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8
9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

Case No. 5887

12 **WELLS PHARMACY NETWORK LLC**
13 **450 US Hwy 51 Bypass N**
14 **Dyersburg, TN 38024**

A C C U S A T I O N

15 **Non-Resident Pharmacy Permit No. NRP**
1325
16 **Non-Resident Pharmacy Permit No. NSC**
99824

17 Respondent.

18
19 Complainant alleges:

20 **PARTIES**

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

23 2. On or about May 28, 2013, the Board of Pharmacy issued Original Non-Resident
24 Pharmacy Permit Number NRP 1325 to Wells Pharmacy Network LLC (Respondent). The Non-
25 Resident Pharmacy Permit was in full force and effect at all times relevant to the charges brought
26 herein and will expire on May 1, 2017, unless renewed.

27 3. On or about July 1, 2013, the Board of Pharmacy issued Original Non-Resident
28 Pharmacy Permit Number NSC 99824 to Respondent to compound injectable sterile drug

1 products. The Non-Resident Pharmacy Permit was in full force and effect at all times relevant to
2 the charges brought herein and will expire on May 1, 2017, unless renewed.

3 **JURISDICTION**

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

7 **STATUTORY REFERENCES**

8 5. Section 4301 of the Code states, in pertinent part:

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

13 ...

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

18 6. Section 4300.1 of the Code states:

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

25 7. Section 4127.7 of the Code states:

26 On and after July 1, 2005, a pharmacy shall compound sterile injectable products from
27 one or more nonsterile ingredients in one of the following environments:

28 (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The
cleanroom must have a positive air pressure differential relative to adjacent areas.

(b) An ISO class 5 cleanroom.

(c) A barrier isolator that provides an ISO class 5 environment for compounding.

1 **REGULATIONS**

2 8. Section 1751 of title 16 of the California Code of Regulations (16 CCR 1751) states,
3 in pertinent part: “(c) Any pharmacy compounding a sterile injectable product from one or more
4 non-sterile ingredients shall comply with Business and Professions Code section 4127.7.”

5 9. 16 CCR 1751.7 states, in pertinent part:

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

9 **COST RECOVERY**

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

14 **FIRST CAUSE FOR DISCIPLINE**

15 (Compounding Sterile from Non-Sterile Drugs in Improper Environment)

16 11. Respondent is subject to disciplinary action under Code section 4127.7 and 16 CCR
17 1751(c), by and through Code section 4301(o), in that Respondent compounded sterile injectable
18 drugs from non-sterile ingredients in an improper environment. The circumstances are as follows:

19 12. On or about March 4, 2016, during an inspection of Respondent’s premises, a Board
20 inspector found that Respondent compounded non-sterile to sterile drugs in a clean room that was
21 certified only as an ISO 7 environment, instead of the required ISO 5 environment.¹

22 **SECOND CAUSE FOR DISCIPLINE**

23 (Failure to Document Quality Assurance)

24 13. Respondent is subject to disciplinary action under 16 CCR 1751.7(c), by and through
25 Code section 4301(o), in that Respondent failed to document end product testing for sterility and

26 ///

27 ¹ Clean rooms are classified by the International Organization for Standardization (ISO)
28 according to the size of particles permitted in the air, from ISO 1 (smallest) to ISO 9 (largest).

1 pyrogens of batch-produced sterile injectable drug products compounded from one or more non-
2 sterile ingredients. The circumstances are as follows:

3 14. Between May 2015 and March 2016, Respondent shipped about 2,890 batch-
4 produced non-sterile to sterile compounded injectable drug products into California without
5 documentation of end product sterility or pyrogen testing.²

6 **PRAYER**

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

9 1. Revoking or suspending Non-Resident Pharmacy Permit Number NRP 1325, issued to
10 Wells Pharmacy Network LLC;

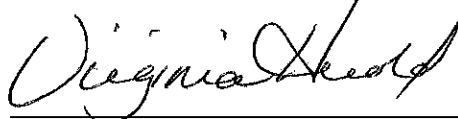
11 2. Revoking or suspending Non-Resident Pharmacy Permit Number NSC 99824, issued
12 to Wells Pharmacy Network LLC;

13 3. Ordering Wells Pharmacy Network LLC to pay the Board of Pharmacy the reasonable
14 costs of the investigation and enforcement of this case, pursuant to Business and Professions Code
15 section 125.3; and,

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

17
18 DATED: _____

10/14/16



19 VIRGINIA HEROLD
20 Executive Officer
21 Board of Pharmacy
22 Department of Consumer Affairs
23 State of California
24 Complainant

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27 _____
28 ² A pyrogen is any substance or agent that causes fever.