IN THE MATTER OF	*	**BEFORE THE**
CANTRELL DRUG COMPANY, INC.	*	**STATE BOARD OF**
RESPONDENT-DISTRIBUTOR	*	**PHARMACY**
	*	
	*	
PERMIT NO: D05438		**CASE NO: PI-17-123**

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CONSENT ORDER

On August 15, 2018, the Maryland Board of Pharmacy (the "Board"), pursuant to Md. Code Ann., Health Occ. §§ 12-6C-01 *et seq.*, charged Cantrell Drug Company, Inc. (the "Respondent-Distributor") with violations of the Maryland Wholesale Distributor Permitting and Prescription Drug Integrity Act (the "Act") (2014 Repl. Vol., 2017 Supp.).

The pertinent provisions of the Act state as follows:

§ 12-601. Denial, suspension, or revocation of permit.

> (a) Subject to the hearing provisions of § 12-315 of this title, for a violation of this subtitle, Subtitle 6C of this title, or any regulation adopted under Subtitle 6C of this title, the Board may:
>
> (1) Deny a permit to an applicant;
> (2) Reprimand a permit holder;
> (3) Place a permit holder on probation; or
> (4) Suspend or revoke a permit.

§ 12-6C-03.2. Inspection of sterile drug products; report

(a) Notwithstanding any other provision of this subtitle, a wholesale distributor applicant or permit holder that prepares sterile drug products shall submit to the Board a report of an inspection conducted by the U.S. Food and Drug Administration or a Board designee:

(1) At the time of application; and
(2) On renewal.

(b) The inspection report required under subsection (a) of this section shall:

(1) Be conducted within 1 year before the date of application or renewal; and

(2) Demonstrate compliance with applicable federal good manufacturing practice standards.

The pertinent provisions of COMAR state as follows:

COMAR 10.34.22.05. Violations and Penalties

A. After a hearing held under Health Occupations Article, §12-601, Annotated Code of Maryland, the Board may deny, suspend, revoke, or place on probation a permit holder, reprimand a permit holder, or impose a fine if the permit holder:

...

(3) Commits any of the following acts:

...

(d) Violates a provision of, or regulation promulgated under, Health Occupations Article, Title 12, Annotated Code of Maryland;

(e) Manufactures, repackages, sells, delivers, or holds or offers for sale any prescription drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution or wholesale distribution;

(f) Adulterates, misbrands, or counterfeits prescription drugs or devices;...or

(v) Otherwise conducts the wholesale distribution of prescription drugs or devices in a manner not in accordance with the law[.]

(4) Is disciplined by a licensing or disciplinary authority of any state or country, or disciplined by a court of any state or country, for an act that would constitute a ground for Board action against a wholesale distributor permit holder under §A or B of this regulation.

On October 10, 2018, James L. McCarley, Jr., owner of the Respondent-Distributor, appeared before members of the Board for a Case Resolution Conference (CRC) to discuss the potential resolution of the Charges by consent. Thereafter, the Respondent-Distributor and the Board agreed to resolve the matter as set forth herein.

FINDINGS OF FACT

The Board finds the following:

1. At all times relevant to Board's Charges, the Respondent-Distributor was located in Little Rock, Arkansas.
2. The Respondent-Distributor was issued wholesale distributor permit number D05438 to distribute drugs into the State of Maryland on March 28, 2014.
3. The Respondent-Distributor's permit expires on May 31, 2019.
4. The Respondent-Distributor performs sterile compounding of prescription drugs

which it distributes to physicians' offices and hospitals for administration.

5. A Food and Drug Administration (FDA) MedWatch alert was received by the Board from the FDA on November 21, 2016, which indicated that on October 14, 2016, the FDA issued a Form 483 List of Observations pertaining to the Respondent-Distributor.

6. The Form 483 was prepared after conducting an inspection of the Respondent-Distributor's facility, and the redacted Form 483 can be found on the FDA's website at:

https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM527806.pdf.

7. The FDA Form 483 cited many sterility issues and violations of current good manufacturing practice (CGMP) requirements, four of which were repeat violations observed in a 2013 inspection and not corrected after the FDA had issued the Respondent-Distributor a Warning Letter on January 21, 2015.

8. The January 21, 2015 Warning Letter includes admonitions regarding the lack of sterility in the Respondent-Distributor's sterile compounding facility and cites violations of the Food, Drug and Cosmetic Act (FDCA) for its failure to obtain valid prescriptions for individually-identified patients, thus causing them to be considered adulterated pursuant to 501(a)(2)(B) of the FDCA.

9. Observations noted by the FDA on the October 14, 2016 Form 483 include but are

not limited to the following:

a. **Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.**

   i. Cleaning solutions were observed stored on rolling carts adjacent to ISO 5[1] Hoods inside of ISO 7 Rooms. On September 15, 2016, sterile wipes were observed being stored openly on a rolling cart which came in contact with the sleeves of the operator's gowning and gloves, the surface of the metal cart, and paper transferred from the non-classified area. The sterile wipes were then observed being used to clean the inside of the ISO 5 Hoods.

   ii. Despite the use of "sporicidal agent," multiple spore forming microorganisms were recovered in the Respondent-Distributor's ISO 5 environment during periods when the Respondent-Distributor was producing products purporting to be sterile.

   iii. On September 15, 2016, an operator failed to adequately sanitize the

[1] "ISO" means International Organization for Standardization. COMAR 11.14.07.02(7). ISO develops and publishes International Standards, http://www.iso.org/iso/home.htm. The relevant ISO standard in this case is ISO 14644-1, Cleanrooms and associated controlled environment – Part 1: Classification of air cleanliness by particle concentration. http://www.iso.org/iso/catalogue_detail?csnumber=53394. ISO 14644-1 provides 10 cleanroom classifications rated according to how much particulate of specific sizes exist per cubic meter; for example, ISO 6 means Class 6. https://www.terrauniversal.com/cleanrooms/iso-classification-cleanroom-standards.php.

IV bags, including the "belly button" (needle port) and secondary port, prior to placing them inside of the ISO 5 hood and performing a needle stick or spike while filling Heparin 5,000 units in NS-1,000 mL bags.

iv. Corded and wireless computer mouses with scroll wheels did not contain any protective covering and were observed being used inside of multiple ISO 5 hoods. Laptops containing exposed keyboards stored on rolling carts adjacent to the ISO 5 Hoods were observed being used, and portable walkie talkies and wall mounted phones were observed in use in the ISO 7 Buffer Room. The aforementioned did not appear to be easily cleanable surfaces.

b. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

i. The media fills did not represent the batch size, worst case scenario or the most challenging conditions.

ii. Numerous deficiencies in aseptic technique were observed, including operators with their upper body inside of the ISO 5 hood during aseptic filling and without adequately sanitized gloves. The operator failed to adequately sanitize all sides of sterile pads prior to

placing them inside of the ISO 5 hood while compounding. Operator gowning continuously came in contact with various items in the ISO 7 Buffer Room which have not been sanitized, and then operator gowning was not changed prior to producing products purporting to be sterile inside of the ISO 5 hood. Further, exposed skin was observed around the goggles, facemask, and neck of multiple operators.

iii. The Respondent-Distributor did not demonstrate that its method of washing and drying glassware and metal ware can achieve appropriate log reduction of microbes, and the Respondent-Distributor did not use any biological indicator during the drying cycle in the dishwasher.

iv. The Respondent-Distributor failed to conduct smoke studies under dynamic conditions.

c. Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

i. The ceiling tiles in the ISO 7 clean rooms[2] contained gaps around the

[2] Clean room" means a room with an International Standards Organization (ISO) Class 5 environment or an ISO Class 7 environment that meets USP 797 Standards, inside which compounding occurs within an ISO Class 5 engineering control device such as a laminar airflow workstation or a biological safety cabinet. COMAR 10.34.19.03(6).

HEPA filters and light fixtures.

ii. A blackish substance was observed in the gap of the ceiling light adjacent to the HEPA filter in the ISO 8 Ante Room. The duct work could be seen through the gaps.

iii. The air returns located in the ISO 8 Buffer Room appeared to be a reddish-brownish color consistent with rust, and the return above the sink appeared to have a whitish substance on it.

iv. The ISO 7 Buffer Room contained exposed porous surfaces from tears in the epoxy flooring, scuffed walls were observed adjacent to the ISO 5 Hood, and the electrical outlet behind a hood contained a gap at the cutout for the plug.

v. Reddish-brownish colored surfaces were noted at the base of the Plexiglass at the glass-metal juncture in the ISO 5 hoods visible in two ISO 7 Buffer Rooms.

vi. Labeled and unlabeled totes contained products at different statuses: finished drug products ready for shipment, rejected products, quarantined products, bulk drugs, retained samples, and samples marked for destruction. Products of all statuses were co-mingled. The staging area contained labeled and unlabeled totes containing products at different statuses.

d. Test procedures relative to appropriate laboratory testing for sterility and pyrogens are not written and followed.

i. The Respondent-Distributor's testing protocol did not establish a threshold of events to be verified as necessary before classifying a result as inconclusive. The "QC specialist stated events are designated as inconclusive if they appear 'suspect' or TNTC (too numerous to count)."

ii. The Respondent-Distributor does not maintain an example of what a viable microorganism positive signal would look like if present. The operator described what a particle and bacteria would look like, but stated, "I do not know what fungal would look like."

iii. The Respondent-Distributor does not always retest inconclusive samples using the remaining sample from the original containers when testing in-house. A new container is always submitted to a third party laboratory for retesting.

iv. The Respondent-Distributor's policy on endotoxins did not define a criterion for retesting endotoxin levels until a result of passing is achieved. The Respondent-Distributor routinely fails to initiate or adequately investigate endotoxin failures. The Respondent-Distributor also does not perform endotoxin testing on

all finished products. On July 5, 2016, the Respondent-Distributor produced and then performed endotoxin testing on Cardiac Reperfusate Solution 188mL bags three times before submitting a new bag for sampling to a 3rd party vendor. The endotoxin result from the 3rd party vendor was 28.68 EU/mL. The Respondent-Distributor identified one of the components used was Monosodium-L-Glutamate (MSG), which contained an endotoxin level >25 EU/mL. At least five products using the contaminated MSG were released to the market.

e. **There is no written testing program designed to assess the stability characteristics of drug products.**

   i. The Respondent-Distributor does not have stability data to support the BUD assigned for all products purporting to be sterile produced by the Respondent-Distributor. Three products on the drug shortage list produced by the Respondent-Distributor did not have stability studies.

f. **Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.**

   i. The Respondent-Distributor did not perform potency testing for five

different products.

ii. The Respondent-Distributor does not visually inspect all finished products prior to release.

g. Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

i. The Respondent-Distributor documented 1 CFU for a plate that was observed as TNTC during the plate reading of the environmental sample taken on September 12, 2016. Two products were produced on this dated and released to the market.

ii. On September 16, 2016, Glove Fingertip Sampling was observed during Personnel Monitoring which consisted of the sterile compounding technician. This Glove Fingertip Sampling method is inadequate.

iii. The Respondent-Distributor's performance qualifications/validations from September 2014 for an incubator located in the quality laboratory were reviewed. The incubator is used to incubate environmental fungal samples. The documents showed that the company the Respondent-Distributor hired to conduct the validation failed the equipment and wrote: "Due to the recovered results the unit was found to be unable to maintain Temperatures within the

acceptance criteria and is considered unreliable to maintain desired temperatures." The recommendation was given that the unit be removed from service and replaced with a more suitable unit. In the last three months the incubator was recorded to have a temperature below the lower limit eleven times and above the upper limit five times. The incubator was still in use as of October 6, 2016.

h. Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

i. The ISO 8 Ante Room separating the ISO 7 Buffer Room (positive pressure) from the ISO 8 Labeling Area lacked HEPA filtration from January 2015 to July 2016; the ISO 7 Buffer Room (negative pressure) is connected to ISO 7 Buffer Room. Your Respondent-Distributor's President stated this was an oversight in design that was not corrected until July 2016. The ISO 8 Ante Rooms leading into ISO 7 Buffer Room did not meet the minimum pressure differential. The Respondent-Distributor does not perform periodical review of the monitoring data to ensure cascading pressure differentials are maintained when drugs purporting to be sterile were produced. The Respondent-Distributor produced from

December 2014 to September 2016 however no evaluation product impact has been assessed to date.

i. **The building lacks adequate space for the orderly placement of equipment and materials to prevent mix-ups between different components, drug product containers, labeling, in-process materials and drug products and to prevent contamination.**

   i. On September 20, 2016, racks of labeled and unlabeled totes in Cleanroom contained Intermediate drug products, saline bags and the finished drug products, "Fentanyl Citrate 10mcg/mL in 0.9% Sodium Chloride 100mL Inj Bag." The Respondent-Distributor's Staff Pharmacist and PIC stated that the bags labeled as the finished drug products, "Fentanyl Citrate 10mcg/mL in 0.9% Sodium Chloride 100mL Inj Bag" did not contain the finished drug product, "Fentanyl Citrate 10mcg/mL in 0.9% Sodium Chloride 100mL Inj Bag."

   ii. Totes labeled as the finished drug product, "Fentanyl Citrate 10mcg/mL in 0.9% Sodium Chloride 100mL Inj Bag" contained bags without their outer sleeves. The Respondent-Distributor's Staff Pharmacist and PIC stated those bags are the finished drug product, but the bags are not labeled as the finished drug product until they

leave the cleanroom.

j. **There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.**

   i. The Respondent-Distributor's Internal Finding Records (IFRs), used to document out-of-specification results for personnel and environmental monitoring samples, potency failures, sterility failures, and endotoxin failures, do not require investigations into issues. 19 out of 19 IFRs reviewed during this inspection revealed the Respondent-Distributor does not fully conduct and document investigations. The SOP on documentation on internal findings does not include the requirement of an investigation of failing testing results.

k. **The labels of the Respondent-Distributor's outsourcing drug products are deficient.**

   i. The labels of the outsourcing drug products do not include information required by section 503B(a)(10)(A).

l. **Deviations from written production and process control procedures are not recorded and justified.**

   i. On October 12, 2016, Glycopyrrolate 1mg/5mL (0.2mg/mL) syringes were observed stored touching a portable space heater reading between 91-92°F during the labeling process. The batch

record and labeling both states the product should be stored at room temperature. No impact assessment has been performed to determine the effect on the identity, quality, strength, and purity of this product.

10. On November 2, 2016, the Respondent-Distributor temporarily ceased sterile compounding to protect their customers while the facility addressed the FDA's observations.

11. On November 21, 2016, the Respondent-Distributor voluntarily recalled 29 lots of sterile drug products due to a lack of sterility assurance.

12. On December 16, 2016, the Respondent-Distributor sent a letter to the Board indicating they would resume manufacturing operations on December 15, 2016.

13. From June 12, 2017 to June 29, 2017, the FDA returned to the facility for a subsequent inspection.

14. Again, the FDA issued the facility an FDA Form 483 citing sterility issues and CGMP violations, four of which were repeat issues from the previous inspection. The four additional deficiencies noted were as follows:

    a. **The quality control unit lacks authority to fully investigate errors that have occurred.**

        i. Environmental and Personnel Monitoring plates are not accurately enumerated to reflect colonies present. In an area housing numerous agar plates attributed as "trash" due to a lack of colonies, several

bags with agar plates containing growth were observed. Colonies were discovered on plates with intact plate covers. The Respondent-Distributor's Microbiologist stated that the plates with intact plate covers and colonies were read by the Respondent-Distributor's technician prior to the FDA's arrival. The Microbiologist also indicated that the plates designated as "trash" would not be further evaluated. In addition, discrepancies in colonies were observed versus those that the Respondent-Distributor recorded.

b. The responsibilities and procedures applicable to the quality control unit are not fully followed.

i. Upon review of documents contained in the Respondent-Distributor's shredding bins, the FDA discovered that the Respondent-Distributor discarded original documentation, including incidences, deviations and manufacturing occurrences not elsewhere officially documented.

ii. The Respondent-Distributor "appears to have a practice of altering manufacturing records." Several batch records were discovered containing instructions (on sticky notes) to modify their contents. This practice is not consistent with contemporaneous batch record

completion, in accordance with the Respondent-Distributor's policies and procedures.

iii. Several "weight checks" (testing data) displayed anomalies.

c. There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

i. Specifically, the Respondent-Distributor documented known environmental excursions and failed to conduct an investigation to determine a root cause or assess the impact to products intended for sterile use.

ii. System and User Abort events were exhibited that had not been investigated, but the products that were the subject of the events were subsequently retested and released.

iii. The Respondent-Distributor failed to perform an investigation after ISO 5 Hoods were identified with HEPA filter leaks during re-certification. From August to November of 2016, these hoods were utilized for aseptic processing, however, the Respondent-Distributor failed to conduct a retrospective investigation into product impact.

d. There is no written testing program designed to assess the stability characteristics of drug products.

i. Endotoxin amount in the drug products was not tested throughout the shelf life in the stability studies.

15. Thereafter, on a monthly basis, the Respondent-Distributor updated the FDA on their progress correcting issues observed in the FDA Form 483.

16. The Respondent-Distributor also hired a third-party compliance firm to assess progress towards remediation, and the facility temporarily ceased production on July 20, 2017, and announced a voluntary recall of all of their sterile drug products on July 25, 2017.

17. In September 2017, the Respondent-Distributor resumed distributing its compounded drugs despite the FDA advising the Respondent-Distributor not to on at least six occasions because there was no sterility assurance.

18. In November 2017, the Respondent-Distributor filed Chapter 11 Bankruptcy, stating the company needed to reorganize its debts due to the two production shutdowns in response to the FDA inspections.

19. On March 1, 2018, the FDA filed an injunction against the Respondent-Distributor in the U.S. District Court for the Eastern District of Arkansas, Case No. 4:18-cv-159, to prevent the company from further producing and distributing drugs and ordering it to recall all drug products. The injunction states the

following:

A. Defendants' drugs are adulterated based on unsanitary conditions.
    1. Defendants fail to respond to environmental monitoring results.
    2. Defendants fail to maintain necessary air quality.
B. Defendants' drugs are adulterated based on failure to comply with cGMP as required by federal law.
    1. Defendants fail to adhere to cGMP regulations.
    2. Defendants have not adequately remediated cGMP deficiencies.
C. Defendants introduce adulterated drugs into interstate commerce.
D. Defendants cause drugs to be adulterated while such drugs are held for sale after shipment of one or more of their components in interstate commerce.
E. There is a cognizable danger that defendants will continue to violate the FDCA.
F. The requested preliminary injunction is tailored to restrain defendants' violations.

20. The Respondent-Distributor then filed a temporary injunction against the FDA for a 45-day stay, claiming it had complied with all FDA requests, and it had received no notification that it had been in violation of the FDCA or that releasing products was prohibited by law.

21. Ultimately, the Court granted the stay.

22. On March 2, 2018, the FDA issued a warning that all health care professionals and patients cease using drug products produced by the Respondent-Distributor including opioid products and other drugs intended for sterile injection due to serious deficiencies in the Respondent-Distributor's compounding operations,

including its processes to ensure quality and sterility assurance that put patient safety at risk.

23. From March 9, 2018 to March 22, 2018, the FDA returned to the facility for an inspection.

24. Again, the FDA issued the facility a Form 483. The Form 483 can be found on the FDA's website at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM604509.pdf.

25. The FDA Form 483 cited seven violations, two of which were repeat violations observed in the June 2017 inspection.

26. Observations noted by the FDA on the March 22, 2018 Form 483 include but are not limited to the following:

    a. **The Respondent-Distributor's quality control unit has not adequately investigated EM excursions and trends as follows:**

        i. Between December 2017 and February 2018, three viable organism recoveries were identified within ISO-7 producing areas on laptop keyboards used by compounding assistants. Assistants were observed placing and removing materials to/from ISO 5 hoods on March 13, 2018. No adequate corrective action has yet been determined and nearby product in ISO 5 hoods are not rejected by

the Quality Unit. Organisms found included Aspergillus spp., Staphylococcus auricularis, and Staphlococcus spp.

ii. Between December 19, 2017 and March 9, 2018, at least 22 viable organisms were identified from employee gown samples who work in ISO 7 areas. There is no adequate trending or root cause analysis for these recoveries. August 2017 smoke studies confirm turbulent flow and stagnant air in ISO 7 class growing rooms where air returns are co-located with HEPA air supply fixtures in the ceiling. Technicians wear "street" shoes inside the clean room which are covered with a fiber cloth shoe cover and inside sterile polyester gowning.

iii. Between June 1, 2017 and March 18, 2018, at least five viable organism recoveries were identified within ISO 5 production area laminar flow hoods that are used for processing sterile injectable drug products. No root cause has yet been identified. A plenum space above the ISO 7 cleanroom is not periodically cleaned or disinfected. Organisms includes Staphylococcus hominis, Talaromyces rugulosus, and Sclerotinia sclerorotiorum.

iv. The 3rd party consultant the Respondent-Distributor contacted beginning in December 2017 for conducting a review of the

compounded sterile finished drug batch records and associated documents made suggestions to documentation changes and provided an initial disposition of the batch, however, there is no internal protocol or mechanism to track and trend the results of this process to determine if the process changes are occurring or needed. The Respondent-Distributor's Director of Quality reported the 3rd party consultant recommended approving/releasing memorandum as part of all sterile finished drug product batch records, however, the Regulatory Administrative Assistant and Batch Record Reviewed reported they fail to include email communications and/or reference the location of received from the 3rd party consultant identifying deficiencies found during their secondary review.

v. The firm failed to follow the written procedure when changes were made to the differential pressure monitoring system for ISO 7 clean rooms where drug products are produced. No change control document was completed when changes were made to the electronic system used in the measuring and monitoring of temperature, differential pressure, and relative humidity.

vi. The written procedure for temperature, humidity, pressure differential monitoring of the classified and controlled areas fails to

require the documentation of the reviews of controls charts and the final conclusions as a result of the review.

vii. Anomalous results for negative controls has been produced and no deviation or "Internal Findings Report" was created to investigate or trend the performance of this equipment.

viii. After the contractor completed a "Certified Test, Adjust, and Balance Report" on February 17, 2018, which included adjustments to air velocities in ISO 7 Cleanrooms, no air visualization (smoke study) was performed on the ISO 7 rooms.

b. Complaint procedures are deficient in that they do not include provisions that allow for the review to determine if the complaints represent serious and unexpected adverse drug experiences which are required to be reported to the FDA. Additionally, full documentation of complaints is not always maintained such as original communication from the complainant and photos or descriptions of returned units.

c. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

i. On March 12, 2018, an operator was observed filling Morphine Sulfate for an injection batch whose glove had come off of the end of the gown sleeve while handling syringes inside the ISO 5 class

hood. A technician was also observed cleaning the ISO 7 room after production completed where the technician's glove had slipped off the end of the sterile gown sleeve.

d. **Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.**

   i. There are no written specifications for water used in topical non-sterile drug products such as topical LET (Lidocaine/Epinephrine/Tetracaine) gel to meet at least the USP purified water standard.

e. **The Respondent-Distributor compounded drugs that are essentially a copy of one or more approved drugs within the meaning of section 503B(a)(5) and 503B(d)(2).**

f. **The labels of the outsourcing drug products do not include information required by section 503B(a)(10)(A).**

g. **The Respondent-Distributor failed to submit a report to the FDA identifying a product compounded during the June 1, 2017 through November 30, 2017 reporting period as required by section 503B(b)(2)(A).**

27. On April 19, 2018, the Respondent-Distributor and the FDA entered into a Consent Decree of Permanent Injunction which prohibits the Respondent-Distributor from manufacturing, processing, packing, holding, or distributing drugs until it complies with the Federal Food, Drug, and Cosmetic Act (FDCA) and FDA regulations, in addition to other requirements. The Consent Decree remains in place for at least 60 months from the date of its execution.

28. The Boards of Pharmacy of several states have taken action against the Respondent-Distributor based upon the FDA's action. They are as follows:

    a. In 2017, Georgia denied the facility a license.

    b. In 2016, Alabama issued an emergency suspension.

    c. In 2017, Alabama fined the facility $30,000, and then later in October 2017 issued a second emergency suspension.

    d. In 2016, South Carolina restricted sterile compounded products from being shipped to the state.

    e. In 2017, South Carolina removed the restrictions but put the Respondent-Distributor on probation for two years.

    f. In 2017, New Hampshire granted an outsourcing permit to the Respondent-Distributor with the stipulation that it submit its biannual environmental monitoring reports and inspection reports to the New Hampshire board and report all environmental issues immediately.

g. In 2017, Illinois restricted the Respondent-Distributor's shipping into that state.

h. In 2017, Florida allowed the Respondent-Distributor to withdraw its application in that state.

i. In 2018, Alabama permanently revoked the Respondent-Distributor's license in that state.

j. On May 2, 2018, Ohio summarily suspended the Respondent-Distributor's license in that state.

k. On August 10, 2018, Virginia summarily suspended the Respondent-Distributor's license in that state.

29. According to a distribution report provided to the Board by the Respondent-Distributor, it has distributed approximately 71,892 drug products into Maryland between June 1, 2016 and March 1, 2018.

30. Drugs that are prepared, packed or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health are adulterated under the FD&C Act. Thus, the Respondent-Distributor's failure to demonstrate compliance with applicable federal good manufacturing practice standards is a violation of § 12-6C-03.2.

31. Drugs that are manufactured, repackaged, sold, or delivered in unsanitary conditions are adulterated. The Respondent-Distributor's manufacturing,

repackaging, sale, delivery, or offer for sale any prescription drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution or wholesale distribution is a violation of COMAR 10.34.22.05(A)(3)(e).

32. The Respondent-Distributor's violation of COMAR and/or the Act is a violation of COMAR 10.34.22.05(A)(3)(d).

33. The Respondent-Distributor's adulteration, misbranding, or counterfeit prescription drugs or devices is a violation of COMAR 10.34.22.05(A)(3)(f).

34. The Respondent-Distributor's failure to conduct distribution of prescription drugs or devices in a manner in accordance with the applicable federal and State law, including but not limited to, failing to maintain proper sterility, violations of current good manufacturing practice requirements, violations of the FDCA, alteration of manufacturing records, and failure to include required information on the labels of outsourcing drug products, is a violation of COMAR 10.34.22.05(A)(3)(v).

35. The Respondent-Distributor's Consent Decree of Permanent Injunction preventing the Respondent-Distributor from manufacturing, processing, packing, holding, or distributing drugs filed in the U.S. District Court for the Eastern District of Arkansas, as well as the disciplinary action taken in at least eight states against the Respondent-Distributor due to deficiencies in its operations, are violations of

COMAR 10.34.22.05(A)(5).

36. The Respondent-Distributor notes that Cantrell was not found in violation of the law by the DOJ or FDA.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent-Pharmacy violated the following provisions of the Act: § 12-601 and § 12-6C-03.2.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, it is this 9 day of JANUARY, ~~2018~~ 2019 by the affirmative vote of a majority of the members of the Board then serving:

ORDERED that the Respondent-Distributor's license to operate as a wholesale drug distributor in the State of Maryland is hereby **REPRIMANDED**; and it is further

ORDERED that the Respondent-Distributor shall provide to Board an FDA end of Inspection (EIR) Report indicating resolution of all issues identified in its 483 report issued on August 22, 2018 within ten days of its completion; and it is further

ORDERED that the Respondent-Distributor shall provide all correspondence with the FDA to the Board, including reports created by the CGMP expert required under Cantrell's Consent Decree with the U.S. government; and it is further

ORDERED that the Respondent-Distributor shall provide the Board with all inspection reports produced by the Arkansas Board of Pharmacy within ten days of receipt; and it is further

ORDERED that the Respondent-Distributor shall provide the Board with all adverse event reports within 48 hours of an occurrence; and it is further

ORDERED that the Respondent-Distributor shall operate in accordance with the Maryland Wholesale Distributor Permitting and Prescription Drug Integrity Act and corresponding regulations; and be it further

ORDERED that if the Respondent-Distributor violates any of the terms or conditions of this Consent Order, the Board, in its discretion, after notice and an opportunity for a hearing, may impose any other disciplinary sanctions the Board may have imposed under § 12-409 of the Act, including a suspension, revocation and/or a monetary fine, said violation being proven by a preponderance of the evidence; and it is further

ORDERED that the Respondent shall be responsible for all costs incurred in fulfilling the terms and conditions of the Consent Order, and it is further

ORDERED that this Consent Order is considered a **PUBLIC DOCUMENT** pursuant to Md. Code Ann., Gen. Prov. Gen. Prov. §§ 4-101, *et seq.* (2014 Repl. Vol., 2017 Supp.).

1/9/189 DSN

Date

Deena Speights-Napata, Executive Director, for
Kevin Morgan, Pharm.D., President
State Board of Pharmacy

CONSENT

By signing this Consent, I hereby affirm the findings of fact contained herein and agree to be bound by the foregoing Consent Order and its conditions:.

1. By this Consent, I submit to the foregoing Consent Order as a resolution of this matter.
2. By signing this Consent, I waive any rights I may have had to contest the findings and determinations contained in this Consent Order.
3. I acknowledge the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.
4. I sign this Consent Order freely and voluntarily, after having had the opportunity to consult with counsel.
5. I fully understand the language, meaning, and effect of this Consent Order.

12/18/2018

Date

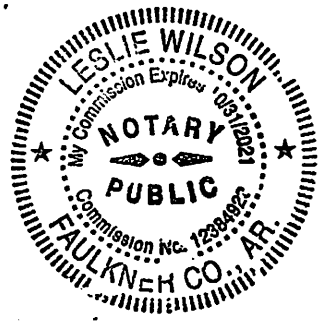
James L. McCarley, Jr. for Cantrell Drug Company, Inc.

NOTARY

STATE OF MARYLAND

COUNTY/CITY OF Faulkner :

I hereby certify that on this 18 day of December, 2018, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared James L. McCarley, Jr. for Cantrell Drug Company, Inc., and made an oath in due form that the foregoing Consent was his voluntary act and deed.



Leslie Wilson

Notary Public

My commission expires: 10/31/2021