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MISBRANDING OF DRUGS, FOOD, DEVICES

21 U.S.C. § § 331 & 333 and 21 U.S.C. § 352

The misbranding provision of, **21 U.S.C. Section 331**, prohibits the introduction of any drug, food, cosmetic, tobacco product, or device into interstate commerce that is misbranded or adulterated, the adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce, or the receipt of any drug, food, cosmetic, tobacco product, or device that is misbranded, and the delivery or attempted delivery thereof for pay or otherwise.

“Misbranded” drugs or devices may include:

- A drug or device containing false or misleading labeling;
- A package containing a drug or device that does not contain certain labeling;
- A package of a drug or device containing labels that do not bear adequate directions for use **or** adequate warnings.

The FBI, the Food and Drug Administration Office of Investigations (FDA-OCI), and the Drug Enforcement Agency (DEA) are responsible for investigating and enforcing the misbranding provisions. Recently, the government has

used the misbranding provisions to investigate and prosecute a wide array of conduct including:

- Wholesaler importation of counterfeit cancer drugs into the U.S. for sale.
- Importation of counterfeit Botox vials into the U.S. for sale.
- Importation and sale of Chinese Viagra.
- Distribution of weight-loss pills sold as “all natural” even though pills contained Bumetanide, an ingredient which is banned by National Football League and other major sports organizations.
- Importation and dispensing medications by a pharmacy without proper or adequate labeling.
- Off-label promotion of pharmaceutical drugs by pharmaceutical manufacturers.
- Administration of liquid silicone injections by a spa owner.

Contact the Feldman Firm if you have any reason to believe that you may be the subject of a misbranding investigation or have received notice that you have violated the misbranding statute. Misbranding is a serious offense and a violation of the misbranding statute may result in imprisonment, hefty fines, or exclusion from a particular business activity for a period of years pursuant to 21 U.S.C. § 333.



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