FAQs About CBD From the FDA:

What to Know About Products Containing Cannabis and CBD

What You Should Know About Using CBD When Pregnant or Breastfeeding

Some Medicines and Driving Don't Mix

1. What are cannabis and marijuana?

A. Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Parts of the *Cannabis sativa* plant have been controlled under the Controlled Substances Act (CSA) since 1970 under the drug class "Marihuana" (commonly referred to as "marijuana") [21 U.S.C. 802(16)]. "Marihuana" is listed in Schedule I of the CSA due to its high potential for abuse, which is attributable in large part to the psychoactive effects of THC, and the absence of a currently accepted medical use of the plant in the United States.

2. How does the 2018 Farm Bill define hemp? What does it mean for FDA-regulated products?

A. At the federal level, the Agriculture Improvement Act of 2018, Pub. L. 115-334, (the 2018 Farm Bill) was signed into law on Dec. 20, 2018. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as "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 concentration of not more than 0.3 percent on a dry weight basis." These changes include removing hemp from the CSA, which means that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under federal law.

The 2018 Farm Bill, however, explicitly preserved FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products — meaning they're

subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill.

3. Why hasn't FDA approved more products containing cannabis or cannabis-derived compounds for medical uses?

A. FDA is aware that unapproved cannabis or cannabis-derived products are being used for the treatment of a number of medical conditions including, for example, AIDS wasting, epilepsy, neuropathic pain, spasticity associated with multiple sclerosis, and cancer and chemotherapy-induced nausea.

To date, FDA has not approved a marketing application for cannabis for the treatment of any disease or condition and thus has not determined that cannabis is safe and effective for any particular disease or condition. The agency has, however, approved one cannabis-derived and three cannabis-related drug products (see Question #2).

FDA relies on applicants and scientific investigators to conduct research. The agency's role, as laid out in the FD&C Act, is to review data submitted to the FDA in an application for approval to ensure that the drug product meets the statutory standards for approval.

The study of cannabis and cannabis-derived compounds in clinical trial settings is needed to assess the safety and effectiveness of these substances for the treatment of any disease or condition. FDA's December 2016 *Guidance for Industry: Botanical Drug Development* provides specific recommendations on submitting INDs for botanical drug products, such as those derived from cannabis, in support of future marketing applications for these products. The FDA will continue to facilitate the work of companies interested in appropriately bringing safe, effective, and quality products to market, including scientifically-based research concerning the medicinal uses of cannabis. Additional information concerning research on the medical use of cannabis is available from the National Institutes of Health, particularly the National Cancer Institute (NCI) and National Institute on Drug Abuse (NIDA).

4. Is it legal for me to sell CBD products?

A. It depends, among other things, on the intended use of the product and how it is labeled and marketed. Even if a CBD product meets the definition of "hemp" under the 2018 Farm Bill (see Question #2), it still must comply with all other applicable laws, including the FD&C Act. The below questions and answers explain some of the ways that specific parts of the FD&C Act can affect the legality of CBD products.

We are aware that state and local authorities are fielding numerous questions about the legality of CBD. There is ongoing communication with state and local officials to answer questions about requirements under the FD&C Act, to better understand the landscape at the state level, and to otherwise engage with state/local regulatory partners.

5. What is FDA's position on cannabis and cannabis-derived ingredients in cosmetics?

A. A cosmetic is defined in 201(i) 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."

Under the FD&C Act, cosmetic products and ingredients are not subject to premarket approval by FDA, except for most color additives. Certain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients. Ingredients not specifically addressed by regulation must nonetheless comply with all applicable requirements, and no ingredient – including a cannabis or cannabis-derived ingredient – can be used in a cosmetic if it causes the product to be adulterated or misbranded in any way. A cosmetic generally is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual (section 601(a) of the FD&C Act [21 U.S.C. § 361(a)]).

If a product is intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent disease, it is a drug, or possibly both a cosmetic and a drug, even if it affects the appearance. (See Question #3 for more information about drugs.)

FDA can take action if it has information that an ingredient or cosmetic product is unsafe to consumers. Consumers can report adverse events associated with cosmetic products via the FDA's MedWatch reporting system, either online or by phone at 1-800-FDA-1088, or by contacting your nearest FDA district office consumer complaint coordinator. For more information, please see the FDA's webpage on how to report a cosmetic-related complaint.

Research and Expanded Access

1. What is FDA's role when it comes to the investigation of cannabis and cannabis-derived products for medical use?

A. To conduct clinical research that can lead to an approved new drug, including research using materials from plants such as cannabis, researchers need to work with the FDA and submit an IND application to the Center for Drug Evaluation and Research (CDER). The IND application process gives researchers a path to follow that includes regular interactions with the FDA to support efficient drug development while protecting the patients who are enrolled in the trials. For research for use as an animal drug product, researchers would establish an investigational new animal drug (INAD) file with the Center for Veterinary Medicine to conduct their research, rather than an IND with CDER.

As discussed above (see Question #2), the 2018 Farm Bill removed hemp from the CSA. This change may streamline the process for researchers to study cannabis and its derivatives, including CBD, that fall under the definition of hemp, which could speed the development of new drugs.

Conducting clinical research using cannabis-related substances that are scheduled by the DEA often involves interactions with several federal agencies. This includes: a registration administered by the DEA; obtaining the cannabis for research from NIDA, within the National Institutes of Health, or another DEA-registered source; and review by the FDA of the IND or INAD application and research protocol. Additionally:

- For a Schedule I controlled substance under the CSA, DEA provides researchers with investigator and protocol registrations and has Schedule I-level security requirements at the site cannabis will be studied.

- NIDA provides research-grade cannabis for scientific study. The agency is responsible for overseeing the cultivation of cannabis for medical research and has contracted with the University of Mississippi to grow cannabis for research at a secure facility. Cannabis of varying potencies and compositions is available. DEA also may allow additional growers to register with the DEA to produce and distribute cannabis for research purposes.
- Researchers work with the FDA and submit an IND application to the appropriate division in the Office of New Drugs in CDER depending on the therapeutic indication. Based on the results obtained in studies conducted at the IND stage, sponsors may submit a marketing application for formal approval of the drug.

2. How can patients gain access to cannabis or cannabis-derived products for medical use through expanded access?

A. Expanded access is a potential pathway for a patient with a serious or life-threatening disease or condition to try an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when there are no comparable or satisfactory therapies available. Manufacturers may be able to make investigational drugs available to individual patients in certain circumstances through expanded access, as described in the FD&C Act and implementing regulations.

Children and Pregnant/Lactating Women

1. Does the FDA have concerns about administering a cannabis product to children?

A. We understand that parents are trying to find treatments for their children's medical conditions. However, the use of untested drugs can have unpredictable and unintended consequences. Caregivers and patients can be confident that FDA-approved drugs have been carefully evaluated for safety, efficacy, and quality, and are monitored by the FDA once they are on the market. The FDA continues to support sound, scientifically-based research into the medicinal uses of drug products containing cannabis or cannabis-derived compounds, and will continue to work with companies interested in bringing safe, effective, and quality products to market. With the exception of Epidiolex, Marinol, and Syndros, no product containing cannabis

or cannabis-derived compounds (either plant-based or synthetic) has been approved as safe and effective for use in any patient population, whether pediatric or adult.

2. Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?

A. The FDA is aware that there are potential adverse health effects with use of cannabis products containing THC in pregnant or lactating women. Published scientific literature reports potential adverse effects of cannabis use in pregnant women, including fetal growth restriction, low birth weight, preterm birth, small-for-gestational age, neonatal intensive care unit (NICU) admission, and stillbirth. [1, 2, 3] Based on published animal research, there are also concerns that use of cannabis during pregnancy may negatively impact fetal brain development. [4, 5, 6] The American College of Obstetricians and Gynecologists (ACOG) recommends that women who are pregnant or contemplating pregnancy should be encouraged to discontinue cannabis use. In addition, ACOG notes that there are insufficient data to evaluate the effects of cannabis use on breastfed infants; therefore, cannabis use is discouraged when breastfeeding. [7] Pregnant and lactating women should talk with a health care provider about the potential adverse health effects of cannabis use.

3. What does the FDA think about making CBD available to children with epilepsy?

A. The FDA has approved Epidiolex, which contains a purified form of the drug substance CBD, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means the FDA has concluded that this particular drug product is safe and effective for its intended use. Controlled clinical trials testing the safety and efficacy of a drug, along with careful review through the FDA's drug approval process, is the most appropriate way to bring cannabis-derived treatments to patients. Because of the adequate and well-controlled clinical studies that supported this approval, and the assurance of manufacturing quality standards, prescribers can have confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

4. What should I do if my child eats something containing cannabis?

A. With the exception of products such as the hemp seed ingredients discussed in Question #12, which have been evaluated for safety, it is important to protect children from accidental ingestion of cannabis and cannabis-containing products. FDA recommends that these products are kept out of reach of children to reduce the risk of accidental ingestion. If the parent or caregiver has a reasonable suspicion that the child accidentally ingested products containing cannabis, the child should be taken to a physician or emergency department, especially if the child acts in an unusual way or is/feels sick.

Pets and other Animals

1. I've seen cannabis products being marketed for pets. Are they safe?

A. FDA is aware of some cannabis products being marketed as animal health products. We want to stress that FDA has not approved cannabis for any use in animals, and the agency cannot ensure the safety or effectiveness of these products. For these reasons, FDA cautions pet-owners against the use of such products and recommends that you talk with your veterinarian about appropriate treatment options for your pet.

Signs that your pet may be suffering adverse effects from ingesting cannabis may include lethargy, depression, heavy drooling, vomiting, agitation, tremors, and convulsions.

If you have concerns that your pet is suffering adverse effects from ingesting cannabis or any substance containing cannabis, consult your veterinarian, local animal emergency hospital or an animal poison control center immediately.

While the agency is aware of reports of pets consuming various forms of cannabis, to date, FDA has not directly received any reports of adverse events associated with animals given cannabis products. However, adverse events from accidental ingestion are well-documented in scientific literature. If you feel your animal has suffered from ingesting cannabis, we encourage you to report the adverse event to the FDA. Please visit Reporting Information about Animal Drugs and Devices to learn more about how to report an adverse event related to an animal drug or for how to report an adverse event or problem with a pet food.

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[1] Gray, et al. Identifying Prenatal Cannabis Exposure and Effects of Concurrent Tobacco Exposure on Neonatal Growth. Clinical Chemistry. 2010; 56(9): 1442-1450.

[2] Gunn, et al. Prenatal Exposure to cannabis and maternal and child health outcomes: a systematic review and meta-analysis. BMJ Open. 2016; 6:e009986.

[3] Hayatbakhsh, et al. Birth Outcomes associated with cannabis use before and during pregnancy. Pediatric Research. 2012; 71 (2): 215-219.

[4] Silva, et al. Prenatal tetrahydrocannabinol (THC) alters cognitive function and amphetamine response from weaning to adulthood in the rat. Neurotoxicol and Teratol 2012; 34(1): 63-71.

[5] Trezza, et al. Effects of perinatal exposure to delta-9-tetrahydrocannabinol on the emotional reactivity of the offspring: a longitudinal behavioral study in Wistar rats. Psychopharmacology (Berl) 2008; 198(4): 529-537.

[6] Campolongo, et al. Perinatal exposure to delta-9-tetrahydrocannabinol causes enduring cognitive deficits associated with alteration of cortical gene expression and neurotransmission in rats. Addict Biol 2007; 12(3-4): 485–495.

[7] ACOG Committee Opinion: Marijuana Use During Pregnancy and Lactation