2661 Dow Ave, Tustin California 92780

April 18, 2022

Via e-mail (publiccomment@cannabis.ca.gov)

DCC Legal Division
2920 Kilgore Road
Rancho Cordova, CA 95670

Re: Public comment submission: regular rulemaking

To Whom It May Concern:

ABSTRAX is the leader in research, development, and production of botanically-derived terpenes and cannabis-inspired flavors. Our company is committed to researching the additives and ingredients commonly used within the industry to ensure the safety of their continued use. We thank the Department of Cannabis Control (DCC) for the opportunity to provide feedback on the **Consolidated Medicinal and Adult-Use Cannabis Regulations.**

Our public comments related to this rulemaking:

Comment #1

Applicable regulation number: §17303.1. Additional Requirements for Inhaled Products.

Comment:

We believe it is unnecessarily restrictive to limit the inactive flavoring ingredients in an inhaled cannabis product to "botanically-derived terpenes" and generally inappropriate to require that ingredients must be permitted by the United States Food and Drug Administration (FDA) as inactive ingredients for inhalation.

The terminology "botanical terpenes" is generally insufficient and likely to mislead consumers about the complex mixture of flavoring substances they are vaporizing and inhaling. Instead, we encourage the DCC to permit any internationally accepted flavor or fragrance ingredients, as well as any isolates naturally found in cannabis, which together are often the true components of the "terpene" flavors used by the cannabis industry.

No flavors are currently banned by the FDA in tobaccoless vaporizers, e-cigarettes, and electronic nicotine delivery systems (END). Rather, the FDA accepts any ingredients that are Generally Recognized As Safe (GRAS) by the independent Flavor Extract Manufacturer's Association (FEMA) Expert Panel for use as flavors for foods, drugs, cosmetics, vaporizers, e-cigarettes, and END. Further, the FDA does not require any ingredients used in these applications to be "inactive ingredients" already used in pharmaceuticals approved for inhalation.

The "Inactive Ingredients Database" (IID) is actually intended to be an FDA database that provides information on inactive ingredients present in existing FDA-approved drug products. This information is only intended to be used by the pharmaceutical industry as an aid in developing new drug products. For new drug development purposes, once an inactive ingredient has appeared in an approved drug product for a particular route of administration, the inactive ingredient is not considered new and may require a less extensive review the next time it is included in a similar new drug product. EPIDIOLEX is the first and only prescription cannabidiol (CBD) drug product currently approved by the FDA and it is used orally. So, for the foreseeable future, no cannabis-inspired flavors, carriers or diluents commonly used by the cannabis industry are expected to appear in this FDA database as inactive ingredients in an inhaled pharmaceutical. It is also important to stress that FDA will allow any flavor to be used in drug products, even if it is not listed in the IID, as long as an appropriate safety justification is submitted with the new drug application. The IID is simply a list of what drug inactive ingredients have a precedence of use. It is not a "positive list" of the only flavors which can be used in pharmaceutical development. New flavors are periodically added to the IID whenever they are used in an approved drug application where appropriate safety information has been included.

We hope the DCC will also permit those ingredients that are widely used in applications involving inhalation such as fragrances for perfumes, aerosol deodorants, candles, incense, and heated oil plug-in air fresheners. The Research Institute for Fragrance Materials (RIFM) and/or the Cosmetic Ingredient Review (CIR) evaluate ingredients for safe use in these aromatic applications on behalf of the International Fragrance Association (IFRA). These ingredients are also inhaled and sometimes exposed to heating before inhalation and they have been safely used for years.

For the few cannabis-inspired isolates which have not been affirmed FEMA-GRAS or reviewed by RIFM and/or CIR, acceptability should be based on a history of safe use. Considering that cannabis plants have been safely used both historically and currently by millions of consumers in topicals, foods, beverages, and inhaled applications, it is reasonable to expect isolates that are identical to those found naturally in cannabis to also be safe for use in flavors intended for inhalation.

Being an internationally accepted flavor or fragrance ingredient, or an isolate naturally found in cannabis, still does not guarantee the safety of flavors when inhaled. Although GRAS status does provide some assurance that we will not likely see systemic effects, an inhalation risks assessment is still advisable before using a GRAS ingredient in an inhalable application. For example, Vitamin E Acetate is GRAS for use in foods pursuant to 21CFR 182.8892 but not safe for inhalation. Following CDC's investigation of E-cigarette or Vaping use-Associated Lung Injury (EVALI), the CDC concluded that Vitamin E Acetate is the primary cause of EVALI. Vitamin E Acetate was identified in >94% of the lung samples taken from studied EVALI patients and was primarily found in the black-market products that consumers are likely to use if regulations make licensed products less appealing. Similarly, diacetyl and 2,3-pentanedione are FEMA-GRAS flavoring chemicals used to create buttery and caramel notes. When heated and inhaled, these chemicals can cause bronchiolitis obliterans which creates scarring of the tiny air sacs in the lungs. Therefore, we support a ban on Vitamin E Acetate, Diacetyl and 2,3-pentanedione from use in inhaled cannabis products as well as a ban on any other ingredients conclusively identified by the scientific community as posing an inhalation hazard. We also recommend companies are required to reference toxicological risk assessments, that specifically consider inhalation exposure, to support the maximum use level of each component of a flavor that is intended for use in an inhaled cannabis product.

We would welcome the opportunity to discuss our Toxicology Program with you and ensure it exceeds your expectations. Working with highly reputable Inhalation Toxicologists, our program has been modeled after the FDA Premarket Tobacco Product Application (PMTA) Testing Guidelines. Given the complexity of the program, we encourage the DCC to allow companies 12 months from the date the final regulations are published to comply with a requirement for flavors to be formulated based on inhalation risk assessments. To ensure accountability within the industry, while also protecting the trade secret protections widely available to the flavor industry, we recommend the DCC adopt a safety certification policy

modeled after the FDA's procedure for issuance of flavor natural certificates pursuant to 21CFR101.22 (i)(4).

Finally, we support all reasonable efforts to prevent marketing or sale of inhalable cannabis products to minors. This aligns with the 2009 FDA ban on cigarettes with characterizing flavors, other than menthol, which was enacted only because these non-menthol flavors appeal to youth and not because of a safety concern regarding the inhalation of flavors.

Suggested change:

(a) Cannabis products intended for inhalation shall only contain cannabis; cannabis concentrate; flavor ingredients affirmed FEMA-GRAS; IFRA supported ingredients; isolates identified in cannabis; rolling paper or leaf.

(b) For the purposes of an ingredient listing, the non-cannabis ingredients that contribute flavor and fragrance to an inhalable product should be collectively identified as "Natural Flavors", "Artificial Flavors" or "Natural & Artificial Flavors" as appropriate considering the definitions in 21CFR101.22. See also Section 17406 (a)(5)(C).

(1) An incidental additive, originating in a flavor used in the manufacture of an inhalable cannabis product, need not be declared in the statement of ingredients if it meets the requirements described in 21CFR101.100(a)(3).

(2) If the flavor contains a major food allergen, it should be labeled in alignment with the FDA's Food Allergen Labeling and Consumer Protection Act (FALCPA). Label the word "contains" under the ingredient listing followed by a list of the applicable major food allergen(s). See also Section 17406 (a)(6).

(3) If the flavor contains a directly added fragrance allergen as per Annex III of the EU Cosmetics Regulation No 1223/2009 and subsequent updates, it should be labeled when at or above 0.001% (10 ppm) following the word "contains" at the end of the ingredient list.

(c) The Maximum Use Level (MUL) of each ingredient used in a flavor that is intended for inhalation should be based on a toxicological risk assessment that specifically considers inhalation exposure.

(1) A flavor supplier shall certify, in writing, that any flavor he/she supplies which is designated as safe for inhalation, to the best of his/her knowledge and belief, is safe for

inhalation based on the necessary toxicological assessments and corresponding levels of ingredients in the flavor. The requirement for such certification may be satisfied by a guarantee. The cannabis product manufacturer may rely upon the flavor supplier's certification and need make no separate certification regarding the flavor. All such certifications shall be retained by the certifying party throughout the period in which the flavor is supplied and for a minimum of three years thereafter, and shall be subject to the following conditions:

(i) The certifying party shall make such certifications available upon request at all reasonable hours to any duly authorized office or employee of the DCC. Such certifications are regarded as reports to the government and subject the certifying party to the penalties for making any false report to the government.

(ii) The DCC can verify the accuracy of a reasonable number of certifications made pursuant to this section, constituting a representative sample of such certifications, and shall not request all such certifications.

(iii) Where no person authorized to provide such information is reasonably available at the time of inspection, the certifying party shall arrange to have such person and the relevant materials and records ready for verification as soon as practicable.

(iv) The certifying party shall provide, to an officer or representative duly designated by the DCC, such quantitative statement of the composition of the flavor covered by the certification as may be reasonably expected to enable the DCC's representative to determine which relevant records are reasonably necessary to verify the certifications. The examination conducted by the DCC's representative shall be limited to inspection and review of inventories and flavor records for those certifications which are to be verified.

(v) Review of flavor records shall include the quantitative formula but only as necessary and under strict confidentiality. The person verifying the certifications may make only such notes as are necessary to enable him/her to verify such certification. Only such notes or such flavor records as are necessary to verify such certification or to show an actual violation may be removed or transmitted from the certifying party's place of business. The relevant records and notes shall be

retained as separate documents in DCC Administration files, shall not be copied in other reports, and shall not be disclosed publicly other than in a judicial proceeding.

(d) The direct addition of the following ingredients is prohibited:

(1) Vitamin E Acetate, CAS#7695-91-2

(2) Diacetyl, CAS #431-03-8

(3) 2,3-Pentadione, CAS #600-14-6

(e) All reasonable efforts should be made to prevent marketing or sale of inhalable cannabis products to minors. See also Section 15040(a)(2)-(a)(3) and Section 17408(a)(2).

Comment #2

Applicable regulation number: §15719. Residual Pesticides Testing.

Comment:

Pursuant to section 17214, a licensed cannabis manufacturer shall establish and implement a written product quality plan to control potential risk to product quality for each type of product manufactured at the premises. This risk assessment includes the evaluation of potential chemical hazards, including pesticides, that could be introduced to a cannabis product at each stage of the manufacturing operations. The quality plan should also document preventive measures taken to control the hazard.

Preventative measures could include ensuring that ingredients are tested, as appropriate, for pesticide residues throughout the supply chain. Testing individual ingredients against their respective pesticide crop tolerances through-out the supply chain is more appropriate than testing a multi-ingredient product against the crop tolerances for a single crop (eg. cannabis crop tolerances).

Section 15719 proposes testing samples of cannabis and cannabis products to determine whether residues of pesticides used on cannabis crops are withing tolerances established by CA. The definition for “cannabis product” in section 15000 (j) includes product containing concentrated cannabis and other ingredients. Only cannabis should be required to comply with the pesticide tolerances established by CA for cannabis crops. We believe it is redundant and inappropriate for regulations to require that a cannabis product be tested against the CA pesticide tolerances for cannabis crops because cannabis products have the potential to contain

ingredients derived from crops other than cannabis. Therefore, cannabis products should be removed from the scope of this section and a Quality Plan/Risk Assessment should identify if and where additional pesticide testing is required to control this chemical hazard in the remaining supply chain.

Please consider the simplified example of a multi-ingredient cannabis product that is flavored with citrus derived flavor ingredients. If the citrus ingredients comply with EPA pesticide tolerances for citrus crops and the cannabis products comply with CA pesticide tolerances for cannabis crops, then the pesticide hazards have been controlled for the finished multi-ingredient cannabis product. If California would instead require the finished multi-ingredient cannabis product to comply with CA pesticide tolerances for cannabis crops, then the product could fail for citrus pesticide residues that are within appropriate EPA citrus crop pesticide tolerances.

Suggested change:

(a) The licensed laboratory shall analyze at minimum 0.5 grams of the representative sample of cannabis to determine whether residual pesticides are present

…

(d)(2)

Category II Residual Pesticide	CAS No.	Action Level (µg/g) for Cannabis intended for inhalation	Action Level (µg/g) for Cannabis not intended for inhalation

…

(f) Non-cannabis ingredients should comply with any EPA pesticide tolerances relevant to their source crop.

(g) The manufacturer of a cannabis product should consider testing for pesticide residues as a preventative control pursuant to section 17214 when:

(1) an ingredient has not been tested earlier in the supply chain;

(2) an ingredient has been further concentrated;

(3) pesticides have been introduced into the cannabis product at a later manufacturing step or process.

Comment #3

Applicable regulation number: §15721. Mycotoxin Testing.

Comment:

Pursuant to section 17214, a licensed cannabis manufacturer shall establish and implement a written product quality plan to control potential risk to product quality for each type of product manufactured at the premises. This risk assessment includes the evaluation of potential chemical hazards, including mycotoxins, that could be introduced to a cannabis product at each stage of the manufacturing operations. The quality plan should also document preventive measures taken to control the hazard.

Preventative measures could include ensuring that ingredients are evaluated for risk of contamination with mycotoxins and testing, as appropriate, for mycotoxins throughout the supply chain. Evaluating individual ingredients for risk of mycotoxin contamination is preferred to testing a finished multi-ingredient cannabis product for mycotoxins. Mycotoxins are naturally occurring toxins produced by certain molds (fungi) and can be found in some but not all crops at various stages in the supply chain.

Since mycotoxin can form on cannabis, only mycotoxin testing of cannabis should be required in this section. A Quality Plan/Risk Assessment should identify if and where additional mycotoxin testing is required to control this chemical hazard in the remaining supply chain to the cannabis goods. Therefore, it is redundant for regulations to require that a multi-ingredient cannabis product be tested for mycotoxins and cannabis products should be removed from the scope of this section.

Suggested change:

(a) The licensed laboratory shall analyze at minimum 0.5 grams of the representative sample of cannabis to determine whether mycotoxins are present.

…

(e) Non-cannabis ingredients, in a multi-ingredient cannabis product, should be evaluated and/or tested for the presence of mycotoxins as appropriate pursuant to section 17214.

(f) The manufacturer of a cannabis product only needs to consider testing for mycotoxins as a preventative control pursuant to section 17214 where:

(1) an ingredient that is a potential source for mycotoxin contamination has not been tested earlier in the supply chain;

(2) an ingredient that is a potential source for mycotoxin contamination has been further concentrated;

(3) any ingredients or finished product have been stored under conditions that may have introduced mycotoxins into the cannabis product at a later manufacturing step or process.

Comment #4

Applicable regulation number: §15723. Heavy Metals Testing.

Comment:

Pursuant to section 17214, a licensed cannabis manufacturer shall establish and implement a written product quality plan to control potential risk to product quality for each type of product manufactured at the premises. This risk assessment includes the evaluation of potential chemical hazards, including heavy metals, that could be introduced to a cannabis product at each stage of the manufacturing operations. The quality plan should also document preventive measures taken to control the hazard.

Preventative measures could include ensuring that ingredients are evaluated for risk of contamination with heavy metals and testing, as appropriate, for heavy metals throughout the supply chain. Evaluating individual ingredients for heavy metals is preferred to testing a finished cannabis product for heavy metals. Testing of a cannabis product may be conducted on a periodic basis to ensure that the hazard is properly being controlled earlier in the supply chain. A Quality Plan/Risk Assessment should identify if and where additional heavy metal testing is required to control this chemical hazard in the remaining supply chain to the cannabis good.

Therefore, it is redundant for regulations to require that a cannabis product be tested for heavy metals and cannabis products should be removed from the scope of this section.

Suggested change:

(a) The licensed laboratory shall analyze at minimum 0.5 grams of the representative sample of cannabis to determine whether heavy metals are present

…

(c)

Heavy Metal	CAS No.	Action Level (µg/g) for Cannabis intended for inhalation	Action Level (µg/g) for Cannabis not intended for inhalation

…

(e) Non-cannabis ingredients, in a multi-ingredient cannabis product, should be evaluated and/or tested for the presence of heavy metals pursuant to section 17214.

(f) The manufacturer of a cannabis product only needs to consider testing for heavy metals as a preventative control pursuant to section 17214 where:

(1) an ingredient that is a potential source for heavy metal contamination has not been tested earlier in the supply chain;

(2) an ingredient that is a potential source for heavy metal contamination has been further concentrated;

(3) heavy metals have been introduced into the cannabis product at a later manufacturing step or process.

Comment #5

Applicable regulation number: §15720. Microbial Impurities Testing.

Comment:

Pursuant to section 17214, a licensed cannabis manufacturer shall establish and implement a written product quality plan to control potential risk to product quality for each type of product manufactured at the premises. This risk assessment includes the evaluation of potential biological hazards, including microbiological, that could be introduced to a cannabis product at each stage of the manufacturing operations. The quality plan should also document preventive measures taken to control the hazard.

Preventative measures could include ensuring that ingredients are evaluated for risk of microbiological contamination and testing, as appropriate, throughout the supply chain. Testing of some ingredients and cannabis products may be conducted on a periodic basis to ensure that the hazard is properly being controlled earlier in the supply chain. Micro challenge studies as well as statistically strategic product testing can show a product to be micro stable and not susceptible to micro growth. For example, when the risk is determined to be extremely low, a quality program may test 3 batches from a product SKU before reducing test frequency to

quarterly. A Quality Plan/Risk Assessment should identify if and where additional microbiological testing is required to control this biological hazard in the remaining supply chain to the cannabis good and the risk can be re-assessed as needed.

Therefore, it is redundant for regulations to require that a cannabis product be tested for microbiological contamination and cannabis products should be removed from the scope of this section.

Suggested change:

(a) The licensed laboratory shall analyze at minimum 1.0 grams of the representative sample of cannabis to determine whether microbial impurities are present.

…

(c) The sample of cannabis shall be deemed to have passed the microbial impurities testing if all of the following conditions are met:

…

(d) If the sample fails microbial impurities testing, the batch from which the sample was

collected shall not be released for retail sale until the batch is processed to control the hazard pursuant to section 17214.

Comment #6

Applicable regulation number: §15722. Foreign Material Testing.

Comment:

Pursuant to section 17214, a licensed cannabis manufacturer shall establish and implement a written product quality plan to control potential risk to product quality for each type of product manufactured at the premises. This risk assessment includes the evaluation of potential physical hazards, including foreign material, that could be introduced to a cannabis product at each stage of the manufacturing operations. These foreign objects include, but are not limited to metal flakes or fragments, pieces of product packaging, stones, glass or wood fragments, insects or other filth, personal items, or any other foreign material not normally expected to be in the consumable product. Sources for such contaminants include raw materials, badly maintained facilities and equipment, improper production procedures and poor

employee practices. The quality plan should also document preventive measures taken to control the hazard.

Preventative measures could include ensuring that ingredients are evaluated for risk of foreign material contamination, as appropriate, throughout the supply chain. Control methods include raw material inspection and specification, vendor certification and letters of guarantees, metal detectors, filters, effective pest control in the facility, preventative equipment maintenance and proper sanitation procedures. Laboratory testing is not generally recognized as a necessary preventative measure to control physical hazards. These hazards are generally controlled by using appropriate Good Manufacturing Practices (GMPs). A Quality Plan/Risk Assessment should identify if and where foreign material testing is required to control this physical hazard in the supply chain to produce safe cannabis goods.

Therefore, it is redundant for regulations to require that cannabis or cannabis product be tested for foreign material contamination. Foreign material testing of cannabis or cannabis product should be optional to validate the effectiveness of preventative controls in a quality plan.

Suggested change:

(a) If requested, the licensed laboratory shall analyze the representative sample of cannabis or cannabis product to determine whether foreign material is present.
(b) …

Comment #7

Applicable regulation number: §15718. Residual Solvents and Processing Chemicals Testing.

Comment:

Pursuant to section 17214, a licensed cannabis manufacturer shall establish and implement a written product quality plan to control potential risk to product quality for each type of product manufactured at the premises. This risk assessment includes the evaluation of potential chemical hazards, including solvent residues, that could be introduced to a cannabis product at each stage of the manufacturing operations. The quality plan should also document preventive measures taken to control the hazard.

Preventative measures could include ensuring that ingredients are tested, as appropriate, for solvent residues throughout the supply chain. They could also include additional processing steps to reduce or remove solvents for compliance with acceptable residue limits.

Section 15718 proposes testing samples of cannabis product or pre-rolls to determine whether residues of solvents are withing tolerances established by CA. A "pre-roll" is defined as any combination of the following rolled in paper: flower, shake, leaf, or kief that is obtained from accumulation in containers or sifted from loose, dry cannabis flower or leaf with a mesh screen or sieve. Therefore, a pre-roll may not contain any solvent extracted components and it is inappropriate to require residual solvent testing for this product. However, "cannabis product" includes product containing concentrated cannabis and other ingredients which may be solvent extracted. A Quality Plan/Risk Assessment should identify if and where additional testing for solvent residues is required to control this chemical hazard in the supply chain to the cannabis good. Residual solvent testing of cannabis products should be optional to validate the effectiveness of preventative controls in a quality plan.

Suggested change:

(a) If requested, the licensed laboratory shall analyze at minimum 0.25 grams of the representative sample of cannabis product to determine whether residual solvents or processing chemicals are present.
(b) …

Comment #8

Applicable regulation number: §15303. Packaging, Labeling, and Rolling.

Comment:

It has been our experience that testing laboratories are currently very limited in their ability to detect and identify terpenes. In fact, Abstrax has validated methods to detect and analyze >300 aroma compounds in cannabis. Therefore, we encourage the DCC not to limit labels to identifying only those cannabinoids and terpenoids based on optional testing under section 15725. Instead, a manufacturer should be able to label any cannabinoids and/or terpenoids detected by a validated method and substantiated with data.

Suggested change:

(c) Licensed distributors may label and re-label a package containing manufactured cannabis goods with the amount of cannabinoids and terpenoids present as substantiated by analysis with validated methods.

Comment #9

Applicable regulation number: §15307. Quality-Assurance Review

Comment:

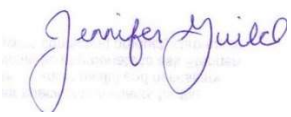
It has been our experience that testing laboratories are currently very limited in their ability to detect and identify terpenes. In fact, Abstrax has validated methods to detect and analyze >300 aroma compounds in cannabis. Therefore, we encourage the DCC not to limit labels to identifying only those cannabinoids and terpenoids based on optional testing under section 15725. Instead, a manufacturer should be able to label any cannabinoids and/or terpenoids detected by a validated method and substantiated with data.

Suggested change:

(1) If the cannabis goods are labeled with the content for cannabinoids, terpenoids, Total THC, and/or Total CBD prior to receiving the certificate of analysis for regulatory compliance testing, the licensed distributor shall ensure that the labeled amounts are accurate in accordance with section 15307.1 and 15303 (as amended per comment #8) of this division, and
(2) If the cannabis goods are not labeled with the content for cannabinoids, terpenoids, Total THC, and/or Total CBD prior to receiving the certificate of analysis for regulatory compliance testing, the licensed distributor shall label the cannabis goods with the amounts listed on the certificate of analysis pursuant to section 15303.

- End of Comments -

Thank you for your consideration.
Sincerely,



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