

however, FDA counterfeit drug investigations have increased to an average of over 20 per year.

On July 16, 2003, FDA announced an initiative to more aggressively protect American consumers from the risks associated with counterfeit drugs and reduce the possibility of potentially unsafe counterfeit drugs reaching consumers. As part of this effort, FDA established an internal task force that will develop recommendations for steps that FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs getting into the supply chain. Some of the areas that FDA's task force is exploring are included in the following topics:

- *Technology*: Assess the extent to which currently available and potential technologies can help assure the authenticity of drugs;

- *Regulatory/Legislative Issues*: Evaluate potential State and Federal regulatory and legislative changes that could be made to strengthen the nation's protections against counterfeiting;

- *Public Education*: Evaluate ways to educate consumers and health providers on steps they can take to minimize risks associated with counterfeit drugs as well as what to look for and do if they suspect they have received a counterfeit drug;

- *Industry and Health Professional Issues*: Identify actions industry and health professionals can take to prevent, detect, and respond to counterfeit drugs.

The task force anticipates the following deliverables:

- Interim task force report to be released in September 2003. We intend to include preliminary findings on which all interested parties may comment;

- Final task force report to be released in January 2004. We intend to provide recommendations for public and private sector actions to address the problem of counterfeit drugs.

## II. Scope of Discussion

FDA is planning this public meeting in order to hear public comments on ways to combat counterfeit drugs. The objective of the meeting is for FDA to gather information to assist FDA's counterfeit drug task force in finalizing its report, which will include recommendations on steps that FDA, other government agencies, and the private sector can take to minimize the risks to the public from counterfeit drugs entering the supply chain. We anticipate that discussions at this meeting will include presentations from members of the public.

FDA plans to include with the task force interim report a series of questions specifically addressing the preliminary findings. The questions will be posted on FDA's Web site at [www.fda.gov](http://www.fda.gov). We request that presenters address these questions at the public meeting as well as the topics of interest listed in the following paragraphs. Specific topics of interest include, but are not limited to the following topics:

### A. Technology

1. What anti-counterfeit technologies currently are available for use as anti-counterfeit measures for pharmaceuticals (e.g., track/trace, authentication)? What are the costs associated with these technologies?

2. What is the current status of, and barriers to, adopting an industry standard for use of anti-counterfeiting technology?

3. What role should FDA play in facilitating the use of anti-counterfeit technologies and in the creation of an industry standard for use of anti-counterfeiting measures?

4. Should anti-counterfeiting measures be used for all drugs and biologics or just for drugs at high risk for counterfeiting? Is there a way to identify drugs at high risk for counterfeiting?

### B. Regulatory and Legislative Issues

1. In 2001, FDA submitted a report to Congress (<http://www.fda.gov/oc/pdma/report2001/default.htm>) on the status of the implementation and enforcement of the Prescription Drug Marketing Act (PDMA). As explained in this report, we raised concerns regarding implementation of the wholesale distribution provisions at 21 CFR 203.50, and these provisions have been stayed until April 2004. Have circumstances changed since the issuance of the report to Congress that could affect FDA's decision to continue the stay or implement these provisions?

2. How could PDMA be strengthened or augmented to reduce the risk of counterfeit drugs and biologicals from reaching consumers?

3. If PDMA were amended by Congress to require wholesale distributors to prepare and pass on a pedigree to all customers ("universal pedigree"), including to retail pharmacies, would the risk of distribution of counterfeit, expired, or otherwise unsuitable drugs to consumers be decreased?

4. How could state pharmacy practice acts be augmented or strengthened to minimize the introduction of counterfeit drugs into the drug distribution chain? Please give specific suggestions.

### C. Public Education

1. What are the information needs of consumers, trade groups, the media, state governments, manufacturers, wholesalers, pharmacists, and other health care professionals to help identify and report suspected counterfeit drugs?

2. What is the most effective and efficient way for FDA to notify the public and health professionals that a counterfeit product has been identified? What are the emergency messages that FDA should deliver to its various audiences when a report of a suspected counterfeit drug is received by the agency?

3. What types of communication tools are already in existence and/or should be developed to assist FDA in delivering its messages about counterfeiting?

4. How can FDA, other governmental agencies, and private stakeholders work together to create and disseminate education messages to various audiences (e.g., consumers, wholesalers, pharmacies) that are consistent while delivering the information that each stakeholder needs?

### D. Industry and Health Professional Issues

1. What is the role of manufacturers, wholesalers, retailers, repackagers, and pharmacists in the following areas: (1) Identifying counterfeits, (2) preventing the introduction of counterfeits into the distribution chain, and (3) educating consumers. Should these stakeholders create in-house committees to develop and implement security and anti-counterfeit measures? Should stakeholders develop compliance programs?

2. Should a counterfeit drug alert network be developed? If so, should it be adapted from existing systems or should a new system be created? What would be the associated costs of adapting or creating a network?

We invite public comment on the overall FDA anti-counterfeit drug initiative, with a focus on the questions listed previously in this document.

## III. Comments

Interested persons may submit to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments by November 3, 2003. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Groups should submit two copies. Individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the