Report to the U.S. House Committee on Appropriations and the U.S. Senate Committee on Appropriations

Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent That Products are Mislabeled or Adulterated

Report in Response to

Further Consolidated Appropriations Act, 2020

U.S. Food and Drug Administration

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs

Executive Summary

On December 20, 2019, the Further Consolidated Appropriations Act, 2020 (P.L. 116-94), which provided the U.S. Food and Drug Administration (FDA or the Agency) with appropriations under Division B, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Act, 2020, for the fiscal year ending September 30, 2020, was enacted into law. The accompanying Joint Explanatory Statement directed FDA to conduct a sampling study of the current Cannabidiol (CBD) marketplace to determine the extent to which products are mislabeled or adulterated and report to the Committees within 180 days of enactment.

This report fulfills the above requirement by providing an update on the Agency's sampling study of the current CBD marketplace and efforts to determine the extent to which products are mislabeled or adulterated.

Table of Contents

I. Introduction

On December 20, 2019, the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) (2020 Appropriations Act), which provided the U.S. Food and Drug Administration (FDA or the Agency) with appropriations under Division B, the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Act, 2020, for the fiscal year ending September 30, 2020, was enacted into law. The accompanying Joint Explanatory Statement included the following Congressional Directive regarding Cannabidiol (CBD):

"The FDA is further directed to perform a sampling study of the current CBD marketplace to determine the extent to which products are mislabeled or adulterated and report to the Committees within 180 days of enactment of this Act."

In response to this directive, FDA has prepared the following report.

II. Background

FDA recognizes the significant public interest in CBD products. However, there are many questions about the characteristics of currently marketed CBD products because the Agency lacks significant information on what CBD-containing products are on the market and there are little data available on those products themselves.

In recent years, FDA has conducted some sampling (see section III of this report) and has sought to review studies and other information on marketed CBD products from third parties in several ways, including through outreach to domestic and foreign regulatory partners and academic research institutions; through a May 31, 2019 public hearing[1] and its accompanying open docket;[2] and through a search of publicly available information.

These efforts have yielded useful information and raised concerns about the characteristics of currently marketed CBD products, including whether the actual CBD content in these products has matched the content described in these products' labeling and whether these products have contained other cannabinoids[3] (such as delta-9 tetrahydrocannabinol (THC)) or contaminants (such as heavy metals and pesticides). For example, during the public hearing, specific concerns were raised and data was shared regarding contaminants including heavy metals in marketed products[4].

However, these efforts have been limited in scope and have not provided for a comprehensive understanding of the marketplace. For example, many existing CBD product studies, which were performed by external parties and reviewed by FDA, included a limited number of samples

[1] See https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds

[2] See https://www.regulations.gov/docket?D=FDA-2019-N-1482

[3] The term "cannabinoids" refers to a class of more than 100 different chemical compounds that occur naturally in the *Cannabis sativa* L. plant. The most commonly known cannabinoids are THC and CBD, but many others (e.g., cannabinol (CBN), cannabigerol (CBG), cannabichromene (CBC)) exist. Some of these cannabinoids were analyzed and quantified by FDA on the products described in this report.

[4] A transcript of the public hearing is available at https://www.fda.gov/media/128593/download

(often performed on fewer than 30 products) or had study descriptions which lacked important information, such as the sample selection method, product specifications, and the actual levels of detected contaminants. In addition, it is not clear whether the studies that reported variability of CBD product characteristics (i.e., product composition and impurities/contaminants) were more likely to be presented, published, or submitted to FDA's public meeting docket (i.e., publication bias) than studies that did not demonstrate widespread product characteristic variability. These uncertainties leave questions about how these findings should be interpreted and whether they can accurately be extrapolated to the CBD marketplace in the United States, which makes it challenging for FDA to determine the variability in CBD product characteristics.

FDA believes that understanding the characteristics of marketed CBD products is critical to making informed decisions about how best to protect public health in the current marketplace. As such, pursuant to the language in the Joint Explanatory Statement, FDA has undertaken its own CBD product testing to better understand the contents and characteristics of currently marketed CBD products. This report (1) discusses the CBD product testing conducted by FDA both before and after the passage of the Agriculture Improvement Act of 2018 (P. L. 115-334) (2018 Farm Bill)[5] and (2) outlines the Agency's plans for more comprehensive product sampling (a process that is currently ongoing pursuant to the Joint Explanatory Statement). Together, this information will provide the Agency with a better understanding of product characteristics in the current CBD marketplace and will help protect and promote public health.[6]

III. Historical (2014 – 2018) Testing Results

Prior to the enactment of the 2018 Farm Bill, FDA tested cannabinoid content of 74 CBD products that were sold for human use and four CBD products that were sold for consumption by pets (total number, n = 78).[7] The products marketed for human use[8] included products marketed as oils, tinctures, capsules, tablets, gummies, vape liquids, conventional foods (candy, coffee, juice), and topicals (salve, balm, gel); the products marketed for animal use included products marketed as pet treats and capsules. Several factors were considered when selecting products for laboratory analysis:

[5] Among other things, this law changed certain federal authorities relating to the production and marketing of hemp. These changes included removing hemp from Schedule I of the Controlled Substances Act, 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. However, the 2018 Farm Bill also explicitly preserved FDA's 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.

[6] As directed by Congress, this report addresses FDA's sampling activities. FDA has separately, and on numerous occasions, articulated its position regarding the legality of CBD in different types of commodities regulated by the Agency. For purposes of this report, FDA describes products using terminology that best reflects how these products might appear to an ordinary consumer. Nothing in this report is intended to change or otherwise alter FDA's prior statements regarding the legal or regulatory status of products containing CBD.

[7] "n" represents the total number of samples tested. Some testing results are available on the FDA website: https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products

[8] The CBD product sampling described in this report often included products marketed as dietary supplements; however these products are not described as such because CBD products do not meet the definition of a dietary supplement under section 201(ff) of the FD&C Act (21 U.S.C. 321(ff)).

- Products that made serious disease claims.
- Products that were produced or sold in several states to reflect interstate variation.
- Products that were readily accessible to consumers and available for online purchase.
- Products that were the basis for consumer complaints or adverse event reports.

Because the decision to test particular products was based on particular risk factors, the Agency does not know the extent to which the body of this testing work was representative of the overall market during this time period.

Of the 78 products tested (from 2014 to 2018), cannabinoids were detected in 69 (88 percent) of them, and 67 (86 percent) of them were found to contain CBD (see Table 1). Two products were referred to the Drug Enforcement Agency (DEA) because of the controlled substances they contained – a CBD oil capsule with an average of 16 mg/g THC and a CBD gummy found to contain the synthetic cannabinoid, MMB-FUBINACA,[9] at 1.9 mg/gummy.

A report of the 23 products analyzed in 2014 was prepared by FDA regarding consistency in labeled cannabinoid content. Only eight products (35 percent) were consistent with the labeled amount of CBD. In addition, many of the products contained THC and/or other cannabinoids.[10]

Table 1. Historical (2014-2018) Testing Results of Marketed CBD Products[a]

	2014	2015	2016	2017	2018
Products Tested	23	23	22	4	6
Containing CBD[b]	16	21	21	4	5
Containing THC[c]	9	19	15	1	2
Containing Other Cannabinoids[d]	6	12	10	1	2

[a] Table includes products where the analyzing laboratory reported the presence of CBD, THC or Other Cannabinoids.
[b] CBD was considered present if either CBD or cannabidiolic acid (CBDA) were detected.
[c] THC was considered present if either delta-9-tetrahydrocannabinol (THC) or tetrahydrocannabinolic acid-A (THCA) were detected.
[d] Other Cannabinoids: CBC, CBG, CBN, and MMB-FUBINACA

[9] This indazole-based synthetic cannabinoid is classified as DEA Schedule I drug; N-[[1-[(4-fluorophenyl)methyl]-1H-indazol-3-yl]carbonyl]-L-valine, methyl ester; also known as FUB-AMB.
[10] A. Ruth, C. Gryniewicz-Ruzicka, M. Trehy, N. Kornspan, G. Coody, 2016, Consistency of Label Claims of Internet-Purchased Hemp Oil and Cannabis Products as Determined using IMS and LC-MS: A Marketplace Survey, Journal of Regulatory Science, 3: 1-6.

IV. 2019 Testing Results

In 2019, FDA identified 34 CBD products for the testing of certain characteristics, including cannabinoid content and certain elements,[11] by reviewing consumer and industry complaints submitted to the Agency and by conducting online surveillance. Products identified for testing included products marketed with disease claims and products intended for vulnerable populations, and were marketed as tinctures/oils, capsules/powders, edibles, beverages, and products marketed for pets (see Table 2).

Again, because FDA's decision to test particular products was based on particular risk factors, the Agency does not know the extent to which the body of this testing work is representative of the overall market during this time period.

All 34 products[12] were analyzed for elements such as arsenic (As), cadmium (Cd), mercury (Hg), lead (Pb,), manganese (Mn), nickel (Ni), copper (Cu), zinc (Zn), selenium (Se), molybdenum (Mo), antimony (Sb), barium (Ba), cobalt (Co), lithium (Li), tin (Sn), and vanadium (V). The levels found in these 34 products did not raise significant public health concerns[13]. Because two of the products were vape related and outside the scope of this study, and one product did not contain enough sample to analyze for cannabinoids, FDA analyzed 31 of the products for 11 cannabinoids, including a quantitative determination of total CBD and total THC[14] (see Table 2).

Of the 31 products tested for cannabinoids, 21 products specified the amount of CBD in the product (e.g., CBD amount per serving). Of these 21 products, seven products (33 percent) contained CBD within 20 percent of the amount indicated. Of the 10 products that did not indicate the amount of CBD included in the product, six contained CBD and four did not. In addition, 15 of the 31 products (48%) contained THC. The results obtained for these 34 products is from a limited sample size and cannot be used to draw definitive conclusions and further testing is warranted.

Table 2. CBD and THC Results for Non-Cosmetic Marketed Products

	Tincture/ Oil	Capsule/ Powder	Edible	Beverage	Pet
Products Tested	16	1	7	4	3

[11] Per the May 31, 2019, public hearing, multiple stakeholders expressed concerns over heavy metal poisoning and other potential contaminants.

[12] In 2019, one additional sample was obtained outside of the selection and testing process described above. FDA received an adverse event report for a product marketed as a dietary supplement labeled to contain CBD. Although the product was labeled to contain 50 mg/capsule of CBD, it was found to contain 70 mg/capsule. In addition, the capsules were found to contain 1.6 mg THC and 0.3 mg CBN.

[13] The results yielded one product containing As, one product containing Cd, four products containing Pb, and four products containing Cu, but levels did not raise public health concern.

[14] Total CBD was calculated as the sum of CBD and CBDA. Total THC was calculated as the sum of THC and THCA.

Products with CBD Amount Indicated on Label	10	1	4	4	2
<80% of CBD Amount Indicated	6	0	2	2	0
± 20% of CBD Amount Indicated	4	1	0	0	2
>120% of CBD Amount Indicated	0	0	2	2	0
Containing THC [a]	11	1	1	0	2

[a] These products contained THC or THCA above the limit of quantitation (LOQ).

Also, FDA has been working with the University of Mississippi to develop a method to detect and quantify hemp ingredients in cosmetic products. As part of this process, a total of 109 hemp and/or CBD-containing cosmetic products were selected[15] for testing the presence and levels of CBD, THC, and five other marker cannabinoids.[16] Of these 109 cosmetic products, 41 of them (38 percent) indicated the product contained CBD, and the remaining 68 of them (62 percent) claimed to contain hemp ingredients but did not specifically claim to contain CBD. Results showed that all 41 products that indicated CBD was present in the cosmetic were found to contain CBD. Of those 41 products, 12 also contained THC,[17] although the products did not indicate the presence of THC. In addition, of the 41 products that indicated CBD was present, 14 indicated a specific amount of CBD on the label. Of those 14 products, eight products contained less than 80 percent of the CBD amount indicated, four products contained within 20 percent of the CBD amount indicated, and two products contained greater than 120 percent of the CBD amount indicated. The 68 cosmetic products tested claiming to contain hemp ingredients, but not specifically claiming to contain CBD, did not contain any measurable cannabinoids[18].

V. 2020 Testing: Near-Term Sampling Plan and Results

Given the extensive data gaps regarding the current CBD marketplace, the results from previous product testing, and in response to the congressional directive from the Joint Explanatory

[15] These 109 products were selected from public databases for products that claimed to contain hemp-derived ingredients.
[16] These five cannabinoids are CBDA, CBG, cannabigerolic acid (CBGA), CBN, and THCA.
[17] Levels ranged from below the LOQ to 0.0294 percent.
[18] Of these 68 products, 53 of them were labeled to contain cannabis sativa seed oil and 15 of them were labeled to contain hemp/cannabis sativa oil in their list of ingredients.

Statement, FDA is undertaking a more extensive CBD product sampling effort. To obtain useful and comprehensive information going forward, FDA has developed a sampling plan that is divided into two phases: near- and long-term. Near-term results will inform the long-term sampling plan.

For the near-term sampling plan, FDA generated a list of 500 marketed CBD and hemp products. Only products available on-line were captured in this initial phase of testing. Firms selling CBD and hemp products were identified from several public sources, including from (1) internet searches (using terms such as "CBD," "cannabidiol," "hemp," "hemp extract," "Best CBD"), (2) searching on-line distributors, (3) firms that had previously been issued warning letters, (4) industry event participants, and (5) advertisers in trade journals. This list included products that appeared to contain CBD, hemp, or hemp extract as an ingredient, though it was not a requirement that the products on the list explicitely indicated the presence of CBD (either on their label or on their on-line product description). The products were divided into seven categories (see Table 3). Two hundred products were randomly selected for testing proportionally from each category based on the total number of products in that category. Tincture/oils/gel caps represent approximately half of the products selected (n = 83).

All products were analyzed for 11 cannabinoids,[19] including a quantitative determination of total CBD and total THC.[20] Quantitative analysis for the elements As, Cd, Hg, and Pb was also performed. A subset of products, based on the product type, will be analyzed for pesticides, residual solvents and microbial contaminants (*Salmonella* and *Listeria monocytogenes*).

Of the 200 products purchased, testing for cannabinoids was completed on 147 of them (see Table 3).[21] Of the 147 products tested, 138 products (94 percent) contained CBD. Of the samples that did not contain CBD (n = 9), seven either did not indicate CBD or clearly indicated "zero CBD" on the label. Two products that listed CBD on the label were not found to contain CBD. For products that indicated a specific amount of CBD, those amounts were compared to the testing results. Of the 102 products that indicated a specific amount of CBD, 18 products (18 percent) contained less than 80% of the amount of CBD indicated, 46 products (45 percent) contained CBD within 20 percent of the amount indicated, and 38 products (37 percent) contained more than 120 percent of the amount of CBD indicated. THC levels in the products tested ranged from below the LOQ to 3.1 mg/serving, with 72 products (49 percent) found to contain THC or THCA at concentrations above the LOQ (see Table 3).

Of the 147 products analyzed for cannabinoids, 133 products[22] were also analyzed for the elements As, Cd, Hg and Pb. Of the 133 samples analyzed, 132 of them did not contain As, Cd,

[19] These 11 cannabinoids included CBC, CBD, CBDA, cannabidivarin (CBDV), CBG, CBGA, CBN, THC, Δ8-tetrahydrocannabinol (Δ8-THC), THC, THCA, tetrahydrocannabivarin (THCV).
[20] Total CBD was calculated as the sum of CBD and CBDA. Total THC was calculated as the sum of THC and THCA.
[21] Products were tested as they were received, but testing was paused due to the COVID-19 (SARS-CoV-2) pandemic. Testing of the remaining products will continue once normal operations are resumed.
[22] Products were analyzed for cannabinoids prior to analysis for toxic elements. Products were tested as they were received, but testing was paused due to the COVID-19 (SARS-CoV-2) pandemic. Testing of the remaining products will continue once normal operations are resumed.

Hg, or Pb at levels that represent a health concern and one product, a tincture, had a Pb concentration that requires additional evaluation, which is currently ongoing. It is noted that the 133 products tested are from a limited sample size and cannot be used to draw definitive conclusions regarding the prevalence of these elements in marketed products.

Table 3. Summary of Total CBD and Total THC Results (Number of Products)

	Tincture/ Oil	Capsule/ Powder	Gummy	Edible	Beverage	Pet[a]
Products Tested	82	1	17	17	8	22
Products with CBD Amount Indicated on Label	56	0	14	14	6	12
<80% of CBD Amount Indicated	6	n/a[c]	5	3	2	2
± 20% of CBD Amount Indicated	25	n/a	7	6	3	5
>120% of CBD Amount Indicated	25	n/a	2	5	1	5
Containing THC[b]	54	1	5	3	0	9

[a] The pet products purchased were tinctures, oils and drops sold for consumption by pets.
[b] Contained THC or THCA above the LOQ.
[c] n/a – Not applicable

VI. Future Testing: Long-Term Sampling Plan

FDA has developed a sampling methodology to create a representative, random sample of the current CBD product marketplace. The Agency is purchasing data on brands, product categories, and distribution channels for CBD products. FDA is also in the process of developing its own comprehensive list of brands operating in the CBD market space by assembling data from targeted internet searches and analytics. FDA intends to leverage both data sets to randomly sample products across brands, product categories, and distribution channels, while favoring products with a higher market share.

FDA expects the sampling protocol to include most, if not all, of the following product categories:

- Tinctures, oils, and extracts
- Capsules and powders
- Gummies
- Water and other beverages

- Other conventional foods
- Leave-on cosmetic products, like face and body lotions
- Device and combination products, like personal lubricants, tampons, and suppositories
- Vape cartridges
- Products sold for consumption by pets

As was done in the near-term study, all products will be analyzed for 11 cannabinoids,[23] including a quantitative determination of total CBD, total THC, and the elements As, Cd, Hg, and Pb. The testing methods will be equivalent to those used in the near-term study. Additional analyses, including pesticides, residual solvents, and microbial testing will be performed on a subset of products. The specific number and type of testing will be determined based on product type and the results from the near-term study.

Product sampling and testing will be conducted by a third party and FDA expects this long-term study to be initiated in 2020.

VII. Conclusion

This report outlines the Agency's approach toward the requirement of the Joint Explanatory Statement to perform a sampling study of the current CBD marketplace to determine the extent to which products are mislabeled or adulterated. In addition to providing the plan for a long-term sampling study, FDA has, in this report, provided a summary of previously completed sample testing and described the methodology as well as some preliminary results from a smaller 2020 near-term sampling study (n = 147). Again, these preliminary data are from a limited sample size and cannot be used to draw conclusions about the marketplace and supports the need for the long-term study, which will capture multiple retail sources (on-line and brick and mortar) and a greater number of products.

The results from the planned sampling study will help the Agency gain insight into the characteristics of representative products in the current CBD marketplace. FDA will report again on the results from both the near- and long-term studies when complete data sets are available.

[23] These cannabinoids will include CBC, CBD, CBDA, CBDV, CBG, CBGA, CBN, THC, Δ8-THC, THCA, and THCV.