



## FDA News

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### FDA Announces Initiative to Heighten Battle Against Counterfeit Drugs

Commissioner of Food and Drugs Mark B. McClellan, M.D., Ph.D., today announced a major new initiative to more aggressively protect American consumers from drugs that have been counterfeited. The new initiative includes creating an internal task force to explore the use of modern technologies and other measures such as stronger enforcement that will make it more difficult for counterfeit drugs to get distributed with - or deliberately substituted for -- safe and effective drugs.

The task force will submit its initial findings and recommendations in approximately 60 days and will issue a final report six months from now, after opportunities to hear from the public. In addition, FDA plans to coordinate more closely with other federal agencies and state and local governments that share the responsibilities with FDA for ensuring the safety of the U.S. drug supply and distribution system as well as with members of Congress who have worked closely with FDA in the past on these important public health issues.

"It's essential for consumers that the medicines that they buy are the actual drugs that their doctors prescribe," said Secretary of Health and Human Services Tommy G. Thompson. "The dangers of counterfeit drugs are real, and we must protect consumers from these dangerous frauds. We will aggressively investigate instances of drug counterfeiting and will seek criminal prosecution of all offenders to the fullest extent of the law."

Counterfeit prescription drugs are not only illegal but are also inherently unsafe. Many counterfeit drugs are visually indistinguishable from the authentic versions, and thus pose a potentially serious health threat to Americans. Consumers can protect themselves from counterfeit drugs by purchasing their medications from licensed, domestic pharmacies and contacting their pharmacist or doctor if they notice anything unusual about their medication --including its packaging, taste, or unfamiliar side effects such as an unfamiliar feeling at an injection site.

"The sole purpose of this initiative is to develop new and innovative ways to make sure that Americans can continue to have confidence that the drugs they buy are, in fact, the real deal," said Commissioner McClellan. "There are new technologies and new opportunities for counterfeit drugs to reach Americans, but there are also new technologies and opportunities for FDA to protect the integrity of our drug supply. One thing isn't changing: counterfeiting - and counterfeiters - have no role to play in the American health care system."

In the United States, drug counterfeiting is a relatively rare event. Although FDA believes domestic counterfeiting is not widespread, the agency has recently seen an increase in counterfeiting activities as well as a more sophisticated ability to introduce finished dosage counterfeits into the otherwise legitimate drug distribution channels. FDA has likewise seen its counterfeit drug investigations increase to over 20 per year since 2000, after averaging only about 5 per year through the late 1990's.

At the same time, worldwide counterfeiting of drugs is believed to be more commonplace. The World Health Organization has estimated that perhaps seven or eight percent of drugs worldwide are counterfeit, and reports from some countries suggest that as much as one-half of those countries' drugs are counterfeit.

The FDA initiative is designed to better identify the risks and threats from counterfeit drugs, to coordinate public and private efforts to fight drug counterfeiting and distribution, and to develop new tools to aid in identifying, deterring and

combating counterfeiting.

Specifically, the internal FDA task force will:

- Develop a strategic action plan to decrease the risk of counterfeit drugs entering the U.S. marketplace and to protect consumers from potentially harmful effects of using these products.
- Continue to strengthen FDA's collaborative relationships with other federal agencies, including the Bureau of Immigration and Customs Enforcement (BICE), the Bureau of Customs and Border Protection (BCBP), and the U.S. Secret Service in the Department of Homeland Security and entities within the Department of Justice, as well as with health professionals, industry, consumer, and other stakeholders to gather information regarding the best practices for dealing with drug counterfeiting.
- Identify mechanisms for strengthening the nation's protections against counterfeiting, including such possibilities as model practice acts for adoption by the states, best practices for those who sell and distribute prescription drugs, and better education for patients, pharmacists, and others about how to identify counterfeit drugs and alert others to their existence.
- Assess the extent to which new technologies, e.g., counterfeit-resistant packaging, product identifiers such as chemical taggants, and implanted radio-frequency chips in packaging can help assure the authenticity of drugs. Although some of this technology is not currently mature enough to adequately protect the drug supply, it may have great promise as an added counter-measure against counterfeit pharmaceutical products.

FDA believes the increase and shift in this illicit activity has occurred for a number of reasons. These include:

- better counterfeiting technology, including improved technology to make labeling, packaging and products that appear real but are not;
- better organized, more effective criminal groups attracted by financial opportunities;
- the online sale of prescription drugs by unlicensed pharmacies and/or foreign websites;
- opportunities for introducing foreign-made counterfeit and unapproved drugs into large and rapidly growing import flows; and
- weak spots in the domestic wholesale drug distribution chain, including some wholesalers who acquire most of their inventory from secondary sources, do not maintain effective due diligence efforts on these sources and ignore warning signs indicative of illegal or unethical behavior.

"At the forefront of this effort will be the special agents of our Office of Criminal Investigations (OCI). Their record and dedication is impressive. Working together, I am confident we will defeat the criminal element engaged in counterfeit drug activity," added Commissioner McClellan.

For example, OCI has recently launched a major counterfeit investigation relating to Lipitor, a widely prescribed cholesterol-lowering drug, and three convictions that occurred as a result of their investigation of counterfeited Procrit, a drug used to stimulate the production of red blood cells to treat severe anemia.

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