

AGENDA
Department of Business and Professional Regulation
Drug Wholesale Distributor Advisory Council
1940 N. Monroe Street
Board Room
Tallahassee, FL 32399

Conference Call Number 888-670-3525
Conference Code 9259887749

August 14, 2014
9:30 a.m.

Council Members:

Gary Cacciatore, Pharm.D., J.D., Chair,
Primary Prescription Drug Wholesalers
Mike Ayotte, Vice Chair, Retail Pharmacy
Steve Mays, Primary Prescription Drug Wholesalers
Scott Brock, Pharmaceutical Manufacturers
Jenn Ungru, Agency for Health Care Administration
Dean Ellis, Secondary Prescription Drug Wholesalers
William Mahoney, Primary Prescription Drug Wholesalers
Patrick Barnes, Hospital Pharmacist
Michelle Renae Mendez, DO, Physician
Board of Pharmacy Member- Vacant

DBPR Staff:

Reggie Dixon, Director,
Division of Drugs, Devices and Cosmetics Program
Ken Lawson, Secretary
Tim Vaccaro, Deputy Secretary
Renee Alsobrook, Compliance Manager
Dinah Greene, Controlled Substance Reporting
Rebecca Burnett, Regulatory Supervisor
Amy Bennett, Office Manager

Call to Order: Gary Cacciatore, PharmD.,J.D., Chair

- TAB 1: Approval of Minutes –May 15, 2014
- TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD
1. Elections
- TAB 3: Executive Director's Report – Reginald Dixon
1. Rules Report
2. CSR Report
3. HD Smith Declaratory Statement
- TAB 4: Other Business

Notice of Meeting/Workshop Hearing

DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Drugs, Devices and Cosmetics

The Division of Drugs, Devices and Cosmetics announces a public meeting to which all persons are invited.

DATE AND TIME: August 14, 2014, 9:30 a.m.

Conference Call Number 1(888)670-3525; Conference Code 9259887749

PLACE: Department of Business and Professional Regulation, Board Room, 1940 N. Monroe Street, Tallahassee, FL 32399

GENERAL SUBJECT MATTER TO BE CONSIDERED: General Business.

A copy of the agenda may be obtained by contacting: Dinah Greene, Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800.

Pursuant to the provisions of the Americans with Disabilities Act, any person requiring special accommodations to participate in this workshop/meeting is asked to advise the agency at least 10 days before the workshop/meeting by contacting: Dinah Greene, Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800. If you are hearing or speech impaired, please contact the agency using the Florida Relay Service, 1(800)955-8771 (TDD) or 1(800)955-8770 (Voice).

If any person decides to appeal any decision made by the Board with respect to any matter considered at this meeting or hearing, he/she will need to ensure that a verbatim record of the proceeding is made, which record includes the testimony and evidence from which the appeal is to be issued.

For more information, you may contact: Dinah Greene, Division of Drugs, Devices and Cosmetics, 1940 N. Monroe Street, Suite 26A, Tallahassee, FL 32399, (850)717-1800.

1 **DRUG WHOLESALE DISTRIBUTOR ADVISORY COUNCIL**
2 **Draft Meeting Minutes**
3 **May 15, 2014**
4 **9:30 a.m.**
5
6

7 **9:30 a.m. Call to Order by Gary Cacciatore, Chair**

8 The meeting was called to order by the Chair.
9

10 The following members were present:

11 Mike Ayotte, Steve Mays, Scott Brock, Dean Ellis, Bill Mahoney, Patrick Barnes, Michelle
12 Mendez, Gary Cacciatore and Albert Garica.
13

14 Molly McKinstry was substituting for Jenn Ungru and the Agency for Healthcare Administration.
15 A quorum was present.
16

17
18 **TAB 1: Approval of February 27, 2014 Meeting Minutes**

19
20 Mr. Barnes stated there was a correction on page two 6th paragraph corrected
21 the word gold to goal.
22

23 **Motion by:** Mr. Ellis to approve the minutes with corrections, Seconded by: Mr.
24 Brock. Motion Carried
25

26 **TAB 2: Chair's Report – Gary Cacciatore, PharmD, JD**

27 Mr. Cacciatore encouraged the council to begin thinking of nominations for a new
28 Chair and Vice Chair. This will be decided at the August 14, 2014 meeting.
29

30 **TAB 3: Executive Director's Report – Reginald Dixon**

31 **1. Rules Report:**

32 a. Mr. Dixon gave a briefing on the rules report.
33

34 Mr. Dixon stated the Department thought there would be language addressed
35 during the legislative session on the "limited quantities". That did not happen so
36 the department will be moving forward scheduling a workshop.
37

38 Mr. Dixon stated the department would like to invite the manufacturers to
39 participate in the writing of the "limited quantities" rule. The Department will keep
40 the council advised of a meeting date.
41

42 Mr. Dixon stated the department is working on language to incorporate the
43 applications into rule. There has been some discussion within the department
44 and we will continue to update the council.
45

46 Mr. Dixon stated for Rule 61N-1.018 and 61N-1.023 we will be noticing those in
47 regards to the Blood Establishments.
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49 Mr. Dixon stated once the department begins we will keep the council informed.
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2. Legislative update

- a. Medical Gas SB 836
Mr. Dixon stated this bill separates out medical gases in Chapter 499. It creates a part 3 for medical gases. It adds a council member for the Medical Gas Association who will be appointed by the Secretary. It allows for medical gas wholesale and medical gas manufacturer permits be issued outside the state of Florida
- b. Military Bill SB 860
This bill changes Chapter 499 to allow for military experience from applicants who are applying for a Certified Designated Representative.

3. Declaratory Statements/ Variance Waivers

Mr. Dixon stated the Declaratory Statements were provided to the council as informational purposes only.

- a. Publix
- b. Amerisource Bergen

4. Mr. Dixon provided an update in regards to Scott Harkins of Unit-Dose Services question on providing a "service only" question below.

In the case of providing "service only"; the company is not taking ownership of the medication, we would request to be exempt from the product registration process and fees, as we are technically only selling a "packaging service."

Mr. Dixon stated the Division is reviewing it internally on what changes we would have to make. It seems like a simple request but when you get down to it may take some system changes. We are still in the review process and will keep the council informed when a decision is made.

5. Customer Success

Mr. Dixon stated the Department has created workgroups to study different processes. The DDC office is currently reviewing the licensing process and enforcement process. We hope to come up with ideas and ways of improving business.

Mr. Cacciatore complimented the Department on the changes in the enforcement process.

Mr. Dixon informed the council that Mr. Jernigan has submitted his resignation and this would be his last meeting.

100 Mr. Cacciatore stated that he would like to thank Mr. Jernigan for his guidance
101 and help to the industry over the years. You have always been a pleasure to
102 work with and open to working with the industry.
103
104 Mr. Jernigan stated it has been a pleasure to work with the Department and
105 the council.
106
107 Mr. Cacciatore stated he would like the Department to provide and update on
108 the Controlled Substance Reporting at the next meeting.
109
110 **Motion By:** Mr. Barnes Seconded by: Mr.Cacciatore to adjourn the meeting.
111 Motion Carried

en Lawson, Secretary

Rick Scott, Governor

RULES REPORT

To: Drug Wholesale Distributor Advisory Council

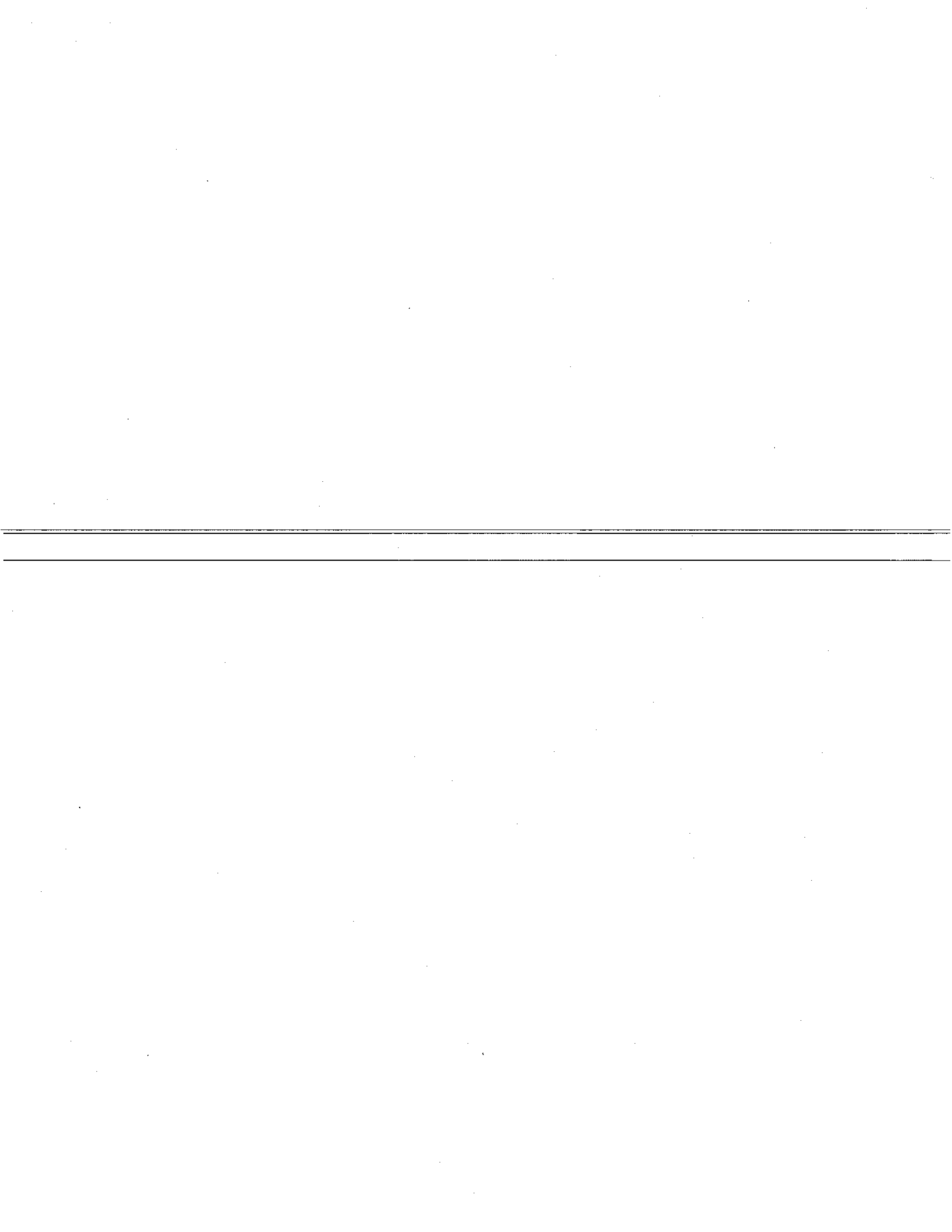
From: Reginald D. Dixon, Director

Date: July 31, 2014

Re: Division Rulemaking (rev. 7/31/14)

The following chart is a summary of the Division's current rulemaking efforts.

Rule #	Title	Purpose	Current Action	Next Action
61N-1.001	General Regulations; Definitions	Clear up the definitions of certain terms, as well as to define "limited quantities" as used in ss. 499.01(3) & (4), F.S.	12/17/13 Not. Development filed	Draft language Notice Rulemaking
61N-1.012	Records of Drugs, Cosmetics and Devices	Set forth recordkeeping requirements for Florida manufacturers engaging in "limited quantities" of Rx drugs obtained from non-Florida licensed entities.	12/17/13 Not. Development filed	Draft language Notice Rulemaking
61N-1.013	Prescription Drugs; Receipt, Storage and Security.	Set forth Rx drug storage requirements for Florida manufacturers engaging in "limited quantities" of Rx drugs obtained from non-Florida licensed entities.	12/17/13 Not. Development filed	Draft language Notice Rulemaking
61N-1.015	Licensing, Application, Permitting	Rearrange the rule and to incorporate the new DDC application forms	2/21/14 Not. Development filed	Draft language Notice Rulemaking
61N-1.020	Forms	Set forth the various DDC applications forms	2/21/14 Not. Development filed	Draft language Notice Rulemaking
61N-1.018	Fees	Specify fee for restricted Rx drug distributor – blood establishment permit; and for device product registration.	4/17/14 Not. Development re-filed due to technical errors (language attached to notice of development)	Notice Rulemaking
61N-1.023	Restricted Prescription Drug Distributor Permits; Special Provisions	Create/set forth the restricted Rx drug distributor permit; identify Rx drugs these permits can distribute per s. 499.01(2)(g)1.c., F.S.	2/21/14 Not. Development filed	Draft language Notice Rulemaking



CSR Controlled Substances Reporting System

Number of Registered Distributors That Are Reporting

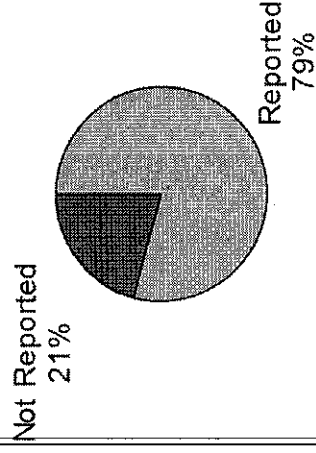
Since 8/6/2014

Registered Distributors Who Have Reported = 468

Registered Distributors Who Have Not Reported = 125

Total Registered Distributors = 593

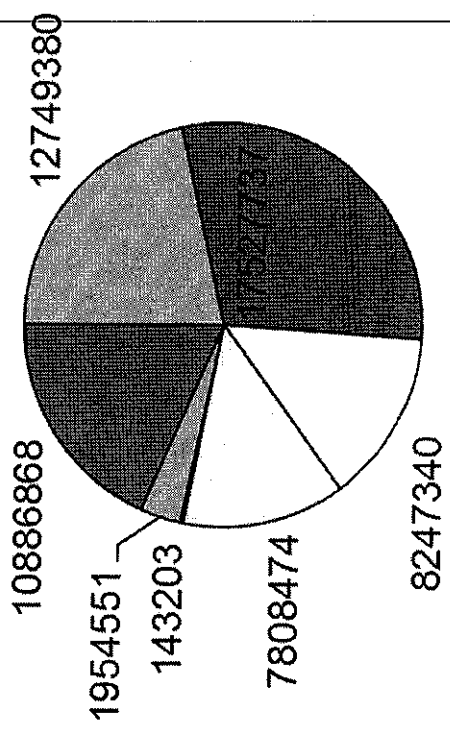
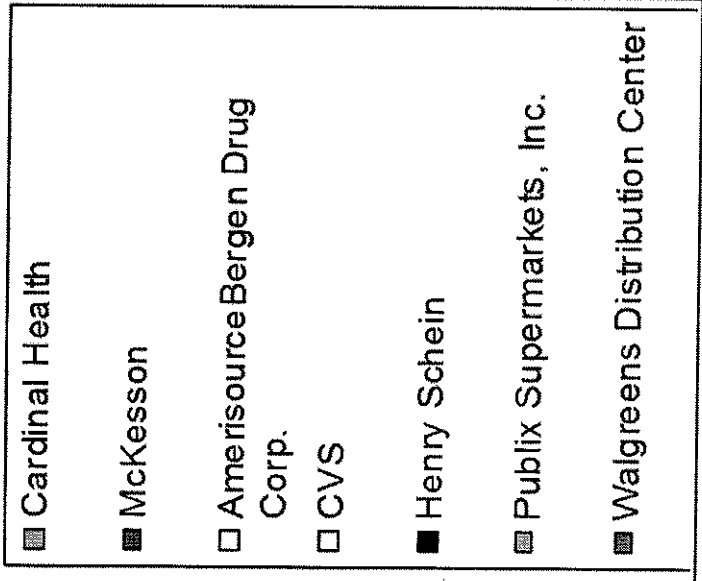
Number of Potential Reporting Distributors



Total of All Reports Submitted = 11,438

Total of All Transactions = 26,391,740

Highest Reporter By Volume



CSR Controlled Substances Reporting System

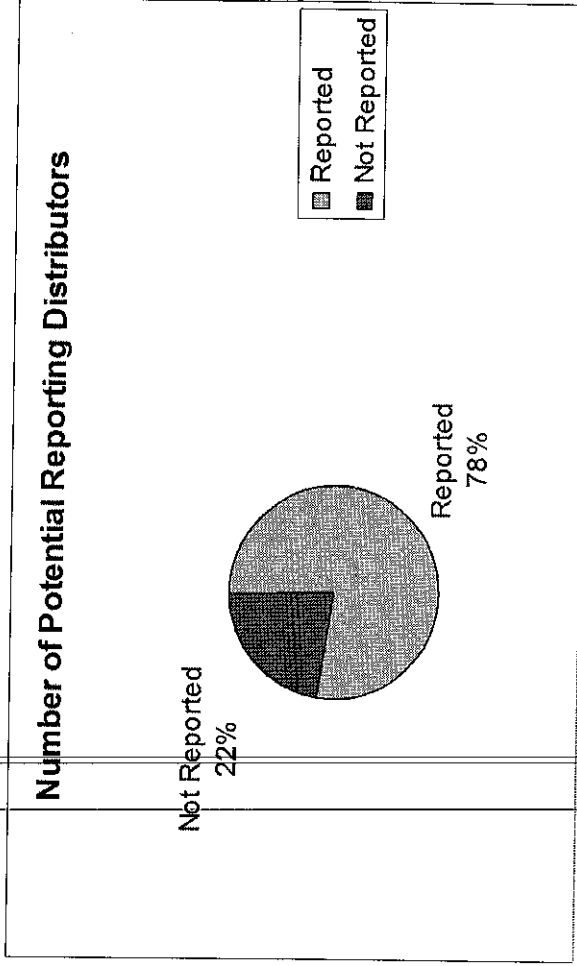
Number of Registered Distributors That Are Reporting

Since 7/1/2011

Registered Distributors Who Have Reported = 434

Registered Distributors Who Have Not Reported = 125

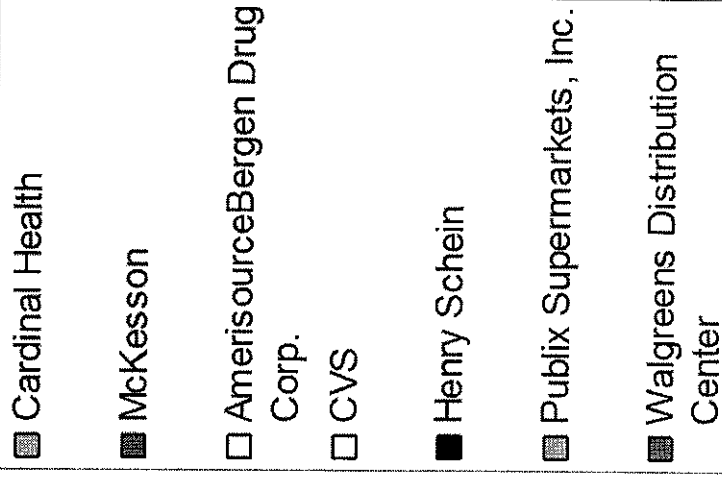
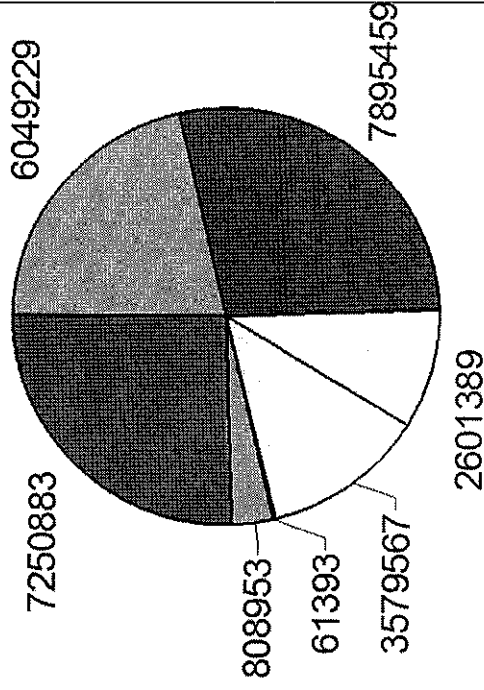
Total Registered Distributors = 559

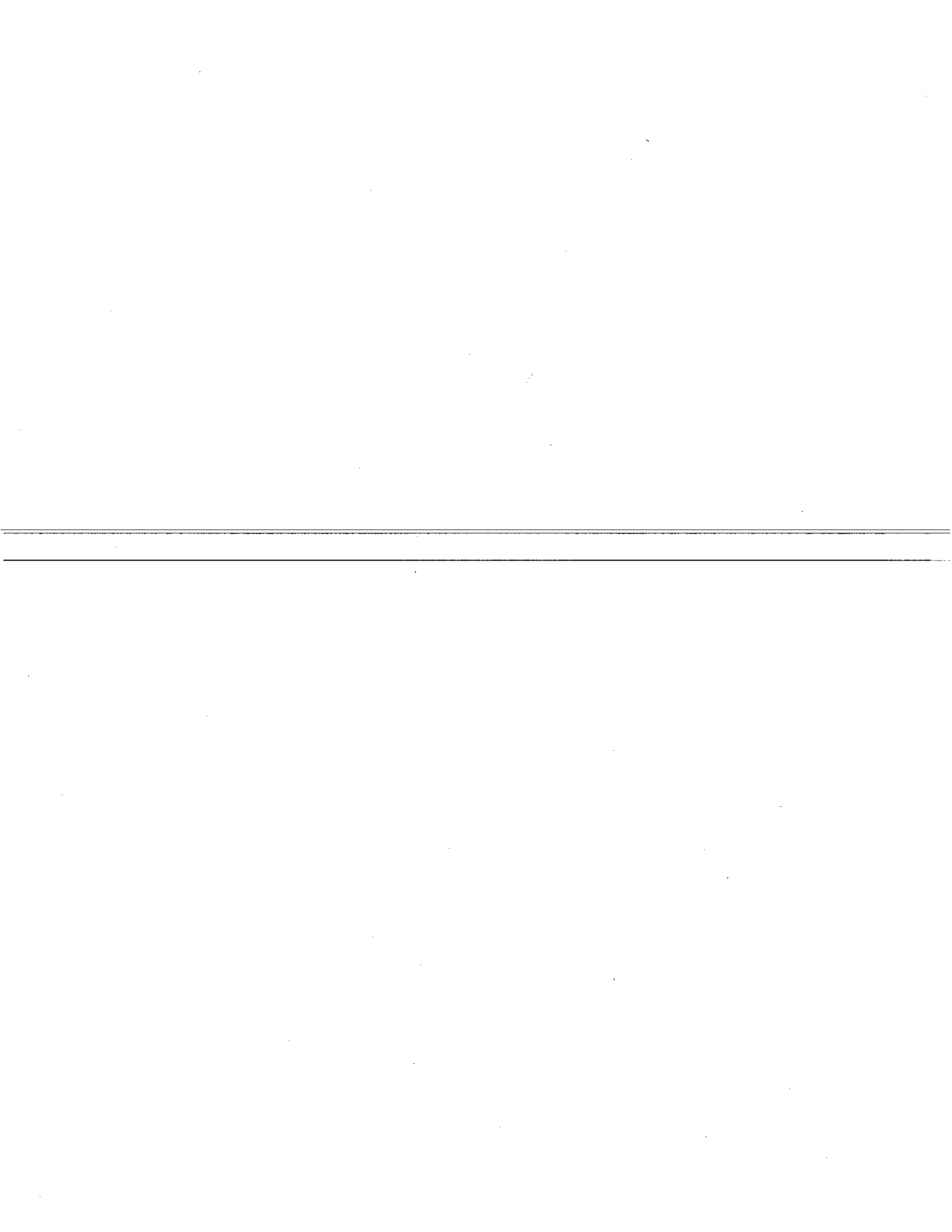


Total of All Reports Submitted = 5051

Total of All Transactions = 11,604,262

Highest Reporter By Volume





BEFORE THE STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FILED	
Department of Business and Professional Regulation	
Deputy Agency Clerk	
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.


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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.

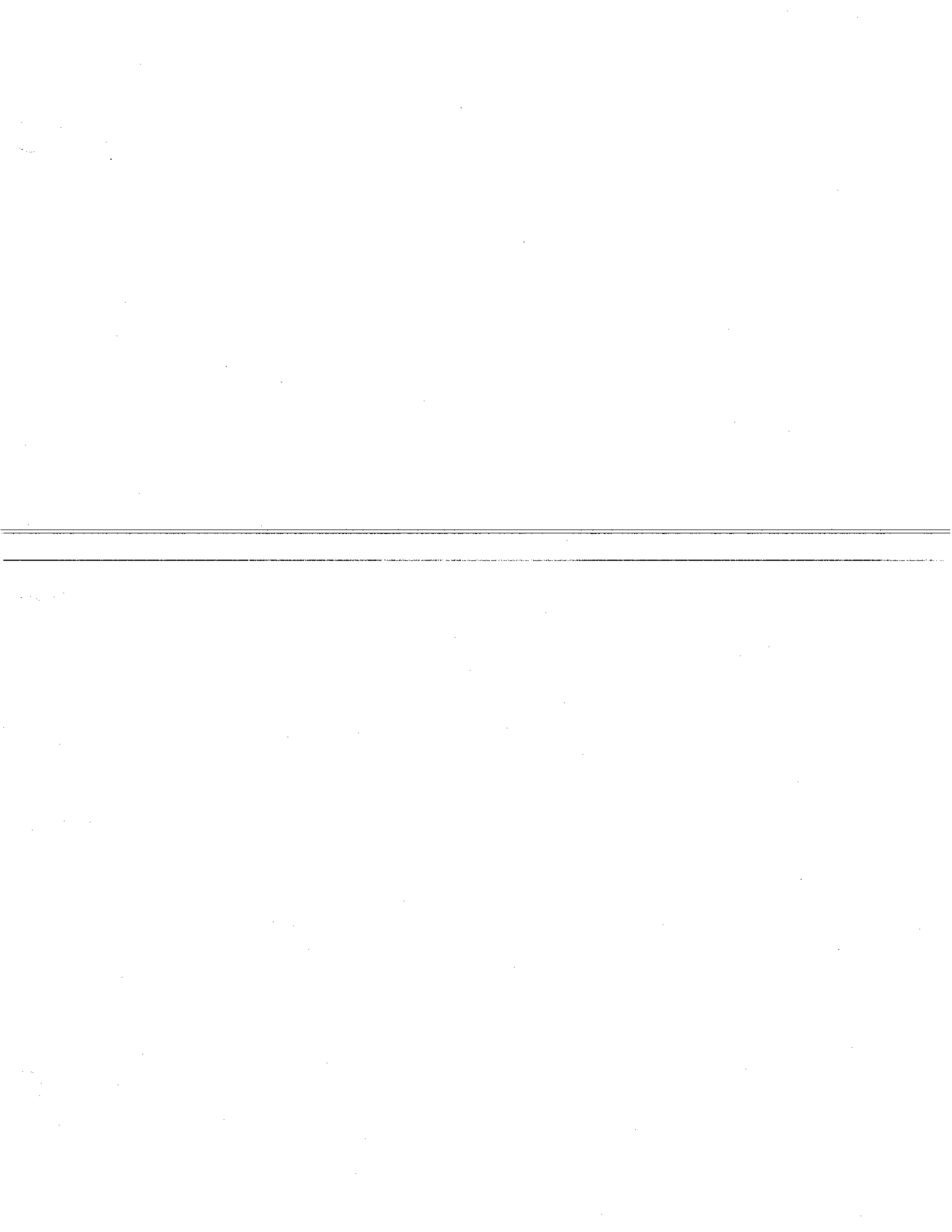
If you have any additional questions, please contact me at jspencer@americanhealthpackaging.com or (614)345-8920.

Thank you in advance for your support.

Sincerely,

Jeff Spencer
Vice President – National Accounts
American Health Packaging

EXHIBIT A



BEFORE THE STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FILED	
Department of Business and Professional Regulation	
Deputy Agency Clerk	
CLERK	Brandon Nichols
Date	7/9/2014
File #	

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

DS 2014-087

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") determine whether a third party logistics provider ("3PL") must still be licensed to conduct activities in Florida despite any of the provisions 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.

RECEIVED
JUL 09 2014
DBPR Agency Clerk

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 499.01, Florida Statutes lists the categories of persons and establishments that are required to have a permit from DBPR. Section 499.01(1)(s), Florida Statutes list "a third party logistics provider"

5. Section 499.01(2)(s), Florida Statutes provides:

(s) ~~Third party logistics provider permit.—A third party logistics provider permit is required for any person that contracts with a~~ prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer or wholesale distributor, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. Each third party logistics provider permittee shall comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, with the exception of those wholesale distributions described in s. 499.01212(3)(a), and other rules that the department requires.

6. DBPR has developed an application for a 3PL permit; Form No. DBPR-DDC-220, which is hereby incorporated by reference. This same form is used regardless of whether the 3PL establishment is located in Florida or elsewhere.

Drug Quality and Security Act

7. 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.¹

8. Section 581(22) of DQSA defines a third-party logistics provider as follows:

(22) THIRD-PARTY LOGISTICS PROVIDER.—The term “third-party logistics provider” means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

9. State law licensing of wholesale distributors and 3PLs is subject to an express preemption provision in DQSA as follows:

SEC. 585. UNIFORM NATIONAL POLICY.

(b) WHOLESAL E DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER STANDARDS.—

(1) IN GENERAL.— 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 any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under . . . section 584, in the case of a third-party logistics provider.

(2) STATE REGULATION OF THIRD-PARTY LOGISTICS PROVIDERS.— No State shall regulate third-party logistics providers as wholesale distributors.

10. While DQSA prohibits a state from regulating 3PLs as wholesale distributors, DQSA also provides:

¹ 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.

SEC. 584. NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.

(a) REQUIREMENTS.— No third-party logistics provider in any state may conduct activities in any State unless each facility of such third-party logistics provider—

(1)(A) is licensed by the State from which the drug is distributed by the third-party logistics provider, in accordance with the regulations promulgated under the subsection (d); or

(B) if the State from which the drug distributed by the third-party logistics provider has not established a licensure requirement, is licensed by the Secretary, in accordance with the regulations promulgated under subsection (d); and

(2) if the drug is distributed interstate, is licensed by the State into which the drug is distributed by the third-party logistics provider if such State licenses third-party logistics providers that distribute drugs into the State and the third-party logistics provider is not licensed by the Secretary as described in paragraph (1)(B).

STATEMENT OF FACTS AND MANNER IN WHICH HDS IS SUBSTANTIALLY AFFECTED

11. HDS is a prescription drug wholesaler. HDS has historically and continues to comply with the requirements of Florida law that it only engage in transactions with properly licensed parties as it relates to the distribution of prescription drugs.

12. Certain 3PLs shipping products to HDS for distribution in Florida have taken the position that a Florida 3PL license is not required due to the provisions of DQSA.

13. HDS has held to its belief that a 3PL license is required. This disagreement regarding the interaction of state and federal law has made it difficult in certain instances for HDS to obtain products and provide these medications to Florida pharmacies.

14. HDS is substantially affected by these regulations. If HDS obtains and distributes product from an unlicensed 3PL and if DBPR determines that the 3PL should have been

licensed, then HDS is subject to sanctions for violating Chapter 499, Florida statutes. HDS is therefore 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 if HDS obtains prescription drug products from a 3PL for distribution in Florida, then the 3PL must hold a valid Florida 3PL license.

Respectfully submitted this 9th day of July, 2014.



MICHAEL J. GLAZER

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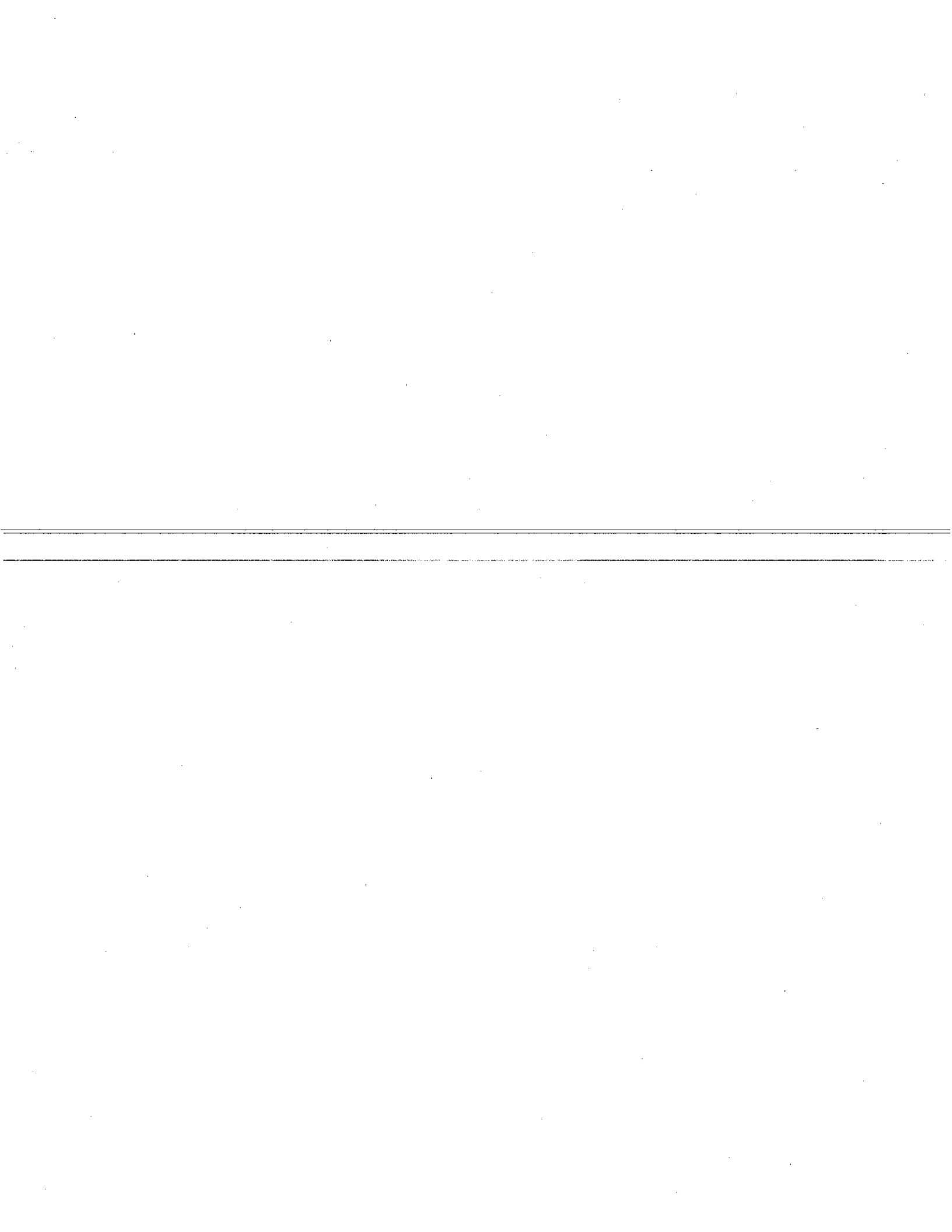
Attorneys for H.D. Smith Wholesale Drug
Company

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 9th day of July, 2014.



Michael J. Glazer



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

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

**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.



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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