribute purportedly sterile drugs in disregard to FDA's ongoing concerns.

FDA's 2016 Inspection of Cantrell

35. FDA inspected Cantrell between September 14 and October 14, 2016 (the "2016 Inspection") and observed similar insanitary conditions and CGMP deficiencies.

36. During the 2016 Inspection, FDA investigators documented that Defendants manufacture drug products under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health, and in a manner that does not conform to CGMP. The FDA investigators' inspectional observations were listed in a Form 483, which was provided to Defendant McCarley at the conclusion of the inspection. The FDA investigators discussed each of the inspectional observations with Defendant McCarley.

Adulteration Based on Insanitary Conditions

37. FDA investigators observed and documented evidence of insanitary conditions during the 2016 Inspection, including:

A. Failure to prevent microbial contamination within the ISO 5 and surrounding areas. Spore-forming microorganisms, including bacteria and mold, were recovered in six (6) different ISO 5 hoods. The presence of mold is especially concerning in light of other findings during the 2016 Inspection. For instance, an operator stated that she did not know what fungal growth would look like under the microscope, and stated that she did not have reference photos for epifluorescent microorganisms and particles. Additionally, Cantrell was observed using an incubator for environmental fungal samples that had failed a validation more than two years prior for its inability to maintain temperatures within acceptable criteria. Temperature readings taken from the incubator in the three months prior to the 2016 Inspection noted a total of sixteen (16) temperature readings outside the acceptable criteria;

B. Failure to maintain positive pressure differentials to ensure air quality in aseptic processing rooms. Cantrell was notified during a routine certification that pressure differentials between certain rooms that did not meet minimum requirements. This was not corrected nine (9) months later, when FDA conducted the 2016 Inspection;

C. Failure to ensure proper personnel practices. For example, Defendants' operators were observed storing sterile wipes openly on a cart, where the wipes came into contact with, among other things, sleeves of operator gowning, the surface of the cart, and paper transferred from a non-classified area. The same wipes were then used to clean the inside of ISO 5 hoods. Multiple operators were also observed with skin exposed around their goggles, facemasks, and necks;

D. Failure to maintain HEPA filters and light fixtures located in aseptic processing rooms. In a gap around a ceiling light adjacent to a HEPA filter in an ISO 8 room, a blackish substance was observed. Duct work could also be seen through the gaps; and

E. Failure to adequately clean and disinfect equipment to produce aseptic conditions. Equipment that was not easily cleanable, including corded and wireless computer mouses without any protective coverings and laptops containing exposed keyboards, were observed being used inside of and adjacent to multiple ISO 5 hoods. Additionally, a diluted cleaning agent was observed being stored with expiration dates 28 days and 56 days, in contradiction to the manufacturer's instructions that it only be stored for 14 days after dilution.

38. The insanitary conditions that FDA investigators observed at Defendants' facility during the 2016 Inspection establish that drugs manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that they are prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health.

Adulteration Based on CGMP Violations

39. During the 2016 Inspection, FDA investigators also documented serious deviations from CGMP requirements, many of which were subsequently observed during the 2017 Inspection, including:

A. Failure to establish and follow appropriate written procedures, including validation of all aseptic and sterilization processes, designed to prevent microbiological contamination of drug products expected to be sterile (as exemplified by recurring environmental monitoring excursions) (*see* 21 C.F.R. § 211.113(b));

B. Failure to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess, and to record and justify deviations from the written procedures (*see* 21 C.F.R. § 211.100(a) & (b));

C. Failure to clean and disinfect equipment to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug (*see* 21 C.F.R. § 211.67); and

D. Failure to thoroughly review and investigate unexplained discrepancies and the failure of a batch or any of its components to meet any of its specification, whether or not the batch has already been distributed (*see* 21 C.F.R. § 211.192).

40. These observations establish that Defendants' drugs are 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, or holding do not comply with CGMP to assure that they meet the requirements of the Act as to their safety and that they have the identity

and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

Defendants' 2016 Recall of Sterile Drug Products

41. Shortly after the conclusion of FDA's 2016 Inspection, on November 18, 2016, Defendants conducted a voluntary recall of certain unexpired sterile drug products due to lack of sterility assurance. These recalled drug products were distributed nationwide from May 25 to October 31, 2016.

42. The recall notice stated that "Administration of a drug product intended to be sterile that is not sterile could result in serious infections that may be life-threatening."

FDA Warning Letter to Defendants

43. FDA issued Defendants a Warning Letter on January 21, 2015, as a result of an inspection between October 15 and November 4, 2013 (the "2013 Inspection") that revealed many similar inspectional observations as were noted during the 2016 and 2017 Inspections.

44. The January 21, 2015, Warning Letter put Defendants on notice that their products "may be produced in an environment that poses a significant contamination risk." (January 21, 2015 Warning Letter to Defendant McCarley, available at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm434906.htm.)

45. The Warning Letter also contained a detailed explanation of the deficiencies in the corrective actions proposed by Defendants.

46. Defendants responded in writing to the 2016 and 2013 inspectional observations and Warning Letter. These written responses contain repeated promises to take corrective actions.

47. Despite promises to correct their deficiencies, Defendants' violations persisted, as evidenced by the insanitary conditions and CGMP violations observed during FDA's 2017 Inspection.

48. Despite FDA communicating to Defendants on multiple occasions that it had no assurance of Defendants' products' sterility, and urging that the company not resume sterile compounding, Defendants proceeded to manufacture and distribute purportedly sterile drugs.

49. Documentation of purported remediation that Defendants have submitted to FDA subsequent to the 2017 Inspection fails to establish that Defendants are operating in compliance with the law.

50. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering 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).

51. Defendants violate 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), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

52. Based on the foregoing, Plaintiff believes that, unless restrained by the Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Order that 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, cease 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. Order that 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, are preliminarily and permanently restrained and enjoined under 21 U.S.C. § 332(a) 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

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), while such drug is held for sale after shipment of one or more of its components in interstate commerce;

III. Order that FDA be authorized 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 ___ day of _____, 2018.

Respectfully submitted,

CODY HILAND
United States Attorney

/s/ Shannon Smith
SHANNON SMITH
Arkansas Bar No. 94172
Assistant United States Attorney
425 West Capitol, Suite 500
Little Rock, AR 72201
501-340-2600
Shannon.Smith@usdoj.gov

CHAD A. READLER
Acting Assistant Attorney General
Civil Division

GUSTAV EYLER
Acting Director
Consumer Protection Branch

/s/ Raquel Toledo
RAQUEL TOLEDO
Pennsylvania Bar No. 321175
Trial Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
(202) 532-4719
Raquel.Toledo@usdoj.gov

OF COUNSEL:

ROBERT P. CHARROW
General Counsel

REBECCA K. WOOD
Chief Counsel
Food and Drug Division

ANNAMARIE KEMPIC
Deputy Chief Counsel for Litigation

JENNIFER KANG
Associate Chief Counsel
Office of the General Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 31, Room 4545
Silver Spring, MD 20993-0002
(240) 402-0347

CERTIFICATE OF SERVICE

I hereby certify that I have mailed and served the document or paper to the following participants in the manner indicated by the participant's name:

S. Graham Catlett (overnight mail and email)
Catlett Law Firm, PLC
323 Center Street, Suite 1800
The Tower Building
Little Rock, Arkansas 72201
Attorney for Defendants

By: */s/ Raquel Toledo*
RAQUEL TOLEDO
Pennsylvania Bar No. 321175
Trial Attorney
Consumer Protection Branch
Department of Justice, Civil Division
P.O. Box 386
Washington, D.C. 20044
202-532-4719
Raquel.Toledo@usdoj.gov