

April 2019

News



Minnesota Board of Pharmacy

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Disciplinary Actions

Because of space limitations, information on disciplinary actions is no longer being included in the *Minnesota Board of Pharmacy Newsletter*. A document that provides information about recent Board disciplinary actions can be found on the [Minnesota Board of Pharmacy website](#) under the “Resources/FAQs” menu item.

Products Containing CBD Extracted From Hemp

The Board continues to receive questions from pharmacists and pharmacies concerning the legality of products that contain cannabidiol (CBD) derived from hemp. Federal and state laws do not permit CBD (or any other cannabinoid) to be extracted from hemp and sold as a dietary supplement or drug. Federal and state laws also do not permit cannabinoids to be added to any food products. Products other than food that contain cannabinoids extracted from hemp and that are sold with the intent to prevent, treat, or cure diseases – or to alter the structure and function of the human body – are drugs. Such products have not been approved by Food and Drug Administration (FDA), have not had their labeling approved by FDA, and are not manufactured by a manufacturer that is licensed by the Board, registered by FDA, and following current Good Manufacturing Practices (cGMPs).

Consequently, the products are misbranded and adulterated, and they cannot be legally sold. It is unprofessional conduct for a pharmacist or pharmacy to violate any statute, rule, or ordinance at the federal, state, or local level related to the practice of pharmacy. Therefore, pharmacies cannot sell these products. Pharmacists and pharmacies might also want to check with their own legal counsels and with malpractice insurers, if they are considering selling products that are illegal, unregulated, and for which unsubstantiated medical claims are being made.

Cannabis Sativa and CBD

Cannabis sativa is an herbaceous plant that originated in Central and South Asia. It has been cultivated throughout human history and has been used as a source of fiber, food, seed oil, and medicinal substances. Because of the psychoactive effects of delta-9-tetrahydrocannabinol (THC), *Cannabis sativa* varieties with larger percentages of THC have been widely used recreationally. Cannabis has also been used in religious ceremonies.

Different varieties of *Cannabis sativa* can have differing concentrations of the cannabinoids discussed here. In fact, growers have been breeding plants in order to produce strains that have desired levels of either THC or CBD, depending on the intended use of the resultant strains. Hemp is a strain of *Cannabis sativa* that has lower concentrations of THC, either naturally or as the result of breeding. Natural hemp has been used for several millennia as a source of fiber to make ropes, cloth, paper, and other products. Hemp seeds are used as a food substance and are a source of protein, fiber, and magnesium. Varieties of *Cannabis sativa* that are high in THC concentration and that are used for recreational purposes due to their ability to produce a “high” are commonly referred to as marijuana or marihuana. The difference in concentrations of THC has important legal ramifications, as explained in the next article.

CBD is one of dozens of cannabinoid substances produced by *Cannabis sativa*. Unlike THC, CBD does not produce the high associated with marijuana use. Since CBD does not cause a high, CBD advocates sometimes mistakenly claim that it is not psychoactive. But pharmacologically, a psychoactive substance is one that acts on the central nervous system and alters brain function, resulting in temporary changes in perception, mood, consciousness, and behavior. CBD does act on the central nervous system, and it can alter perception and mood. It can also cause sedation. Advocates for CBD often claim that CBD can have a calming effect,

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National Pharmacy Compliance News

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The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an [FDA press release](#). Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the [Federal Register](#).

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements.

These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm>.

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy*. The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- ◆ **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- ◆ **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- ◆ **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the “most important criterion of success” is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at <https://www.whitehouse.gov/opioids>.

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP’s PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWARD[®] Prescription Drug Safety Program’s Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWARD program, visit the Initiatives section of the NABP website at www.nabp.pharmacy.

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open*. The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as “modest,” due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take “a stronger and multipronged approach” to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405>.

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

“Now that these risks are identified, we’re applying what we’ve learned to the evaluation of similar manufacturing processes where we now know these risks could arise,” the statement notes. The FDA press release is available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm>.

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency’s primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug’s benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- ◆ **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- ◆ **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at <https://www.fda.gov/drugs/drugsafety/remis>.

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reduce anxiety, and even treat depression. CBD acts on a variety of signaling systems and receptors within the body, including serotonin receptors, but it does not activate cannabinoid receptors. It is metabolized by the cytochrome P450 enzymes and can therefore potentially interact with many commonly prescribed medications.

Legal Considerations for CBD

When the Minnesota Legislature enacted the Industrial Hemp Development Act (Minnesota Statute Chapter 18K), it defined “industrial hemp” to mean (**emphasis added**):

. . . the plant *Cannabis sativa* L. and any part of the plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. **Industrial hemp is not marijuana as defined in section 152.01, subdivision 9.**

The emphasized sentence is important because Minnesota Statute §152.02 does not specifically list CBD by name as a Schedule I controlled substance (CS). Listed instead are marijuana, tetrahydrocannabinols, and a large number of synthetic cannabinoids. CBD is neither a tetrahydrocannabinol nor a synthetic cannabinoid.

The definition of “marijuana” found in Minnesota Statute §152.01 includes the phrase, “every compound, manufacture, salt, derivative, mixture, or preparation of such plant . . .” Consequently, a compound, manufacture, preparation, or derivative of the marijuana plant is itself defined as marijuana. Since marijuana is a Schedule I CS, its compounds and derivatives are also scheduled. But as noted above, industrial hemp is explicitly excluded from the definition of marijuana – so, when derived from a hemp plant, CBD is not a Schedule I CS, at least not directly. However, CBD **derived from marijuana** would appear to be a CS. There is a possibility that CBD derived from hemp might **indirectly** be a Schedule I CS if it was considered to be an analog of CBD derived from marijuana.

Even though CBD derived from hemp may not be a CS, the sale of products that contain CBD is illegal under both federal and state law. The federal Agricultural Act of 2014 legalized the growing and cultivating of industrial hemp for **research** purposes in states where such growth and cultivation is legal under state law. However, the federal Agricultural Act of 2014 only allowed growth and cultivation by an institution of higher education or state department of agriculture, and only for purposes of agricultural or other academic **research** or under the auspices of a state agricultural **pilot program** for the growth, cultivation, or marketing of industrial hemp. It

did not authorize general commercial sales of products that contain CBD derived from hemp.

The federal Agricultural Act of 2018 went further by explicitly stating that none of the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) are preempted by the hemp provisions. That effectively means that products containing CBD cannot be sold when drug claims are made – unless the product goes through the new drug approval process, the manufacturer is registered by FDA, and cGMPs are followed. Any products that do not meet those requirements are considered to be misbranded and adulterated drugs. Finally, certain provisions in the FD&C Act also prohibited the sale of CBD as a dietary supplement.

When the Minnesota Legislature enacted the Industrial Hemp Development Act in 2015, growing of industrial hemp was authorized only for **research** purposes. In addition, part of the session law for that legislation indicates that the legislature knew that the federal law did not allow for commercial sales of hemp-derived products. The Industrial Hemp Development Act does not preempt any provisions of Minnesota Statute Chapter 151. Consequently, CBD products derived from industrial hemp and intended for human consumption are drugs, as defined in Minnesota Statute §151.01, Subdivision 5. (An exception being if they are food products). Under Minnesota law, drugs are misbranded and adulterated if: they are not approved for medical use by FDA; their labeling has not been approved by FDA; they are not manufactured at a facility registered by FDA and licensed by the Board; or they are not manufactured using cGMPs.

From the labeling of some CBD products, it is clear that they are intended to affect the structure or function of the bodies of humans and animals. In some cases, the labeling claims that the products can be used to treat specific diseases. Any products, other than a food product, that make such claims fall under the legal definition of the word “drug” that is found in Minnesota Statutes Chapter 151. And if the products are drugs, their sales are illegal under Minnesota Statute §151.34, which begins as follows:

It shall be unlawful to:

- (1) manufacture, sell or deliver, hold or offer for sale any drug that is adulterated or misbranded;
- (2) adulterate or misbrand any drug;
- (3) receive in commerce any drug that is adulterated or misbranded, and to deliver or proffer delivery thereof for pay or otherwise[.]

Note that the sections of Minnesota Statute Chapter 151 that have been referenced do not apply to products made by manufacturers regulated by the Minnesota Department

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of Health under the state's Medical Cannabis Program because Minnesota Statute §152.29 states, "For purposes of sections 152.22 to 152.37, a medical cannabis manufacturer is not subject to the Board of Pharmacy licensure or regulatory requirements under chapter 151."

In summary, the sale of most products that contain CBD extracted from any type of cannabis plant and intended to be used to treat medical conditions or to alter the structure and function of human or animal bodies, remains illegal under both federal and state law. The exceptions would be FDA-approved drugs, such as the recently approved Epidiolex[®], and the products allowed to be sold under state law by the manufacturers that are regulated by the Minnesota Department of Health, Office of Medical Cannabis.

The Board is aware that numerous businesses that are not licensed by the Board are selling such products within the state of Minnesota. In addition, hundreds of websites are offering such products for sale. The Board has made it clear to reporters who have interviewed Board staff, to businesses that call to ask about such products, and to legislators, that no business can legally sell such products. Unfortunately, so many unlicensed businesses are selling them that it would be very difficult to take enforcement

actions against all of them, especially those that are located outside of the state and that rely on internet sales. The Board can and will take action in situations where there is evidence that purchasers are being harmed or defrauded.

Board staff is working with other state departments and with legislators on possible legislation that would allow for the sale of such products, provided appropriate labeling and quality control requirements are met. FDA has also announced that it is considering whether or not it can take action to allow the products to be sold as dietary supplements. However, it may take at least a year to complete these efforts.

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