

Cardinal Health
7000 Cardinal Place
Dublin, OH 43017
main 614.757.5000

www.cardinal.com



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October 31, 2003

VIA AIRBORNE EXPRESS

Airbill #19480419453

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

Dear Sir or Madam:

On behalf of Cardinal Health, Inc. I wish to thank you for the opportunity to comment on the issue of drug counterfeiting and to the questions posed in FDA's Drug Counterfeit Task Force Interim Report. We commend the agency's openness and efforts in working with all stakeholders throughout the U.S. prescription drug supply chain in developing viable solutions to attack the issue of counterfeit drugs.

Cardinal Health is an active member of the Healthcare Distribution Management Association's (HDMA) Product Safety Task Force and the National Association of Chain Drug Stores (NACDS) Counterfeit Drug Task Force. Through these industry trade groups we are working to develop recommendations for regulatory and enforcement measures, business policies and practices, and technology prevention measures that can be implemented in a cost effective manner and can strengthen the safety net of the U.S. drug supply chain against counterfeiting.

If you have any questions concerning our comments please feel free to contact me. Again, thank you for this opportunity and for consideration of our comments.

Yours truly,

Rich Kirkendall

Richard Kirkendall
Vice President
Global Regulatory Compliance

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Regulatory and Enforcement Measures

Cardinal Health advocates a federal regulation strengthening the wholesaler license requirements, stronger criminal penalties for prescription drug diversion and counterfeiting, and appropriations for dedicated inspection and investigation resources with greater enforcement abilities.

We support a federal licensing standard which would be endorsed by state licensing agencies. We believe that FDA is best positioned to adopt and regulate a federal licensing standard. We support FDA's efforts to work with state licensing and enforcement agencies to establish a set of minimum licensing requirements that can be adopted across each state. Prescription drug wholesaler license requirements should include:

- Full disclosure of company principals
- License denial for criminal convictions or license revocation actions of applicant or company principals
- Bond of minimum \$50,000 to maximum \$100,000
- Wholesale/distribution facility inspection

The license application review should require background checks of the license applicant and company principals for criminal convictions and drug wholesale license revocations. We believe a national clearing house for such background checks should be developed and accessible by state licensing agencies.

A federal regulatory licensing and enforcement system can establish the model for all states and provide a consistent and uniform approach. Varying state licensing requirements and regulatory enforcement practices are not practical for the legitimate drug wholesalers who operate in multiple states.

State agencies should undertake the responsibility to conduct detailed due diligence with license applications, routine inspections of all wholesalers, and appropriate enforcement actions when violations occur. We endorse legislative changes at the national and state level to enhance the authority of those agencies charged with regulating the drug wholesale and pharmacy supply chains.

Criminal penalties must be strengthened as a means to deter drug counterfeiting and to punish those individuals who choose to knowingly manufacture, sell, and distribute counterfeit drugs. We endorse tougher federal and state civil and criminal penalties for such crimes. Furthermore, we recommend that FDA be given the authority to debar any individual who has a felony drug counterfeit conviction, from the drug wholesale and distribution industry. A debarment program for the drug wholesale and distribution industry modeled after the authority granted to FDA by the Generic Drug Enforcement Act would provide

further deterrence against individuals previously convicted of drug counterfeiting offenses, from reentering into the drug supply chain.

We strongly recommend that the definition of Authorized Distributor of Record be strengthened. We would suggest the ADR definition from the HDMA Guidelines for Pharmaceutical Distribution System Integrity:

- Wholesaler must be on the manufacturers list, or
- Have a written agreement currently in effect with the manufacturer, or
- Have a verifiable account with the manufacturer and minimal transactional or volume requirement thresholds from the manufacturer:
 - 5000 sales units within 12 months, or
 - 12 purchases (invoices) within 12 months

We support a paper pedigree requirement for those prescription drugs deemed to be a high risk for counterfeiting as an interim solution. We recommend that any paper pedigree requirements be flexible to recognize electronic technologies as they become available. We endorse a uniform national system for identifying which drugs fit this profile.

Importation of prescription drugs from outside sources will present an unmanageable drug supply chain compliance dilemma. Any legal allowance for importation and distribution of prescription drugs that are not approved by the FDA must include all wholesale and distribution regulatory requirements and enforcement by the FDA.

Technology Prevention Measures

Cardinal Health considers track and trace technology to be the best long term solution for deterring drug counterfeiting. As this technology continues to evolve and business operations studies advance, we envision a phased in approach of electronic track and trace application beginning at the case and pallet level of supply for those drugs that present the highest risk of counterfeiting.

Track and trace technologies can only be effective in deterring counterfeit drugs if the application is utilized across the drug supply chain, from manufacturer to pharmacy. Application of track and trace technologies requires further development. The cost/benefit of track and trace technologies requires further analysis. The cost of track and trace application will likely present some added cost to the consumer.

We recommend that FDA consider additional packaging requirements of prescription drugs that present a high potential for counterfeiting

We recommend that FDA commission further study of unit dose and unit of use packaging as a deterrent to drug counterfeiting. We suggest that FDA undertake a study of the successes and failures of this packaging application as it exists in Europe, with respect to drug counterfeiting. Cardinal Health recognizes that a complete shift to this form of packaging would be an expensive endeavor to manufacturers which would pass along to consumers. A thorough cost/benefit analysis is justified for further consideration of unit of use or unit dose packaging as a long term technology application.

Business Practices

Cardinal Health has been an active participant in the HDMA task force working to develop the Guidelines for Pharmaceutical Distribution System Integrity. We endorse these guidelines and suggest that FDA consider them best practices to be applied across the drug distribution supply chain. We believe that the industry will force all legitimate wholesalers to adopt and abide by the guidelines. This will be effective in driving out unscrupulous individuals or less than diligent secondary wholesalers that compromise the safety of the drug supply chain. Similar guidelines should be adopted by the chain drug and closed door pharmacy industry groups to assure greater authenticity of prescription drugs through these supply chain links.

Cardinal Health has developed internal policies and procedures which define our quality assurance and compliance program for sourcing products from secondary wholesalers. Our alternate source vendor compliance program addresses secondary wholesaler compliance assessment and qualification, authorized distributors, non-qualified vendors, restricted products, secondary wholesale supplier agreements, and pedigree review.

Our internal procedure for secondary wholesaler compliance assessments provide a detailed checklist which is utilized in our on-site assessment activities with the secondary wholesalers that we purchase products from. This checklist covers the following areas: license review and verification, facility review, personnel hiring and training procedures, prescription drug storage handling procedures, record keeping and supplier qualification.

We have internal procedures that provide instructions on how drug pedigrees are reviewed and accepted. These controls have proven effective in Cardinal Health refusing to accept products from secondary wholesalers when a pedigree could not be authenticated. Cardinal Health continuously evaluates those secondary wholesalers from whom we are purchasing products. We would welcome the opportunity to discuss our internal procedures with members of the FDA Counterfeit Drug Task Force.

We recommend that FDA develop and own a communication and alert network that can rapidly disseminate critical information on counterfeit drugs to healthcare professionals. We acknowledge that incidents of known counterfeit drug

discoveries are investigated by FDA's Office of Criminal Investigation and these investigations require confidentiality. However, we believe that it is important that there be a standard rapid communication and alert system to drug manufacturers, wholesalers, and healthcare professionals.

Drug Repackaging

The FDA task force interim report discusses vulnerabilities of drug repackaging operations and the potential for introduction of counterfeit drugs into the supply chain. Legitimate drug repackagers play an important role and service in the drug supply chain. Repackagers provide economically viable packaging sizes and formats for retail and institutional pharmacy use that are not readily available from the manufacturer. Repackagers are licensed and inspected by FDA for adherence to Good Manufacturing Practices.

We encourage the FDA to work with legitimate drug repackagers to adopt appropriate technology solutions and enhance business practices as necessary to minimize the vulnerability of counterfeit drugs permeating the supply chain through repackaging operations.

Cardinal Health's drug repackaging business adheres to GMPs and maintains exceptional product integrity and security. We would welcome the opportunity to work with the FDA Task Force and share our repackaging quality assurance and compliance program in strengthening repackaging guidance for the industry.

Comments to Selected Questions posed in the FDA Task Force Interim Report

A. Questions Concerning Technology (Options 1-9)

1. Discuss the advantages and disadvantages of unit of use packaging. Please provide any information on the economic impact of requiring unit of use packaging.

Unit of use packaging may provide a deterrence to drug counterfeiting. We recommend to FDA that further economic cost/benefit studies be commissioned to examine unit of use packaging as a potential long term solution for assuring the safety of the U.S. drug supply chain. We encourage the agency to study the unit of use concept utilized in the European Union.

2. Should the European Union requirements be used as a model for unit of use packaging?

FDA should study the European Union unit of use packaging model for consideration in the U.S. market. This should include a review of drug counterfeit incidents and investigations, as well as the parallel import trading practices and associated labeling requirements and approvals in the European Union.

5. What, if any, minimum number of anti-counterfeiting technologies should be utilized on packaging and labeling? Should technologies be utilized on all dosage forms (e.g., APIs, finished dosage forms) and products or just dosage forms and products at high risk of being counterfeited?

We suggest that anti-counterfeiting packaging and labeling technologies should be applied across all forms of drugs; active pharmaceutical ingredients, and finished dosage forms. The sophistication demonstrated by the recent counterfeiting incident of Lipitor® is an example of a well planned counterfeiting scheme that started at the active ingredient stage. With the global sourcing of active ingredients and drug excipients and FDA's resource limitations to inspect all imported drugs, anti-counterfeiting technology applications across all drug components would be an added and appropriate safeguard.

6. Should any specific anti-counterfeiting technologies be utilized? Should covert technologies always be utilized? Should overt technologies always be utilized?

Experts on counterfeiting have stated that overt technology applications must be consistently renewed in order to stay ahead of potential counterfeiters. A combination of overt and covert technology applications should be considered as a short-term solution for those products considered to be a high counterfeit risk. These applications can be useful in making it more difficult to counterfeit a

product and to drug manufacturers and FDA when needed to authenticate a product. However, overt and covert applications cannot be effectively and efficiently utilized by drug wholesalers or pharmacists in authenticating a product.

7. Should some anti-counterfeiting technologies only be identifiable by the manufacturer and/or the FDA?

As indicated by our response to question 6, we consider that most covert technology applications would be unknown to wholesalers and distributors. Such applications known only by the manufacturer and FDA would be useful in counterfeit investigations and provide the ability to rapidly authenticate a product.

9. What role should the FDA play in reviewing the use of (i) anti-counterfeiting technologies incorporated into the packaging and labeling, (ii) taggants, markers, and other unique characteristics incorporated into the product itself, and (iii) track and trace technologies?

FDA has a role in assuring that the application of anti-counterfeiting technologies incorporated into the product (taggants, markers), and packaging and labeling does not adversely effect the product or omit required packaging and labeling information. FDA should provide manufactures with guidance that will assist in the development and application of such technologies in a cost effective and timely manner.

As the pharmaceutical manufacturing and supply chain stakeholders work toward implementing track and trace technologies, we would expect these groups to continue to update FDA on progress. FDA can be an important industry partner particularly in determining database content, ownership, and access. FDA's role should not be to review and approve what and how these technologies are implemented as a security enhancement.

10. How should "validation" of an anti-counterfeiting measure or track and trace technology be determined? Should only "validated" anti-counterfeiting measures be used? Who should do the validation?

Pilot trials will be conducted across the drug supply chain to challenge the functionality of track and trace technology. We encourage the FDA to rely on the industry to conduct appropriate trials in advance of full implementation and throughout live implementation. We see no value in adding unnecessary regulatory compliance hurdles on track and trace technology implementation which will impede progress and add cost to these technology solutions.

11. Should a database, as described in Technology Option 5 be created? If so, who should develop the database? Where should it be housed? Who should have access to the data? Who should be responsible for updating and maintaining it?

An information database housed by a third party is necessary to manage and provide access to the data that electronic track and trace technology will generate throughout the supply chain. The FDA task force should work with industry trade groups in developing the standards for information requirements, information access, confidentiality/privacy, and security.

12. Discuss the advantages and disadvantages and the role of track and trace technologies, in particular bar codes and RFID.

RFID offers the best track and trace technology opportunity to authenticate products and provide an electronic pedigree. RFID applications have the potential to improve supply chain efficiencies over the long-term. The upfront cost of RFID applications will present economic challenges. For RFID to be effective throughout the drug supply chain it will require implementation and endorsement by all links in the supply chain. The challenge to RFID applications will be the data storage, ownership, and access.

Bar coding presents limitations for use as a track and trace technology. Bar coding reader requirements are not efficient for track and trace applications of drugs. Bar codes can only provide unidirectional product information.

14. Tracking and tracing drugs and biologics throughout the drug distribution chain may result in the creation of a large database that includes tracking data from each entity that “handles” the product. Who should create and maintain such data? Where and how should the data be housed? Who should have access to the data? How can appropriate confidentiality be assured?

The database must be managed by a third party. All supply chain participants should have licensed access to appropriate data necessary to provide product authentication and an electronic pedigree. At the end user level, patient confidentiality must be maintained. Within the balance of the supply chain, pricing data must be protected.

15. Are there additional benefits beyond the ability to detect counterfeit product that anti-counterfeiting and track/trace technologies can provide for industry, (e.g., inventory control, facilitation of product recalls, and identification of theft and product diversion)? Give specific examples.

Track and trace technology applications will provide the opportunity to improve efficiencies in inventory management across the supply chain. Real time supply inventory data should be more readily available. This can be a benefit in managing drug shortages.

Product recall management across the supply chain and with FDA can be greatly improved with the application of electronic track and trace technology. A product recall notice can be tagged to the product, which should block further transfer of the product in the supply chain and facilitate recall effectiveness.

16. Discuss the logistic, economic, and public health effects of direct shipment of product to retailers and other end users.

Primary drug wholesalers provide an essential service in delivering prescription drugs timely and efficiently to pharmacies and healthcare providers across the United States. Wholesalers take on the responsibility of delivering multi-product orders and quantities to customers in an efficient manner that eases the burden of pharmacies having to carry large inventories, place multiple orders with varying manufacturers, and manage multiple receiving activities. Without this service, the supply of drugs across the United States would be fraught with delivery slowdowns and drug supply shortages.

The implementation of more stringent licensing requirements and regulatory enforcement measures, enhanced business practices, and technology applications across the drug supply chain will provide an appropriate safety net against counterfeiting.

17. For products that are shipped directly from manufacturers to retailers, would the use of track and trace technology on those products provide any additional benefits?

Retail chain pharmacies may operate as secondary wholesalers and sell drugs to other retailers. Products undergo inter-company transfers. Products are returned by retailers due to order errors, shipping errors, expired product, recalls, etc. Track and trace technologies would be beneficial for the purpose of product authentication under these circumstances.

18. Should all products be considered at high risk of being counterfeited? How can products at high risk of being counterfeited be identified? Which, if any, of the following criteria should be considered: (a) potential impact on public health if the product were counterfeited, (b) any history of, or the potential for, counterfeiting, tampering, or diversion of the product, (c) wholesale and retail price of the product, (d) volume of product sold, both on a unit and dollar basis, (e) the dosage form of the product, e.g., injectable, (f) approved and unapproved uses of the product, (g) current and potential misuse or abuse of the product, e.g., "street value", (h) other products in the class with a history of being counterfeited, (i) the length of remaining patent life for the product?

FDA should consider a risk based assessment of drugs in determining their counterfeit risk. The incidents of drug counterfeiting to date have targeted high priced and high volume drugs. All drugs that are injectable biologicals should be considered a high counterfeit risk. Drugs that are first to market should be evaluated as a potential for counterfeiting (using approved use and projected population utilization as a criteria). Other factors for consideration include drug price, product availability, internet pharmacy product availability. FDA should consider establishing an advisory panel to review and determine drug counterfeit risk.

19. Discuss what could be included in an FDA guidance on the use of anti-counterfeiting technologies.

An FDA guideline for anti-counterfeiting technologies should provide examples of common packaging attributes which have been shown to be easy targets for drug counterfeiting. General guidance on packaging and labeling security considerations would be useful. FDA's Office of Criminal Investigation can be a useful resource in providing specific guidance and working with manufacturers in assessing proposed technology applications.

21. Discuss what could be included in an FDA guidance on physical site security and supply chain integrity.

We recommend that FDA work with DEA and study the physical security requirements of the Controlled Substances Act as defined by 21CFR1301.71(8)(9)(10)(11)(12)(13).

B. Questions Concerning Regulatory Requirements and Secure Business Practices (Options 10-13)

1. Discuss the most effective ways to achieve the goals of the wholesale distribution rule (21 CFR 203.3(u) and 203.50). Given recent or impending advances in technology, comment on the feasibility of using an electronic pedigree in lieu of a paper pedigree.

21CFR 203.3(u), which defines an ongoing relationship between a manufacturer and distributor and 203.50, Requirements for wholesale distribution of prescription drugs can be effective by strengthening the requirements of the authorized distributor definition and aligning the ongoing relationship to this definition. The recommendation for the authorized distributor definition is:

- Wholesaler must be on the manufacturers list, or
- Have a written agreement currently in effect with the manufacturer, or

- Have a verifiable account with the manufacturer and minimal transactional or volume requirement thresholds from the manufacturer:
 - 5000 sales units within 12 months, or
 - 12 purchases (invoices) within 12 months

An electronic pedigree should be considered a long term solution to meet the requirements of 21CFR 203.50.

2. Discuss the advantages and disadvantages of the new Florida and Nevada requirements for wholesale distributors, including the costs involved with compliance.

The new Florida requirements for wholesale distributors were implemented to address the epidemic problem of drug counterfeiting incidents originating in a state which has over 1400 licensed drug wholesalers and as described by the Florida Grand Jury report, "has weak permitting requirements" and "lax agency oversight of wholesalers". The "Florida model" should not be considered as the standard for regulations on a national basis. The requirement by Florida to establish and provide a pedigree back to the manufacturer and to the pharmacy for all drugs by 2006 will present an unnecessary burden on drug wholesalers. Paper pedigrees required for low cost generics or other prescription drugs that do not present a target or market for counterfeiting serve no purpose in securing the safety of the U.S. drug supply chain and may dilute the efforts to focus on those drugs which do present a high risk for counterfeiting. Segregating product for the state of Florida in a national distribution system to meet the pedigree requirement will impose a logistical burden and may ultimately lead to drug shortages in the state. Authentication of every transaction, as required in Florida, is extremely burdensome, particularly for small distributors, and could result in many distributors exiting the market. This would result in some populations being underserved and unable to obtain needed drugs.

The Nevada model also presents unnecessary challenges for wholesalers. The problem is not sales between legitimate wholesalers, but rather rogue wholesale distributors. Limiting sales to other wholesale distributors could restrict sales by an authorized distributor to a chain drug store distribution center, which may be licensed as a Wholesale Distributor.

We are concerned that multiple states will choose to implement multiple regulatory approaches to combat counterfeit drugs entering the supply chain. Regulatory requirements and secure business practices are one facet of a multi-pronged approach as recognized by the FDA Task Force in combating drug counterfeiting. We encourage FDA to work with NABP and individual states as necessary to develop and implement a consistent and manageable approach to regulate drug wholesalers. This approach should consider the following:

- a risk based analysis of counterfeit drug targets
- full pedigree requirements for drugs considered to be a high risk for counterfeiting
- tighter requirements for authorized distributor designation
- appropriate due diligence and enforcement by regulatory agencies
- business practice enhancements across the drug supply chain
- anti-counterfeit technology applications

3. Discuss the advantages and disadvantages of requiring a pedigree if track and trace technology is also being utilized for a given product?

Track and trace technologies will provide the capability of an electronic pedigree for prescription drug products. These technologies if properly implemented and utilized throughout the drug supply chain will provide greater assurance of product authenticity than any paper pedigree.

Any regulatory requirement for a paper pedigree should provide an allowance for an equally effective electronic track and trace technology to meet the requirement.

4. Identify areas where the NABP Model Rules for Licensure of Wholesale Distributors could be strengthened. Please give specific language for new provisions.

We recommend the following modifications to the NABP Model Act and Rules:

Require non-Authorized Distributors to transmit with each shipment of drugs a Pedigree containing information about each transaction for the drugs back to an Authorized Distributor. For products susceptible to counterfeiting, all Wholesale Distributors must transmit a Pedigree tracing the transactions for the drugs back to the manufacturer.

Purchasers are prohibited from accepting any drugs that are not accompanied by a Pedigree, if a Pedigree is required under the Model Act.

Require Wholesale Distributors to conduct due diligence of its suppliers. Due diligence – which includes criminal background and credit checks – will ensure that Wholesale Distributors know that their suppliers are trustworthy.

Require authentication of the transactions listed on the pedigree if the Wholesale Distributor has reason to suspect that the product may be counterfeit, as well as on a random basis to audit the distribution chain.

Authentication of each transaction is unnecessary if the purchasing Wholesale Distributor has the Pedigree, which provides traceability, as well as certification from the seller that the seller has conducted due diligence.

Pedigrees will increase the traceability of drugs, without excluding secondary distributors from the distribution chain, as is likely to occur under the Prescription Drug Marketing Act rules.

5. Discuss the strengths and weaknesses of a pedigree as a means of tracking product integrity. Is there a deterrent value in having a pedigree? What is the most cost-effective approach to obtaining reliable pedigree information?

Requiring a pedigree for all prescription drug products is an unnecessary burden with minimal value in securing the supply chain. Any paper pedigree regulation should be a risk-based approach. Those drugs which present a high counterfeit risk should require a pedigree back to the manufacturer. A List of Counterfeit Susceptible Products should be developed by FDA and routinely evaluated and updated accordingly. This list should be considered by state regulatory agencies as the basis for full drug pedigree requirements by all drug wholesalers back to the manufacturer.

A paper pedigree should be required for all drugs, only when the drug is being sold by a wholesaler that is not considered to be an authorized distributor. The pedigree should list all transactions back to an authorized distributor.

6. Discuss the advantages and disadvantages of increased penalties for counterfeiting drugs?

Increased fines and criminal sanctions for counterfeiting and failing to comply with licensing, pedigree, and due diligence requirements will act as a deterrent to drug counterfeiting and to the introduction of counterfeit drugs into the legitimate drug supply chain. Increasing enforcement efforts and prosecution of individuals engaging in drug counterfeiting will help to deter this criminal activity.

7. Identify areas where business practices could be changed to prevent the introduction, and facilitate the identification, of counterfeit drugs.

Manufacturers must recognize an authorized distributor, as defined by the PDMA (current or revised definition), and provide access to drug wholesalers requesting information to verify the authorized distributor status and/or *ongoing relationship* between a wholesaler/distributor and the manufacturer

Wholesalers have an opportunity to adopt business practices that strengthen the due diligence and qualification activities that they engage in when establishing a business relationship with a secondary wholesaler and in an ongoing review and acceptance of the secondary wholesaler's practices.

HDMA's Guidelines for Pharmaceutical Distribution System Integrity provides a best practices model for wholesalers. We encourage FDA to endorse these guidelines as the model for the prescription drug wholesale industry.

We are confident that the primary wholesalers will adopt these guidelines as standard operating procedures and require secondary wholesalers to abide by them. These steps will provide greater scrutiny in purchasing and distributing drugs and provide greater counterfeit deterrence.

We encourage FDA to work the pharmacy industry trade groups and their membership in developing best practice models for purchasing, distribution, product returns, and pharmacist education to deter counterfeit drugs.

8. Describe the current use of designated personnel and teams to implement and monitor anti-counterfeiting measures by manufacturers, wholesalers, re-packagers, and pharmacies.

We utilize a dedicated internal resource in managing our quality assurance and regulatory compliance program of secondary wholesalers. This includes audits of secondary wholesalers, receiving product from non-authorized distributors, and pedigree review and acceptance.

9. Comment on the advantages and disadvantages of manufacturers sharing market data with the FDA for use in identifying counterfeit products.

Market data can be useful to FDA in evaluating the counterfeit risk of a particular product. Market data will also become a component of track and trace information. FDA must be sensitive to the concerns of manufacturers in sharing sensitive and highly confidential market information.

10. Comment on the need for FDA guidance dealing with site security and supply chain integrity in light of the importance of drug treatment for bioterrorism incidents.

Drug manufacturers and wholesalers that handle controlled substances are required to adopt and adhere to strict security procedures to deter theft and diversion within their facilities. These procedures provide appropriate security for such facilities and should be studied by FDA. Components of these security requirements such as physical barriers and electronic surveillance and monitoring should be considered for any facility manufacturing or distributing prescription drugs.

C. Questions Concerning Rapid Alert and Response Systems (Options 14-16)

1. What are the advantages and disadvantages of adapting the MedWatch system for use in disseminating information about counterfeit drugs?

FDA's MedWatch system is a well developed product safety information communication link that is widely utilized across the healthcare industry. MedWatch provides a system framework that could be modified to assure information security and access privileges, and consistency in receiving and disseminating counterfeit drug alert information.

2. What are the current capabilities of private communication systems or networks (e.g., association list-serves, websites) for handling information about counterfeit drugs in a timely manner?

Industry representative groups such as HDMA and NACDS provide communication system capabilities that could be used to rapidly convey appropriate information on counterfeit drugs. FDA should be a clearing house for such information to assure accurate dissemination of information and appropriate action steps in handling counterfeit drugs

4. What capabilities should a communication network have in order to be part of a counterfeit alert system? For example: Should the system be accessible to all stakeholders (e.g., pharmacies, wholesalers)? How fast should the system be able to disseminate information about suspect product? Should messaging be active? How should the system flag messages about suspect product as opposed to less urgent information? Should access be at no cost? Should all networks in the system have a uniform method of presenting and distributing information? How secure must the system be? Should access to information be selective? Should the system be capable of direct linkage to the FDA? Should the system be able to transmit educational information?

A rapid communication network system should be accessible to all stakeholders and healthcare professionals. Timely information is important and necessary but must be balanced with accuracy and risk to consumer safety and consumer panic. Forensic evidence needed to evaluate and determine a health hazard risk may not be readily available at the same time as authentication information. FDA and the drug manufacturer are best positioned to work together in developing rapid communication alerts when counterfeit drug incidents occur.

HDMA and PhRMA have adopted policies requiring association members to alert FDA's Office of Criminal Investigation within 5 days of discovering and substantiating a product suspected of being counterfeit. FDA should encourage

all supply chain stakeholders and healthcare professionals to adopt and adhere to this reporting policy.

D. Questions Concerning Education and Public Awareness (Options 17-21)

1. How can FDA best assist in making sure the public knows what they need to know to help them avoid counterfeit drugs?

We encourage FDA to work primarily with healthcare professionals and trade associations in educating the healthcare industry stakeholders on the potential of counterfeit drugs. Consumers should be educated to be cognizant of noticeable differences in their medication, the packaging, or any adverse events experienced and to report any suspicions to their pharmacist. Consumers should also be educated on the risks of purchasing prescription drugs via the internet.

2. What role should the private sector, professional/trade associations and consumer representatives play in educating consumers and health professionals? Are there other groups that FDA should solicit for help?

Professional/trade associations offer the best opportunity to educate a wide network of healthcare professionals. We want to encourage FDA and the professional and trade associations to develop continuing education forums that can provide useful and informative information to healthcare professionals that they can pass on to the consumers.