CCSS
The Collaborative for Cannabinoid Science & Safety

Common Terminology & Glossary

As described more fully in this Glossary, the 2018 Farm Bill removed hemp and its constituents from the federal controlled substances schedules but reiterated the Food and Drug Administration (FDA) authority over hemp products (including its components, tetrahydrocannabinol (THC) and cannabidiol (CBD)) pursuant to the Federal Food, Drug & Cosmetic Act (FDCA) and the Public Health Service Act. In exercising that authority, FDA has determined based on the available evidence that it is unlawful under the FDCA to introduce or market:

- Drugs containing CBD or THC that have not been approved by FDA;
- Food or dietary supplements containing CBD or THC—regardless of whether hemp derived.

Products containing CBD (whether marketed as drugs, food, dietary supplements, cosmetics, personal care products, or products to be inhaled) are all subject to the same regulations and requirements as other non-cannabis FDA-regulated products.

D = General Purpose Definitions / SD = Statutory Definition		
Agricultural Act of 2014 and 2018 (Farm Bill)	D	Known as the "2014 Farm Bill," this was signed by President Obama on February 7, 2014. Section 7606 of the 2014 Farm Bill, entitled, the "Legitimacy of Industrial Hemp Research," authorizes industrial hemp (cannabis plants containing 0.3% or less THC by dry weight) to be used in research and pilot programs by institutions of higher education or state departments of agriculture studying the growth, cultivation or marketing of industrial hemp. Known as the "2018 Farm Bill," this was signed by President Trump on December 20, 2018. Section 12619 of the 2018 Farm Bill removes hemp and hemp-derived products (including hemp-derived CBD) from control under the federal Controlled Substances Act (CSA) provided the material contains 0.3% or less THC by dry weight but preserves the FDA jurisdiction over hemp pursuant to the FDCA and the Public Health Service Act.
Animal Drug	D	An animal drug is any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed. Any non-food product intended to affect the structure or any function of an animal is also an animal drug.
	SD	(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,- (1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or (2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions. *21 USC §321(g) and (v).*
Cannabidiol	D	Cannabidiol is a non-psychogenic cannabinoid derived from cannabis or synthesized.

Cannabinoids	D	Cannabinoids are molecules that can be classified as phytocannabinoids, endocannabinoids, or synthetic cannabinoids. • *Phytocannabinoid:* Over 100 naturally occurring chemicals found in the cannabis plant with a chemical structure related to endocannabinoids. Some of the most well-characterized so far include CBD and THC. • *Endocannabinoid:* Chemicals produced by the body that target cannabinoid receptors. • *Synthetic Cannabinoid:* Cannabinoids produced in the laboratory to structurally or functionally mimic the endocannabinoids or phytocannabinoids.
Cannabis	D	The generic term for all parts and derivatives of the plant, Cannabis sativa L. Historically this included varieties Sativa, Indica, and ruderalis. Now, most varieties of cannabis are hybrids, needing a composition analysis to determine cannabinoid content. Legally, cannabis is subdivided into two terms: hemp & marijuana. With limited exceptions, cannabis (and its cannabinoid components) is a Schedule I controlled substance in the U.S.; this classification denotes a drug with a high potential for abuse and no currently accepted medical use. *See definitions for hemp and marijuana for clarification.
	SD	The FDCA defines the term "cosmetic" as (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap. *21 USC §321(i).*
DEA Drug Scheduling	D	Drugs, substances, and certain chemicals used to make drugs are classified into five distinct categories (or schedules) at the federal level by the Drug Enforcement Administration (DEA); classification is determined by evaluating the substance's acceptable medical uses in the U.S., its relative abuse potential, and the likelihood of causing dependence when abused.
	SD	As explained by the DEA, drugs, substances, and certain chemicals used to make drugs are classified into five (5) distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs have a high potential for abuse and the potential to create severe psychological and/or physical dependence. As the drug schedule changes-- Schedule II, Schedule III, etc., so does the abuse potential-- Schedule V drugs represent the least potential for abuse. A listing of drugs and their schedule are located at CSA Scheduling or CSA Scheduling by Alphabetical Order. These lists describe the basic or parent chemical and do not necessarily describe the salts, isomers and salts of isomers, esters, ethers and derivatives that may also be classified as controlled substances. These lists are intended as general references and are not comprehensive listings of all controlled substances. *21 USC §801*

Dietary Supplement	D	The FDCA defines a "dietary supplement" as a product (other than tobacco) intended for ingestion to supplement the diet that contains one or more of the following dietary ingredients (or a constituent/extract of these ingredients): vitamin, mineral, amino acid, concentrate, metabolite, herb or other botanical, substance to increase total dietary intake. Dietary supplements are FDA regulated as foods.
	SD	"(ff) The term "dietary supplement" - **>> "(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:** • "(A) a vitamin; • "(B) a mineral; • "(C) an herb or other botanical; • "(D) an amino acid; • "(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or • "(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); **>> "(2) means a product that -** • "(A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or • "(ii) complies with section 411(c)(1)(B)(ii); • "(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and • "(C) is labeled as a dietary supplement; and **>> "(3) does -** • "(A) include an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and • "(B) not include - ▪ "(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507, or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or ▪ "(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act. *21 USC 321*
Dispensary	D	The term "dispensary" most often refers to a regulated retail store where medical marijuana is sold to qualified patients. It is not a pharmacy, although some dispensaries employ pharmacists. Products that dispensaries are allowed (or in some cases required) to sell vary from state to state along with the criteria by which patients are qualified to receive medical marijuana.

FDA	D	U.S. Food and Drug Administration is the federal regulatory body that is responsible for protecting the public health by assuring that foods (except for meat from livestock, poultry and some egg products, which are regulated by the U.S. Department of Agriculture) are safe, wholesome, sanitary and properly labeled; ensuring that human and veterinary drugs, vaccines and other biological products and medical devices intended for human use are safe and effective, protecting the public from electronic product radiation, assuring cosmetics and dietary supplements are safe and properly labeled, regulating tobacco products, and advancing the public health by helping to speed product innovations.
FDA-Approved Medication	D	A designation granted by FDA's Center for Drug Evaluation and Research following completion of a drug development program consisting of extensive pre-clinical trials, rigorous placebo-controlled clinical studies, numerous safety studies and submission of a new drug application. FDA drug approval guides correct dosing, safety, and efficacy of new compounds for medical use. Demonstration of product consistency is also required for FDA approval.
	SD	**(a) Necessity of effective approval of application** No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) [for new drug] or (j) [for a generic drug] is effective with respect to such drug. **(a) Biologics license** (1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless— (A) a biologics license under this subsection or subsection (k) [for biosimilars] is in effect for the biological product… *21 USC §355* | *42 USC §262*
Food	SD	The FDCA defines the term "food" as (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. *21 USC §321(f).*
Hemp	D	Hemp is a type of Cannabis sativa L. historically grown for seeds and fibrous materials found in stalks. In 2014, hemp was legally defined as a cannabis plant containing less than 0.3% of THC by dry weight. The 2018 Farm Bill expanded the definition of hemp to include extracts, derivatives, and cannabinoids with less than 0.3% of THC by dry weight.
	SD	"The term 'hemp' means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol [delta-9 THC] concentration of not more than 0.3 percent on a dry weight basis." *7 USC § 1639o*
	D	The FDCA defines a drug as an article recognized in the U.S. Pharmacopeia, National Formulary or Homeopathic Formulary, and any article that is intended to diagnose, mitigate, treat, cure, or prevent disease. Additionally, if a non-food article is intended to affect the structure or any function of the human body, it is also a drug.

Human Drug	SD	The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). 21 USC § 321(g)(1)
Label	D	The label is what is printed on a product's immediate container. Products regulated by the FDA may be legally required to include specific information (or exclude with respect to information that could be false or misleading) on the label.
	SD	The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper. *21 USC § 321(k)*
Labeling	D	Labeling is what is printed on the immediate container (the label) and any other material on or in the product or that accompanies the product. Labeling is a very broad category.
	SD	The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. *21 USC § 321(m)*
Marijuana	D	Marijuana is the name commonly applied to the dried resinous flower buds and leaves of the Cannabis sativa L. plant (or extracts or concentrates thereof) with a THC content of more than 0.3% (and often 15% to more than 80%) on a dry weight basis. It is often smoked, vaped, or ingested, especially for its intoxicating effect.
	SD	Subject to subparagraph (B), the term "marihuana" means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. (B) The term "marihuana" does not include— (i) hemp, as defined in section 1639o of title 7; or (ii) the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination. *21 USC § 802(16)*
Medical Marijuana	D	Non-FDA-approved cannabis-based products where, despite limited clinical evidence regarding effectiveness, the patient's intended use is to prevent, treat or mitigate a disease or alleviate its symptoms. Medical marijuana differs from recreational marijuana only in its intended use rather than its composition or formulation.
	D	OTC drugs are defined as drugs that are determined by FDA to be safe and effective for use by the general public for self-care without obtaining a prescription from a health professional.

Over-the-Counter (OTC) (Non-prescription)	SD	There are two bases for the lawful marketing of OTC drugs under the FDCA. • An approved application (see discussion of "FDA-Approved Medication" above. – 21 CFR 314 • A drug which falls outside the FDCA definition of "new drug" and is Generally Recognized as Safe and Effective. – 21 CFR 330
Pharmaceutical Cannabinoid Formulations	D	Can be plant-derived or synthetic and must be approved by the FDA for quality, safety, and efficacy before marketing. All pharmaceutical FDA-approved cannabinoid products must conform to current good manufacturing practices standards for pharmaceutical medicines and meet standards for purity, consistency, stability, safety and efficacy.
Recreational/ Adult Use Marijuana	D	Recreational/adult use marijuana includes cannabis or cannabis products that are used for non-medical use to induce pleasure, euphoria, relaxation and to enhance sociability. They are classified by intended use rather than by formulation-based differences.
Vape/Vaping Device	D	According to the FDA, a vape is one of the many terms used to describe electronic nicotine delivery systems (ENDS). ENDS are noncombustible tobacco products. These products use an "e-liquid" that may contain nicotine, cannabinoid formulations, or other psychoactive substances, as well as varying compositions of flavorings, solvents, and other ingredients. The liquid is heated to create a vapor that the user inhales.
Vaporizer	D	Inhalation device that heats up crude plant product and allows for the cannabinoids to be dispersed in a vapor without burning.