STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATI

CVS VERO FL DISTRIBUTION CENTER, L.L.C. AND CVS ORLANDO FL DISTRIBUTION CENTER, L.L.C.

Petitioners,

vs.

DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION

Respondent.
_____/

VW 2013-165

NOTICE OF INTENT TO GRANT IN PART AND DENY IN PART PETITIONERS' PETITION FOR VARIANCE OR WAIVER

Respondent, Florida Department of Business & Professional Regulation (the "Department"), hereby notifies Petitioner CVS Vero FL Distribution Center, L.L.C. ("Vero DC") and Petitioner CVS Orlando Distribution Center L.L.C. ("Orlando DC"), that the Department, pursuant to Chapter 120.542, Florida Statutes, intends to grant in part and deny in part the petition for variance or waiver of administrative rules 61N-1.012(2)(e); 61N-1.013(3)(c); and 61N-1.013(5)(d)1.a, Florida Administrative Code ("F.A.C."), attached as Exhibit "A" and incorporated by reference, as follows:

Facts

For the purposes of this Notice, the department adopts the facts from the Petition for Variance or Waiver

Conclusions

Based on the foregoing facts, the department concludes as follows:

1. Petitioner Vero DC requests a waiver of 61N-1.012(2)(e), F.A.C., so that the perpetual inventory, process, and automation, as described in the variance request, be accepted in lieu of conducting a biennial physical inventory. That request is granted.

2. Petitioner Vero DC and Petitioner Orlando DC request a waiver of 61N-1.013(3)(c), F.A.C., so that electronic temperature monitoring systems, as described in the variance request, be deemed acceptable without having to record the initials of personnel reviewing the temperature information taken from 2:00 to 4:00 PM at least 5 days each week. That request is granted for both Vero DC and Orlando DC.

3. Petitioner Vero DC and Petitioner Orlando DC request a waiver of specific provisions of 61N-1.013(5)(d)4., F.A.C., related to authentication. That request is denied for both Vero DC and Orlando DC.

a. Petitioner Vero DC failed to demonstrate that a literal application of the rule affects Vero DC in a manner significantly different from the way the rule affects other similarly situated persons subject to the rule.

b. Petitioner Vero DC failed to demonstrate that the purpose of the underlying statute will be or has been achieved by other means.

c. Petitioner Vero DC failed to demonstrate that the application of the rule would create a substantial hardship.

d. Petitioner Orlando DC failed to demonstrate that a literal application of the rule affects Orlando DC in a manner significantly different from the way the rule affects other similarly situated persons subject to the rule.

e. Petitioner Orlando DC failed to demonstrate that the purpose of the underlying statute will be or has been achieved by other means.

f. Petitioner Orlando DC failed to demonstrate that the application of the rule would create a substantial hardship.

4. Any other requests for variances or waivers contained in the attached Petition for Variance or Waiver, whether requested directly or indirectly, are denied.

Notice of Intended Agency Action

The department hereby notifies CVS Vero FL Distribution Center, L.L.C. and CVS Orlando Distribution Center L.L.C. that the department intends to **GRANT** in part the petition for variance or waiver of Rules 61N-1.012(2)(e) and 61N-1.013(3)(c), Florida Administrative Code and **DENY** in part 61N-1.013(5)(d)1.a, Florida Administrative Code, as stated above.

Dated this 28th day of May, 2013.

For: Ken Lawson,
Secretary

By: _____
Reginald D. Dixon
Division Director
Division of Drugs, Devices & Cosmetics

Notice of Rights to Hearing and Appeal

Petitioner has the right to request a hearing pursuant to Sections 120.569 and 120.57, Florida Statutes if Petitioner wishes to challenge the referenced intended agency action. Such proceedings are governed by and conducted in accordance with Sections 120.569 and 120.57, Florida Statutes, and Chapter 28-106, Florida Administrative Code.

Petitioner has the following rights as regards any hearing requested on this notice of intended agency action (the "notice"): (i) to be represented by counsel or other qualified representative at Respondent's expense, (ii) to present evidence and to make arguments, (iii) to call and cross-examine witnesses, and (iv) to have subpoenas and subpoenas *duces tecum* issued.

Mediation is not available as an alternative remedy.

A request for administrative hearing must be in writing, and must be <u>received</u> by the Agency Clerk for the Department of Business & Professional Regulation within twenty-one (21) days of your receipt of this document. The Agency Clerk's address is 1940 North Monroe Street, Suite 92, Tallahassee, FL 32399-2202. The Agency Clerk's facsimile number is 850-488-5761.

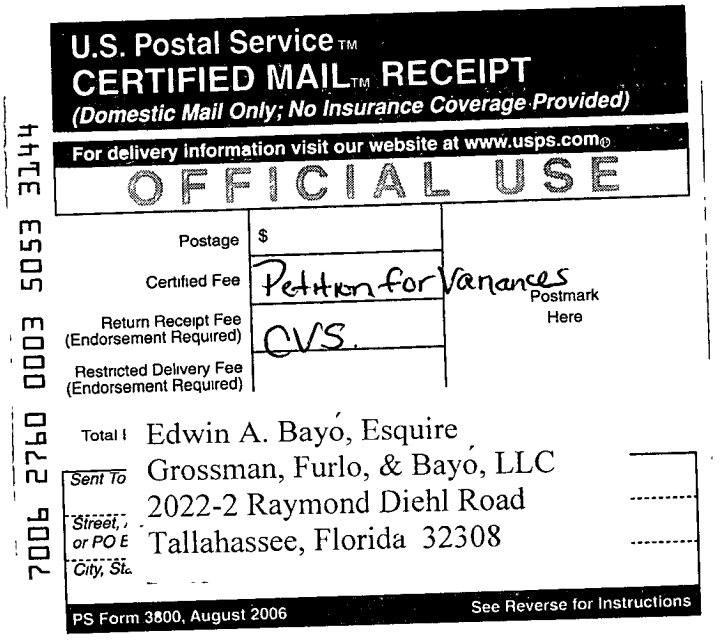
Your failure to submit a request for hearing within twenty-one (21) days of your receipt of this notice will constitute a waiver of your right to an administrative hearing; and pursuant to Rule 28-106.111, Florida Administrative Code, shall become the basis for a "final order" of the department adopting the notice's allegations of fact and conclusions of law.

Should such a final order be entered, Petitioner, as an adversely affected party, is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings may be commenced by filing one copy of a Notice of Appeal with the Agency Clerk of the Department of Business & Professional Regulation, and a second copy, accompanied by the filing fees required by law, with the Court of Appeal in the appropriate District Court. The Notice of Appeal must be filed within thirty (30) days of rendition of the final order.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing **Notice of Intent to Grant in Part and Deny in Part Petitioners' Petition for Variance or Waiver** was mailed by Certified U.S. Mail, to counsel for Petitioner, Edwin A. Bayó, Esquire, Grossman, Furlow, & Bayó, LLC, 2022-2 Raymond Diehl Road, Tallahassee, Florida 32308 this 29th day of May, 2013.

Brenda M. Nichols
Agency Clerk's Office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Sent To Edwin A. Bayó, Esquire
Grossman, Furlo, & Bayó, LLC
Street, or PO E 2022-2 Raymond Diehl Road
City, St Tallahassee, Florida 32308
PS Form 3800, August 2006 See Reverse for Instructions
7006 2760 0003 5053 3144

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DIVISION OF DRUGS, DEVICES & COSMETICS

PETITION FOR VARIANCE OR WAIVER OF RULES 61N-1.012(2)(e); 61N-1.013(3)(c), AND 61N-1.013 (5)(d)1.a., FLORIDA ADMINISTRATIVE CODE, ON BEHALF OF CVS VERO FL DISTRIBUTION, L.L.C. AND CVS ORLANDO FL DISTRIBUTION, L.L.C.

_____/

PETITION FOR VARIANCE OR WAIVER

COMES NOW Petitioners, CVS Vero FL Distribution Center, LLC, (hereinafter "Vero DC), and CVS Orlando Distribution Center, L.L.C. (hereinafter "Orlando DC") by and through its undersigned legal counsel and hereby petition the Division of Drugs, Devices and Cosmetics (hereinafter, "DDC") for a variance or waiver of its administrative rules 61N-1.012(2)(e); 61N-1.013(3)(c); and 61N-1.013(5)(d)1.a., F.A.C. In support thereof, Petitioners states as follows:

1. Petitioner Vero DC holds License 221484 as a Prescription Drug Wholesale Distributor. Petitioner Orlando DC holds license 221430 as a Prescription Drug Wholesale Distributor. In addition, Petitioners meet the definition of "chain pharmacy warehouse" as provided in §499.003(7), F.S.

2. Rule 61N-1.012(2)(e), F.A.C., indicates that a drug wholesaler maintaining perpetual inventory records must complete a physical inventory once every two years.

3. Petitioner Vero DC's facility was designed and built to operate using automation to maximize efficiency, avoid errors, and maintain a perpetual inventory.

4. At the Vero DC, all pharmaceutical orders are received into the Warehouse Management System through purchase orders. When the products are received at the

facility, the boxes are opened and the product is physically counted and validated. They are then logged as received into the system.

5. Received products are transported to a repack station. Prescription items are removed from vendor packaging, validated via computer screen and are then "repacked" into plastic storage/pick totes. Prior to leaving the repack station, each tote is weighed to again validate the number of expected items. The tote is then inducted into the Automated Storage and Retrieval System. Each tote is placed on a conveyor belt and fully automated cranes pick the tote and place it in a specific storage aisle in a secure storage area.

6. The secure storage area has 30 foot high metal stacks and is fenced off. Personnel are not permitted in the stacked fenced area because the automated cranes are fast and dangerous. When a store order is received, an automated crane will pick a corresponding tote and bring it to the pick area.

7. Once a tote is empty the picker receives a message that the tote should be empty. The picker physically checks the tote to ensure that it is empty. Once the tote has been confirmed empty, it is scanned before being inducted back into the system.

8. Under Petitioner's current system, the inventory is physically validated when it is received, a second time when it is repacked into the storage totes, and then a third time through the empty tote check process.

9. Although the fully automated system is very efficient for picking and maintaining a perpetual inventory, it would be extremely inefficient to conduct a physical count. To do a physical count of all bins would require specific orders for an automated crane to go to a location and send product to an audit station. Petitioner is limited to six audit stations and two cranes for that requirement.

10. According to Petitioner's calculations, the number of totes that would have to be counted at a particular point in time would be 16,105. Applying historical rates of processing inventory checks, Petitioner calculates that the facility would have to shut down for 5.29 days running the inventory check 24 hours per day, without any allowance for system, people, or staffing problems. Petitioner would likely be unable to conduct a physical count during production because the system gives priority to production tasks over moves to support inventory functions.

11. The purpose of the statutes which rule 61N-1.012(2)(e), F.A.C., is intended to implement is to ensure that prescription drug wholesale distributors maintain an accurate track of all drugs received and maintained at the facility. A physical inventory can also assist in detecting theft or diversion, as well as identifying product that may be deteriorated or expired.

12. Petitioner Vero DC's automated system maintains an accurate, perpetual, and continuous inventory. The high level of automation minimizes the number of times employees handle prescription items, thereby significantly reducing errors and opportunities for diversion. As stated in paragraph 8, inventory is physically validated three (3) separate times.

13. Petitioner Vero DC is therefore requesting a Waiver of 61N-1.012(2)(e), F.A.C. so that the perpetual inventory, process, and automation as described herein be accepted in lieu of conducting a biennial physical inventory.

14. Rule 61N-1.013(3)(c), F.A.C., states that a record of temperatures must be maintained recording the date, time, thermometer one temperature, thermometer two temperature; and the initials of the person recording the data or reviewing the data if

electronically monitored. This record and temperature reading must be recorded at least five (5) days each week with the temperature readings taken between 2:00 p.m. and 4:00 p.m. E.S.T.

15. Petitioners Vero DC and Orlando DC use Honeywell electronic temperature monitoring systems that record temperature at various monitoring locations inside each distribution center. The file log is recorded into the appropriate server at each facility and backed up every day. Each monitoring location has individual setpoint capabilities, and temperatures at each location are recorded every 5 seconds. The system has a power loss back-up system tied to emergency generators. Each system is maintained and calibrated by Honeywell yearly. Any alarms generated by the system are routed to CVS Central Alarm Station which then uses a call list for notification that includes the Rx Manager, the Facilities Service Manager and the Loss Prevention Manager.

16. The purpose of the statutes which rule 61N-1.013(3)(c), F.A.C., is intended to implement is to ensure that prescription drugs are maintained at proper temperatures and that records be created demonstrating that appropriate monitoring of temperatures at the facility is being conducted.

17. The electronic temperature monitoring equipment used by Petitioners maintains a proper record of temperatures at the facility, not just once per day, but 17,280 times every 24 hours. Petitioners respectfully submit that the requirement contained in the rule for recording "the initials of the person recording the data or reviewing the data if electronically monitored" were designed for either manual recording systems or more rudimentary electronic monitoring systems. Petitioners advanced electronic temperature monitoring equipment does not readily lend itself to the recording of initials of personnel that may have

reviewed the information. Further, the Facilities Service Manager at each distribution center has the overall responsibility for the electronic temperature recording/monitoring system at each facility.

18. Petitioners Vero DC and Orlando DC therefore request a Waiver of 61N-1.013(3)(c), F.A.C. so that the electronic temperature monitoring system as described herein be deemed acceptable without having to record the initials of personnel reviewing the temperature information taken from 2:00 to 4:00 PM at least 5 days each week.

19. Finally, Rule 61N-1.013(5)(d)4. states that a purchasing wholesaler may use a written contract between the purchasing wholesaler and its wholesale supplier, which is a primary wholesaler as defined in Section 499.012(1)(d), F.S., that requires that all prescription drugs distributed to the purchasing wholesaler by the wholesale supplier must be purchased by the wholesale supplier from the manufacturer. If this method is used to authenticate a pedigree, the purchasing wholesaler shall establish and adhere to policies and procedures for the random verification of the authenticity of the pedigrees that disclose the supplier wholesaler purchased the prescription drug from the manufacturer according to statistically valid standards. (e.s.)

20. Petitioners have written contracts with their wholesale suppliers that require that all drugs purchased for distribution to Petitioners must be purchased directly from the manufacturers. Petitioners have policies and procedures that provide for the random verification of the authenticity of the direct purchase pedigrees received from their suppliers. Such verification is accomplished by randomly contacting suppliers and requesting copies of the invoices from the manufacturer to the supplier demonstrating that a particular drug was purchased directly from the manufacturer.

21. Rule 61N-1.013(5)(d)1.a., F.A.C., on authentication, indicates that if a prior transaction invoice is used as a method of authentication, then the wholesaler must randomly authenticate with the manufacturer that the invoice is authentic.

22. All wholesale drug distributions to Petitioners meet the definition of "normal distribution chain" pursuant to §499.003(34), F.S. and are thus eligible for the direct purchase pedigree. Petitioners' suppliers also meet the definition of "primary wholesale distributor" contained in §499.003(47), F.S.

23. The purpose of the statutes which rule 61N-1.013(5)(d)1.a., F.A.C., is intended to implement is to ensure that prescription drugs are purchased from legitimate sources and that purchasers randomly authenticate the validity of the pedigrees received from their suppliers.

23. Petitioners believe that the specific provision of 61N-1.013(5)(d)4., F.A.C., taken in conjunction with the definitions of "normal distribution chain" and "primary wholesaler" allow it to authenticate the direct purchase pedigrees it receives as described in paragraph 20, without having to authenticate back to the manufacturer. Stated differently, Petitioners submit that when a chain pharmacy warehouse contractually requires its suppliers to only distribute drugs purchased directly from the manufacturer, and where such suppliers meet the statutory definition of primary wholesale distributors by virtue of purchasing over 90% of annual volume directly from manufacturers, that the authenticity of the drugs so purchased are beyond question.

24. Nevertheless, and in the event that the DDC is of the opinion that authentication back to the manufacturer as provided in Rule 61N-1.013(5)(d)1.a., F.A.C. is required, Petitioners respectfully request a waiver of such requirement.

25. Florida District Courts of Appeal have held that where certain licensing requirements are too burdensome, it is appropriate to petition for variance or waiver from the burdensome requirement. See, *The University of South Florida v. Dep't of Children and Family Services*, 787 So. 2d 223 (Fla. 2nd DCA 2001). Section 120.542(2), Florida Statutes requires DDC to grant such a variance or waiver when the applicant subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means and when application of the rule would create either a substantial hardship or would violate principles of fairness.

26. Section 120.542(2), Florida Statutes, provides that "For purposes of this section, 'substantial hardship' means a demonstrated economic, technological, legal, or other type of hardship to the person requesting the variance or waiver."

27. It is reasonable to conclude that Petitioner Vero DC would suffer an economic and technological hardship in that it would be forced to suspend its operations for a week to conduct a physical inventory that its highly automated system is not designed to accommodate.

28. Petitioner would also suffer an economic and technological hardship by having to change its state of the art electronic temperature monitoring system to accommodate the manual recording of the initials of personnel reviewing the temperature information taken from 2:00 to 4:00 PM at least 5 days each week.

29. Finally, Petitioners respectfully submit that it would violate the principles of fairness to require Petitioners to use the same authentication method imposed on other drug wholesalers who are purchasing from non-primary wholesale distributors or otherwise outside of the "normal distribution chain."

WHEREFORE, Petitioner respectfully requests that the Division of Drugs, Devices & Cosmetics review this Petition, conclude that the automated system at the Vero DC described herein maintains an accurate perpetual inventory; conclude that the electronic temperature monitoring equipment used by Petitioners maintains an accurate record of same; conclude that the authentication as described in paragraph 20 is appropriate, and grant permanent Variances or Waivers as requested herein.

Respectfully submitted, this 27 day of February, 2013.

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