

**STATE OF FLORIDA
DEPARTMENT OF BUSINESS & PROFESSIONAL REGULATION**

FILED	
<small>Department of Business and Professional Regulation Deputy Agency Clerk</small>	
CLERK	Brandon Nichols
Date	9/18/2014
File #	2014-07140

**In Re: Petition for Declaratory
Statement,**

DS 2014-081

H.D. Smith Wholesale Drug Company,

Petitioner.

DECLARATORY STATEMENT

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereafter, "Department"), issues this Declaratory Statement in accordance with Section 120.565, Florida Statutes.

PRELIMINARY STATEMENT

On June 24, 2014, the Division received a petition for declaratory statement (Exhibit A) filed by H.D. Smith Wholesale Drug Company (hereafter, "HDS" or "Petitioner"), which holds Department permit number 22:1454 as a prescription drug wholesale distributor at 1901 N.W. 25th Avenue, Pompano Beach, Florida 33069-5226. HDS also holds permit number 23:2382 as an out-of-state prescription drug wholesale distributor at 6001 Global Distribution Way, Suite 102, Louisville, Kentucky 40228. The Petitioner is seeking a declaratory statement regarding the applicability of Sections 499.003(37), 499.0121(4)(d), and 499.01212, Florida Statutes, and Rules 61N-1.012(3)(f), and 61N-1.013(5)(d), Florida Administrative Code, to the Petitioner's facts.

The Department published notice of the petition for declaratory statement in the July 3, 2014, issue of the Florida Administrative Register.

FINDINGS OF FACT

The following findings of fact are based on the information submitted by the Petitioner. The Department takes no position as to the accuracy of the facts, but merely accepts them as submitted for purposes of this Declaratory Statement.

1. HDS is a prescription drug wholesale distributor. HDS has historically and continues to distribute drug products that under Florida law would have to comply with the pedigree paper requirements of Section 499.01212, Florida Statutes.

2. HDS is an "authorized distributor of record" for all of the prescription drug products it distributes in Florida.

3. An authorized distributor of record is defined as a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.

4. HDS distributes only finished dose products that it purchases directly from manufacturers.

5. HDS complies with Florida's pedigree paper requirements, including authentication as set forth in Florida law (when applicable), and also handles returns in the manner set forth in the applicable Florida administrative rule.

6. HDS asserts that its ability to continue to comply with Florida requirements is becoming increasingly difficult and costly in light of changes in the federal law applicable to distribution of prescription drugs.

7. At least two of HDS's suppliers have advised HDS that, due to recent changes in the federal law applicable to wholesale distributions of prescription drugs,

they will no longer pass pedigrees when distributing prescription drugs to HDS. This is indicative of the experience HDS is having with other suppliers.

8. HDS asserts that compliance with authentication and return requirements contained in Florida law, but not in recently amended federal law, adds time and expense to the distribution process.

9. HDS asserts that extensive additional expense will be incurred if HDS must comply with Florida requirements that have been preempted by federal law. In some instances, compliance will become impossible, and HDS will be forced to stop doing business in Florida with regard to companies that will not provide pedigrees.

10. HDS wishes to avoid criminal and administrative prosecution and sanctions for violating provisions of Chapter 499, Florida Statutes, and Rule Chapter 61N-1, Florida Administrative Code.

11. Petitioner asserts that the following laws apply to Petitioner's set of circumstances:

A. Section 499.003(5), Florida Statutes, (2013), provides:

499.003 Definitions of terms used in this part.—As used

in this part, the term:

* * *

(5) "Authenticate" means to affirmatively verify upon receipt of a prescription drug that each transaction listed on the pedigree paper has occurred.

* * *

B. Section 499.003(37), Florida Statutes (2013), provides:

499.003 Definitions of terms used in this part.—As used

in this part, the term:

* * *

(37) "Pedigree paper" means a document in written or electronic form approved by the department which contains information required by s. 499.01212 regarding the sale and distribution of any given prescription drug.

C. Section 499.01212, Florida Statutes (2013), provides:

499.01212 Pedigree paper.—

(1) APPLICATION.—Each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.

(2) FORMAT.—A pedigree paper must contain the following information:

(a) For the wholesale distribution of a prescription drug within the normal distribution chain:

1. The following statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."
2. The manufacturer's national drug code identifier and the name and address of the wholesale distributor, and the purchaser of the prescription drug.
3. The name of the prescription drug as it appears on the label.
4. The quantity, dosage form, and strength of the prescription drug.

The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers, the date of the shipment from the manufacturer to the wholesale distributor, the lot numbers of such drugs, and the invoice numbers from the manufacturer.

(b) For all other wholesale distributions of prescription drugs:

1. The quantity, dosage form, and strength of the prescription drugs
2. The lot numbers of the prescription drugs.

3. The name and address of each owner of the prescription drug and his or her signature.
4. Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.
5. An invoice number, a shipping document number, or another number uniquely identifying the transaction.
6. A certification that the recipient wholesale distributor has authenticated the pedigree papers.
7. The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.
8. The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.

D. Section 499.0121(4)(d), Florida Statutes (2013), provides:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

* * *

(4) EXAMINATION OF MATERIALS AND RECORDS.—

* * *

(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. This includes authenticating each transaction listed on a pedigree paper, as defined in s. 499.003(37).

E. Section 499.0051(2)(a), Florida Statutes (2013), provides:

499.0051 Criminal acts.—

* * *

(2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.—Effective July 1, 2006:

(a) A person engaged in the wholesale distribution of prescription drugs who is in possession of pedigree papers concerning prescription drugs or contraband prescription drugs and who fails to authenticate the matters contained in the pedigree papers and who nevertheless attempts to further distribute prescription drugs or contraband prescription drugs commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

F. Rule 61N-1.013(5)(d), Florida Administrative Code, provides, in relevant part:

61N-1.013 Records of Drugs, Cosmetics, and Devices.

* * *

(5) Examination of Prescription Drugs; Physical Products and Records

(d) Authentication.

1. A prescription drug wholesaler may use any, all, or any combination of the following methods to authenticate each transaction on a pedigree paper and must maintain the corresponding documentation regarding the authentication for the method used:

a. Receipt of an invoice (or shipping document) from the seller to the purchaser, which may have the prices redacted. Documentation requirements include at a minimum a copy of the invoice or shipping document. If this method is used to authenticate a pedigree, the wholesaler must review the document received for signs of tampering, incompleteness, or inconsistency with other invoices or shipping documents from that manufacturer or wholesaler, and must randomly verify the authenticity of the invoice or shipping document with the seller or shipping point reflected on that document using one of the methods in sub-subparagraph b., c., or d. below. Each wholesaler shall establish and adhere to

policies and procedures for the random verification of the authenticity of the invoices or shipping documents according to statistically valid standards.

b. Telephone call to the seller. Documentation requirements include a signed statement by the person placing the telephone call identifying the person's name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.

c. E-mail communication with the seller. Documentation requirements include a copy of the e-mail that identifies the person's name and position title representing the seller who provides the information, the date the information was provided, and verification of the sales transaction between the parties, including verification of the date of the transaction and the quantity of prescription drugs involved in the transaction.

d. Verification of the transaction per a web-based system established by the seller or an independent person that is secure from intentional or unintentional tampering or manipulation to conceal an accurate and complete history of the prescription drug transaction(s). Documentation requirements include a written representation from the seller or independent person that the seller or independent person, as applicable, is responsible for the information included on the web site and has adequate security on the information posted to prevent unauthorized tampering, manipulation, or modification of the information and a copy of the (dated) web site page that confirms the sales transaction between the parties, including the date of the transaction and the quantity of prescription drugs involved in the transaction.

e. Receipt of a legible and unaltered copy of a previous transaction's pedigree paper that had been signed under oath at the time of the previous transaction to support the transaction to which the pedigree paper relates. If this method is used to authenticate a pedigree, the wholesaler must review the document received for signs of tampering, incompleteness, or inconsistency, and must randomly verify the authenticity of pedigrees using one of the methods in sub-subparagraph b., c., or d. above. Each wholesaler shall establish and adhere to policies and procedures for the random verification of the authenticity of these copies of pedigrees according to statistically valid standards.

f. Receipt of a pedigree in an electronic form from an automated system that complies with this sub-subparagraph that was successfully opened and decrypted by an automated system that complies with this sub-subparagraph.

* * *

G. Rule 61N-1.012(3)(f), Florida Statutes (2013), provides:

61N-1.012 Records of Drugs, Cosmetics and Devices.

(3) Pedigree Papers.

* * *

(f) Returns.

1. When a distribution of a prescription drug by a wholesale distributor to a pharmacy or a health care entity, including a practitioner, licensed and authorized under Florida law to purchase and receive the prescription drug is the result of a mistake in ordering or shipment, the return of that prescription drug by the recipient to the wholesale distributor need not be reflected in a pedigree paper. For purposes of this subparagraph, a mistake in ordering or shipment shall be deemed to have occurred if, within fourteen calendar days after the date of receipt of the original shipment:

a. The recipient ships the specific unit of the prescription drug back to the wholesale distributor from which that specific unit was purchased; or

b. The recipient transmits a documented communication to the wholesale distributor from which the prescription drug was purchased stating the recipient's intent to return the shipment in accordance with the wholesale distributor's prescribed written policies and procedures and the wholesale distributor communicates authorization for return of the product.

2. Any returns to a wholesale distributor that are not within the scope of subparagraph 1. shall be reflected in a pedigree paper for any subsequent wholesale distributions of the returned drug product to the extent required by Section 499.01212, F.S.

3. A recipient that returns a prescription drug to the wholesale distributor in accordance with subparagraph 1. or 2. shall verify by written declaration as set forth in Section 92.525(2), F.S., a written document submitted with the

returned product,

a. That the specific unit (exact unit) being returned was purchased from the receiving wholesale distributor (including the corresponding sales invoice number and the date of the sale from that wholesale distributor to the authorized recipient); and

b. That the product was or was not stored and shipped in accordance with the requirements of Section 499.0121, F.S., and the rules adopted thereunder while in the purchaser's custody and control.

c. The written declaration shall be printed or typed at the end of or immediately below the statements in subparagraphs 3.a. and 3.b. and shall state: "Under penalties of perjury, I declare that I have read the foregoing and that the facts stated in it are true," followed by the signature of the person making the declaration.

12. Petitioner asserts the following with respect to the Drug Quality and Security Act (DQSA) of 2013:

A. Section 585 of the DQSA provides:

"SEC. 585. UNIFORM NATIONAL POLICY.

"(a) PRODUCT TRACING AND OTHER REQUIREMENTS.— Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with—

"(1) any waiver, exception, or exemption pursuant to section 581 or 582; or

"(2) any restrictions specified in section 582.

- B. Section 582(a)(5) of DQSA contains a grandfathering provision that provides, in pertinent part:

(5) GRANDFATHERING PRODUCT —

* * *

(B) TRACING. — For a product that entered the pharmaceutical distribution supply chain prior to January 1, 2015 —

(i) authorized trading partners shall be exempt from providing transaction information as required under subsections (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and (e)(1)(A)(ii).

(ii) transaction history required under this section shall begin with the owner of such product on such date; and

(iii) the owners of such product on such date shall be exempt from asserting receipt of transaction information and transaction statement from the prior owner as required under this section.

- C. Section 582(d)(1)(C)(i)-(ii) states with respect to returns by a dispenser, which includes retail and hospital pharmacies:

(C) RETURNS.—

(i) SALEABLE RETURNS.—A dispenser may return product to the trading partner from which the dispenser obtained the product without providing the information required under subparagraph (A).

(ii) NONSALEABLE RETURNS.—A dispenser may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, to a returns processor, or to a person acting on behalf of such a person without providing the information required under subparagraph (A).

- D. The DQSA states that the wholesale distributor's requirements with respect to returns are coordinated with this dispenser's exemption and are as follows:

(B) Returns —

(i) SALEABLE RETURNS. — Notwithstanding subparagraph (A)(i) [§ 582(c)(1)(A)(i)], the following shall apply:

(I) REQUIREMENTS. – Until the date that is 6 years after the date of enactment . . . (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager pursuant to the terms and conditions of any agreement between the parties, and, notwithstanding subparagraph (A)(ii), may distribute such returned product without providing the transaction history. For transactions subsequent to the return, the transaction history of such product shall begin with the wholesale distributor that accepted the returned product, consistent with the requirements of this subsection.

(II) ENHANCED REQUIREMENTS. – Beginning 6 years after the date of enactment . . . (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. For all transactions after such date, the transaction history, as applicable, of such product shall begin with the wholesale distributor that accepted and verified the returned product. For purposes of this subparagraph, the transaction information and transaction history, as applicable, need not include transaction dates if it is not reasonably practicable to obtain such dates.

13. HDS asserts that it is substantially affected by the provisions of Florida law cited in paragraphs 11A-G above regarding prescription drug pedigree, authentication of pedigree, and returns.

14. HDS asserts that extensive additional expense will be incurred if HDS must comply with Florida requirements. In some instances, compliance will become impossible and HDS will be forced to stop doing business in Florida with regard to companies that will not provide prescription drug pedigrees.

15. HDS wishes to avoid criminal and administrative prosecution and sanctions for violating provisions of Chapter 499 and Florida Administrative Code Chapter 61N-1 and is therefore both sufficiently and substantially affected and is

justified in requesting this declaratory statement to clarify its rights under the referenced statutes and rules.

16. Petitioner requests a statement declaring the following:

A. HDS does not have to comply with the pedigree requirements of Section 499.01212, Florida Statutes, and related administrative rules, to the extent they impose requirements that are inconsistent with, more stringent than, or in addition to, any requirements of DQSA.

B. HDS does not have to comply with the authentication requirements of Florida law, to the extent they impose requirements that are inconsistent with, more stringent than, or in addition to, any requirements of DQSA.

C. HDS does not have to comply with the return requirements of Florida Administrative Code Rule 61N-1.012, to the extent they impose requirements that are inconsistent with, more stringent than, or in addition to, any requirements of DQSA.

CONCLUSIONS OF LAW

17. The Department is the state agency charged with regulation of drugs, devices, and cosmetics, pursuant to Chapter 499, Florida Statutes.

18. The Department has jurisdiction to enter this order pursuant to Section 120.565, Florida Statutes, and Rule 28-105.003, Florida Administrative Code.

19. Section 120.565, Florida Statutes, provides:

120.565 Declaratory statement by agencies.—

(1) Any substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a

statutory provision, or of any rule or order of the agency, as it applies to the petitioner's particular set of circumstances.

(2) The petition seeking a declaratory statement shall state with particularity the petitioner's set of circumstances and shall specify the statutory provision, rule, or order that the petitioner believes may apply to the set of circumstances.

(3) The agency shall give notice of the filing of each petition in the next available issue of the Florida Administrative Weekly and transmit copies of each petition to the committee. The agency shall issue a declaratory statement or deny the petition within 90 days after the filing of the petition. The declaratory statement or denial of the petition shall be noticed in the next available issue of the Florida Administrative Weekly. Agency disposition of petitions shall be final agency action.

20. Rule 28-105.003, Florida Administrative Code, provides:

28-105.003 Agency Disposition.

The agency may hold a hearing to consider a petition for declaratory statement. If the agency is headed by a collegial body, it shall take action on a petition for declaratory statement only at a duly noticed public meeting. The agency may rely on the statements of fact set out in the petition without taking any position with regard to the validity of the facts. Within 90 days of the filing of the petition, the agency shall render a final order denying the petition or issuing a declaratory statement.

21. The Petitioner is substantially affected by the statutes and rules cited in paragraphs 11A-G above and has standing to seek a declaratory statement from the department.

22. The Department is authorized to enforce the provisions of Chapter 499, Florida Statutes, and the administrative rules adopted pursuant to the statute¹.

23. Prior to November 27, 2013, the provisions of Chapter 499, Florida Statutes and of the Florida Administrative Code cited in paragraphs 11A-G above,

¹ The Department's authority to regulate activity under Chapter 499, Florida Statutes, is limited to regulatory enforcement. While the interpretation of statutes by agencies charged with their enforcement is entitled to great deference and will not be overturned unless clearly erroneous, Gay v. Canada Dry Bottling Co., 59 So.2d 788, 790 (Fla. 1952), the department's interpretation does not bind the authority of Florida's criminal prosecutors to bring charges under the criminal provisions of the statute.

were interpreted by the Department to require a prescription drug pedigree to be provided by the wholesale distributor prior to or simultaneously with the distribution of a prescription drug; the pedigree had to include the information enumerated in the statute; the pedigree paper had to be authenticated in one or more of the ways set forth in Rule 61N-1.013(5)(d); electronic pedigrees had to be authenticated according to that rule; if a pedigree could not be authenticated, the prescription drugs had to be quarantined and the Department notified; returns of drugs from a pharmacy, health care entity or licensed health care practitioner that were the result of a mistake in ordering or shipment need not be included in a pedigree; returns not in that category had to be included in a pedigree and had to otherwise comply with rule 61N-1.012(3)(f), Florida Administrative Code.

24. Effective November 27, 2013, the Drug Quality and Security Act (DQSA) was signed into law. The Act is comprised of Title I, the Compounding Quality Act, and Title II, the Drug Supply Chain Security Act.

25. The DQSA Title II requires a uniform national system for tracking and tracing prescription drugs through the supply chain, and a uniform licensing system for prescription drug wholesale distributors, repackagers, and third party logistics providers. The Act applies to human finished dosage forms of prescription drugs only.

26. The DQSA contains preemption language regarding tracking and tracing prescription drugs through the supply chain and regarding licensing of prescription drug manufacturers, wholesale distributors, and third party logistics providers. Currently, wholesale distributors are still required to obtain a permit from the Department to

operate in this state, and to be in compliance with federal law. See, Sections 582-585, Drug Quality and Security Act.

27. The preemption language in Section 585 of the Act as cited in paragraph 12 above, makes it clear that states may not establish or continue in effect any requirement for tracing products through the distribution system (including any requirement with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as the product changes ownership in the supply chain, or verification, investigation, disposition, notification or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act).

28. The Department has previously taken the position that the Florida pedigree requirements are preempted by the federal law. See, Declaratory Statement, In Re Petition for Declaratory Statement, Publix Supermarkets, Inc., Petitioner, Declaratory Statement Case Number DS2014-007. The DQSA does not have any specific references to or provisions requiring authentication.² The Department takes the position that the Florida requirements for authentication are inconsistent with, more stringent than or in addition to the requirements in the amended federal law, and are preempted.

² Beginning January 1, 2015, the DQSA requires manufacturers, wholesale distributors and repackagers to perform verification in certain circumstances of products they receive and requires verification of product upon requests therefor from the Secretary. However, the verification process differs from the authentication of pedigree requirements in Chapter 499, Florida Statutes.

29. With respect to returns, the provisions of the DQSA categorizes returns from dispensers and those from a wholesale distributor differently, and requires no transaction history, transaction statement, or transaction information for most returns. By contrast, the Florida provisions on returns require information to be included in a pedigree except in limited circumstances set forth in Florida Administrative Code Rule 61N-1.012(3)(f). Because the provisions for returns under Florida law are inconsistent with, and more stringent than, the provisions in the DQSA, those provisions are preempted as well.

30. The amended federal tracking and tracing requirements become effective January 1, 2015. The Department has previously taken the position that in the interim period before the effective date of the tracking and tracing requirements of the provisions of the DQSA, current federal minimum standards for wholesale distribution of prescription drugs, set forth in 21 C.F.R. §203, the Prescription Drug Marketing Act (PDMA), are applicable, and states may enforce those requirements of the PDMA. See, Declaratory Statement, In Re Petition for Declaratory Statement, Publix Supermarkets, Inc., Petitioner, Declaratory Statement Case Number DS2014-007.

31. However, Petitioner asserts that it is an authorized distributor of record, and the PDMA, by its terms, does not address requirements for documenting the movement of prescription drugs for those in Petitioner's status as an authorized distributor of record. In addition, the PDMA does not address returns of prescription drug product. It is not clear how Petitioner is to handle tracking and tracing requirements for distributions or returns in the interim period.

32. While Petitioner implies that the grandfathering product provision of the DQSA operates retroactively to govern Petitioner's distributions that occur prior to January 1, 2015, the Department cannot address the applicability of the DQSA provisions to Petitioner's facts. However, as discussed above, the Department will not pursue administrative enforcement action against Petitioner if Petitioner does not comply with pedigree, authentication and returns requirements.

33. Accordingly, applying the foregoing to Petitioner's facts, Petitioner's request for a declaratory statement is answered as follows:

A. The Department will not pursue an administrative enforcement action against HDS if HDS does not comply with the pedigree and authentication requirements of section 499.01212, Florida Statutes, and Rule 61N-1.013, Florida Administrative Code.

B. The Department will not pursue an administrative enforcement action against HDS if HDS does not comply with the return requirements set forth in Florida Administrative Code Rule 61N-1.012.

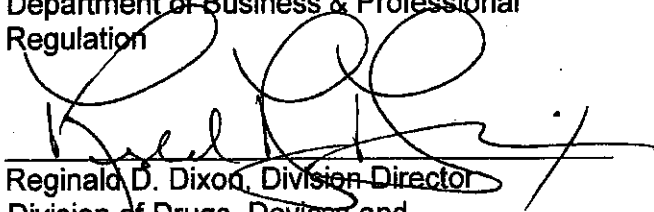
C. Nothing herein shall be construed as affecting or negating requirements of federal law for wholesale distribution of prescription drugs as such requirements apply to Petitioner³.

³ Section 499.067(5), Florida Statutes, authorizes the department to take appropriate actions against the permit of those persons authorized to purchase prescription drugs if the person has been found guilty of a violation(s) of any federal or state law.

Done and ordered this 17th day of September 2014, at Tallahassee, Leon
County, Florida.

KEN LAWSON, SECRETARY
Department of Business & Professional
Regulation

BY:


Reginald D. Dixon, Division Director
Division of Drugs, Devices and
Cosmetics
1940 North Monroe Street, Suite 26A
Tallahassee, FL 32399-1047
Telephone: (850) 717-1800
Facsimile: (850) 414-8240

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been
furnished by U.S. mail to Michael J. Glazer, Ausley McMullen, Post office Box 391, 123
South Calhoun Street, Tallahassee, Florida 32301, this 18th day of
September, 2014.


for: Brandon M. Nibbs
Agency Clerk

Copies furnished to:

Reginald D. Dixon
DDC Division Director

Kathryn E. Price
DDC Chief Attorney

NOTICE OF RIGHTS TO APPEAL

THIS FINAL ORDER CONSTITUTES FINAL AGENCY ACTION AND MAY BE APPEALED BY ANY PARTY ADVERSELY AFFECTED PURSUANT TO SECTION 120.68, FLORIDA STATUTES, AND RULE 9.110, FLORIDA RULES OF APPELLATE PROCEDURE, BY FILING A NOTICE OF APPEAL CONFORMING TO THE REQUIREMENT OF RULE 9.110(C), FLORIDA RULES OF APPELLATE PROCEDURE, BOTH WITH THE APPROPRIATE DISTRICT COURT OF APPEAL ACCOMPANIED BY THE APPROPRIATE FILING FEE AND WITH THE AGENCY CLERK, 1940 NORTH MONROE STREET, NORTHWOOD CENTRE, TALLAHASSEE, FLORIDA 32399-2217, WITHIN THIRTY DAYS OF RENDITION OF THIS FINAL ORDER.

**BEFORE THE STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

FILED	
<small>Department of Business and Professional Regulation Deputy Agency Clerk</small>	
CLERK	Brandon Nichols
Date	7/15/2014
File #	

**IN RE: H.D. SMITH WHOLESALE DRUG
COMPANY'S PETITION FOR DECLARATORY
STATEMENT BEFORE THE DEPARTMENT OF
BUSINESS AND PROFESSIONAL REGULATION,**

DS 2014-081

**H.D. SMITH'S SUPPLEMENT TO JUNE 24, 2014
PETITION FOR DECLARATORY STATEMENT**

H.D. Smith Wholesale Drug Co. ("HDS"), by and through its undersigned attorneys, hereby files the following attachment as a Supplement to its June 24, 2014 Petition for Declaratory Statement¹ and says:

1. In its June 24, 2014 Petition for Declaratory Statement, HDS included a copy of a May 16, 2014 letter from American Health Packaging noting that one of HDS's suppliers will no longer pass pedigree in light of the federal Drug Quality and Security Act ("DQSA").

2. Attached hereto as Exhibit B² is a copy of a letter that HDS recently received from McKesson, another major supplier of prescription drug products to HDS. This letter is consistent with the letter from American Health Packaging and underscores the need for the requested Declaratory Statement.

¹ HDS currently has two Petitions for Declaratory Statement pending before the Department of Business and Professional Regulation. This Supplement is to the Petition filed on June 24, 2014 regarding pedigree issues.

² Exhibit A is the American Health Packaging letter attached to the Petition.

Respectfully submitted this 15th day of July, 2014.



MICHAEL J. GLAZER

Florida Bar No. 0286508

mglazer@ausley.com

Ausley McMullen

Post Office Box 391

123 South Calhoun Street

Tallahassee, Florida 32301

Telephone: (850) 425-5474

Facsimile: (850) 222-7560

Attorneys for H.D. Smith Wholesale Drug
Company

CERTIFICATE OF SERVICE

I hereby certify that the original of the foregoing Petition for Declaratory Statement was hand delivered to: Agency Clerk, Department of Business & Professional Regulation, 1940 North Monroe Street, Suite 92, Tallahassee, Florida 32399-2202, with a copy sent by electronic mail to Reginald Dixon at reggie.dixon@myfloridalicense.com and Kathryn Price at kathryn.price@myfloridalicense.com this 15th day of July, 2014.



Michael J. Glazer

EXHIBIT B

MCKESSON

June 20, 2014

Dear Valued Customer:

On November 27, 2013, President Obama signed into law the Drug Quality and Security Act (DQSA) which contained Title II - Drug Supply Chain Security Act (DSCSA). The DSCSA establishes new federal traceability requirements to create a consistent, national structure for tracing drugs throughout the United States. Over the next 10 years, the new requirements will evolve towards unit-level serialization across the country.

The DSCSA immediately preempted all existing state requirements for drug pedigrees effective as of November 27, 2013. McKesson has been voluntarily continuing the previous state pedigrees while we prepared for an orderly shutdown of the systems that were supporting state pedigrees, but there are currently no state requirements for drug pedigrees. The existing *federal* Prescription Drug Marketing Act (PDMA) is the sole pedigree requirement effective in the United States until January 1, 2015.

McKesson will discontinue authentication of state pedigrees and the transmission of state pedigree documents effective July 11, 2014. Pedigrees that were created prior to July 11th will continue to be available through McKesson Connect for customer downloading and storage according to your previous retention schedule.

Florida customers: Effective April 30, 2014, the state-required shortened saleable returns period no longer exists and the agreed upon returns privilege are in effect.

McKesson values your business and has established dedicated resources to make compliance with the DSCSA requirements as seamless as possible. We will provide additional information about the January 1, 2015 requirements in the coming months. If you have any questions, please contact your sales representative.

Sincerely,



Mark Walchirk
President, U.S. Pharmaceutical

**BEFORE THE STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION**

FILED	
<small>Department of Business and Professional Regulation Deputy Agency Clerk</small>	
CLERK	Brandon Nichols
Date	6/24/2014
File #	

**IN RE: H.D. SMITH WHOLESALE DRUG
COMPANY'S PETITION FOR DECLARATORY
STATEMENT BEFORE THE DEPARTMENT OF
BUSINESS AND PROFESSIONAL REGULATION,**

DS 2014-081

H.D. SMITH'S PETITION FOR DECLARATORY STATEMENT

H.D. Smith Wholesale Drug Co. ("HDS"), by and through its undersigned attorneys, and pursuant to section 120.565 and Florida Administrative Code Chapter 28-105, hereby files this Petition for Declaratory Statement and says:

INTRODUCTION

1. HDS is requesting that the Department of Business and Professional Regulation ("DBPR") declare that the purchase and sale of certain prescription drugs by HDS can be made without meeting the pedigree, authentication and return requirements of Florida law to the extent they impose requirements that are inconsistent with, more stringent than, or in addition to, any requirements of the new federal Drug Quality and Security Act.

2. The Petitioner is H.D. Smith Wholesale Drug Co. HDS is located at 1901 N.W. 25th Avenue, Pompano Beach, Florida 33069-5226 and holds Florida Prescription Drug Wholesale Distributor license number 221454 issued by DBPR. HDS also holds Florida Out-of-State Prescription Drug Wholesale Distributor license number 232382 located at 6001 Global Distribution Way, Suite 102, Louisville, Kentucky 40228. For purposes of this Petition, the contact information for HDS is through its undersigned counsel.

STATUTES ON WHICH THE DECLARATORY STATEMENT IS SOUGHT

Florida Law

3. DBPR may bring actions against persons violating the provisions of Chapter 499, Florida Statutes. Criminal sanctions also apply to certain violations, as set forth in section 499.0051, Florida Statutes. Sections 499.002, 499.0051, 499.066, 499.0661, and 499.067, Florida Statutes, and related administrative rules set forth DBPR's enforcement authority.

4. Section 499.003(37), Florida Statutes defines a "pedigree paper" as:

"Pedigree paper" means a document in written or electronic form approved by the department which contains information required by s. 499.01212 regarding the sale and distribution of any given prescription drug.

5. Section 499.01212, Florida Statutes, is entitled "Pedigree paper." This statute defines the requirements for a pedigree paper for the wholesale distribution of drug products.¹

6. Florida Administrative Code Rule 61N-1.012(3) also prescribes requirements for pedigree papers.

7. Of particular note for purposes of this Petition, Florida's law requires that, for drug products that are not in the normal distribution chain, the wholesale distributor's pedigree papers contain "[t]he lot numbers of the prescription drugs." Section 499.01212(2)(b)2, F.S. This statute also requires a wholesale distributor's pedigree papers to include:

- Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.
- An invoice number, a shipping document number, or another number uniquely identifying the transaction.

Section 499.01212(2)(b)4.-5, Fla. Stat.

¹ Section 499.01212 has different requirements depending on whether the products are distributed in the "normal distribution chain" or not. The products that HDS is concerned about for purposes of this Petition fall outside of the "normal distribution chain." The documentation requirements of federal law discussed below should still satisfy the Florida documentation requirements for products in the "normal distribution chain."

8. Florida's regulations require the wholesale distributor's pedigree papers to include "the transaction dates." F.A.C. Rule 61N-1.012(3)(a)1.
9. Florida Administrative Code Rule 61N-1.024 provides penalties for noncompliant pedigree.
10. Also related to the pedigree paper is the concept of "authentication." Section 499.003(5), Florida Statutes provides:

"Authenticate" means to affirmatively verify upon receipt of a prescription drug that each transaction listed on the pedigree paper has occurred."
11. Section 499.0121(4)(d), Florida Statutes provides:

(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. This includes authenticating each transaction listed on a pedigree paper, as defined in s. 499.003(37).
12. Section 499.0051(2)(a), Florida Statutes provides:

(b) A person engaged in the wholesale distribution of prescription drugs who fails to acquire complete and accurate pedigree papers concerning a prescription drug or contraband prescription drug prior to, or simultaneous with, the receipt of the prescription drug or contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
13. Florida Administrative Code Rule 61N-1.013(5)(d) provides additional rules regarding authentication.
14. Florida Administrative Code Rule 61N-1.015(4) relates to written policies and procedures for the security of digital signatures used to electronically authenticate electronic signatures.

15. Florida Administrative Code Rule 61N-1.024 provides penalties for noncompliant authentication.

16. Florida Administrative Code Rule 61N-1.012(3)(f) provides rules related to the pedigree paper requirements associated with drug product returns and says:

(f) Returns.

1. When a distribution of a prescription drug by a wholesale distributor to a pharmacy or a health care entity, including a practitioner, licensed and authorized under Florida law to purchase and receive the prescription drug is the result of a mistake in ordering or shipment, the return of that prescription drug by the recipient to the wholesale distributor need not be reflected in a pedigree paper. For purposes of this subparagraph, a mistake in ordering or shipment shall be deemed to have occurred if, within fourteen calendar days after the date of receipt of the original shipment:

a. The recipient ships the specific unit of the prescription drug back to the wholesale distributor from which that specific unit was purchased; or

b. The recipient transmits a documented communication to the wholesale distributor from which the prescription drug was purchased stating the recipient's intent to return the shipment in accordance with the wholesale distributor's prescribed written policies and procedures and the wholesale distributor communicates authorization for return of the product.

2. Any returns to a wholesale distributor that are not within the scope of subparagraph 1. shall be reflected in a pedigree paper for any subsequent wholesale distributions of the returned drug product to the extent required by Section 499.01212, F.S.

3. A recipient that returns a prescription drug to the wholesale distributor in accordance with subparagraph 1. or 2. shall verify by written declaration as set forth in Section 92.525(2), F.S., a written document submitted with the returned product,

a. That the specific unit (exact unit) being returned was purchased from the receiving wholesale distributor (including the corresponding sales invoice number and the date of the sale from that wholesale distributor to the authorized recipient); and

b. That the product was or was not stored and shipped in accordance with the requirements of Section 499.0121, F.S., and the rules adopted thereunder while in the purchaser's custody and control.

c. The written declaration shall be printed or typed at the end of or immediately below the statements in sub-subparagraphs 3.a. and 3.b. and shall state: "Under penalties of perjury, I declare that I have read the foregoing and that the facts stated in it are true," followed by the signature of the person making the declaration.

17. Florida Administrative Code Rule 61N-1.024 provides penalties for noncompliant returns.

Drug Quality and Security Act

18. On November 27, 2013, federal legislation designated as Public Law 113-54 (HR 3204), the "Drug Quality and Security Act" (hereinafter "DQSA"), was signed into law.²

19. The DQSA, which substantially amends and in part displaces 21 U.S.C. § 353(e) ("section 503(e)"), contains an express preemption statute. It provides:

SEC. 585 UNIFORM NATIONAL POLICY

(a) PRODUCT TRACING AND OTHER REQUIREMENTS — Beginning on the date of enactment . . . no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with —

² Title II of DQSA, entitled "Drug Supply Chain Security" has been codified at 21 U.S.C. §§360eee through 360eee-4. Section references in this Petition are to those in Public Law 113-54 rather than the United States Code references.

- (1) any waiver, exception, or exemption pursuant to section 581 or 582; or
- (2) any restrictions specified in section 582.

20. Section 582(a)(5) of DQSA contains a grandfathering provision that provides, in pertinent part:

(5) GRANDFATHERING PRODUCT —

* * *

(B) TRACING. — For a product that entered the pharmaceutical distribution supply chain prior to January 1, 2015 —

- (i) authorized trading partners³ shall be exempt from providing transaction information as required under subsections (b)(1)(A)(i),⁴ (c)(1)(A)(ii),⁵ (d)(1)(A)(ii),⁶ and (e)(1)(A)(ii).⁷
- (ii) transaction history required under this section shall begin with the owner of such product on such date; and
- (iii) the owners of such product on such date shall be exempt from asserting receipt of transaction information and transaction statement from the prior owner as required under this section.

21. Thus, for any product that entered the supply chain at any date prior to January 1, 2015, the requirement to possess, generate, or provide transaction history documentation begins on the date such a product “entered the . . . supply chain,” such requirements begin with the owner of that product on that date, but these provisions apply only if ownership on that date was the result of a prior transaction with an authorized trading partner (such as a properly licensed manufacturer). Florida’s pedigree paper requirements, therefore, are expressly preempted to the extent they would impose upon the owner on that date any requirement to possess, generate, or

³ “The term ‘trading partner’ means —

(A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product;” § 581(23)(A).

⁴ This subsection requires that a manufacturer, beginning not later than January 1, 2015, “shall — prior to, or at the time of, each transaction in which the manufacturer transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in an [sic] paper or electronic format.” § 582(b)(1)(A)(i).

⁵ This subsection sets forth wholesale distributor product tracing requirements “beginning not later than January 1, 2015.”

⁶ This subsection sets forth dispenser product tracing requirements.

⁷ This subsection sets forth repackager product tracing requirements.

provide any transaction history documentation for any transaction antecedent to that date. And, importantly, this text evidences Congressional intent that this provision applies to dates of ownership that predate the effective date of DQSA and, in that sense, this section has retroactive effect.

22. DQSA's wholesale distributor tracing requirements with respect to product tracing provide that "[b]eginning not later than January 1, 2015," and except for returns, separately addressed below, "a wholesale distributor shall not accept ownership of a product unless the previous owner prior to, or at the time of, the transaction provides the transaction history,⁸ transaction information,⁹ and a transaction statement¹⁰ for the product, as applicable under this subparagraph." § 582(c)(1)(A)(i).

⁸ "The term 'transaction history' means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product." § 581(25).

⁹ "The term 'transaction information' means —

- (A) the proprietary or established name or names of the product;
- (B) the strength and dosage form of the product;
- (C) the National Drug Code number of the product;
- (D) the container size;
- (E) the number of containers;
- (F) the lot number of the product;
- (G) the date of the transaction
- (H) the date of the shipment, if more than 24 hours after the date of the transaction;
- (I) the business name and address of the person from whom ownership is being transferred; and
- (J) the business name and address of the person to whom ownership is being transferred."

§ 581(26).

¹⁰ "The 'transaction statement' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction —

- (A) is authorized as required under the Drug Supply Chain Security Act;
- (B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;
- (C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;
- (D) did not knowingly ship a suspect or illegitimate product;
- (E) had systems and processes in place to comply with verification requirements under section 582;
- (F) did not knowingly provide false transaction information; and
- (G) did not knowingly alter the transaction history."

§ 581(27).

23. “If the wholesale distributor purchased the product directly from the manufacturer [or the manufacturer’s exclusive distributor or direct-purchase repackager], then prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a product, the wholesale distributor shall provide to the subsequent purchaser a transaction statement, which shall state that such wholesale distributor . . . purchased the product directly from the manufacturer [or the manufacturer’s exclusive distributor or direct-purchase repackager],” § 582(c)(1)(A)(ii)(I)(aa)(AA), and “*subject to subclause (II)*, the transaction history and transaction information.” § 582(c)(1)(A)(ii)(I)(aa)(BB) (emphasis added).

24. In turn, subsection (II) provides: “(II) For purposes of transactions described in subclause (I), transaction history and transaction information shall not be required to include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer (as defined in subparagraphs (F), (G), and (H) of section 581(26)).” § 582(c)(1)(A)(ii)(II).

25. With regard to returns, pursuant to DQSA § 582(d)(1)(A)(ii), a dispenser¹¹ transferring ownership of a product by returning it need not “provide the subsequent owner with transaction history, transaction information, [or] a transaction statement for the product . . .” *Id.*

26. Section 582(d)(1)(C)(i)-(ii) is more specific with regard to returns by a dispenser:

(C) RETURNS.—

(i) SALEABLE RETURNS.—A dispenser may return product to the trading partner from which the dispenser obtained the product without providing the information required under subparagraph (A).

(ii) NONSALEABLE RETURNS.—A dispenser may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, to a returns processor, or to a person acting on behalf of such a person without providing the information required under subparagraph (A).

¹¹ A “dispenser” includes retail and hospital pharmacies. DQSA § 581(3).

27. DQSA states that the wholesale distributor's requirements with respect to returns are coordinated with this dispenser's exemption and are as follows:

(B) Returns –

(i) SALEABLE RETURNS. – Notwithstanding subparagraph (A)(i) [§ 582(c)(1)(A)(i)], the following shall apply:

(I) REQUIREMENTS. – Until the date that is 6 years after the date of enactment . . . (except as provided pursuant to subsection (a)(5)),¹² a wholesale distributor may accept returned product from a dispenser or repackager pursuant to the terms and conditions of any agreement between the parties, and, notwithstanding subparagraph (A)(ii), may distribute such returned product without providing the transaction history. For transactions subsequent to the return, the transaction history of such product shall begin with the wholesale distributor that accepted the returned product, consistent with the requirements of this subsection.

(II) ENHANCED REQUIREMENTS. – Beginning 6 years after the date of enactment . . . (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. For all transactions after such date, the transaction history, as applicable, of such product shall begin with the wholesale distributor that accepted and verified the returned product. For purposes of this subparagraph, the transaction information and transaction history, as applicable, need not include transaction dates if it is not reasonably practicable to obtain such dates.

§ 582(c)(1)(B)(i)(I)-(II). *See also* § 582(c)(1)(B)(ii) (“A wholesale distributor may return a nonsaleable product to the manufacturer . . . for whom such product was purchased . . . without providing the information required under subparagraph (A)(i).”).

28. These provisions operate to preempt Florida's pedigree paper requirements imposed on dispensers returning products to wholesale distributors by Florida Administrative Code Rule 61N-1.012(3)(f). Thus, a wholesale distributor accepting a return from a dispenser

¹² § 582(a)(5) governs “Grandfathering Product.”

will not be provided with any transaction history, transaction information, or a transaction statement for the returned product.

**STATEMENT OF FACTS AND MANNER IN
WHICH HDS IS SUBSTANTIALLY AFFECTED**

29. HDS is a prescription drug wholesaler. HDS has historically and continues to distribute drug products that under Florida law would have to comply with the pedigree paper requirements of section 499.01212, Florida Statutes.

30. HDS is also an “authorized distributor of record” for all of the prescription drug products it distributes in Florida. See, 21 C.F.R. §203.3(b). HDS will also be an “authorized trading partner” under DQSA. § 581(2) & (23).¹³

31. HDS also distributes only finished dose products that it purchases directly from manufacturers.

32. HDS complies with Florida’s pedigree paper requirements including, without limitation, the requirements to include information no longer required by DQSA. Further, HDS “authenticates” as set forth in Florida law (when applicable) and also handles returns in the manner set forth in the applicable Florida administrative rule. Again, those requirements are more extensive than what is required by DQSA.

33. However, HDS’s ability to continue to comply with Florida requirements that exceed those contained in DQSA is becoming increasing difficult and costly. Suppliers and customers are no longer willing to pass Florida compliant pedigree. For example, attached hereto as Exhibit A is a May 16, 2014 letter from American Health Packaging, a supplier of

¹³ Without going into additional detail regarding the changes in federal law, the transition from “authorized distributors of record” to “authorized trading partners” under the Prescription Drug Marketing Act and DQSA, with the attendant changes in the required levels of what Florida has traditionally required for pedigree purposes, further supports a conclusion that HDS should not have to comply with Florida pedigree requirements under the circumstances set forth in this Petition.

prescription drug products to HDS. The letter could not be clearer in its statement that it will no longer pass pedigree.¹⁴ This is indicative of the experience HDS is having with others.

34. Further, compliance with authentication and return requirements contained in Florida law but not in DQSA adds time and expense to the distribution process.

35. HDS is substantially affected by these regulations. Extensive additional expense will be incurred if HDS must comply with Florida requirements preempted by DQSA. In some instances, compliance will become impossible and HDS will be forced to stop doing business in Florida with regard to companies that will not provide pedigree.

36. HDS also wishes to avoid criminal and administrative prosecution and sanctions for violating provisions of Chapter 499 and Florida Administrative Code Chapter 61N-1 and is therefore both sufficiently and substantially affected and is justified in requesting this declaratory statement to clarify its rights under the referenced statutes and rule.


WHEREFORE, HDS respectfully requests that DBPR issue a Final Order determining that:

- A. HDS does not have to comply with the pedigree requirements of section 499.1212, Florida Statutes and related administrative rules to the extent they impose requirements that are inconsistent with, more stringent than, or in addition to, any requirements of DQSA.
- B. HDS does not have to comply with the authentication requirements of Florida law to the extent they impose requirements that are inconsistent with, more stringent than, or in addition to, any requirements of DQSA.

¹⁴ While the letter has a June 1, 2014 effective date, American Health Packaging, at the request of HDS, verbally extended that deadline until July 31, 2014.

C. HDS does not have to comply with the return requirements of Florida Administrative Code Rule 61N-1.012 to the extent they impose requirements that are inconsistent with, more stringent than, or in addition to, any requirements of DQSA.

Respectfully submitted this 24th day of June, 2014.


MICHAEL J. GLAZER
Florida Bar No. 0286508
mglazer@ausley.com
Ausley McMullen
Post Office Box 391
123 South Calhoun Street
Tallahassee, Florida 32301
Telephone: (850) 425-5474
Facsimile: (850) 222-7560

Attorneys for H.D. Smith Wholesale Drug
Company

CERTIFICATE OF SERVICE

I hereby certify that the original of the foregoing Petition for Declaratory Statement was hand delivered to: Agency Clerk, Department of Business & Professional Regulation, 1940 North Monroe Street, Suite 92, Tallahassee, Florida 32399-2202, with a copy sent by electronic mail to Reginald Dixon at reggie.dixon@myfloridalicense.com this 24th day of June, 2014.


Michael J. Glazer



May 16, 2014

Dear Valued Customer:

On November 27, 2013 President Obama signed the Drug Quality and Security Act (DQSA) into law which outlines critical steps to trace certain prescription drugs as they are distributed in the United States. Title II of the law focuses on the security of the supply chain and stipulates a timetable for implementing federal requirements, and as such, requires drug manufacturers, re-packagers, wholesale distributors, and dispensers pass pharmaceutical transaction information as a product moves through the supply chain. The new law preempts all state pedigree requirements and establishes one national traceability standard.

As a result of this change, effective June 1, 2014 American Health Packaging will no longer be passing pedigrees.

This notice is to alert you in anticipation of any internal processes that you may need to make to continue working with American Health Packaging after this change. Additionally, American Health Packaging will be contacting you to discuss account changes as appropriate.

American Health Packaging is actively engaged with all of our Supply Chain partners to migrate from state pedigree laws to one national traceability standard.

If you have any additional questions, please contact me at jspencer@americanhealthpackaging.com or (614)345-8920.

Thank you in advance for your support.

Sincerely,

Jeff Spencer
Vice President – National Accounts
American Health Packaging

EXHIBIT A

American Health Packaging, 2550-A John Glenn Ave., Columbus, Ohio 43217
800-707-4621 | 614-497-9275 Fax | americanhealthpackaging.com