STATE OF FLORIDA
DEPARTMENT OF HEALTH
DRUGS, DEVICES, AND COSMETICS PROGRAM

IN RE: - PETITION FOR DECLARATORY STATEMENT

PHARMALINK, INC.

PETITION FOR DECLARATORY STATEMENT OR IN THE ALTERNATIVE, PETITION FOR VARIANCE OR WAIVER

Petitioner, Pharmalink, Inc. ("Petitioner" or "Pharmalink"), pursuant to Section 120.565, Florida Statutes (2008) and Rule 28-105.001, Florida Administrative Code, petitions the Florida Department of Health, Drugs, Devices, and Cosmetics Program ("Department") for a Final Order setting forth a Declaratory Statement on the facts and law presented herein or in the alternative, Petitioner requests a variance or waiver under Section 120.542, Fla. Stat. from Rule 64F-12.023(3)(a), F.A.C. ("Petition") In support of this Petition, Petitioner states as follows:

1. Petitioner, Pharmalink, Inc. is a reverse distributor of pharmaceutical products based in Pinellas County, Florida serving customers throughout the United States which ship a variety of pharmaceutical products to Petitioner's Florida location at 12345 Starkey Rd, Suite. L, Largo, FL 33773. Pharmalink is licensed by the Department as a Restricted Prescription Drug Distributor – Reverse

Distributor operating under permit number 524. Pharmalink is also licensed by the D.E.A. and the D.E.P./E.P.A. Petitioner has never been disciplined by the Department during its eight (8) years of operation.

2. For purposes of this Petition, all correspondence and communication should be provided to undersigned counsel for Petitioner at the address, telephone number and facsimile number provided below.

3. On October 15, 2007, Petitioner was inspected by a Department representative as part of a routine compliance inspection, and cited for violations, including alleged violations related to Petitioner's acceptance of shipments of pharmaceuticals which were not appropriately inventoried by shippers prior to Petitioner's receipt ("Inspection"). Due to this alleged "major non-compliance," the Department inspector prohibited Petitioner's operation from October 15, 2007 until early November 2007 at significant expense to Petitioner.

4. On March 19, 2008, the Department issued a Notice of Violation related to the Inspection to which Petitioner responded by letter dated April 30, 2008 seeking the Department's reconsideration of the basis for the Notice of Violation and questioning the inspector's interpretation of the referenced statutes and regulations. After review of Petitioner's letter, the Department placed the disciplinary case in abeyance so that further exploration of the underlying legal issues could occur. This Petition seeks the Department's interpretation of the

statutes and rules governing inventories as applied to Petitioner's particular set of circumstances.

5. Prior to the Inspection, Petitioner's practice of creating an inventory of inbound products upon receipt of the shipment had been accepted by the Department as compliant with statutory and regulatory requirements governing reverse distributors. During the Inspection, the new Department inspector informed Petitioner that it could no longer accept shipments which did not include an inventory prepared by the shipper prior to the shipment's arrival at Petitioner's facility. Petitioner is aware of only three states, (Georgia, Florida, and Ohio[1]), that require a customer to perform an inventory of non-scheduled products prior to a shipment leaving the customer's facility. Even in those instances, it is the responsibility of the shipping customer to comply with the inventory requirements, not the duty of the reverse distributor to ensure that its customers are complying with their respective state laws. Florida law does not require licensed pharmacies to send a copy of the inventory to the reverse distributor.

6. The statutory requirements pertaining to Petitioner are found at Section 499.01 and Section 499.0121, Fla. Stat. (2008). More specifically, Section 499.01(2) (g) (2), Fla. Stat. (2008) requires restricted prescription drug distributors,

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[1] Florida licensed pharmacies are required to prepare an inventory of the drugs transferred to the reverse distributor in accordance with Rule 64F-12.012 (2) (d). However, pharmacies in other states outside of Florida have no such requirements. Additionally, Florida licensed pharmacies are not required under the rules to provide a copy of the inventory to the reverse distributor.

such as Petitioner, to comply with the recordkeeping requirements for wholesale distributors as set forth in Section 499.0121, Fla. Stat. (2008). Section 499.0121, Subsection (6), Fla. Stat. mandates that wholesale drug distributors must establish and maintain inventories and records of all transactions regarding **the receipt** and distribution or other disposition of prescription drugs. These records must provide a complete audit trail **from receipt** to sale or other disposition, be readily retrievable for inspection, and include at a minimum the following information: 1. The source of the drugs, including name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped 2. The name, principal address, and the state license permit or registration number of the person authorized to purchase prescription drugs; 3. The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of; 4. The dates of receipt and distribution of the drugs; and 5. Any financial documentation supporting the transaction. (Emphasis added.)

7. Rule 64F-12.012(2), F.A.C. requires that each person receiving or distributing prescription drugs must maintain records, including records required by Section 499.0121(6) described above and per subsection (2)(d) that the records "are to be created during the transaction (i.e., at the time of order, **receipt**, processing, picking or shipping) and not retroactively created." (Emphasis added.)

8. Rule 64F-12.023(3)(a), F.A.C. governing reverse distributors provides "as a part of the audit trail and documentation required by Rule 64F-12.012, F.A.C., the records must identify at a minimum the name of the prescription drug product and whether it is a prescription drug sample, the manufacturer, and the quantity for each prescription drug removed from the establishment. The NDC code may be used to identify the manufacturer. For partially filled containers, the quantity at a minimum must be estimated."

9. Petitioner agrees that Florida licensed pharmacies have a duty to prepare, or have prepared, an inventory or other record of prescription drugs transferred to a reverse distributor and that the inventory or record kept by the Florida pharmacy must include the name of the prescription drug, an indication of whether or not the drug is a sample, the name of the manufacturer, and the quantity removed from the pharmacy. See Rules 64F-12.012(2)(d), F.A.C. and 64F-12.023(3)(a), F.A.C. (2008). However, Petitioner locates no authority that requires any pharmacies licensed in other states or non-pharmacy customers of prescription medications to comply with Florida's recordkeeping requirements.

10. Petitioner is seeking the Department's interpretation of Section 499.0121(6), Fla. Stat. and subsection (3)(a) of Rule 64F-12.023, F.A.C. as applied to Petitioner's particular set of circumstances. More specifically, Petitioner is asking the Department whether its creation of the required inventory upon receipt

of a shipment satisfies the referenced statute and rules, or whether the Petitioner is required by statute or rule to reject all inbound shipments which do not contain an inventory prepared by the customer prior to shipping.

11. In support of this Petition, Petitioner relies on the plain language of the statute found at Section 499.0121(6) which mandates that records must provide an audit trail ~~**from receipt**~~ to sale or other disposition of the prescription medications. (Emphasis added.) Petitioner also notes that its practice of creating an inventory upon receipt of medications has been deemed compliant for years under the same statutory language. Further, Petitioner questions the statutory basis for any interpretation of the referenced rules which concludes that an inventory created upon receipt of the medications is improper.

WHEREFORE, Petitioner respectfully requests the Department issue a Declaratory Statement concluding that Petitioner's creation of the required inventory upon its receipt of a shipment of prescription medications complies with Section 499.0121(6), Fla. Stat. and Rules 64F-12.023(3)(a) and 64F-12.012(2)(d), F.A.C.

In the event that the Department determines that the referenced rules require Petitioner to mandate its customers prepare a detailed inventory of all prescription medications shipped by them to Petitioner, Petitioner respectfully requests that the Department grant a waiver, or in the alternative, a variance of that portion of Rule

64F-12.023(3)(a) or Rule 64F-12.012, F.A.C, which is being interpreted by the Department to require an inbound inventory from Petitioner's customers, which are not licensed by the Florida Department of Health. In support of this request, Petitioner states as follows:

12. Petitioner incorporates paragraphs numbered one (1) through eleven (11) as set forth herein.

13. Since the Inspection, Petitioner has required its customers to complete and provide an inventory of all prescription medications shipped to Petitioner. This requirement has caused great financial hardship to Petitioner and its customers with loss of material numbers of customers, reduction of workforce as a result of Petitioner's financial hardship, and may result in closure of Petitioner's Florida operations as further described below.

14. A waiver or variance is appropriate where certain licensing requirements are too burdensome for an applicant. *The Univ. of South Florida. v. Dep't of Children and Family Services*, 787 So. 2d 223 (Fla. 2d DCA 2001). Moreover, section 120.542(2), Fla. Stat. (2008) provides that an agency must grant variances from and waivers of their own rules when a person subject to the rule demonstrates that he or she can achieve or has achieved the purpose of the underlying statute by other means and when application of the rule would "create a substantial hardship or would violate principles of fairness." A "substantial

hardship" is defined as "a demonstrated economic, technological, legal, or other type of hardship to the person requesting the variance or waiver." *Id.*

15. In this case, the purpose of the underlying statute is to deter adulterated prescription drugs from re-entering the marketplace or from being disposed of in a manner that might jeopardize the public health, safety, or welfare of the citizens of Florida.

16. Petitioner has an eight (8) year history of substantial compliance with the Florida laws governing its operation as a licensed reverse distributor. Petitioner has fully cooperated with the Department and believes that it is in compliance with all Florida laws governing its operation, including those pertaining to recordkeeping.

17. Requiring Petitioner's customers to prepare an inbound inventory has resulted in loss of business for Petitioner, and loss of more than $500,000.00 in annual revenue.

18. Ninety-one percent (91%) of Petitioner's business is generated from out-of-state customers. These customers do not have to comply with inventory requirements in their states and are greatly impacted by the requirements of Florida that Petitioner ensure its customers provide an inbound inventory. Petitioner has lost at least 426 customers expressly because of this requirement of an inbound inventory. Moreover, Petitioner has seen an increase in order cancellations

because customers do not want to complete the inventory being requested when the customer has the option of sending the shipment to another company which is not required to have an inbound inventory provided upon receipt of shipments. Petitioner's competitors have used Petitioner's inventory requirement as a basis to lure business away from Petitioner. This loss of business has created a substantial financial hardship on Petitioner. Typical of Petitioner's many customers which have cancelled services with Petitioner is the customer which stated "Cancelling contract, inventory is too labor intensive for my pharmacy." (Customer from Abbeville, LA). Other similar comments made to Petitioner by its customers can be provided upon request. Since the addition of this requirement, Petitioner's orders and sales have declined significantly and they continue to do so month after month.

19. Further, implementation of the inbound inventory requirement has also resulted in lost revenue to Petitioner from increased costs of implementing computer changes to assist customers with preparation of the inventory. Since the implementation of the inbound inventory requirement, Petitioner has been forced to reduce its staff by 17%. Still the Petitioner has been unable to generate a profit with this inbound inventory requirement.

20. If Petitioner is not granted some regulatory relief from the Department's interpretation that the Petitioner must require its customers to

include an inbound inventory with their shipments, Petitioner may have to terminate additional staff or be forced to relocate to another state in order to effectively pursue its purpose and serve those who benefit from its services.

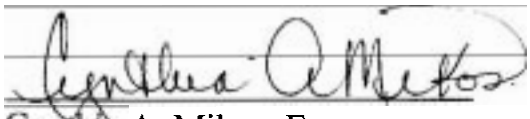
21. Petitioner's preparation of an inventory upon receipt of all prescription medications shipped to it meets the underlying purpose of the rules and protects the public by creating an audit trail of the drugs received in Florida until their destruction or removal from Florida.

22. For the reasons outlined above, the Department should grant Petitioner's request for a permanent variance or waiver of any regulatory requirement the Department interprets as mandating Petitioner decline all shipments from its customers which do not include an inventory prepared by the customers prior to shipping. Such a requirement has created a substantial hardship to Petitioner significant enough to threaten its ability to operate in Florida as evidenced by the information provided above. Allowing Petitioner to prepare an inventory for its customers upon receipt of the prescription medications satisfies the underlying purpose of the rules.

WHEREFORE, Petitioner, Pharmalink, respectfully requests that pursuant to Section 120.542, Fla. Stat. (2008), the Department grant Petitioner's request for a waiver or variance of any and all rules which the Department interprets as

requiring Petitioner to mandate its customers prepare and provide to Petitioner an inbound inventory prior to shipping prescription medications to Petitioner.

Respectfully submitted,



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Certificate of Service

I HEREBY CERTIFY that a true and correct copy of the foregoing was furnished on this 20th day of January 2009 to:

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☑ Via Overnight Mail
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