Complaint #
104484

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BOARD OF PHARMACY

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Division of Consumer Affairs

STATE BOARD OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF PHARMACY

IN THE MATTER OF:	Administrative Action
CVS PHARMACY, INC.	CONSENT ORDER

This matter was opened to the New Jersey Division of Consumer Affairs (the "Division") and the New Jersey State Board of Pharmacy (the "Board")[1] upon receipt of information regarding possible temperature excursions at CVS Pharmacy #1956, located in Scotch Plains, New Jersey ("Scotch Plains Store") and CVS Pharmacy # 2796, located in Clark, New Jersey ("Clark Store"), both owned by CVS Pharmacy, Inc. ("CVS"), in 2012. An investigation by the Board and

[1] The Board has jurisdiction over registered pharmacies and pharmacy departments pursuant to the Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq. The Division has authority over the conduct of CVS Pharmacies based upon its mandate to protect the consumers of the State of New Jersey pursuant to the Consumer Fraud Act, N.J.S.A. 56:8-1 et seq., regulation of the sale of non-prescription drugs, infant formula and baby food (see, e.g., N.J.S.A. 56:8-2.27) and the administration of the provisions of the Controlled Dangerous Substances Act, N.J.S.A. 24:21 et seq.

the Division confirmed the pharmacies had continued to operate when the temperature inside the stores exceeded the maximum recommended temperature for storage of drugs and other items for an extended period of time.

Subsequently, CVS worked with the Division and the Board to investigate and address all issues arising from medications and products in those stores having been exposed to elevated temperatures. CVS also worked to improve its ability to respond to HVAC equipment failures and similar events in the future, including: (1) converting all New Jersey stores to a web accessible, on-line monitoring and reporting system for energy operations; (2) establishing a formal protocol for the inspection of pharmacy and front store merchandise during mechanical failures and local power outages and a formal mechanism to timely notify management and corporate headquarters of potentially serious events; (3) changing its HVAC service provider in New Jersey; and (4) assigning new senior field leadership to provide management and oversight of CVS pharmacies in New Jersey.

CVS has advised the Division and the Board that it is aware of no temperature excursion having occurred in any New Jersey store since the incidents that are the subject of this order, and that, if it had been aware of any such incidents, CVS would have alerted the Division and Board to them. CVS has agreed to contemporaneously make the Board aware of any future temperature

excursions and to work with the Board to address any resulting concerns to ensure public safety during the term of this Order. CVS recognizes that the Board is in the process of promulgating regulations to address the control and monitoring of temperature of prescription drugs and chemicals, and has agreed the terms of the Order will remain in full force and effect until the earlier of one year from its entry or the promulgation and adoption of these contemplated regulations, at which time this Order will be superseded by those regulations.

The Division and the Board recognize and appreciate the substantial positive steps taken by CVS to rectify past concerns and better respond to any future incidents. Notwithstanding those efforts, the Division and the Board also considered that CVS delayed in reporting, recognizing and addressing the potential risks to the purchasing public of the temperature excursions at the Scotch Plains and Clark pharmacies.

The parties, having agreed to resolve this matter without further formal proceedings; and CVS, having agreed and given voluntary consent to entry of the within Order and having waived the right to a hearing; and the Board and the Division having found that the within disposition adequately protects the public health, safety, and welfare, and good cause having been shown;

IT IS THEREFORE on this 21st day of January, 2015,

ORDERED AND AGREED that:

1. CVS will conduct continuous temperature monitoring in all CVS registered pharmacies and stores in the State of New Jersey. The web accessible system that has been installed in stores will record temperatures at various locations in the stores and will be viewable at CVS headquarters. In the event any store does not have the web accessible system, CVS will use other units to record pharmacy area temperatures that will cause reporting when the temperature deviates from a range of between 60 degrees and 80 degrees Fahrenheit. Information on store temperatures will be maintained consistent with the record keeping requirements for pharmacies, and will be made available for inspection and review by the Division or the Board upon request.

2. If for any reason the temperature in a CVS Pharmacy deviates from the acceptable guidelines for room temperature, as defined by General Chapter 671 of United States Pharmacopeia (USP) for more than 72 hours, CVS will quarantine all drugs and products that are visibly affected by the deviation and those with packaging or manufacturer direction that requires or recommends storage within a particular temperature range. CVS will cease and desist from the sale of those medications and products, including all prescription medication and over-the-counter medication and products, such as infant formula. If medications or other products are required to be refrigerated and such refrigeration is maintained without interruption, those products may continue to be

sold. The quarantined medications and products will be disposed of in accordance with applicable law.

3. In the event any such temperature deviation continues beyond 72 hours, any failure to quarantine medications and products and cease and desist from the sale of those products as set forth above shall violate this Order. In such event, CVS will assign all dispensed medications to Priority Levels 1-3 as defined and described in attached Appendix A, and shall notify patients in Priority Levels 1 and 2 by telephone call from a pharmacist and by mail, and those in Priority Level 3 by mail and public notice. Notices required under this paragraph must commence no later than 72 hours after the outset of the temperature diversion, and must be completed within the following 72 hours.

4. CVS is hereby assessed civil penalties, pursuant to N.J.S.A. 45:1-25 and N.J.S.A. 56:8-13, in the amount of $500,000 for the violations set forth herein.

5. CVS is hereby assessed costs of investigation in this matter, pursuant to N.J.S.A. 45:1-25, in the amount of $4,885.07. Payments shall be submitted by certified check or money order made payable to the State of New Jersey and shall be sent to Anthony Rubinaccio, Executive Director, Board of Pharmacy, P.O. Box 45013, 124 Halsey Street, Newark, New Jersey 07101.

6. Violations of this Order will subject CVS and/or its registered pharmacies to discipline pursuant to applicable law,

including suspension of permit or civil penalties for violation of the Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq. or the Consumer Fraud Act, N.J.S.A. 56:8-1 et seq.

NEW JERSEY DIVISION OF CONSUMER AFFAIRS

By: _____
Steve C. Lee
Acting Director

NEW JERSEY STATE BOARD OF PHARMACY

By: Thomas F.X. Bender, Jr., RPh
Thomas F.X. Bender, R.Ph.
President

I have read and understand the within Consent Order and agree to be bound by its terms. Consent is hereby given to the Division and the Board to enter this Order. I certify that I am authorized to sign this Consent Order on behalf of CVS-Caremark.

_____ Date: 1/13/2015

Print name and title:

Elizabeth S. Ferguson, SVP + AGC, Retail + Litigation

Consent is given as to form and entry of this Order:

_____
Kevin Marino, Esq.
Marino, Tortorella & Boyle, P.C.
Attorney for CVS Pharmacy, Inc.