

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

FILED	
Department of Business and Professional Regulation Deputy Agency Clerk	
CLERK	Brandon Nichols
Date	4/18/2014
File #	2014-02805

**IN RE: PETITION FOR FOR WAIVER AND
VARIANCE FROM RULE 61N-1.012(3)(A)1.,
FLORIDA ADMINISTRATIVE CODE,**

**AMERISOURCEBERGEN
DRUG CORPORATION,**

Petitioner.

VW 2013-334

FINAL ORDER GRANTING VARIANCE/WAIVER

The Department of Business & Professional Regulation, Division of Drugs, Devices, and Cosmetics (hereafter, "Department"), issues this final order granting variance/waiver, in accordance with Section 120.542, Florida Statutes (2013).

PRELIMINARY STATEMENT

On October 3, 2013, Petitioner, AmerisourceBergen Drug Corporation (hereafter, "ABDC"), filed a petition for waiver and variance from the requirements of Rule 61N-1.012(3)(a)1., Florida Administrative Code (hereafter, "F.A.C."). Thereafter, the Department and ABDC engaged in discussions concerning the facts set forth in the petition. Notice of the petition was published in the October 24, 2013, issue of the Florida Administrative Register, Volume 39, number 208.

FINDINGS OF FACT

1. ABDC is a foreign corporation authorized to do business in the state of Florida. ABDC's corporate address is 1300 Morris Drive, Chesterbrook, PA 19087.

2. ABDC holds five permits from the Department to operate as an out-of-state prescription drug wholesale distributor and one permit to operate as a prescription drug wholesale distributor in this state.

3. Prescription drug wholesale distributors doing business in this state are subject to the provisions of Chapter 499, Florida Statutes, the Florida Drug and Cosmetics Act, and are subject to the rules that are adopted under the Act.

4. Section 499.01212, Florida Statutes, requires pedigree papers to be provided prior to or simultaneous with each wholesale distribution, unless a specific exemption applies. The pedigree paper is to include certain information that identifies the drug, the manufacturer, the seller, and certain other information as specified in the provision.

5. Section 499.002, Florida Statutes, sets out the primary purposes of Part I, Chapter 499, Florida Statutes, as follows:

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.

6. Section 499.01212, Florida Statutes, provides:

499.01212 Pedigree paper.—

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

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

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

1. The following statement: “This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer.”

2. The manufacturer’s national drug code identifier and the name and address of the wholesale distributor and the purchaser of the prescription drug.

3. The name of the prescription drug as it appears on the label.

4. The quantity, dosage form, and strength of the prescription drug.

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

7. Section 499.003(28), Florida Statutes (2013), defines “label” as a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic .

8. Rule 61N-1.012(3)(a)1., which was adopted pursuant to Section 499.01212, Florida Statutes, provides:

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

* * *

(3) Pedigree Papers.

(a)1. The pedigree papers required by Sections 499.01212, F.S., must include either the proprietary name or the generic name with the name of the manufacturer, repackager, or distributor as reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required

to be identified on the pedigree paper; the name and address of each location from which it was shipped if different from the owner's; and the transaction dates. The pedigree paper must clearly identify the invoice to which it relates; however, if an invoice number has not been generated at the time the pedigree is prepared then an alternate reference number that is easily traceable to the invoice number may be used.

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9. Petitioner requests a permanent variance from the requirement of Rule 61N-1.012 (3)(a)1., F.A.C., that the pedigree paper include the full proprietary or generic name of the drug, and requests that instead, Petitioner be permitted to utilize an abbreviated form of the prescription drug name, as long as other information sufficient to conclusively identify the drug is also included. The abbreviated names are well-known in the industry.

10. The "other information" that petitioner contemplates is the national drug code number (hereinafter "NDC"), which is a unique identifier specific to each drug.

11. Petitioner asserts that the inclusion of the NDC number in addition to the abbreviated form of the drug name provides sufficient information to ensure there is no confusion with respect to which drug is being distributed.

12. Petitioner asserts that a substantial hardship exists because the complete proprietary or generic name of a drug may contain too many characters to fit into the drug name field on Petitioner's electronic pedigree. The only remedy Petitioner has for this situation is to re-engineer the electronic pedigree form to accommodate additional characters. Such re-engineering would be prohibitively costly to Petitioner.

13. Petitioner also asserts that the electronic pedigree information transmitted to Petitioner by the manufacturer or distributor, already lists the drug name in abbreviated form. The information is automatically transmitted to Petitioner's electronic pedigree form. It would also be prohibitively costly and time consuming for petitioner to

check the names of each drug when Petitioner receives electronic information from its manufacturers or distributors with an abbreviated drug name.

14. Finally, Petitioner asserts that the variance from the requirements of Rule 61N-1.012(3)(a), Florida Statutes, would serve the statutory purpose of Section 499.01212, Florida Statutes, because the drugs would be specifically identified by its NDC number and further identified by use of an abbreviated form of the drug name, thereby eliminating any confusion regarding the identity of the drug.

15. Petitioner requests:

A. A waiver from the requirement of Rule 61N-1.012(3)(a)1., F.A.C., that the pedigree paper contain the full proprietary or generic name of each drug; and

B. A variance permitting Petitioner to utilize the abbreviated name of each proprietary or generic drug, as supplied by the manufacturer, in combination with the drug's unique NDC number.

CONCLUSIONS OF LAW

16. The Department has jurisdiction to issue this final order pursuant to Section 120.542(8), Florida Statutes (2013).

17. Petitioner has standing to seek this Petition for variance/waiver.

18. Section 120.542 (2), Florida Statutes, provides:

120.542 Variances and waivers.—

(1) Strict application of uniformly applicable rule requirements can lead to unreasonable, unfair, and unintended results in particular instances. The Legislature finds that it is appropriate in such cases to adopt a procedure for agencies to provide relief to persons subject to regulation. A public employee is not a person subject to regulation under this section for the purpose of petitioning for a variance or waiver to a rule that affects that public employee in his or her capacity as a public employee. Agencies are authorized to grant variances and waivers to requirements of their rules

consistent with this section and with rules adopted under the authority of this section. An agency may limit the duration of any grant of a variance or waiver or otherwise impose conditions on the grant only to the extent necessary for the purpose of the underlying statute to be achieved. This section does not authorize agencies to grant variances or waivers to statutes or to rules required by the Federal Government for the agency's implementation or retention of any federally approved or delegated program, except as allowed by the program or when the variance or waiver is also approved by the appropriate agency of the Federal Government. This section is supplemental to, and does not abrogate, the variance and waiver provisions in any other statute. [Emphasis supplied].

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19. Prior to November 27, 2013, the Department interpreted Section 499.01212, Florida Statutes, as requiring the name of the prescription drug as it appears on the label to appear on the prescription drug pedigree.

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

21. The DQSA Title II, Section 585(a), 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.

22. In light of the language in the federal statute pre-empting states’ laws regarding requirements for tracking and tracing prescription drug products through the distribution chain, including requirements for paper and electronic pedigrees, Section 499.01212(2)(a)3., Florida Statutes, is preempted.

23. Section 120.542, Florida Statutes (2013), places the burden on Petitioner to demonstrate that the underlying purpose of the statute will be or has been achieved by some other means.

24. Petitioner has met the burden of demonstrating that the use of the abbreviated proprietary or generic name of prescription drugs in addition to the specific NDC number unique to such drug, on the electronic pedigrees, satisfies the safety concerns addressed by the existing Rule 61N-1.012(3)(a)1., F.A.C.

25. Petitioner has met the burden of demonstrating that substantial economic and technological hardship would result if the rule was strictly applied to Petitioner.

26. Granting the petition for variance/waiver would not remove the safety provisions of the Rule and would sufficiently protect the public.

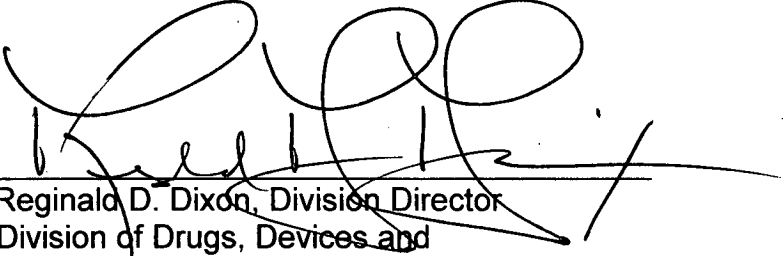
27. Based on the foregoing, Petitioner’s request for a variance and waiver as set forth in paragraph 12 A and B above, is granted.¹

¹ Petitioner should note that effective January 1, 2015, manufacturers and wholesale distributors will begin using transaction history, transaction information, and transaction statements in the distribution of prescription drug product. “Transaction information” is defined in Section 581(26) of the DQSA, as including the proprietary or established name or names of the product.

Done and ordered this 18th day of April, 2014, at
Tallahassee, Leon County, Florida.


KEN LAWSON, SECRETARY
Department of Business & Professional
Regulation

BY:


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Division of Drugs, Devices and
Cosmetics
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Tallahassee, FL 32399-1047
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Order has
been furnished by U.S. mail to Martha Harrell Chumbler, Carlton Fields, P.A., Post
Office Drawer 190, Tallahassee, FL 32302-0190, and Adam P. Schwartz, Post Office
Box 3239, Tampa, Florida 33601-3239, this 18th day of April, 2014.


for: Brandon M. Nibbs
Agency Clerk

Copies furnished to:

Reginald D. Dixon
DDC Division Director

Kathryn E. Price
DDC Chief Attorney

NOTICE OF RIGHTS TO APPEAL

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

STATE OF FLORIDA
DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

FILED	
Department of Business and Professional Regulation Deputy Agency Clerk	
CLERK	Brandon Nichols
Date	10/3/2013
File #	

In re: AMERISOURCEBERGEN DRUG CORPORATION,

Petitioner.

VW 2013-334

PETITION FOR WAIVER AND VARIANCE FROM RULE 61N-1.012(3)(a)1

Pursuant to section 120.542, Florida Statutes, and Florida Administrative Code Rule 28-104.002, AMERISOURCEBERGEN DRUG CORPORATION ("Petitioner") petitions the State of Florida, Department of Business and Professional Responsibility ("DBPR") for a permanent waiver and variance from Florida Administrative Code Rule 61N-1.012(3)(a)1. In support, Petitioner states as follows:

Identity of Petitioner

1. Petitioner is a foreign corporation that is authorized to do business in the State of Florida. Its corporate address is 1300 Morris Drive, Chesterbrook, Pennsylvania 19087. For purposes of this Petition, Petitioner's telephone and facsimile numbers are 407-856-6239 and 407-856-8720, respectively. The address, telephone number, and facsimile number for its attorneys are as indicated below.

2. Petitioner holds five (5) licenses from DBPR to operate as an out-of-state prescription drug wholesale distributor and one (1) license to operate as an in-state prescription drug wholesale distributor. As a prescription drug wholesale distributor ("a wholesale distributor"), Petitioner is subject to regulation under chapter 499, part I, Florida Statutes, and Florida Administrative Code Chapter 61N-1.

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DBPR Agency Clerk

Rules From Which Variance Is Sought

3. Rule 61N-1.012(3)(a)1 states as follows:

(3) Pedigree Papers.

(a)1. The pedigree papers required by Sections 499.01212, F.S., must include either the *proprietary name or the generic name* with the name of the manufacturer, repackager, or distributor as reflected on the label of the product; dosage form; strength; container size; quantity by lot number; the name and address of each owner of the prescription drug that is required to be identified on the pedigree paper; the name and address of each location from which it was shipped if different from the owner's; and the transaction dates. The pedigree paper must clearly identify the invoice to which it relates; however, if an invoice number has not been generated at the time of the pedigree is prepared then an alternate reference number that is easily traceable to the invoice number may be used.

(Emphasis supplied). DBPR construes the italicized language as prohibiting an abbreviation of the name of the prescription drug. Petitioner seeks a variance from the rule as so construed.

Statute Implemented by Rule 61N-1.

4. Rule 61N-1.012(3)(a)1 implements section 499.01212, Florida Statutes, which requires pedigree papers for all wholesale distributions of prescription drugs. The primary purposes of this provision, as with all of chapter 499, part I, Florida Statutes, are 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 provision of 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.

§ 499.002(1), Fla. Stat.

5. The variance sought through this petition fully complies with these underlying purposes.

Type of Action Requested

6. Petitioner requests a permanent variance from the requirement in Rule 61N-1.012(3)(a)1 that the pedigree paper include the *full* proprietary or generic name of the drug and requests that, instead, Petitioner be permitted to utilize an abbreviated form of the prescription drug's name, as long as other information sufficient to conclusively identify the drug is also included.

Facts Demonstrating a Substantial Hardship

7. Compliance with 61N-1.012(3)(a)1 is problematic because the complete names of some proprietary or generic drugs contain too many characters to be fully listed on the pedigree papers. In other words, there are simply too few fields on the electronic pedigree form to accommodate the entire name of some proprietary or generic drugs. The only remedy for this issue would be to reengineer the current pedigree form to allow for additional characters. This remedy would be prohibitively expensive in terms of IP engineering costs.

8. Additionally, when Petitioner receives a shipment of drugs, Petitioner also electronically receives the names of the drugs from the manufacturer or distributor, often in an abbreviated form. This electronic information is automatically transmitted to Petitioner's pedigree form in the exact form received from the manufacturer or distributor. It would be prohibitively expensive, as well as tremendously inefficient and time consuming, for Petitioner to manually check the electronic information transmitted by every manufacturer to ensure that the drug name conveyed is, in fact, the full name of the proprietary or generic drug.

9. A variance allowing the use of an abbreviated form of proprietary or generic drug names will not result in confusion regarding the identity of the drug. Each drug has a unique national drug code identifier (“NDC number”) that is included on every pedigree that Petitioner provides to customers, as well as on the invoice provided to the customer. The NDC number is the best evidence of identification of any drug. Furthermore, the abbreviated names of the drugs, which Petitioner receives electronically from the manufacturer or wholesaler, are typically well known, industry-standard abbreviations. The inclusion of the NDC number, in conjunction with a well known abbreviated name, provides ample redundancy to ensure that there is no confusion regarding the identity of the drug.

10. The strict application of Rule 61N-1.02(3)(a)1 – as construed by DBPR – results in a substantial hardship, violates principles of fairness, and does nothing to further the purposes of chapter 499, part I.

The Variance Would Serve the Statutory Purposes

11. As indicated above, the purposes to be served by chapter 499, part I, Florida Statutes, can be achieved by means other than strict compliance with Rule 61N-1.012(3)(a)1.

12. Petitioner will continue to list the NDC number of each and every proprietary or generic drug on every pedigree of drugs it distributes, as well as including the abbreviated form of the drug name as supplied by the manufacturer, thereby eliminating any confusion concerning the identity of the drug.

BASED ON THE FOREGOING, Petitioner requests that DBPR enter an order granting Petitioner a waiver and variance to Rule 61N-1.012(3)(a)1 as follows:

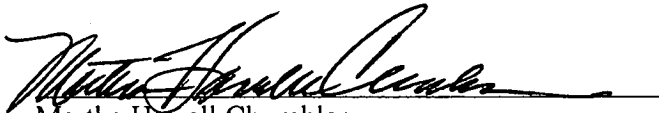
- a. A waiver from the requirement that the pedigree paper contain the *full* proprietary or generic name of each drug; and

- b. A variance permitting Petitioner to utilize the abbreviated name of each proprietary or generic drug, as supplied by the manufacturer, in combination with the drug's unique NDC number.

Respectfully submitted
this 3rd day of October, 2103,

Attorneys for AmerisourceBergen Drug
Corporation

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