

THE FOOD AND DRUGS ACT (FDA)

Law enforcement can utilize the FDA to help stop the production and distribution of illegal drugs.

- If a drug is not controlled under the CDSA, the FDA still applies.
- The FDA and its Regulations apply to the manufacture, sale, and import of **all drugs** irrespective of whether or not they are scheduled.
- “Drug” is broadly defined and includes any substance that modifies organic functions in human beings or animals.
- It is an offence under the FDA to sell or advertise drugs that have not been approved by Health Canada. This could include synthetic new psychoactive substances that have not yet been scheduled under the CDSA.
- As with the CDSA definition, the FDA definition of “sell” has a broader meaning than a strictly commercial sense. It includes **any** transfer of product, whether or not payment is made (i.e. gifting, as well as offering to sell or possessing the product for the purpose of selling it).
- Penalties for offences under the FDA can include:

OFFENCES AND PENALTIES UNDER THE FDA			
TYPE OF OFFENCE	Contraventions of any provision of the FDA or regulations.*	Offences relating to therapeutic products (drugs).** Subject to due diligence defence.	Offences relating to contraventions of any provision of the FDA or regulations that: 1) knowingly or recklessly cause a serious risk of injury to human health, or 2) knowingly make a false or misleading statement or providing false or misleading information to the Minister concerning a therapeutic product (drug). (s.21.6 in FDA)
APPLIES TO	All FDA products (including natural health products)	Drugs (excluding natural health products) and medical devices	Drugs (excluding natural health products) and medical devices

continued



	OFFENCES AND PENALTIES UNDER THE FDA		
CHARGING SECTION IN FDA	s.31	s.31.2	s.31.4
SUMMARY CONVICTION FOR A FIRST OFFENCE	A fine up to \$500 or to imprisonment for a term up to 3 months, or to both.	A fine up to \$250,000 or to imprisonment for a term up to 6 months, or to both.	A fine up to \$500,000 or to imprisonment for a term up to 18 months, or to both.
SUMMARY CONVICTION FOR SUBSEQUENT OFFENCE	A fine up to \$1,000 or to imprisonment for a term up to 6 months, or to both.	A fine up to \$500,000 or to imprisonment for a term up to 18 months, or to both.	A fine up to \$1,000,000 or to imprisonment for a term up to 2 years, or to both.
CONVICTION ON INDICTMENT	A fine up to \$5,000 or to imprisonment for a term up to 3 years, or to both.	A fine up to \$5,000,000 or to imprisonment for a term up to 2 years, or to both.	A fine at the discretion of the court or to imprisonment for a term up to 5 years, or to both.

* Subject to due diligence defence (s.31.3) and “want of knowledge” defence (s.34) (information below).

** Subject to due diligence defence.

Note: two common defence arguments used against charges under the FDA include:

- **Due diligence:** When the defendant proves they made reasonable efforts to comply with the law.
- **Want of knowledge:** The defendant proves that they purchased the drug in package form, sold it in the same package and same condition, and could not with reasonable diligence have known that the sale would contravene the law.

FDA CASE STUDY

Did you know that in 2016 the Ontario Court of Appeal upheld the conviction in a case against Adam Wookey and Purepillz Corporation for selling and marketing a recreational drug without a licence? At the time of offence, the drug, 1-Benzyl-Piperazine (BZP), was not approved for use under the FDA and was not yet controlled under the CDSA. The ruling confirms that FDA offences are not limited to drugs that are medicines. They can equally apply to recreational drugs as these also fall within the definition of “drug” under the FDA. The application for leave to appeal from the judgment of the Court of Appeal was dismissed by the Supreme Court of Canada.

Follow this **link** for additional details: www.ontariocourts.ca/decisions/2016/2016ONCA0611.htm