KAMALA D. HARRIS
Attorney General of California
JANICE K. LACHMAN
Supervising Deputy Attorney General
KRISTINA T. JARVIS
Deputy Attorney General
State Bar No. 258229
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 324-5403
Facsimile: (916) 327-8643
*Attorneys for Complainant*

**BEFORE THE**
**BOARD OF PHARMACY**
**DEPARTMENT OF CONSUMER AFFAIRS**
**STATE OF CALIFORNIA**

| | |
|---|---|
| In the Matter of the Accusation Against:<br><br>**MAIN STREET FAMILY PHARMACY LLC**<br>**126 E. Main Street**<br>**Newbern, TN 38059**<br><br>**Original Non-Resident Pharmacy Permit No. NRP 1138**<br>**Original Non-Resident Pharmacy Permit No. NSC 99696**<br><br>Respondent. | Case No. 5555<br><br>**A C C U S A T I O N** |

Complainant alleges:

**PARTIES**

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about December 20, 2011, the Board of Pharmacy issued Original Non-Resident Pharmacy Permit Number NRP 1138 to Main Street Family Pharmacy LLC (Respondent). The Original Non-Resident Pharmacy Permit was cancelled on February 18, 2014, due to a discontinuance of business effective December 20, 2013.

3. On or about February 17, 2005, the Board of Pharmacy issued Original Non-Resident Pharmacy Permit Number NSC 99696 to Respondent. The Original Non-Resident Pharmacy

Permit was cancelled on February 18, 2014, due to a discontinuance of business effective December 20, 2013.

## JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

## STATUTORY PROVISIONS

5. Section 4300 of the Code states in pertinent part:

"(a) Every license issued may be suspended or revoked.

"(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

"(3) Suspending his or her right to practice for a period not exceeding one year.

"(4) Revoking his or her license.

"(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper..."

6. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

7. Section 4301 of the Code states in pertinent part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

"(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency..."

8. Section 4303, subdivision (b) of the Code states:

"(b) The board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located."

**TENNESSEE STATUTES AND REGULATIONS**

9. Tennessee Code Annotated Section 63-10-305 states in pertinent part:

"The board is authorized to deny, restrict or condition any application for licensure or certification and is authorized to revoke or suspend any license or certification previously issued or otherwise discipline and assess civil penalties against a applicant, licensee or holder of a certificate upon a finding that the applicant, licensee or holder of a certificate has:

"(4) Engaged in conduct prohibited or made unlawful by any of the provisions of parts 2-5 of this chapter or any other laws of the state or of the United States relating to drugs or to the practice of pharmacy;

"(6) Been guilty of dishonorable, immoral, unethical or unprofessional conduct;

"(7) Had the license to practice pharmacy suspended or revoked by another state for disciplinary reasons."

10. Tennessee Board of Pharmacy Rule section 1140-07-.02, subdivision (1), states:

"All sterile products shall be prepared in compliance with applicable USP standards[1] for pharmaceutical compounding."

///

///

///

---

[1] Pursuant to Tennessee Board of Pharmacy Rule section 1140-01-.01, subdivision (41), "USP standards" means any applicable standard or standards published in the most current version of United States Pharmacopeia National Formulary guidelines, to the extent that such guidelines do not conflict with state law, rules, or Board Policy Statements and as those guidelines may, from time to time, be amended.

11. Tennessee Board of Pharmacy Rule section 1140-07-.05 states in pertinent part:

"(1) A policy and procedure manual related to sterile product compounding shall be available for inspection at the pharmacy practice site. The manual shall include policies and procedures for sterile compounding pursuant to USP standards...

"(3) Failure by any licensee or registrant to comply with its policy and procedure manual, or any part of this rule shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6)."

**CALIFORNIA CODE OF REGULATIONS**

12. California Code of Regulations, title 16, section 1714 (Regulation) states in pertinent part:

"(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

"(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes."

13. California Code of Regulations, title 16, section 1735.2 states in pertinent part:

"(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

14. California Code of Regulations, title 16, section 1735.3 states in pertinent part:

"(a) For each compounded drug product, the pharmacy records shall include:

"(3) The identity of the pharmacy personnel who compounded the drug product.

"(4) The identity of the pharmacist reviewing the final drug product.

"(7) A pharmacy assigned reference or lot number for the compounded drug product."

15. California Code of Regulations, title 16, section 1735.6 states:

"(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.

"(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.

"(c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy."

16. California Code of Regulations, title 16, section 1735.8 states in pertinent part:

"(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

"(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

"(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength."

17. California Code of Regulations, title 16, section 1751 states in pertinent part:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.

"(b) Any pharmacy compounding sterile injectable drug products shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:

"(1) Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.

"(2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.

"(5) The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment..."

18. California Code of Regulations, title 16, section 1751.1 states in pertinent part:

"(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.

"(b) In addition to the records required by section 1735.3 and subdivision (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be made and kept by the pharmacy:

"(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

19. California Code of Regulations, title 16, section 1751.4 states in pertinent part:

"(a) No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

"(b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.

"(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination."

20. California Code of Regulations, title 16, section 1751.7 states in pertinent part:

"(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

"(1) Cleaning and sanitization of the parenteral medication preparation area.

"(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

"(b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.

"(c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

"(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures."

21. California Code of Regulations, title 24, section 1250.4 states in pertinent part:

"The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:

"2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings."

**COST RECOVERY**

22. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

///

## FIRST CAUSE FOR DISCIPLINE

**(Out of State Discipline)**

23. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (n), in that on or about March 13, 2013, in case number L12-PHR-RBS-2013000051, Respondent's pharmacy license was disciplined by the Tennessee State Board of Pharmacy by consent decree and placed on probation. The circumstances are that on December 6, 2011, Tennessee Board of Pharmacy inspectors observed the following violations of Tennessee pharmacy laws:

a. The condition of the laminar flow hood at Respondent's facility was not compliant with Board regulations;

b. 89 outdated or deteriorated medications were found on pharmacy shelves;

c. Respondent's facility had shipped 11 compounded prescriptions directly to physician's offices for use; however, none of those prescriptions were patient-specific as required by Board rules; and

d. a nurse had been working as a pharmacy technician in Respondent's facility without proper registration for 4 years and 3 months.

24. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (n), in that on or about December 23, 2013, in case number 2013-07092, Respondent's Non-Resident Pharmacy permit Number PH 24815 was disciplined by the Florida State Board of Pharmacy in that Respondent voluntarily relinquished its Non-Resident Pharmacy permit. The circumstances are that Respondent's license had been disciplined by the Tennessee Board of Pharmacy as set forth in paragraph 23, above, for one or more offenses that would also constitute a violation of Florida Board of Pharmacy Laws, Rules, or Regulations.

25. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (n), in that on or about October 10, 2013, in case number 2013-80, Respondent's Nonresident Pharmacy License Number 3941, was disciplined by the Iowa State Board of Pharmacy in that Respondent's license was revoked by voluntary surrender. The circumstances are that Respondent's license had been disciplined by the Tennessee Board of

Pharmacy as set forth in paragraph 23, above. Further, Respondent issued a voluntary nationwide recall of all lots of sterile products compounded by Respondent with beyond-use dates of 11-20-13 or sooner. Five Iowa patients received compounded medications subject to the recall.

26. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (n), in that on or about July 16, 2014, in case number 2013003822, Respondent's Pharmacy License was disciplined by the Illinois State Board of Pharmacy by being placed on probation by consent decree. The circumstances are that Respondent's license had been disciplined by the Tennessee Board of Pharmacy as set forth in paragraph 23, above.

27. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (n), in that on or about October 2, 2013, in case number 2013-2009, Respondent's Non-Resident Prescription Drug Outlet Registration License No. OSP 5914 was disciplined by the Colorado State Board of Pharmacy by a stipulation for interim cessation of practice until such time as future administrative actions are taken against the licensee. During the stipulation period, Respondent's license in Colorado expired and has not been renewed.

28. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (n), in that on or about September 11, 2013, in case number 0002599, Respondent's Pharmacy License No. 587-43 was disciplined by the Wisconsin Pharmacy Examining Board in that Respondent's license was revoked by stipulation for voluntary surrender. The circumstances are that Respondent's license had been disciplined by the Tennessee Board of Pharmacy as set forth in paragraph 23, above.

**SECOND CAUSE FOR DISCIPLINE**

**(Violation of Regulations Governing Pharmacy)**

29. Respondent is subject to disciplinary action for unprofessional conduct pursuant to section 4301, subdivision (o), in that between May 22, 2013, and June 3, 2013, Respondent's facilities were inspected by the Food and Drug Administration (FDA) and found to have violated regulations governing the practice of pharmacy. The circumstances are as follows:

a. Respondent violated Regulation 1714, subdivision (b), by failing to maintain its facilities, space, fixtures, and equipment so that drugs can be safely prepared as follows:

i. The ante room for employees entering the clean room is inadequate in size to allow proper gowning.

ii. No mirror is available to ensure full hair net coverage.

iii. No space is provided for sterile glove donning.

iv. The water faucet for employees to sterilize their hands prior to entering the clean room is not hands-free.

b. Respondent violated Regulation 1714, subdivision (c), by failing to maintain its facilities free from insects. Two (2) spiders were observed inside the clean room.

c. Respondent violated Regulation 1735.2, subdivision (g), by failing to maintain records establishing hold times for compounded sterile products between processing steps. No records existed to document hold times between filling finished product vials from bulk vials, and Respondent's management employees stated that the time could vary from immediately up to two (2) days.

d. Respondent violated Regulation 1735.2, subdivision (h), and Regulation 1751.7, subdivision (a)(4), by failing to maintain written documentation regarding expiration dates, and the Pharmacist's reasoning and justification for the chosen expiration date for compounded sterile injectable products. Specifically, Respondent assigned a 3-month expiration date for all preservative-free compounded sterile injectable products, and a 6-month expiration date for all compounded sterile injectable products with preservatives. Respondent had no alternative stability data for these products, which indicates both products should have expiration dates of no longer than forty-five (45) days.

e. Respondent violated Regulation 1735.3, subdivisions (a)(3), (a)(4), and (a)(7), and Regulation 1751.7, subdivisions (a), (c), and (d), by failing to provide required information in compounding records for both sterile and non-sterile compounding. Specifically:

i. Respondent failed to provide the identification of the persons performing and checking each significant step in the compounding and sterile compounding operations.

///

ii. Respondent failed to perform, or maintain documentation, of the bubble point filter testing.

iii. Respondent failed to maintain documentation of lot numbers for the finished sterile and non-sterile drug products.

iv. Respondent failed to maintain records of in-process and laboratory control testing results.

f. Respondent violated Regulation 1735.6, subdivisions (a), and (b), by failing to use and maintain equipment for safe preparation of sterile and non-sterile compounded drug products. Specifically:

i. Respondent failed to document which product lots were produced in each laminar airflow hood.

ii. Respondent failed to document the time, temperature, and pressure employed by the autoclave.

iii. Respondent failed to document continuous temperature monitoring for the incubator used for endotoxin and sterility testing.

iv. Respondent failed to document which product lots were autoclaved and when.

v. Respondent failed to document which product lots were tested for sterility or endotoxins in the incubator.

vi. Respondent failed to document which product lots were lyophilized, and when.

vii. Respondent failed to document cleaning, disinfection, or maintenance of the autoclave, incubator, or lyophilizer.

viii. Respondent failed to document continuous monitoring of the air pressure difference between the clean room, ante room, and unclassified room.

g. Respondent violated Regulation 1735.6, subdivision (b), and Regulation 1751.7, subdivision (a)(1), by failing to have clean equipment that was appropriately maintained pursuant to the manufacturer's specifications. Specifically:

i. Product splatter was observed on the HEPA filter in laminar airflow hood #3 in the clean room.

ii. Product splatter was observed on and around the edges of laminar airflow hood #3 in the clean room.

iii. Product splatter was observed on the black paper used for visual inspections of drug products in laminar airflow hood #3.

iv. Product splatter was observed on the light directly above the workbench for laminar airflow hood #2.

v. Charred black debris and stains were observed on the hot plate and stirrers in laminar airflow hood #1.

vi. Charred black debris and stains were observed on the hot plate and stirrers in laminar airflow hood #2.

vii. Splatter marks were observed on the front face of the trash can in the clean room.

viii. Splatter marks were observed on the HEPA filter located in the ceiling of the clean room.

ix. The workbench surfaces of all laminar airflow hoods were stained.

x. An unidentified spray bottle of clear liquid was observed in the ante room.

xi. The motor for the lyophilizer was observed to be leaking oil in the clean room. An ordinary paper towel was placed between the motor and the lyophilizer to absorb the oil. This is also a violation of Respondent's SOP number 8.049, item #7, which states that objects that shed particles, such as paper towels, should not be brought into the ante room or the clean room.

h. Respondent violated Regulation 1735.6, subdivision (c), by failing to perform, or document the performance of, routine calibration on equipment. Specifically:

i. Respondent failed to calibrate the gauge used for bubble point testing of filters used in the aseptic sterilization process. The filter had not been calibrated in the three (3) years that it had been in use.

///

///

ii. Respondent calibrated scales on an infrequent basis using an uncertified, single 100 gram weight, without any documentation maintained of calibration activities. Further, no linearity tests were conducted for the scales.

i. Respondent violated Regulation 1735.8, subdivision (c), in that Respondent failed to follow an appropriate standard operating procedure for potency testing. Respondent's SOP number 9.018 stated Respondent was to do random testing at the discretion of the Pharmacist-In-Charge; however, as of June 3, 2013, no testing had been done since December, 2012. Further, random testing does not meet the scientifically justifiable basis required for potency testing. The SOP further stated that every lot of compounded medroxyprogesterone/lidocaine (MPL) injection should be assayed for medroxyprogesterone potency. Three (3) lots of MPL were sold to physicians in California without any potency testing.

j. Respondent violated Regulation 1735.8, subdivision (d), in that Respondent failed to investigate quality assurance results which exceeded specifications for quantitative testing. On or about August 14, 2012, Respondent submitted three (3) vials of MPL for potency testing. One of the vials showed it had 125.98% of the labeled strength. The specifications for this product can range from 90% to 110%, but 125.98% far exceeds the acceptable range. Respondent's SOP numbers 9.005.1, and 9.014 stated an investigation would be performed, the improper lots would be destroyed, and appropriate action taken to ensure the error did not recur. Respondent failed to follow their SOPs, no investigation was performed, the improper lots were not destroyed and were sold to physicians, and no action was taken to ensure the error did not recur.

k. Respondent violated Regulation 1751, subdivision (b)(2), by failing to have or maintain a designated area for preparation of sterile injectable products meeting the standards set forth in Regulation 1250.4, with walls, ceilings, and floors made of nonporous and cleanable surfaces. Respondent's facilities had the following violations:

i. The floor in the clean room was composed of pieces of flooring joined by caulking. The caulking was worn away, creating a crack in the floor of the clean room.

ii. The ceiling above the ante room was open to an uncontrolled environment, and there was exposed insulation directly above the door into the ante room.

l. Respondent violated Regulation 1751, subdivision (b)(5), by failing to store items relating to sterile compounding in such a way as to maintain the integrity of an aseptic environment. Vials intended for use for injectable drug products were observed to be stored open to the environment for multiple hours inside a laminar airflow hood used for compounding sterile injectable drug products. The laminar airflow hood was not in use at the time, and no drug product was processed during this period. Further, this was a violation of Respondent's Standard Operating Procedures (SOP) number 8.034, item #10, which states to only place the necessary supplies for immediate drug preparation in the laminar airflow hood and on the laminar airflow workbench, and not to use the laminar airflow workbench to store items.

m. Respondent violated Regulation 1751.1, subdivision (b)(4), in that Respondent failed to have or maintain records of cleaning, disinfection, or maintenance for any of the laminar airflow hoods.

n. Respondent violated Regulation 1751.4, subdivision (a), in that Respondent failed to clean, or failed to appropriately clean, equipment prior to placing it in the sterile compounding environment. Specifically

i. During the sterile compounding process for Total Parenteral Nutrition (TPN), components were brought into the clean room from the uncontrolled environment rooms and placed on the work surface of laminar airflow hood #3 without being disinfected with sterile isopropyl alcohol.

ii. During the sterile compounding process for Human Chorionic Gonadotropin (HCG), components were brought into the clean room from the uncontrolled environment rooms and placed on the work surface of laminar airflow hood #3 without being disinfected with sterile isopropyl alcohol.

iii. Prior to beginning the sterile compounding process, Respondent used wipes that were not sterile to clean the laminar airflow hood workbench.

o. Respondent violated Regulation 1751.4, subdivision (b), and Regulation 1751.5, subdivision (b)(1), by failing to limit access to the clean room to properly attired individuals, which includes removal of all cosmetics and jewelry or piercings that cannot be covered by personal protective equipment. Specifically:

i. During the sterile compounding process for TPN and HCG, Respondent's employee wore a non-sterile gown and surgeons mask which left facial areas exposed. Respondent's SOP number 7.011 requires sterile, non-shedding gowns be used in the clean room.

ii. During the sterile compounding process for TPN and HCG, Respondent's employee had exposed legs, visible eye make-up, and studded earrings that were not covered by personal protective equipment.

p. Respondent violated Regulation 1751.4, subdivision (d), in that Respondent failed to properly clean and disinfect the ante room weekly, and after any unanticipated event that could increase the risk of contamination. There were stains on the floor of the ante room while Respondent's employees were compounding sterile injectable products.

q. Respondent violated Regulation 1751.7, subdivision (a), by failing to practice appropriate quality assurance measures for sterile compounding equipment, including ongoing monitoring of personnel performance, equipment, and facilities. Specifically:

i. No biological indicators were used, and no load mapping studies were conducted to determine proper load configuration of the autoclave.

ii. No positive or negative indicators were used to test the incubator.

iii. Smoke studies of the clean room and laminar airflow hoods were not documented.

iv. The lyophilization unit was not validated.

v. Expired filters used for aseptic sterilization of drug products were stored intermixed with in-date filters intended for use.

r. Respondent violated Regulation 1751.7, subdivision (b), by failing to ensure that process validation for compounding staff was representative of common compounding activities,

including type of manipulation, product, and batch size. Annual process validation was conducted under static conditions, and were not of sufficient batch size to be representative of Respondent's drug processing activity.

s. Respondent violated Regulation 1751.7, subdivision (c), by failing to have or comply with SOPs for sterility and pyrogen testing of compounded sterile drug products. Specifically:

i. Respondent conducted sterility and pyrogen testing on a random basis with no scientifically justified schedule or plan.

ii. There were 15 sterility tests for approximately 90 injectable drug product batched compounded between December 2012 and June 2013.

iii. There were 14 pyrogen tests for approximately 90 injectable drug product batched compounded between December 2012 and June 2013.

iv. Respondent's SOP number 9.018 states every lot of compounded injectable product sold for "office use" would be tested for sterility and endotoxin/pyrogen. Respondent failed to comply with this SOP.

v. Respondent's SOP number 9.021.01 for pyrogen testing did not include any schedule or plan for regular pyrogen testing.

**PRAYER**

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Original Non-Resident Pharmacy Permit Number NRP 1138, issued to Main Street Family Pharmacy LLC

2. Revoking or suspending Original Non-Resident Pharmacy Permit Number NSC 99696, issued to Main Street Family Pharmacy LLC;

3. Ordering Main Street Family Pharmacy LLC to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

///

4. Taking such other and further action as deemed necessary and proper.

DATED: 7/11/16

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
*Complainant*

SA2015105022
12057029.doc