In Re: Petition for Declaratory Statement,

Owens and Minor Distributions, Inc.,

Petitioner.

____________________________________

DECLARATORY STATEMENT

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

PRELIMINARY STATEMENT

On October 9, 2014, the Department received a petition for declaratory statement (Exhibit A) filed by Owens and Minor Distribution, Inc., (Petitioner). Petitioner operates three wholesale distributor warehouses in Florida. The Petitioner is seeking a declaratory statement as to the requirements of resident and non-resident wholesale distributors, repackers, manufacturers, and third party logistics providers to obtain state licensure and comply with the recordkeeping requirements of Chapter 499, Florida Statutes, in light of changes in applicable federal law.

The Department published notice of the petition for declaratory statement in the October 14, 2014, issue of the Florida Administrative Register, Volume 40, Number 200.
FINDINGS OF FACT

The following findings of fact are based on the information submitted by 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. Petitioner’s three wholesale distributor warehouses are: Owens and Minor Distribution, Inc., 4807 Northeast 63rd Avenue, Gainesville, Florida 32609, holding permit number 22:20179; Owens and Minor Distribution, Inc., 8489 Westside Industrial Drive, Jacksonville, Florida 32219, holding permit number 22:20152; and Owens and Minor Distribution, Inc., 14599 N.W. 8th Street, Sunrise, Florida 33256, holding permit number 22:414.

2. Petitioner states that the Owens and Minor distributor warehouses buy, receive, and distribute “medical convenience kits (drug kits)” as that term is referenced in Section 499.01212 (3)(i), Florida Statutes, and Section 581 of the Drug Quality and Security Act (DQSA or Act), paragraph (24)(B)(xiii).

3. Owens and Minor distribution warehouses (Owens and Minor) centers also buy, receive, and distribute to their customers “IV solutions” as that term is referenced in Section 581 of the DQSA, paragraph (24)(B)(xiv), that they receive from resident and non-resident wholesale drug distributors, third party logistics providers (3PLs), repackers, and manufacturers.

4. Owens and Minor has been receiving drug kits and IV solutions from vendors who believe that the DQSA has preempted pedigree and authentication requirements, as well as the licensing and recordkeeping requirements of Sections

---

1 Petitioner uses the term "IV solutions"; Section 581 of the DQSA, paragraph (24)(b)(xiv), refers to "intravenous product."
499.01 and 499.0121(6)(a)2, Florida Statutes, and Rule 61N-1.012(1)(a)2, Florida Administrative Code, for those products that the DQSA exempts from the definition of “transaction” in Section 581 (24) of the DQSA.

5. Owens and Minor asserts that it cannot verify their vendor’s drug kits and IV solutions and also cannot meet the recordkeeping requirements of Section 499.0121(6)(a)1.-5., Florida Statutes, and Rules 61N-1.012(1)(a) and (2), Florida Administrative Code.3

6. Owens and Minor alleges that it is being forced to cancel orders, return merchandise and quarantine product, resulting in a substantial financial burden and possibly leading to shortages at the health care entities it serves.

7. Petitioner wishes to avoid administrative and criminal prosecution for violating Chapter 499, Florida Statutes, and the administrative rules adopted thereunder, by requesting this declaratory statement to clarify its rights under the statutes and rules referenced herein.

8. Petitioner asserts that the following laws apply to Petitioner’s set of circumstances:

   A. Section 499.01(1), Florida Statutes (2014), provides, in relevant part:
      (1) Prior to operating, a permit is required for each person and establishment that intends to operate as:
      (a) A prescription drug manufacturer;
      (b) A prescription drug repackager;
      (c) A nonresident prescription drug manufacturer;
      (d) A prescription drug wholesale distributor;
      (e) An out-of-state prescription drug wholesale distributor.

2 Though Petitioner referred to Rule 64N-1, the correct citation is to Rule 61N-1, Florida Administrative Code.
3 Owens and Minor requested pedigree information not records required by Rule 61N-1.012(1) and (2), Florida Administrative Code, and 499.0121(6), Florida Statutes. (See Exhibit A1 and A2 of Petition for Declaratory Statement)
(p) A third party logistics provider; or

B. Section 499.01(2), Florida Statutes (2014), provides, in relevant part:

(2) The following permits are established:
(a) Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.
1. A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, which apply to a wholesale distributor.
2. A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(b) Prescription drug repackager permit.—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.
1. A person that operates an establishment permitted as a prescription drug repackager may engage in wholesale distribution of prescription drugs repackaged at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.
2. A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.

(c) Nonresident prescription drug manufacturer permit.—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a wholesale distributor under this part, except s. 499.01212.
1. A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third
party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(30)(e).

(d) Prescription drug wholesale distributor permit.—A prescription drug wholesale distributor is a wholesale distributor that may engage in the wholesale distribution of prescription drugs.

(e) Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part.

(p) 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.

C. Section 499.01212(3)(i), Florida Statutes (2014), provides, in relevant part:

499.01212 Pedigree Paper.—

(3) EXCEPTIONS. A pedigree paper is not required for:
(i) The wholesale distribution of prescription drugs within a medical convenience kit if:

1. The medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a medical device manufacturer;
2. The medical convenience kit manufacturer purchased the prescription drug directly from the manufacturer or from a wholesaler that purchased the prescription drug directly from the manufacturer;
3. The medical convenience kit manufacturer complies with federal law for the distribution of the prescription drugs within the kit; and
4. The drugs contained in the medical kit are:
   a. Intravenous solutions intended for the replenishment of fluids and electrolytes;
   b. Products intended to maintain the equilibrium of water and minerals in the body;
   c. Products intended for irrigation or reconstitution;
   d. Anesthetics; or
   e. Anticoagulants.

This exemption does not apply to a convenience kit containing any controlled substance that appears in a schedule contained in or subject to chapter 893 or the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

D. Section 499.0121(6), Florida Statutes (2014), provides, in relevant part:

(6) RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.
(a) Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:
1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
2. The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs;
3. The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of;
4. The dates of receipt and distribution or other disposition of the drugs; and
5. Any financial documentation supporting the transaction.

(b) Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials for a period of 2 years following disposition of the drugs or 3 years after the creation of the records, whichever period is longer.

(c) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and must be readily available.

(d) Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain records that include the name and principal address of the seller or transferor of the product, the address of the location from which the product was shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person who purchased the product.

(e) When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part.

E. Section 585(b)(1) of the DQSA provides:

"SEC. 585. UNIFORM NATIONAL POLICY.
(b) WHOLESALE 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 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

F. Section 581 of the DQSA provides:

"SEC. 581. DEFINITIONS"

"(24) TRANSACTION.—"

"(A) IN GENERAL.—The term ‘transaction’ means the transfer of product between persons in which a change of ownership occurs.

"(B) EXEMPTIONS.—The term ‘transaction’ does not include—"

"(xii) a combination product that is not subject to approval under section 505 or licensure under section 351 of the Public Health Service Act, and that is—"

"(I) a product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

"(II) 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or

"(III) 2 or more finished medical devices plus one or more drug or biological products that are packaged together in what is referred to as a 'medical convenience kit' as described in clause (xiii);

"(xiii) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this clause as a 'medical convenience kit') if—"
"(I) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

"(II) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

"(III) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

"(aa) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

"(bb) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

"(IV) in the case of a medical convenience kit that includes a product, the product is—

"(aa) an intravenous solution intended for the replenishment of fluids and electrolytes;

"(bb) a product intended to maintain the equilibrium of water and minerals in the body;

"(cc) a product intended for irrigation or reconstitution;

"(dd) an anesthetic;

"(ee) an anticoagulant;

"(ff) a vasopressor; or

"(gg) a sympathomimetic;

"(xiv) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);
"(xv) the distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

9. Petitioner requests a declaratory statement as to the following:

a. Whether resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers and manufacturers doing business with the State of Florida must maintain a license with the State of Florida, DBPR if conducting distributions of DQSA exempted drug products, or whether entities conducting distributions of drug products exempted under the DQSA are no longer required to maintain State DBPR licensure as resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers or manufacturers since distributions of these products are not by definition a "transaction" under Federal Law.

b. Whether resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers and manufacturers doing business with the State of Florida must continue to comply with the recordkeeping requirements of F.S. 499.0121(6)(a) 1-5 and FAC 64N-I.012(l)(a) and (2) (sic), with regard to the sale or transfer of DQSA exempted prescription drug containing kits and IV solutions into or within Florida, or whether entities so engaged need not comply with recordkeeping laws since distributions of these products are not by definition a "transaction" under Federal Law.

c. Whether resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers and manufacturers doing business with the State of Florida must, starting January 1, 2015, provide prior to or at the time of each transaction, transaction history (TH), transaction information (TI) and a transaction statement (TS), defined by Section 581 of the DQSA paragraphs (25), (26) and (27) and further implemented into tracing requirements under Section 582 of the DQSA paragraph (b)(I)(A)(i) et. al., and paragraph (c)(I)(A)(i) et. al., for the sale and transfer (distribution) of "exempt" prescription drug containing kits and IV products into or within the State of Florida.
Florida or whether entities so engaged need not comply with recordkeeping laws since distributions of these products are not by definition a "transaction" under Federal Law.

CONCLUSIONS OF LAW

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

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

12. 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.

13. 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.

14. The Petitioner is substantially affected by the statutes and rule cited in paragraph nine above and has standing to seek a declaratory statement from the department.

15. The Department is authorized to enforce the provisions of Chapter 499, Florida Statutes.

16. Section 499.002 (1), Florida Statutes (2014), provides:

499.002 Purpose, administration, and enforcement of and exemption from this part.—
(1) This part is intended to:
(a) Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.
(b) Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.
(c) Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.

Based on the provision cited above, the Department seeks to develop and interpret its laws and rules to conform to federal laws and rules under the authority of the Federal Food, Drug, and Cosmetic Act, and as further described above.
17. Effective November 27, 2013, the 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.

18. 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, and 3PLs.

19. Section 204 of the DQSA amends 21 USC Section 353(e), to include exemptions from the definition of “wholesale distribution:”

(a) AMENDMENTS.—

(1) REQUIREMENT.—Section 503(e) (21 U.S.C. 353(e)) is amended by striking paragraphs (1), (2), and (3) and inserting the following:

“(1) REQUIREMENT.—Subject to section 583:

(2) WHOLESLE DISTRIBUTION.—Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (1), is further amended by adding at the end the following:

“(4) For the purposes of this subsection and subsection (d), the term ‘wholesale distribution’ means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include—

“(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a ‘medical convenience kit’) if—

“(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug
Administration as a device manufacturer in accordance with section 510(b)(2);

"(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

"(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

"(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

"(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

"(iv) in the case of a medical convenience kit that includes a product, the product is—

"(I) an intravenous solution intended for the replenishment of fluids and electrolytes;

"(II) a product intended to maintain the equilibrium of water and minerals in the body;

"(III) a product intended for irrigation or reconstitution;

"(IV) an anesthetic;

"(V) an anticoagulant;

"(VI) a vasopressor; or

"(VII) a sympathomimetic;

"(N) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);
20. Petitioner describes its practices as buying, receiving, and distributing medical convenience kits as defined by Section 581 of the DQSA, paragraph 24(B)(xiii), and IV solutions (IV products) as defined in Section 581(24)(B)(xiv) of the Act.

21. A plain reading of the DQSA discloses that the amended law includes exemptions from the definition of “transaction,” the effect of which is that items that are exempted are not required to meet tracking and tracing requirements as set forth in the amended act (transaction history, transaction information, transaction statement). See, Sec. 582(c) of the amended Act.

22. The DQSA also contains exemptions from “wholesale distribution,” the effect of which is that items that are exempted do not require licensure as described under the federal law for wholesale distribution of the item. The entity must, however, have authority to possess prescription drugs and to sell prescription drugs. The exemptions from “transaction” and from “wholesale distribution” became effective on January 1, 2015, when the provisions that employ these terms became effective.4

23. As noted above, even though the DQSA exempts medical convenience kits and IV products from the requirement of wholesale distribution and from tracking and tracing requirements of the DQSA, it does not preclude states from enacting or continuing to enforce state requirements for recordkeeping or state requirements for licensure of those persons engaging in distributions that are not “wholesale distributions” or “transactions” under the amended Act.

4 Though technically, the definitions contained in Section 581 of the DQSA carry no effective date and could be deemed to be effective as of November 27, 2013, the provisions to which the definitions apply are not effective until January 1, 2015. The exemptions from “wholesale distribution” become effective January 1, 2015, according to Section 204(c) of the DQSA.
24. The DQSA sets forth licensing and tracking and tracing standards for transactions and wholesale distributions, and sets forth exemptions from those standards. This does not mean states are precluded from establishing or continuing in effect licensing standards and recordkeeping requirements for those distributions not considered wholesale distributions by the federal government. Such an interpretation would leave states with no authority to regulate distributors, repackagers, and 3PLs who distribute prescription drugs in non-DQSA wholesale distributions and transactions, or to enforce recordkeeping requirements for the myriads of prescription drug transactions by entities, simply because such distributions are exempted from the tracking and tracing and wholesale distributor requirements of the amended Act.

25. Indeed, the DQSA is "not intended to pre-empt state requirements related to the distribution of prescription drugs, if such requirements are not related to product tracing as described in subsection (a), or wholesale distributor and third party logistics provider licensure as described in subsection (b) applicable under section 503(e), (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder)."

26. Currently, Florida Statutes do not exempt medical convenience kits from recordkeeping requirements of Chapter 499, and the administrative rules, though pedigree requirements do not apply. Likewise, Chapter 499, Florida Statutes, does not exempt distributions involving medical convenience kits and those involving IV products from licensure requirements. (Section 499.01(1)(g) and (2)(g), Florida Statutes). Regardless of the fact that the DQSA exempts medical convenience kits and IV products from the definitions of "transaction" and wholesale distribution", Florida is not
preempted from imposing licensure and recordkeeping requirements on non-wholesale distributions, just as it currently does under Chapter 499, Florida Statutes, with the permit requirements for the restricted distributors as described in Section 499.01(1)(g) and (2)(g), Florida Statutes (2014), and Rule 61N-1.023, Florida Administrative Code.

27. Accordingly, Petitioner's questions are answered as follows:

A. Resident and non-resident prescription drug wholesale distributors, third party logistics providers, repackers, and manufacturers distributing in or into the State of Florida products that are exempted from the definition of "transaction" under the DQSA, must maintain a license with this Department. The fact that products are exempted from the definition of "transaction" under the DQSA does not mean such products are currently exempted from prescription drug distribution recordkeeping requirements of Section 499.0121(6)(a) 1.-5., Florida Statutes, or Rule 61N-1.012, Florida Administrative Code.  

B. Resident and non-resident prescription drug wholesale distributors, third party logistics providers, repackers, and manufacturers distributing in or into the State of Florida products that are exempted from the definition of "transaction" under the DQSA, must comply with the recordkeeping requirements of Section 499.0121(6)(a)1.-5., Florida Statutes.

C. The Department declines to answer this inquiry as it relates solely to an interpretation of the DQSA, and not Chapter 499, Florida Statutes.

5 Not all requirements of Rule 61N-1.012, Florida Administrative Code, are currently applicable to Petitioner. The Department will initiate rulemaking to clarify rule requirements.
Done and ordered this 13th day of January 2015, 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 Edwin A. Bayó Esquire, Grossman, Furlow, & Bayó, LLC, 2022-2 Raymond Diehl Road, Tallahassee, Florida 32308 this 14th day of January 2015.

for: 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.
STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION
DRUGS, DEVICES AND COSMETICS PROGRAM

PETITION FOR DECLARATORY STATEMENT
BEFORE THE DEPARTMENT OF BUSINESS
& PROFESSIONAL REGULATION, DRUGS, DEVICES
AND COSMETICS PROGRAM, ON BEHALF OF
OWENS AND MINOR DISTRIBUTION, INC.

Owens and Minor Distribution, Inc.
Petition for Declaratory Statement

Owens and Minor Distribution, Inc., ("Owens and Minor") by and through its
undersigned counsel, files this Petition for Declaratory Statement pursuant to Section
120.565, Florida Statutes and Rule 28-105.002, FAC and states::

1. Owens and Minor, a duly permitted drug wholesaler in the State of Florida, is
requesting that the Department of Business and Professional Regulation ("DBPR") declare
whether wholesale and manufacturer entities licensed as resident and non-resident wholesale
drug distributors, third party logistics providers, re-packers and manufacturers by the DBPR
must continue to maintain State of Florida DBPR licensure, under F.S. 499.01 if the only sell
and transfer (distribute) "exempt" prescription drug containing kits and IV products into or
within the State of Florida.

2. Owens and Minor is requesting that the Department of Business and
Professional Regulation ("DBPR") also declare whether wholesale and manufacturer entities
licensed as resident and non-resident wholesale drug distributors, third party logistic providers,
re-packers and manufacturers by the DBPR must continue to comply with Chapter 499 and the
corresponding FAC, 64N-1, (with the exception of applicable portions of F.S. 499.01212 with
regard to pedigree and authentication and other related sections of Florida Law pre-empted by
Section 585 of the Federal Drug Quality and Security Act and denoted in prior Florida
Declaratory Statements, i.e., in Re: HD Smith Wholesale Drug Company, DS 2014-081 and In
Re: Publix Supermarkets, Inc. DS 2014-007), and specifically must continue to comply with,
F.S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2), with regard to the sale or transfer of
"exempt" prescription drug containing kits and IV solutions (medical convenience kits, IV
solutions) into or within Florida.

3. Owens and Minor, is also requesting that the Department of Business and
Professional Regulation ("DBPR") declare whether wholesale and manufacturer entities
licensed as resident and non-resident wholesale drug distributors, third party logistic providers,
re-packers and manufacturers by the DBPR must provide, on and after January 1, 2015,
transaction history (TH), transaction information (TI) and a transaction statement (TS),
defined by Section 581 of the DQSA paragraphs (25), (26) and (27) and further implemented
into tracing requirements under Section 582 of the DQSA paragraph (b)(1)(A)(i) et. al, and
paragraph (c)(1)(A)(i) et. al., for the sale and transfer (distribution) of "exempt" prescription
drug containing kits and IV products into or within the State of Florida.

4. Owens and Minor headquarters are located at 9120 Lockwood Boulevard
Mechanicsville, VA, but for purposes of this Petition, its address shall be that of its
undersigned attorney.

5. Owens and Minor operates numerous licensed entities that are permitted by the
State of Florida as well as three Florida wholesale warehouses located in Gainesville, FL
permit #2220179, Jacksonville, FL permit #2220152 and Sunrise, FL permit #22414.

6. These Owens and Minor distribution centers, buy, receive and distribute
medical convenience kits as defined by Section 581 of the DQSA paragraph (24)(B)(xiii) and
F.S. 499.01212(3)(i) and IV solutions as defined by Section 581 of the DQSA paragraph (24)(B)(xiv) they receive from resident and non-resident wholesale drug distributors, third party logistic providers, re-packers and manufacturers to their customers throughout the State of Florida. [hereinafter “kits” and “IV solutions”]

**Legal Basis for this Declaratory Statement**

7. With certain exceptions, Florida law defines the term "wholesale distribution" in relevant part to include:

"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient." Section 499.003(54), Florida Statutes.

8. Florida law defines "distribute" or "distribution" as:

"Distribute" or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction. Section 499.003(17), Florida Statutes.

9. Section 499.005(14), Florida Statutes, prohibits the purchase or receipt of a prescription drug from a person not authorized by Chapter 499, Florida Statutes to distribute such drugs.

10. Section 499.01(1), Florida Statutes, requires a permit in order to engage in drug distribution activities including kits and IV drugs.

11. A prescription drug is defined in F.S. 499.003(43) as “a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and

Petition for Declaratory Statement of Owens and Minor Distribution, Inc.
Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection (11), subsection (46), or subsection (53), ..."

12. Section 499.01212(3)(i), F.S., provides an exception ONLY to the requirement for pedigree, not recordkeeping, for the distribution of prescription drugs within the medical convenience kit meeting specific requirements. (kits)

13. Unless an applicable exception applies, the DBPR has required that an entity the buys and sells prescription drugs, excepted from pedigree or not, (specifically IV solutions and kits) must continue to comply with F.S. 499.01 (licensing) and F.S. 499.0121 storage and recordkeeping, specifically, F.S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2). Florida Statute 499.0121(6)(a) states:

(a) Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2. The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs;

3. The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of;

4. The dates of receipt and distribution or other disposition of the drugs; and
5. Any financial documentation supporting the transaction.

14. The Department has enforcement authority to bring actions against persons violating the provisions of Chapter 499, Florida Statutes. This enforcement authority is set forth in Sections 499.002, 499.051, 499.06, 499.066, 499.061, and 499.067, Florida Statutes. Florida also imposes criminal sanctions for certain violations as set forth in Section 499.051, F.S.

15. 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. The DQSA provides for preemption of state requirements for product tracing and statements of distribution history and other requirements. Specifically, Section 585 of the Act 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. (emphasis added)

16. The DQSA provides for preemption of state wholesale distributor licensure laws beginning on its enactment. Specifically, Section 585 of the Act provides:

(b) WHOLESALE 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 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

17. Further Section 581 of the Drug Quality and Security Act (DQSA) paragraph (24)(B)(xii) and (xiii) provides an exemption to medical convenience kits explaining that the term “transaction” does not apply to drug kits meeting the specific requirements of the law.

18. In addition, Section 581 of the DQSA paragraph (24)(B)(xiv) provides an exemption to products that are intended for replenishment of fluids and electrolytes that are administered intravenously (IV solutions) again explaining that the term “transaction” does not apply to these fluids.

19. A “transaction” is defined by Section 581 of the DQSA in paragraph (24)(A) meaning the transfer of product between persons in which a change of ownership occurs.
20. The DQSA dictates that manufacturers and wholesalers under Section 582 of the DQSA paragraph (b) and (c) must "(i) prior to, or at the time of, each transaction in which such 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 paper or electronic format..." (emphasis added).

21. Transaction information, under the DQSA includes: (section 585 paragraph (26))

(26) Transaction information.--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.

22. Section 585(a) and (b) of the DQSA, as cited above, provides that 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... and no state may not continue any standards, requirements, or regulations with respect to wholesale prescription drug licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e). It is unclear if these pre-empted “standards, requirements, or regulations” include requirements under F.S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2) or if the DQSA Transaction Information will replace F.S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2).

23. Owens and Minor has been receiving drug kits and IV solutions from vendors who believe that the DQSA has pre-empted not only pedigree and authentication, as acknowledged in the aforementioned Florida Declaratory Statements, but also, due to the broad breath of the language, also pre-empted the licensing and recordkeeping requirements of F.S. 499.01 and .S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2) for those products exempted by the DQSA, namely kits and IV solutions since no “transaction” is occurring. (see Exhibit A1 & A2 – email string and noted vendor letter, edited for style not content)

24. Owens and Minor cannot verify their vendor’s kits and IV solutions and also cannot meet the requirements of Florida law with regards to F.S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2). (see Exhibit B – Packing list omitting requirements of F.S. 499.0121(6) and also not listing their permit number. The invoice is EDI and does not contain the information at issue.)
25. Owens and Minor is being forced to cancel orders, return merchandise and quarantine products resulting in substantial financial burdens and also potential shortages at the health care entities they service. This issue is only anticipated to escalate as time progresses.

26. Owens and Minor wishes to avoid administrative and criminal prosecution for violating Chapter 499 and 61N-1 FAC, and therefore is justified in requesting this declaratory statement to clarify its rights under the above statutes.

Wherefore, Owens and Minor requests that the DBPR issue a Final Order determining whether:

a. Resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers and manufacturers doing business with the State of Florida must maintain a license with the State of Florida, DBPR if conducting distributions of DQSA exempted drug products, or whether entities conducting distributions of drug products exempted under the DQSA are no longer required to maintain State DBPR licensure as resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers or manufacturers since distributions of these products are not by definition a “transaction” under Federal Law.

b. Resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers and manufacturers doing business with the State of Florida must continue to comply with the recordkeeping requirements of F.S. 499.0121(6)(a) 1-5 and FAC 64N-1.012(1)(a) and (2), with regard to the sale or transfer of DQSA exempted prescription drug containing kits and IV solutions into or within Florida, or whether entities so engaged need not comply with recordkeeping laws since distributions of these products are not by definition a “transaction” under Federal Law.
c. Resident and non-resident prescription drug wholesale distributors, third party logistics providers, re-packers and manufacturers doing business with the State of Florida must, starting January 1, 2015, provide prior to or at the time of each transaction, transaction history (TH), transaction information (TI) and a transaction statement (TS), defined by Section 581 of the DQSA paragraphs (25), (26) and (27) and further implemented into tracing requirements under Section 582 of the DQSA paragraph (b)(1)(A)(i) et. al., and paragraph (c)(1)(A)(i) et. al., for the sale and transfer (distribution) of "exempt" prescription drug containing kits and IV products into or within the State of Florida or whether entities so engaged need not comply with recordkeeping laws since distributions of these products are not by definition a "transaction" under Federal Law.

CERTIFICATE OF SERVICE

I hereby certify that the original of the foregoing Petition for Declaratory Statement was hand delivered to the Agency Clerk, Department of Business & Professional Regulation, 1940 North Monroe Street, Suite 92, Tallahassee, FL 32399-2202, with courtesy copies via e-mail to Reginald Dixon, Executive Director and Kathryn Price, Chief Attorney, this 9th day of October, 2014.

Respectfully submitted,

Edwin A. Bayó
Fla. Bar No. 327727
Grossman, Furlow & Bayó, L.L.C.
2022-2 Raymond Diehl Rd.
Tallahassee, FL 32308
(850)385-1314/fax(850)385-4240
Counsel for Petitioner
Hi Amy,
For Exempt, packing slip must contain the drug detail information listed for the pedigree items to ensure compliance with Florida’s Recordkeeping requirement (F.S. 499.0121 (6)(a).)

THANKS! 😊

Ina Richardson | Compliance Analyst | Jacksonville DC 59
Owens & Minor | 8489 Westside Industrial Drive, Jacksonville, FL 32219
p 904.596.4605 | VoIP 60594605
ina.richardson@owens-minor.com | www.owens-minor.com

Ms. Richardson,

I apologize for the confusion surrounding this issue. However, please reference the federal Drug Quality And Security Act (H.R. 3204, Section 585) which was signed into law in November 2013. This section defines “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 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) or this subchapter”.

Centurion kits are exempt from drug track and trace requirements. The federal Drug Quality and Security Act, H.R. 3204, supersedes the state of Florida’s Recordkeeping requirement.

I hope this addresses any questions you may have regarding our medical convenience kits and pedigree information on the packing slips. If you have further questions or concerns, please do not hesitate to contact me.

Amy Ganton
Regulatory Affairs
Centurion Medical Products
517.545.1159
aganton@centurionmp.com

EXHIBIT A1
Ms. Richardson,

Please see the attached memo for an explanation of Centurion Medical Product's business practice regarding pedigree (drug track and trace) requirements for the state of Florida. Please feel free to contact me directly with questions. Thank you.

Amy Ganton  
*Regulatory Affairs*  
Centurion Medical Products  
517.545.1159  
aganton@centurionmp.com
September 18, 2014

RE: Track and Track Requirements for Centurion Kits Containing Prescription Drugs

Ms. Richardson,

This memo is in response to your inquiry regarding missing pedigree information on the packing lists for Centurion medical convenience kits.

On July 1, 2010, kits containing prescription drugs meeting specified criteria were exempted from drug track and trace requirements (i.e. pedigree) in the State of Florida. Since then, the federal Drug Quality and Security Act (H.R. 3204) was signed into law on November 27, 2013, which established a national system for tracing pharmaceutical products, and included an exemption for transactions involving kits consistent with the approach implemented by the State of Florida in 2010.

This exemption applies to kits provided the kit manufacturer and the product meet the following criteria:

- Kits are assembled in an establishment registered with the FDA as a device manufacturer;
- Kits do not contain prescription drug products classified as controlled substances;
- Prescription drugs included within kits are purchased directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased them directly from the pharmaceutical manufacturer;
- The kit manufacturer does not alter the primary container or label of the prescription drug product as purchased from the manufacturer or wholesale distributor; and
- Prescription drug products included within kits are of a type exempted by the Act.

It should be noted Centurion kits containing prescription drugs meet these criteria, and are thereby exempted from prescription drug track and trace requirements.

I hope this addresses any questions you have regarding the omission of pedigree information on the packing lists. Please do not hesitate to contact me if you have further questions or concerns.

Regards,
Amy Ganton
Regulatory Analyst
517-545-1159
aganton@centurionmp.com
### Packing List

**Shipping Address**
OWENS & MINOR #59
8489 WESTSIDE INDUSTRIAL DR
JACKSONVILLE FL 32219-3274

**Sold-to Address**
OWENS & MINOR
ACCOUNTS PAYABLE
PO BOX 85007
RICHMOND VA 23285-5007

**Information**
- Drop Ship PO: 18075
- Customer No.: 990005
- **Shipping Conditions**
  - Incoterms: SOUTHEASTERN FREIGHT
  - WF WAREHOUSE FREIGHT
- Total Weight: 1535 LB
- Number of Packages: 4
- Carrier: SOUTHEASTERN FREIGHT
- Tracking/Pro
- External Order Text

**Receiving instructions**

<table>
<thead>
<tr>
<th>PurchaseOrder No</th>
<th>Delivery#</th>
<th>Batch#</th>
<th>Material</th>
<th>Packed Quantity</th>
<th>Sales Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td></td>
<td>SB69BZ</td>
<td>3.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td></td>
<td>YL4045E</td>
<td>15.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014063001</td>
<td>66415</td>
<td>1.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014061790</td>
<td>75175</td>
<td>1.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014071490</td>
<td>CIT4260</td>
<td>1.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014062790</td>
<td>CTR300MG</td>
<td>1.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014053090</td>
<td>SUT10360</td>
<td>4.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014060990</td>
<td>VXHS910S</td>
<td>1.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td></td>
<td>4538623</td>
<td>1.000</td>
<td>PK</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td></td>
<td>PCS250</td>
<td>6.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014062503</td>
<td>W234</td>
<td>1.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>3000180358</td>
<td>FM4AF</td>
<td>2.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td></td>
<td>992102</td>
<td>1.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014072190</td>
<td>CKF5065L</td>
<td>1.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014060901</td>
<td>MS120</td>
<td>9.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014033190</td>
<td>CKF105</td>
<td>1.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014060990</td>
<td>PE295</td>
<td>1.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014050990</td>
<td>DT14070</td>
<td>1.000</td>
<td>CS</td>
</tr>
<tr>
<td>59-44772</td>
<td>81823100</td>
<td>2014060690</td>
<td>DT14225</td>
<td>4.000</td>
<td>CS</td>
</tr>
</tbody>
</table>

59-44772
81823100
2013102180
MNS3790

**EXHIBIT B.**