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

Stakeholder Webinars
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FDA Statement: January 26, 2023

• Existing regulatory frameworks for foods and supplements are not appropriate for CBD.

• 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

• Given the available evidence, it is not apparent how CBD products could meet safety standards for dietary supplements or food additives.

• We are prepared to work with Congress on a new way forward.
The 2018 Farm Bill removed hemp from regulation under the CSA

- 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

CBD MARKET SIZE
(2022-2027, WITH AND WITHOUT FDA GUIDANCE EFF. 2024)

$12
$10
$8
$6
$4
$2
$0

BILLIONS

2022 2023 2024 2025 2026 2027

With FDA Guidance
Without FDA Guidance

Source: Brightfield Group Consumer Insights; June 2022 N=5,408
CBD products come in a wide variety of formats

- **Ingestible**
  - Gummies
  - Beverages
  - Other “Edibles”
  - Tinctures
  - Capsules

- **Inhalable**
  - Vapes
  - Combustible

- **Topical**
  - Beauty/Personal
  - Cream/Ointment

- **Animal**
  - Pet Products

- **Approved Drug**
  - Epidiolex

- 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**

**Reason for use (n=16)**

- Pain
- Insomnia
- Anxiety
- Free sample/Gift
- Stress
- Inflammation
- Arthritis
- Stiffness
- Seizures
- Relaxation
- Multiple Sclerosis
- Malignant Neoplasm

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.
Statutory barriers prevent marketing of CBD in foods and supplements

- 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)

- 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

- 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.

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

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

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

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.

FDA Statement: Existing frameworks not appropriate

- 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

<table>
<thead>
<tr>
<th>Typical users:</th>
<th>Drugs</th>
<th>Dietary Supplements</th>
<th>Food Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific Group</td>
<td>Those with a specific medical condition</td>
<td>Broad Group</td>
<td>Those seeking to supplement their diet and maintain health</td>
</tr>
<tr>
<td>Broad Group</td>
<td></td>
<td>Reasonably expected to be safe (benefits not considered)</td>
<td></td>
</tr>
<tr>
<td>Everyone</td>
<td></td>
<td></td>
<td>Everyone</td>
</tr>
<tr>
<td>All people, including vulnerable groups</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Summary of safety standard:</th>
<th></th>
<th>Pre-market standard for new dietary ingredients:</th>
<th>Reasonable certainty of no harm (benefits not considered)</th>
</tr>
</thead>
<tbody>
<tr>
<td>For new drug approval:</td>
<td>Benefit outweighs risk</td>
<td>Reasonably expected to be safe (benefits not considered)</td>
<td></td>
</tr>
</tbody>
</table>

| Examples of risk management options: | | Safety standards | | Users can report adverse events |
|-------------------------------------|-----------------------------|--------------------------------------------------|---------------------------------|
| - Labeling with detailed instructions and warnings | - Firms can indicate conditions of use, e.g. recommended serving, duration of use, population | - Primarily through strict pre-market safety standard (not labeled conditions of use) |
| - Prescription and behind counter | - Users can report adverse events | - Users can report adverse events |
| - Risk Evaluation and Mitigation Strategy (REMS) program | - DEA scheduling |
| - Spontaneous adverse event reporting | | - Spontaneous adverse event reporting |

- Safety standards
- Firms can indicate conditions of use, e.g. recommended serving, duration of use, population
- Users can report adverse events
FDA does not intend to initiate rulemaking…

- 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

• 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 way forward

• 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

- **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.
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

Risks from CBD in foods

From fda.gov: *Conversations with Experts on Food Topics: “What the FDA is Doing to Protect Consumers from Cannabidiol (CBD) in 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

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.
We have warned consumers about accidental ingestion of foods 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, Starburst, 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.
We are working with state partners to address risky products

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.

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.
Conclusions

• Existing regulatory frameworks for foods and supplements are not appropriate for CBD.
  – It is not apparent how CBD products could meet safety standards for dietary supplements or food additives.

• We look forward to working with Congress on a new way forward.
  – A harm reduction regulatory approach

• Our enforcement efforts continue to target products posing the greatest risks.
  – We will continue to take action against CBD and other cannabis-derived products to protect the public, in coordination with state regulatory partners, when appropriate.
  – We will remain diligent in monitoring the marketplace and acting within our authorities.
Information on FDA Regulation of Cannabis Products

On this web page:
• FDA News Releases & Statements
• Consumer Information
• FDA Remarks and Testimony
• Science & Research
• Other Regulatory Resources
• Questions and Answers

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