Anda

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November 3, 2003

VIA ELECTRONIC MAIL AND OVERNIGHT COURIER

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments to 2003N-0361
Anti-Counterfeit Drug Initiative

To Whom It May Concern:

I hereby submit comments via electronic mail for Docket Number 2003N-0361, Anti-Counterfeit Drug Initiative. A hard copy of the electronic mail submission will follow by overnight courier.

Sincerely,

Daniel H. Movens
Executive Vice President-Operations

cc: Richard J. Lane
Scott Lodin

2003N-0361 C 23

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AN ANDRX COMPANY

FDA COUNTERFEIT DRUG TASK FORCE INTERIM REPORT COMMENTS

Anda, Inc., a division of Andrx Corporation ("Andrx"), appreciates this opportunity to raise certain issues and concerns with respect to the Prescription Drug Marketing Act ("PDMA"), and the Healthcare Distribution Management Association's ("HDMA") proposed "best practices" for pharmaceutical distribution system integrity. We would also like to express our viewpoint with respect to Florida's new regulations. Additionally, we will discuss "track and trace" technology and product authentification.

Through its various divisions, Andrx manufactures and markets its own brand and generic pharmaceutical products and distributes generic products manufactured by itself and others. As such, Andrx entities are members of the National Association of Chain Drugstores ("NACD"), HDMA, Generic Pharmaceuticals Association ("GPhA") and American Society of Consulting Pharmacists ("ASCP"), and are otherwise familiar with the issues that are being faced by the many facets of our industry.

We believe that counterfeiting is borne out of greed and the ease in which the counterfeiting party can accomplish its goal. Though counterfeiting can be minimized if the windows of opportunity are closed, we do not believe that it will ever be fully eliminated. We also do not believe that there is any magic dollar amount or any sales position (i.e., top ten injectibles) that makes that product any more susceptible to counterfeiting. Rather, whenever there is an opportunity for the non-legitimate person to game the system and reap large financial windfalls, left unchecked, they will attempt to take advantage of the opportunity. Accordingly, we believe that the FDA should create a system of regulation and/or licensing that both limits such opportunities and allows the legitimate wholesaler to properly fulfill its important role in our economy. Our view on how to achieve that objective follows.

I. REVIEW OF HDMA'S "BEST PRACTICES"

The HDMA "best practices" was not prepared by the membership at large and contains provisions that may be impractical or extremely difficult for small and mid-sized wholesalers to implement. We have reviewed the best practices of HDMA and have addressed what we perceive to be some of the more invasive points that we feel the industry should not be required to follow. The preamble is fairly unerring and the definition of legitimate wholesalers in general terms corresponds to what we expect to be a legitimate enterprise. For the most part there is a lot of quality information and direction in HDMA's "best practices" document. On an overall basis we are pleased with the direction of HDMA. However, some of the elements within the document were too far reaching and we take exception to the following HDMA provisions.

I Initial Information Request

Item 1
A listing of states the company is domiciled in and shipping into and copies of all current state/federal regulatory licenses/registrations including license/registration numbers(s).

Having competitors see where their competitors are shipping product should not be a prerequisite to do business. Detailed and appropriate state and federal licensing procedures should ensure that wholesalers are doing business with trustworthy pharmaceutical companies.

Item 8
The number of employees at the facility and screening procedures for hiring.

All the HDMA members are in competition with each other. Detailing the number of employees and the Company's hiring procedure is proprietary confidential information and would be invasive to one's business. Current Florida regulations require a designated company employee be trained in licensing and pedigree issues. If the FDA adopts the Florida regulations, many of these concerns would be ameliorated.

Item 9
A full description of each facility/warehouse. Include all locations utilized for drug storage and/or distribution, including:

a) **Square footage;**
b) **Security and alarm system description;**
c) **Terms of lease/own;**
d) **Address; and**
e) **Temperature and humidity controls.**

Licensing by state and federal regulators would alleviate the need for this proprietary company information and ensure legitimate wholesalers are selling bona fide products.

Item 10
A description of prescription drug import/export activities, including:

a) **A listing of all countries importing from and exporting to;**
b) **A listing of what products are being imported/exported;**
c) **The nature of the company's import/export activities pertaining to prescription drugs (i.e., repackaging, re-labeling, etc.); and**
d) **How are products designated for import/export separated from domestic inventory?**

This information is only pertinent if it relates to actual products that are being sold, not the company as a whole. We believe the proposed regulations request too much information.

Item 11
A description of the process the company uses to validate and certify its suppliers and purchases including the supplier's ADR status, (particularly if the process differs from the Recommended Guidelines for Pharmaceutical Distribution System Integrity.)

The process of validating suppliers and purchases should follow a pedigree back to a verifiable authenticated ADR.

Item 12
A list of the classes of trade the seller is purchasing or selling his/her product from or to.

The information being requested is proprietary company information and does not assist in determining a product's pedigree.

Section II Certification of ADR Status
If the selling pharmaceutical wholesaler claims to be an ADR, it is recommended that the purchaser obtain a written statement from the seller stating that it is an ADR and on what basis. It is also recommended that the purchaser verify the seller's ADR on the initial purchase and then at least annually thereafter.

Item 9
We recommend adopting Florida's current regulations which include, but are not limited to the above requirements. Additionally, licensing by state and federal regulators would alleviate the need for this proprietary company information and ensure wholesalers selling bona fide products.

Section III Background Check
It is recommended that the purchaser require consent for and then conduct a background check on any prescription drug wholesaler it conducts business with prior to the initial transaction. This background check should include;

3) **A driver's license and social security verification of all company owners, officers and key management;**

Social security numbers should not be required.

Section IV Physical Site Inspection

Item 1

Establish the authority, training, and experience of the individual providing the information to them on behalf of the seller;

We believe "authority" needs to be more clearly defined. Authority, training and experience can come from having a company designee who is licensed and well trained on pedigree (and as currently required by Florida law) and maintaining the integrity of the supply chain.

Item 2

Request and examine the seller's organizational chart to identify key management and structure of the company; and

This information is too invasive and is not necessary to ensure proper product pedigree.

Item 3

Verify the number of employees at the facility.

Identifying the number of employees may be anti-competitive and has no bearing on the ability of the company to comply with all applicable laws. Providing the building size should allow sellers to comply with applicable laws as defined in Florida license requirements.

IV Operations

It is recommended that the purchaser examine the following:

The word "examine" should be more fully defined as it pertains to Operations line items 1-10.

Item 2

Procedures for stock rotation

Rotating stock is not germane to a sale of product already identified by date of expiration and lot. How and when you recognize rotation is irrelevant and when a company rotates its stock is a company's business decision.

Item 3

Policies and procedures for conducting inspections of samples of product purchases;

Documenting policies and procedures may be good in theory, but in practice, this does not occur and is impractical. Even if one were to adopt policies and procedures, it would not accomplish the desired results. Additionally, wholesalers and distributors are not subject matter experts in inspecting and packaging. Until authentication and track and trace methodologies are in place, it would be cumbersome and ineffective to be reliant on these procedures.

Item 5
Temperature monitoring program and documentation;

If the FDA was to follow the Florida Department of Health requirement for licensing and specifically temperature control, having a license would constitute following and adhering to that regulation. There would be no reason for a third party to see or have a copy of that documentation.

Item 6
Systems/procedures for detecting adulterated/misbranded product, including systems and procedures to verify that manufacturer identified anti-tampering devices are intact;

Systems and procedures for detecting adulterated misprinted product including systems and procedures are a little futuristic. There are many opportunities today to counterfeit a product. We agree that it is important that a standard methodology to track and trace products be implemented. If the UCC can determine a standard for systems and process, then we can further protect the integrity of the supply chain.

Section VI Ongoing PDMA Compliance Review
Item 3
Performing appropriate supplemental review actions when:

a) **The "Identifying Statement" has more than three entities on it; or**
b) **The price of the product being sold is substantially less than the prevailing market prices.**

We believe "substantially" needs to be further defined. The industry has seen competitors buy products then sell products to another wholesaler for two percentage points. Anytime there is a savings of 2% or more it would have to be considered substantial. In the case of Lipitor, which is currently being investigated for alleged counterfeiting, 10% savings on that product is substantial and the savings are dramatic.

Definitions
Authorized Distributor Record - We believe the 5000 sales units threshold are too high.

Summary
In summary, the HDMA best practices do address a number of issues that will help improve or minimize the availability of counterfeit products in the US market. While we believe it is important to authenticate a relationship with a legitimate seller and purchaser buying products, some of the proposed best practices give competitors too much access to confidential proprietary information at the expense of the small and mid-sized wholesalers and do not do enough to improve the integrity of the supply chain.

II. PDMA-RELATED ISSUES

Item 1

After reviewing the PDMA rules, we have the following general comments. Updating the state-based "Model Rules" could help to stymie the current increasing trend of counterfeit drugs. Florida and Nevada are examples of states that have taken this step and are already revising these "Model Rules." These rules focus on licensure requirements, regulations and due diligence provisions. If the PDMA modeled its rules after the newly enacted state guidelines, we believe this could be a strong deterrent to those who seek to counterfeit drugs.

Item 2

Further pedigree rule development/refinement will help alleviate the present situation in a few ways. As of today, the PDMA rules are still on a "stay" until April 1, 2004 on a federal level due to the inability to get a consensus on adoption in 2001. Therefore, unless there is a technology option that will eliminate the need for reconciling the pedigree rules further, and such option could gain mass acceptance quickly, the pedigree rule issues will need to be resolved. Meanwhile, the barriers that prevented the pedigree rules from being finalized at a federal level previously were cost and logistics. It is not clear at this point how the touted "track and trace" technology options (such as RFID) can take these barriers and turn them into enablers. This also indicates the need to reconcile the pedigree rules. Additionally, the continual shifting of the definition of the "authorized distributor" is another indicator of the need for final resolution, because this definition is one of the key determinants of the scope and speed of implementation on pedigree rule reform.

As a remedy to the current state of affairs on pedigree, the State of Florida adopted a good framework (Senate Bill 312, modifying Requirements section 499.0121(6)) for the "Identifying Statements" (pedigree papers) and "authorized distributor" definition that will facilitate the transition from the current pedigree status to the need for pedigree on all transactions back to the supplier and forward to the customer by July 2006. These rules combined with some of the HDMA's suggested best practices for due diligence testing, could provide a strong framework for the industry to tackle counterfeit drug pressures. <u>It is our recommendation, therefore, that PDMA be amended to put these Florida regulations in place at a federal level.</u>

However, it is important to note that this framework relates to testing and process only, while the governmental structures (federal and state levels) will need to use their investigative powers that only the public sector possesses to attempt to eliminate the counterfeit drugs in the country's drug distribution in the future.

Item 3

PDMA still contains certain exemptions relating to the resale of drug products by hospitals or other end-user health care entities. These exceptions should be eliminated, since this opening in the current matrix of drug distribution laws allows room for counterfeiters to create confusion regarding drug pedigrees and provide entry for counterfeit drugs into the drug supply.

III. REVIEW OF FLORIDA'S NEW DRUG AND COSMETIC ACT

In light of the FDA's request for comments on the interim report with respect to the growing threat of counterfeit drugs and its possible modeling of a federal statute similar to the State of Florida's "**Florida Drug and Cosmetic Act**" (Florida Statutes, Chapter 499, Part I) ("FDCA"), we have reviewed the FDCA, which we generally support and affirm, and make the following suggestions and recommendations.

Section 499.05 Prohibited Acts -- It is unlawful for a person to perform or cause the performance of any of the following acts in this state...

We believe "intentionally" or "with "reckless disregard" should be included to modify "**perform**" or "**cause to be performed,**" as there maybe instances where genuine mistakes are made. A literal interpretation would find unintended consequences for unknowing parties.

(3) The receipt of any drug, device or cosmetic that is adulterated or misbranded and the delivery or proffered delivery of such drug, device, or cosmetic, for pay or otherwise. A purchaser can unintentionally receive adulterated or misbranded goods and be in violation of the law, if the purchaser obtains a pedigree in advance and at the time of receipt, the pedigree does not match the physical receipt. The definition of "**receipt**" should be more clearly defined to include receipt and delivery and to allow for time to resolve unintentional misshipments. During such resolution period, goods can be quarantined until resolution.

(15) The sale or transfer of a legend drug to a person not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess legend drugs from the person selling or transferring the legend drug.
There should be a 30-60 day grace period for a previously licensed person to receive legal drugs. This allows for processing delays by state or federal agencies. Additionally, all authorized distributors of record, secondary wholesalers, pharmacies, and physician and healthcare entities should have their licenses posted on each state's website and on the FDA's website so that all parties can have a central location where licenses can be confirmed. The websites would help companies authenticate an ADR both on state and federal levels.

(28) Failure to obtain or pass on a pedigree paper.
As we discussed in the lead in to §499.05, the additional language of "intentionally" or "with reckless disregard" would address our concerns in this area. Even if companies have well-reasoned policies and procedures in place for this manual paper process, it is very possible that misplaced documents or mistyped information can cause a violation of this statute.

Sections 499.01-499.012
We are unclear why retail pharmacy wholesalers, veterinary legend drug retail establishments and complimentary drug distributors are included in this section and how they impact pedigree. As an example, pedigree guidelines would require a retail pharmacy wholesaler license to follow pedigree yet the retail side of the pharmacy is not required to pass on pedigree or maintain product integrity. Additional questions include: How is the 30% wholesale cap policed? How does the pharmacist separate the wholesale transactions from the retail product dispensing and how will state inspectors ensure that the pharmacist complied with the law?

The regulation requires pharmacists to comply and attest under oath that the product bought is from an ADR or directly from the manufacturer authorized product is the same product which is being sold to the public. If the reason for the law is to protect the public at large, it needs to require the pharmacy to comply with the same attestations required throughout the supply chain. The loophole in the retail side should be closed. Finally, the pharmacist should certify that all returns to the ADR have been stored according to the products' requirements and is in fact the product bought from the ADR or manufacturer that sold it to them. Otherwise, the returned product would lack proper pedigree and could not be resold by the ADR.

499.012 (7) For permits for prescription drug wholesalers or out-of-state prescription drug wholesalers:

(a) The department shall adopt rules for the annual renewal of permits.
We believe that annual reviews are too short a time period and propose reviews be conducted every two years, with annual on-site inspection to ensure annual licensing compliance. Due to the extensive lead time necessary to prepare and complete the annual license application, licensees would be constantly in this process. Biannual licensure would give states the necessary protections, while reducing the administrative burden on the licensees and the states.

499.012 (11)(f) (See attached Appendix A for text of statute)
We believe that the 10 days should be extended to 30 days due to the constant movement of employees. We also believe a better methodology would be to allow for two alternate designees. If the lead designee leaves the employ of the Company, there would be no notice requirement to the state as long as the alternates were still employed by the Company. Upon the designation of the new designee, the Company should be required to notify the state within 30 days. Additionally, with respect to sales of companies, as long as the designated representative moves to the new entity, the Company should be in

compliance with applicable regulatory laws. Following a sale, the notification of the new owner and designated representative should be submitted to the department within 60 days. We also suggest that the language at the end of the section state: "Nothing in this section shall be construed to prevent a wholesaler from obtaining approval of an alternate designated representative who may serve in the designated representative's absence."

499.0121 Storage and Handling of Prescription Drugs; Recordkeeping

499.0121(6)(d)(1) Recordkeeping (See attached Appendix A for text of statute)
We believe that further detail should be given to how the written statement accompanies the drug. Should it be included with the invoice, the packing slip or as a separate document? Provision should also be contemplated for the eventual use of electronic pedigree papers.

499.0121 (6)(d)(4) (See attached Appendix A for text of statute)
The requirement to notify the state within 10 days after a change to the manufacturer's authorized distribution list is too limiting. We believe 30 days is a more practical amount of days.

499.0121 (6)(d)(5)(c) (See attached Appendix A for text of statute)
There needs to be an adequate amount of time for a manufacturer to file a copy of the manufacturers list of authorized distributors of record. The requirement to update the list within 10 days is too short. We recommend 30 days. In our experience, manufacturers were slow to respond in providing a list of ADR's. There should be a phase-in period of up to six months.

499.0121 (6)(e)(1)(a) (See attached Appendix A for text of statute)
We believe there should be a shorter statement which conveys the same message so it can be easily included on all invoices and which maintains the confidence and integrity of the supply chain. For example, the statement could say, "(The Company) is an authorized distributor of record for above product(s) unless otherwise noted."

499.0121 (6)(e)(3)(a) (See attached Appendix A for text of statute)
The criteria used to identify items to have on the specified drug list is helpful, but should not be all-inclusive. Items outside the defined criteria, can be potential candidates for counterfeit products. A catch-all provision should be added to allow for products which would not fall into the listed categories.

499.0121 (6)(g) (See attached Appendix A for text of statute)
Consistent with our prior recommendations, we believe the 10-day requirement to notify the department is too short when there is a change to the written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription drugs. For example, if there is a national backorder on a product, you may have to go to alternative suppliers to satisfy demand. Additionally in today's environment of mergers and product switches, it is possible for the wholesale distributor

to not even recognize a change. We believe 30 days is a more appropriate amount of days.

499.0121 (12) (See attached Appendix A for text of statute)
Sections C-E provide too much competitive and proprietary company information. The state's licensure requirements will cover many of the items listed in this section and the very fact that a selling wholesale drug distributor is licensed by the State of Florida should provide adequate comfort to a buying wholesale drug distributor that the selling wholesale drug distributor is selling products with proper pedigree.

In summary, Florida's adoption of the Florida Drug and Cosmetic Act goes a long way towards addressing the counterfeiting issues. The FDA should consider the FDCA as a model when enacting its federal regulations. However, as set forth above, we believe that there are some practical improvements that should be addressed prior to any federal enactment of the FDCA.

IV. BENEFITS OF UTILIZING BAR CODING STANDARDS VERSUS RFID

While no single solution can completely eliminate the counterfeiting of prescription drugs, there are some steps that can be taken to significantly reduce the problem. There are many proposed solutions to this problem, such as RFID, that require significant investments by all concerned. Some of these proposed technologies are still several years from implementation. The solution to the problem requires a "phased in" approach with several steps, implemented over several years.

The industry enthusiasm for the potential benefits of newly introduced bar code labeling standards extends throughout the life sciences supply chain. These new standards of labeling provide all participants the ability to make improvements in patient safety, while positioning manufacturers and distributors with the more immediate benefit of improving processes and tracking a product to its end use.

A thoughtful approach to meeting the impending FDA labeling requirements by pharmaceutical manufacturers, relabelers, repackagers and distributors can create a new standard that will provide unprecedented controls. Implementing this new coding standard will improve supply chain visibility and improve the quality of information available. Product traceability can play a major role in deterring product counterfeiting and diversion.

Adopting a universal product identification standard must be the first step in this process. The Uniform Code Council (UCC) and the EAN International are two not for profit organizations recognized as providing the premiere identification methods necessary to conduct efficient global commerce. These organizations are the most equipped and

experienced to handle the tasks of developing and implementing a universal product identification standard.

The joint venture between these organizations has recently introduced a new Reduced Space Symbology (RSS) standard that addresses the need for a universal identification bar code scanning symbology. This new symbology provides methods to encode more data in a small space. The new RSS standard provides for the encoding of the manufacturer, product identification, lot number and date of manufacture. RSS was developed as a family of seven linear symbologies that provide the required features that address the additional data encoding needed by space constrained applications. RSS bar codes can be read by most legacy, low cost scanners in use today. Some may require a firmware upgrade to decode the RSS bar code format. The ability of using scanning systems already in use gives RSS symbols many advantages in the proposed adoption timeframe over other coding symbols and technologies. RSS symbols should be considered as a step in the "phase-in" solution to deterring the counterfeiting of prescription drugs.

The proposal to use RFID as a future solution will better insure the ability of all concerned to identify, track and trace products from origin to its end use. The technology and products needed to implement RFID throughout the supply chain are still in the development stages. There are examples of RFID technology in use today, including use in bulk packaging, shipping containers, and identifying high value products.

While the use of RFID technologies may lead to more efficient processes, controls and tracking systems it would be errant for the members of the prescription drug supply chain to depend on RFID alone as a "the" anti-counterfeiting method of protecting and identifying products. Much like satellite cable services are being acquired by users duplicating electronic encrypted access cards, the technology required to duplicate and defeat electronic RFID tags is already readily available. It should be considered that the use of RFID tags might also make it easier for someone to identify the location of drugs with high street value. Using a RFID scanner one could without any knowledge of drug identification, easily identify prescription drugs of interest in shipping containers, warehouses, pharmacies and doctors offices.

The EAN.UCC has developed standards for an Electronic Product Code (EPC) that can be coded and decoded with RFID tags, however at this time it would be more timely and efficient to implement the EAN.UCC RSS bar coding standards. Additionally, RFID technologies are not available in a cost effective format today. The cost of implementation of the RFID coding, and the decoding equipment necessary to support RFID in all stages of the supply chain, is prohibitive to the industry at this time.

By first implementing product identification standards and technologies that can be easily adopted by the members of the prescription drug supply chain, the ability to track and trace prescription drugs will improve without requiring the prohibitive cost associated with implementing new technologies. As new technologies such as RFID and other

identification standards become available and cost effective in industry, they could then be considered.

Conclusion

While the HDMA best practices and the PDMA proposed rules are very helpful in addressing the pedigree issue and minimizing the counterfeiting of pharmaceuticals, we believe the FDCA is more encompassing and complete and should form the foundation for the Federal Guidelines. However, the HDMA best practices, the PDMA proposed rules and the FDCA are only part of the solution. Authentication and track and trace technology in concert with regulations and licensing will help accomplish these objectives.

APPENDIX A
Selected Florida Statutes (Section 499 – Part 1)

499.012 (11)(f)
A wholesale distributor may not operate under a prescription drug wholesaler permit or an out-of-state prescription drug wholesaler permit for more than 10 business days after the designated representatives leaves the employ of the whole distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.

499.0121 Storage and Handling of Prescription Drugs; Recordkeeping

499.0121(6)(d)(1) Recordkeeping

...
(d)1. Each person who is engaged in the wholesale distribution of a prescription drug, and who is not an authorized distributor of record for the drug manufacturer's products, must provide to each wholesale distributor of such drug, before the sale is made to such wholesale distributor, a written statement under oath identifying each previous sale of the drug back to the last authorized distributor of record, the lot number of the drug, and the sales invoice number of the invoice evidencing the sale of the drug. The written statement must accompany the drug to the next wholesale distributor. The department shall adopt rules relating to the requirements of this written statement. This paragraph does not apply to a manufacturer unless the manufacturer is performing the manufacturing operation of repackaging prescription drugs.

...
(d)4. Each manufacturer shall file a written list of all of the manufacturer's authorized distributors of record with the department. A manufacturer shall notify the department not later than 10 days after any change to the list. The department shall publish a list of all authorized distributors of record on its website.

....

(d)5. For the purposes of this subsection, the term "authorized distributors of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. Effective March 1, 2004, an ongoing relationship is deemed to exist when a wholesale distributor, including any affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member:

...

c. Has reported to the department pursuant to s. 499.012(2)(g)2. that the wholesale distributor has total annual prescription drug sales of $100 million or more, and has a verifiable account number issued by the manufacturer authorizing the wholesale distributor to purchase the manufacturer's drug products directly from that manufacturer and that wholesale distributor makes not fewer than 12 purchases of that manufacturer's

drug products directly from the manufacturer using said verifiable account number in 12 months. The provisions of this sub-subparagraph apply with respect to a manufacturer that fails to file a copy of the manufacturer's list of authorized distributors of record with the department by July 1, 2003; that files a list of authorized distributors of record which contains fewer than 10 wholesale distributors permitted in this state, excluding the wholesale distributors described in sub-subparagraph b.; or that, as a result of changes to the list of authorized distributors of record filed with the department, has fewer than 10 wholesale distributors permitted in this state as authorized distributors of record, excluding the wholesale distributors described in sub-subparagraph b.

A wholesale distributor that satisfies the requirements of sub-subparagraph b. or sub-subparagraph c. shall submit to the department documentation substantiating its qualification pursuant to sub-subparagraph b. or sub-subparagraph c. The department shall add those wholesale distributors that the department has determined have met the requirements of sub-subparagraph b. or sub-subparagraph c. to the list of authorized distributors of record on the department's website.

499.0121 (6)(e)(3)(a)

(e)1. Notwithstanding paragraph (d), each person who is engaged in the wholesale distribution of a specified drug must provide to each wholesale distributor of such specified drug:

a. Upon any sale, a written statement that:

(I) If the establishment is not a member of an affiliated group: "This establishment purchased the specific unit of the specified drug directly from the manufacturer"; or

(II) If the establishment is a member of an affiliated group: "This establishment or a member of my affiliated group purchased the specific unit of the specified drug directly from the manufacturer"; or

b. Before the wholesale distribution, a written statement, under oath, that identifies each previous sale of the specific unit of the specified drug back to the manufacturer of the specified drug, the lot number of the specific unit of the specified prescription drug, and the sales invoice number of the invoice evidencing each previous sale of the specific unit of the specified drug. The written statement identifying all sales of such specific unit of the specified drug must accompany the specific unit of the specified drug for each subsequent wholesale distribution of the specific unit of the specified drug to a wholesale distributor.

The department shall adopt rules to administer the requirements of these written statements.

2. As used in this paragraph, the term "specified drug" means a specific prescription drug on the list of drugs adopted by the department by rule.

3.a. A drug may be placed on the list of specified drugs if the department has seized or issued a stop sale notice on the prescription drug because of the adulteration, counterfeiting, or diversion of the prescription drug from the legal channels of distribution for prescription drugs, or the United States Food and Drug Administration, a manufacturer, a wholesale distributor, a law enforcement agency, or a government agency responsible for regulating the sale or distribution of prescription drugs in another state has notified the department in writing or through a website operated by one of said entities that the prescription drug has been adulterated, counterfeited, or diverted from the legal channels of distribution for prescription drugs; and the prescription drug satisfies one of the following criteria:

(I) The prescription drug is included among the top 150 prescription drugs for which the state has incurred the highest amount of Medicaid claims in the most recently ended state fiscal year;

(II) The prescription drug is available for normal prescription use in dosages or strengths that have a wholesale cost of $200 or more;

(III) The prescription drug is used extensively for patients with human immunodeficiency virus, acquired immune deficiency syndrome, cancer, or other serious, life-threatening conditions, where drug nonresponsiveness would not be considered to be medically unusual;

(IV) The prescription drug is an injectible drug;

(V) The prescription drug is subject to a special, limited distribution process and is not generally sold to wholesale distributors by the manufacturer of the prescription drug;

(VI) The department has found not less than five instances where statements required pursuant to paragraph (d) for the prescription drug were not passed on other than because of unintentional oversight, or have been passed on by or to a wholesale distributor and such statements were fraudulent; or

(VII) A shipment of a prescription drug has been reported to a law enforcement agency as having been stolen or as missing.

499.0121 (6)(g)

(g) Each wholesale distributor, except for a manufacturer, shall annually provide the department with a written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list. Such portions of the information required pursuant to this paragraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

499.0121 (12)

(12) DUE DILIGENCE OF SUPPLIERS.--Prior to purchasing any prescription drugs from another wholesale drug distributor, a wholesale drug distributor must:

(a) Enter an agreement with the selling wholesale drug distributor by which the selling wholesale drug distributor will indemnify the purchasing wholesale drug distributor for any loss caused to the purchasing wholesale drug distributor related to the purchase of drugs from the selling wholesale drug distributor which are determined to be counterfeit or to have been distributed in violation of any federal or state law governing the distribution of drugs.

(b) Determine that the selling wholesale drug distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department pursuant to s. 499.012(3)(g) or $500,000; however the coverage need not exceed $2 million.

(c) Obtain information from the selling wholesale drug distributor, including the length of time the selling wholesale drug distributor has been licensed in this state, a copy of the selling wholesale drug distributor's licenses or permits, and background information concerning the ownership of the selling wholesale drug distributor, including the experience of the wholesale distributor in the wholesale distribution of prescription drugs.

(d) Verify that the selling wholesale drug distributor's Florida permit is valid.

(e) Inspect the selling wholesale drug distributor's licensed establishment to document that it has a policies and procedures manual relating to the distribution of drugs, the appropriate temperature controlled environment for drugs requiring temperature control, an alarm system, appropriate access restrictions, and procedures to ensure that records related to the wholesale distribution of prescription drugs are maintained as required by law:

1. Before purchasing any drug from the wholesale drug distributor, and at least once each subsequent year; or

2. Before purchasing any drug from the wholesale drug distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale drug distributors in the state in which the establishment is located.