Congressional Research Service
Informing the legislative debate since 1914

Legal Sidebar

Legal Effect of Marijuana Rescheduling on FDA's Regulation of Cannabis

September 16, 2024

Cannabis and its derivatives are regulated under various federal laws, depending on the particular characteristics and uses of the substance or product. Currently, unless an exception applies, cannabis and its derivatives are legally classified as *marijuana*, which is a Schedule I controlled substance under the Controlled Substances Act (21 U.S.C. §§ 801 et seq.; CSA), meaning that it is in the category of substances subject to the most stringent regulation, and unauthorized activities involving marijuana are subject to significant criminal penalties. On May 21, 2024, the U.S. Department of Justice (DOJ) issued a proposed rule to transfer marijuana from Schedule I to Schedule III of the CSA, which would partially relax the controls of marijuana under federal law. A previous Legal Sidebar outlined the legal consequences of rescheduling marijuana. Regardless of a substance's status under the CSA, if a substance is included in consumer products such as food or drugs, the product containing the substance must also comply with the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.; FD&C Act) in order to be legally distributed in U.S. commerce under federal law. This Legal Sidebar focuses on the U.S. Food and Drug Administration's (FDA's) regulation of products containing cannabis and the effect marijuana's rescheduling, if finalized, may have on this regulation.

Background Information

Cannabis is a plant that contains chemical compounds known as cannabinoids. The most well-known cannabinoids are delta-9 tetrahydrocannabinols (THC) and cannabidiol (CBD), but there are more than 80 others. Cannabinoids can be derived from cannabis or they can be synthetically created in a laboratory. With certain exceptions, cannabis and products derived from it are classified as marijuana under the CSA.

Substances, such as marijuana, become subject to the CSA and oversight by the U.S. Drug Enforcement Administration (DEA) through their placement on five lists, known as Schedules I through V. Substances are placed on schedules based on findings related to the potential for their abuse and likelihood and severity of potential physical or psychological dependence to the drug, as well as whether there are currently accepted medical uses. A lower schedule number reflects a higher likelihood of abuse and dependence and accordingly carries higher restrictions under the CSA, with Schedule I having the most stringent controls. Unlike the other four schedules, Schedule I substances also must have no currently accepted medical use in the United States at the time they are scheduled. Substances that are classified as

Congressional Research Service
https://crsreports.congress.gov
LSB11227

Schedule II, III, IV, and V drugs have an accepted medical use and may be lawfully prescribed, assuming other federal legal requirements are satisfied. Marijuana is a Schedule I controlled substance under the CSA.

Unless otherwise authorized by the statute, controlled substances generally cannot be knowingly or intentionally manufactured, distributed, or dispensed, or possessed with intent to engage in those activities, among other prohibitions. Although Schedule I substances are subject to the most stringent controls, they may be legally used in medical research that is approved by the DEA. The CSA does not authorize recreational use of controlled substances on any schedule—meaning recreational use of marijuana would continue to be prohibited even if it were moved from Schedule I to Schedule III.

One exception to the general classification of cannabis and its derivatives as marijuana is *hemp*. The 2018 farm bill (Agriculture Improvement Act of 2018; P.L. 115-334) established a definition of hemp (7 U.S.C. § 1639o(1)) and excluded hemp from the definition of marijuana (21 U.S.C. § 802(16)) under the CSA. Hemp is defined as the cannabis plant and its derivatives with a "delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent." With the amendments made by the 2018 farm bill, hemp, including non-THC cannabinoids such as CBD, are no longer subject to the CSA's controls. The 2018 farm bill, however, explicitly preserved the authority of the FDA to regulate these products under the FD&C Act. Products containing hemp remain subject to the provisions of the FD&C Act and FDA's regulations. For purposes of this Sidebar, "hemp" has the definition from the 2018 farm bill and is exempt from regulation under the CSA, and "marijuana" means the cannabis plant and products derived from the plant that qualify as a controlled substance under the CSA.

FDA, under the FD&C Act, promotes public health by regulating food, drugs, dietary supplements, and a number of other products marketed in interstate commerce. FDA categorizes products based on how the nature of the product and the purpose for which it is sold, including marketing claims about how the product may be used or the effect it may have, align with the statutory definitions. A product may be considered to be adulterated or misbranded unless a manufacturer meets the requirements for that product category, including, in some cases, receiving prior approval from FDA. Generally, the FD&C Act prohibits the introduction of any adulterated or misbranded products into interstate commerce. Manufacturers have included cannabis-derived substances in many products that are subject to the FD&C Act, including foods, dietary supplements, drugs, cosmetics, and tobacco products. Due to its scheduling under the CSA, adding marijuana to any of these products for recreational use in any product category is prohibited and would remain prohibited if marijuana were moved to Schedule III.

Drugs and Biologics

Aside from Schedule I substances, controlled substances have accepted medical uses and may be lawfully dispensed by prescription under the CSA, subject to various restrictions. Accordingly, rescheduling marijuana from Schedule I to Schedule III would open the door for the medical marijuana industry to market their products consistent with federal law. Any such products must still comply with other federal legal requirements, such as the FD&C Act, before they could be legally marketed in the United States. Rescheduling thus would not automatically legalize medical marijuana in the United States.

The FD&C Act requires new drugs, including both small-molecule drugs that are synthesized in a laboratory and biologics that are derived from living organisms (e.g., vaccines), to be approved by FDA before they can be marketed and sold in the United States. For FDA to approve a new drug, the drug sponsor must submit a new drug application (NDA) with "substantial evidence" that the drug is safe and effective for its proposed use. Similarly, for FDA to approve a biologic, a sponsor must submit a biologics license application (BLA) demonstrating that the product is safe, potent, and pure. Certain chemicals related to or derived from marijuana may be considered small-molecule drugs, while other components of the cannabis plant—including marijuana itself—may be considered a biologic.

Marijuana itself is not an approved drug, but FDA has approved four drugs derived from or related to cannabis. FDA approved a drug containing CBD called Epidiolex, which is used to treat certain kinds of seizures. FDA also approved Marinol and Syndros for the treatment of anorexia associated with weight loss in AIDS patients, as well as Cesamet for the treatment of nausea and vomiting in patients undergoing chemotherapy. Marinol and Syndros contain the active ingredient dronabinol, a synthetic delta-9-tetrahydrocannabinol (THC), which is considered the psychoactive component of cannabis. Cesamet contains the active ingredient nabilone, which is synthetically derived and has a chemical structure similar to THC. Despite obtaining FDA approval, Epidiolex, Marinol, Syndros, and Cesamet could not immediately be marketed in the United States because CBD and synthetic tetrahydrocannabinols were considered Schedule I substances. The DOJ rescheduled each of these drugs within a few months to a couple years of their approval by FDA, thereby allowing the drugs to be marketed and prescribed. The DOJ rescheduled Epidiolex as a Schedule V drug, and the 2018 farm bill completely descheduled Epidiolex because it is considered hemp under the new definition. FDA-approved products containing dronabinol were rescheduled to Schedule II or Schedule III under the CSA, depending on their form, and FDA-approved products containing nabilone were rescheduled to Schedule II. Other tetrahydrocannabinols remain Schedule I substances, and, because they are scheduled separately from marijuana, they are not included in the DOJ's proposed rule rescheduling marijuana.

Drugs Marketed Without FDA Approval

New drugs that FDA has not approved cannot legally be marketed in interstate commerce under the FD&C Act. FDA categorizes products based on how they are marketed rather than based on how the manufacturer or seller categorizes them. FDA may therefore consider some products marketed as a food, dietary supplement, tobacco product, or cosmetic to be illegal drugs (assuming they have not obtained FDA approval for marketing as a drug) if the product's packaging makes claims that it is intended to cure, mitigate, or treat a disease or health-related condition. The FD&C Act defines a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." Therefore, FDA may deem products to be "drugs" under this definition if they are marketed as a treatment for a disease. FDA has issued warning letters to companies marketing cannabis products, including CBD tea and hemp-infused body butter, whose labeling makes these kinds of treatment claims, advising that drugs must undergo the NDA process before they can be marketed in interstate commerce. A manufacturer or seller of one of these products can remedy the issue by submitting an NDA and obtaining FDA approval to market its product as a drug, or by removing the claims.

Medical Research

To obtain approval for a new drug or biologic, sponsors must conduct research, including clinical trials on human subjects, to generate the required evidence regarding the drug's safety and effectiveness. Before conducting research with marijuana, a researcher must obtain a DEA registration and an FDA authorization of an investigational new drug application (IND) containing details on how the researcher plans to conduct the study. Then, the researcher must use marijuana from a DEA-registered source.

Generally, rescheduling a drug from Schedule I to Schedule III loosens the controls on medical research involving that drug. Researchers and manufacturers of Schedule III substances are subject to less-onerous registration requirements than researchers and manufacturers of Schedule I substances. However, medical researchers and drug sponsors of marijuana or CBD containing drugs would not benefit from these looser restrictions associated with rescheduling without congressional action. In 2022, Congress passed the Medical Marijuana and Cannabidiol Research Expansion Act (P.L. 117-215), which amended the CSA for medical research involving marijuana or CBD to lessen the stringent controls typically applicable for Schedule I substances. The act created separate requirements for marijuana researchers and manufacturers

to expedite registration with the DEA, and these separate requirements would not be affected by rescheduling without additional congressional action.

Food and Dietary Supplements

Marijuana cannot legally be marketed in foods or dietary supplements due to its status as a controlled substance under the CSA. The CSA criminalizes the possession, distribution, and manufacture of marijuana, except for the purpose of federally approved research, due to its status as a Schedule I controlled substance. Rescheduling marijuana to Schedule III would not legalize the use of marijuana in food or dietary supplements because recreational uses of marijuana are illegal under the CSA. Activities involving marijuana in food or dietary supplements would remain criminal offenses under the CSA, even if the proposed rule rescheduling marijuana goes into effect.

Since the enactment of the 2018 farm bill, the addition of hemp, including CBD, to food and dietary supplements does not violate the CSA. Any food or dietary supplement that contains a form of hemp would still have to comply with FD&C Act requirements. Generally, the FD&C Act does not require FDA to approve new food product or dietary supplements, but food and dietary supplements must still meet the relevant safety standards. For example, a food is generally considered adulterated if it contains "any poisonous or deleterious substance" that renders it "injurious to health," among other things. Similarly, a dietary supplement is considered adulterated if it "presents a significant or unreasonable risk of illness or injury." The FD&C Act also deems a food to be adulterated if it contains a food additive, unless FDA has promulgated a regulation prescribing the conditions for safe use of the additive and the use conforms with that regulation. Any person may petition FDA to issue such a regulation for an intended use of a food additive, supported with certain required data related to the additive's safety, among other things. Similarly, FDA deems a dietary supplement to be adulterated if it uses a new dietary ingredient (NDI)—a dietary ingredient that was not marketed in the United States before October 15, 1994—for which there is inadequate information included in the premarket notification. Additionally, the FD&C Act requires the manufacturer of a product containing an NDA to submit a premarket notification to FDA, which must contain information demonstrating that the NDI is "reasonably … expected to be safe."

To date, FDA has approved three hemp food additives as safe to add to food: hulled hemp seeds, hemp seed protein powder, and hemp seed oil. FDA has not, however, approved the use of any cannabinoids in food or dietary supplements. FDA has not determined that products containing CBD, Delta-8 THC, and other cannabinoids meet the FD&C Act's safety requirements for food and dietary supplements. FDA stated in a press release in January 2023 that, "given the available evidence, it is not apparent how CBD products could meet safety standards for dietary supplements or food additives." FDA has objected to NDI premarket notifications for the inclusion of hemp-related substances in dietary supplements on the basis that the manufacturers did not present sufficient safety data.

FDA has provided an additional reason for prohibiting food or dietary supplement products containing CBD and THC. The FD&C Act excludes ingredients that are used in an approved drug from the definition of dietary supplement. Under that provision, an article that is used in an approved drug cannot generally be used in a dietary supplement, except in limited circumstances. Similarly, the FD&C Act prohibits introducing food into interstate commerce that contains an added substance that has been approved as a drug, except in limited circumstances. Since FDA has approved drugs containing CBD and THC, FDA has taken the position that CBD and THC cannot legally be used in food or dietary supplements.

Even though FDA has determined that most uses of hemp-derived substances violate the FD&C Act, these products have nevertheless proliferated in the market. Under its risk-based approach to enforcement, FDA has sent warning letters to companies selling illegal cannabis products that are marketed to children or are in a form in which people may have difficulty consuming only an appropriate dosage. FDA has also

prioritized enforcement of products whose packaging contains unsubstantiated health claims, or claims that link an ingredient to a disease or health-related condition.

Tobacco Products

FDA has authority to regulate tobacco products, defined to mean "any product made or derived from tobacco," including products that contain nicotine from any source, that is "intended for human consumption." Tobacco products may include but are not limited to cigarettes, cigars, hookah, and electronic nicotine delivery systems (ENDS), which include e-cigarettes and vape pens. So long as marijuana is classified as a controlled substance, it cannot legally be a component of a tobacco product for recreational purposes, even if the rescheduling rule is finalized, because the CSA does not authorize recreational uses of any controlled substance. Hemp, however, may be incorporated into tobacco products without running afoul of the CSA.

Generally, new tobacco products (meaning tobacco products not commercially marketed prior to February 15, 2007, which includes all ENDS products) need to obtain marketing authorization from the FDA, which requires a showing that marketing the product is "appropriate for the protection of the public health." A product containing both a cannabinoid, such as CBD, and nicotine (or another tobacco-derived substance) would likely meet the statutory definition of "tobacco product" because it would include a tobacco-derived substance. Any such products would likely be considered adulterated until and unless FDA authorized them. These products would not receive marketing authorization if FDA determined that allowing the products to be marketed would not be appropriate for the protection of the public health. To date, none of the 56 new tobacco products FDA has authorized pursuant to a premarket tobacco product application (PMTA) contain a cannabinoid.

An inhalable product that does not contain tobacco, a tobacco-derived substance, or nicotine from any source likely would not meet the statutory definition of "tobacco product." FDA may consider some of these cannabinoid-only products to be drugs if the product affects the structure or function of the body. Products that do not meet the definitions of any FDA-regulated product types are not subject to any FDA oversight. FDA has requested that Congress create a new regulatory pathway for CBD products in part to address this possible gap in its authority.

Cosmetic Products

The FD&C Act generally does not require FDA to approve cosmetic products before they enter the market, nor does it require manufacturers to submit safety data regarding cosmetics products. Rather, the FD&C Act gives FDA the power to take certain enforcement action if a cosmetic is adulterated, which occurs if, among other things, it bears "any poisonous or deleterious substance which may render it injurious to users." FDA may take action if it has information that an ingredient or cosmetic product is unsafe. To date, FDA has not issued any warning letters to companies marketing hemp products on the basis that those products are adulterated. FDA also prohibits or restricts the use of certain ingredients in cosmetics by regulation; it has not done so with respect to any hemp or hemp-derived ingredients.

Considerations for Congress

If DEA reschedules marijuana, any drug containing marijuana would need to be approved by FDA before it could be legally marketed and sold in the United States. Even if DEA reschedules marijuana as a Schedule III substance, it cannot be used recreationally in food, dietary supplements, tobacco products, or cosmetics. Both Congress and the executive branch have the authority to reschedule marijuana, and Congress recently has considered rescheduling marijuana or removing marijuana from control under the CSA. If Congress considers the latter, Congress may consider whether to impose a new regulatory

framework on marijuana and, if so, which agency should be tasked with such authority. When crafting any such legislation, Congress might consider standards for safety, manufacturing, labeling, adverse event reporting, inspection, testing, premarket review, enforcement authority, and any other relevant considerations.

Companies are selling consumer products containing CBD and other cannabinoids despite their illegal status under the FD&C Act. FDA has called on Congress to create a new pathway to regulate products containing CBD. According to FDA, food and dietary supplements containing cannabinoids do not meet the safety standards required of these products. Also, certain inhalable products that contain cannabinoids and not tobacco or nicotine derived from any source may not be subject to regulation by FDA or any other agency without further congressional action. Congress could consider passing legislation that provides a framework for FDA to regulate these products. For example, Congress has recently considered passing legislation (e.g., H.R. 4849, S. 2451, H.R. 1628, H.R. 1629) that would require FDA to regulate CBD in dietary supplements.

Author Information

Dorothy C. Kafka
Legislative Attorney

Disclaimer