



Counterfeit Medicinal Products

USA, FLORIDA Akerman Senterfitt

CONTACT INFORMATION

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**1. Is the problem of counterfeit medicinal products identified in your jurisdiction?
What is the amount of falsified medicinal products on the market?**

Florida had that problem about 10 years ago. The state instituted a drug pedigree program to trace each step the drug travels in the channel of trade and instituted more laws on counter-feit drugs. Florida also increased restrictions on secondary wholesalers where some of these drugs were making it into the drug distribution system. Florida has a very broad definition of adulterated and counter-feit drugs. It is still a problem for some foreign manufactured drugs.

2. Have there recently been any cases related to counterfeit medicinal products?

Not in Florida that I am aware of.

3. Is activity related to counterfeiting a medicinal product a crime? Please state which criminal law provisions may be potentially used against entities engaged in such activity.

Yes. 499.0051, Florida Statutes, makes several activities involving "contraband drugs" which includes counter-feit drugs a crime.

4. Is there a definition of a falsified medicinal product in your jurisdiction?

Yes. 499.003, FS (12) "Contraband prescription drug" means any adulterated drug, as defined in s. 499.006, any counterfeit drug, as defined in this section, and also means

any prescription drug for which a pedigree paper does not exist, or for which the pedigree paper in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter. (14) “Counterfeit drug,” “counterfeit device,” or “counterfeit cosmetic” means a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor. 499.0051 499.0051 Criminal acts.—

(1) FAILURE TO MAINTAIN OR DELIVER PEDIGREE PAPERS.— (a) A person, other than a manufacturer, engaged in the wholesale distribution of prescription drugs who fails to deliver to another person complete and accurate pedigree papers concerning a prescription drug or contraband prescription drug prior to, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. (b) A person engaged in the wholesale distribution of prescription drugs who fails to acquire complete and accurate pedigree papers concerning a prescription drug or contraband prescription drug prior to, or simultaneous with, the receipt of the prescription drug or contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. (c) Any person who knowingly destroys, alters, conceals, or fails to maintain complete and accurate pedigree papers concerning any prescription drug or contraband prescription drug in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. (2) FAILURE TO AUTHENTICATE PEDIGREE PAPERS.—Effective July 1, 2006: (a) A person engaged in the wholesale distribution of prescription drugs who is in possession of pedigree papers concerning prescription drugs or contraband prescription drugs and who fails to authenticate the matters contained in the pedigree papers and who nevertheless attempts to further distribute prescription drugs or contraband prescription drugs commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. (b) A person in possession of pedigree papers concerning prescription drugs or contraband prescription drugs who

5. Please advise on regulations in place to ensure safety of medicinal products and to prevent falsification of medicinal products. Who is authorized to enforce relevant laws?

Department of Business and Professional Regulation and Law Enforcement Agencies.

6. Please advise regarding existing boarder measures (and related legal provisions) allowing regulatory authorities and right holders to fight against counterfeited medicinal products and about the efficiency of such measures.

Florida has a very detailed drug pedigree program which is strictly enforced.

- 7. Are there any regulations allowing manufacturers, distributors or marketing authorization holders to eliminate falsified products from the market? Are there any other legal measures competitors, manufacturers, distributors or marketing authorization holders could take?**

If there is no drug pedigree, the drug cannot be distributed. Bar coding and RF Tags on drugs for tracking the movement in commerce.

- 8. Do public authorities or non - governmental organizations inform of dangers related to falsified drugs?**

Yes.

- 9. Have draft acts implementing 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use been already prepared?**

I do not know.

- 10. Does your jurisdiction consider signature and ratification of the Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats to public health?**

I do not believe so but do not know about European measures. I am in Florida in the US.