

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

**Cannabidiol (CBD)**

**Report in Response to**

**Further Consolidated Appropriations Act, 2020**

**U.S. Food and Drug Administration**

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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), was enacted into law, which provided FDA 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. The accompanying Joint Explanatory Statement directed the U.S. Food and Drug Administration (FDA or the Agency) to provide a report regarding the Agency's progress toward obtaining and analyzing data to help determine a policy of enforcement discretion and the process in which cannabidiol (CBD) meeting the definition of hemp will be evaluated for use in FDA-regulated products within 60 days of enactment.

This report fulfills the above requirement by providing an update on the Agency's evaluation of potential regulatory pathways for CBD products and efforts to gather data to support evaluation of a policy of enforcement discretion.

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## **I. Introduction**

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On December 20, 2019, the Further Consolidated Appropriations Act, 2020 (P.L. 116-94), was enacted into law, which provided FDA 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. The accompanying Joint Explanatory Statement directed the Food and Drug Administration (FDA or the Agency) to report on Cannabidiol (CBD):

“Within 60 days of enactment of this Act, the FDA shall provide the Committees with a report regarding the agency's progress toward obtaining and analyzing data to help determine a policy of enforcement discretion and the process in which CBD meeting the definition of hemp will be evaluated for use in products.”

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

## **II. Overview**

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The Agency has been taking a variety of concerted actions to advance its continued evaluation of potential regulatory pathways for FDA-regulated consumer products containing or derived from cannabis (*Cannabis sativa* L.) and its components, including cannabidiol (CBD). This report discusses actions FDA has been taking, as well as additional new steps the Agency is taking or intends to take soon.

While the scientific data in this area continue to develop, we are reporting on FDA's work to date to explore possible pathways for various types of CBD products to be lawfully marketed. FDA is aware that there is a significant interest in the development of therapies and other consumer products derived from cannabis and its components, including CBD. FDA recognizes the potential opportunities that CBD may offer and acknowledges the significant interest in these possibilities. This report does not repeat all the information that we have previously conveyed on this topic.

FDA continues to be concerned about the potential safety risks of using CBD and about problems related to a number of currently marketed CBD consumer products under FDA jurisdiction, like mislabeling or the potential for contamination with delta-9-tetrahydrocannabinol (THC), pesticides, and heavy metals. In addition, since the May 31, 2019, public meeting, available data have further demonstrated that CBD is not a risk-free substance. Consumers should be aware of the potential risks associated with CBD products.

FDA acknowledges the vast proliferation of CBD consumer products, which are sold increasingly widely since passage of the Agriculture Improvement Act of 2018 (2018 Farm Bill). Given this proliferation, and limited FDA resources to initiate enforcement action against all these products, this report outlines an action plan that includes evaluating issuance of a risk-based enforcement policy that would provide greater transparency and clarity regarding FDA's enforcement priorities while FDA potentially engages in the process of a rulemaking.

It was difficult to study CBD before the 2018 Farm Bill was passed in December 2018, because cannabis-derived CBD was a Schedule I controlled substance. Thus, limited systematic data exist to inform our approach. As more data on CBD become available, we will be able to refine — and, perhaps in some cases, revise — our thinking and approaches.

This report focuses on the product areas that fall under FDA’s jurisdiction. Key areas include:

### 1. Safety

Currently available clinical data demonstrate that CBD is associated with potential risks, including liver injury, drowsiness, and potential for drug interactions.<sup>1</sup> Animal studies found risks including those related to male reproductive toxicity,<sup>2</sup> with some risks existing even at the lowest levels of exposure studied. FDA is working to further understand the safety profile of CBD, especially for sustained and/or cumulative exposure, co-administration with other medicines, and vulnerable populations like children, pregnant and lactating women, the elderly, and unborn children.

### 2. Human and Animal Drugs

For human and animal drugs, there are clear regulatory pathways available for CBD drug development and review of new drug applications (NDAs) and new animal drug applications (NADAs). In 2018, FDA approved the NDA for a CBD drug, Epidiolex, for the treatment of two rare and life-threatening seizure disorders in children.

FDA encourages and supports research to explore the therapeutic potential of CBD, as well as other compounds in cannabis, and will continue to make available regulatory mechanisms to expedite cannabis and CBD drug development as appropriate.

### 3. Dietary Supplements

FDA is actively considering potential pathways for certain CBD products to be marketed as dietary supplements. Under current law, CBD products cannot lawfully be marketed as dietary supplements, but FDA has the authority to create an exemption through notice-and-comment rulemaking (rulemaking) that would allow products containing CBD to be sold legally as dietary supplements.<sup>3</sup> The Agency is actively evaluating what and how much data would be sufficient to support a conclusion that CBD can safely be allowed in dietary supplements under certain

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<sup>1</sup> See, for example, Epidiolex’s prescribing information.

<sup>2</sup> See Rosenkrantz H, Fleischman RW, Grant RJ. Toxicity of short-term administration of cannabinoids to rhesus monkeys. *Toxicol. Appl. Pharmacol.* 1981 Mar 30;58(1):118-131; Carvalho RK, Souza MR, Santos ML, et al. Chronic cannabidiol exposure promotes functional impairment in sexual behavior and fertility of male mice. *Reprod. Toxicol.* 2018 Oct;81:34-40; and Carvalho RK, Santos ML, Souza MR, et al. Chronic exposure to cannabidiol induces reproductive toxicity in male Swiss mice. *J. Appl. Toxicol.* 2018 Sep;38(9):1215-1223.

<sup>3</sup> See Section 201(ff)(3)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). For further information, please see [FDA Regulation of Cannabis and Cannabis-Derived Products: Questions & Answers](https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd). Available at <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>. Current as of 12/31/2019.

conditions. To further advance and expedite our activities, we are taking steps described below, which include evaluating issuance of a risk-based enforcement policy that would provide greater transparency and clarity regarding FDA's enforcement priorities while FDA potentially engages in the process of a rulemaking.

#### 4. Human and Animal Food

There are established pathways for introducing new substances into the human or animal food supply, which apply to hemp-derived substances in the same way as they do to any other substances. Under one such pathway, certain hemp seed-derived products (dehulled hemp seeds, hemp seed protein, and hemp seed oil), which contain de minimis levels of CBD, currently can be lawfully marketed in human food without the need for any further FDA approval, provided the products do not make drug claims or claims that are false or misleading, and that they comply with all other applicable requirements. Because the same ingredient may present different risks to humans and animals, these ingredients would need to be separately evaluated before they could be introduced into animal food or feed.

It is not currently lawful to add CBD to human or animal food,<sup>4</sup> and the data currently available to FDA raise safety concerns about the use of CBD in food. We encourage interested parties to continue to develop and share with FDA information regarding whether there are conditions under which CBD could safely be added to food.

#### 5. Cosmetics

Cosmetic ingredients do not generally require premarket approval (with the exception that most color additives do require premarket approval). Those marketing a cosmetic product are responsible for ensuring the safety of the product. FDA is aware of only limited data on CBD when used topically. No ingredient — including CBD — can be used in a cosmetic if it causes the product to be adulterated or misbranded in any way.

#### 6. Products Outside FDA's Jurisdiction

Although the focus of this report is on products that fall under FDA's jurisdiction, it is possible that some individual products containing CBD fall outside of FDA's jurisdiction. In such cases, FDA would not have authority to exercise regulatory oversight over such products, even to address potentially serious matters of public health and safety.

#### 7. Enforcement

As FDA works to evaluate potential pathways for the lawful marketing of CBD in products regulated by FDA, we are actively obtaining more data about potentially safe levels of CBD and evaluating issuance of a risk-based enforcement policy that would provide greater transparency and clarity regarding FDA's enforcement priorities while FDA potentially engages in the process

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<sup>4</sup> See, e.g., Sections 301(ll) and 409(a) of the FD&C Act. FDA is not currently aware of a basis to conclude that CBD is generally recognized, among qualified experts, as safe for use in conventional foods. See Section 321(s) of the FD&C Act.

of a rulemaking. Any enforcement policy would need to balance the goals of protecting the public and providing more clarity to industry and the public regarding FDA's enforcement priorities based on the known risks to public health. As we move forward, FDA intends to continue taking action to address violations we identify that put the public at risk.

### III. Report

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Since FDA launched its CBD Policy Working Group in the Spring of 2019, the Agency can report numerous actions with respect to our work in this area.

One of FDA's top priorities has been to evaluate scientific information about the safety of CBD from all available sources. This includes reviewing findings published in the literature and data available to FDA as part of regulatory submissions and through our adverse event reporting databases. In addition, the Agency sought data from the public, on not only safety, but also other topics related to CBD. We accomplished this by, among other things, holding a public hearing<sup>5</sup> on cannabis in May 2019. The hearing was attended by more than 600 participants in person, with over 2,300 joining remotely. FDA heard presentations by over 100 speakers, representing a broad and diverse array of stakeholders. Although this hearing was not exclusively about CBD, we heard a lot of excitement about CBD products, but also a lot of concern about CBD products on the market, including concerns about potential contamination and false labeling. Nearly 4,500 comments were submitted to the docket associated with the hearing. We extended the docket's closing date to July 16, 2019, and we have reviewed the comments we received to the docket<sup>6</sup> and continue to evaluate specific information and issues that were raised.

FDA made specific requests in the *Federal Register* notice<sup>7</sup> announcing the hearing for data regarding the safety of cannabis products, including CBD products. We received only limited amounts of data in response to this request, which in part reflects the limited body of research that was available at that time. We are aware that some studies may be ongoing, and that new studies have been initiated since passage of the Farm Bill, which made it easier in certain respects for parties to conduct CBD-related research. The Agency encourages parties to share new data with us as they become available. To that end, we are taking a number of additional steps to obtain new information as it emerges, which are described in greater detail later in this report.

FDA also regularly engages with government partners at the federal, state, local, territorial, and international levels, and national organizations representing these officials, in a variety of ways – both reactive and proactive – to discuss the regulation of cannabis and cannabis-derived products, including CBD. The regulatory landscape in the states continues to change, and state and local government officials are seeking clarity as they navigate an expanded market for CBD products. The Agency has engaged with representatives from state departments of health, departments of agriculture, and governors' offices, to discuss cannabis regulatory structures that

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<sup>5</sup> [Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing May 31, 2019](https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds). Available at <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds>. Current as of 7/3/2019.

<sup>6</sup> Regulations.gov: [Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments](https://www.regulations.gov/docket?D=FDA-2019-N-1482). Available at <https://www.regulations.gov/docket?D=FDA-2019-N-1482>.

<sup>7</sup> Federal Register: [Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments](https://www.federalregister.gov/documents/2019/04/03/2019-06436/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds). Available at <https://www.federalregister.gov/documents/2019/04/03/2019-06436/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds>.

have been established or that are currently being considered at the state level. These engagements include participation in a meeting with a number of state cannabis regulators who meet quarterly to discuss regulatory issues in the cannabis space, and engagement with officials from state departments of health regarding CBD safety.

FDA also has met with the leadership of a number of state departments of agriculture to discuss concerns in the agricultural space subsequent to the enactment of the 2018 Farm Bill. As part of these and other conversations with our state regulatory partners, FDA has communicated our interest in information regarding the safety of these products, including aspects of CBD for which we do not yet have enough information, such as the long-term effects of sustained use and interaction with other substances. We have also had conversations with local and territorial government officials, and we continue to solicit input from our regulatory partners and remain interested in any available data concerning the safety of CBD.

### **What have we learned so far?**

There's an incredible amount of interest in CBD across a wide range of product areas. For example, at the public hearing we heard from stakeholders who wanted to see more studies into the potential therapeutic benefits of CBD. At the same time, much of the commercial activity we are seeing involves non-therapeutic consumer products (e.g., CBD in cosmetics, animal and human foods, or products marketed as dietary supplements).

CBD is not a risk-free substance. As evidenced in the public clinical development data for Epidiolex and in the publicly available published scientific literature, CBD is associated with risks including liver injury, drug-drug interactions, drowsiness that may affect driving, and the possibility of male reproductive toxicity.

We are still looking to better understand potential long-term effects of sustained use and other unanswered questions about the safety profile of CBD outside of the one FDA-approved prescription drug. This is especially critical as we consider whether there are safe conditions of use that could allow for broader access to CBD in other FDA-regulated consumer products. FDA is actively working to fill such information gaps through a variety of efforts described in this report, including (among other things) engaging with stakeholders who may have relevant data, as well as by initiating its own research efforts both internally and through partners.

Key questions we are seeking to address include:

1. What happens if you use CBD daily for sustained periods of time?
2. What level of intake triggers the known risks associated with CBD?
3. How do different methods of exposure affect intake (e.g., oral consumption, topical, smoking or vaping)?
4. What is the effect of CBD on the developing brain (such as children who take CBD)?
5. What are the effects of CBD on an unborn child or breastfed newborn?
6. How does CBD interact with herbs and botanicals?
7. Does CBD cause male reproductive toxicity in humans, as has been reported in studies of animals?
8. Are there differing safety concerns for use in certain animal species, breeds, or classes?

9. Are any residues formed in edible tissues of food producing animals?

While working to clarify the safety profile of CBD, we also have been considering how CBD fits into FDA's existing regulatory framework. FDA regulates CBD-containing products applying the same standards and the same authorities as we do products containing any other substance. But the relevant standards, authorities, and regulatory frameworks differ depending on the product type. What follows is an overview of FDA-regulated CBD products, by type of product, and next steps the Agency is taking to provide additional regulatory clarity.

### **Human Drugs**

There is a clear regulatory pathway for CBD drug development and approval. Under the FD&C Act, any product, including a CBD product, that is intended to diagnose, mitigate, treat, cure, or prevent disease, is a drug. Additionally, if a non-food product is intended to affect the structure or any function of humans, it is also a drug. A drug can be either prescription or nonprescription (generally referred to as OTC). Generally speaking, a drug must be approved by FDA as safe and effective for its intended use or meet the requirements of an OTC drug monograph before it may be introduced into interstate commerce.

In 2018, FDA approved the prescription drug Epidiolex through the drug development (new drug application) pathway. There are currently no approved OTC drugs containing CBD or any OTC drug monographs that include CBD as an active ingredient.

As FDA considers additional non-drug products containing CBD that are products regulated by FDA, the Agency is also focused on encouraging further CBD-drug development and ensuring that there remain adequate incentives for clinical research. If the widespread availability of consumer CBD products were to significantly discourage clinical research, our knowledge of CBD's potential medical uses could be stunted.

FDA is excited about potential new therapeutic uses for CBD that may be substantiated through further clinical study, as we are committed to doing all we can to encourage the development of CBD drug products and additional cannabis-derived drug products through existing, legal pathways. Further clinical study of CBD will help to promote the public health by providing greater information on whether there are additional therapeutic uses for which CBD can be safely used. As we consider potential new pathways for CBD products to be marketed, we are mindful of the need to ensure that adequate incentives remain to encourage further clinical study.

Those interested in CBD drug development are encouraged to contact the relevant Center for Drug Evaluation and Research (CDER) review division<sup>8</sup> and CDER's Botanical Review Team

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<sup>8</sup> [Office of New Drugs](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-new-drugs). Available at <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-new-drugs>. Current as of 12/6/2019.

(BRT)<sup>9</sup> to answer any questions related to their specific drug development program. The BRT serves as an expert resource on botanical issues and has developed the Botanical Drug Development Guidance for Industry<sup>10</sup> to assist those pursuing drug development in this area. FDA encourages researchers to request a pre-investigational new drug application (PIND) meeting<sup>11</sup> to obtain feedback on their specific cannabis-derived or CBD-containing drug product early in drug development. As needed, the Agency will include the BRT, Controlled Substance Staff (CSS), as well as chemistry, manufacturing, and controls (CMC) staff within the relevant CDER review division to obtain feedback on their specific cannabis-derived or CBD-containing drug product.

Early engagement with BRT, CSS, and CMC staff will help clinical researchers ensure appropriate botanical raw material quality controls, federal compliance of controlled substances, and appropriate manufacturing practices at the beginning stages of their program to develop a cannabis-derived drug product. In addition, FDA has informational resources that may be useful to clinical researchers.<sup>12,13,14,15,16,17</sup> Importantly, for products intended for serious and life-threatening diseases, several existing expedited programs are available if the applicable

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<sup>9</sup> [Botanical Review Team \(BRT\)](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/botanical-review-team-brt). Available at <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/botanical-review-team-brt>. Current as of 9/27/2018.

<sup>10</sup> See FDA Guidance for Industry, Botanical Drug Development. Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/botanical-drug-development-guidance-industry>. Current as of 8/24/2018.

<sup>11</sup> See FDA Draft Guidance for Industry, Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products. Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-pdufa-products-guidance-industry>. Current as of 10/18/2019.

<sup>12</sup> [FDA Regulation of Cannabis and Cannabis-Derived Products: Questions & Answers](https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd). Available at <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>. Current as of 12/31/2019.

<sup>13</sup> [What You Need to Know \(And What We're Working to Find Out\) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD](https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis). <https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis>. Current as of 11/25/2019.

<sup>14</sup> [FDA is Committed to Sound, Science-based Policy on CBD](https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd). <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd>. Current as of 07/17/2019.

<sup>15</sup> [FDA and Cannabis: Research and Drug Approval Process](https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process). <https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process>. Current as of 01/09/2020.

<sup>16</sup> See FDA Draft Guidance for Industry, IND Applications Prepared and Submitted by Sponsor-Investigators. Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-new-drug-applications-prepared-and-submitted-sponsor-investigators>. Current as of 8/24/2018.

<sup>17</sup> [Drug Master Files: Guidelines](https://www.fda.gov/drugs/guidances-drugs/drug-master-files-guidelines). Available at <https://www.fda.gov/drugs/guidances-drugs/drug-master-files-guidelines>. Current as of 11/16/2017.

qualifying criteria are met.<sup>18</sup> These programs are intended to facilitate and expedite drug development for products intended for serious and life-threatening diseases.

### **Animal Drugs**

A CBD product for animals that is intended to have a therapeutic benefit, or to otherwise diagnose, mitigate, treat, cure, or prevent disease, is a drug under the FD&C Act. Additionally, a non-food product intended to affect the structure or any function of an animal is a drug. New animal drugs, including CBD drugs, must be approved, conditionally approved, or index-listed to be legally marketed for animals in interstate commerce. Before a new animal drug can receive FDA approval, the sponsor must establish, among other things, that the new animal drug is safe and effective. Certain new animal drugs for minor species, minor uses in major species, or for serious diseases or unmet animal or human health needs for which effectiveness demonstration would require complex or particularly difficult studies may be eligible for conditional approval. A conditional approval permits a sponsor to market the drug for a limited time before collecting all necessary effectiveness data, but after proving the drug is safe in accordance with the full FDA approval standard and showing that there is a reasonable expectation of effectiveness. Alternatively, certain new animal drugs for minor species may be eligible for addition to the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species if their safety and effectiveness is affirmed through an alternative FDA review process.<sup>19</sup>

FDA supports and encourages research into the therapeutic potential for CBD-containing products intended for animal diseases. At this time, FDA has not approved, conditionally approved, or index-listed any CBD drugs for animals. However, we encourage research and development in this space, and we urge those interested in developing CBD drug products for animals to contact CVM.<sup>20</sup>

### **Dietary Supplements**

Under current law, CBD products cannot lawfully be sold as dietary supplements, but FDA has the authority to remove this exclusion through rulemaking. We recognize the high level of interest in dietary supplements as a potential pathway for products containing CBD, and we are actively evaluating potential rulemaking to allow CBD in dietary supplements. In the coming months, as we further evaluate such rulemaking, we are also evaluating issuance of a risk-based enforcement policy that would provide greater transparency and clarity regarding FDA's enforcement priorities while FDA potentially engages in the process of a rulemaking. This is further discussed below, under Additional Next Steps.

Given the significant public interest in the potential for CBD dietary supplements, as well as the extent to which many such products are available on the market, FDA has been taking a highly

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<sup>18</sup> See FDA Guidance for Industry, Expedited Programs for Serious Conditions – Drugs and Biologics. Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics>. Current as of 4/10/2019.

<sup>19</sup> Unlike for humans, there is no legal category of dietary supplements for animals. CBD products promoted as supplements for animals are considered either drugs or food depending on their specific intended use.

<sup>20</sup> Inquiries can be sent to: [askcvm@fda.hhs.gov](mailto:askcvm@fda.hhs.gov).

proactive approach to analyzing relevant safety questions. Rather than waiting for data to be submitted, we have been actively working to identify and review all available data to understand the risk profile of CBD and the potential for CBD to be safely included in dietary supplements, under certain conditions of use.

As we move forward, we are mindful of the need to consider and address a number of concerns. For example, we are cognizant that consumers might use CBD-containing dietary supplements for a sustained period and/or in combination with other CBD-containing products, possibly in the absence of a doctor's supervision, and we need to consider the potential health impacts of this kind of exposure and what measures might be needed to mitigate any presented risks.

We are also evaluating what impact such potential rulemaking might have on FDA's ability to provide adequate and effective oversight for CBD products marketed as dietary supplements, as well as other dietary supplement products for which we have responsibility. Although the existing regulatory framework for dietary supplements includes certain controls over product safety and quality and labeling standards, there are certain challenges in overseeing CBD in the dietary supplement marketplace. We are mindful of such challenges as we consider potential next steps, with consideration toward issues such as the following:

- Unlike with many other products we regulate, we lack clear authority to require individual participants in the dietary supplement industry to tell FDA what products they are making and selling to consumers. This would limit our ability to provide systematic and comprehensive oversight over all CBD products marketed as dietary supplements.
- Expanding the responsibilities of FDA's dietary supplement program to include a large number of new products would have implications for the program's overall workload and prioritization. In considering potential rulemaking, FDA needs to evaluate potential impacts on existing work.
- Under the existing framework for dietary supplements, FDA has limited authorities to identify and address violative products that put the public at risk. In any action FDA might take, we would need to ensure that consumers have an accurate awareness of the degree to which FDA is (and is not) able to provide regulatory oversight, so that they are able to make well-informed decisions.

One new step we are taking to advance our work relates to the collection of safety information on individual products. Much of the safety information that FDA has collected to date relates to CBD as a substance. However, for CBD, we currently lack much of the product-specific information that is submitted to FDA for dietary supplements containing new dietary ingredients. Some of this information may be proprietary, but is important to our evaluation of potential pathways to allow the marketing of certain CBD products subject to the same standards that apply to all dietary supplements.

To this end, we are working to establish a clear process by which proprietary information regarding specific products could be submitted to the Agency, with appropriate protection

against disclosure of trade secret or confidential commercial information. It is our hope that this process will enable responsible industry participants to share relevant information with FDA about specific products, which could help inform appropriate regulatory steps.

This, in addition to the steps outlined later in this report, will advance our work in the most efficient possible timeframe while also ensuring that our policies are grounded in sound data and consistent with our mission to protect and promote the public health.

### **Foods for Humans, Pets, and Other Animals**

The same safety standards apply to CBD as apply to any other substance that might be introduced into human or animal food. Applying these standards, certain hemp-derived ingredients containing only de minimus amounts of CBD (i.e., dehulled hemp seeds, hemp seed protein, and hemp seed oil) can lawfully be added to human food. The use of ingredients in animal food or feed must be separately evaluated because, among other things, there may be species-specific considerations and animal diets tend to be less varied than those of humans.

It is not currently lawful to add CBD to human or animal food, and the data currently available to FDA raise safety concerns about the use of CBD in food. We encourage interested parties to continue to develop and share with FDA information regarding whether there are conditions under which CBD could safely be added to food.

### **Cosmetics**

No ingredient — including CBD — can be used in a cosmetic if it causes the product to be adulterated or misbranded in any way. The FD&C Act defines cosmetics by their intended use, as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance.”<sup>21</sup> One way in which a cosmetic can be adulterated is if it contains a poisonous or deleterious substance that may render it injurious to users when used under the directions in the labeling or under usual conditions of use. Moreover, if a topical product, including one that contains CBD, is intended to affect the structure or function of the body, or is intended for a therapeutic use or other drug use, it is a drug, even if it is also a cosmetic, and it must be approved as a new drug or comply with an applicable OTC drug monograph.

Those marketing any cosmetic product should ensure the safety of their cosmetic product, even though cosmetic ingredients do not generally require premarket approval (with the exception that most color additives do require premarket approval). FDA is aware of only limited data on CBD when used topically. Some animal studies, not necessarily done for cosmetic products, have provided information on the skin permeability of CBD cream or gel. However, clinical evidence of safety with respect to the dermal penetration and sensitization of topically applied CBD products is lacking. As discussed later, this is an area where FDA is working to help address data gaps.

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<sup>21</sup> FD&C Act, sec. 201(i)

## **Vape Products**

FDA is aware that vape products can be used for the inhalation of a variety of substances, including CBD. FDA is concerned that CBD vapes pose public health risks in that vaping CBD raises toxicity concerns — both inherent to the substance and due to potential contaminants — and could attract children and adolescents, which are vulnerable populations.

In addition to our general public health concerns about vaping and CBD, we note that CBD-containing vape products meeting the definition of tobacco products will be regulated by FDA as such — meaning, among other things, that they cannot be marketed without FDA pre-market authorization. CBD-containing vape products that are intended for use as a drug, by definition, cannot be tobacco products and are regulated as drugs — meaning, among other things, that they cannot be marketed without FDA-approved drug applications.

More safety data and research are needed on this route of administration and potential implications for local and systemic effects.

## **Products Outside FDA’s Jurisdiction**

Although the focus of this report is on products that fall under FDA’s jurisdiction, it is possible that some individual products containing CBD fall outside of FDA’s jurisdiction. Specifically, a product containing CBD falls outside FDA’s jurisdiction if it is not intended for use as a human or animal drug; is not a human or animal food; and is not a cosmetic, medical device, biological product, tobacco product, or combination product. FDA does not have authority to exercise regulatory oversight over such products, even to address potentially serious matters of public health and safety.

## **Enforcement**

FDA has been actively monitoring the CBD market for violative products that pose the greatest risk to consumers. For example, we have seen many CBD products being marketed with claims of therapeutic benefit, or other drug claims, without having gone through the drug approval process. Some of these products are marketed for serious diseases and conditions like cancer, Alzheimer’s disease, and opioid use disorder. Selling products with unsubstantiated therapeutic claims can put patients at risk, such as by influencing them not to use proven, approved therapies to treat serious and even fatal diseases. Moreover, health care providers and patients may not be aware of potentially dangerous drug interactions and toxicity associated with CBD. These products are unapproved drugs, and FDA has sent warning letters to companies marketing such unlawful products.

We also have serious concerns about products that put the public at risk in other ways. For example, we are acutely aware of the risks posed by product contaminants (e.g., heavy metals, high levels of THC, or other potentially harmful substances). We also have significant concerns about products marketed with false claims or statements (e.g., omitted ingredients, incorrect statements about the amount of CBD), products marketed for use by vulnerable populations (e.g., children or infants), and products that otherwise put the public health at risk.

FDA intends to continue monitoring the marketplace, and to initiate and expand appropriate compliance and enforcement action against unlawful CBD products that pose the greatest risk of harm to the public.

### **Additional Next Steps**

As we noted earlier, FDA is actively working to evaluate potential lawful pathways for the marketing of CBD. As the Agency does so, we are taking the following additional new steps to advance our work on the fastest possible timeframe while also ensuring that our policies are grounded in sound data and in accordance with our mission to protect and promote the public health:

#### *Enforcement Policy*

FDA is currently evaluating issuance of a risk-based enforcement policy that would provide greater transparency and clarity regarding factors FDA intends to take into account in prioritizing enforcement decisions. Any enforcement policy would need to balance the goals of protecting the public and providing more clarity to industry and the public regarding FDA's enforcement priorities while FDA takes potential steps to establish a clear regulatory pathway. As we move forward, FDA intends to continue taking action to address violations we identify that put the public at risk.

#### *Additional Safety Information*

In addition to establishing a clear process for providing product-specific information, we also want to ensure there is a transparent way for FDA to receive new data and other information as they emerge. We recognize that decontrolling hemp in December 2018 opened significant new opportunities for research, and as that body of research develops and grows, there will be considerably more information available than there was shortly after the Farm Bill passed in December 2018. Researchers and other stakeholders should have a clear way to submit information to the Agency as it becomes available. To facilitate such information sharing, we are reopening the docket that we established as part of the May 2019 public meeting, in order to have a central, publicly accessible place to receive new information. The docket will remain open indefinitely.

#### *Further Engagement with Federal, State, Local, Territorial, Tribal, and International Partners*

FDA continues to collaborate with our regulatory partners and counterparts, and we look forward to ongoing and future collaboration. This includes collaboration with federal partners in other Agencies within the Department of Health and Human Services (HHS) who are dealing with issues related to the use of CBD, including the Centers for Disease Control and Prevention (CDC), Substance Abuse and Mental Health Services Administration (SAMHSA) and National Institute on Drug Abuse (NIDA). In addition, FDA continues to engage with the U.S. Department of Agriculture as implementation of the 2018 Farm Bill continues.

We also continue to engage with state and local regulators and meet with foreign regulatory counterparts to discuss shared interests concerning cannabis and cannabis-derived compounds with a focus on obtaining and evaluating scientific and safety/risk data and understanding our respective countries' regulatory landscape. For example, in the past two years, we have met with regulatory counterparts from Canada, Israel, and Scotland. We will continue to collaborate and encourage the exchange of safety information with our foreign counterparts in an effort to better

understand the broader impact of cannabis and cannabis-derived compounds on the public health and to inform our future surveillance strategies.

Finally, although to date we have not engaged with tribal authorities relative to cannabis issues, we stand ready to do so.

We will continue to proactively engage with our governmental partners related to CBD, and we are continually looking for ways to further such partnerships. For instance, the Agency plans to conduct a call with state public health officials (including state epidemiologists) regarding CBD safety surveillance issues later this year.

#### Further Evaluation of “Full Spectrum” and “Broad Spectrum” Hemp Extracts

Some product developers have raised questions about whether, or under what circumstances, “full spectrum” or “broad spectrum” hemp extracts can be lawfully marketed. Products that are being marketed with such terms can vary widely in their characteristics, but our understanding is that such terms generally are intended to convey that the product is not a CBD isolate, and that the products contain other substances extracted from the plant. At the same time, we are aware that many products currently marketed as “full spectrum” or “broad spectrum” hemp extracts may contain very high concentrations of CBD, and may be derived from varieties of the hemp plant that have been selected specifically for their high CBD content.

We are actively seeking information from individual manufacturers, trade groups, and others regarding the processes by which “full spectrum” and “broad spectrum” hemp extracts are derived, what the content of such extracts is, and how these products may compare to CBD isolate products. Such information will be critical to informing our evaluation of the regulatory status of such products.

#### Research

We also are working to generate data to help inform our work in this area. For example, FDA’s Office of the Chief Scientist recently awarded a grant to the FDA’s National Center for Toxicological Research to conduct a study to better understand the effects of CBD exposure during pregnancy. This study is to be launched this year and will examine the effects of CBD exposure during development on cognition and behavior in rats. In addition, the Agency initiated a research study in partnership with the University of Mississippi to evaluate CBD and THC levels in a sample of cosmetic products (about 100 products, including some positive controls), to assess sensitization of THC and CBD topically, and dermal penetration. These are example studies intended to fill in a few of the scientific data gaps as outlined previously, while we anticipate additional research activities will also be undertaken by various government organizations, industry, and academia.

#### Product Sampling

Congress directed FDA to perform a sampling study of the current CBD marketplace to determine the extent to which products are mislabeled or adulterated, and to report to the Committees on this effort within 180 days. In furtherance of this directive, FDA is actively

developing an action plan for product sampling, specifically related to the extent to which products are mislabeled or adulterated.

#### **IV. The Future**

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The marketplace for CBD-containing products continues to quickly evolve. FDA is committed to efficiently working and using science as our guide as we determine the most appropriate path forward. It is critical that we protect consumers from unsafe products.

In light of our role as a science-based, public health agency, obtaining information to address evidence gaps is essential and, to date, outside groups have not provided the robust data and information needed to fully inform potential paths forward. FDA is exploring the most efficient ways to collect this needed information as quickly as possible, including leveraging collaborations to help address identified data gaps. A more extensive scientific agenda is under development, although, as is consistent with all areas of scientific exploration, scientific findings may signal additional research is needed.

Our work also involves continuing to provide regulatory clarity on important topics, such as quality and manufacturing, considerations for other hemp-derived products, and labeling. FDA is also committed to frequent communication, and to educating the public about what we have learned. This focus on education is a key factor of our mission and inherent in our work to protect and promote public health. To collect needed information and to hear perspectives from other stakeholders, we have participated in many events. We have also updated our webpage<sup>22</sup> to include links to many of our speeches, letters, and other communications on CBD. We hope that this is a helpful resource.

As this report outlines, we have made progress, but there are still areas where timely attention is needed. As mentioned earlier, we will be reporting again on sampling performed on the current CBD marketplace to determine the extent to which products are mislabeled or adulterated. In addition, we hope to expand our efforts, not only in areas related to communication and transparency, but also in leveraging data and partnerships to address existing data gaps. Ultimately, we remain steadfast and committed to working with all stakeholders to ensure the protection and promotion of public health. This is especially so with respect to our government partners at the federal, state, local, territorial, tribal and international levels.

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<sup>22</sup> [FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol \(CBD\)](https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#news). Available at <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#news>. Current as of 12/31/2019.