AMERICAN FREE TRADE ASSOCIATION

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COMMENTS REGARDING RFID TECHNOLOGY AND PDMA IMPLEMENTATION
DOCKET NUMBER: 2005N-0510

Dear Sirs:

In response to the Federal Register notice of January 11, 2006, the American Free Trade Association (AFTA) respectfully provides these comments in response to specific inquiries relating to the delayed date of implementation of Sections 203.3(u) and 203.40 of the Prescription Drug Marketing Act (PDMA) and the feasibility of RFID implementation as a means of complying with those sections.

1. BACKGROUND ABOUT AMERICAN FREE TRADE ASSOCIATION

The American Free Trade Association is a not-for-profit trade association of independent American importers, distributors, retailers and wholesalers, dedicated to preservation of the secondary, parallel market to assure competitive pricing and distribution of genuine and

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legitimate brand-name goods for American consumers. AFTA has been an active advocate of parallel market interests for over twenty years. It has appeared as *amicus curiae* in the two leading Supreme court cases affirming the legality of parallel market trade under the federal trademark, customs and copyright acts (the *Kmart v. Cartier* case, 485 US 176 (1988) and *Quality King Distributors v. L'Anza Research International, Inc.* 523 US 123 (1998)) and in numerous lower court decisions.

2. BACKGROUND ON THE INDUSTRY AND THE ISSUE

In December 2005, the U.S. Department of Labor published a report about the wholesale trade industry (http://www.bls.gov/oco/cg/cgs026.htm) that details why this segment of the American marketplace is critical to the continued success of the U.S. economy.

> *Wholesale trade firms are essential to the economy. They simplify product, payment, and information flows by acting as intermediaries between the manufacturer and the final customer. They may store goods that neither manufacturers nor retailers can store until consumers require them. In so doing, they fill several roles in the economy. The provide businesses a nearby source of goods made by many different manufacturers; they provide manufacturers with a manageable number of customers, while allowing their products to reach a large number of users; and they allow manufacturers, businesses, institutions and governments to devote minimal time and resources to transactions by taking on some sales and marketing.*

In particular, the report cites statistics evidencing that the domestic wholesale trade industry, comprising primarily small businesses, accounted for approximately 5.7 million wage and salary jobs in 2004. Interestingly and of most import to this communication, when addressing the issue of potential growth in this obviously significant part of the domestic economy, the report specifically states that "*...due to the nation's aging population, growth is expected to be higher than average for wholesale trade firms that distribute pharmaceuticals and medical devices*" clearly confirming the government's belief that wholesale trade within the pharmaceutical supply chain is crucial to continued employment and provision of benefits to this clearly defined segment of the American population.

Similarly, in May 2005, Harvard student, Afia K. Asamoah[1], published a paper entitled "Not As Easy As It May Appear: Using RFID to Fulfill PDMA's Elusive Pedigree Requirement" (found at http://leda.law.harvard.edu/leda/data/728/Asamoah05.html). In this paper, Ms. Asamoah specifically discusses the impact of RFID on the wholesale drug industry, which she described as follows: *Wholesalers allow manufacturers to make bulk sales to one entity while consolidating the drug purchase process for drug retailers. As such, drug wholesalers provide a cost-effective, efficient means for the purchase, delivery and sale of prescription drugs.*

It is indisputable that drug wholesalers are vital participants in the national pharmaceutical supply chain and it is also a fact that implementation of RFID technology will most affect this sector of the economy, which by its very nature consists predominantly of small businesses providing critical and essential services for American consumers. In fact, the delay in

[1] 2005 JD Candidate

implementation of the subject sections of the PDMA is largely a result of the concerns of legislators and others about the impact of the pedigree requirement, electronic or otherwise, on small domestic businesses and particularly on the pharmaceutical wholesalers.

On May 16, 2000, in its Committee Report on the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill for 2001 (House Report 106-619), the House Committee on Appropriations commended the FDA on its delay in implementation of the PDMA citing specifically its belief that *"....the agency should thoroughly review the potential impact of the proposed provisions on the secondary wholesale pharmaceutical industry."* This concern for the impact of the regulations on the small wholesaler trade was echoed again when, in 2001, the same Committee applauded the FDA's decision to delay implementation of the pedigree requirement set forth in the PDMA stating in even more emphatic terms that *"The Committee is concerned about the potential impact of the proposed revisions on the secondary wholesale pharmaceutical industry. Specifically, the Committee is concerned that the rule in its current form may disproportionately favor a few large distributors at the expense of consumers and genuine competition in the marketplace. The Committee urges the FDA to revise the rule to address the Committee's concerns.* (House Report 107-116). The Small Business Administration also petitioned the FDA in 2000 to reconsider the final rule, projecting that implementation would have a significant economic impact on over 4000 small businesses[2].

[2] SBA's letter to the FDA can be found at http://www.sba.gov/advo/laws/comments/fda00_0229.html

The feasibility of RFID implementation has been an ongoing concern for small businesses because they may not be able to assume the costs of this technology. Moreover, there is ongoing debate about the potential security benefits of an expensive electronic tagging program that may be realized through less painful and costly means. Nevertheless, if the FDA and Congress are committed to an electronic technological means to ensure product integrity and security, AFTA - a national trade association specifically representing the needs of the wholesale trade industry - respectfully requests that it be included within the standards setting discussions and that it be considered a significant stakeholder as a necessary and critical component of the domestic pharmaceutical supply chain.

The following are specific responses to certain questions raised in the *Federal Register* notice, but do not purport to address all issues addressed therein or raised by other stakeholders.

3. SUMMARY POSITION

AFTA believes that the use of RFID technology may greatly enhance the security of the pharmaceutical supply chain and looks forward to becoming an active participant in the standards setting dialogue that must take place between all critical supply chain participants. The delayed enforcement of the PDMA's pedigree requirements is still requested. RFID standards necessarily need to evolve as the FDA develops information and experience which will allow it to better determine its role in overseeing implementation of the RFID technology in a manner best suited to protect the interests of American consumers in safe pharmaceutical products and, continued access to all types of competitive, cost-effective remedies.

4. IMPLEMENTATION OF RFID

What incentives are needed for more rapid and widespread adoption of RFID in the U.S. drug supply chain? How can these incentives be achieved?

Within the wholesaler industry, there is considerable concern not only about the costs of RFID adoption but also about the possible anti-competitive disclosure of proprietary business information. Confidential business information which is not intended to be disclosed to parties other than purchasers under the PDMA, may now be contained within the electronic product codes embedded in the RFID tags. If this information is accessible to all competitive supply chain participants—even those to whom disclosure is not required under the PDMA—there is a major disincentive, compelling wholesalers to avoid adoption of this technology. Without regulation satisfactorily protecting the confidential nature of proprietary business information, there is little doubt that RFID will be adopted not only as a means of ensuring product integrity but also as a method to eliminate competition within the marketplace.

As stated above, the wholesale pharmaceutical industry maintains a special relationship with American consumers by providing cost-effective drugs that may not otherwise be readily available. Oftentimes, these products are purchased directly from authorized distributors – or indirectly from them through their customers or other wholesalers – with excess inventory. Oftentimes, these sales occur without the original manufacturer's knowledge or explicit consent. It is a long-standing commercial reality that if a drug wholesaler or manufacturer is able to learn to whom another wholesaler sells its product, the second wholesaler may easily be bypassed in subsequent transactions, despite long-term and protected customer relationships. Manufacturers

might, alternatively, take punitive action against authorized distributors, whether or not authorized by its contractual arrangement, based upon this disclosure --- through RFID --- of protected information. The law has long treated the identity of customers and sources as a trade secret, in order to protect competition in pricing and distribution.

There is no reason for a supplier of the product to have access to the identity of the wholesaler's customer as part of the effort to ensure compliance with the PDMA and/or to otherwise protect American consumers from counterfeit or unsafe product. Yet, as a result of the FDA's promotion of RFID technology as a means of enabling compliance with the pedigree sections of the PDMA, without provisions to limit the disclosure or sharing of proprietary information, there is substantial reticence on the part of wholesalers reasonably concerned about their future business opportunities and advantages. Clearly, only the upstream information confirming the history of a drug up to the point it is sold to a particular recipient is of importance to that recipient in confirming the integrity or pedigree of the drug. In addition, utilizing a secure third party database administrator who can verify to such recipient that the drug has been properly traced back to its manufacturer is sufficient, in full compliance with the PDMA and in no way contradictory to the congressional intent of the authorizing legislation. Learning of a drug's downstream history does not further the goal of protecting the integrity of the stream of supply to a particular recipient; it simply provides competitively sensitive intelligence to upstream suppliers if they can gain access to it.

The PDMA requires that wholesalers be licensed and that purchasers receive a pedigree so that they may verify the authenticity and integrity of the pharmaceuticals they purchase. In

that regard, AFTA's members have worked tirelessly in the years since passage of the PDMA to ensure that these mandates are adopted in a form designed to avoid any impact on competition and/or product availability. Regulators must now similarly undertake measures to ensure wholesaler stakeholders that their businesses will not be threatened as a result of RFID adoption. Once such protective measures are put in place, AFTA is comfortable than many more secondary market and other wholesalers will put in place the necessary technology to ensure product authenticity and security.

5. RFID STANDARD SETTING

Who should set the standards for RFID? Is there a role for Federal leadership by FDA to advance the standard setting efforts? What is that role?

The FDA should take a leadership role in standards setting and should publicly and comprehensively include all categories of supply chain stakeholders in this exercise, including drug wholesalers and secondary market suppliers. It is not the FDA's role to encourage use of RFID to track and trace product distribution for anti-competitive purposes, and FDA should, in fact, publicly state its aversion to such a practice which in the majority cases is a business practice unrelated to the need to protect American consumers from anything other than a freely competitive marketplace.

The FDA should institute limits, rules, regulations and procedures for the use, dissemination and access to the information contained within the data tags and must take a leadership role in ensuring that this technology is not able to be used for any reason other than compliance with the PDMA. The FDA should insist that its reliance on RFID technology is as a tool to facilitate

compliance with the PDMA - a means of providing pedigrees to buyers – not sellers - of pharmaceuticals so that consumers may know that the drugs they purchase are safe and authentic. In this regard, the FDA should provide a database administrator to verify for pharmacists or other purchasers of pharmaceuticals that the product source is a duly licensed wholesaler or otherwise permitted to sell the drug.

6. UNIVERSAL PEDIGREE FIELDS

Are there logistical concerns or barriers to passing a pedigree for a drug that moves from one State to another with different pedigree requirements? Would a Universal pedigree alleviate these concerns or barriers? How? What common fields/information are the most important in a pedigree? Why?

Were it not concerned about the viability of the critical wholesale pharmaceutical industry, as Congress has agreed it should be, the FDA could easily overcome any logistic concerns that may exist at the states' level by adopting unreasonably strict pedigree laws that would prohibit distribution of pharmaceuticals outside of the "normal distribution chain" and/or which would require information in pedigrees that would be unavailable to unrelated third party wholesale distributors. But AFTA does not believe that this is the Agency's intention. The FDA should not be concerned with the hodgepodge of state pedigree laws that have been enacted since passage of the PDMA as it hopes to create a uniform system of wholesaler licensing and drug pedigree laws intended to protect American consumers against counterfeit drugs.

The PDMA was passed after a Congressional committee in the 1980s determined that drug diversion undermined the integrity of pharmaceuticals and threatened consumer safety.

Consumers needed a way to verify that their drugs had been manufactured by an FDA regulated drug manufacturer and had been supplied through businesses known to store, handle and distribute these products as necessary to maintain product safety and genuineness. As a result of this legitimate concern, many AFTA members have contributed to the efforts of the Pharmaceutical Distributors Association (PDA) and others to institute rigorous (yet fair) licensing requirements for wholesalers - to ensure that drugs are not diverted to anyone other than licensed wholesalers subject to best practices and similar requirements.

However, while AFTA members and certain trade associations have worked to ensure that properly licensed, legitimate wholesalers remain critical components of the regulated pharmaceutical supply chain in order that drugs not be diverted away from these recognized sources of unadulterated product, others have been working just as diligently to make sure that states' laws eliminate this critical wholesale trade by craftily defining what is and what is not a "normal distribution chain." There are different "model" pedigree laws adopted or proposed in the states by various drug manufacturers, which clearly have the impact if not the intent to eliminate secondary wholesalers that compete directly with these pharmaceutical companies.

State laws vary tremendously with some requiring pedigrees only from third party wholesalers, others requiring pedigree statements that are unreasonable for small businesses to maintain or gain access to and still others containing a convoluted definition of what may be a transaction within the "normal distribution chain." As a result, wholesalers – together with other small businesses – are urging federal oversight as the only means to provide uniformity and survival

The FDA's promotion of RFID technology as the preferred means of implementing the pedigree requirements of the PDMA will necessarily fail to adequately protect the critical stakeholders of this nation's legitimate pharmaceutical supply chain if each State is permitted to erect barriers to the free flow of competitive and cost-effective products to American consumers through enactment of complicated, confusing and contradicting state statutes. It is in the best interests of all supply chain participants for the FDA to implement universal federal pedigree requirements and standards binding upon all drug suppliers, whether "authorized" or otherwise. The FDA's implementation of the PDMA must create a uniform pedigree law that protects legitimately licensed wholesalers – even those outside of the manufacturer's preferred "normal distribution channel" - without compromising product integrity or sacrificing the health and safety of the American consumer.

Following are some recently enacted state laws to illustrate the differing standards that wholesalers and other small businesses must now struggle to simultaneously comply:

- In 2005, Arizona passed HB 2193 which become effective on August 12, 2005. That law, ARS §32-1981(4), defines a "normal distribution channel" as: *the chain of custody for a prescription-only drug that begins with the delivery of the drug by a manufacturer to a wholesale distributor who then delivers the drug to a pharmacy or a practitioner for final receipt by a patient. Normal distribution channel includes the receipt of a prescription-only drug by a common carrier or other delivery service that delivers the drug at the direction of the manufacturer, full service wholesale permittee or pharmacy and that does not purchase, sell, trade, or take title to any prescription-only drug.* The

pedigree must include the container size and number of containers with a certification that each recipient has authenticated the pedigree.

- In Connecticut, HB 6713 was signed in July 2005 and creates pedigree requirements from the manufacturer to any wholesaler or repackager and requires any such wholesaler to sell 95% of its inventory to a pharmacy.
- The Florida Drug Prescription Protection Act will require full pedigrees on all pharmaceuticals by July 2006 and the State is leading the way in recommending electronic pedigree technology. As of July 1, 2006, every person who is engaged in the wholesale distribution of a pharmaceutical except for the manufacturer must provide a pedigree that records each distribution from sale by manufacturer through sale by any wholesaler or re-packager until final sale to pharmacy or other person administering or dispending the drug. The pedigree must include the amount of drug, dosage form, strength, lot numbers, name and address of each owner and his or her signature, its shipping information, certification that the recipient has authenticated the pedigree papers, and the name, address and contact information of each wholesaler involved in the chain of custody.
- In Indiana, IC 25-26-14-8.5 defines the "Normal distribution chain of custody" as the route that a legend drug travels: (1) from a manufacturer to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent; (2) from a manufacturer to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent; (3) from a manufacturer to a

chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent; (4) from a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent; (5) from a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent; (6) from a manufacturer to a third party logistics provider, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent; or (7) as prescribed by rules adopted by the board.

- In California (SB 1307 2004), commencing on January 1, 2007, a pedigree *must* be in electronic form and must include: (1) The source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source; (2) The quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers; (3) The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

- New Jersey, Chapter 206 of the State Statutes, confusingly defines a pedigree as a statement or record identifying each previous sale of a prescription drug, from the sale by a manufacturer through acquisition and sale by a wholesale distributor, including each

distribution to an authorized distributor, starting with the last authorized distributor, or the manufacturer if the prescription drug has not been purchased previously by an authorized distributor or is a prescription drug on the specified list of susceptible products. A pedigree must include the following information: the proprietary and established name of the prescription drug; the dosage; container size; number of containers; the date, business name and address of all parties to each prior transaction involving the prescription drug starting with the last authorized distributor or the manufacturer if the prescription drug has not been purchased previously by an authorized distributor or is a prescription drug on the specified list of susceptible products.

- New Mexico's new law (Chapter 152) indicates that a pedigree is merely "the recorded history of a drug"

- Nevada's Administrative Code (NAC 609.603) provides that a pedigree is only required when the wholesaler selling the product does not have an "ongoing relationship" with the manufacturer of that drug. An "ongoing relationship" is established by (NAC 6059.594) *(a) Evidence of the existence of a written franchise, license or other agreement between a manufacturer and wholesaler to distribute prescription drugs; or (b) Evidence of the existence of two or more sales of a prescription drug to a wholesaler in any 24-month period.*

- Texas, HB 164, requires wholesale licenses of wholesale distributors of even non-prescription drugs and defines a "normal distribution chain" as "*a chain of custody for a*

drug from: (A) a manufacturer to an authorized distributor of record or to a wholesale distributor licensed under this subchapter to a pharmacy or practitioner to a patient; (B) a manufacturer to an authorized distributor of record to one other authorized distributor of record to a pharmacy or practitioner to a patient; or (C) a manufacturer to an authorized distributor of record to a chain pharmacy warehouse to a pharmacy or practitioner to a patient. The law also defines an "ongoing relationship" between a manufacturer and distributor as one requiring a written agreement between the parties and requires a pedigree for each prescription drug sold or distributed outside the "normal distribution chain."

These differences in state law not only compromise the feasibility of effective and desirable RFID implementation but also frustrate stakeholders committed to operating in an environment in which there appears to be joint Federal and State regulation without clear congressional oversight.

7. DATA MANAGEMENT AND SECURITY

One issue that has been raised is whether the data/information should be stored in one central database or if a distributed approach (where each stakeholder's system exchanges *information with other systems) should be used. Can/should the pedigree information be passed and authenticated using either model? If some stakeholders subscribe to a central database and others use a distributed approach, can the pedigree information still be passed and authenticated? If there is to be a central database, who should host it? Why?*

For all of the reasons already set forth in these comments, AFTA believes that there must be strict standards fostered by the FDA for RFID technology given its easy abuse by parties within the supply chain who are committed to depriving the marketplace of competition and fair price incentives. There must be an objective, centralized database and pedigree verification system which does not compromise proprietary trade secrets but works, instead, to only verify and authenticate the licensing status of each distributor within the supply chain and information related to original manufacture. Any other model for verification and authentication will destroy the competitive landscape and eliminate a vast number of wholesalers to the substantial detriment of American consumers.

AFTA appreciates that it is unlikely that the FDA, or any other federal governmental agency, will intentionally intercede in normal commercial transactions between manufacturers and their supply chain partners. To that end, AFTA understands that manufacturers will act, as they have historically, to stop any and all product distribution that occurs outside their control. Nevertheless, it is crucial that the FDA, as it publicly advocates for RFID standards and implementation, not encourage or promote standards that will foster this idea of a "normal distribution channel" that excludes wholesale distributors.

Only through third party maintenance of a verification database will the FDA be able to control possible abuse of information disclosure. That is, pharmacists and other consumers should be able to verify and authenticate through a federally administered database that the selling wholesaler is licensed in its state or through a federal licensing program to distribute the applicable pharmaceutical and that the drug was actually manufactured by the manufacturer

identified in the pedigree statement. However, that pharmacist and/or consumer should not be required, expected or encouraged to contact the manufacturer directly to verify that its commercial source (e.g. secondary distributor) had the "authority" of some unrelated, upstream supply chain participant to distribute that drug product. Not only would this compromise the competitiveness of the American marketplace by placing full marketplace control in the hands of a few aggressive domestic product manufacturers, but it would disclose the wholesaler's customers to the manufacturer itself thereby violating, with the sanction of the FDA, federal protections against violation of proprietary trade secrets (see *Economic Espionage Act of 1996).*

As stated above, the FDA should adopt universal pedigree requirements and standards that protect America's drug supply and *all* legitimate stakeholders. If the Agency is determined to promote a particular technology as a means of facilitating the PDMA it must do so with an objective eye towards the most beneficial and lawful means of ensuring compliance. For a federal agency to wonder and hypothecate over feasibility of such technology, concerned that domestic manufacturers and perhaps others may not want the FDA to protect legitimate business interests, is, frankly, an unacceptable debate and discussion.

The possibility that certain overzealous stakeholders may seize upon RFID technology to impermissibly and unlawfully share and disclose proprietary third party business information should not derail legitimate debate about whether, if properly regulated, this same technology may be relied upon to ensure American consumers of product safety and authenticity. The FDA should insist strongly that it will impose rules for purposes of verifying pharmaceutical pedigree but that those rules, with equal strength, will protect the small businesses operating within the

wholesale drug industry. Through adoption of a third party, centralized database, accessible only to an objective verifier or administrator, the FDA will be taking effective steps toward protecting the proprietary business information critical to small legitimate and duly licensed wholesalers throughout the country.

8. PRIVACY ISSUES

Is it possible for someone to read the information from an RFID tag on a drug product without the possessor of the product knowing it? If it is possible, what information would they learn, and how could the information be used?

The June 28, 2004 volume of The RFID Gazette (found at http://www.rfidgazette.org/2004/06rfid_101.html) describes the two types of electronic product tags available. "There are two types of RFID tags. An **active tag** uses its own battery power to contact the reader. It works over a greater distance than passive tags, but its larger size is its main drawback. On the other hand, a passive tag does not require a battery. Rather, a **passive tag** derives its power from the electromagnetic field created by the signal from the RFID reader." This same article, when boasting of the power of RFID technology in general, states that "Everyone in the RFID-enabled supply chain, from the manufacturers at the factory to the inventory trackers at the retail location, has the ability to instantly call up the location, condition, and supply of a particular product."

Although manufacturers and certain other supply chain participants may imbed products with active tags, which are accessible on a whim and at their option, it is also true that passive tags are less expensive to manufacture and may generally limit reading of the data to the

individual in close proximity to the product, i.e. the possessor of the good. In this way, the PDMA's pedigree requirements are simply met – the purchaser of any pharmaceutical will be able to read the tag and verify product authenticity preferably through a third party database verifier. If, on the other hand, parties other than the immediate owner of the product are encouraged to read electronic tags, whether because they are the more expensive active tags or similar technology, the breach of proprietary business confidential records will, without a doubt, eliminate the wholesale pharmaceutical industry, force American consumers to pay even more exorbitant prices for their much-needed drug products and limit availability of the most critical drug supply.

9. Small Business Impact

How has the potential impact of the 1999 rule on small businesses changed since the 2001 public meeting?

As stated above, members of the American Free Trade Association have been involved at both the state and federal level in the implementation of strict licensing regulations and best business practices for pharmaceutical wholesalers. Largely as a result of this investment, AFTA members may now, to a certain extent, be even more concerned about the potential impact of the 1999 rule.

The variety of states' laws have already created tremendous uncertainty in the marketplace. Unchecked, the domestic pharmaceutical manufacturers have managed to cause substantial damage to the industry by insisting that there is a "normal distribution chain" which must exclude wholesale distributors in order to guarantee product integrity and safety. The

Agency must take an active role in fostering re-emergence of the wholesale pharmaceutical industry as a means of providing American citizens with cost-effective, critical and oftentimes scarce drug supplies.

10. DELAY OF THE EFFECTIVE DATE

If the delay of the effective date is not extended, how will implementation of the rule affect primary and secondary wholesalers? Would it impact the distribution of drugs to small retail outlets or rural communities? Will secondary wholesalers have access to the information they need to meet the pedigree requirements? What is the regulatory significance of the fact that the current federal pedigree requirements apply only to wholesalers who are not authorized distributors of record? Please explain. Should the delay of the effective date be further extended? If so, how long should it be extended? Why?

The effective date of the PDMA should be extended until the FDA reconfirms its exclusive authority to implement the PDMA in a manner that sufficiently protects American consumers from unsafe, counterfeit products and American businesses from predatory acts of competitors hoping to rob those same consumers of cost-effective, genuine and critical medical supplies. There are no standards yet in place for RFID technology; a hodgepodge of state laws related to pedigrees and wholesale licensing are confusing and contradictory; there are no regulations in place to protect proprietary business trade secrets; and pharmaceutical manufacturers are committed to a public relations and lobbying campaign which could decimate if not destroy the wholesale pharmaceutical drug industry. The cost of technology implementation alone will drive many of the primary and secondary wholesale businesses out of

the marketplace and others will be unable to survive if reasonable standards are not developed by stakeholders committed to maintenance of this critical supply chain participant. The effective date must be extended not only to a point in time when technology is more affordable to all participants but also to a date when the federal government has put in place guidelines to prevent abuse of such RFID technology.

With all due respect to authorized manufacturers' distributors, despite what may appear to be successful efforts to convince state legislatures that there is a "normal distribution chain" of pharmaceuticals, wholesale suppliers of pharmaceutical products are subject to just as stringent licensing, inspection and recordkeeping requirements as any other distributor of drug products. It is, therefore, illogical to exclude any distributor – regardless of its relationship with the original manufacturer – from the pedigree requirements set forth in the PDMA. If the intention of the Act is to protect consumers without regard to manufacturer reputation then the FDA must ensure that pedigrees are required from all pharmaceutical distributors - not only as a means of full compliance with the intention of the original legislation, but also as the only method of enabling compliance by primary and secondary wholesale market suppliers dependent upon supplier generated pedigrees to pass along to their customers.

11. MINIMUM STANDARDS FOR WHOLESALER LICENSING

The PDM A required FDA to issue minimum standards for wholesaler licensing (21 CFR 205.3). These standards were adopted by the states and incorporated into state law. How effective are these standards?

For all of the reasons set forth above, the standards enacted by the various states effectively mandate licensure of wholesale pharmaceutical distributors and seek to distinguish between lawful and unlawful pharmaceutical distribution. The problem is that these state laws are different from one another, are oftentimes confusing and contradictory and, in many cases, ultimately work to eliminate wholesale drug distribution.

The U.S. Congress has, already two times, complimented the FDA in its delayed implementation of the PDMA recognizing that the federal law must protect critical wholesale trade. Certain state laws, however, explicitly exclude wholesalers from "normal distribution chains" even though it is recognized that they provide safe and authentic pharmaceutical products to American consumers. Although AFTA does not intend this communication to debate the propriety of state laws so obviously overlapping and conflicting with federal initiatives, it is worth briefly reminding the Agency that Article VI of the United States Constitution provides that "the Laws of the United States . . . shall be the supreme Law of the Land . . . anything in the Constitution or Laws of any State to the Contrary notwithstanding." As the United States Supreme Court declared in *Hillsborough County, Florida v. Automated Med. Labs.*, 471 U.S. 707, 712 (1985), "[i]t is a familiar and well-established principle that the Supremacy Clause . . . invalidates state laws that 'interfere with, or are contrary to,' federal law (quoting *Gibbons v. Ogden*, 9 Wheat. 1, 211, 6 L.Ed. 23 (1824)) and that any understanding of the scope of a preemption statute "must rest primarily on 'a fair understanding of *congressional purpose.*'" *Lohr*, 518 U.S. at 485-86 (quoting *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530 n.27 (1992)).

It is clearly not in the best interests of this country, nor reflective of congressional intent, to consider state laws, which clearly contradict congressional concern for maintenance of the domestic wholesale pharmaceutical industry, to be effectively complying with federal standards.

CONCLUSION

As standards are further developed for implementation of and access to RFID technology as a means to comply with the PDMA's pedigree requirements, AFTA sincerely hopes that the FDA will require uniform, federal standards that will protect both consumers and lawful American small businesses in safe products widely distributed in a competitive marketplace. AFTA looks forward to continuing its role of representing the needs of the wholesale pharmaceutical industry before the Agency and Congress and welcomes any further questions or concerns to its undersigned General Counsel at any time.

AFTA appreciates and thanks you for this opportunity to comment on the FDA's intended implementation of the PDMA and related RFID technology concerns. Should you wish to discuss these comments or AFTA's continued contribution to standards setting, please feel free to contact the undersigned directly at any time.

Sincerely,

AMERICAN FREE TRADE ASSOCIATION

By: _____

Gilbert Lee Sandler
General Counsel

cc: Board of Directors