

A New Way Forward for Cannabidiol (CBD) and Other Hemp Products

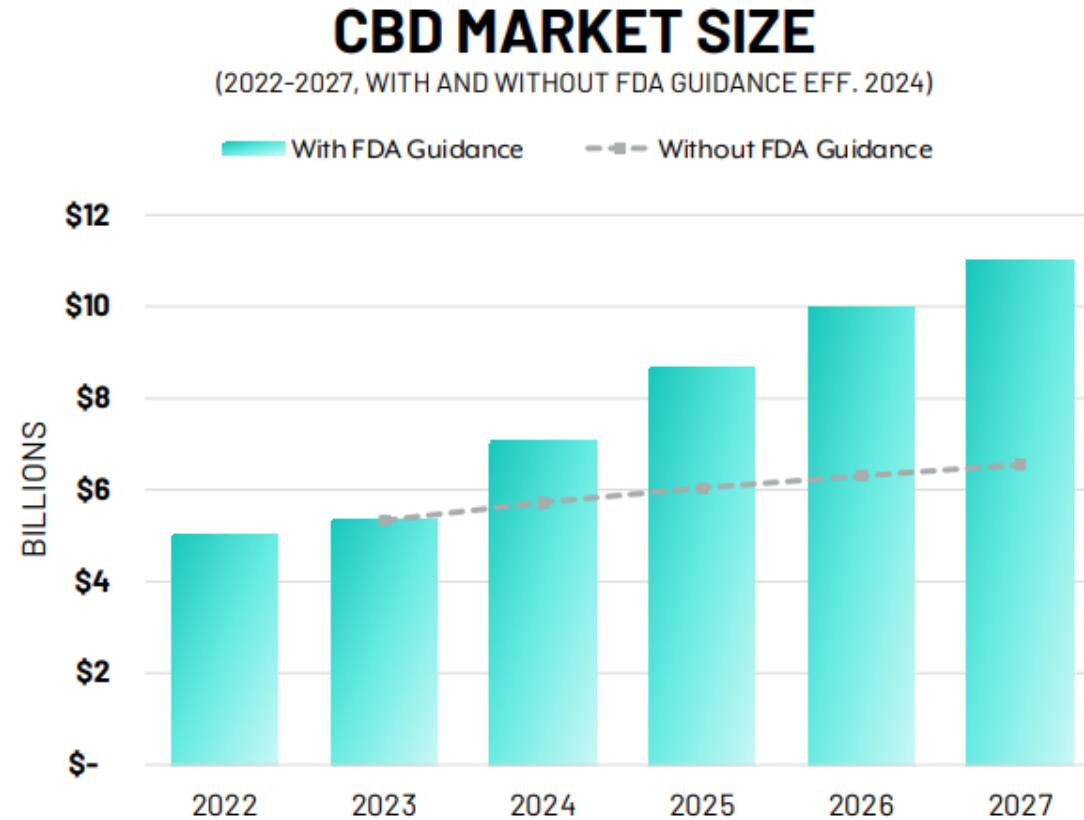
**Association of Food and Drug Officials
Annual Education Conference**

June 12, 2024

Patrick Cournoyer, PhD
Senior Science Advisor
Lead, Cannabis Product Committee

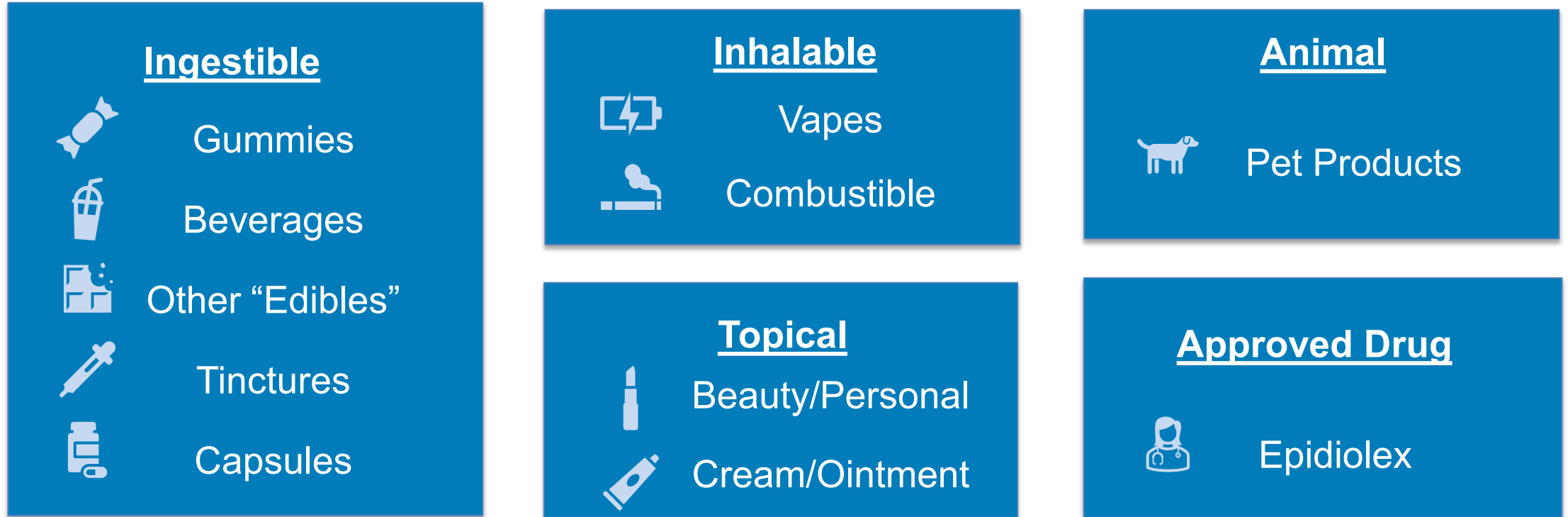
- The Agriculture Improvement Act (Farm Bill) of 2018 removed hemp from regulation by the Drug Enforcement Administration (DEA) under schedule 1 of the CSA
- The Farm Bill defined hemp as *Cannabis sativa* L. with delta-9 THC concentration not more than 0.3 percent (on a dry weight basis)
 - Includes hemp derivatives, e.g. CBD
 - Hemp can have high concentrations of CBD
- **Hemp products remain subject to regulation under the Federal Food Drug & Cosmetic Act (FD&C Act), when applicable:**
 - As drugs, foods, dietary supplements, cosmetics, veterinary products

CBD is estimated to be a \$5B+ market



Source: Brightfield Group Consumer Insights; June 2022 N=5,408

CBD products come in a wide variety of formats

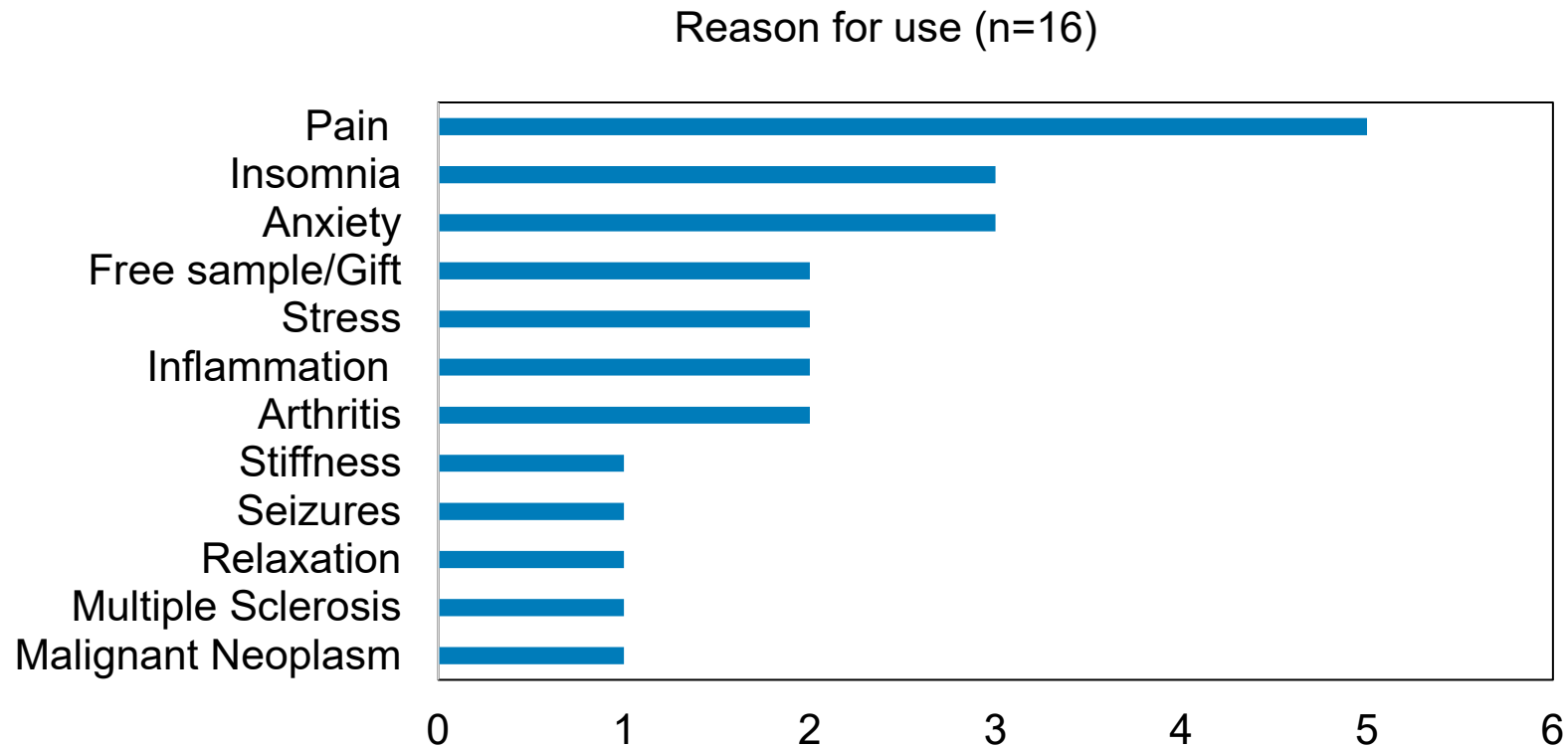


- FDA has regulatory authority only over specific product types, including drugs, foods, dietary supplements, cosmetics, and tobacco products.

Self-reported reasons for using CBD: pain, anxiety, and insomnia

- In an FDA analysis of CBD-related adverse event reports received in 2020, the top three self-reported conditions for using CBD products were **pain, anxiety, and insomnia**.
- These findings are consistent with other sources.

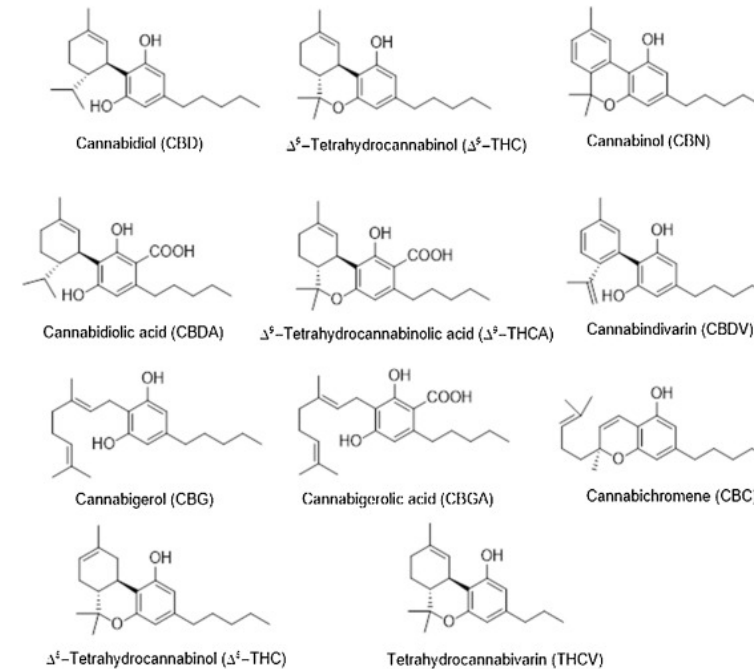
Cannabidiol (CBD)-Related Adverse Events Reports from the FDA CFSAN Adverse Event Reporting System (CAERS), 2020



Consumer interest in other cannabinoids is growing

- Hemp contains substances related to CBD that are growing in popularity, including cannabigerol (CBG), cannabinol (CBN), and cannabichromene (CBC).
- Like CBD, these substances are not believed to be intoxicating, and people are interested in access.
- Their safety profiles are largely unknown.

<https://doi.org/10.1016/j.jfca.2020.103800>



Examples of CBG, CBN, and CBC products

- CBD is the active ingredient in an FDA-approved drug and was the subject of substantial clinical investigations before it was marketed as a food or dietary supplement.
 - FD&C Act §301(ll): Food prohibition (human and animal food)
 - FD&C Act §201(ff)(3)(B): Dietary supplement exclusion
- FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement
- Commissioner Gottlieb stated in 2018 that, **“FDA would only consider doing so if the agency were able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients”**
- Commissioner Gottlieb established the CBD Policy Working Group (now the Cannabis Product Committee, CPC)
- **Can CBD meet the safety standards for ingredients in foods and dietary supplements?**

Since 2018 we have collected information

- May 2019 public meeting
- Open public docket
- Analytical sampling study of CBD products
- Collecting information on market and usage
- FDA-led toxicological studies on CBD
- Monitoring adverse event reports
- Scientific literature review
- Established cooperation with external research groups
- Studies as a part of drug development, including post-market studies

CBD raises important safety concerns

What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD

The FDA is working to answer questions about the science, safety, and quality of products containing cannabis and cannabis-derived compounds, particularly CBD.

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Potential harm, side effects and unknowns

1. CBD has the potential to harm you, and harm can happen even before you become aware of it.
 - CBD can cause liver injury.
 - CBD can affect how other drugs you are taking work, potentially causing serious side effects.
 - Use of CBD with alcohol or other drugs that slow brain activity, such as those used to treat anxiety, panic, stress, or sleep disorders, increases the risk of sedation and drowsiness, which can lead to injuries.
 - Male reproductive toxicity, or damage to fertility in males or male offspring of women who have been exposed, has been reported in studies of animals exposed to CBD.

- The use of CBD raises various safety concerns, especially with long-term use.
- Studies have shown the potential for harm to the liver, interactions with certain medications and possible harm to the male reproductive system.
- CBD exposure is also concerning when it comes to certain vulnerable populations such as children and those who are pregnant.

FDA Statement: Existing frameworks not appropriate

FDA STATEMENT

FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward

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For Immediate Release: January 26, 2023
Statement From: Janet Woodcock, M.D.
Principal Deputy Commissioner - Office of the Commissioner

[Español](#)

Given the growing cannabidiol (CBD) products market, the U.S. Food and Drug Administration convened a high-level internal working group to explore potential regulatory pathways for CBD products. Today we are announcing that after careful review, the FDA has concluded that a new regulatory pathway for CBD is needed that balances individuals' desire for access to CBD products with the regulatory oversight needed to manage risks. The agency is prepared to work with Congress on this matter. Today, we are also denying three citizen petitions that had asked the agency to conduct rulemaking to allow the marketing of CBD products as dietary supplements.

The use of CBD raises various safety concerns, especially with long-term use. Studies have shown the potential for harm to the liver, interactions with certain medications and possible harm to the male reproductive system. CBD exposure is also concerning when it comes to certain vulnerable populations such as children and those who are pregnant.

- Given the available evidence, it is not apparent how CBD products could meet statutory requirements for dietary supplements or food additives.
- This is because of two key factors:
 - (1) CBD's inherent risk profile
 - (2) the highly protective safety standards and the limited risk management options for the food ingredient and dietary supplement pathways

The food ingredient and dietary supplement pathways differ from the drug pathway

	Drugs	Dietary Supplements	Food Ingredients
Typical users:	<p>Specific Group Those with a specific medical condition</p>	<p>Broad Group Those seeking to supplement their diet and maintain health</p>	<p>Everyone All people, including vulnerable groups</p>
Summary of safety standard:	<p><i>For new drug approval:</i> Benefit outweighs risk</p>	<p><i>Pre-market standard for new dietary ingredients:</i> Reasonably expected to be safe (benefits not considered)</p>	<p>Reasonable certainty of no harm (benefits not considered)</p>
Examples of risk management options:	<ul style="list-style-type: none"> - Labeling with detailed instructions and warnings - Prescription and behind counter - Risk Evaluation and Mitigation Strategy (REMS) program - DEA scheduling - Spontaneous adverse event reporting 	<ul style="list-style-type: none"> - Safety standards - Firms can indicate conditions of use, e.g. recommended serving, duration of use, population - Users can report adverse events 	<ul style="list-style-type: none"> - Primarily through strict pre-market safety standard (not labeled conditions of use) - Users can report adverse events

FDA does not intend to initiate rulemaking...

FDA Issues Response to Three Citizen Petitions Related to CBD and Dietary Supplements

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Constituent Update

January 26, 2023

Today, the U.S. Food and Drug Administration (FDA) denied the requests in three citizen petitions, from the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN), and the Natural Products Association (NPA), that the FDA issue a regulation that would allow cannabidiol (CBD) products to be marketed as dietary supplements. Such a regulation would be needed in order to provide a potential pathway for CBD products to be lawfully marketed as dietary supplements, because a provision in the law prohibits the marketing of certain drug ingredients as dietary supplements. The FDA's responses explain that we do not intend to initiate such a rulemaking, because in light of the available scientific evidence, it is not apparent how CBD products could meet the applicable safety standard for dietary supplements.

The separate citizen petitions included other requests related to CBD and dietary supplements that were all thoroughly reviewed and addressed in the respective FDA responses.

In addition, the FDA issued a statement today on the broader work of the cross-agency Cannabis Product Committee to explore potential regulatory pathways for CBD products. That statement explains that the agency does not consider the existing dietary supplement and conventional food pathways to be appropriate for CBD and that the FDA is interested in working with Congress to develop a new pathway that balances consumers' desire to access CBD products with the regulatory oversight necessary to better manage the risks these products present.

- We do not intend to initiate such a rulemaking, because in light of the available scientific evidence, it is not apparent how CBD products could meet the applicable safety standard for dietary supplements.
- The responses give detailed rationale.
- The responses are publicly available.

FDA Statement: A new path forward

FDA STATEMENT

FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward

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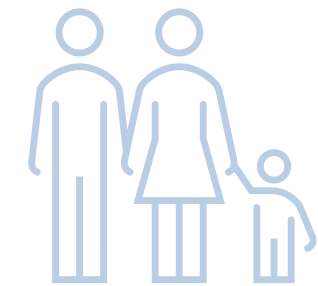
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- Working with Congress to develop a new pathway that takes a harm reduction approach.
- A new pathway could balance consumer access with regulatory oversight.
- A new pathway could implement standards to help people:
 - manage and reduce their risk
 - make more informed choices about their health

- A new pathway could provide...
- Basic oversight, e.g.:
 - Measures to mitigate the risk of contaminants
- Additional safeguards to mitigate specific risks, which could include:
 - CBD content limits
 - Clear labels
 - Measures to mitigate the risk of ingestion by children



A new way forward

- Major segments of the CBD market include
 - Topical CBD products
 - Electronic CBD vapes
 - Smokeable hemp flower
 - CBD pet products



Examples of topical CBD products



Examples of CBD products for animals

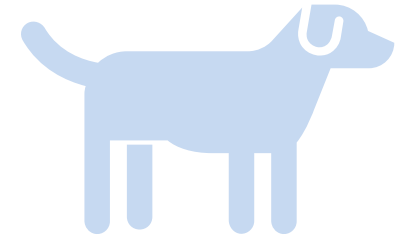
- **Inhalable hemp** products that do not meet the definition of an FDA-regulated product type would not have FDA oversight in the absence of a new regulatory framework.



Examples of smokeable CBD products or CBD vapes

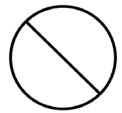
Products for animals

- CBD also poses risks to animals.
- People could be unknowingly exposed to CBD through meat, milk, and eggs from animals fed CBD.
- It is not apparent how CBD could meet the safety standard for substances in animal food.
- A new pathway could provide access and oversight for certain CBD-containing products for animals.



A new pathway...

Would not be necessary for products regulated through existing means:



Marijuana



Hemp plants under cultivation



Hemp products for industrial uses



Approved drugs



Hempseed food ingredients

Enforcement: We continue acting against products posing immediate risks

- **Our January 2023 announcement did not change our approach to enforcement.**

- We have issued warning letters to firms marketing:
 - CBD products marketed to treat diseases or for other therapeutic uses for humans and/or animals
 - CBD products for food-producing animals
 - Foods for humans and animals with added CBD
 - CBD products with concerning routes of administration, including nasal, ophthalmic, and inhalation
 - Delta-8 THC products

Warning Letters and Test Results for Cannabidiol-Related Products



Over the past several years, FDA has issued several warning letters to firms that market unapproved new drugs that allegedly contain cannabidiol (CBD). As part of these actions, FDA has tested the chemical content of cannabinoid compounds in some of the products, and many were found to not contain the levels of CBD they claimed to contain. It is important to note that these products are not approved by FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease. Consumers should beware purchasing and using any such products.

2022 Warning Letters	▼
2021 Warning Letters	▼
2020 Warning Letters	▼
2019 Warning Letters	▼
2018 Warning Letters	▼
2017 Warning Letters	▼
2016 Warning Letters and Analytical Results	▼
2015 Warning Letters and Analytical Results	▼

Risks from CBD in foods

From [fda.gov](https://www.fda.gov): *Conversations with Experts on Food Topics*:

“What the FDA is Doing to Protect Consumers from Cannabidiol (CBD) in Foods”

<https://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-cannabidiol-cbd-foods>

- Particular concerns:
 - Products that may result in accidental consumption or overconsumption of CBD
 - Products in forms that are appealing to children, such as gummies, hard candies, and cookies
 - Caffeinated beverages
- Using food to administer CBD makes it hard for people to control how much CBD they’re taking.
- Consumers eat food for other reasons than to take CBD, and they may end up taking more CBD than they meant to.
- It can also be easy for someone to consume CBD accidentally when it’s in an ordinary-looking food.
- Caffeine is one of CBD’s possible drug interactions.

We have warned consumers about delta-8 THC products

5 Things to Know about Delta-8 Tetrahydrocannabinol – Delta-8 THC

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Content current as of:
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Regulated Product(s)
Animal & Veterinary
Dietary Supplements
Drugs
Food & Beverages

1. Delta-8 THC products have not been evaluated or approved by the FDA for safe use and may be marketed in ways that put the public health at risk.
2. The FDA has received adverse event reports involving delta-8 THC-containing products.
3. Delta-8 THC has psychoactive and intoxicating effects.
4. Delta-8 THC products often involve use of potentially harmful chemicals to create the concentrations of delta-8 THC claimed in the marketplace.
5. Delta-8 THC products should be kept out of the reach of children and pets.

FDA Warns Consumers About the Accidental Ingestion by Children of Food Products Containing THC



May 13, 2022

Audience

- All consumers

What is the problem?

- Edible products containing tetrahydrocannabinol (THC) can be easily mistaken for commonly consumed foods such as breakfast cereal, candy, and cookies, and accidentally ingested.
- Accidental ingestion of these products can lead to serious adverse events, especially in children.
- Some edible products are designed to mimic the appearance of well-known branded foods by using similar brand names, logos, or pictures on their packaging. These copycats are easily mistaken for popular, well-recognized foods that appeal to children.
- The FDA is aware of reports of copycat products packaged to look like Cap'n Crunch, Cocoa Pebbles, Cocoa Puffs, Froot Loops, Fruity Pebbles, Nerds Ropes, Starbursts, Sour Patch Kids, and Trix, among others.

Examples of Products



Who is at risk?

The FDA is advising consumers about the risk of accidental ingestion, especially by children, of edible products that contain THC. Accidental ingestion of these edible products may cause serious adverse events.

Summary of Problem and Scope

Some manufacturers are packaging and labeling edible products containing THC to look like popular brands of commonly consumed foods, such as breakfast cereal, candy, and cookies. These products appeal to children and may be easily mistaken for popular, well-recognized foods.

The FDA is aware of multiple media reports describing children and adults who accidentally consumed copycat edible products containing THC and experienced adverse events. Additionally, from January 2021 through April 24, 2022, the FDA received over 100 adverse event reports related to children and adults who consumed edible products containing THC. Some individuals who ate these edible products reportedly experienced adverse events such as hallucinations, increased heart rate and vomiting, and many required medical intervention or hospital admission. Seven of the reports specifically mention the edible product to be a copycat of popular foods, such as Cocoa Pebbles, Nerds Rope, Skittles, Sour Patch Kids, and Starburst.

We have warned consumers about accidental ingestion of foods containing THC

FDA U.S. FDA @US_FDA · May 13, 2022

SAFETY ALERT: Risk of accidental ingestion, especially by children, of edible products that contain THC. Some manufacturers package & label these products to look like cereal, candy, and cookies that appeal to children & easily mistaken for popular foods. [fda.gov/food/alerts-ad...](https://www.fda.gov/food/alerts-ad...)

9 57 47

FDA U.S. FDA @US_FDA · May 13, 2022

Accidental ingestion of these products can lead to serious adverse events, especially in children. We're aware of reports of copycat products packaged to look like Cap'n Crunch, Nerds Ropes & Starburst, among others.

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FDA U.S. FDA @US_FDA · May 13, 2022

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We are working with state partners to address risky products

FOR IMMEDIATE RELEASE

CONTACT: Jill Phillips, Executive Director
 Jill.Phillips@state.mn.us

Minnesota Board of Pharmacy files suit against Moorhead-based manufacturers and retailers of edible cannabinoids

Board of Pharmacy embargoes and seeks destruction of over \$7 million of edible cannabinoids exceeding the THC limits set by state law

December 5, 2022 (SAINT PAUL) — The Minnesota Board of Pharmacy announced today that it has filed a [civil lawsuit](#) in Clay County District Court against Northland Vapor Company Moorhead LLC, Northland Vapor Company Bemidji LLC, and Wonky Confections LLC, (collectively “Northland Vapor”) alleging they have violated Minnesota’s edible cannabinoid laws (Minnesota Statute 151.72).

Under the law, an edible cannabinoid product sold in Minnesota must not contain more than five milligrams of any hemp-derived tetrahydrocannabinol (THC) in a single serving or more than a total of 50 milligrams per package. The lawsuit alleges Northland Vapor sold edible cannabinoid products that contain THC far in excess of five milligrams per serving and far in excess of 50 milligrams per package. Investigators found packages containing 2,500 milligrams of THC, 50 times the amount permitted under Minnesota law.

https://mn.gov/boards/assets/Edibles%20Release_Final_tcm21-550091.pdf



Common misconceptions in media reports

- **Misconception: “FDA said for years it was working toward regulations for CBD”**
 - We stated, “the FDA would only consider doing so if the agency were able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients.”
- **Misconceptions: “CBD is legal,” “Delta-8 THC is federally legal”**
 - The Farm Bill removed hemp from the Controlled Substances Act.
 - Congress explicitly preserved the agency’s current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act.
 - To be lawful, hemp products must comply with applicable provisions of the FD&C Act.
- **Misconception: “The FDA refused to regulate [CBD]”**
 - Given the available evidence, it is not apparent how CBD products could meet safety standards for dietary supplements or food additives, or how FDA could justify rulemaking.