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December 2, 2003

Dockets Management Branch
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5630 Fishers Lane
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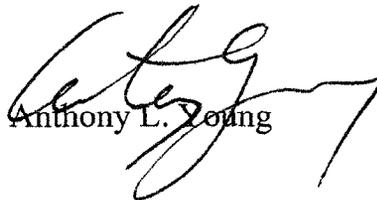
RE: Docket No. 2003N-0361

Dear Sir/Madam:

Please file the enclosed Petition in the above-referenced docket. Three copies are enclosed.

Thank you for your assistance.

Sincerely,


Anthony L. Young

Enclosures

2003N-0361

PSA 1

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RE: Pharmaceutical Distributors Association –
Responses to Questions and Petition for Stay, etc.

Dear Doctor Rudolph:

Thank you again for meeting with representatives of the Pharmaceutical Distributors Association on November 10, 2003 and for the opportunity to have a frank exchange of views regarding how small licensed prescription drug wholesalers who are not full line wholesalers can help assure the integrity of the pharmaceuticals that they distribute. As we promised at our meeting, we are responding below to the specific questions that you and your colleagues posed at that meeting. In addition, we are enclosing a copy of the Petition for Continuation of Stay of Action and Suspension of Effective Date and for Issuance of a Draft Agency Guidance Document Setting Forth the Recommended Guidelines for Pharmaceutical Distribution Integrity. That Petition was filed today with the Docket Management Branch.

We look forward to a continuing dialog on these issues that are important to the integrity of the drug supply and to our members.

Q.1. Would PDA support a third-party organization certifying distributors with respect to adherence to the Recommended Guidelines for Pharmaceutical Distribution Integrity. And would PDA support paying fees to fund this third-party?

If such inspections were to be performed by State inspectors, PDA would support a fee increase at the state level to fund such inspections. If States were not able to perform such inspections, PDA supports the involvement of some form of independent third-party organization to perform inspections and to certify that the Recommended Guidelines are being adhered to. PDA would be most interested

in this concept if it were under the auspices of a coalition of prescription drug wholesaler "customer" groups such as the National Association of Chain Drug Stores, the National Association of Community Pharmacists, the American Pharmacists Association and the relevant association of veterinarians. . Since they represent the ultimate dispensers of prescription drug products, they have a direct interest in the integrity of these products. PDA believes there are a number of consulting firms already providing these kinds of services in the drug and device manufacturing sector and that, operating under Recommended Guidelines adopted by these organizations and through audit procedures adopted by the organizations, these firms would be able promptly to provide audit services.

PDA has also considered whether the National Association of Boards of Pharmacy would be an appropriate third-party organization. PDA has not been successful in reaching NABP staff to discuss this concept. PDA is concerned that that the NABP would not be able to adopt Recommended Guidelines and begin auditing companies as quickly as organizations that are more closely associated with the private than the public sector.

Q.2. How does the current and "proposed" status quo work (practically). Specifically, what has changed, if anything, with "status quo" practices since the 2000 public hearing?

Regarding "pre" and "post" 2000 status quo practices, the only changes have been with respect to the efforts by some wholesalers to effectuate counterfeit checks on certain incoming product (i.e., over \$200 per unit of sale). Some wholesalers have also determined not to carry products for infusion or injection other than insulin. Recently, customers are requiring that suppliers substantiate their status as authorized distributor of record ("ADR").

The present status quo involves the passage of a pedigree paper from an entity that is not an ADR to a subsequent purchaser. The information about each prior transaction reported in pedigree paper includes all that is required in the December 1999 final rule. One point to note is that standard "status quo" practices do not involve the passage of a pedigree paper prior to the receipt of the actual drug products. The actual practice is that in most cases the pedigree arrives after the product, but payment for product and placement into inventory does not occur without receipt of the pedigree.

Current status quo practices in the industry also involve the signing of a guaranty and indemnity agreement by the supplier. Such agreement contains the standard form of guaranty under the Federal Food, Drug, and Cosmetic Act as well as a certification that the vendor is complying with PDMA and that they are not offering products that have been procured through fraud or products that were purchased by the supplier or that supplier's supplier that have restrictions on resale.

Q.3. What is PDA's position regarding removal of the ADR concept entirely.

The idea of scrapping the ADR concept has its pros and cons. It is PDA's opinion that the ADR concept is necessary, because of the inability of the large national distributors to provide pedigree papers. As they have testified on numerous occasions, they cannot possibly comply with this requirement without spending tens of millions of dollars and without disrupting the normal flow of products. PDA believes that the ADR concept should be done away with when the electronic pedigree (track and trace technology) is operational. To make the change before that time would cause large national distributors to ramp up for one technology only to be required to change to track and trace technology. Therefore, the large national wholesaler's inability to comply with a manual pedigree system back to the manufacturer, along with the current ADR exemption from pedigree that is in the law, necessitates that the ADR concept continue. PDA believes, however, that raising the bar on the requirements to become an ADR is the most effective way to address this issue until new technology is in place.

Q.4. How do the "Recommended Guidelines" impact small purchasers, i.e., drug stores, that receive daily faxes and phone solicitations with low price prescription drug offers? How will the guidelines "trickle down" to these people?

PDA believes that some the burden on identifying "problematic" wholesalers is the responsibility of all persons purchasing from wholesalers, including small pharmacies. Accordingly, it is the responsibility of the purchaser, be it pharmacy or wholesaler, to perform some level of due diligence on suppliers, including a request for their wholesale license in the state in which they are located and in the state they will be shipping to, asking for a food and drug guaranty and indemnity, and asking whether the supplier follows the Recommended Guidelines. One reason that PDA supports the concept of "customer" associations being involved in the oversight of third-party audits of wholesalers is that they can then recommend to their members that they look to suppliers that follow the Recommended Guidelines and that have been audited. If this were done, a list of such suppliers could be created and made available through association websites and to members.

Finally, the Recommended Guidelines could be truncated by customer associations to a form more feasible of accomplishment by smaller purchasers at the retail level.

Q.5. When will PDA members begin inspecting sources?

PDA anticipates that members will begin a process of inspecting sources beginning January 1. (In fact, some companies are already beginning to do this

as a matter of policy and some entered into a program of inspections over two years ago). PDA believes that a 12 month window should be established to get out to see all sources, but that in the interim, all PDA members should request copies of the suppliers most recent state inspection report, and that they should validate the good standing of the suppliers licenses with the appropriate state licensing agencies. In addition, PDA is in favor of, and will look closely at, the involvement of an independent third-party to conduct these inspections in the future.

Q.6. How will PDA members be aggrieved if the final rule were to go into place?

PDA members would be aggrieved by the final rule being implemented "as is" b/c of the requirement that all transactions back to the manufacturer be reported. Since ADR's are exempt from passing a pedigree, the non-ADR wholesaler has no way of complying with the requirement, since it won't have the information required to be included on its pedigree when it sells prescription drug products. As a result, PDA members would basically only be able to sell what we buy direct from the manufacturers. Since PDA members are not able to buy direct from most manufacturers, and since the prices that PDA members are offered are often not competitive with those offered to the ADR wholesalers, PDA member businesses would fade away. PDA members' customer bases would become more reliant on the manufacturer and/or ADR wholesaler, and would end up paying more for their products. Additionally, due to the reluctance of manufacturers to provide written contracts/ many large "ADR" wholesalers may find themselves in a position where they are required to give pedigree.

Finally, we believe there are thousands of non-PDA member small wholesalers, and many customers of these wholesalers, who will be aggrieved by the "as is" implementation of the final rule.

Q.7. What is the PDA member business profile?

At our November 11th meeting, PDA submitted profiles of 15 companies that operate within the secondary market. These profiles provide an overview of the variety of markets served by secondary or "smaller" wholesalers.

Primarily as result of the multi-tiered pricing strategies employed by the drug manufacturers, smaller wholesalers are able to obtain product from a variety of licensed wholesalers throughout the U.S. Also, as a result of manufacturer price increases, or product shortages in certain markets, secondary suppliers are able to facilitate the movement of product to places where there is need, in a very timely manner. Products are often shipped via overnight carrier, and because of the limited number of items (as compared to the full line wholesalers) that smaller suppliers typically carry, they are able to implement pedigree tracking systems that are not achievable by the Big Three and other large wholesalers.

Secondary suppliers are also an outlet for overstocks from wholesalers and manufacturers. Inventory turns are critical to a wholesaler's profit margin, and they cannot afford to tie up capital in an item that doesn't move rapidly. Secondary companies provide an outlet for those goods.

Q.8. They want our opinion on a performance bond.

PDA fully supports the requirement of a performance bond (or some other equivalent financial instrument) as a requirement for licensing. Underwriters will likely not issue bonds to companies without a compliance history or, at a minimum, will charge a price that may be cost prohibitive. PDA's view is that there must be some form of national bond created, one that gives each of the relevant licensing and compliance agencies in the ability to draw on the bond if necessary. A requirement by multiple states for performance bonds could prove to be financially devastating to smaller wholesalers and extremely burdensome to larger wholesalers.

Q.9. What is PDA's view of the Nevada wholesale application.

PDA supports strong state licensure requirements. California has a very strong system, as does Florida. While PDA has no direct experience with the new Nevada application, PDA has no objection to extensive information requests. PDA does object to Nevada's old definition of wholesaler that would have required wholesalers to sell 90% to retail. Similarly, PDA objects to Nevada's present requirement that wholesalers selling to other wholesalers sell only to those other wholesalers who will sell to retailers.

Q.10. What is PDA's view of Florida's new requirements?

PDA was an active participant in the Committee that gathered information for Florida lawmakers. PDA believes that the Florida law has many good components, but that the law has some parts that are not conducive to being able to conduct legitimate business. In our testimony before the NABP at their October counterfeit drug task force meeting, we outlined many of these areas as follows:

- 1) The proposed pedigree authentication requirements slow down the speed by which drugs can be distributed.
 - Product is backing up on the docks of companies who must authenticate all items received. The response time of vendors in terms of answering phone calls, emails, etc. has a direct impact on this logjam.
 - The ADR list being maintained by the state is very incomplete, and contains many inaccuracies (bankrupt companies, acquired companies), and also is far from comprehensive because of extremely poor responses from manufacturers. As a result, companies have to go thru the more time consuming processes of authenticating a supplier's ADR status.

- 2) The proposed pedigree requirement slows down and/or restricts commerce.
 - The requirement that the invoice number of the source selling the drug be included on a pedigree paper causes wholesalers to "hold" inventory for days, pending receipt of an invoice number from their source. It is not unusual for product to arrive several days in advance of the vendors invoice, and this product cannot be legally resold because the seller will not be able to include the required invoice number on the pedigree paper.
 - Because of differing requirements from state to state on pedigrees (and the ADR definition) there are many transactions that can no longer take place in Florida because the sources involved in the distribution chain had no knowledge of the Florida law or more importantly, no legal requirement to comply with the law because they were selling to someone outside Florida that now wishes to ship that product to a customer in Florida. This limits the amount of otherwise good product getting into the state.
- 3) The bond requirement, while a good concept, could become extremely cost prohibitive if every state decides to implement a similar requirement. There should be consideration given to a bond being posted in the wholesaler's home state, and somehow allowing other states to draw on the bond if violations occur in their states.
- 4) The proposed authorized distributor requirement will reduce the number of ADR's dramatically, and potentially eliminate the ADR status of some smaller companies who buy almost exclusively from the manufacturer. This should not be the intent of the law. If the manufacturers don't include these companies on their lists, the companies risk losing their ADR status. In addition, if the other objective requirements set in the Florida law, all of which are based upon \$100 million in sales, can't be met, these companies could again lose their ADR status.

Q.11. Can FDA promulgate the Recommended Guidelines as Guidance?

PDA's view is that the Recommended Guidelines could be proposed by FDA as Guidance for public comment. This issue is addressed in the accompanying PDA petition.

Q.12. Should dollar volume be a determinant regarding the type of license a wholesaler receives?

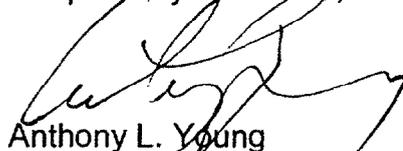
Dollar volume could be a determinant of the kind of licensing application process that a company must complete and the size of the bond that might be required. PDA understands the need for more disclosure from the newer or smaller wholesalers, since it appears that such wholesalers appear to have been the vehicle through which counterfeits have been introduced into the distribution channel. Financial weakness is often a sign of susceptibility to criminal conduct.

However, once a license is approved, there should not be differences in how the smaller and larger companies can operate.

Q.13. What would our "phase-in" plan be if our platform were implemented?

First, it is important to reiterate that all PDA members have made a pledge to adhere to the industry guidelines that we have shared with FDA. In addition, certain member companies are rolling out implementation plans, and notifying their customers of these plans, so that they can get comfortable that the supplier is committed to protecting the drug supply. For example, we have attached the action plan of one PDA member company that they will be distributing to all of their pharmaceutical customers and suppliers. This represents a reasonable implementation approach, allowing adequate time to perform the various tasks that need to be accomplished.

Respectfully submitted,



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Regulatory Counsel to the Pharmaceutical
Distributors Association

Enclosure

cc: Sal Ricciardi
President
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800-323-6980

Docket Nos. 92N-0297
88N-0258

BEFORE
THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

**PETITION FOR CONTINUATION OF STAY OF ACTION AND SUSPENSION OF
EFFECTIVE DATE AND FOR ISSUANCE OF A DRAFT AGENCY GUIDANCE
DOCUMENT SETTING FORTH THE RECOMMENDED GUIDELINES FOR
PHARMACEUTICAL DISTRIBUTION SYSTEM INTEGRITY**

BY THE
PHARMACEUTICAL DISTRIBUTORS ASSOCIATION

**FINAL RULE CONCERNING POLICIES, REQUIREMENTS, AND
ADMINISTRATIVE PROCEDURES;
PRESCRIPTION DRUG MARKETING ACT OF 1987;
PRESCRIPTION DRUG AMENDMENTS OF 1992**

December 1, 2003

Pursuant to 21 C.F.R. § 10.35, the Pharmaceutical Distributors Association ("PDA"), a trade association of state-licensed wholesale distributors of prescription drugs, requests that the Commissioner of Food and Drugs continue the stay and suspend the effective date of 21 C.F.R. § 203.50 and 21 C.F.R. § 203.3(u), which are presently scheduled to go into effect on April 1, 2004. 68 Fed. Reg. 4912 (January 31, 2003).

In connection with a stay and suspension of the effective date for these regulations, the PDA also petitions the Commissioner of Food and Drugs to publish a draft Agency guidance document setting forth the Recommended Guidelines for Pharmaceutical Distribution System Integrity ("Guidelines," attached hereto as Appendix A) for public comment under 21 C.F.R. § 10.1150.

I. DECISION INVOLVED

The Prescription Drug Marketing Act ("PDMA") was enacted on April 22, 1988 (Pub. L. 100-293) and amended on August 26, 1992 (Pub. L. 102-353). Promptly after PDMA was enacted, the Food and Drug Administration ("FDA"), on August 1, 1988, issued a letter to industry to provide guidance on compliance with the new law ("1988 guidance"). Also in 1988, FDA proposed regulations setting forth minimum requirements for state licensure of wholesale drug distributors. These regulations were made final in September of 1990 and appear at 21 C.F.R. Part 205. It was not until March of 1994, however, that FDA proposed rules regarding the paperwork requirements of PDMA. And, five years later, on December 3, 1999, the FDA made these into a "final rule." 64 Fed. Reg. 67720.

The final rule requires, for the first time since PDMA was passed in 1988, that the paperwork accompanying wholesale distributions of prescription drugs ("prescription drug pedigree") include prior sale information back to the manufacturer even though some wholesale distributors, known as authorized distributors of record ("ADRs"), are

not required to provide pedigrees when they sell drugs to other distributors. 21 C.F.R. § 203.50(a)(6). In addition, these regulations, also for the first time, indicate that the only indicia of an ongoing relationship (a prerequisite to ADR status) is the existence of a written agreement between a wholesaler and manufacturer. 21 C.F.R. § 203.3(u).

The final rule was published December 3, 1999, and had an effective date of December 4, 2000. By Notice published May 3, 2000 the FDA stayed the December 2, 2000 effective date to October 1, 2001. 65 Fed. Reg. 25639. Further stays of the effective date to April 1, 2002, April 1, 2003, and April 1, 2004 were promulgated on March 1, 2001, February 13, 2002, and January 31, 2003, respectively. 66 Fed. Reg. 12850 (March 1, 2001); 67 Fed. Reg. 6645 (February 13, 2002); 68 Fed. Reg. 4912 (January 31, 2003).

II. ACTION REQUESTED

The PDA requests the regulations noted above be stayed and suspended until one year after the FDA issues reconsidered final regulations implementing the PDMA.

III. STATEMENT OF GROUNDS

A. Background

The controversy pertaining to the regulations at issue has been on-going since FDA issued its about-face final regulation in December 1999. Specifically, since December 1999, the following has occurred:

- PDA and a delegation of trade associations met with FDA on March 29, 2000 to express their concerns regarding the final rule. On that same date, PDA filed a petition for stay of those parts of the final rule that are the subject of this petition.

- A similar petition was submitted to the FDA by the Small Business Administration (“SBA”) seeking reconsideration of the final rule and suspension of its effective date based on the severe economic impact it would have on more than 4,000 small businesses.
- In a Notice discussing the meeting, FDA noted that petitions and other communications were received from various associations and from Members of Congress.
- FDA stayed those parts of the final rule sought to be stayed herein until October 1, 2001. 65 Fed. Reg. 25639 (May 3, 2000).
- On May 16, 2000, in its report accompanying the FDA Appropriations bill for 2001 (Rept. 106-619), the House Appropriations Committee stated that the FDA should thoroughly review the potential impact of its PDMA regulations on the secondary wholesale pharmaceutical industry. The Committee directed the FDA to provide a report by January 15, 2001, to summarize the comments and issues raised by the public and to propose FDA plans to address those concerns.
- In order to gather information about the impact of the PDMA and the final rule, the FDA held a public hearing on October 27, 2000 to receive comment and to dialog with wholesale distributors, representatives of manufacturers and public interest groups. PDA and other trade associations participated in that hearing. Written comments were received through November 20, 2000.
- FDA issued an additional stay of the final rule until April 1, 2002 on March 1, 2001. 66 Fed. Reg. 12850 (March 1, 2001). FDA granted the extension of the effective date based on the time necessary to evaluate comments and other information

regarding the PDMA final rule. In particular, FDA noted in the March 1, 2001 Federal Register that the House Committee on Appropriations had directed the agency to provide a report to the Committee by January 15, 2001 (the Report was already one and one-half months late), summarizing the comments and issues raised about the PDMA final rule and FDA's proposals to address them. In its March 1, 2001 Federal Register notice, the FDA noted that even if its PDMA Report to Congress were timely submitted, it would take a significant amount of time beyond January 15, 2001 to initiate and carry out either an administrative modification to the final rule or to achieve a legislative change.

- The FDA's Congressional Report on the Prescription Drug Marketing Act, House Report 106-619 ("PDMA Report to Congress"), was signed and sent to the Congress on June 5, 2001.
- FDA issued additional stays of the final rule on February 13, 2002, and January 31, 2003, such that the final rule is currently stayed until April 1, 2004. 67 Fed. Reg. 6645 (Feb. 13, 2002); 68 Fed. Reg. 4912 (January 31, 2003). In the January 31, 2003 notice announcing the stay until April 1, 2004, FDA concluded that:

In its report to Congress, the agency concluded that it could address some, but not all, of the concerns raised by the secondary wholesale industry and the blood industry through regulatory changes. However, Congress would have to act to amend Section 503(e) of the act to make the types of changes requested by the secondary wholesale industry. As a result, on February 13, 2002, FDA further delayed the effective date of the relevant provisions of the final rule until April 1, 2003, in part to give Congress time to consider the information and conclusions contained in the agency's report and to determine if legislative action was appropriate. Based on a recent petition submitted by affected parties, FDA understands that members of Congress are, in fact, considering the issues presented in the agency's report. Due to competing legislative priorities, however, the issues have not yet been resolved. Therefore, to give Congress additional time to determine if legislative actions appropriate, the agency is further delaying the effective date for Sections 203.3(u) and 203.50 The

further delay of the effective date until April 1, 2004, will also give the agency additional time to consider whether regulatory changes are warranted. [68 Fed. Reg. at 4913.

- In July 2003, the PDA filed with FDA a Memorandum of Law outlining the FDA's current authority to revisit and revise the final regulation set forth at 21 C.F.R. § 203.50(a)(6) and to issue, through proposed regulations under its formal notice and comment procedures, a revised regulation consistent with the Agency's 1988 Guidance permitting pedigree to commence with a manufacturer or authorized distributor of record. A copy of that Memorandum is attached hereto as Appendix B.
- In July 2003, the Commissioner of FDA established the Counterfeit Drug Task Force ("CDTF"), charging it with developing recommendations for achieving four fundamental goals: (1) preventing the introduction of counterfeit drugs; (2) facilitating the identification of counterfeit drugs, (3) minimizing the risk and exposure to consumers to counterfeit drugs; and (4) avoiding the addition of unnecessary costs on the prescription drug distribution system, or unnecessary restrictions on lower-cost sources of drugs. CDTF Interim Report, p. 1.
- On October 2, 2003, the CDTF issued an Interim Report setting forth a multi-pronged approach to the goals set by the Commissioner. In its Interim Report, the CDTF concluded: (1) there is no single "magic bullet" against the growing number of sophisticated counterfeiters; rather, a multi-pronged strategy to secure the drug supply could be much more difficult for counterfeiters to overcome; (2) there are many new technologies and approaches that have the potential to prevent and contain counterfeit drug threats; (3) because many of these new

technologies have not been fully developed, broad public comment was warranted to guide the CDTF's further work in connection with achieving the most-cost effective manner to keep drugs in America secure. *Id.*, pp. 1-2.

- In its Interim Report, the CDTF emphasized the following factors, among other things: (1) the value and importance of continued availability of discounted drug pricing;¹ (2) weaknesses in PDMA and its implementing regulations with regard to the paper pedigree requirement;² (3) the need to implement cost-effective technologies in place of paper pedigree requirements to maximize authentication and to minimize burdens placed on participants in the distribution system;³ (4) the need to increase the due diligence and secure business practices by all purchasers in the system (identifying as a potential option to improve prescription drug security, "issuance of an FDA guidance document concerning physical site security and supply chain integrity")⁴; and (5) the need to maximize criminal penalties for drug counterfeiting.⁵
- The CDTF held a public meeting and technology forum on October 15, 2003 to collect testimony regarding the problem of counterfeit drugs and to learn more about specific anti-counterfeiting technologies. The President of PDA, Mr. Sal Ricciardi, presented testimony at that public meeting.
- In its Interim Report, the CDTF sought public comment on no less than 45 questions. *See id.*, pp. 29-34. Public comments were due on the CDTF on November 3, 2003. The PDA filed comments in response to numerous questions

¹ *See e.g., id.*, pp. 7, 10.

² *See e.g., id.*, pp. 14-15.

³ *Id.*

⁴ *Id.*, p. 26.

⁵ *See e.g., id.*, p. 16.

posed by the Interim Report, including therewith a copy of the Guidelines attached hereto as Appendix A.

- The CDTF is in the process of reviewing the information presented at the public meeting and in the comments submitted, and anticipates releasing a final report in January 2004. *See id.*, p. 6.

B. The Definition of Ongoing Relationship In The Final Rule Must Continue to Be Stayed

In the 1988 Guidance, FDA provided that an “ongoing relationship”

may be interpreted to mean a continuing business relationship in which it is intended that the wholesale distributor engage in wholesale distribution of a manufacturer’s prescription drug product or products. Evidence of such intent would include, but not be limited to, the existence of a written franchise, license, or other distribution agreement between the manufacturer and wholesale distributor, and the existence of ongoing sales by the manufacturer to the distributor, either directly or through a jointly agreed upon intermediary. The Agency would consider two transactions in any 24-month period to be evidence of a continuing relationship.

1988 Guidance. In March 1994, FDA proposed the following definition for “ongoing relationship”:

Ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to sell the manufacturer’s products for a period of time or for a number of shipments, at least one sale is made under that agreement, and the name of the authorized distributor of record is entered on the manufacturer’s list of authorized distributors of record.

59 Fed. Reg 11842, 11863 (March 14, 1994).

In final rules promulgated by the FDA in 1999, FDA defined an “ongoing relationship” for the purposes of determining whether one is an authorized distributor of record in 21 C.F.R. § 203.3(u) as follows:

Ongoing relationship means an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturers' products for a period of time or for a number of shipments. If the distributor is not authorized to distribute the manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

64 Fed. Reg. 67757 (December 3, 1999).

Thus, under the final rules FDA requires the existence of a written agreement as the sole objective criteria by which to attain ADR status. The final rule's narrowing of the definition of ongoing relationship and ADR status from that set forth in the 1988 Guidance has raised concerns not only among industry, but even with FDA since the final rules were promulgated.

Indeed, in FDA's PDMA Report to Congress, the Agency agreed that the ongoing relationship definition of the final rule "is restrictive and places control of who can be an authorized distributor in the hands of manufacturers," and that "it could prohibit many secondary distributors, including those who make regular purchases from manufacturers, from qualifying as authorized distributors of record." PDMA Report to Congress at 19. The FDA also concluded that "this could have anticompetitive consequences without the corresponding benefit of protecting the public health." *Id.* PDA agrees.

The PDA has provided FDA with extensive comments on the anticompetitive impact of § 203.3(u) as it is presently drafted. Those comments concluded that two transactions in the previous twenty-four month period should be sufficient evidence of the on-going relationship required by PDMA. Moreover, in its PDMA Report to Congress, FDA stated that it "believes that an on-going relationship could be

demonstrated by evidence of two sales within the previous 24-month period.” PDMA Report to Congress at 20.

In its comments filed in response to the CDTF Interim Report, the PDA emphasized the need for a single, federal definition for ADR, and recommended that the definition of ADR be modified from that set forth in the 1988 Guidance to include additional objective criteria as evidence of an ongoing relationship as follows:

1. The distributor appears on the manufacturer’s list of ADR’s, or
2. The distributor has a written agreement currently in effect with the manufacturer, or
3. The distributor has a verifiable account number with the manufacturer (by phone check or invoices with account numbers), and a minimal transactional or volume requirement as follows:
 - 5000 sales units (unit is the manufacturer unit of sale, e.g., bottle of 100 100 mg. tablets) within 12 months, or
 - 12 purchases (invoices) from the manufacturer within 12 months.

PDA Comments on Selected Goals, Plans And Questions Posed By The Food And Drug Administration’s Counterfeit Drug Task Force Interim Report (November 3, 2003). This revised definition is more stringent than that provided in the 1988 Guidance, but removes control over ADR status from the hands of manufacturers and provides objective verifiable criteria for ADR status.⁶

⁶ Below, the PDA separately requests that the FDA issue a revised definition of ongoing relationship through promulgation of an Agency Guidance document.

Given that there appears to be agreement between industry and the FDA on the anticompetitive impact of §203.3(u) in its present form, implementation of this provision should be stayed and its effective date suspended until one year after the FDA issues a reconsidered regulation.

C. The Scope of the Pedigree Requirement Must Continue to Be Stayed

As is evidenced by the long history of the controversies surrounding the scope of the pedigree requirement set forth in Section III.A above, PDA and other trade associations have diligently attempted to achieve a legislative solution, although these efforts have not been successful. The legislative discussions initiated on these subjects by FDA and by PDA and others were not frivolous and were pursued in good faith.

The issues presented by the FDA's PDMA Report to Congress and by PDA to the Congress are serious ones regarding the effect of FDA regulation on a significant number of businesses, most of them small businesses. Indeed, the SBA filed a petition on this point – a petition that remains pending. In July 2003, the PDA filed with FDA a Memorandum of Law outlining the FDA's current authority to revisit and revise the final regulation set forth at 21 C.F.R. § 203.50(a)(6) and to issue, through proposed regulations under its formal notice and comment procedures, a revised regulation consistent with the Agency's 1988 Guidance permitting pedigree to commence with a manufacturer or authorized distributor of record.

In light of the fact that FDA is faced with resolving these outstanding issues, as well as numerous legitimate questions raised by the CDTF in its Interim Report that strike at the heart of whether a paper pedigree requirement remains sensible at all, a continued stay and suspension of the effective date is clearly warranted. This is

particularly so because unless a continued stay and suspension of the effective date is granted as requested herein, PDA members will soon begin to suffer irreparable injury.

In its October 27, 2000 hearing testimony and in a letter submitted on November 3, 2000 to the FDA docket in this proceeding, PDA noted that if the final rule were to apply to drugs already in distribution as of the effective date of the final rule, a significant number of these drugs would have to be taken out of distribution because of the absence of a proper pedigree as defined by the final rule. What PDA stated in November of 2000 -- that if the final rule as published were to go into effect October 1, 2001, distributors would need to stop buying drugs that do not have the required pedigree under the final rule and would have to begin to exhaust existing inventories of drugs that do not have acceptable pedigrees by the beginning of the year 2001 to avoid economic harm -- is equally true now with respect to the April 1, 2004 effective date.

PDA then sought a decision by FDA that the final rule not apply to prescription drugs already in distribution as of any new effective date so that those safe and effective approved drugs could continue to be distributed. Although FDA has granted extensions of the effective date, it has not yet interpreted the effective date to apply only to drugs first entering commerce on that date as PDA has requested. PDA herein reiterates its request that in granting a stay of the regulation, FDA issue an interpretation which states that only drugs first shipped by a manufacturer into interstate commerce after any new effective date shall be required to be in compliance with the reconsidered final regulation and that the new final regulation be made to be effective one year after its publication, the same time that was provided for affected parties to come into compliance that was granted with respect to the December 3, 1999 final rule.

PDA's request regarding the effective date is not an unusual or controversial request and it is common and usual for the FDA to make its regulations effective in this fashion. Doing so allows predictability and stability in commerce and business and assures that inventories of valuable safe and effective pharmaceuticals are not lost to the technicalities of a recordkeeping regulatory initiative. FDA's failure to grant this request in the past has had no reasoned basis.

There is also a substantial public policy in favor of small businesses, small businesses that will be most adversely impacted by the final rule unless the stay requested herein is granted. Moreover, there is a substantial public policy against concentration in the wholesale prescription drug industry. FDA's PDMA Report to Congress describes five major wholesalers, but since its publication, mergers have reduced that number to three. See *e.g.*, CDTF Interim Report, p. 7 ("There are three large wholesalers who account for about 90% of the primary wholesale market"). The public policy against market concentration will be advanced if the relief requested herein is granted.

The stay requested herein and the resulting delay in the implementation date of these portions of the final rule are not outweighed by public health or other public interests. FDA and the prescription drug wholesale industry have operated under the 1988 Guidance for fifteen years. And FDA has already stayed the effective date of the final rule from December 4, 2000 to April 1, 2004. Continuing to operate under the 1988 Guidance, until the efforts of PDA, other trade associations, and FDA to continue to work through the issues presented by the PDMA Report To Congress and the CDTF Interim Report, to analyze FDA's current authority to implement technological solutions as an alternative to paper pedigree requirements, and/or to seek a more comprehensive

solution to perceived weaknesses in PDMA in Congress does not deserve the public interest.

Accordingly, implementation of 21 CFR § 203.50 in its present form should be stayed and its effective date suspended until one year after FDA issues a reconsidered final regulations regarding the scope of the pedigree requirement under PDMA.

D. FDA Has The Authority To Issue An Agency Guidance Document Setting Forth the Guidelines For Public Comment

This petition separately requests that the Commissioner of FDA issue a draft Agency guidance document for public comment under 21 C.F.R. § 10.115 that incorporates the Guidelines attached hereto in the form of a Guidance Document Submission as Appendix A.⁷

The Guidelines do essentially two things, both of which FDA has the authority to implement through issuance of a draft guidance document for public comment. First, through their definition of ADR, they propose an interpretation of PDMA's definition of "ongoing relationship." Second, they propose a system of due diligence checks, which, if followed, will help ensure the integrity of the drug supply.

FDA has ample authority to issue a draft Guidance for public comment as requested herein. As an initial matter, it is clear that an Agency guidance document need not originate with the Agency. Under 21 C.F.R. § 10.115(f), the public can suggest areas for guidance document development and can submit drafts of proposed guidance for FDA to consider. 21 C.F.R. §§ (f)(1)-(2).

⁷ These Guidelines (with slightly different definitions) have also been adopted by HDMA.

It is equally clear that FDA may issue a guidance document for the purposes of describing the agency's interpretation of or policy on a regulatory issue. 21 C.F.R. § 1-115(b)(1). Indeed, FDA does this routinely. See *e.g.*, Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of The Federal, Food & Cosmetic Act (Sept. 1999) (setting forth guidance, including various definitions, on qualifying for pediatric exclusivity under Section 505A of the FDCA while final regulations on that subject are not yet in place).

By implementing the definition section of the proposed Guidelines, FDA would be doing no more than it has routinely done before: it would be providing a slightly revised and more stringent (from the 1988 Guidance) interpretation of "ongoing relationship" pending finalization of the regulations. It is clear that the Agency is authorized to do this in the form of a Guidance document because it did so in 1988. See *also* 21 C.F.R. § 10.115(c)(1) (explaining that a "Level 1" guidance document as including those that set forth initial interpretations of statutory or regulatory requirements; set forth changes in interpretation or policy that are of more than a minor nature; or cover highly controversial issues).⁸

The balance of the Guidelines essentially sets forth a series of due diligence voluntary mechanisms through which those in the prescription drug distribution chain may help ensure the integrity of the drug products that they buy and sell, i.e., that these drug products are not being bought from wholesalers who might be wholesalers of drug

⁸ The PDA notes that this definition could alternatively be implemented by the Agency through formal rulemaking procedures. The PDA has elected to request that the Agency issue these definitions in the form of a draft Guidance for public comment as PDA believes that this is a more efficient method for getting the definition in place.

products that are adulterated or misbranded. The CDTF, in their Interim Report, flagged this very issue as one that needed to be addressed. The CDTF stated that:

lack of high level of diligence by members of the U.S. drug distribution chain can facilitate the introduction of counterfeit drugs into the U.S. drug supply. Investigations performed by Federal and State authorities have repeatedly shown the existence of illicit nationwide networks designed to capitalize on the inadequate due diligence performed by members of the drug distribution system in order to introduce potentially unsafe diverted and counterfeit drugs into the distribution system.

CDTF Interim Report, p. 10.

Not only is it clear through the CDTF Interim Report that FDA should be interested in maximizing industry standards for due diligence, it is also crystal clear that the CDTF believes that FDA has the authority to issue guidance on it. In its Interim Report, the CDTF envisioned “[i]ssuance of a guidance document concerning physical site security and supply chain integrity.” CDTF Interim Report, p. 26. Surely this would not have been an option on the table if the CDTF believed such an activity to be beyond the authority of FDA. In fact, nothing in the Agency’s Good Guidance Practices regulation precludes issuance of an agency guidance document on such topics.⁹

The Good Guidance Practices regulation expressly permits issuance of guidance on FDA’s “inspection and enforcement policies.” 21 C.F.R. § 10.115(b)(2). Indeed, FDA’s Office of Regulatory Affairs routinely publishes such guidance in the form of Compliance Policy Guides (“CPGs”). See *e.g.*, Compliance Policy Guidance for FDA Staff and Industry: Pharmacy Compounding, Section 460.200 (setting forth guidance on

⁹ By regulation, the only items that may not be issued in the form of Guidance documents are: documents relating to internal FDA procedures, agency reports, general information documents provided to consumers or health professionals, speeches, journal articles and editorials, media interviews, press materials, warning letters, memoranda of understanding, or other communications directed to individual persons or firms. 21 C.F.R. § 10.115(b)(2). The Guidelines cannot reasonably be characterized as falling into any of the prohibited categories of guidance.

what types of compounding might be subject to enforcement action under the current law, and outlining therein the factors that FDA will consider with regard to its determination whether or not to take enforcement actions under the new drug, adulteration, or misbranding provisions of the FFDCA).

It is PDA's view that the Guidelines could also form the basis of an Agency enforcement policy that creates a "safe harbor" from any strict criminal liability that might attach under FFDCA § 301 with respect to the unknowing, unintentional and non-negligent commerce in counterfeit or otherwise unlawful prescription drugs.

Finally, as a policy matter, putting the Guidelines in place now through issuance of a draft Guidance document for public comment makes sense. FDA is continuing to analyze 21st Century technology and the other information it received in response to the CDTF Interim Report to determine whether it currently has the authority to do more vis-à-vis anti-counterfeiting efforts, or whether it will need to approach Congress with a more comprehensive plan. If the history of these regulations tells us anything, it tells us that this effort will take time. Given that this is the case, and given that counterfeiters are not going to stop their bad behavior, it only serves the public interest to issue voluntarily guidelines that the trade believes will help ensure the integrity of the products reaching the American consumer.

IV. CONCLUSION

For the reasons set forth above, the PDA respectfully requests FDA continue the stay and to suspend the effective date of 21 C.F.R. § 203.50 and 21 C.F.R. § 203.3(u), which are presently scheduled to go into effect on April 1, 2004, and that in connection

APPENDIX A

Guidance Document Submission

Recommended Guidelines for Pharmaceutical Distribution System Integrity

Preamble

Prescription drug wholesalers, like all nongovernmental entities, do not have the investigative powers and resources to guarantee that certain products are not counterfeit. But they are uniquely situated to perform due diligence in order to protect the integrity of the pharmaceutical distribution system. Even with due diligence, in today's fast paced, just-in-time market, it is not always possible to determine the authenticity of specific prescription drugs being offered for sale. But rigorous due diligence can establish whether the sources of those prescription drugs meet certain criteria which provide a greater level of assurance that those sources are legitimate and present no reasonable probability of distributing counterfeit prescription drugs.

Experience with counterfeit drug distributors indicates that they are distinctly different from legitimate prescription drug wholesalers. Therefore, the first step in defining due diligence criteria is to identify the pertinent characteristics shared by legitimate prescription drug wholesalers. Once identified, these pertinent characteristics are the basis for the due diligence requirements contained herein. The logical nexus between the characteristics of legitimate prescription drug wholesaler and the due diligence criteria is an important safeguard to help assure the integrity of the prescription drug distribution system without disadvantaging law abiding wholesalers.

Legitimate prescription drug wholesalers share the following pertinent characteristics:

1. Their business is structured as a "going concern"
2. They demonstrate appropriate financial responsibility
3. They have robust operational standards
4. They have rigorous compliance systems
5. They can demonstrate their corporate and compliance history

An entity that does not display these characteristics may be identified as a suspect source of prescription drugs, or a source that may present an unreasonable risk to the integrity of the pharmaceutical distribution system and the public health.

The due diligence criteria and due diligence best practices in this guideline have been designed to identify facts and information about an entity that would demonstrate whether that entity displays the characteristics of a legitimate prescription drug wholesaler or, in the alternative, is reasonably likely to be a suspect source of prescription drugs. It is recommended that a prescription drug wholesaler:

1. Independently apply these Guidelines when evaluating proposed purchases from prescription drug wholesaler;
2. Use the due diligence best practices to determine whether the source of the prescription drugs meets the due diligence criteria; and
3. Purchase prescription drugs from sources that substantially demonstrate the characteristics of a legitimate prescription drug wholesaler in accordance with 2, above.

These Guidelines, therefore, outline best practices for the exercise of due diligence by prescription drug wholesalers to enhance the detection and elimination of illegitimate sources which market counterfeit products.

The public interest in drug product safety and efficacy is well served by this industry effort to detect and prevent counterfeit products from entering the prescription drug distribution pipeline in the United States.

I. Initial Information Request

When a prescription drug wholesaler is considering making purchases from another prescription drug wholesaler for the first time, it is recommended that a completed information request be obtained from the prospective selling wholesaler prior to the purchase. The information request should include the following information and it is recommended that this information request be updated annually:

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 number(s). (Note: purchaser is advised to check to ensure expiration dates have not passed);
2. The company's most recent site inspection(s) dates and inspection reports or resolutions (both state and federal inspections);
3. The minimum liability insurance limits the company maintains including general as well as product liability insurance;
4. All other "doing business as" (d/b/a's) names, and formerly known as (f/k/a's), including all affiliated businesses;
5. A complete list of all corporate officers;
6. A complete list of all owners of greater than 10 percent of the business unless it is a publicly-held company;
7. A list of all disciplinary actions by state/federal agencies against the company as well as principals, owners or officers over the last ten years, or since the company was first licensed, or any of the listed individuals were first in the prescription drug wholesale business;
8. The number of employees at the facility and screening procedures for hiring;
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.
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 from each country identified in 10a;
 - 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?
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).
12. A list of the classes of trade (e.g., manufacturer, wholesale, retail, hospital, institutional, clinics, etc.) the seller is purchasing from or selling his/her product from or to.
13. Available financial statements or SEC filings.

14. Systems and procedures in place for prompt reporting of any suspected counterfeit, stolen or otherwise unlawful prescription drug products or buyers or sellers of same to the appropriate state and federal authorities and manufacturer(s) of the product(s).

II. Certification of ADR Status

If the selling prescription drug 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 independently verify the seller's ADR status on the initial purchase and then at least annually thereafter.

III. Background Check

It is recommended that the purchaser conduct a background check of any prescription drug wholesaler it conducts business with prior to the initial transaction. This background check should include:

1. Subject to the requirements of the Fair Credit Reporting Act:
 - a. A criminal background and criminal and civil litigation check of all company officers, key management, principals and owners with 10 percent or greater interest in the company (the latter applying to non-publicly held companies only);
 - b. A driver's license and social security verification of all company officers, key management and owners;
 - c. Before completing a background check on the referenced individuals in 1a and 1b above, the purchaser must obtain the written consent of each such individual, clearly indicating how the information will be used. If the purchaser decides not to purchase from the prescription drug wholesaler based on the background information obtained, the purchaser must notify the individual (orally or in writing) in accordance with the notice requirements of the Fair Credit Reporting Act, 15 U.S.C. §1681(a);
2. A credit history maintained by an independent third party credit evaluation organization;
3. A check of the national database of licensed prescription drug wholesalers (if such a database is created);
4. A check to determine if civil/criminal litigation exists against the company; and
5. Verification of the date of incorporation and years in business, place of incorporation and form of entity.

IV. Physical Site Inspection

It is recommended, prior to an initial purchase, that a purchaser conduct a physical site inspection(s) of any prescription drug wholesaler seller it intends to do business with to ensure that the company's facility(ies) is/are in compliance with appropriate storage and operational conditions and practices. These inspections should be conducted on a biannual basis. A third party, so long as not a prescription drug wholesaler, may be used to conduct the inspections on behalf of the purchaser. A standard checklist for site inspections should be utilized and incorporate the following:

Administrative/Management

It is recommended that the purchaser:

1. Establish the authority, training, and experience of each individual providing the required information to them on behalf of the seller and each individual who controls and is responsible for the direct supervision of all persons who inspect, handle or have access to prescription drug products;
2. Request and examine the seller's organizational chart to identify key management and structure of the company; and
3. Verify the number of employees at the facility.

Building (size, physical conditions, etc.)

It is recommended that the purchaser check the

1. Structural appearance and general integrity based on a visual inspection;
2. Square footage;
3. Year of construction;
4. General security and alarm system;
5. Climate control; and
6. Surrounding area (e.g., zoning)

Operations

It is recommended that the purchaser examine the following:

1. Documentation of PDMA compliance status including receipt and provision of “identifying statements,” ADR status, requirements for PDMA compliance guarantees, recordkeeping and compliance with state and federal laws relating to the purchase and sale of prescription drugs.
2. Procedures for stock rotation;
3. Policies and procedures for conducting inspections of samples of product purchases;
4. Visually inspect a sample of the seller’s product;
5. Temperature monitoring program and documentation;
6. Systems/procedures for detecting adulterated/misbranded product, including systems and procedures to verify that manufacturer-identified anti-tampering devices are intact;
7. Systems/procedures for validating Identifying Statements;

8. Condition of medical product inventory in the warehouse;
9. Compliance with 21 CFR 1304.22 DEA recordkeeping requirements; and
10. Form of payment the seller uses to purchase product.

V. Seller Qualification

Once the site inspection has been completed, the results should be discussed with those employees or representatives of purchaser who are responsible for approving new suppliers. If the seller’s background check, the completed information request, and the site inspection are determined to be satisfactory and the purchaser obtains the appropriate internal approval of the new supplier, the seller should execute signed agreements or contract provisions with language specific to PDMA compliance and compliance with all state and federal laws relating to the purchase and sale of pharmaceuticals and that the purchaser will be notified if the seller receives information that the integrity or legal status of prescription drugs sold to purchaser has been called into question by the manufacturer, retailers, wholesalers, or state or federal authorities. The signed agreements should include language stating that the seller agrees to notify the purchaser of any changes in its information request within 30 days.

VI. Ongoing PDMA Compliance Review

It is recommended that the purchaser conduct ongoing compliance reviews and document all findings. These reviews should include:

1. Verifying that the seller is meeting the requirements for obtaining an “Identifying Statement”, and that the “Identifying Statements” contain the required information;

2. Verifying that the seller has an effective process in place to authenticate the accuracy and integrity of the "Identifying Statement."
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.

VII. Additional Purchaser Responsibilities

In addition to all the previous steps, it is also recommended that the purchaser:

1. Maintain an internal company list of non-complying/at risk companies that are not reputable, or otherwise suspect, whose products prescription drug wholesaler would not purchase, based upon prior experience or other criteria;
2. Maintain an internal list of non-complying/at risk products (i.e. biologics, previously counterfeited drugs) that the prescription drug wholesaler would not purchase from a non-manufacturing vendor (NMV) or non-ADR;
3. Have systems and procedures in place for prompt reporting of any suspected counterfeit, stolen or otherwise unlawful prescription drug products or buyers or sellers of same to the appropriate state and federal authorities and manufacturer(s) of the product(s).
4. Cooperate with state and federal regulatory authorities by promptly providing copies of requested records and other information relevant to administrative, civil and criminal investigations related to prescription drug products.

Definition of Authorized Distributor of Record

1. The distributor appears on the manufacturer's list of ADR's, or
2. The distributor has a written agreement currently in effect with the manufacturer, or
3. The distributor has a verifiable account number with the manufacturer (by phone check or invoices with account numbers), and a minimal transactional or volume requirement as follows:
 - a. 5000 sales units (unit is the manufacturer unit of sale, e.g., bottle of 100 100 mg. tablets) within 12 months, or
 - b. 12 purchases (invoices) from the manufacturer within 12 months

APPENDIX B

MEMORANDUM

TO: The Food and Drug Administration

FROM: The Pharmaceutical Distributors Association

DATE: July 23, 2003

SUBJECT: Authority Under the Federal Food, Drug, and Cosmetic Act to Strengthen Minimum Requirements for State Licensure of Prescription Drug Wholesalers and to Require Anti-Counterfeiting Technologies in the Manufacture of Prescription Drugs

I. Introduction

The Pharmaceutical Distributors Association ("PDA") is a trade association of licensed prescription drug wholesalers. This is one of two memoranda that the PDA is providing to the Food and Drug Administration in support of PDA's position that FDA has the legal authority to implement the Prescription Drug Marketing Act, as amended,¹ in a fashion that will preserve the businesses of small licensed prescription drug wholesalers and provide 21st century protections to the prescription drug supply.

In this memorandum, PDA describes examples of various regulatory measures that the FDA is currently authorized to implement in its effort to combat counterfeiting of prescription drug products and distribution of adulterated drugs. Specifically, for the reasons set forth below, it is PDA's position that FDA is authorized under existing law to tighten the minimum standards for state prescription drug wholesaler licensure to significantly reduce the likelihood that felons or other unqualified individuals are licensed to wholesale prescription drugs. FDA is also currently authorized to require manufacturers of new prescription drugs to use anti-counterfeiting and anti-tampering technologies to significantly increase industries' and the Agency's ability to protect against counterfeiting, tampering, and adulteration.

PDA understands that FDA launched a major initiative to more aggressively protect consumers from counterfeit drugs on July 16, 2003. The PDA strongly supports efforts to effectively and practically protect the prescription drug supply against counterfeit, adulterated or misbranded products. That effort should allow licensed legitimate businesses, large and small, to continue to distribute prescription drugs so that prescription drugs remain available at competitive prices. PDA supports FDA's creation of an internal Counterfeit Drug Task Force to explore the use of modern technologies and other measures to make it more difficult to counterfeit drugs and to distribute them. The PDA provided information to FDA's contractor with respect to the Agency's June 2001 Report to Congress on the PDMA, and stands ready and willing to provide the Task

¹ Pub. L. 100-293, as amended by the Prescription Drug Amendments of 1992, Pub. L. 102-353.

Force with any additional information that it or its members may have that would be useful to the Task Force.

II. FDA Has The Authority To Strengthen The Minimum Standards For State Licensing of Prescription Drug Wholesalers

PDA worked cooperatively with State of Florida authorities in their successful effort to pass legislation to strengthen wholesale distributor licensing requirements. FDA should exercise its existing authority to propose and promulgate regulations to strengthen the minimum standards for state licensing.

The PDMA amended the Federal Food, Drug & Cosmetic Act (“FFDCA”) by providing, in pertinent part, that:

(A) No person may engage in the wholesale distribution in interstate commerce of drugs subject to subsection (b) in a State unless such person is licensed by the State in accordance with the guidelines issued under subparagraph (B)

(B) The Secretary shall by regulation issue guidelines establishing minimum standards, terms, and conditions for the licensing of persons to make wholesale distributions in interstate commerce of drugs subject to subsection (b). Such guidelines shall prescribe requirements for the storage and handling of such drugs and for the establishment and maintenance of records of the distributions of such drugs.

FFDCA, § 503(e)(2).

Thus, FDA was directed in 1988 to issue guidelines establishing minimum requirements for licensing. These guidelines were also required to prescribe requirements for drug storage/handling, and maintenance of drug distribution records. FDA did this via final regulations set forth in 21 CFR Part 205. 55 Fed. Reg. 38012 (September 14, 1990). In the final rule, FDA made clear that States are free to adopt standards that exceed the FDA-established minimum requirements. *See e.g., id.* at 38013.

The minimum qualifications for licensing are currently set forth at 21 CFR § 205.6. In that section, FDA sets forth a list of non-exclusive factors that the State must consider when assessing a wholesale prescription drug license application, including the applicant's: past convictions (including felonies); past experience in the manufacture or distribution of prescription drugs; furnishing of false or fraudulent material in any application made in connection with drug manufacturing or distribution; compliance history under previously granted licenses (including consideration of any suspension or revocation thereof and compliance history with regard to maintenance of required records). 21 CFR § 205.6(a)(1)-(7). The state licensing authority is also free to consider other factors it considers relevant to and consistent with the public health and safety. 21 CFR § 205.6(a)(8). A state may deny a license to an applicant if it “determines that the granting of such a license would not be in the public interest.” 21 CFR § 205.6(b).

In its summary of § 205.6 in the preamble to the final rule, FDA stated,

[t]he agency believes that careful screening of applicants is necessary and prudent in reducing the opportunities for diversion of prescription drugs. State authorities must consider an applicant's history, which may reflect upon the applicant's ability to prevent drug diversion. Where granting a license would not be in the public interest, State authorities may deny a license to an applicant.

55 Fed. Reg. 38012, 38012 (Sept. 14, 1990). In the Preamble to the final rule, FDA specifically “declined” to set a federal standard for what was meant by “not in the public interest.” *Id.* at 38018.

FDA is authorized by PDMA to do more than it has done with regard to establishing minimum standards for state licensure while leaving the states vested with, and primarily responsible for, licensure. For example, FDA could, consistent with the mandate of FFDCFA § 503(e)(2)(A) & (B), affirmatively require the state licensing authority to investigate an applicant’s prior violations relating to the handling of prescription drugs, *and affirmatively preclude that authority from granting a license to an applicant with any such history.* Stated differently, FDA can and should by regulation identify a non-exclusive, categorical, list of prescription drug-related or fraud-related activities that are “not in the public interest” and accordingly require the states to deny licenses for individuals with criminal records in these activities. FDA likewise has the authority under § 503(e)(2)(A) & (B) to determine that certain other minimum protective measures must be in place before a wholesale distributor license can issue, such as a requirement that the licensee carry a bond and/or carry product liability insurance.

Using the authority of existing law to promulgate stronger minimum requirements for state licensure in light of new information and threats to the integrity of the prescription drug supply raises no legal issues and should not be controversial. Where the FDA is authorized to establish minimum requirements, as it is undoubtedly the case here, and where more is needed to adequately implement congressional concerns about the integrity of prescription drugs, FDA has the authority to revisit its regulations and to strengthen them to better effectuate the intent of Congress.

There can be little question that more stringent state licensure requirements are warranted. Notwithstanding the current statutory and regulatory scheme, drug counterfeiting and the adulteration of drugs in the wholesale distribution system is on the rise. In response to these continuing problems, at least one state – Florida -- has enacted wholesale distribution licensing legislation that is significantly more stringent than the standards promulgated by FDA under PDMA. *See Florida Prescription Drug Protection Act, S.B. 2312.* The Florida Prescription Drug Protection Act tightened the prescription drug wholesale distribution application process by requiring extensive sworn background information, fingerprints, and a statewide and national criminal background check. In addition, applicants for a prescription drug wholesaler permit must submit a bond of \$100,000 (or other equivalent means of security) to the Florida Department of Health.

The Department of Health is authorized to deny an application for a permit for no less than eighteen separate reasons, including the following:

- management, officers, or directors of the applicant or any affiliated party are incompetent or untrustworthy
- lack of experience in distribution of prescription drugs
- lack of experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health, or to jeopardize the reasonable promise of successful operation;
- past experience in manufacturing or distributing prescription drugs that indicates that the applicant poses a public health risk;
- affiliation (directly or indirectly) with any person or persons whose business operations are or have been detrimental to the public health;
- guilty finding or plea, or nolo contendere plea by applicant or affiliated party to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country;
- applicant or affiliates are currently charged with a felony;
- applicant has submitted false information to Florida or any other state in connection with obtaining a distribution permit
- any distribution permit previously granted to applicant or affiliated party by any federal, state, or local authority has been disciplined, suspended, or revoked
- lack of financial and physical resources to operate in compliance with the permit
- receipt of financial support/assistance by applicant or any affiliated party by a person whose permit was subject to discipline, suspended, or revoked
- receipt of financial support/assistance by applicant or any affiliated party from a person found guilty of any violation of Florida drug laws or regulations, or any federal or state drug law, or any felony where the underlying facts relate to drugs
- failure to comply with requirements for distribution of prescription drugs under Florida laws, similar federal laws, similar laws in other states, or regulations adopted under such laws.

These are the kinds of factors that should be considered by FDA in proposing stronger requirements for state licensure.

III. FDA Has The Authority To Require Manufacturers of New Drugs to use Anti-Counterfeiting Technologies

FDA likewise has the current authority to require use of anti-counterfeiting/anti-tampering technology to protect the integrity of prescription drugs and their packaging. Although FDA has recently stated that, "PDMA does not envision the use of modern technologies that can assist with tracking or verifying the authenticity of legitimate

prescription drugs,”² nothing in PDMA limits its use. Indeed, FDA appears to have already determined – both through the materials provided in connection with its announcement of its recent Anti-Counterfeiting initiative, and through comments it has made about these technologies elsewhere, that imposing a requirement to utilize these technologies is within the ambit of FDA’s authority. In FDA’s view, the new drug regulatory provisions of the FDCA, as amended, provide ample authority to require the use of such technology.

Specifically, in the Agency’s recent proposed rule to require certain drug product and biological product labels to carry bar codes, FDA contemplated requiring use of non-linear technologies, such as radio frequency identification (“RFID”). In describing these non-linear technologies, FDA stated,

We realize that other technologies may be able to encode more data or be more versatile compared to linear bar codes. For example. . . .RFID’s ability to track individual items could help drug companies and public health agencies identify and eliminate counterfeit drug products.

68 Fed. Reg. 12499, 12509 (March 13, 2003). Although FDA declined to specify the use of nonlinear technologies in the bar code proposal due to concerns about costs, it solicited comments about the use of other technologies and formats as part of the on-going rule making process. *Id.* at 12509-10.

FDA’s recent announcement regarding its Anti-Counterfeiting initiative makes clear that FDA has determined that it possesses the authority under the FDCA to require use of these modern technologies to protect the integrity of the prescription drug supply. Thus, FDA states that its new Task Force will explore:

Technology. The task force will examine currently available and potential, future, low-cost technologies that can be used to assure product and package integrity and track legitimate products through the distribution chain. Known technologies include those visible to the naked eye, such as inks and watermarks. These features could be used with existing packaging and the existence of such a mark would help consumers and pharmacists identify counterfeit drugs. In some cases covert features may be used to authenticate products when used with special equipment (e.g., magnifying lens, special lamps). However, one limitation of packaging technologies is that, if they are not linked inextricably to particular drug product (e.g., using marks on “blister packs” or similar technology), it is possible that counterfeiters would repackage illegitimate drugs in legitimate packaging. Moreover, it may be costly and time-intensive to use the tools required to authenticate such printed package labels. In addition, incorporation of one or more substances into the drug product itself, (e.g., taggants) may also be useful

² www.fda.gov/oc/initiatives/counterfeit/background.html (July 16, 2003).

in distinguishing legitimate from counterfeit drugs. Technologies are being developed to track products through the distribution chain. These include bar coding and radio frequency chips. These technologies are able to transmit a great deal of very specific information about the product and can enable distributors and retailers to track products through the entire distribution network. Although many of these technologies are not now mature and have limitations, and further cost-benefit analysis is needed, they offer great promise as counter-measures to make legitimate prescription drugs more secure from counterfeiters.³

As FDA determined was the case with its proposed bar-coding requirements, various provisions of the FFDCA authorize FDA to issue regulations requiring use of technology to assure that new drugs are not adulterated or misbranded while in interstate commerce or held for sale. In particular:

- Section 502(a) of the FFDCA prohibits false or misleading labeling of drugs. This prohibition includes, under section 201(n) of the act, failure to reveal material facts relating to potential consequences under customary conditions of use. Information that could be readily accessed through the use of these technologies, such as the authentic nature of the drug, is material with respect to consequences which might result from use of the drug under customary conditions of use.
- The premarket approval provisions of the FFDCA authorize FDA to require that prescription drug labeling provide the practitioner with adequate information to permit safe and effective use of the drug product. Under section 505 of the act, FDA approves a new drug application (“NDA”) only if the drug is shown to be safe and effective for its intended use under the conditions set forth in the drug's labeling. Use of anti-counterfeiting/anti-tampering technologies will ensure the safe and effective use of drugs by reducing the incidence of ingestion of fake, subpotent, or contaminated products. Such technology could allow those in the distribution system to verify that an authentic product is being provided.
- Section 505(b)(1)(D) requires an NDA to contain a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug. The same requirement exists for abbreviated new drug applications (see section 505(j)(2)(A)(vi) of the FFDCA). Anti-counterfeiting technology would confirm that the facilities and controls used to manufacture the product are those that are authorized by the NDA or the ANDA.
- Requiring use of anti-counterfeiting technologies would permit the efficient enforcement of the adulteration provisions of the FFDCA. A regulation requiring their use should avert unintentional mix up and mislabeling of drugs during labeling, packaging, relabeling, and repackaging. Anti-counterfeiting technologies therefore prevent adulteration under section 501(a)(2)(B) of the act. It is a manufacturing method or control necessary to ensure that a drug product

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www.fda.gov/oc/initiatives/counterfeit/background.html (July 16, 2003)

has the identity and strength its labeling represents it to have, and meets the quality and purity characteristics which the drug purports or is represented to possess.

Thus, use of anti-counterfeiting/anti-tampering technology in packaging for drugs would permit the efficient enforcement of the adulteration provisions of Section 501, the misbranding provisions in section 502(a), the safety and effectiveness provisions of section 505 of the FFDCA, as amended.

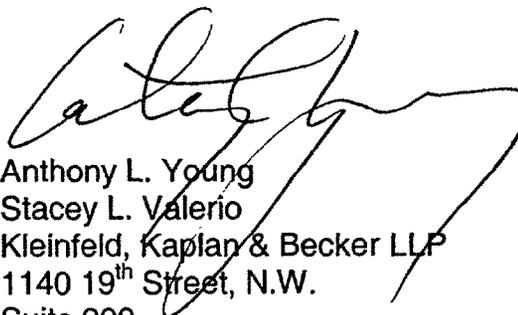
IV. Conclusion

FDA has ample authority to strengthen the minimum standards for state licensure and to require use of 21st Century technology to protect the integrity of the prescription drug supply.

with that stay, to issue a draft Agency guidance document for comment under 21 C.F.R.

§ 10.115 setting forth the Guidelines attached hereto as Appendix A.

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SUPREME DISTRIBUTOR

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561-241-1935

To: Our Valued Customers

From: Supreme Distributors

Subject: Recently Published "Recommended Guidelines for Pharmaceutical System Integrity"

As many of you are aware, the HDMA recently issued its "Recommended Guidelines for Pharmaceutical System Integrity", in an effort to combat the entry of counterfeit drugs into the drug supply.

In response to the publication, and as a sign of Supreme's commitment to the same goal, we will be implementing a comprehensive set of guidelines. Attached you will find our implementation plan, as well as a copy of the recently published HDMA guidelines.

You will notice that "full implementation" will take some time to accomplish. Certain areas can be achieved in a relatively short time frame, while others (particularly compliance with the new ADR standard) will require a longer time to achieve.

Supreme Distributors understands that different companies may have varying expectations of how and/or when the guidelines should be implemented. With that in mind, we thought it was important to present our plan to you so you could communicate any concerns or inconsistencies with what your expectations may be.

Again, thank you for your continued confidence and business!

Sincerely,

Sal Ricciardi
President & CEO

Bruce Krichmar
VP of Accounting & Pharmaceutical Compliance

Robin Salmeron
VP Sales & Purchasing

: Attached Implementation Plan

SUPREME DISTRIBUTOR

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SUPREME DISTRIBUTORS IMPLEMENTATION OF RECOMMENDED GUIDELINES FOR PHARMACEUTICAL DISTRIBUTION SYSTEM INTEGRITY

Supreme Distributors is beginning an immediate implementation of the recently released wholesale industry Recommended Guidelines for Pharmaceutical distribution integrity ("Guidelines"). Keeping in mind that certain portions will take some time to "fully" implement, the purpose of this communication is to describe our implementation plan and our proposed effective dates of each section (I-VII) and/or subsection within each section. A copy of the Guidelines is attached.

As you know, the Guidelines reflect the level of due diligence that should be exercised by a wholesaler buying pharmaceuticals from a non-manufacturer source. It is Supreme's plan to analyze all of the information it gathers on each of its non-manufacturer sources and then make a determination whether to continue to do business with that source.

Section I. Initial Information Request

- Supreme Distributors will immediately prepare a mailing to its non-manufacturer sources, requesting all of the information in items 1-14 of the "initial information request". Our initial mailing will address our Top 20 Sources and a subsequent mailing (no later than December 15, 2004) will go to the balance of our sources. Our target date for receiving all of this information back is January 31, 2004.

Section II. Certification of ADR Status

- Effective immediately, Supreme Distributors will ask all sources to prove compliance with the current ADR standard, (which is two (2) purchases in 24 months from a manufacturer). Our target date for completing these requests and receiving documentation from our sources is January 31, 2004.
- A migration to the new ADR definition as described in the Guidelines will require a "ramping up" period, and we expect full compliance from our sources with the new definition by December 31, 2004.

- We will request that our sources update our files every few months so we can monitor their progress towards achieving compliance with the new ADR criteria.

Section III. Background Check

- In regards to #1(a)–(c): Concerning criminal background checks, drivers license, and Social Security verification, we will institute the same phase-in period as in Section I above. We will send a request immediately to our Top 20 Sources and then a request to the remainder of our sources by December 31, 2003. Our Human Resource department will coordinate the conduct of all background checks required.
- Regarding #2 on the company credit history, we will run Dunn & Bradstreet reports on all sources.
- Regarding #3 which involved checking a national database of wholesalers, no such database currently exists. We will, however, validate the “good standing” of each source license with the appropriate state licensing authorities. This means that we will validate source licenses in the states where it has facilities and in the State of Indiana, where Supreme Distributors’ facility is located.
- Regarding #4, we will check public sources of information (via the internet), in an attempt to learn about any litigation (civil or criminal) involving the source.
- Regarding #5, we will again use the Dunn & Bradstreet report to verify the sources’ location, years in business, and corporate status.

Our target completion date for all items in this section is January 31, 2004.

Section IV. Physical Site Inspection

- The implementation of this section will require a “phase-in period” which we believe will be approximately 12 months (by December 31, 2004). **In the interim, we will immediately request copies of the most recent inspection reports our sources have received from their state licensing agency.**
- Following is our plan for each of the three (3) sections (Administration/Management, Building, and Operations):
 1. Administrative / Management
All items will be addressed in a mailing to our sources, which will request all information in this category. Again we will approach our 20 largest sources first and then contact the balance of our sources by December 31, 2003.
 2. Building

We will request this information to be submitted via mail, according to the schedule referenced in #1 above. All information will be verified during the site visit.

3. Operations

These are ten (10) items filed under this section and some will be requested via mail prior to the inspection, while others will be performed exclusively at the time of the actual inspection (as follows).

- Items 1, 4, 5, and 8 will need to be verified at the time of inspection. All other items will be included in our request for information and mailing that we will do according to the previously mentioned timeline (Top 20 Sources first, remaining sources by December 31, 2003). Also, information received via mail will be verified at the time of our inspection.

We anticipate all document requests in this section can be received and completed by January 31, 2004.

Section V. Seller Qualification

- Based upon all available information received, the President, VP of Sales and Marketing, and VP of Pharmaceutical Compliance of Supreme Distributors will review the information and make a decision whether to continue to do business with the source. If approved, we will execute a new guarantee and indemnification agreement with the source.

Section VI. Ongoing PDMA Compliance Review

- Supreme Distributors will perform certain ongoing PDMA compliance procedures throughout the course of its relationships with its sources including a review of the pedigrees we receive. Pedigrees are checked for completeness, as well as for names of sources who may be considered problematic.
- In addition, any pedigrees with more than three (3) entries after the ADR will be closely scrutinized and verified.
- Comparison on product price versus actual market price is a responsibility of the head buyer. In addition, the VP of Accounting and Pharmaceutical Compliance will check our inventory daily for any such pricing "irregularities".

Section VII. Additional Purchaser Responsibilities

- Supreme Distributors currently has procedures or documentation in place that address each of the four (4) items listed in this category. Specifically, we maintain a list of vendors who we will not buy from, and a list of products that

we won't buy from sources other than the manufacturer or from a full line wholesaler who purchases it from the manufacturer.

- Additionally, we have established processes for the detection of "unlawful" products and for the communication of these findings, both internally and externally. We also willingly participate and cooperate in any matters involving state and/or federal regulatory authorities.

Supreme Distributors is committed to protecting the drug supply and welcomes your comments or questions on any of the information contained herein.