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DIVISION OF DRUGS, DEVICES AND COSMETICS – FAQs

Drugs, Devices & Cosmetics FAQs

To obtain an interpretation of statute or rule from an agency requires the submission of a Petition for Declaratory Statement that is authorized by Chapter 120, Florida Statutes and an agency cannot provide an informal legal opinion. The responses to the frequently asked questions are not intended to be legal opinions

Drugs, Devices &
Cosmetics

Drugs, Devices and
Cosmetics Home
(<https://www2.myfloridalicense.com/drugs->

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or statements of agency policy and you are strongly encouraged to seek the assistance of a regulatory consultant to assist you regarding the interpretation and application of Florida Statutes and rules. (<https://www2.myfloridalicense.com/>)



Definitions:

- “DBPR” or the “department” or refers to the Florida Department of Business and Professional Regulation.
- “DEA” refers to the U.S. Drug Enforcement Administration.
- “ARCOS” refers to the Automation of Reports and Consolidated Orders System operated by DEA.
- “CSR” refers to Florida’s state analogue to ARCOS, the Controlled Substance Reporting system.
- “E-FORCSE (<https://florida.pmpaware.net/login>)” refers to Florida’s “Electronic-Florida Online Reporting of Controlled Substances Evaluation”, aka the “Prescription Drug Monitoring Program” or “PDMP”. For more information visit the E-FORCSE homepage at <https://www.floridahealth.gov/statistics-and-data/e-forcse/index.html> (<https://www.floridahealth.gov/statistics-and-data/e-forcse/index.html>).
- “FTP” File Transfer Protocol

— Division of Drugs, Devices and Cosmetics

- Does my company need a permit?

devices-and-cosmetics/




Council Information
(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/council-information/>)

Apply for License
(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/apply/>)

Drug Price Increase Reporting
(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/apply/#drug-price-increase-reporting>)

Fingerprinting
(<https://www2.myfloridalicense.com/fingerprin>)

Renew & Manage My License
(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/renew-and-manage-my-license/>)

 DDC permitting requirements as regards drugs, (medical) devices and cosmetics fall into two main categories: (a) manufacturing and repackaging of drugs, medical devices and cosmetics conducted in Florida, and (b) distributing drugs, medical devices and cosmetics in and into Florida.

Activity Description	Location	Permit (Generally) Required under Chapter 499?
Manufacturing a Drug, Device or Cosmetic	In Florida	Yes
Repackaging a Drug, Device or Cosmetic	In Florida	Yes
Distributing a Prescription Drug	In or Into Florida	Yes
Distributing an Over-the-Counter Drug	In or Into Florida	No

[cosmetics/renew-manage-my-license/](#)



Exemptions
(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/exemption-letter-research-teaching-testing/>)

Controlled Substance Reporting
(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/controlled-substances-reporting/>)

CBD/Hemp/Marijuana
(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/cbd-hemp-marijuana/>)

Cancer Drug Donation Program
(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/cancer->

Distributing a device in or into Florida does not require licensure. PN Medical is a distributor of medical devices that DO NOT contain drugs, so does not require this business license.



Distributing a Device
(<https://www2.myfloridalicense.com/>)

Distributing a Device	In or Into Florida	No
Distributing a Cosmetic	In or Into Florida	No

- What is a “drug”, “device”, or “cosmetic”?

Refer to Section 499.003, Florida Statutes:

[http://www.leg.state.fl.us/statutes/index.cfm?](http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections/0499.003.html)

[App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections/0499.003.html](http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections/0499.003.html)

([http://www.leg.state.fl.us/statutes/index.cfm?](http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections/0499.003.html)

[App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections/0499.003.html](http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections/0499.003.html)) Please note that

“drug” specifically includes active pharmaceutical ingredient (API). Also, “devices” that contain “drugs” are classified as drugs if any of the principal intended purposes is achieved through chemical action.

- What is “distributing”?

Understanding this term is critical to avoid violating Chapter 499, Florida Statutes. Florida law defines “distributing” or “distribution” to implicate both physical possession and legal title or ownership. The term means

drug-donation-program/)

Complaints

(<https://www.myfloridalicense.com/datamart/cload=true?from=loginPage>)

Resources

(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/resources/>)



to sell; offer to sell; give away; transfer, whether by
change of title, physical movement, or both; deliver; or
offer to deliver. For example, a broker of a prescription
(<https://www2.myfloridalicense.com/>)
drug wholesale transaction may require a permit under
Florida law. The term excludes, however, certain
administrative activities,

My company distributes medical convenience kits and
+ other “combination products” to customers in Florida. Do
we need a permit?

My company’s administrative office does not handle any
+ prescription drugs. Do we still need to get a permit for that
location?

My company is relocating its operation. Do we need to
+ apply for a new permit?

My company is undergoing a change of ownership. Do we
+ need to (re)apply?

My company is a prescription drug wholesale distributor
+ (in-state or out-of-state). Our Certified Designated
Representative (CDR) just quit. What do we do?

My company manufactures and/or distributes active
+ pharmaceutical ingredient (“API”) to customers in Florida.
Do we need a permit?





Are there any exceptions to the licensing requirements

Chapter 499, Florida Statutes?

(<https://www2.myfloridalicense.com/>)

+ Are there any special provisions under Chapter 499, Florida Statutes for research and development?

+ What does the Division of Drugs, Devices, and Cosmetics inspection authority cover? Does inspection authority include access to protected health information (subject to HIPAA)? Does inspection authority include photography?

+ What if I am discovered to have operated without a permit?

+ Prescription drugs and medical gases already listed with FDA, do I need to do the same at the state level in FL? Who is required to list the RX drugs and medical gases with DBPR? Manufacturers, wholesale distributors, retail distributors?

Permitting

Health Care Clinic Establishment

Medical Gas



 Product Registration Department of Business & Professional Regulation
(https://www2.myfloridalicense.com/) Controlled Substances Reporting
CBD/Hemp/Marijuana
Certificate of Free Sale Information
Cancer Drug Donation Program



Quick Links

- **FAQs**
(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/faqs/>)
- **Forms and Publications**
(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/forms-and-publications/>)

Need Help?

All requests for publications, documents, forms, applications for licenses, permits and other similar certifications can be obtained by contacting the Customer Contact Center.

Division of Drugs, Devices and Cosmetics
2601 Blair Stone Road
Tallahassee, FL 32399-1047

Telephone: 850.717.1800



Public Records
(<https://www2.myfloridalicense.com/>)

CONTACT US
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- **Statutes and Rules**
(<https://www2.myfloridalicense.com/drugs-devices-and-cosmetics/statutes-and-rules/>)
- **Military Services**
(<https://www2.myfloridalicense.com/military-services/>)

RESOURCES

RESOURCES

MOBILE

GET IN TOUCH

Open MyFlorida Business eGuide
(<https://openmyfloridabusiness.gov/eguide/>)

MyFlorida.gov
(<https://www.myflorida.com/>)
Job Opportunities
(<https://jobs.myflorida.com/go/Department-of-Business-and-Professional-Regulation/2815000/>)



(<https://www2.myfloridalicense.com/mobile-app/>)


Customer Contact Center
2601 Blair Stone Road
Tallahassee, FL 32399

FDACS A to Z Resource

Professional-Regulation/2815000/)

Search DBPR records for businesses and professionals licensed by the department. Users can verify

 Guide https://www2.myfloridalicense.com/ Bridge Loan https://floridacommerce.com/RebuildFloridaBusinessFund/s/ Disclaimer https://www2.myfloridalicense.com/disclaimer/ Americans With Disabilities (ADA) https://www2.myfloridalicense.com/privacy-policy/ Hurricane Resources https://www2.myfloridalicense.com/emergency/	Florida Has a Right To Know https://www2.myfloridalicense.com/ Report State Fraud https://www.flgov.com/report-waste-fraud-and-abuse-in-state-government-1/ Employ Florida https://www.employflorida.com/vosnet/Default.aspx Florida Child Abuse Hotline https://www.myflfamilies.com/services/abuse/abuse-hotline/how-report-abuse Human Trafficking https://www.myflfamilies.com/services/abuse/human-trafficking Florida Disaster https://www.floridadisaster.org/getaplan/	licenses by name or license number https://www2.myfloridalicense.com/AZGuide/AZGuideSearch.aspx Copyright © 2024 Department of Business and Professional Regulation
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