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

11 In the Matter of the Accusation Against:

Case No. 5785

12 **ALERE HOME MONITORING INC.**  
13 **6465 National Drive**  
**Livermore, CA 94550**

**A C C U S A T I O N**

14 **Wholesale Permit No. WLS 6079**

15 **and**

16 **THEODORE LLOYD WALKER**  
17 **6465 National Drive**  
**Livermore, CA 94550**

18 **Designated Representative License No. EXC**  
19 **22009**

20 Respondents.

21 Complainant alleges:

22 **PARTIES**

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

25 2. On or about May 16, 2013, the Board of Pharmacy issued Wholesale Permit Number  
26 WLS 6079 to Alere Home Monitoring Inc. ("Respondent Alere"). The Wholesale Permit expired  
27 on May 1, 2016, and is currently delinquent.  
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1           3.     On or about November 8, 2013, the Board of Pharmacy issued Designated  
2 Representative License Number EXC 22009 to Theodore Lloyd Walker (“Respondent Walker”).  
3 The Designated Representative License expired on November 1, 2014, and was cancelled on  
4 April 8, 2015. Respondent Walker was the Designated Representative-in-Charge of Respondent  
5 Alere from May 16, 2013, through August 5, 2015.

6   JURISDICTION

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

10          5.     Section 4011 of the Code provides that the Board shall administer and enforce both  
11 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances  
12 Act [Health & Safety Code, § 11000 et seq.].

13          6.     Section 4300, subdivision (a), of the Code provides that every license issued by the  
14 Board may be suspended or revoked.

15          7.     Section 4300.1 of the Code states:

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

21          8.     Section 118, subdivision (b), of the Code provides, in pertinent part, that the expiration  
22 of a license shall not deprive the Registrar of jurisdiction to proceed with a disciplinary action  
23 during the period within which the license may be renewed, restored, reissued or reinstated.  
24 Under Code section 7076.1, the Registrar may reinstate a cancelled license if the licensee pays all  
25 of the fees and meets all of the qualifications and requirements for obtaining an original license.

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STATUTORY AND REGULATORY PROVISIONS

9. Code section 4301, 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:

...

“(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.”

10. Section 4043 of the Code, in pertinent part, defines “wholesaler” to mean and include “a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022.”

11. Code section 4053, subdivision (a), states:

“Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.”

12. Section 4160 of the Code states, in pertinent part:

“(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

...

“(c)(1) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business,

1 at least one designated representative, in the case of a wholesaler, or designated representative-  
2 3PL in the case of a third-party logistics provider, shall be present.

3 “(d) Every wholesaler shall be supervised or managed by a designated representative-in-  
4 charge. The designated representative-in-charge shall be responsible for the wholesaler’s  
5 compliance with state and federal laws governing wholesalers. As part of its initial application for  
6 a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide  
7 identifying information and the California license number for a designated representative or  
8 pharmacist proposed to serve as the designated representative-in-charge. The proposed designated  
9 representative-in-charge shall be subject to approval by the board. The board shall not issue or  
10 renew a wholesaler license without identification of an approved designated representative-in-  
11 charge for the wholesaler. The designated representative-in-charge shall maintain an active license  
12 as a designated representative with the board at all times during which he or she is designated as  
13 the designated representative-in-charge.

14 . . .

15 “(f) A wholesaler shall notify the board in writing, on a form designed by the board, within  
16 30 days of the date when a designated representative-in-charge ceases to act as the designated  
17 representative-in-charge, and shall on the same form propose another designated representative or  
18 pharmacist to take over as the designated representative-in-charge. The proposed replacement  
19 designated representative-in-charge shall be subject to approval by the board. If disapproved, the  
20 wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall  
21 continue to name proposed replacements until a designated representative-in-charge is approved  
22 by the board.”

23 13. Code section 4101, subdivision (b), states:

24 “A designated representative or a pharmacist may take charge of, and act as, the designated  
25 representative-in-charge of a wholesaler or veterinary food-animal drug retailer upon application  
26 by the wholesaler or veterinary food-animal drug retailer and approval by the board. A designated  
27 representative-in-charge who ceases to act as the designated representative-in-charge at that entity  
28 shall notify the board in writing within 30 days of the date of that change in status.”

1 14. California Code of Regulations, title 16, section 1784 states, in pertinent part:

2 “(a) The designated representative-in-charge of each wholesaler as defined under section  
3 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler’s  
4 compliance with federal and state pharmacy law. The assessment shall be performed before July 1  
5 of every odd-numbered year. The primary purpose of the self-assessment is to promote  
6 compliance through self-examination and education.

7 ...

8 “(d) Each self-assessment shall be kept on file in the licensed wholesale premises for three  
9 years after it is completed.

10 “(e) The wholesaler is jointly responsible with the designated representative-in-charge for  
11 compliance with this section.”

12 COST RECOVERY

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

17 FACTUAL ALLEGATIONS

18 16. Prior to May 1, 2015, the Board received a permit renewal application and fee  
19 payment from Respondent Alere for the renewal of their Wholesale Permit. The Board flagged  
20 the renewal application and determined that the renewal could not be processed because the  
21 designated representative license of Respondent Alere’s designated representative, Respondent  
22 Walker, was expired. Respondent Walker’s license expired on November 1, 2014, and after  
23 failing to respond to communication from the Board, Respondent Walker’s license was cancelled  
24 on April 8, 2015. The Board did not receive any communication from Respondent Alere  
25 requesting approval of a new designated representative. The Board could not process Respondent  
26 Alere’s renewal application because it lacked a valid designated representative, and, therefore, its  
27 Wholesale Permit expired on May 1, 2015.

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1 17. On or about August 10, 2015, the Board received a "Change of Representative In  
2 Charge" form from Respondent Alere. The form identified a new designated representative,  
3 effective August 5, 2015. The Board processed Respondent Alere's Wholesale Permit renewal  
4 and approved its new designated representative.

5 18. On or about September 18, 2015, a Board inspector conducted a complaint-related  
6 inspection at Respondent Alere's place of business. The inspector requested and received  
7 documentation related to Respondent Alere's sales activity for prescription items sold between  
8 November 1, 2014, and September 18, 2015. The report showed 85 sales transactions for items  
9 requiring a wholesale permit between November 1, 2014, through May 15, 2015. There was no  
10 sales activity for the prescription items requiring a wholesale permit after May 15, 2015.

11 **RESPONDENT ALERE**

12 **FIRST CAUSE FOR DISCIPLINE**

13 (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (a))  
14 (Engaging in Wholesaler Activity Without an Active License)

15 19. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it  
16 engaged in wholesaler activity after its license expired on May 1, 2015. (Bus. & Prof. Code, §§  
17 4301, subd. (o), 4160, subd. (a).) Respondent Alere's sales transactions report indicated at least  
18 three sales transactions requiring a wholesale permit between May 1, 2015, and May 15, 2015,  
19 after Respondent Alere's wholesale permit had expired. The circumstances are set forth in further  
20 detail in paragraphs 16 through 18, above.

21 **SECOND CAUSE FOR DISCIPLINE**

22 (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (c)(1))  
23 (Acting as a Wholesaler Without a Designated Representative Present)

24 20. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it was  
25 open for business and engaged in wholesaler activity during a time in which it did not have a  
26 currently licensed designated representative present. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160,  
27 subd. (c)(1).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent  
28 Alere did not identify a new designated representative until August 2015. The circumstances are set  
forth in further detail in paragraphs 16 through 18, above.

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1 THIRD CAUSE FOR DISCIPLINE

2 (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (d))  
3 (Operating as a Wholesaler Without a DRIC)

4 21. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it  
5 operated as a wholesaler without a designated representative. (Bus. & Prof. Code, §§ 4301, subd.  
6 (o), 4160, subd. (d).) Specifically, Respondent Walker's license expired on November 1, 2014.  
7 Respondent Alere did not identify a new designated representative until August 2015. The  
8 circumstances are set forth in further detail in paragraphs 16 through 18, above.

9 FOURTH CAUSE FOR DISCIPLINE

10 (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (f))  
11 (Failure to Notify Board of No Designated Representative)

12 22. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it  
13 failed to notify the Board within 30 days of the date in which Respondent Walker was no longer  
14 the designated representative. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (f).)  
15 Specifically, Respondent Walker's license expired on November 1, 2014. Respondent Alere did  
16 not identify a new designated representative until August 2015. The circumstances are set forth in  
17 further detail in paragraphs 16 through 18, above.

18 FIFTH CAUSE FOR DISCIPLINE

19 (Cal. Code Regs., tit. 16, sec 1784, subs. (a), (d), (e))  
20 (Failure of Designated Representative to Complete Required Self-Assessment)

21 23. Respondent Alere has subjected its Wholesale Permit to disciplinary action in that it  
22 failed to cause Respondent Walker, its designated representative, to submit the required self-  
23 assessment of its compliance with federal and state pharmacy law. (Cal. Code Regs., tit. 16, sec  
24 1784, subs. (a), (d), (e).) Specifically, Respondent Alere failed to have Respondent Walker  
25 complete a self-assessment on July 1, 2015. Respondent Alere was educated of its need to  
26 complete a self-assessment every odd year during a prior inspection in 2013.

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1 **RESPONDENT WALKER**

2 **FIRST CAUSE FOR DISCIPLINE**

3 (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subds. (a), (d))  
4 (Engaging in Wholesaler Activity Without an Active License)

5 24. Respondent Walker has subjected his Designated Representative License to  
6 disciplinary action in that Respondent Alere engaged in wholesaler activity after its license  
7 expired on May 1, 2015. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subds. (a), (d).)  
8 Respondent Alere's sales transactions report indicated at least three sales transactions requiring a  
9 wholesale permit between May 1, 2015, and May 15, 2015, after Respondent Alere's wholesale  
10 permit had expired. The circumstances are set forth in further detail in paragraphs 16 through 18,  
11 above.

12 **SECOND CAUSE FOR DISCIPLINE**

13 (Bus. & Prof. Code, § 4160, subds. (c)(1), (d))  
14 (Acting as a Wholesaler Without a Designated Representative Present)

15 25. Respondent Walker has subjected his Designated Representative License to  
16 disciplinary action in that between November 1, 2014, the date Respondent Walker's license  
17 expired, and May 15, 2015, the date of Respondent Alere's last pharmaceutical sales transaction,  
18 Alere was open for business and engaged in wholesaler activity without a valid designated  
19 representative present. (Bus. & Prof. Code, § 4160, subds. (c)(1), (d).) Specifically, Respondent  
20 Walker's license expired on November 1, 2014. Respondent Alere did not identify a new  
21 designated representative until August 2015. The circumstances are set forth in further detail in  
22 paragraphs 16 through 18, above.

23 **THIRD CAUSE FOR DISCIPLINE**

24 (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (d))  
25 (Failure to Maintain an Active License While DRIC)

26 26. Respondent Walker has subjected his Designated Representative License to  
27 disciplinary action in that Respondent Walker failed to maintain an active license with the board  
28 during a time in which he was the designated representative-in-charge of Respondent Alere.  
(Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subd. (d).) Respondent Walker allowed his license  
to expire on November 1, 2014, yet he was identified as the designated representative of



1 Respondent Alere until August 5, 2015. The circumstances are set forth in further detail in  
2 paragraphs 16 through 18, above.

3 FOURTH CAUSE FOR DISCIPLINE

4 (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subs. (c)(1), (f))  
5 (Failure to Notify Board of No Designated Representative)

6 27. Respondent Walker has subjected his Designated Representative License to  
7 disciplinary action in that in that he and Respondent Alere failed to notify the Board within 30  
8 days of the date in which Respondent Walker ceased to act as the designated representative-in-  
9 charge. (Bus. & Prof. Code, §§ 4301, subd. (o), 4160, subs. (c)(1), (f).) Specifically,  
10 Respondent Walker's license expired on November 1, 2014. Respondent Alere did not identify a  
11 new designated representative until August 2015. The circumstances are set forth in further detail  
12 in paragraphs 16 through 18, above.

13 FIFTH CAUSE FOR DISCIPLINE

14 (Bus. & Prof. Code, §§ 4301, subd. (o), 4101, subd. (b))  
15 (Failure to Notify Board No Longer In Charge)

16 28. Respondent Walker has subjected his Designated Representative License to  
17 disciplinary action in that he failed to notify the Board within 30 days of his change in status as  
18 the designated representative of Respondent Alere. (Bus. & Prof. Code, §§ 4301, subd. (o), 4101,  
19 subd. (b).) Specifically, Respondent Walker's license expired on November 1, 2014. Respondent  
20 Alere did not identify a new designated representative until August 2015, and Respondent Walker  
21 never sent notification to the Board that he was no longer the designated representative of  
22 Respondent Alere. The circumstances are set forth in further detail in paragraphs 16 through 18,  
23 above.

24 SIXTH CAUSE FOR DISCIPLINE

25 (Cal. Code Regs., tit. 16, § 1784, subs. (a), (d), (e))  
26 (Failure of DRIC to Complete Required Self-Assessment)

27 29. Respondent Walker has subjected his Designated Representative License to  
28 disciplinary action in that he failed to submit the required self-assessment of Respondent Alere's  
compliance with federal and state pharmacy law. (Cal. Code Regs., tit. 16, sec 1784, subs. (a),  
(d), (e).) Specifically, Respondent Walker failed to complete a self-assessment on July 1, 2015, a

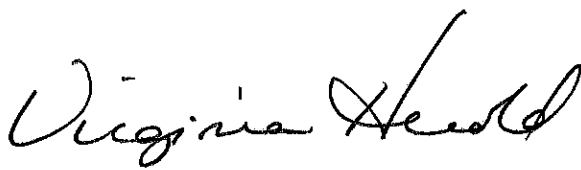
1 time in which he was still identified as the designated representative of Respondent Alere.  
2 Respondent Walker was educated of his need to complete a self-assessment every odd year during  
3 a prior inspection in 2013.

4 PRAYER

5 WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this  
6 Accusation, and that following the hearing, the Board of Pharmacy issue a decision:

- 7 1. Revoking or suspending Original Wholesale Permit Number WLS 6079, issued to  
8 Alere Home Monitoring Inc.;
- 9 2. Revoking or suspending Designated Representative License No. EXC 22009, issued  
10 to Theodore Lloyd Walker;
- 11 3. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the  
12 investigation and enforcement of this case, pursuant to Business and Professions Code section  
13 125.3;
- 14 4. Taking such other and further action as deemed necessary and proper.

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18 DATED: 7/26/16



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

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