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Example:

Component	Amount per tablet	Amount per batch
Senna	250 mg (equivalent to 2000 mg dried leaves)	10.0 kg (equivalent to 80.0 kg of dried leaves)
Excipient 1	100 mg	4.0 kg
Excipient 2	10 mg	0.4 kg

- The name and address of the manufacturer of the finished drug product
- A description of the manufacturing process. (If the botanical drug substance is filled and packaged directly as the finished product without the addition of excipients and further processing, this item and items listed in the immediately preceding two bullets will not apply.)
- A list of the quality control tests performed on each batch of the drug product, and the analytical procedures used and the available test results. These tests should include, but need not be limited to, the following attributes:
 - Appearance
 - Chemical identification by spectroscopic and/or chromatographic fingerprints
 - Assay for active constituents or characteristic markers, if available. If several botanical raw materials are combined to produce a multi-herb substance and a quantitative determination of each individual active constituent or marker is infeasible, a joint determination can be carried out for several active constituents or markers. When multiple active constituents or markers are known, they should be chemically characterized and their relative amounts should be defined.
 - Biological assay (when the active chemical constituent(s) are not known or quantifiable), if available. If the botanical drug substance is considered potent (i.e., highly active), toxic, addictive, or has abuse potential (e.g., ephedra or marijuana), an assay for biological activity and/or a chemical assay for the active constituent(s) should be performed.
 - Strength by dry weight (of drug substance)
 - Microbial limits
 - Other attributes specific to the dosage form of interest (e.g., dissolution for solid oral dosage forms, sterility and nonpyrogenicity for parenterals, animal safety test for parenterals, when appropriate).

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- A description of the container/closure in which the drug product is to be packaged
- Available stability data on the drug product. The sponsor should develop stability-indicating analytical methods (using markers when feasible) and conduct stability studies as the IND progresses.

4. *Placebo (see section VII.B.5)*

5. *Labeling (see section VII.B.6)*

Additionally, a quantitative description of the drug substance per dosage unit (as described in section VIII.B.2.h and 3.b) should be provided. An example of a quantitative description for a multi-herb botanical drug product is shown below:

BRAND X. 100 tablets. Each 1-gram tablet contains:
300 mg of *Lonicera japonica* Thunb.4:1 solid extract and
300 mg of *Forsythia suspensa* Vahl. 6:1 solid extract

6. *Environmental Assessment or Claim of Categorical Exclusion*

A claim for categorical exclusion from the requirement for preparation of an EA ordinarily can be made for an IND (§ 25.31(e)). However, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment (21 CFR 25.21; 40 CFR 1508.4). CDER will evaluate INDs on a case-by-case basis when the drug or biological product is derived from wild plants or animals to determine whether the extraordinary circumstance provision in § 25.21 is applicable. FDA encourages early consultation with the Agency on environment-related aspects of a requested action, especially one that involves harvesting a wild species, to ensure that planning and decisions reflect environmental values, avoid delays later in the process, and avoid potential conflicts (§ 25.10(b) and (c)). For additional information, see 21 CFR part 25, 40 CFR parts 1500-08, and the CDER/CBER guidance for industry on *Environmental Assessment of Human Drug and Biologics Applications* (July 1998). An environmental assessment or a claim for categorical exclusion must be provided as required under § 25.15(a).

C. Nonclinical Safety Assessment

1. *Traditional Preparations*

Nonclinical pharmacology and toxicology studies are particularly important in establishing the safety of a new botanical drug for which there is no current marketing experience. The information is used for assessing the botanical drug's risk-to-benefit ratio, guiding early clinical studies, and predicting potential toxicity.

Because of their extensive use in humans, there may be sufficient information on

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traditional herbal medicines to support initial clinical studies without standard nonclinical testing. Therefore, such products may require fewer nonclinical safety studies under § 312.23(a)(8) than would be expected for synthetic or highly purified drugs with which there is little experience.

A traditional herbal preparation, which may have evolved over time, generally has the following characteristics:

- It meets official compendia or other published standards in terms of the botanical identity and plant part used for each botanical raw material.
- In the case of a multi-herb substance, it is composed of the same formulation as a historical formula, with the amount of each botanical ingredient falling within the range of traditional usage.
- It is prepared by the same processing methodology as traditionally used.
- It is used in the traditional manner in terms of therapeutic indication, route and schedule of administration, and quantities or doses.

For initial clinical studies on a botanical drug product that is not currently lawfully marketed in the United States or elsewhere but is prepared, processed, and used by humans according to an established methodology, sufficient information might be available to support the studies without standard nonclinical testing. In general, the considerations listed under section VII.C are applicable. When the initial clinical study for such a drug shows promising results and further clinical development of the drug is intended, pharmacology and toxicology studies carried out prior to the later phases of the clinical trials may be needed to support a risk-benefit assessment and to identify potential toxicities not readily detected in clinical studies (see section IX.C below).

2. Others

For a botanical product that is not prepared according to a traditional methodology, the extent of variation from the traditional formulation, preparation, or processing should be described in full detail. The nature of nonclinical pharmacology/toxicology information needed before conducting an initial clinical study (in addition to that described under section VII.C) will be determined on a case-by-case basis, depending on the indications, extent of safe human experience, and safety concerns about the new formulation, preparation, or processing methodology used.

3. Products with Known Safety Issues

For those botanical drugs for which there are known safety issues, the nature of the nonclinical pharmacology/toxicology information needed will be determined on a case-by-case basis to address those issues (see section VI.A).

D. Bioavailability

Pharmacokinetic and pharmacodynamic information is helpful in the design and

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interpretation of clinical studies. As stated in section VII.D, a botanical product's active constituents may be unknown, and standard pharmacokinetic measurements to demonstrate systemic exposure to a product in animals and/or humans may be infeasible due to the complexity of the botanical drug. However, when feasible, a sponsor is encouraged to monitor the blood levels of known active constituents, representative markers, or other major chemical constituents in a botanical drug product. Because there is less human use experience with botanical products that have never been lawfully marketed than with those that have been, a sponsor of a drug that has not been lawfully marketed should consult FDA's guidances *Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro* (April 1997) and *In Vivo Drug Metabolism/Drug Interaction Studies—Design, Data Analysis, and Recommendations for Dosing and Labeling* (November 1999) to assess potential drug-drug interaction when a clinical study includes co-administration with another drug (see section IX.D).

For a botanical product that is prepared according to traditional methodology, the nature of clinical pharmacology information needed should be determined on a case-by-case basis, depending on the indications, extent of human experience, target patient population, and projected length of clinical use.

E. Clinical Considerations

In general, initial clinical investigations of nonmarketed botanical preparations should be similar to those of marketed products (see section VII.E). Because of the lack of current marketing experience, however, greater concerns could exist about toxicity. Therefore, FDA will seek greater assurance of the safety of the product for initial clinical trials in the United States. Such assurance may be provided in the form of additional chemical analysis and/or additional toxicology data. It may also be helpful to provide documentation of the product's previous safe human use by referencing literature and/or pharmacopoeias.

IX. INDS FOR PHASE 3 CLINICAL STUDIES OF ALL BOTANICAL PRODUCTS

When conducting expanded (i.e., phase 3) clinical studies on a botanical drug product, an IND sponsor is expected to provide more detailed information on CMC and nonclinical safety than when conducting a phase 1 or phase 2 study (§ 312.22(b), 312.23(a)(7)(i) and (8)). The better definition of the product will ensure an ability to apply data from trials to a well-controlled, reproducible substance. The additional toxicology data are needed to support wider use. This additional information should be provided regardless of whether the product is currently lawfully marketed in the United States or elsewhere as a dietary supplement.

For phase 3 clinical studies of a botanical product, the following information should be provided in meeting the requirements of § 312.23:

A. Description of Product and Documentation of Human Experience

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See sections VII.A and VIII.A for guidance on how to describe the botanical product and human experience with it.

B. Chemistry, Manufacturing, and Controls

To support phase 3 clinical trials of a botanical product, regardless of its marketing experience in the United States or other countries, the following CMC information should be provided in accordance with § 312.23(a)(7) unless already submitted in the IND for phase 1/phase 2 studies on the product:

1. Expanded Clinical Studies

a. Botanical raw material

- A description of the botanical raw material as outlined in sections VII.A.1 and VIII.A.1. If the botanical has no documented history of use, this should be indicated. Proper identification by trained personnel of the plant, plant parts, alga, or macroscopic fungus used, including organoleptic, macroscopic, and microscopic examination, should be provided. The identification should be done against a voucher specimen (reference specimen). If more than one variety or source of a given species is used, they should be blended in a fixed proportion in a consistent manner. A sample of the plant, plant parts, or other botanical materials should be retained for every batch by the raw material supplier and drug substance manufacturer, and stored under appropriate conditions for future verification of identity. In addition, a certificate of authenticity and information on the grower and/or supplier, growing conditions (including pesticides used), harvest location, harvest time (including stage of plant growth at harvest), handling, and shipping should be provided.
- A spectroscopic and/or chromatographic fingerprint of each botanical raw material and the chemical identity of the active constituents or characteristic markers in the botanical raw material
- The name and address of the botanical raw material manufacturer (processor)
- A description of the preparation of the botanical raw material, including collection, washing, drying, preservation, and/or detoxification and preservation procedures. Equipment and quantity used, temperature employed, processing time, in-process controls, and yield should be specified.
- The quality control tests and analytical procedures applied by the botanical raw material supplier, and the proposed acceptance criteria. These tests should include, but need not be limited to, the following attributes:
 - Botanical identification
 - Chemical identification by spectroscopic and/or chromatographic fingerprint
 - Chemical identification for active constituents or characteristic markers if

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active constituents are not known

- Assay for active constituents or characteristic markers if active constituents are not known
- Biological assay (when the active chemical constituents are not known or quantifiable), if available
- Heavy metals
- Microbial limits
- Residual pesticides, including parent pesticides and their major toxic metabolites
- Adventitious toxins (e.g., aflatoxins)
- Foreign materials and adulterants

In some cases (e.g., when the botanical raw material undergoes further processing to prepare the botanical drug substance), reduced testing may be appropriate for certain assays (e.g., heavy metals), if these assays are routinely performed on the botanical drug substance. If some of these tests cannot be performed by the raw material supplier, the botanical drug substance manufacturer should perform the tests upon receipt of the botanical raw material.

- A photocopy of the voucher specimen (reference specimen) of the botanical raw material used in identification, fingerprinting, and other comparative and noncomparative tests
 - A certificate of analysis for representative batch(es) of the botanical raw material
 - A description of the storage conditions, including the container/closure system and temperature
- b. Botanical drug substance (§ 312.23(a)(7)(iv)(a))
- A qualitative and quantitative description of the drug substance and the name and address of the manufacturer (see section VIII.B.2).
 - A chemical identification for the active constituents or characteristic markers in the drug substance, if possible. If the chemical identity is unknown, a representative spectroscopic and/or chromatographic fingerprint may suffice.
 - Appropriate acceptance specifications (tests, test procedures, and acceptance criteria) for the botanical raw material, similar to the list of quality control specifications in section IX.B.1.a, established by the botanical drug substance manufacturer. Upon receipt of each batch of the raw material and its certificate of analysis, the manufacturer should, at a minimum, conduct an identification test and assay.
 - A description of the manufacturing process for the botanical drug substance. The description should include the quantity of botanical raw material,

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equipment, solvents, temperature/time for mixing, grinding, extraction and/or drying, yield, and in-process controls. The yield of the process, expressed as the amount of the original botanical raw material relative to the amount of the extract, also should be indicated. If more than one botanical raw material is introduced to produce a multi-herb substance, the quantity of each raw material and the sequence of addition, mixing, grinding, and/or extraction should be provided. If a multi-herb substance is prepared by combining two or more individually processed botanical drug substances, the process leading to each botanical drug substance should be described separately.

- The quality control tests performed on each batch of drug substance, the analytical procedures used, and the proposed acceptance criteria. These tests should include, but need not be limited to, the following attributes:
 - Appearance
 - Chemical identification by spectroscopic and/or chromatographic fingerprints
 - Chemical identification for the active constituents or, if unknown, the characteristic markers
 - Chemical assay for the active constituents, or the characteristic markers if the active constituents cannot be determined. If several botanical raw materials are combined to produce a multi-herb substance and a quantitative determination of each individual active constituent or marker is infeasible, a joint determination can be made for several active constituents or markers. When multiple active constituents or markers are known, they should be chemically characterized and their relative amounts should be defined.
 - Biological assay (when the active chemical constituents are not known or quantifiable), if available. If the botanical drug substance is considered potent (i.e., highly active), toxic, or addictive, or has abuse potential (e.g., ephedra or marijuana), an assay for biological activity and/or a chemical assay for the active constituent(s) should be performed.
 - Strength by dry weight
 - Residue on ignition
 - Water content
 - Residual solvents
 - Heavy metals
 - Microbial limits
 - Animal safety test, if applicable
 - Residual pesticides
 - Radioisotope contaminants, if applicable

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- Adventitious toxins (e.g., aflatoxins)
 - Endogenous toxins (e.g., pyrrolizidine alkaloids)
 - Other attributes specific to the botanical raw materials from which the drug substance is derived
-
- Validation reports of all analytical procedures, where appropriate
 - A description of the batch of botanical drug substance designated as the *reference standard* for use in fingerprinting and other comparative tests
 - Batch analysis (i.e., test results for representative batches)
 - A description of the container and closure used to package the botanical drug substance
 - Sufficient stability data on the drug substance to support its safe use during clinical studies; stability-indicating analytical methods
 - Information on the container label as described in section VIII.B.2
- c. Botanical drug product (§ 312.23(a)(7)(iv)(b))
- A qualitative description and the composition of the dosage form and the name and address of the manufacturer (see section VIII.B.3)
 - Appropriate acceptance specifications established by the botanical drug product manufacturer for the botanical drug substance, similar to the quality control tests in section IX.B.1.b. Upon receipt of each batch of the drug substance and its certificate of analysis, the manufacturer should, at a minimum, conduct an identification test and assay.
 - A description of the manufacturing process, without the actual batch record. The description should include weighing, mixing, blending, sieving, in-process controls, and other processes, as appropriate.
 - The quality control tests performed on each batch of drug product, the analytical procedures used, and the proposed acceptance criteria. These tests should include, but need not be limited to, the following attributes:
 - Appearance
 - Chemical identification by spectroscopic and/or chromatographic fingerprints
 - Chemical identification for the active constituents or, if unknown, the characteristic markers
 - Chemical assay for active constituents or, if unknown, the characteristic markers. If several botanical raw materials are combined to produce a multi-herb substance and a quantitative determination of each individual active constituent or marker is infeasible, a joint determination can be

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made for several active constituents or markers. When multiple active constituents or markers are known, they should be chemically characterized and their relative amounts should be defined.

– Biological assay (when the active chemical constituent(s) are not known or quantifiable), if available. If the botanical drug substance is considered potent (i.e., highly active), toxic, addictive, or has abuse potential (e.g., ephedra or marijuana), an assay for biological activity and/or a chemical assay for the active constituent(s) should be performed.

– Strength by dry weight (of drug substance)

– Residual solvents

– Microbial limits

– Adventitious toxins (e.g., aflatoxins)

– Other attributes specific to the dosage form of interest (e.g., dissolution for solid oral dosage forms, sterility for parenterals, animal safety test for parenterals, when appropriate).

- Validation reports of all analytical procedures, where appropriate
- Batch analysis (i.e., test results for representative batches)
- A description of the container and closure used to package the finished product
- Sufficient stability data on the drug substance to support its safe use during clinical studies. Stability-indicating analytical methods should be established.

d. Placebo (see section VII.B.5)

e. Labeling (see sections VII.B.6 for investigational labels and VIII.B.5 for quantitative description)

f. An EA or a claim of categorical exclusion (see section VIII.B.7)

2. End-of-Phase 3 Clinical Studies and Pre-NDA Considerations

Sponsors must continue to characterize the drug substance and the drug product throughout the entire clinical development program (§ 312.23(a)(7)). By the end of the phase 3 clinical trial, as the sponsor prepares to submit an NDA, the following objectives should be reached:

- Adequate controls for botanical raw materials should be established.
- The manufacturing processes of the drug substance and the drug product should be finalized and validated, and in-process controls should be established. An executed

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batch record should be available.

- Batch-to-batch consistency should be demonstrated for the botanical drug substance and drug product based on results from all chemical, physical, and biological tests on all relevant batches. To achieve this goal, multiple fingerprints, using a combination of analytical methods with different separation principles and test methods, can be useful. All chemical constituents detected by spectroscopic and/or chromatographic fingerprinting should be qualitatively and quantitatively comparable from batch to batch.
- Appropriate specifications (i.e., tests, analytical procedures, and acceptance criteria), including identification and assay for active constituents, identification and assay for characteristic markers, and/or biological assay (when the active chemical constituent(s) are not known or quantifiable), should be established to control the quality of the drug substance and product. Both the active constituents and the biological assay should be clinically relevant. If the identity of the active constituents is not known or a suitable assay cannot be developed, the characteristic markers should be demonstrated to be clinically relevant by direct or indirect correlation to the clinical outcome.
- Analytical procedures should be properly validated. Analytical procedures used for fingerprinting should be verified for specificity and should be capable of detecting as many chemical classes (e.g., proteins, carbohydrates, fatty acids, small organic compounds) present and as many individual chemical constituents as possible. Additionally, when multiple fingerprints are used, the analytical procedures in combination should be able to demonstrate the mass balance in the test sample, on the basis of the different classes of chemicals and, if appropriate, among the individual constituents detected within a chemical class.
- A suitable voucher specimen (reference specimen) for each of the botanical raw materials should be established, along with a reference standard for the drug substance and drug product.
- Stability-indicating analytical methods should be developed to monitor the stability of the drug substance and drug product. The stability of a botanical drug substance or product generally should not be based entirely on the assay of the active constituents, assay of the characteristic markers, or biological assay, because degradants formed during storage from other chemical constituents in the botanical drug substance or product should also be controlled. An analytical method capable of detecting these degradants (such as a spectroscopic and/or chromatographic fingerprint) should be established through exploratory studies by subjecting the drug substance and drug product to stress conditions.
- A biological assay, when used for characterization and quality control of a drug substance and drug product, should be properly validated. The ICH Guideline *Q6B Specifications: Test Procedures and Acceptance Criteria for*

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Biotechnological/Biological Products (August 1999) and the USP XXV *Biological Tests <111>: Design and Analysis of Biological Assays* provide useful information on biological assays. Performing a biological assay calls for the use of a suitable reference standard and, frequently, positive and negative controls. Because biological assays are usually more variable than chemical assays, a relatively higher coefficient of variation is generally justifiable.

- A comparison of the similarities and/or differences in CMC among the nonclinical, clinical, and intended commercial products should be made regarding raw materials, drug substance, and drug product.
- The manufacturing, processing, and controls (receipt, identification, storage, handling, sampling, testing, and approval or rejection of components, drug products, and container closures) for botanical drug products must be in conformance with CGMP as set forth in 21 CFR parts 210 and 211. In addition, the manufacturing, processing, and controls for the botanical drug substance (starting from the botanical raw material) should be in conformance with CGMP because these elements can affect the quality, safety, and efficacy of the drug product. A satisfactory inspection is necessary for NDA approval.
- A sponsor should be preparing the submission in the NDA of either an EA or a claim for categorical exclusion from the requirement for preparation of an EA (§ 25.15(a)). Classes of NDAs that are categorically excluded and, therefore, ordinarily do not require preparation of an EA are listed in § 25.31. However, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment (§ 25.21; 40 CFR 1508.4). The Agency regards the submission of an NDA for a drug derived from plants taken from the wild as an extraordinary circumstance requiring the submission of an EA. See section VIII.B.6 for additional information.

Applicants are encouraged to discuss with the review division any CMC issues regarding a botanical drug prior to the preparation and submission of an NDA.

C. Nonclinical Safety Assessment

To support safety for expanded clinical studies or to support marketing approval of a botanical drug product, toxicity data from standard toxicology studies in animals may be needed in accordance with § 312.23(a)(8). A botanical product submitted for marketing approval as a drug will be treated like any other new drug under development. Safety data from previous clinical trials conducted in foreign countries will be considered in determining the need for nonclinical studies. However, previous human experience may be insufficient to demonstrate the safety of a botanical drug product, especially when it is indicated for chronic therapy. Systematic toxicological evaluations could be needed to supplement available knowledge on the general toxicity, teratogenicity, mutagenicity, and carcinogenicity of the final botanical drug product. Depending on the indication

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(e.g., target patient population, disease to be treated), route of administration, and duration of recommended drug exposure, the timing of these animal studies in relation to concurrent clinical trials and other requirements for nonclinical animal studies can vary.

In general, animal studies should, as much as possible, be conducted using the same drug substance prepared and processed in the same manner as the drug substance used in clinical trials.

The following are points to consider in preparing a nonclinical pharmacology/toxicology development plan for a botanical drug product that is intended to be used in large-scale human trials or to support an NDA. If questions arise during any stage of the clinical development of a botanical drug, sponsors are encouraged to consult the appropriate review division in CDER.

1. Repeat-Dose General Toxicity Studies

The primary objective of long-term, repeat-dose toxicity studies in animals is to identify the organs and/or systems that are the targets of the drug's toxicity and the threshold doses for producing toxic effects. The studies provide information valuable for designing long-term clinical studies at safe doses, with appropriate monitoring for predicted adverse reactions. Existing literature on the animal toxicity of a botanical drug is often limited to single-dose (acute) studies. These studies would be inadequate to support long-term use.

To support expanded clinical trials, repeat-dose toxicity of a botanical drug should usually be evaluated in two mammalian species (one of which is a nonrodent) by employing sufficiently high doses to produce a toxic effect or by using a maximum feasible dose. If possible, the drug should be tested using the same route of administration as proposed for clinical use. Animal studies should be of a duration at least equal to that of the clinical trial (usually a minimum of 2 weeks). Routinely, general animal toxicity studies need not exceed 6 months of testing in a rodent species and 9 months of testing in a nonrodent species. For additional information on the timing of animal toxicity studies in relation to clinical trials, see the ICH guidance *M3 Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals* (November 1997).

2. Nonclinical Pharmacokinetic/Toxicokinetic Studies

In the development of a new drug that is a single molecular entity, it is often useful to compare pharmacokinetics in animals and humans and to relate exposure levels to toxicities in both animals and humans. Because botanical drugs usually consist of more than one chemical constituent, standard pharmacokinetic measurements to substantiate the systemic exposure of a botanical drug product in animals may be technically infeasible. However, monitoring representative chemical constituents in a botanical drug can provide valuable information regarding systemic exposure. Depending on the complexity of the botanical drug product to be studied, pharmacokinetics could be helpful in the design and interpretation of toxicity studies. For additional information on

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toxicokinetic evaluations, see the ICH guidances *S3A Toxicokinetics: The Assessment of Systemic Exposure in Toxicity Studies* (March 1995) and *S3B Pharmacokinetics: Guidance for Repeated Dose Tissue Distribution Studies* (March 1995).

3. Reproductive Toxicology

Reproductive toxicology studies, such as those on fertility/reproductive performance, teratology, and prenatal/perinatal development in animals, provide information on the potential of a botanical drug for producing toxicity during the different stages of reproductive and developmental processes. In the absence of documented data on reproductive toxicity in humans or animals, these tests should be conducted prior to expanded clinical trials. For detailed information regarding reproductive toxicology, sponsors should refer to the ICH guidances *S5A Detection of Toxicity to Reproduction for Medicinal Products* (September 1994) and *S5B Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility* (April 1996).

4. Genotoxicity Studies

We recommend that information on the potential of a botanical drug to produce genetic toxicity be obtained as early as possible, preferably before the initiation of human clinical trials (see ICH *M3 Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals* (November 1997)). A complete assessment of genetic toxicity may be needed before expanded clinical trials. A standard battery of tests is defined in the ICH guidances *S2A Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals* (April 1996) and *S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals* (November 1997).

If the standard battery of tests chosen indicate that a drug is devoid of genetic toxicity, additional genotoxicity studies may not be needed to comply with § 312.23(a)(8)(ii)(a). If one or more test results are positive, the sponsor may need to carry out additional genotoxicity tests to comply with this provision, in consultation with the appropriate CDER review division.

5. Carcinogenicity Studies

Carcinogenicity studies may be needed to comply with § 312.23(a)(8)(ii)(a) to support marketing approval of a botanical drug, depending on the duration of therapy or any specific cause for concern. The toxicity profile of the botanical drug and the indication and duration of the intended use may influence the need under this regulation for carcinogenicity studies and their timing relative to clinical development (see ICH *S1A The Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals* (March 1996)). Draft protocols for carcinogenicity studies should be submitted to the appropriate review division and the CDER Carcinogenicity Assessment Committee for review and concurrence prior to the initiation of such studies to ensure the acceptability of dose selection and study design. Study types should be in accordance with the ICH guidance *S1B Testing for Carcinogenicity of Pharmaceuticals* (February 1998). Doses

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used should be chosen according to the principles outlined in the ICH guidances *SIC Dose Selection for Carcinogenicity Studies of Pharmaceuticals* (March 1995) and *SIC(R) Dose Selection for Carcinogenicity Studies of Pharmaceuticals: Addendum on a Limit Dose and Related Notes* (December 1997).

6. *Special Pharmacology/Toxicology Studies*

A general evaluation of the pharmacological effects of a drug on physiological functions (e.g., central nervous system, cardiovascular system) is often performed during new drug development. This evaluation can be accomplished using established *in vitro* and *in vivo* assays of broad specificity that screen for the modes and sites of action of the botanical drug. When significant and unique toxicities to certain organs and/or systems are evident, the sponsor should provide further explanation of the mechanism of toxic actions, if appropriate, by performing additional *in vitro* or *in vivo* studies.

7. *Regulatory Considerations*

Nonclinical toxicity studies conducted as part of botanical drug development and intended to support safety must be in accordance with regulations governing good laboratory practices under 21 CFR part 58. Both the drug substance and the drug product should be made with batch-to-batch consistency. If changes occur in the drug substance or product during clinical development, bridging toxicity studies might be needed to comply with § 312.23(a)(8)(ii)(a).

D. *Bioavailability and Clinical Pharmacology*

The general requirements for *in vivo* bioavailability data in an NDA, described in § 320.21, are applicable to botanical drug products. The type of bioavailability study that is appropriate for a specific botanical drug product is based on the following:

(1) information on the active constituent, if known; (2) the complexity of the drug substance; and (3) the availability of analytical methods. Because there could be more than one active constituent in a botanical drug or the active constituent may not be identified, it could be difficult or impossible to perform standard *in vivo* bioavailability and pharmacokinetic studies (e.g., by measuring, as a function of time, the concentration of the active moiety, active ingredients, or active metabolites in whole blood, plasma, serum, or other appropriate biological fluid, or by measuring the excretion of the active moiety or active metabolites in urine). In some cases, it may be possible to measure an acute pharmacological effect as a function of time using an appropriate biological assay method. If this is not possible, the bioavailability of a botanical drug could be based on clinical effects observed in well-controlled clinical trials.

The general criteria for waiver of *in vivo* bioavailability data in an NDA, described in § 320.22, are applicable to botanical drug products. FDA may, for good cause, waive or defer the *in vivo* bioavailability study requirement if a waiver or deferral is compatible with the protection of the public health (§ 320.22(e)).

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Interactions between botanicals and other commonly used drugs and/or dietary supplements should be investigated. This may include characterization of the metabolic enzymes and/or pathway affected by the drug (see section VIII.D).

Where possible, the effects of impaired clearance (renal or hepatic) on the drug's pharmacokinetics should be examined. This is easiest when the active substance(s) are known, but even if they are not, knowledge of the major constituents should make it possible to determine the effects of impaired clearance. Dose-response information may indicate the proper level of concern about impaired excretion.

As with synthetic and/or highly purified drugs, pharmaceutical and biopharmaceutics studies for botanical drug products are important for product quality control, batch comparison, and linkage between different strengths. These studies may involve, for example, in vitro dissolution testing, in situ drug absorption testing, in vitro-in vivo correlation studies, or in vitro percutaneous absorption/penetration testing, depending on the indication and formulation of the botanical product.

E. Clinical Considerations

Expanded studies of botanicals have the same purpose as expanded studies of synthetic drugs, including further evaluation of dose-response for favorable and unfavorable effects and evaluation of long-term safety and effectiveness, different populations, different stages/severity of disease, and drug-drug interactions. Many general and therapy-specific guidances are available on CDER's Web page (see title page for URL).

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GLOSSARY

The following definitions are intended for use in this guidance only and may not be appropriate in other contexts.

Active Constituent: The chemical constituent in a botanical raw material, drug substance, or drug product that is responsible for the intended pharmacological activity or therapeutic effect

Botanical; Botanical Product: A finished, labeled product that contains vegetable matter, which may include plant materials (see below), algae, macroscopic fungi, or combinations of these. Depending in part on its intended use, a botanical product may be a food, drug, medical device, or cosmetic.

Botanical Drug Product; Botanical Drug: A botanical product that is intended for use as a drug; a drug product that is prepared from a botanical drug substance. Botanical drug products are available in a variety of dosage forms, such as solutions (e.g., teas), powders, tablets, capsules, elixirs, and topicals.

Botanical Drug Substance: A drug substance derived from one or more plants, algae, or macroscopic fungi. It is prepared from botanical raw materials by one or more of the following processes: pulverization, decoction, expression, aqueous extraction, ethanolic extraction, or other similar process. It may be available in a variety of physical forms, such as powder, paste, concentrated liquid, juice, gum, syrup, or oil. A botanical drug substance can be made from one or more botanical raw materials (see Single-Herb and Multi-Herb Botanical Drug Substance or Product). A botanical drug substance does not include a highly purified or chemically modified substance derived from natural sources.

Botanical Ingredient: A component of a botanical drug substance or product that originates from a botanical raw material

Botanical Raw Material: Fresh or processed (e.g., cleaned, frozen, dried, or sliced) part of a single species of plant or a fresh or processed alga or macroscopic fungus

Cosmetic: An article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, or an article intended for use as a component of any such article, except that such term does not include soap (21 U.S.C. 321(i))

Dietary Supplement: The following definition is taken directly from 21 U.S.C. 321(ff).

The term *dietary supplement* —

“(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent,

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extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that (A)(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i) [of the Act]; or (ii) complies with section 411(c)(1)(B)(ii); (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and (C) is labeled as a dietary supplement; and

(3) does (A) include an article that is approved as a new drug under section 505 [of the Act] or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless [FDA] has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f) [of the Act]; and (B) not include (i) an article that is approved as a new drug under section 505 [of the Act], certified as an antibiotic under section 507 [of the Act], or licensed as a biologic under section 351 of the Public Health Service Act (42 U.S.C. 262), or (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless [FDA], in [its] discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act. Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.”

Dosage Form: A pharmaceutical product type, for example, tablet, capsule, solution, or cream, that contains a drug ingredient (substance) generally, but not necessarily, in association with excipients

Drug: The following definition is taken directly from 21 U.S.C. 321(g)(1).

The term drug means “(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) [of the Act] or sections 403(r)(1)(B) and (r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.”

Drug Product: A finished dosage form, for example, tablet, capsule, solution, etc. (21 CFR 210.3 (b)(4))

Drug Substance: An active ingredient that is intended for use to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body (21 CFR 314.3(b))

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Food: The term *food* means (1) articles used for food or drink, (2) chewing gum, and (3) articles used for components of such articles (21 U.S.C. 321(f)).

Formulation: A formula that lists the components (or ingredients) and composition of the dosage form. The components and composition of a multi-herb botanical drug substance should be part of the total formulation.

Marker: A chemical constituent of a botanical raw material, drug substance, or drug product that is used for identification and/or quality control purposes, especially when the active constituents are not known or identified.

Multi-Herb (Botanical Drug) Substance or Product: A botanical drug substance or drug product that is derived from more than one botanical raw material, each of which is considered a botanical ingredient. A multi-herb botanical drug substance may be prepared by processing together two or more botanical raw materials, or by combining two or more single-herb botanical drug substances that have been individually processed from their corresponding raw materials. In the latter case, the individual single-herb botanical drug substances may be introduced simultaneously or at different stages during the manufacturing process of the dosage form.

Plant Material: A plant or plant part (e.g., bark, wood, leaves, stems, roots, flowers, fruits, seeds, or parts thereof) as well as exudates thereof.

Single-Herb (Botanical Drug) Substance or Product: A botanical drug substance or drug product that is derived from one botanical raw material. Therefore, a single-herb substance or product generally contains only one botanical ingredient.

Spectroscopic and/or Chromatographic Fingerprint: A spectroscopic and/or chromatographic profile of a botanical raw material, drug substance, or drug product that is matched qualitatively and quantitatively against that of a reference sample or standard to ensure the identity and quality of a batch and consistency from batch to batch.

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QUESTIONS AND ANSWERS

Q1: Are INDs required for clinical studies of botanical products that are lawfully marketed as dietary supplements in the United States?

A1: It depends on what the botanical product is being studied for. If a lawfully marketed botanical dietary supplement is studied for a dietary supplement use, i.e., effect on the structure and/or a function of the body, an IND is not required (see final rule on “Structure and Function Claims for Dietary Supplements,” 65 FR 1000, January 6, 2000). Although an IND is not legally required for such a study, CDER encourages sponsors to submit one. If you have questions on how to design such a study, FDA would be willing to review and provide advice on protocols. You may contact CDER’s Botanical Review Team at 301-827-2250 or BOTANICALTEAM@cder.fda.gov. If a botanical preparation is being studied for its effects on a disease in the proposed investigation (i.e., to cure, treat, mitigate, prevent, or diagnose disease, including its associated symptoms), it is considered a new drug and will need to be studied under an IND (see § 312.2).

Q2: Are INDs required for clinical studies on marketed dietary supplements for research purposes only?

A2: Again, it depends on the use. If the intent is to study the effect of the product on the structure and/or a function of the body, no IND is needed. If the study is to assess the effects on disease, an IND is needed.

Q3: Is there any other setting in which an IND is not required for the botanical study?

A3: When a nonmarketed botanical preparation is studied in the United States for a dietary supplement use, an IND is not required. In addition, clinical studies conducted in foreign countries require no IND. However, FDA will accept an IND for either kind of study. In the absence of an IND, an investigational new drug intended for export for the purpose of clinical investigation must comply with the requirements set forth in § 312.110(b)(2) unless the new drug has been approved or authorized for export under section 802 of the Act (21 U.S.C. 382).

Q4: May a sponsor submit an IND for a phase 3 study of a botanical product not previously studied under an IND?

A4: Yes. Clinical data collected from phase 1 and phase 2 studies conducted without an IND can be used to support a phase 3 study involving the same drug substance if they are adequately designed and conducted. The formulation/dosage form of the botanical product used in the proposed phase 3 study ideally would be the same as that of the product used in phase 1 and 2 studies as well as in the preclinical (nonclinical) studies. If the product is different, additional studies may be appropriate.

Q5: For NDA approvals of botanical drug products, must all studies be carried out under

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INDs?

A5: No. FDA does not require that all studies submitted in an NDA be conducted under an IND. Clinical studies need not necessarily be conducted under an IND (i.e., if they are carried out abroad). The clinical data generated from these studies conducted without an IND can be used to support an NDA if the studies were adequately designed and conducted under good clinical practices.

Although an IND is not required by law in all cases, the sponsor is encouraged to go through the IND process. Compliance with the IND requirements will help to ensure that an adequate pharmaceutical product development program is in place so that the material will meet the quality standards not only for various phases of clinical trials but also for eventual marketing. It will also help to ensure that the clinical trials will be well designed so that data generated can be persuasive.

Q6: It appears that the changes in regulatory approaches described in the guidance on Botanical Drug Products concern only IND applications. How will these changes be applied to the NDA requirements for botanical drugs?

A6: To facilitate the clinical development of botanical drugs, FDA decided to focus initially on a guidance for INDs, especially the early phases of clinical study. The standards for the safety and efficacy required for marketing approval of a botanical drug are the same as those required for a conventional chemical drug for the same indication. However, the product quality standards for a botanical drug can be different from those for a purified chemical drug. The Botanical Drug Products guidance contains recommendations for establishing appropriate quality standards for botanical drugs.

Q7: Some botanical preparations are not administered orally, e.g., intravenous, topical, and inhalation products. How are these nonoral formulations considered in the guidance?

A7: The guidance applies to all dosage forms of botanical products. All parenteral, topical, inhalation, or other nonorally administered botanical products are considered to be drugs, not dietary supplements, and must be studied under an IND for any use (see section 201(ff) of the Act). Just as for purified chemical drugs, the type of quality testing varies from dosage form to dosage form. For example, all injectables are required to be sterile and pyrogen-free (211.165(b) and 211.167 and 314.50(d)(1)(ii)(b)); oral tablets are not. In addition, dietary supplements are orally ingested and the human experience of an orally administered botanical dietary supplement may not be applicable to the same botanical product given through other routes.

Q8: In terms of IND requirements and regulatory review by the Agency, is there any difference between a commercial development program and an academic research project?

A8: No. The Agency applies the same standards to both commercial and academic sponsors when evaluating the safety and quality of human studies proposed in INDs.

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Q9: Intellectual property rights are a difficult issue for developing new drugs from well-known botanical preparations. How does FDA protect the confidentiality of a sponsor's submission? What kind of IND/NDA data may FDA release without prior permission from the sponsor?

A9: IND information generally is not publicly available (see §§ 312.130, 314.430). Once an NDA is approved, FDA may release certain safety and efficacy information (§ 314.430(e)). Manufacturing information (including information related to growers and suppliers) provided in an NDA or a Drug Master File (DMF) is considered proprietary and may not be released (21 U.S.C. 331(j); 21 CFR 20.61).

Q10: How does FDA ensure that the new Botanical Drug Products guidance will be implemented consistently across the different new drug review divisions?

A10: FDA will provide reviewers in all divisions with training on how to implement the guidance.

Q11: One of the major premises of the new guidance is that because many botanical products have been used by a large population for a long period of time, they are presumed to be safe enough to be studied in clinical trials without first undergoing conventional nonclinical studies. What kind of documentation should a sponsor submit to demonstrate prior human experience with the sponsor's product?

A:11 The Agency recognizes that prior human experience with a botanical product can be documented in many different forms and sources, some of which may not meet the quality standards of modern scientific testing. The sponsor is encouraged to provide as much data as possible, and the review team for the botanical drug IND generally will accept all available information for regulatory consideration. FDA will assess the quality of the submitted data on a case-by-case basis. It should be emphasized that, in reviewing botanical drugs, the Agency does not lower or raise the safety and efficacy standards for marketing approval that apply to purified chemical drugs. The guidance simply recommends the use of different types of data for preliminary safety consideration of human trials (for example, large quantities of mostly anecdotal human data instead of animal studies).

Q12: In many cases, botanical therapies are highly individualized with variations in relative contents of multiple plant ingredients tailored for each patient. Must a sponsor submit a separate IND for every change in composition, if similar patients are being treated for the same indication?

A12: Studies can be designed to take into account individualized treatments. Multiple formulations can be included in one IND if they are being studied under a single clinical trial. It is important that the IND provide the rationale for using multiple formulations and the criteria used to assign patients to different treatment regimens.

Q13: Many medicinal plants with therapeutical potential are quite toxic. Does the new

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guidance address the study of such botanicals?

A13: The guidance discusses this issue in the sections addressing botanical drug products with known safety issues (e.g., section VI.A). Well-known examples of safety issues concerning botanicals include the nephrotoxicity associated with herbal preparations containing aristolochic acid and the hepatotoxicity associated with comfrey products containing pyrrolizidine alkaloid. Other examples include the cardiovascular and central nervous system effects associated with yohimbe and the hepatotoxicity associated with germander and chapparal. In such cases, FDA will evaluate the known risk and the potential benefit of an investigational drug for its intended use. When the potential benefit of an investigational drug outweighs its risk in the intended patient population, clinical trials may be allowed to proceed under an IND (see § 312.42). For example, FDA will accept a relatively higher level of toxicity of an investigational drug when studied to treat terminally ill cancer patients. However, additional nonclinical studies may be appropriate to adequately characterize the toxicity (e.g., can a dose be identified that would not be expected to produce toxicity?) and/or additional monitoring may be appropriate during the clinical trial. Also, FDA may recommend against human studies (e.g., bioavailability, clinical pharmacology) in healthy volunteers.

Q14: There is a concern that if a botanical is being studied under an IND or is approved as a new drug in an NDA, its subsequent status as a dietary supplement may be jeopardized. Is this true?

A14: No, it is generally not true for products already on the market before approval of an NDA. It is also generally not true for products marketed before authorization of an IND for which substantial clinical investigations have been instituted and the existence of such investigations has been made public (see section 201(ff)(3) of the Act).

Q15: What is FDA's advice on the initial approach for sponsors not familiar with new drug development and regulatory processes?

A15: A sponsor should first consult the guidance. If there are questions concerning the guidance document or other questions about the submission of INDs for botanical drugs, consult the appropriate CDER review division for the therapeutic class of the sponsor's product. CDER also grants pre-IND meetings with sponsors.

Q16: The guidance states that the submission of an NDA for a drug derived from plants taken from the wild is an extraordinary circumstance requiring the submission of an environmental assessment (EA) under § 25.21. Are plants maintained in their native setting on private land considered wild?

A16: Yes. Plants that are obtained from their native setting on either public or private land are considered to be taken from the wild. Cultivated plants are considered those that are grown collectively in controlled settings such as plantations, farms, or greenhouses, i.e., purposely segregated from wildlife to the extent practicable.

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Q17: Is a drug made with a commercially available crude extract viewed the same as a drug derived from plants taken from the wild for purposes of determining the need for an EA?

A17: Yes. If an NDA is submitted for a drug made from a crude extract or intermediate from a plant taken from the wild, an EA is required under § 25.21. This is true whether or not the extract or intermediate is commercially available. As for an IND for a drug made from a crude extract or intermediate from a plant taken from the wild, FDA will decide on a case-by-case whether an EA is required.

Q18: What is the GMP status of botanical raw materials (starting materials) in terms of compliance and inspection?

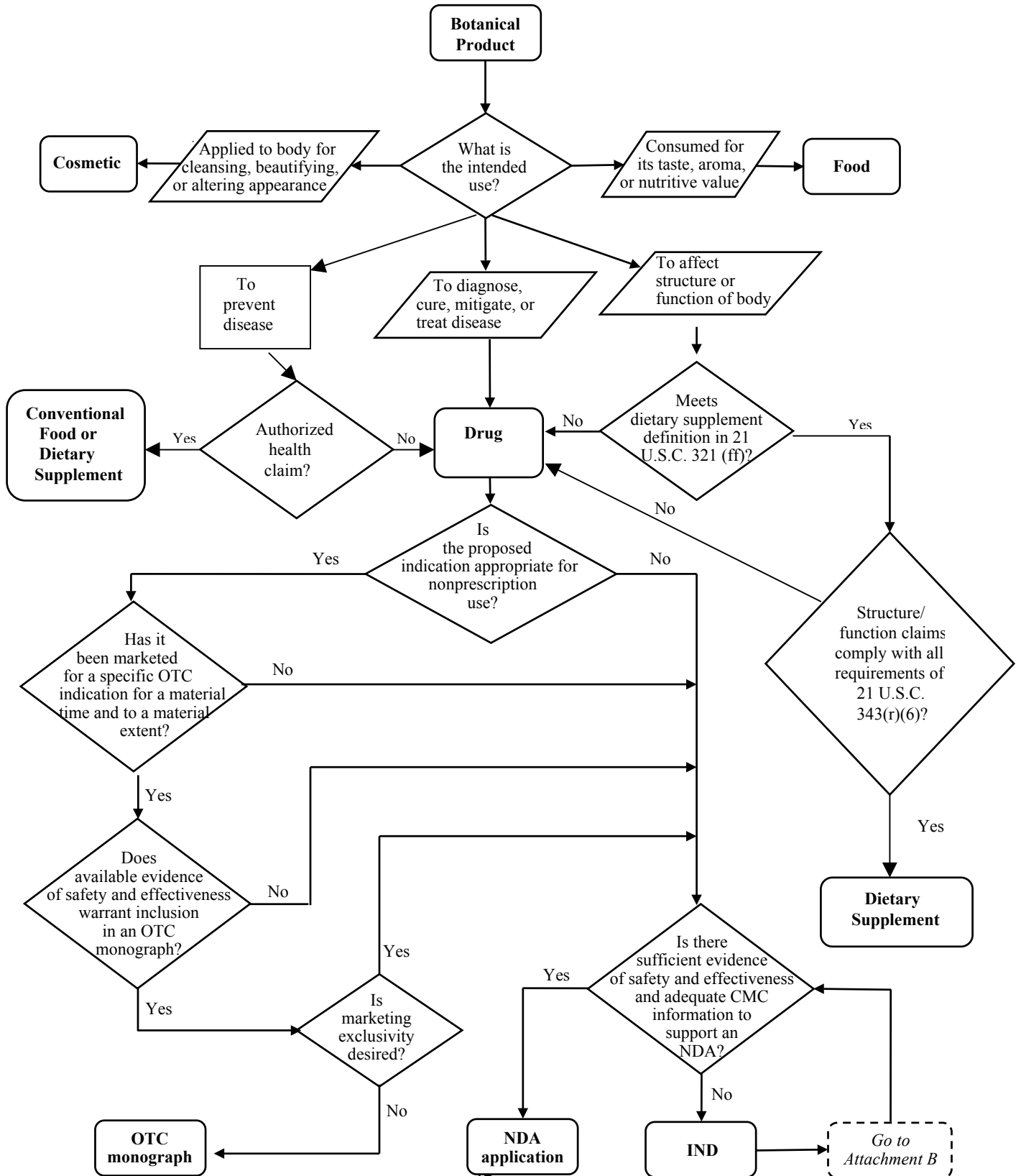
A18: Starting materials of botanical origin that are used to produce a botanical drug substance should be evaluated for quality. The use of appropriate starting materials and the drug substance manufacturer's ability to control the source depend on appropriate specifications (tests, analytical procedures, and acceptance criteria). In addition to establishing specifications, manufacturers can achieve adequate quality control of starting materials by applying the principles outlined in FDA's botanical guidance and by following good agricultural and good collection practice for starting materials of herbal origin (e.g., European Medicines Evaluation Agency *HMPWP/31/99*). Upon receipt of the starting materials at a processing facility, it is the responsibility of the drug substance manufacturer to determine the suitability of these raw materials before use. This can be accomplished by examining and/or testing to ensure that the acceptance criteria are met and by documenting the quality control for the processing of the starting materials. FDA will review the inspection and examination of starting materials upon receipt when conducting a current good manufacturing practice (CGMP) inspection of a drug substance manufacturer.

Q19: Will FDA assign the same level of priority to botanical drug products as to other drugs with respect to meeting with IND sponsors and NDA applicants?

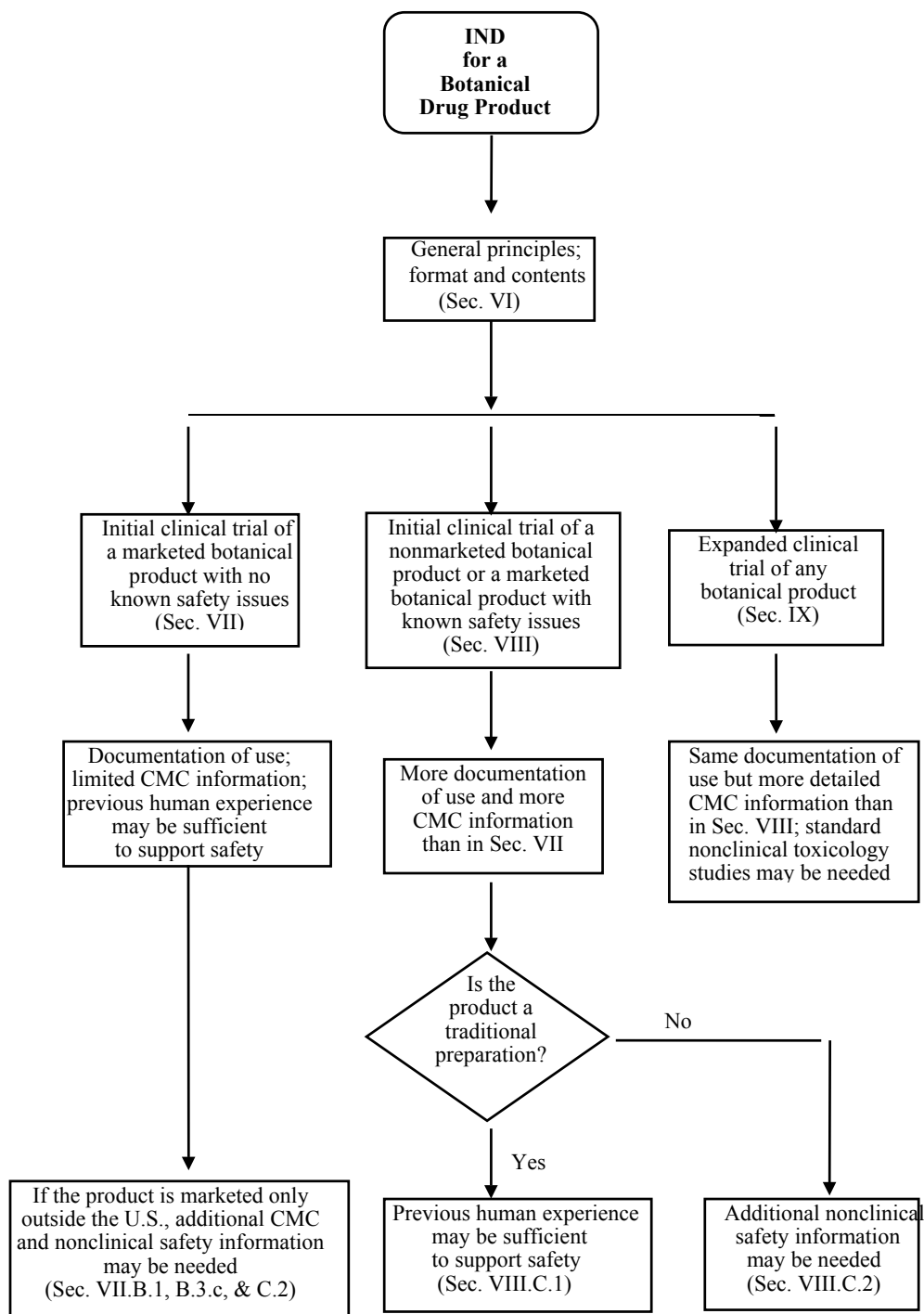
A19: Yes, FDA treats botanical and purified chemical drugs the same.

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ATTACHMENT A: REGULATORY APPROACHES FOR MARKETING BOTANICAL DRUG PRODUCTS



ATTACHMENT B: INFORMATION TO BE PROVIDED IN AN IND FOR A BOTANICAL DRUG



From: [Cheryl Bowie](#)
To: [Calder, John P. \(CED\)](#)
Subject: Guidance for Botanical industry.pdf
Date: Monday, January 04, 2016 7:21:53 PM
Attachments: [Guidance for Botanical industry.pdf](#)
Importance: High

Can you forward this to Bruce it's the guidance on marijuana grows

From: [smithsteve12356](#)
Subject: Hello!!
Date: Monday, January 18, 2016 9:57:39 PM

Hi,

From: [stracy.smith](#)
To: [stracy.smith](#)
Subject: Hello!!
Date: Tuesday, January 19, 2016 9:00:38 PM

Hi,

From: [Crisi Matthews](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Help please :)
Date: Monday, January 25, 2016 12:18:19 PM

I remember reading somewhere in FAQs that retail would not be permitted on government land...I can't seem to find a reference to that in the final regs...I'm asking because I'm concerned about Homer Spit being much of it is City owned. Could you point me to that reference? Thanks!

--

Loyally,
Crisi Matthews, Broker
c: 907-299-8700
f: 888-552-2805
AK DRE Li #19150
CA BRE Li #01894501
4025 Homer Spit Rd#7, Homer, AK 99603
affiliate: Luminary RE

click: [Alaska Vacation Rental on the BEACH](#)
OR
[Alaska Halibut and Salmon Fishing Charter Packages](#)



From: [Taneeka Hansen](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Cc: [Fowler, Micaela R \(CED\)](#)
Subject: inquiry regarding fee payments, out of state applications, and outside investors
Date: Friday, January 08, 2016 3:42:46 PM

Good afternoon,

On behalf of a constituent I have the following questions regarding marijuana licenses

- 1). What is the final decision on out-of-state funding of a marijuana establishment? In skimming the final regulations I could not find specific reference to an allowed amount of out of state funding. I remember there was interest in keeping the business for Alaskan residents, but there was also discussion about the need to allow some sort of outside financing (loans, etc.) to help get the business started. Will outside financing be allowed? Or does the residence license restriction and the restriction of no financial interests other than the licensee effectively mean that no out of state funding will be allowed?
- 2). Since the license application must be started electronically, will the division track the ISP location of the filing computer and tie that to the residency requirement like the PFD application? For context, my constituent has recently been spending time out of state caring for family but is a resident. If they were to file from Oregon while visiting family, would the computer location call their residency into question?
- 3). What payment options will be available for license fees? I noted in the regulations that fees can be submitted electronically or by mail. Does this mean that credit card, check and cash will all be accepted?

Thank you very much for your guidance on these questions.

Sincerely,

Taneeka Hansen
Legislative Aide, Representative Paul Seaton
(907) 235-2921

From: [Amanda Bohman](#)
To: [Calder, John P. \(CED\)](#)
Subject: legal opinion on marijuana clubs
Date: Tuesday, January 12, 2016 11:35:40 AM
Importance: High

Hi John,

This email is following up on our conversation this morning about standalone marijuana consumption facilities.

As I understand it, the Alaska Department of Law provided a legal opinion to the Marijuana Control Board on the issue.

If the opinion is in writing, I would like to request a copy.

If the opinion was oral, I would like a recording of the meeting or the minutes.

Thank you in advance.

Cordially, Amanda Bohman
Fairbanks Daily News-Miner
907-459-7587

From: [Loren Dreyer](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: legal review and signing of marijuana regulations
Date: Tuesday, January 12, 2016 11:13:13 AM

To whom it may concern,

- 1) How long does the legal office have to review the regulations? What are they screening for? What power does the law department have to change the timeline of the beginning of this industry?
- 2) After the regulations pass legal review, how long does the lieutenant governor have to review and sign the regulations into law? What power does the governors office have to delay or change the timing of the beginning of this industry?

Thanks!

--

with respect,
Loren Dreyer
lorendreyer@gmail.com
541-556-0768

Gordon Warren Epperly
P.O. Box 34358
Juneau, Alaska 99803

Telephone (907) 789-5659

November 23, 2015

You must be connected to Internet to view "*hyperlinks*" found within this Message.

Honorable Members of the Marijuana Control Board
and Assemblies of the Cities and Boroughs of the State of Alaska

As many of you know, Judge Sharon L. Gleason of the U.S. District Court for the District of Alaska issued a "Court Order" dismissing my "Petition for Redress of Grievance" known as Gordon Warren Epperly vs. State of Alaska and The United States of America (U.S. District Court Case No. 1:15-CV-00002-SLG) /¹ "with prejudice" for "Want of Standing." The following day, Judge Sharon L. Gleason corrected the ruling within the "Judgment" to read "the merits are dismissed without prejudice." /² I am not in agreement with the "Court Order" for there are established exceptions to the "Standing" requirement of a "Federal Article III Judicial Court" as applied to the issuance of "Declaratory Judgments," /³ but as my only source of income is "Social Security Checks," I am not in a financial position to file "Notice of Appeals" or employ members of the BAR Association.

Assistant Attorney General, Christopher D. Peloso for the State of Alaska did you and your fellow "Officials" no favors when he chose to avoid the "Constitutional Questions of Law" that were presented to the U.S. District Court for the District of Alaska by moving the Court to dismiss my "Petition for Redress of Grievance" for "Want of Standing." Christopher D. Peloso has now

¹/ See "Petition for Redress of Grievance" (<http://tinyurl.com/qezd6x9>).

²/ See "Court Order" (<http://tinyurl.com/pxsvsct>).

³/ See <http://tinyurl.com/pgbu6gh>
See also <http://tinyurl.com/or9zmba>

shifted "liability" (civil and criminal) to every "Member" of the "Marijuana Control Board" and "Assemblies" of the "City and Boroughs" of the State of Alaska.

When Judge Sharon L. Gleason issued forth her "Court Order" to dismiss my "Petition for Redress of Grievance" for "Want of Standing" (with the exception of "the merits without prejudice") is a statement that the "Constitutional Questions of Law" presented may have merit which may be addressed by the Court sometime in the future. For this reason I would encourage you to read the "merits" of my "Petition for Redress of Grievance." /⁴

The "Marijuana Laws" of the States are "Colorable Laws" /⁵ for they all have the appearance of being laws, but in fact they are not laws at all. They are in conflict with many provisions of the "Federal Control Substance Law," /⁶ a law that was made pursuant to the U.S. Constitution, and thus is the "Supreme Law" of our Nation notwithstanding any Law or Constitution of a State. /⁷ No Attorney General of any State of our Nation has ever questioned the findings of 21 U.S.C. 801 /⁸ and thus they all have acknowledged the authority of the U.S. Congress to regulate the intra-State Commerce of "Marijuana" within the borders of their States. All laws of a State that are in conflict with lawful Federal Laws are "null and void" ab initio. For an "activity" involving "Marijuana" to be "lawful," that "activity" must be "lawful" not only under the laws of the State, but must also be "lawful" under the laws of The United States of America. /⁹

When a "Public Official" of a "State" or its "Municipal Corporations" exercises "Color of Office," /¹⁰ that individual does so in his/her individual capacity, not as an "Official" of a "Public Office" and may be personally liable as such.

⁴/ See <http://tinyurl.com/qezd6x9>

⁵/ See <http://tinyurl.com/nldbwxl>

⁶/ See <http://tinyurl.com/3mau7kd>

⁷/ See U.S. Constitution, Article VI, Sections 9 and 10.

⁸/ See <http://tinyurl.com/ozxu4sh>

⁹/ See unanimous "Court Ruling" of the State of Colorado Supreme Court (Brandon Coats vs. Dish Network, L.L.C. 13SC394-(103897)).

¹⁰/ Color of Office - A description of an act by an officer done without authority under the pretext that he or she has an official right to do the act by reason of the officer's position.

As an "Officer" of the "Marijuana Control Board" or as an "Assembly Member" of a "City and Borough" of the "State of Alaska," you are on the front lines that may damage fellow "Citizens" of the State of Alaska through wrongful issuance of "Marijuana Licenses" and "Permits" which may bring an adverse effect upon "Property Values," "Business Profits," and "Physical Harm" through the violence of "Monetary Theft," "Dwelling Robberies" that are financing the support of those purchasing "Marijuana" and other drugs on the open market. You may also be made liable for any injury or fatalities that may occur from those that operate "Motor Vehicles" under the influence of "Marijuana," for unlike "Alcoholic Beverages" which are not prohibited by "Law" of The United States of America, the use of "Marijuana" within the boundaries of any State of the Union has been made "unlawful" for any use by "Federal Law." /¹¹ At the present time, there are "Civil Actions" pending before the U.S. District Court for the District of Colorado declaring that "Public Officials" of the State of Colorado and its "Counties" and "Cities" have in their personal and individual capacities damaged the Plaintiffs upon their issuances of "Marijuana Building Permits" and "Marijuana Business Licenses." The "Plaintiffs" are seeking damages in the thousands of dollars. /¹²

Governor Bill Walker has placed you in "harms way" when he refused to uphold his "Oath of Office" in supporting lawful "Statutes" of the government of The United States of America. This occurred when he had been duly "noticed" that the year 2014 "Marijuana Ballot Initiative" was in conflict with the "Federal Control Substance Law" (as that law applies to the use of "Marijuana") and he has refused to issue forth "Executive Orders" declaring that the "Marijuana Ballot Initiative" to be "null and void" absent a "Court Order." This is a problem for "Employees" and "Officers" of the State for under the doctrine of "Separation of Powers," no Judge of the State of Alaska has authority to interfere with "discretionary actions" taken by the Governor in the performance of his Office.

I am sure a "Cause of Action" may be brought before the Superior Court for the State of Alaska as that Court is a "Court of Record" with "General Jurisdiction." The Alaska Supreme Court in the case of State of Alaska v. American Civil Liberty Union (No. S-12370, Decided: April 3, 2009) /¹³ has ruled that under the "ripeness doctrine," there are exceptions to "the constitutionality of a statute generally may

^{11/} See [21 USC 841](#), [21 USC 842](#), [21 USC 843](#), [21 USC 844](#), [21 USC 846](#), etc..

See also Federal RICO Statutes [18 USC 1961-1988](#) and Federal RICO Statute [18 USC 1964\(c\)](#).

^{12/} See Safe Streets Alliance et al v. Alternative Holistic Healing, LLC et al (<http://tinyurl.com/ofzpaef>).

See New Vision Hotels Two, LLC v. Medical Marijuana of the Rockies, LLC et al (<http://tinyurl.com/ng526hk>).

See Smith et al v. Hickenlooper (<http://tinyurl.com/pz3pseg>).

^{13/} See <http://tinyurl.com/o2ee53r>

not be challenged as an abstract proposition." As you are being placed in a position of involuntary "liability" when you are being compelled under "defacto" laws to implement the mandates of the Marijuana Ballot Initiative, giving the controversy that exists between the "Laws" of The United States of America and the State of Alaska "Ripeness" and "Standing" for adjudication. This Alaska Supreme Court ruling declared that the Superior Court's conclusion that the Plaintiffs may have had "standing" to challenge the "Statute" (AS 11.71.060(a)) as that "Statute" applied to "Marijuana" because "*they [Plaintiffs] are exposed to potential criminal prosecution*" was within the authority of the Court. You, as an "Official" of the State of Alaska or its Municipal Corporations, is exposed to "Criminal Prosecution" before a U.S. District Court and as the Federal Judiciary has ruled that the "Marijuana Laws" of a State may not be used as a defense before the its Courts, /¹⁴ it appears that you may have "Standing" before the Alaska State Superior Court.

The Federal Controlled Substances Law treats possession and use of "Marijuana" as a much more serious offense than Alaska law. The federal sanction for a first-time offender possessing any quantity of "Marijuana" is a term of imprisonment of not more than one year and a fine of at least \$1,000, or both. /¹⁵ A person who knowingly possesses "Marijuana" for personal use also faces a federal civil penalty of not more than \$10,000. /¹⁶ The federal sanctions apply to "*anyone knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance; manage or control any place, whether permanently or temporarily, either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally rent, lease, profit from, or make available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance.*" /¹⁷

You, as an "Official" of the State of Alaska or its Municipal Corporations, will be identified as a "*person who attempts or conspires to commit any offense defined in this subchapter (SUBCHAPTER I — CONTROL AND ENFORCEMENT)*" and "*shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy*" /¹⁸

¹⁴/ See "U.S. Justice Department Letters and Memos" (<http://tinyurl.com/ngn56nu>).

¹⁵/ See [21 U.S.C. § 844\(a\)](#).

¹⁶/ See [21 U.S.C. § 844\(a\)](#).

¹⁷/ See [21 USC 856](#).

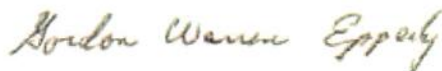
¹⁸/ See [21 USC 846](#).

of the "Federal Control Substance Law" upon the issuance of defacto "Marijuana Building Permits" and defacto "Marijuana Business Licenses."

You should instruct your City and Borough Attorney and the Alaska Attorney General to bring forth an "Action at Law" before the "State of Alaska Superior Court" to address the conflicts and controversy that exist with the "Marijuana Laws" of the State of Alaska and with the "Federal Controlled Substance Law." The Court should declare how those conflicting laws will affect you and your "Office," or in the alternative, convince Governor Bill Walker to issue forth an "Executive Oder" declaring the year 2014 "Marijuana Ballot Initiative" to be "null and void" for being in conflict with the "Federal Control Substance Law." As noted by the Attorney Generals for the States of Nebraska and Oklahoma, the refusal of the U.S. Attorney General to enforce the "Marijuana Statutes" of the Federal Control Substance Law is not a license for any State to regulate the use of "Marijuana" contrary to the prohibitions of the Federal Control Substance Law. /¹⁹ It would be to your benefit to have a "Ruling of a Court" on your side.

You may find the Article "Cannabis in the United States" as found on "Wikipedia, the free encyclopedia" to be of interest. /²⁰

Respectfully Submitted



Gordon Warren Epperly

^{19/} See U.S. Supreme Court - Nebraska and Oklahoma vs. Colorado - (Reply Brief) [<http://tinyurl.com/qzua4kd>].

^{20/} See <http://tinyurl.com/b9cxkl4>

From: [Gordon Epperly](#)
To: [Franklin, Cynthia A \(CED\)](#); robert.beasley@alaska.gov; [Hamilton, Joe \(CED\)](#); [Finney, Richard L \(CED\)](#); [Johnson, Steven M \(CED\)](#); [Bankowski, Joe \(CED\)](#); [Oates, Sarah D \(CED\)](#); [Andrews, Maxine R \(CED\)](#); [Sawyer, Jane Preston \(CED\)](#); [Calder, John P \(CED\)](#); [Mikell, Tan \(CED\)](#)
Cc: [General, Attorney \(LAW sponsored\)](#); [Peloso, Christopher D \(LAW\)](#); james.chennault@alaska.gov; [Alaska Governor Bill Walker \(GOV sponsored\)](#)
Subject: Letter addressing liability of implementing Marijuana Ballot Initiatives
Date: Monday, November 23, 2015 9:05:32 AM
Attachments: [Letter - Members of the Marijuana Board and Assemblies of City and Boroughs \(11-23-15\).pdf](#)
Importance: High



Honorable Members of the Marijuana Control Board and Members of City and Borough Assemblies

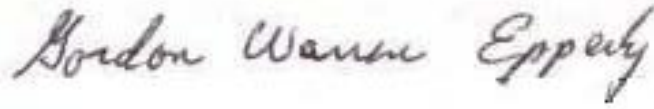
There has been much to say about Marijuana and it has been reported that the Alaska Marijuana Control Board is in the final stages of adopting Regulations to bring the year 2014 Marijuana Ballot Initiative into effect. What is not being told is the liability that our Public Officials may be bringing upon themselves.

Many of you may be aware that I made an attempt to have Constitutional questions of law relating to the conflict that exist between the Marijuana Laws of the State of Alaska and the Federal Control Substance Act to be addressed by the U.S. District Court for the District of Alaska. But this is not to be for an Assistant Attorney General for the State of Alaska had the U.S. District Court remove my "Cause of Action" from the Court for "Want of Standing." The Attorney General and his Assistant Attorneys did you no favors for they have now directed future civil litigation to be brought upon you that may have an adverse effect upon your reputation, career, and finances.

Attached to this message is my letter addressed to you in PDF file format. This letter is documented with several internet hyperlinks. Please stay out

of harms way.

Respectfully Submitted

A handwritten signature in cursive script that reads "Gordon Warren Epperly". The signature is written in black ink on a light-colored background.

Gordon Warren Epperly



City and Borough of Sitka

LEGAL DEPARTMENT

100 Lincoln Street • Sitka, Alaska 99835

January 13, 2016

Alaska Department of Law
Attorney General's Office
Commercial and Fair Business Section
Attn: Harriet Dinegar Milks, Assistant Attorney General
Box 110300
Juneau, AK 99811

Re: Resolution No. 2016-01: A Resolution of the City and Borough of Sitka, Requesting the State Department of Law Revise the 500 foot Set-Back Provision in 3 AAC 306.010

Dear Ms. Milks,

The City and Borough of Sitka passed the attached resolution regarding the 500 ft. setback requirement last night during their regularly scheduled meeting.

This resolution requests that the licensed marijuana establishment setback requirement specified in 3 AAC 306.010 be revised to allow local planning and zoning regulation to determine the ideal setback distance for the given location with the minimum distance being 200 ft.

The City and Borough of Sitka is located on the Western coast of Baranof Island in Southeast Alaska. Given the limited developable land, we are compelled to reconcile incongruent types of zoning forced to exist in close proximity to each other. As a result, the 500 ft. setback requirement would cause considerable difficulty in large swaths of what would otherwise be ideal locations for marijuana establishments.

Thank you for your consideration.

Very sincerely,

Robin L. Koutchak
Attorney for City and Borough of Sitka

cc. Sara Peterson, Municipal Clerk

From: [Britt Ward SR](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: License applications
Date: Friday, January 29, 2016 11:22:55 AM

I've visited the MCB website and I can't locate any place to acquire the forms for applying for licenses. could you provide guidance as to how to apply?

C. Britt Ward, Sr.

"Life is not a journey to the grave
with the intention of arriving safely
in a pretty and well preserved body,
but rather to skid in broadside,
thoroughly used up, totally worn out,
leaking oil and loudly proclaiming

-- WOW--What a Ride!"

From: [Rebecca Rein](#)
To: [Calder, John P. \(CED\)](#)
Subject: Licensing Fees for Marijuana Establishments
Date: Tuesday, December 15, 2015 9:17:34 AM
Attachments: [image001.jpg](#)
Importance: High

Good Morning Mr. Calder,

Per the request of my City Council, I am contacting you to inquire about Marijuana Establishment licensing fees.

I know that per the regulations the MCB has created half of each Marijuana Establishment application fee will be shared with the Local Regulatory Authority that the establishment will be operating in the area of.

My Council would like to know if the MCB will also share half of each licensing fee with the Local Regulatory Authority.

I have contacted DOR Tax Division Director Ken Alper, and he directed me to ask you about this matter.

Thank you for your assistance!

Rebecca Rein
Deputy City Clerk

City of Houston
PO Box 940027
Houston, AK 99694

Phone: 907-892-6869
Fax: 907-892-7677

<http://www.houston-ak.gov/>



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computer, and destroy any paper copies.

From: jeffndol@yahoo.com
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Limited cultivators and permits
Date: Wednesday, January 20, 2016 11:58:15 PM

Hello,

After seeking guidance from the state Fire Marshals office it seems clear that they have not put any consideration into permit requirements for a limited cultivators facility. It is not reasonable to think that any other home occupation similar to a greenhouse would require thousands of dollars in Engineered plans, architectural consultation or an electrical engineer.

Would it be advantageous to create an exemption for limited cultivators from stamped plans and allow them to submit an inspection approval from the same entities to make the monetary requirement a little less harsh for a small home business? I do understand this is not in your control, but if communication was open between the MCB and the Marshal it would provide guidance to the Fire Marshals office what is acceptable and what is not.

The DEC also has not provided any guidance on wastewater requirements for any hydroponic system or possible minimal requirements for a Limited Cultivator. Again this does not give reasonable allowances for Limited Cultivators. Can there be an exemption of some type provided for the small scale grow of only 500 sq. ft.?

Please advise.
Thank you,
Dollynda Phelps
907-252-8026

Sent from Windows Mail

From: jasonpratt31@gmail.com
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Limited grow facility
Date: Wednesday, January 27, 2016 5:50:26 PM

Sent from my iPhone

I live in North Pole and was wondering if a facility can be set up on the same property where I reside or do I have to look elsewhere?

From: [Caleb Saunders](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Local opt out
Date: Saturday, January 30, 2016 12:00:12 PM

I would like to find out if the 10 miles surrounding Wasilla is part of the opt out the city council enacted. The regs state the boundaries of local government or 10 miles unincorporated area. The area around Wasilla is incorporated into the Mat Su Borough correct?

Caleb Saunders
Green Jar, LLC
907-887-3684

From: [Diane Bellecourt](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Location Question
Date: Thursday, January 28, 2016 11:12:31 AM

To The Marijuana Control Board,

I'm interested in incorporating the sale of medical marijuana into my already existing business, Advantage Medical Lab. Our location is in the Northern Lights Professional Building, Suite 110. We have been in this location for 18 years. There are several offices in this building and most tenants are here less than a year. One is a very small room that remains unoccupied all week except on Sunday where it's used as a satellite branch for The Church of God. Their main church is on Bragaw. There are less than 20 people that gather here at this location. The Church of God operates only on Sundays and on Wednesday nights after hours. The room remains unoccupied the rest of the week. My office hours are from 7am-4pm Monday through Friday. We are closed on weekends. The sale of medical marijuana would only be in effect during our office hours and to our established clients.

My question is, Would this be taken into consideration when receiving my application for my retail sale?

Thank you for your time and consideration.

Diane Bellecourt

[Diane Bellecourt, PBT\(ASCP\), NCMA\(NCCT\)](#)
[Owner, Advantage Medical Lab](#)
[207 E. Northern Light Blvd. Ste. 110](#)
[Phone: 907-277-6219 Fax: 907-272-6306](#)
[email: msdrac@hotmail.com](mailto:msdrac@hotmail.com)

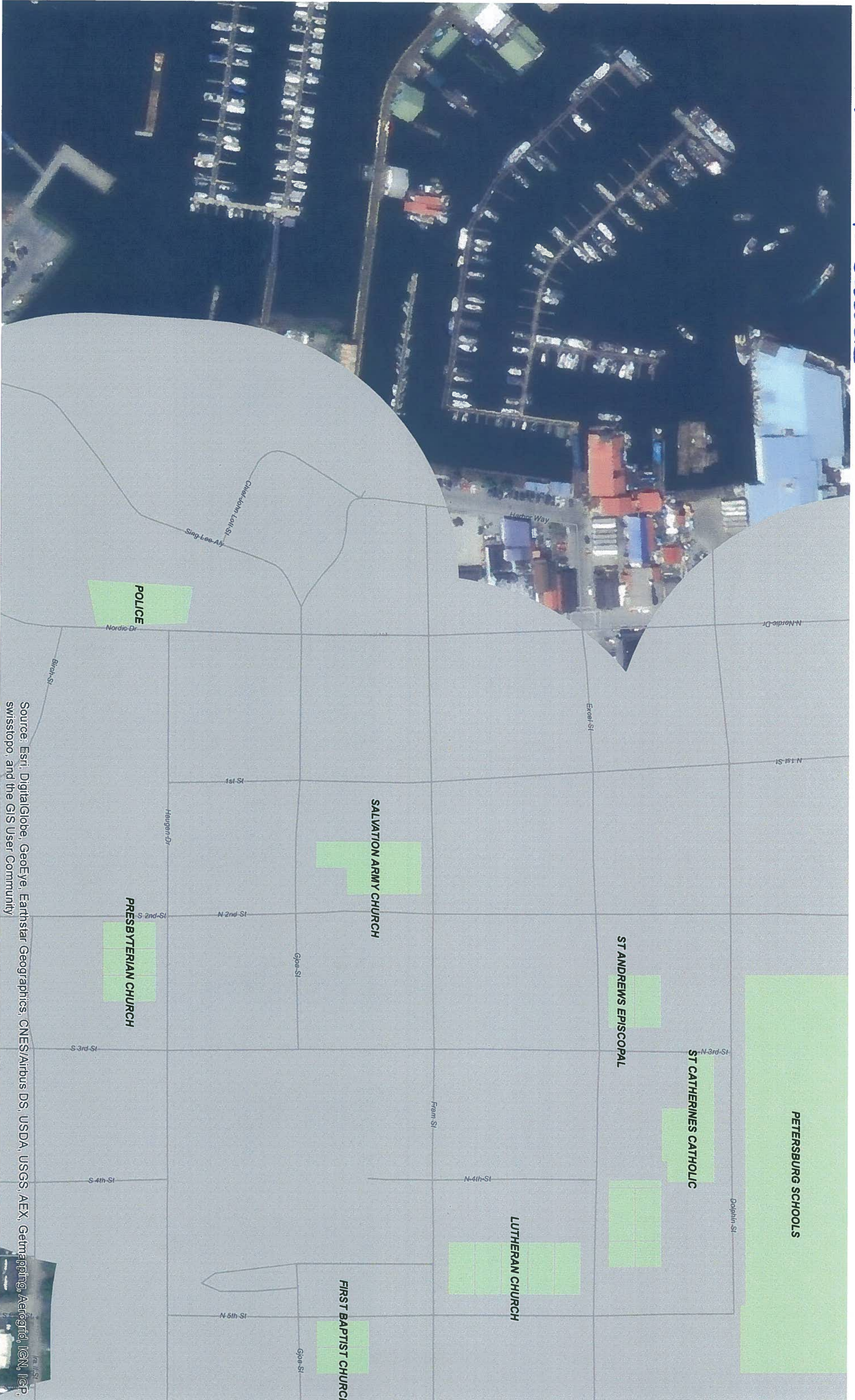
From: [Cheryl Bowie](#)
To: [Calder, John P. \(CED\)](#)
Date: Thursday, December 10, 2015 7:09:34 AM

Results Three states (California, Oregon, and Washington) had medical cannabis laws effective prior to 1999. Ten states (Alaska, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Mexico, Rhode Island, and Vermont) enacted medical cannabis laws between 1999 and 2010. States with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate (95% CI, -37.5% to -9.5%; P = .003) compared with states without medical cannabis laws.

<http://archinte.jamanetwork.com/mobile/article.aspx?articleid=1898878>

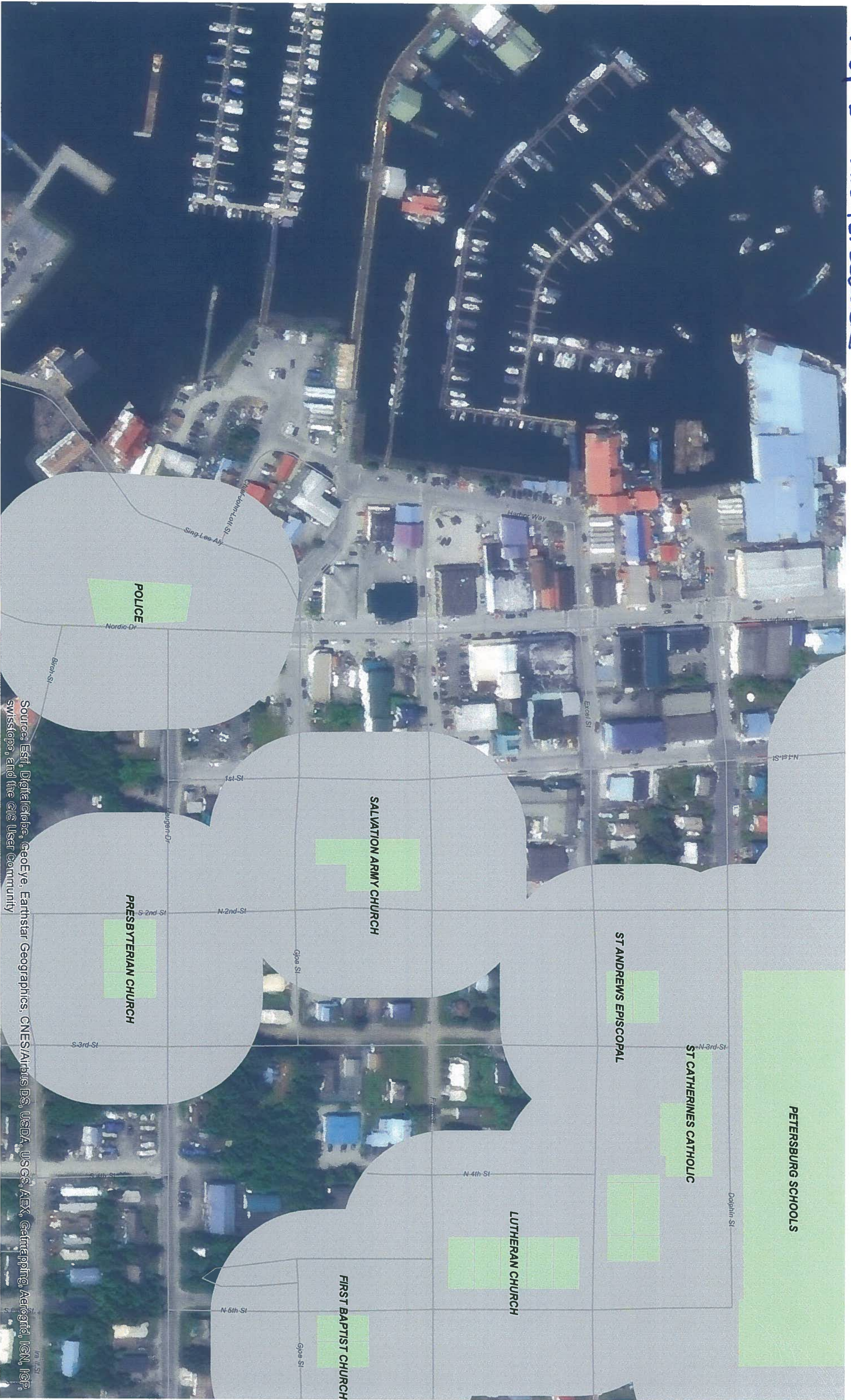
Sent from my Verizon Wireless 4G LTE smartphone

Map A - 500 Ft. setback



Source: Esri, DigitalGlobe, GeoEye, Earthstar Geographics, CNES/Airbus DS, USDA, USGS, AEX, Getmapping, Aerogrid, IGN, IGP, swisstopo, and the GIS User Community

Map B - 200 Ft. setback



Source: Esri, DigitalGlobe, GeoEye, Earthstar Geographics, CNES/Airbus DS, USDA, USGS, AEX, Getmapping, Aergrid, IGN, IGP, Swisstopo, and the GIS User Community

From: [Gordon Epperly](#)
Subject: Marijuana - The binding of "Rulings" of the U.S. Supreme Court
Date: Monday, January 25, 2016 10:19:59 AM
Attachments: [U.S. Supreme Court - Melene James v. City of Boise, Idaho, et... \(Sp.Ct. Interpretation of Laws Binding Upon States\).pdf](#)
Importance: High



An Open Letter

Honorable Members of the Alaska State Legislature and City and Borough Assemblies

The U.S. Supreme Court marijuana case of Nebraska and Oklahoma v. Colorado, No. 220144 ORG has been submitted to "Conference" of the U.S. Supreme Court Justices for consideration. As of today (01-25-16) there has been no "Court Order" of denial or granting of the "Petition" for those States to file an "Original Complaint" with that Court.

As you may know, the States of Nebraska and Oklahoma are suing the State of Colorado for disregarding the "Federal Control Substance Law" (4 Stat. 1242, 21 U.S.C. §801 et seq.) by enacting conflicting laws to legalize the use of "Marijuana" which the States of Nebraska and Oklahoma claims to have damaged their States ability to enforce their own "Marijuana Laws" and the health of their own citizens.

Although the "Court Orders" as issued today (01-25-16) did not include the case of Nebraska and Oklahoma v. Colorado, the Court did issue forth a "Court Order" addressing the binding of its rulings upon the States. As several States, including the State of Alaska, have taken the position that they have no duty to be in compliance with the laws of The United States of America or the rulings of the U.S. Supreme Court in their legalization of the use of "Marijuana," the case of Melene James v. City of Boise, Idaho, et al., No. 15 493 and its ruling on Federal Law 42 USC 1983 & 1988 has significant meaning that should be of interest to the "Attorney General" for the State of Alaska and all "Members" of the Alaska State Legislature and Assembly Members of the Municipal Corporations of the State. The case of Melene James v. City of Boise, Idaho is attached to this message as a PDF file document and the pertinent parts of the case has been highlighted.

When the Justices of the U.S. Supreme Court issues forth its "Court Order" regarding the case of Nebraska and Oklahoma v. Colorado (supra.), I will forward that "Court Order" to you as that "Court Order" will have a direct effect upon the "Marijuana Laws" of the State of Alaska.

Respectfully Submitted

Gordon Warren Epperly

Gordon Warren Epperly

From: [Brooks, James](#)
To: [Franklin, Cynthia A \(CED\)](#)
Cc: [Calder, John P \(CED\)](#)
Subject: Marijuana business heading to Juneau planning commission
Date: Thursday, January 28, 2016 11:28:37 AM
Importance: High

Just wanted to pass on this tidbit while you all are in Juneau ... on Feb. 9, the Juneau planning commission is going to be considering a conditional use permit for a limited cultivation facility. I think this is the first one in the state:
<http://packet.cbjak.org/CoverSheet.aspx?ItemID=2378&MeetingID=335>

James Brooks
News Editor, Juneau Empire
James.K.Brooks@juneauempire.com
(907) 523-2258

From: [Jo-Ann Odtojan](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Marijuana Business License Inquiry
Date: Tuesday, January 19, 2016 1:40:39 PM

Hi,

Is there a residency requirement if we want to apply for marijuana business license?

Are you open to foreign investors?

Thank you.

Joann

From: [Warren Petrasek](#)
To: [Calder, John P. \(CED\)](#)
Subject: Marijuana edibles
Date: Sunday, November 22, 2015 4:32:25 AM
Importance: High

John,

Please create the regulations that allow edibles with the same potency as the other states who legalized (10 - NOT 5). !!

Thank you,

Warren e. Petrasek
P.O. Box 2577
Palmer, AK 99645

907-715-4149

From: [William Mitchell](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Marijuana Edibles
Date: Saturday, January 02, 2016 7:05:30 PM

Hello there. I want to bake & sell marijuana infused baked goods from my home & or maybe open a bakery using infused butter & oils. What sort of license might I need? Will I even be able to sell that sort of thing to the public? Would be easier just to grow my own plants then make my butter? Don't really want to do that grow that is. Could I bake then sell to dispensary's & the like? Or am I OK under the cottage food law? I assume not. Thank you for all your help! Best Regards, Kristin Mitchell

From: [Rebecca Rein](#)
To: [Calder, John P. \(CED\)](#)
Cc: [Dukes, Sonya \(GOV sponsored\)](#)
Subject: Marijuana Establishment Applications
Date: Tuesday, December 15, 2015 12:51:53 PM
Attachments: [image001.jpg](#)
Importance: High

Good Afternoon,

When the local regulatory authority receives a copy of the application for a marijuana establishment, will we receive all parts of the application?

Specifically we are interested in knowing whether or not we will receive the wastewater management plans, security plans, ventilation plans, etc.

Thank you for your assistance!

Rebecca Rein
Deputy City Clerk

City of Houston
PO Box 940027
Houston, AK 99694

Phone: 907-892-6869
Fax: 907-892-7677

<http://www.houston-ak.gov/>



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From: [Jim Brown](#)
To: [Calder, John P. \(CED\)](#)
Subject: Marijuana license application
Date: Friday, December 11, 2015 11:45:45 AM
Importance: High

Hello John,

I am interested in applying for a grow, cultivation and retail sales license. I live in Sand Point, a community that is located 600 miles southwest of Anchorage on an island. The only way in is by air or boat. I used to run a restaurant that served food and beer/wine and would like to use the same facility. I have a few questions:

- 1. Can I get a license to do all of these things? I plan on growing and selling only my product.**
- 2. Are there any differences between the 500 sq ft or unlimited regulations?**
- 3. How do you handle inspections since it costs about \$1000 for a flight here?**
- 4. Can I make a comment or is this it?**

I would really like to do this so I would like to get off on the right foot.

**Thank you,
James Brown**

From: [Lauren Ojeda](#)
To: [Calder, John P. \(CED\)](#)
Subject: Marijuana Licensing Information
Date: Wednesday, December 02, 2015 9:57:04 AM
Importance: High

Hi John,

I have been looking online as updates have become available concerning the licensing application for marijuana retail shops and cultivation licensing. I am sure this information was covered yesterday on the open forum meeting but I had difficulty joining the meeting through the posted call in information so I am sorry if these questions are repetitive to the ones discussed yesterday.

First, is the application packet available online or does it need to be mailed?

Secondly, are there any local ordinances, particularly in Ketchikan, concerning the new laws and regulations pertaining to marijuana? Where has the majority of interest been shown so far?

Can you apply for multiple licenses? And, can you hold multiple licenses?

Thank you so much for your help. If there is a place these answers have already been answered, I apologize. If so, please direct me there and I will be happy to sift through the information myself.

Sincerely,

Lauren Ojeda

From: [Aaron](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Marijuana licensing question
Date: Tuesday, January 05, 2016 1:01:29 PM

Hello,

Question: Would the board issue a marijuana license to a business that shares property with a liquor license establishment? I.e. 123 Front Street -liquor establishment- and 123 Front Street #B -marijuana establishment.-
Please advise.

Thank you,
Aaron Bean

From: [Julian Osorio](#)
To: [Franklin, Cynthia A \(CED\)](#)
Subject: Marijuana permit questions..
Date: Monday, November 23, 2015 5:33:40 PM

Hi Ms. Cynthia, my name is Angel Echeverri and i will try to find out the application for the marijuana retail store and i can't find it at the webside.

I'm interesting in get a permit and i want to sumit my application before the deadline on 2/24/2015.

I call the the ABC board office today and they tell me, the all information about applications and fees is on the webside but i can't find any. If you can help me to find all that information i will be very thankfully.

Thank you for you time and have a great day.

From: [Zeke Richey](#)
To: [Calder, John P. \(CED\)](#)
Subject: Marijuana Policy Suggestions
Date: Monday, November 23, 2015 8:05:17 AM
Importance: High

To whom it may concern,

Our company, Security Camera King, has been working extensively with the Washington State LCB and the I-502 community to meet the security camera requirements to become a licensed participants. I have a few suggestions on the CCTV requirements for your legalized marijuana program.

- It is a good idea to have each camera set up so that is in view of another camera. This will avoid having a blind spot under each camera and make it so that someone can not tampered with a camera with out being caught by another caemra.
- There should be something included about a minimum required resolution. The two best options would be 1 megapixel (1280x720) or D1 (704x480). I would suggest the 1 megapixel option as it will give you enough detail to identify people and discern activity. With recent technological advancements this can be achieved at relatively low cost. D1 resolution is an older, analog resolution which provides a low resolution image. This is the same video technology which has been around for decades and it is now very close to the end of its life cycle.
- Another thing that you may want to include is requirement for video coverage on both the exterior and interior of any fencing which encompasses the licensed premises. I realize that growing marijuana outdoors in Alaska will be limited but if there are multiple buildings involved in any legalized operation then the fence would become the boundary of the licensed area. Twenty feet of video coverage should be sufficient and easily within the realm of possibility.

I hope you find this information useful and please let me know if there is anything else I can assist you with, as I am very passionate about this and want to see it succeed in every state.

--

Regards,

Zeke Richey



[Techpro Security Products, LLC](#)

Toll Free: [866-573-8878 x 113](tel:866-573-8878)

Fax Num: [561-288-5257](tel:561-288-5257)

zrichey@techprosecurity.com

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Boca Raton, FL 33432

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9500 W 49th Ave, D-106
Wheat Ridge, CO 80033

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From: [Helyn Schoepke](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Marijuana questions
Date: Monday, January 04, 2016 3:40:27 PM

The City of Kachemak has not decided on what to do about the local option of marijuana control. We are not anticipating passing an Ordinance until May 2016 and at this time I am thinking there is a big possibility of having a moratorium on the sale and growing of marijuana until after we have an election.

My question is, how does the MCB decide on whether or not to approve an application if a City has not drawn up their own regulations, but intends to do it in the future (after an election). My concern is if someone files an application and if we don't have our regulations in place, will it be approved?

What is the deadline to submit our local option Ordinance to your board?

Helyn Schoepke
City Clerk

From: [Jordan Johnson](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Marijuana questions
Date: Tuesday, January 26, 2016 12:06:45 PM

Hello,

I have a few questions regarding AS 17.38.

1. Once applications are accepted, will there be a list of applicants made public?
 - a. If yes, where can this list be found?
 - b. When will the list be available?
2. Does AS 17.38 require cannabis operations to carry any type of insurance to get licensed?
 - a. If yes, can you please inform me of the limits required or direct me to the wording?

I look forward to hearing from you.

Thank you,

Jordan H. Johnson

From: [Jana Weltzin](#)
To: [Calder, John P. \(CED\)](#); jana@jdwcounsel.com
Subject: Marijuana regulation question re definition of local government
Date: Monday, January 18, 2016 9:37:10 AM
Importance: High

Hi John - just had a quick question - when we are talking about areas that are outside of local government and those applications needing approval of surrounding year round residents, what does local government mean?

For example, if the location is within a borough, does the borough count as a local government? I think that it would, but just want to triple check, thanks!

Jana D. Weltzin, Esq.
JDW, LLC
Principal Owner
601 W. 5th Ave, Second Floor
Anchorage, Alaska 99501
janaweltzin@gmail.com
630-913-1113
*Licensed in Alaska and Arizona

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Thank you.

 Think green, please don't print unnecessarily

From: [Harold Johnston](#)
To: [Calder, John P. \(CED\)](#)
Subject: Marijuana regulations
Date: Sunday, January 03, 2016 3:05:47 PM
Attachments: [Marijuana Regulation Letter Dec 2014.docx](#)
Importance: High

Dear Mr. Calder:

As a physician in Alaska I have a couple of concerns about the regulation of marijuana in the state. There are two ideas I would like to share as the discussion progresses; one about advertising as it affects adolescents, and one about transferability of licenses.

First about Children. Please see the attached letter. In short, adolescents are extremely vulnerable to persuasive advertising, as demonstrated by the tobacco industry over the last 20 years. Marijuana is extremely damaging to the adolescent brain. Consequently persuasive advertising should be prohibited, and regulated like we do advertising for tobacco. The attached letter develops this idea more fully.

Second, about licensing. When licenses issued by the state for limited entry to an industry are transferable between parties, they become extremely expensive on the open market. Witness taxi licenses, liquor licenses, and commercial fishing limited entry permits. One of the major capital expenses of a business entering any of these markets is the purchase of the license, and the license becomes a major financial asset to the holder.

The effect of this is twofold: First whenever the state wishes to regulate or reduce the number of licenses, we are faced with having to compensate the holder for the loss of value. In the example of taxi licenses a city might be sued to pay literally millions of dollars to holders if they want to open the market. This was one of the reasons for the controversy over the advent of Uber ride sharing in Anchorage.

Second, over time the licenses are acquired by those who can afford the high capital expense, which eventually results in large outside companies owning most of the businesses. Although when limited entry salmon permits were originally issued nearly all of them were acquired by Alaskans, now over 80% of the limited commercial fishing permits are in the hands of non-Alaskan companies. This is because practically the day after the permits were issued their market value went from the \$100 originally paid in acquiring them from the state to \$200,000 when transferred from one fisherman to another. This represented a windfall capital asset to those who originally received them, and became a barrier for any others who subsequently wanted to become fishermen. Eventually the only people who could afford to buy these state-created monopolies were larger companies, not Alaskan individuals.

If the state makes marijuana licenses non-transferable two big benefits will happen: Regulation will be easier and entry will be more fair. The state will not have to deal with claims of “taking” if they decide to alter the regulation of the permits, and they will have much greater control over the quality of the potential future marijuana businesses. If one business gives up its permit, for example if they go bankrupt, the license will revert to the state. The state will then take applications from interested parties, and reissue the license (if they think reissuing is appropriate) to the best applicant based on the goals of the state, not on the basis of who has the most money they are willing to pay for the license. The license fee should be kept low so that it is not a barrier to those potentially highly-qualified Alaskans who might have less capital than some less aligned with our commerce department’s goals.

In addition, the basic issue of fairness will be better served if licenses are non-transferable. Instead of creating an instant market with winners and losers, where a lucky few get a windfall asset, all future potential entrants will apply on an equal playing field when a license does become available. And if the state feels that a high cost of entry is appropriate, the state can collect that money each

time a license is issued, rather than having the current license holder collect it. It's just more fair.

Thank you for considering these points. Please feel free to contact me if I can be of any assistance.

Sincerely,
Harold Johnston MD

From: [Smith, Cheryl](#)
To: [Calder, John P. \(CED\)](#)
Subject: Marijuana regulations
Date: Thursday, January 07, 2016 11:17:18 AM
Importance: High

Hello Mr. Calder,

The Kenai Peninsula Borough attorney was wondering about the status of the regulations. Can you tell me if they have gone to the Lt. Governor yet and whether he has filed them? Thanks so much for your help!

Cheryl Smith

Please note my new email address: csmith@kpb.us

Kenai Peninsula Borough

Legal Assistant

144 N. Binkley St.

Soldotna, AK 99669-7520

(907) 714-2126

This message is private or subject to the Attorney-Client privilege. If you are not the person for whom this message is intended, please delete it and notify me immediately, and please do not copy or send this message to anyone else. Thank you.



January 7, 2016

Attorney General Craig W. Richards (attorney.general@alaska.gov)
Cynthia Franklin, ABC Board Director (cynthia.franklin@alaska.gov)
Alaska Marijuana Control Board Members:

Bruce Shulte
Mark Springer
Loren Jones
Peter Mlynarik
Brandon Emmett

Dear Mr. Richards, Ms. Franklin, Mr. Shulte, Mr. Springer, Mr. Jones, Mr. Mlynarik, and Mr. Emmett,

On January 4, 2016, the Petersburg Borough Assembly adopted the attached Resolution #2016-02: A Resolution Requesting the State Department of Law Revise the 500 Foot Setback Provision in 3 AAC 306.010, Regulation of Marijuana Industry, License Restrictions.

Petersburg, located on Mitkof Island in Southeast Alaska, is a small town of approximately 3200 people with a downtown retail district approximately one-quarter mile long and one-seventh mile wide. The proposed 500 foot setback requirement between any licensed marijuana establishment and a school, recreation or youth center, building where religious services are regularly conducted, or correctional facility nearly eliminates Petersburg's retail business district as a viable locale for any legal retail marijuana business. We assume that Petersburg is not the only small municipality that is affected in this way by the 500 foot setback provision.

Resolution #2016-02 requests the licensed marijuana establishment setback provision be revised to 200 feet (the same as for licensed liquor establishments). Attached are two maps of Petersburg's downtown retail district. Map A shows the 500 foot setback, and Map B shows the 200 foot setback.

Thank you for your consideration,

Debra K. Thompson
Borough Clerk

Cc: Senator Bert Stedman
Representative Jonathan Kreiss-Tomkins

From: [Titus Blair](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: marijuana retail store licensing questions
Date: Tuesday, January 19, 2016 6:41:07 PM

Dear Alaska Marijuana Board:

I have several questions in regard to the process to apply for a Retail Marijuana Store license:

It states that an Operating Plan is required. Do you have a set format that will be available or at least specific list of what is required in the plan? Depending upon the answer, we might have additional questions.

What type of inventory control tracking system is required? Is it something you provide or provide access to?

Are we required to have a specific location and a signed lease in place at the time the application is submitted?

Is there a limit to the number of retail store licenses that will be issued? We are looking to open in the Anchorage city area.

Are there limits to the type of name that is used for retail purposes?

Is there a financial minimum that will be required?

There are Food Safety/Health permit requirements. Are they needed at submission of the license application?

Is the Marijuana Handler permit required at submission of the application?

Thank you for your answers in advance.

The Green Tundra



This email has been sent from a virus-free computer protected by Avast.
www.avast.com

From: [Jon Bolling](#)
To: [Calder, John P. \(CED\)](#)
Subject: Marijuana Testing Standards
Date: Monday, January 04, 2016 10:20:51 AM
Importance: High

Good morning, John.

In reading Article 6 of 3 AAC 306 (testing facilities), I cannot determine what specific standard the state will require for marijuana testing labs. For example, is there a minimum level of THC that a lab in Alaska must be able to detect from a given marijuana product sample? I did see two methodologies cited at 3 AAC 306.635 and at the editor's note on page 84 of the regulations, but the actual detection standards are not listed.

Thanks for your help with this.

Jon Bolling
Craig City Administrator
907-826-3275

From: [Brian Templin](#)
To: [Calder, John P. \(CED\)](#)
Subject: MCB Adopted Regulations
Date: Wednesday, December 02, 2015 11:07:29 AM
Importance: High

John,

I have read in the papers that the board adopted regulations on November 20th and made some amendments regarding residency recently. When will the adopted set of regulations be available to download?

Thanks,
Brian

Brian Templin
Craig City Planner
planner@craigak.com
www.craigak.com
907-826-3275 (phone)
907-826-3278 (fax)
@CraigAlaska (Twitter)

Aaron Bean
215 Peterson Ave
Sitka Alaska 99835
(907) 738- 8923

1/27/16

John Calder
C/O MCB and Director Franklin
550 W. 7th Avenue, Suite 1600
Anchorage, AK 99517

RE: Request for agenda item concerning Department of Law review of regulations

To Cynthia Franklin and the Marijuana Control Board through Chairman Bruce Schulte,

As you are aware the department of law reviewed 3 AAC 306 regulations and had some concerns with the, 'alternative means of testing' codified in 3 AAC 306.455(d), and 3 AAC 306.550(e). I reiterate my position, articulated in my public comment regarding the regulatory testing requirement as codified in 3 AAC 306.455. I would like to bring to the boards attention that, as written, 3 AAC 306.455 would make business 'unreasonably impracticable' for off road systems and rural communities in the state, and thus be in direct conflict with AS 17.38.090(a) and inhibit the legal recreational marijuana industry.

I respectfully urge the board to make some appropriate and limited changes prior to accepting any applications for marijuana establishment licenses. My recommended changes will address workability concerns, as these regulations and will serve to protect authority granted in AS 17.38. while addressing all of the department of laws concerns with testing and differential treatment among applicants.

In this context, extending the scope of the regulation to reflect efforts made by licensees' to uphold the expectation of the state's testing standard set forth in 3AAC 306.455 by best means available with testing policy and procedure approved by licensees local regulatory authority (LRA). This would insure the licensee is acting in the best interest of public and remove the any –what could be perceived as-ambiguous or differential treatment by the board. With my recommendation the board would use its statutory authority to allow the standard of testing to be the responsibility of the LRA. This subset of conditional regulations would be outlined by the LRA and then would remain responsibility of the licensees' local government.

As evidenced from the testimony and comments during the boards first time dealing with this testing issue it was made clear the proposed testing regulations would make business reasonably impracticable. Industry commenters noted concern about 3 AAC 306.455, and the board responded appropriately by allowing alternative means of testing. In regard to this particular part of the regulation it is my belief regulatory harmony with the industry could still easily be obtained without litigating this matter.

To assist the board I have taken the liberty of writing a subsection to reflect my suggested amendment. The amended regulation would read as follows:

3 AAC 306.455. Required laboratory testing. (a) Except as provided in (d) of this section, a marijuana cultivation facility shall provide a sample of each harvest batch of marijuana produced at the facility to a marijuana testing facility, and may not sell or transport any marijuana until all laboratory testing required by 3 AAC 306.645 has been completed.

(d) When the board is made aware the licensee is located in a rural area, or does not have reasonable access to a state certified testing facility, the board shall approve a local regulatory recommendation. The local regulatory shall assume reasonability for monitoring compliance with condition unless the board provides otherwise.

Nothing in the workability of my proposed amendment will require industry or the board make changes to the current application timeline or general application processes. I recommend the board move to make permanent my recommended amendment in order to account for smaller communities where the market cannot support a full analytical testing lab. I support the board's goal to create standard for which the cannabis industry will be built on and I thank you for your time.

Sincerely,

A handwritten signature in black ink, appearing to read 'A B', written in a cursive style.

Aaron Bean

From: [19076171461](#)
To: [Calder, John P. \(CED\)](#)
Subject: MMS Message from a GCI Subscriber
Date: Thursday, December 17, 2015 11:24:26 AM
Attachments: [20151217_112136.jpeg](#)



Message: Here's the paragraph proposing alternative means for testing. 3AAC 306.455
(d) I know there are commercially available field tests and wonder what might be legally acceptable. Chris Wilhelm Ketchikan

Municipality	Type of Government	Title of Legislation	Status
City and Borough of Juneau	Unified Home Rule	Serial No. 2014-50 An Ordinance Imposing a Limited Moratorium on the Receipt or Processing of Applications, Permits, or Pending Approvals Pertaining to Marijuana Establishments	Adopted 01/12/15
City and Borough of Juneau	Unified Home Rule	Serial No. 2014-51(c) An Ordinance Amending the Second-hand Smoke Control Code to Regulate the Use of Marijuana	Adopted 02/02/15
City and Borough of Juneau	Unified Home Rule	Serial No. 2015-09 An Ordinance Amending the Penal and Traffic Codes Relating to Marijuana Offenses and Establishing Penalties	Adopted 02/23/15
City and Borough of Sitka	Unified Home Rule	Ordinance No. 2015-06A An Ordinance of the City and Borough of Sitka Adding a New Title to Sitka General Code Entitled "Title 7, Marijuana Regulations" to Regulate and Tax the Use, Possession, Manufacture and Sale of Marijuana as Well as Provide Penalties for Violations as Defined in Chapter 7.30, Section 7.30.10 Entitled "Public Consumption"	Adopted 02/24/15
City and Borough of Wrangell	Unified Home Rule	Ordinance No. 896 An Ordinance of the Assembly of the City and Borough of Wrangell, Alaska Amending Title 10, Public Peace, Morals, and Welfare of the Wrangell Municipal Code to add a New Chapter 10.46 to Prohibit the Consumption of Marijuana in the Public Place, and Establishing a Penalty for Violation	Adopted 03/24/15

Municipality	Type of Government	Title of Legislation	Status
City and Borough of Yakutat	Home Rule Borough	Ordinance 15-584 An Ordinance Amending the Code of the City and Borough of Yakutat, Alaska by Adding a New Chapter 9.16, <u>Marijuana</u> , Defining "Public Places: for the Purpose of Prohibiting Consumption of Marijuana in Public Places and Prohibiting the Manufacture of Marijuana Concentrated by use of Materials or Methods Deemed Dangerous to Public Health and Safety	Introduced 02/19/05 Approved 03/05/15
City of Craig	1st Class City	Ordinance No. 663 An Ordinance Establishing a Limited Moratorium on the Receipt or Processing of Applications, Permits, or Pending Approvals Pertaining to Marijuana Establishments	Hearing Postponed until September
City of Craig	1st Class City	Ordinance No. 664 Amending Section 09.90 of the Craig Municipal Code to Prohibit the Consumption of Marijuana in a Public Place, and Establishing a Penalty for Violation	Approved 02/19/15
City of Dillingham	1st Class City	Ordinance 2015-04 (SUB-1) An Ordinance Amending Dillingham Municipal Code Title 8 – Health and Welfare by the Addition of a New Chapter Providing Regulation of Marijuana in the City of Dillingham, Alaska	Introduced 03/19/15 Adopted on 05/14/15
City of Dillingham	1st Class City	Ordinance 2015-05 An Ordinance Amending Dillingham Municipal Code Title 8.10 Prohibition of Smoking in Public Places, Section 8.10.010 Definitions	Introduced 03/19/15 Adopted on 05/14/15
City of Fairbanks	Home Rule City	Ordinance No. 5694 An Ordinance Amending Fairbanks General Code Chapter 46 Offenses by Adding a New Section to Prohibit the Consumption of Marijuana in a Public Place	Adopted 02/23/15

Municipality	Type of Government	Title of Legislation	Status
City of Fairbanks	Home Rule City	Ordinance No. 5970 An Ordinance Amending Fairbanks General Code Section 46-42 Disturbing the Peace by Adding a New Subsection Relating to Marijuana Smoke	Adopted 04/20/15
City of Fairbanks	Home Rule City	Ordinance No. 5986, As Amended, An Ordinance Enacting a Retail Sales Tax on Marijuana and Referring the Ordinance for Ratification at the General Election	Adopted 06/20/15
City of Houston	2nd Class City	Citizen Initiative Ordinance #15-12: An Initiative Ordinance of the Voters of the City of Houston Enacting Houston Code Chapter 5.10 Marijuana Regulations, Amending Title 5, Business Licenses to Prohibit the Operation of Marijuana Cultivation Facilities, Marijuana Manufacturing Facilities, Marijuana Testing Facilities, and Retail Marijuana Stores Pursuant to AS 17.38.110 Local Control, but Not Restricting Industrial Hemp as Defined Herein	Proposition No. H-1 for the October 6, 2015 City Election
City of Kenai	Home Rule City	Ordinance No. XX-2015 An Ordinance of the Council of the City of Kenai, Alaska, Imposing a Limited Moratorium on the Operations of Marijuana Establishments and/or Businesses within the City of Kenai	Failed Introduction on 07/15/15
City of Nome	1st Class City	Ordinance No. O-15-12-07 An Ordinance Adopting Chapter 3.07 of the Nome Code of Ordinances	1st Reading 02/09/15 2nd Reading 02/23/15 Failed Enactment
City of Nome	1st Class City	Ordinance No. O-15-08-03 An Ordinance Amending Title 3 of the Nome Code of Ordinances to Establish Chapter 3.40 Marijuana Regulation and Amending Section 1.20.040 to Establish a Penalty for Violation	1st Reading 08/10/15 2nd Reading 08/24/15

Municipality	Type of Government	Title of Legislation	Status
City of North Pole	Home Rule City	Ordinance 15-01 An Ordinance of the City of North Pole, Alaska to Amend Chapter 8.04 Nuisances and Add Section 8.04.005 to Prohibit the Extraction of Marijuana Oils within the City Limits	Passed 02/17/15
City of North Pole	Home Rule City	Ordinance 15-02 An Ordinance of the City of North Pole, Alaska to Amend Title 12 Streets, Sidewalks and Public Places and Adding Chapter 12.03, Marijuana Use in Public Places, to Regulate the Consumption of Marijuana in a Public Place	Passed 02/17/15
City of Palmer	Home Rule City	Citizen Initiative Ordinance No. 15-020: An Initiative Ordinance of the Voters of the City of Palmer Enacting Palmer Municipal Code Chapter 5.32 Marijuana Businesses, Prohibiting the Operation of Marijuana Cultivation Facilities, Marijuana Manufacturing Facilities, Marijuana Testing Facilities, and Retail Marijuana Stores Pursuant to AS 17.38.110 Local Control, but Not Restricting Industrial Hemp as Defined Herein	Proposition No. P-1 for the October 6, 2015 City Election
City of Palmer	Home Rule City	Ordinance No. 15-013 An Ordinance of the Palmer Municipal Code Chapter 8.11 Prohibiting Consumption of Marijuana in a Public Place	Introduced 2/24/15 Public Hearing 3/10/15
City of Unalaska	1st Class City	Ordinance No. 2015-04 An Ordinance of the Unalaska City Council Amending the Unalaska Code of Ordinances to Create a New Chapter 11.28 for the Regulation of Marijuana Use	Adopted 02/20/15
City of Valdez	Home Rule City	Ordinance #15-5 An Ordinance of the City Council of the City of Valdez, Alaska Amending the Valdez Municipal Code by Creating Chapter 5.06 Titled Marijuana Regulation	Introduced 08/03/15

Municipality	Type of Government	Title of Legislation	Status
City of Wasilla	1st Class City	Ordinance Serial No. 15-08(AM) An Ordinance of the Wasilla City Council adopting Wasilla Municipal Code, Chapter 9.40 Regulation of Marijuana, pertaining to the manufacture, transport, possession, and use of marijuana and substances derived from marijuana	Adopted 02/23/15
City of Wasilla	1st Class City	Ordinance Serial No. 15-10(AM) An Ordinance of the Wasilla City Council amending Wasilla Municipal Code (WMC), in Regard to the Regulation of Marijuana, and adopting a Sunset Provision, all Pertaining to the Manufacture and Transport of Marijuana within the City Limits of Wasilla	Adopted 03/23/15
Fairbanks North Star Borough	2nd Class Borough	Ordinance 2015-09 An Ordinance Amending Fairbanks North Star Borough Code Title 9 by Adding Chapter 9.17 Entitled Marijuana Regulation and Adding Definitions Pertaining to Marijuana Regulation	Adopted 02/26/15
Fairbanks North Star Borough	2nd Class Borough	Ordinance 2015-12 An Ordinance Amending Chapter 9.17 Entitled Marijuana Regulation and Amending 1.04.050 Regarding the Fine Schedule to Add Violations of Chapter 9.17	Adopted 03/12/15
Fairbanks North Star Borough	2nd Class Borough	Ordinance No. 2015-42 An Ordinance Providing for a Ballot Question to be Placed Before the Qualified Voters at the Regular Election on October 6, 2015, Asking Whether the Borough Shall Levy an Areawide 5% Tax on Sales of Marijuana and Marijuana Products	Introduced on 08/06/15 Hearing on 08/20/15
Fairbanks North Star Borough	2nd Class Borough	Ordinance No. 2015-42 Substitute An Ordinance Providing for a Ballot Question to be Placed Before the Qualified Voters at the Regular Election on October 6, 2015, Asking Whether the Borough Shall Levy an Areawide 8% Tax on Sales of Marijuana and Marijuana Products	Introduced on 08/06/15 Hearing on 08/20/15

Municipality	Type of Government	Title of Legislation	Status
Kenai Peninsula Borough	2nd Class Borough	Ordinance 2014-40 An Ordinance Amending KPB 3.04.030, Employee Conduct Requirements, to Address the Passage of Ballot Measure No. 2 Legalizing Marijuana, and to Reference the Use of, or Impairment by, Controlled Substances	Enacted 01/06/15
Kenai Peninsula Borough	2nd Class Borough	Ordinance 2015-02 An Ordinance Enacting KPB Chapter 10.14 Prohibiting the Operation of Marijuana Cultivation Facilities in the Area of the Kenai Peninsula Borough Outside of the Cities, Subject to Voter Approval	Failed 02/24/15
Kenai Peninsula Borough	2nd Class Borough	Resolution 2015-013 A Resolution Establishing a Marijuana Task Force	Adopted 03/17/15
Ketchikan Gateway Borough	2nd Class Borough	Assembly MOTION: "... to not ban commercial marijuana activities at this time; to allow the regulatory process to proceed and then determine whether to make any adjustments locally"	Approved
Ketchikan Gateway Borough	2 nd Class Borough	Ordinance 1779 Amending KGBC Title 2 to Provide for Assembly Review of Marijuana Establishment Licenses	Adopted 12/21/15
Ketchikan Gateway Borough	2 nd Class Borough	Ordinance 1780 Amending KGBC Chapter 8.10 to Provide for Regulation of Licensed Marijuana Business Establishments	Adopted 12/21/15
Ketchikan Gateway Borough	2 nd Class Borough	Ordinance 1782 Amending KGBC Title 18 (Planning and Zoning) to Regulate the Commercial Growth, Manufacture, Testing, and Sale of Marijuana and Marijuana Products	Adopted 12/21/15

Municipality	Type of Government	Title of Legislation	Status
Matanuska-Susitna Borough	2nd Class Borough	Resolution Serial No. 15-006 A Resolution of the Matanuska-Susitna Borough Assembly to Request Clarification from the State of Alaska on Ballot Measure 2, the Legalization of Marijuana	Adopted 01/20/15
Matanuska-Susitna Borough	2nd Class Borough	Resolution Serial No. 15-007 A Resolution of the Matanuska-Susitna Borough Assembly Establishing a Marijuana Advisory Committee	Adopted 01/20/15
Municipality of Anchorage	Unified Home Rule	AO No. 2015-07 An Ordinance of the Anchorage Assembly Amending Anchorage Municipal Code Chapter 8.35 with a New Section to Prohibit the Consumption of Marijuana in a Public Place; and Amending the Minor Offense Fine Schedule at AMC Section 8.05.025A Accordingly	Amended and Approved 01/27/15 Immediate Reconsideration Failed 01/27/15
Municipality of Anchorage	Unified Home Rule	AO No. 2015-13 An Ordinance Amending Anchorage Municipal Code Title 8 to Prohibit the Extraction of Tetrahydrocannabinol ("THC") or Any Cannabinoid by Use of Materials or Methods Deemed Dangerous to Public Health and Safety, Unless Otherwise Permitted by Law	Approved 02/24/15

From: [Jim Arnesen](#)
To: [Calder, John P. \(CED\)](#)
Subject: Operating plans, applications for MCB
Date: Wednesday, January 20, 2016 4:29:42 PM
Importance: High

John:

I was told you are working diligently on the application(s) for marijuana. I was especially interested in what an Operating Plan should look like since there are requirements listed in the statutes but no guidelines for such. Additionally, I was curious as to the development of the Application form as that is not ready either. I understand you are busy trying to create some of these items and I do not wish to detract you. You guys are doing a good job.

I am not interested in the business per se, only to assist those that are trying to enter the business. If there is anything you can say or send to me, even in draft form, I would be appreciative. Thank you in advance.

If this did not reach the intended recipient, please forward it to the right person there.

Respectfully,

Jim Arnesen
Arnesen Land Services, LLC
425 G Street, Suite 711
Anchorage, AK 99501
Direct (907) 344-7707

From: [Sharon Sibbald](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Palmer's local option
Date: Monday, January 04, 2016 11:43:22 AM

Hello,

I'm trying to determine whether or not the 10 mile radius applies to Palmer's local option ban on marijuana businesses, but the information I've been able to access isn't definitive. Can you tell me?

Thanks!
Sharon Sibbald
sharon_sibbald@yahoo.com
907 350-1872

From: zhutchinson@abraxiskits.com
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Pesticides in Marijuana tolerances
Date: Tuesday, January 19, 2016 11:36:35 AM

Greetings John,

My name is Zak and I work with a company called Abraxis out of Warminster, PA, which is a suburb of Philadelphia.

I had a question of professional curiosity. I was wondering what the tolerances that Alaska allows for pesticides on marijuana, since it is still illegal at the federal level which bars the EPA from making any decisions about it. It seems like every state has different laws and they can be confusing to sift through, which is why I am contacting you directly. I look forward to hearing from you

Thanks,

Zak Hutchinson, MSFS

Technical Support Specialist

Abraxis, LLC

124 Railroad Drive

Warminster, PA 18974

Email: zhutchinson@abraxiskits.com

Phone: (215)-357-3911

Fax: (215)-357-5232

www.abraxiskits.com

**Petersburg Borough
RESOLUTION #2016-02**

**A RESOLUTION OF THE PETERSBURG BOROUGH REQUESTING THE STATE
DEPARTMENT OF LAW REVISE THE 500 FOOT SETBACK PROVISION IN
3 AAC 306.010, REGULATION OF MARIJUANA INDUSTRY, LICENSE
RESTRICTIONS**

WHEREAS, Ballot Measure No. 2, "An Act to Tax and Regulate the Production, Sale, and Use of Marijuana" passed with a majority of the voters in support; and

WHEREAS, due to geographic constraints dictated by local topography, many municipalities have limited real estate on which to develop;

WHEREAS, a result of those limitations on developable real estate is that municipalities are compelled to reconcile highly incongruous zoning and building uses in close proximity to each other; and

WHEREAS, the requirement for there to be a 500 foot space between any licensed marijuana establishment and a school, recreation or youth center, building where religious services are regularly conducted, or a correctional facility limits the ability of an establishment to receive a license from the State; and

WHEREAS, the 500 foot setback requirement severely reduces the ability of a licensed marijuana establishment to exist in the retail business district in Petersburg; and

WHEREAS, such a requirement stands in direct contradiction to AS 17.38.090(a), The Regulation of Marijuana, Rulemaking, which states, in part: "Such regulations shall not prohibit the operation of marijuana establishments, either expressly or through regulations that make their operation unreasonably impracticable"; and

WHEREAS, licensed liquor establishments operate under a 200 foot setback, per AS 04.11.410(a).

NOW THEREFORE BE IT RESOLVED, the Petersburg Borough Assembly requests that the Alaska State Department of Law recommend the setback distance required between all marijuana establishments and any schools, recreation or youth centers, religious buildings and correctional facilities be a minimum of 200 feet to be determined by local planning and zoning regulation.

PASSED and **APPROVED** by the Borough Assembly of Petersburg, Alaska this 4th day of January, 2016.



Mark Jensen, Mayor

ATTEST:



Debra Thompson, Borough Clerk

From: [Jillian](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: pipe shop licenses etc
Date: Friday, November 27, 2015 5:16:36 PM

hello, i'm wanting to open up a pipe store in Wrangell, AK....i know that before marijuana was legalized in AK to have a pipe shop a person would have to obtain a tobacco endorsement from the state, i'm just wondering if i have to obtain that same permit or not at all since, i'm not selling "tobacco smoking products", but "marijuana smoking products"....thanks for helping me clarify

Jillian Privett
box 585
wrangell, ak
cell #907301095

From: [Susan Burrell](#)
To: [Calder, John P. \(CED\)](#)
Subject: Comment
Date: Monday, January 18, 2016 12:23:08 PM
Importance: High

Hello:

Did not know who to send this to so I figured you could hand this off to the person or persons who may want to read it. I do not want to comment on suggestions or anything except one item as it pertains to Petersburg, AK.

I am a business owner here in Petersburg. I have, since January 2015, sold smoking accessories in my gift shop. It was never my intent to be a dispensary but when the Petersburg Pilot published the Dec 17, 2015 news paper, the headline was: <http://www.petersburgpilot.com/story/2015/12/17/news/no-pot-shops-will-be-permitted-downtown/4307.html> and I saw that the map showed our block differently then the headline indicated. When I realized I could possibly be the only business down town to dispense, I decided that I would indeed get a license, when the time came, if I qualify.

You can plainly see on the map that there is a block that is available and not under the restrictions that the State Marijuana Board has set forth. That block is on the left side of the map and just north of the Ocean Beauty dock depicted on the map. The Borough is aware of this block as 4 Borough Board members came down and asked me if I was aware of this fact.

In the Petersburg Pilot published on Jan. 7, 2016, and sorry I do not have a link to that paper, but what concerned me was that after Borough members got done writing letters to late to the MCB, this is what was written:

The Petersburg Borough resolution argues the 500 foot setback stands in contradiction to a section of the Marijuana Control Board's own regulations, which states, "Such regulations shall not prohibit the operations of marijuana establishments, either expressly or through regulations that make their operations unreasonably impracticable..."

This is my concern. That is hogwash. My establishment falls legally into the Alaska MCB regulations, as does 2 other businesses in the same block. In my opinion, the Borough of Petersburg has people in mind they want to grow or sell, that, unless the setback is changed, do not fall legally

outside the 500 ft. setback and would be, if it were changed to 200 ft.

Just wanted the MCB to know what is going on down here.

thank you for your time

Susie Burrell

The Fisherman's Net Café and Gift Shop

Petersburg, AK

907-772-2277

From: [Gordon Epperly](#)
Subject: Marijuana - The binding of "Rulings" of the U.S. Supreme Court
Date: Monday, January 25, 2016 10:19:59 AM
Attachments: [U.S. Supreme Court - Melene James v. City of Boise, Idaho, et al., \(Sp.Ct. Interpretation of Laws Binding Upon States\).pdf](#)
Importance: High



An Open Letter

Honorable Members of the Alaska State Legislature and City and Borough Assemblies

The U.S. Supreme Court marijuana case of Nebraska and Oklahoma v. Colorado, No. 220144 ORG has been submitted to "Conference" of the U.S. Supreme Court Justices for consideration. As of today (01-25-16) there has been no "Court Order" of denial or granting of the "Petition" for those States to file an "Original Complaint" with that Court.

As you may know, the States of Nebraska and Oklahoma are suing the State of Colorado for disregarding the "Federal Control Substance Law" (4 Stat. 1242, 21 U.S.C. §801 et seq.) by enacting conflicting laws to legalize the use of "Marijuana" which the States of Nebraska and Oklahoma claims to have damaged their States ability to enforce their own "Marijuana Laws" and the health of their own citizens.

Although the "Court Orders" as issued today (01-25-16) did not include the case of Nebraska and Oklahoma v. Colorado, the Court did issue forth a "Court Order" addressing the binding of its rulings upon the States. As several States, including the State of Alaska, have taken the position that they have no duty to be in compliance with the laws of The United States of America or the rulings of the U.S. Supreme Court in their legalization of the use of "Marijuana," the case of Melene James v. City of Boise, Idaho, et al., No. 15 493 and its ruling on Federal Law 42 USC 1983 & 1988 has significant meaning that should be of interest to the "Attorney General" for the State of Alaska and all "Members" of the Alaska State Legislature and Assembly Members of the Municipal Corporations of the State. The case of Melene James v. City of Boise, Idaho is attached to this message as a PDF file document and the pertinent parts of the case has been highlighted.

When the Justices of the U.S. Supreme Court issues forth its "Court Order" regarding the case of Nebraska and Oklahoma v. Colorado (supra.), I will forward that "Court Order" to you as that "Court Order" will have a direct effect upon the "Marijuana Laws" of the State of Alaska.

Respectfully Submitted

Gordon Warren Epperly

Gordon Warren Epperly

From: [Stephanie Thompson](#)
To: [Calder, John P. \(CED\)](#)
Subject: Proposal that can satisfy everyone- referred by Alaska Pot Attorney
Date: Wednesday, November 25, 2015 3:28:22 PM
Importance: High

Dear Sir or Madame,

My name is Stephanie Thompson and I am writing in regards to the conundrum the State of Alaska is facing in allowing out-of-state investors to be able to have a role in this new era of business opportunity concerning marijuana in Alaska, and still keep these businesses in the hands of Alaskans.

My partner and I- which are both life-long Alaskans- have an interest in starting a testing facility that would test products before they are approved to be brought to market. We estimate starting this and doing it the right way to take upwards of \$100k, and the simple fact of the matter is that we have had to look at investors that do not live here.

I am aware of the proposed changes that have been made on Friday, November 20th, 2015 and I have some concerns about the residency requirements. Myself and many other Alaskans fear that changing the residency to voter registration only will absolutely open the flood gates. It should continue to be that only people that have qualified for the PFD be eligible to own and operate these businesses.

Solution:

First of all the applications for business licenses would have full disclosure statements of where the business capital came from, and from whom. Then I propose the SOA have a significant flat-rate tax for every dollar pumped into a new start-up- say 25%. So if company x has an investor that has given \$100k, then the permit fee would be \$25K plus the \$1,500 or whatever the fee will be for the for said permits. \$1,500 goes to the municipality and \$25K goes to SOA. Then while business plans/ operating agreements are being reviewed by the approving body- there is a clear and concise plan to pay back the investor on an agreed amount within a certain period of time- say 3-5 years. Obviously if the business fails to comply then the investor would have a first right of refusal to take over the business. I don't see many Alaskans having a problem with this since the original Alaskan owner(s) had their chance to succeed and failed.

Second, I also think that any WORKERS claiming residency in another state should have to pay a state income tax as well as whatever else their home state would require. This would also allow Alaskans the bigger slice of the pie in the actual labor force that will be required to operate these businesses.

A third point I would like considered is the clause where testing facilities are not allowed an interest in any other Marijuana business. I would like for you to consider that as long as we aren't testing our own products we be allowed to exercise our resources of an open market. For example:

I would like to start an edibles line of products for medical patients. If I were to obtain a supplier that has their product tested with another party, how would there be a conflict of interest if I wanted to use their cannabis for my edibles? I have a really great idea for a

product line that isn't being done that would help the medical community but as the regulations sit now, I won't be able to implement it, and it won't ever be available to some of the people that need it most.

I really appreciate you taking the time to read this and considering my suggestions. These are somewhat rough ideas, but it is my sincere hope that the person(s) reading this can take these points into heavy consideration and possibly morph them into something even better that benefits us all.

Best regards,

Stephanie Thompson
907.331.7261

From: [cory_wray](#)
To: [Franklin, Cynthia A \(CED\)](#)
Subject: Proposed amendments
Date: Monday, November 23, 2015 11:55:46 AM

Hi Ms. Franklin,

Can you send me a PDF of the proposed amendments the MCB made. I know they have to go through review before they are finalized, but we are more interested to see what was proposed, and be able to compare those to what ultimately gets approved. It's good context to provide for our students at the Alaska Cannabis Institute. And, Jane at the office said they have no intention of posting the proposed amendments to the MCB website.

Thank you in advance.

Sincerely,

Cory Wray
Alaska Cannabis Institute
907-331-0506

From: [Alaska Small Cultivators Association](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Question About Licensing
Date: Sunday, January 03, 2016 8:30:37 AM

Are facilities expected to be 100% ready when we apply for license, or will we have time to finish construction between February and May, when licenses are expected to be issued?

Thank you!
Jeremiah

From: [ASCA Issues](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Question about Time, Place, and Manner
Date: Monday, January 18, 2016 8:34:38 AM

Local control is quite the quagmire these days. We have a question however, based on a concern we are hearing in our local community.

Light Pollution. Can a local municipality, change the outdoor lighting requirements, to employ the use of a motion light and night vision camera vs having the light on at all times?

Regards,
Jeremiah

From: [Kyle Therrien](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: question regarding marijuana cultivation facility locations
Date: Wednesday, January 27, 2016 10:44:46 AM

hello,

I am looking for information regarding the restricted locations of marijuana cultivation facilities. beside the ones listed in 3 AAC 306.010. License restrictions.

Specifically can a cultivation facility be located on residential property? Or does the property have to be designated say by the a municipality or borough to be for commercial use.

Thanks for your time

From: [mike horwath](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Question regarding MJ cultivator application
Date: Monday, February 01, 2016 1:41:04 PM

Sent from my Samsung Galaxy Tab®|PRO

----- Original message -----

From: mike horwath
Date: 02/01/2016 11:06 AM (GMT-09:00)
To: cynthia.franklin@alaska.gov
Subject: Question regarding MJ cultivator application

Hello-

My question pertains to the application process for a limited scale cultivator licence. Per AS306.025 1A, B and 2B, the regulations state that the application must be posted at the location (A), along with one other conspicuous location (B), and 2B states that the weekly ad must state the location. Does that stated location have to be specific, ie my home address, or can it just state the town or the neighborhood? My concern here is that as a small grower (and I assume all cultivators would be concerned with this) it worries me to have to advertise to everyone that in the future I might be growing marijuana. I think the regulations make sense for every other type of marijuana establishment but there is no reason to have to advertise the location of a grower - in fact it compromises the security of both the operation and my own personal security as well.

Along with that question pertaining to 2B, my question regarding 1A and B is much the same - why would the state want to compromise my security by forcing me to advertise marijuana cultivation? But specifically as a limited scale cultivator with a small secluded property, does 1A have to be visible to everyone who enters my property or visible to everyone who simply drives by? And pertaining to the location of the application for 1B, can that also be on my property or does that have to be elsewhere, ie on the corner, advertising to everyone that I may in the future have large amounts of marijuana on the property?

Again, I think the regulations and the public knowledge that they aim at makes sense for every other type of marijuana establishment but not for cultivators and especially not for small limited production cultivators. Making public the location of cultivation facilities puts farmers at risk and puts their products at risk as well. It also seems to contradict the point of many of the security regulations as well - if I have to make my farms crop public then why should I have to control the smell and why should it be hidden from public view if it's existence has to be public knowledge?

I am hoping the answer to my question regarding 2B is that the stated location in the weekly advertisement can be general - not specific - stating my town and neighborhood as opposed to my specific address. I am hoping that both notifications (1A, B) can be on my property rather

than having to advertise my intentions to everyone including children getting dropped off their busses on the corner.

Thank you for reading and thank you for understanding my concern.
- Michael Horwath

Sent from my Samsung Galaxy Tab®|PRO

From: [Matt Buxton](#)
To: [Calder, John P. \(CED\)](#)
Subject: Questions from the News-Miner
Date: Thursday, December 31, 2015 2:28:34 PM
Importance: High

Hi John,

Thanks for taking my call and spending the time to answer my questions.

What's the level of interest people have for the commercial marijuana businesses from the ABC's perspective? Getting flooded with calls from people looking to break into the business?

Are people being more or less understanding about the fact that they have to wait a bit?
(Especially after everyone jumped the gun with businesses and delivery services)

Are there any sort of changes that ABC is putting into place in anticipation of legal marijuana going into effect? As far as staffing, that sort of thing, I suppose.

And with this big change incoming, what's your general sense of things? Are people excited to see how it goes, dreading it or cautiously optimistic?

Thanks, I think that should be it.
Matt

--

Matt Buxton
Government Reporter
Fairbanks Daily News-Miner
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mbuxton@newsminer.com
Twitter: @FDNMpolitics
www.newsminer.com

From: [Timothy Johnson](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Questions re a limited cultivation license
Date: Saturday, January 02, 2016 5:30:44 PM

1. Assuming an application for a limited cultivation license is approved, where is the licensee supposed to get seeds to start growing? Can the licensee use seeds grown legally (personal use) after Feb. 24, 2015 but before Feb 24, 2016?

2. RE: 3 ACC 306.025 Application Procedures: Assume that a person interested in only a limited cultivation license does not live within sight or within several hundred yards of any neighbors. Is this person still required to put up signs and place advertisements to announce a possible cultivation facility? If so, to what end if that person has no close neighbors? This requirement effectively makes the cultivation facility a target for crime and could create civil and criminal liability for the state and ABC personnel should the facility become a victim of a crime as a result of this particular requirement. Can a potential licensee apply for an exemption from this requirement?

Thank you, Mr. Johnson

From: [The Dalys](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Questions regarding 3 AAC.306.455 of the Marijuana State Regulations
Date: Monday, January 25, 2016 8:35:03 AM

Good Morning,

I am writing you this morning with questions regarding the revised section 3 AAC.306.455 of the newly signed Marijuana State Regulations.

- Will this section be revised or amended again in order not to exclude the various southeast communities that do not have professional labs and are unable to transport their product for testing via air or water?
- Will this revision take place prior to the Feb 24th application process start date?
- Will the state publish information on what type of lab testing equipment is acceptable prior to the application start date of Feb 24th?
- Will this discussion regarding the lack of transportation to these labs or possible use of portable labs in southeast Alaska be addressed at the next board meeting Feb 11th?
- Will the board look into any alternative means to testing, such as portable testing equipment that can be rented or purchased by southeast municipalities or marijuana businesses that is electronically monitored by a certified lab via internet and is regulated by the state?

Living in southeast Alaska I feel we are being discriminated against due to our location. I appreciate the fact the board included wording that did not exclude southeast but later was revised the the another department. With the state in financial despair and the amount of possible tax revenue the marijuana business can bring to the state wouldn't it be to the best interest to continue to try to make this work for all areas on Alaska?

Thank you for your time,

Mike Daly
907-747-5858

From: [Janiese Stevens](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: questions regarding recreational marijuana permits
Date: Monday, January 25, 2016 4:06:10 PM

Hi,

I spoke to an individual on the phone who recommended I ask this question via email. I live on Kodiak and am going to apply for permits to cultivate, process, and sell recreational marijuana. I realize I may receive some/or none of these permits, but in the event that I do, what happens if no one applies for or receives one for a testing facility since I live in Kodiak? Would my dad be able to apply for this license? What are the regulations on related parties? Also, I am a Certified Public Accountant licensed by the state of Alaska, does this pose any problem? If it does, my sister is also a CPA and I would probably shift my clientele her direction and focus on this business endeavor. In addition, when the time comes I am more than happy to contract with the state to help design/implement tax forms for this up and coming industry.

Thank You,

Janiese Stevens

Janiese Stevens, CPA
Wallstrum, Stevens, CPA, LLC
2705 Mill Bay Road, Suite 205
Kodiak, AK 99615
Phone (907) 512-2726
Fax (907) 512-2716

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From: [Mark Woodward](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Questions regarding retail sales
Date: Sunday, January 31, 2016 9:44:58 PM

So some questions:

1. So let's say my retail marijuana business makes money (cash)...how can I spend that money? Can pay cash for personal things, say my house's mortgage, or do sales have to go back into the store only? I don't want to be stacking cash in a safe in my house.
2. Similar question: can I pay cash for rent to the building owner of where the retail sales business will be located? And...should that business owner be concerned about depositing that money?

I don't want to work hard and create a great, respectable business only to make some silly mistake that brings a federal review/charge.

Thanks.

From: [jessica nelson](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Questions regarding state regulations and licensing for marijuana cultivation
Date: Tuesday, January 26, 2016 10:41:09 AM

Hello, I will be applying for a (small indoor) marijuana cultivation license and I have a couple questions.

1. Can I grow in my residence?
2. My property is in the Fairbanks North Star Borough. I understand the processes for the zoning permit from fnsb and a cultivation license from the state to be different. What is confusing is the terminology and definitions. For fnsb I can have a "small indoor cultivation" facility on my GU-1 property:

18.06.010.B - Definitions

"Marijuana cultivation facility, indoor small" means a legally licensed, fully enclosed [commercial marijuana](#) cultivation facility as defined by state law, in which all growing, preparation and packaging activities are conducted completely indoors. [Net floor area](#) of all cultivation facility [structures](#) does not exceed 1,500 square feet.

-The state definitions appear to be different. What kind of license can I apply for?:

3 AAC 306.400. Marijuana cultivation facility license required.

- (1) a standard marijuana cultivation facility license;
- (2) a limited marijuana cultivation facility license to a person operating a marijuana cultivation facility with fewer than 500 square feet under cultivation.

I have heard in the past about a "boutique" license, a small license and a large license, although I don't immediately see those in the December 1 regulations.

Thanks for your help, I look forward to hearing from you,
jessica nelson

--
jessnelson
t: 907.978.5356
e: jessnelson.architect@gmail.com
PO Box 74337 | Fairbanks, AK | 99707
usa

From: [Rebecca Rein](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Questions to Marijuana Control Office
Date: Tuesday, February 02, 2016 10:28:18 AM

1. Will licenses from the state operate on a fiscal year schedule?
2. Will licenses be issued prior to July 1st, 2016?
3. If licenses are issued prior to the beginning of a new fiscal year, will businesses be required to renew by June 30th and pay new fees for the fiscal year beginning July 1st 2016?
4. If the City protests a license due to our regulations being unfinished, will the applicant get their license denied? Will the applicant have to pay another application fee?
5. Will the MCB require an applicant to apply for a license with the local regulatory authority prior to being issued (or being able to apply for) a license from the MCB?

Rebecca Rein
Deputy City Clerk

City of Houston
PO Box 940027
Houston, AK 99694

Phone: 907-892-6869
Fax: 907-892-7677

<http://www.houston-ak.gov/>



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computer, and destroy any paper copies.

From: [Tim Holm](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Questions
Date: Tuesday, January 19, 2016 12:21:51 PM

To Whom it may concern:

I have a couple questions about the final regulations.

In reference to section 3 AAC 306.010. License Restrictions- A person with an SIS or felony ever may not receive a license or is it within the past 2 years?

In reference to section 3 AAC 306.030. Petition for license in area with no local govt.-

If i live just outside the Palmer city limits I would need signatures from 2/3's of the residents within 1 mile?

Thanks, Tim

From: [Christopher Wilhelm](#)
To: [Marijuana, CED ABC \(CED sponsored\): Tia Wilhelm](#)
Subject: raised beds in high tunnel
Date: Monday, January 18, 2016 7:50:10 AM

Hello,

I have a question regarding the square footage for high tunnel growing of cannabis. I have plans to grow a few plants outside. Will the marijuana board count only the area of the interior space that can be used to actually plant and grow cannabis, that is, the raised beds? Will the board count the entire interior space including storage and access paths, as they are under the same canopy but unused for growing?

Simply put, do only the raised beds count or is it the entire covered space? I would like to be a small farm grower when I apply. I will need to know how to measure my square footage to accurately apply for a proper license.

Sincerely,

Christopher Wilhelm
PO Box 9463
Ketchikan, AK 99901

From: [Jake Staser](#)
To: [Calder, John P. \(CED\)](#)
Subject: RE: Database of Local Ordinances
Date: Wednesday, January 20, 2016 5:09:30 PM
Attachments: [MUNICIPAL LEGISLATION CHART \(1-20-16\).docx](#)
Importance: High

John,

Please find attached a chart containing information regarding local marijuana ordinances that some colleagues generated. Apparently, my inquiry has encouraged them to undertake to update the chart. I'll send an updated one when I receive it.

Best regards,

Jake W. Staser, Esq.
Brena, Bell, and Clarkson, P.C.
810 N Street #100
Anchorage, AK 99501
(907) 258-2000
jstaser@brenalaw.com

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From: Jake Staser
Sent: Wednesday, January 20, 2016 11:55 AM
To: 'john.calder@alaska.gov'
Subject: Database of Local Ordinances

Hi Mr. Calder,

I'm writing to inquire whether the MCB had a database or compilation of municipal ordinances. As we craft ordinances addressing the legalization of marijuana on behalf of the City of Valdez I've found it helpful to see what other jurisdictions have done.

Best regards,

Jake W. Staser, Esq.
Brena, Bell, and Clarkson, P.C.
810 N Street #100
Anchorage, AK 99501
(907) 258-2000

jstaser@brenalaw.com

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From: [Jo-Ann Odtojan](#)
To: [Calder, John P \(CED\)](#)
Subject: Re: Marijuana Business License Inquiry
Date: Wednesday, January 20, 2016 10:03:43 AM
Importance: High

Thank you John. What is the required number of years for residency?

On Thu, Jan 21, 2016 at 1:44 AM, Calder, John P (CED) <john.calder@alaska.gov> wrote:

Yes, there is a residency requirement.

No, we are not open to foreign investors.

Please see our regulations found here:

<https://www.commerce.alaska.gov/web/Portals/9/pub/FinalRegsThrough12-1-15.pdf>

From: Jo-Ann Odtojan [mailto:joann@oceandrivepartners.com]
Sent: Tuesday, January 19, 2016 1:40 PM
To: Marijuana, CED ABC (CED sponsored)
Subject: Marijuana Business License Inquiry

Hi,

Is there a residency requirement if we want to apply for marijuana business license?

Are you open to foreign investors?

Thank you.

Joann

--

Jo-Ann Odtojan

Ocean Drive Partners

2929 Ocean Drive, Second Floor

Oxnard, CA 93035

P. 702-425-9100

E. joann@oceandrivepartners.com

From: [William Mitchell](#)
To: [Calder, John P. \(CED\)](#)
Subject: RE: Marijuana Edibles
Date: Monday, January 04, 2016 5:09:10 PM
Importance: High

Thank you for your quick response. Forgive my ignorance. I did read & re read the current regulations. As I now have better internet. I now believe I understand the parts which may apply to me. Thanks again. K. Mitchell

On Jan 4, 2016 2:39 PM, "Calder, John P (CED)" <john.calder@alaska.gov> wrote:

Kristin,

You would need to apply for a Marijuana Product Manufacturing License, or an extract only license. It's doubtful you would be able to do this from your home, due to regulatory requirements and likely zoning restrictions that may or may not be enacted by your local government. Please read the regulations found on our website as well as the updated Frequently Asked Questions. This will help answer some of your questions. Thank you.

<https://www.commerce.alaska.gov/web/abc/>

<https://www.commerce.alaska.gov/web/abc/MarijuanaLicensingFAQs.aspx>

<https://www.commerce.alaska.gov/web/Portals/9/pub/FinalRegsThrough12-1-15.pdf>

John Calder

Administrative Officer

Alcoholic Beverage Control Board

(907)-754-3427

From: William Mitchell [mailto:moshimit3@gmail.com]
Sent: Saturday, January 02, 2016 7:05 PM
To: Marijuana, CED ABC (CED sponsored)
Subject: Marijuana Edibles

Hello there. I want to bake & sell marijuana infused baked goods from my home & or maybe open a bakery using infused butter & oils. What sort of license might I need? Will I even be able to sell that sort of thing to the public? Would be easier just to grow my own plants then make my butter? Don't really want to do that grow that is. Could I bake then sell to dispensary's & the like? Or am I OK under the cottage food law? I assume not. Thank you for all your help! Best Regards, Kristin Mitchell

From: [Aaron](#)
To: [Calder, John P. \(CED\)](#)
Cc: [Jana Weltzin](#)
Subject: Re: Marijuana licensing question
Date: Tuesday, January 05, 2016 4:32:04 PM
Importance: High

John,

Ok, -so I understand correctly- I'll only need to articulate that the marijuana establishment is in a completely different structure, and 'does not violate the best interests of the public?'

What constitutes a violation of public interest? Do you have code or statutory references I could read?

Thank you,
Aaron Bean

Sent from my iPhone

> On Jan 5, 2016, at 4:15 PM, Calder, John P (CED) <john.calder@alaska.gov> wrote:

>

> 3AAC 306.010(b) The board will not issue a marijuana establishment license if the licensed premises will be located in a liquor licensed premises.

>>

>> If the proposed location shares the same address as a licensed liquor establishment, it could be interpreted by the board that the proposed marijuana establishment and liquor licensed establishment are co-located. If the proposed location is truly not "in" a liquor licensed establishment, but adjacent to, the applicant would likely have to be able to demonstrate that fact, as well as assuring the board that the proximity of the two premises does not violate the best interests of the public.

>

> John Calder

> Administrative Officer

> Alcoholic Beverage Control Board

> (907)-754-3427

>

>

> -----Original Message-----

> From: Aaron [<mailto:aaronbean28@gmail.com>]

> Sent: Tuesday, January 05, 2016 1:01 PM

> To: Marijuana, CED ABC (CED sponsored)

> Subject: Marijuana licensing question

>

> Hello,

> Question: Would the board issue a marijuana license to a business that shares property with a liquor license establishment? I.e. 123 Front Street -liquor establishment- and 123 Front Street #B -marijuana establishment.- Please advise.

> Thank you,

> Aaron Bean

>

From: [Sharon Sibbald](#)
To: [Calder, John P. \(CED\)](#)
Subject: Re: Palmer's local option
Date: Monday, January 04, 2016 5:38:56 PM
Importance: High

Here's what it says in the regs:

3 AAC 306.250. Effect on licenses of restriction on sale. If a majority of the voters vote under 3 AAC 306.200(a) to prohibit sale of marijuana and marijuana products or the operation of marijuana establishments, or if the assembly or city council passes an ordinance to the same effect, the board may not issue, renew, or transfer to another person, a license for a marijuana establishment with premises located within the boundary of the local government or in the unincorporated area within ten miles of the boundaries of the local government.

Thanks for your help!

On Monday, January 4, 2016 2:48 PM, "Calder, John P (CED)" <john.calder@alaska.gov> wrote:

I'm sorry but I don't know what you mean by "10 mile radius". Could you please clarify what your question is?

John Calder
Administrative Officer
Alcoholic Beverage Control Board
(907)-754-3427

-----Original Message-----

From: Sharon Sibbald [mailto:sharon_sibbald@yahoo.com]
Sent: Monday, January 04, 2016 11:43 AM
To: Marijuana, CED ABC (CED sponsored)
Subject: Palmer's local option

Hello,

I'm trying to determine whether or not the 10 mile radius applies to Palmer's local option ban on marijuana businesses, but the information I've been able to access isn't definitive. Can you tell me?

Thanks!
Sharon Sibbald
sharon_sibbald@yahoo.com
907 350-1872

From: [Kyle Therrien](#)
To: [Calder, John P \(CED\)](#)
Subject: Re: question regarding marijuana cultivation facility locations
Date: Wednesday, January 27, 2016 1:52:39 PM
Importance: High

looks like the anchorage muni assembly just posted this document with zoning info

<http://www.muni.org/Departments/Assembly/Documents/AO2016-3S.pdf>

Sent from my iPhone

On Jan 27, 2016, at 12:57 PM, Calder, John P (CED) <john.calder@alaska.gov> wrote:

Specifically can a cultivation facility be located on residential property?

This depends on your local government and their zoning restrictions, or lack thereof.
This is not up to the MCB. Thank you for your inquiry.

From: Kyle Therrien [<mailto:kg.therrien@gmail.com>]
Sent: Wednesday, January 27, 2016 10:44 AM
To: Marijuana, CED ABC (CED sponsored)
Subject: question regarding marijuana cultivation facility locations

hello,

I am looking for information regarding the restricted locations of marijuana cultivation facilities. beside the ones listed in 3 AAC 306.010. License restrictions.

Specifically can a cultivation facility be located on residential property? Or does the property have to be designated say by the a municipality or borough to be for commercial use.

Thanks for your time

From: info@akthc.com
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Re: Questions For Marijuana Regulations
Date: Sunday, January 24, 2016 7:31:48 PM
Attachments: [sigimg1](#)

Dear Marijuana Task Force,

I have a few questions regarding the regulations that are out.

1st question.

If a Person/Company applies for a license(s) in February of this year and gets a license in May-June. What if the land is undeveloped waiting for approval? What if the buildings that may not be shipped and erected this year, will that be a problem if the licensee shows that they are moving forward to opening up?

2nd question.

Will drive thru marijuana sales be allowed?

3rd question

Will there be a distance requirement between retail stores?

4th question

Will hours of service be regulated by the local government, or by the State of Alaska?

5th question

Can a retail store be setup like a liquor store? Can a person walk into the store and buy the product openly as liquor is sold or does the product need to be in a separate room once ID's are checked (known as "budbar")?

6th question

Does the company buying or selling need to ship the product? Will the state allow state approved couriers to ship the product? Will manifests need to be approved first before product is shipped? Will manifest be needed if delivering in the same building? Will Alaska setup a MIPS program to assist licensees find/sell product easier between licensees?

7th question

Can a licensee refuse to sell to customer if he/she believes the customer is impaired?

8th question

When applying for a cultivation license is there a way to keep the exact location secret from the public? What about fencing for a greenhouse-what will those requirements be?

9th question

Will there be a interviewing process before the license is issued?

10th question

How about marijuana seeds. Will the state allow cultivation sell to retailers and to other cultivation centers? Will retailers then be able to resell those seeds to end users? How about labeling requirements? Will marijuana seeds need the same regulation that any seed producer in Alaska requires? Here's those requirements.

Labeling requirements

11 AAC 34.010

(a) Each lot or package of agricultural seed sold or offered for sale within the state

must bear on it or have attached to it in a conspicuous place, a legibly written or

printed label or tag, in English, providing the following information:

(1) the commonly accepted name of the kind and variety of the seed;

(2) the country or state where the seed was grown;

(3) the total percentage by weight of pure seed;

(4) the total percentage by weight of all weed seed;

(5) the total percentage by weight of inert matter;

(6) the total percentage by weight of other crop seed;

(7) the name and approximate number per pound of each kind of restricted

noxious weed seed, as listed in 11 AAC 34.020;

(8) the percentage of germination of the agricultural seed, together with the

month and year the seed was tested;

(9) the percentage of hard seed, if any is present;

(10) the name and address of the person labeling the seed or selling, offering,

or exposing the seed for sale within the state; and

(11) the lot number or other lot identification.

(f) Any agricultural or vegetable seed treated with toxic substances must be labeled

to provide the information required by (a) - (e) of this section and the following:

(1) a word or statement, in type no less than eight points, that the seed has

been treated;

(2) the commonly accepted coined or chemical name of the applied substances;

and

(3) a caution statement and appropriate poison symbol if the applied substance

presents a hazard to human or animal health.

(g) Seed packed in hermetically sealed containers must be labeled to provide the

information required by (a) - (f) of this section and the following:

(1) that the container is hermetically sealed;

(2) that the seed has been preconditioned as to moisture content; the purposes of labeling as required by this section.

(j) Hybrid seed, as defined in 7 C.F.R. 201.2(y), must be labeled in accordance

with provisions of 7 C.F.R. 201.11(a).

Records

11 AAC 34.090

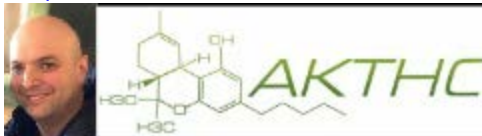
Each person whose name appears on the label as handling agricultural or vegetable seed subject to this chapter shall keep for two years a complete record of each lot of agricultural or vegetable seed handled, and shall keep for two years a file sample of each lot of seed after final disposition of the lot. All records and samples pertaining to the shipment or shipments involved must be accessible for inspections by the director or his designated agent during customary business hours.

Robert (Rob) Carter
Agronomist III
Alaska Plant Materials Center
5310 South Bodenbug Spur
Palmer, Alaska 99645
Office: [\(907\) 745-8127](tel:9077458127)
Fax: [\(907\) 746-1568](tel:9077461568)
Robert.Carter@alaska.gov
<http://plants.alaska.gov/>

Thanks for you time, and hope to be part of this exciting industry.

Sincerely,

Brad Henson-Founder
info@akthc.com
<http://akthc.com>



From: [Timothy Johnson](#)
To: [Calder, John P. \(CED\)](#)
Subject: Re: Questions re a limited cultivation license
Date: Monday, January 04, 2016 7:21:04 PM
Importance: High

Thank you for the quick response.

From: "Calder, John P (CED)" <john.calder@alaska.gov>
To: 'Timothy Johnson' <johnsontimothy47@yahoo.com>
Cc: "Franklin, Cynthia A (CED)" <cynthia.franklin@alaska.gov>
Sent: Monday, January 4, 2016 5:06 PM
Subject: RE: Questions re a limited cultivation license

Mr. Johnson,

Here are our answers to your questions:

1. Assuming an application for a limited cultivation license is approved, where is the licensee supposed to get seeds to start growing? Can the licensee use seeds grown legally (personal use) after Feb. 24, 2015 but before Feb 24, 2016?

The regulations do not outline where you may or may not get your seeds.

RE: 3 ACC 306.025 Application Procedures:

Assume that a person interested in only a limited cultivation license does not live within sight or within several hundred yards of any neighbors. Is this person still required to put up signs and place advertisements to announce a possible cultivation facility? Yes.

If so, to what end if that person has no close neighbors? This provision mirrors language found in liquor licensing. This requirement exists to give notice to the public, which includes other people besides your close neighbors.

This requirement effectively makes the cultivation facility a target for crime and could create civil and criminal liability for the state and ABC personnel should the facility become a victim of a crime as a result of this particular requirement. Can a potential licensee apply for an exemption from this requirement? Licensee's can petition the board, but once the regulations are signed by the Lt. Governor, they become law. Both the licensee and the board must abide by them.

From: [walter carlson](#)
To: [Calder, John P \(CED\)](#)
Subject: RE: Rules for growing
Date: Saturday, January 09, 2016 10:26:25 AM
Importance: High

Hello John, I was reading the regulations for the limited cultivation license and was curious about the square footage under cultivation. Does this mean the room must be under 500 square feet or the area of the plants must be under 500 square feet? Thank you for getting back to me last time as well and have a nice day.

On Jan 4, 2016 5:07 PM, "Calder, John P (CED)" <john.calder@alaska.gov> wrote:

Mr. Carlson,

It's expected that cultivators will either start their plants from seeds, or from cuttings, only AFTER receiving a license from the Marijuana Control Board (MCB). The source of the cultivators' seeds or cuttings is not information that is required by regulation.

John Calder

Administrative Officer

Alcoholic Beverage Control Board

[\(907\)-754-3427](tel:(907)-754-3427)

From: walter carlson [mailto:wrcarlson43@gmail.com]
Sent: Saturday, January 02, 2016 7:20 PM
To: Marijuana, CED ABC (CED sponsored)
Subject: Rules for growing

I was wondering if a person could get a limited cultivation license while having four marijuana plants, before the license went into effect. Would that person be able to take cuttings/clones from those plants and use them to start the cultivation process for when/if the application process was accepted and all regulations followed?

From: [Kevin Schwan](#)
To: [Calder, John P \(CED\)](#)
Subject: Re: Submitting finger prints
Date: Monday, January 25, 2016 4:54:18 PM
Importance: High

John,

I spoke with Maggie at the Fairbanks Daily Miner about running an announcement once a week for 3 weeks for the opening of Denali's Cannabis Cache. She said that the alcohol board has a prescribed template to fill out the information needed for the announcement. Is there a template the Marijuana Control Board is using or should I just type it up based on the information in the regulations?

Thank You for your time.

Kevin Schwan

On Wed, Jan 20, 2016 at 8:21 AM, Calder, John P (CED) <john.calder@alaska.gov> wrote:

You're welcome.

John Calder

Administrative Officer

Alcoholic Beverage Control Board

[\(907\)-754-3427](tel:(907)-754-3427)

From: Kevin Schwan [mailto:kayakkevin33@gmail.com]
Sent: Tuesday, January 19, 2016 8:35 PM
To: Calder, John P (CED)
Subject: Re: Submitting finger prints
Importance: High

John,

Thank you!

Kevin

On Tue, Jan 19, 2016 at 12:22 PM, Calder, John P (CED) <john.calder@alaska.gov> wrote:

Kevin,

The fingerprints will have to be either mailed to us or hand delivered at our offices. We are located at:

550 W 7th Ave, STE 1600

Anchorage, AK 99501

From: Kevin Schwan [mailto:kayakkevin33@gmail.com]
Sent: Sunday, January 17, 2016 3:15 PM
To: Marijuana, CED ABC (CED sponsored)
Subject: Submitting finger prints

Hello,

My name is Kevin Schwan and I had a question regarding submitting fingerprints with our electronic application. I found several locations to obtain finger prints, but will they provide a way or how do we transfer that paper document into an electronic document that we can submit when filling out the application on line?

Thank you,

Sincerely,

Kevin Schwan

From: [ANH LAM](#)
To: [Calder, John P. \(CED\)](#)
Subject: Re: Testing facility
Date: Friday, January 15, 2016 10:47:22 AM
Importance: High

Ok. Thx. Will see what the options are. Do u have specific guidelines on what u want in a lab? Or point me in direction of setup you looking for. It matters in the investment on instruments needed ie mass spect is not cheap!

Sent from my iPhone

> On Jan 15, 2016, at 9:41 AM, Calder, John P (CED) <john.calder@alaska.gov> wrote:

>

> Yes, all applications will be public information.

>

> John Calder

> Administrative Officer

> Alcoholic Beverage Control Board

> (907)-754-3427

>

>

> -----Original Message-----

> From: ANH LAM [<mailto:sefoot@hotmail.com>]

> Sent: Friday, January 15, 2016 8:50 AM

> To: Calder, John P (CED)

> Subject: Re: Testing facility

> Importance: High

>

> Read it. I am interested but this town can probably only support one testing facility. Will it be public info who is applying for what during the application period? Thx. Dr lam

>

> Sent from my iPhone

>

>> On Jan 15, 2016, at 8:20 AM, Calder, John P (CED) <john.calder@alaska.gov> wrote:

>>

>> Please read the regulations on our website.

>>

>> <https://www.commerce.alaska.gov/web/abc/>

>>

>> <https://www.commerce.alaska.gov/web/abc/MarijuanaRegulations.aspx>

>>

>>

>> John Calder

>> Administrative Officer

>> Alcoholic Beverage Control Board

>> (907)-754-3427

>>

>> -----Original Message-----

>> From: ANH LAM [<mailto:sefoot@hotmail.com>]

>> Sent: Monday, January 11, 2016 11:02 AM

>> To: Marijuana, CED ABC (CED sponsored)

>> Subject: Testing facility

>>

>> What are requirements for the testing facility? Is what equipments will be needed? Thx

>>

>> Sent from my iPhone

From: [Franklin, Cynthia A \(CED\)](#)
To: [Calder, John P \(CED\)](#)
Subject: RE: Testing lab questions
Date: Wednesday, December 30, 2015 3:36:03 PM
Importance: High

Hi Monty,

It sounds like this is information you would include in your application. I can't really say if it will worry the board or not. There was a lot of emphasis in the regulations making process on the independence of testing labs. Whether the board will see your operation as independent from the grower who is a partner in your landlord's building is going to be up to them. Will they think that you will test your landlord's marijuana in the same way you would test the marijuana of someone who cannot evict you? I don't know. Sorry I cannot give you more guidance on this.

Cynthia Franklin, Director
Alcoholic Beverage & Marijuana Control Boards
907-269-0351

From: jmh@alaskaone.us [mailto:jmh@alaskaone.us]
Sent: Wednesday, December 30, 2015 9:39 AM
To: Franklin, Cynthia A (CED)
Subject: RE: Testing lab questions

I have been in contact with him about ownership of the building, and it appears I was wrong about ownership. A partnership he is in owns the building. He leases from the partnership. I would be leasing from the partnership also.

> I think that will be a problem. Finances of testing establishments are not
> supposed to be tangled up with finances of other types of licenses.

>
> Cynthia Franklin, Director
> Alcoholic Beverage & Marijuana Control Boards
> 907-269-0351

>
>
> From: jmh@alaskaone.us [mailto:jmh@alaskaone.us]
> Sent: Wednesday, December 30, 2015 8:17 AM
> To: Franklin, Cynthia A (CED)
> Subject: RE: Testing lab questions

>
> He is the owner of the building and I would be leasing from him. He is a
> licensed real estate agent.

>
>> Who owns the building? Does he have a landlord or is he himself the
>> owner
>> of the building?

>>
>> Cynthia Franklin, Director

>> Alcoholic Beverage & Marijuana Control Boards
>> 907-269-0351

>>

>>

>> -----Original Message-----

>>

>

From: jmh@alaskaone.us<<mailto:jmh@alaskaone.us>> [<mailto:jmh@alaskaone.us>]

>> Sent: Tuesday, December 29, 2015 5:07 PM

>> To: Franklin, Cynthia A (CED)

>> Subject: Re: Testing lab questions

>>

>> Hello Cynthia,

>> I have been working with a gentleman who is working on setting up a
>> grow/retail operation. He is the one that would like me to co-locate my
>> test lab on his property. He and I met today and drew up a proposed
>> floor

>> plan that I have attached. The test lab would be completely separate
>> except for one portion of a shared wall, with it's own entrance and
>> bathroom.

>> I have outlined the proposed lab space in yellow.

>> Please let me know if you feel this will work.

>> Thank you

>> Monty

>>

>

From: [Sharon Sibbald](#)
To: [Calder, John P. \(CED\)](#)
Subject: Re: Palmer's local option
Date: Wednesday, January 06, 2016 10:58:50 AM
Attachments: [Draft of Letter.pages](#)
Importance: High

Hello Mr. Calder,

Attached is a draft letter I intend to send to the law department and the lieutenant governor if it's true that Palmer is subject to the 10 mile radius I refer to in the original email. I think this will help clarify what it is I'm asking you.

Thanks again.
Sharon Sibbald

On Monday, January 4, 2016 2:47 PM, "Calder, John P (CED)" <john.calder@alaska.gov> wrote:

John Calder
Administrative Officer
Alcoholic Beverage Control Board
(907)-754-3427

-----Original Message-----

From: Sharon Sibbald [mailto:sharon_sibbald@yahoo.com]
Sent: Monday, January 04, 2016 11:43 AM
To: Marijuana, CED ABC (CED sponsored)
Subject: Palmer's local option

Hello,

I'm trying to determine whether or not the 10 mile radius applies to Palmer's local option ban on marijuana businesses, but the information I've been able to access isn't definitive. Can you tell me?

Thanks!
Sharon Sibbald
sharon_sibbald@yahoo.com
907 350-1872

From: [zells](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: recording
Date: Wednesday, January 27, 2016 10:33:56 AM

Hello,

With the 40 day continuous 24/7 surveillance recording, this is very expensive to do. The storage requirements needed cost allot. Can we use cameras with motion detectors? You still get all movement and it does not cost a small fortune.

Thanks
Peter Zell

This email has been checked for viruses by Avast antivirus software.
<https://www.avast.com/antivirus>

From: [cristopher Konopka](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Regulation Questions
Date: Monday, November 23, 2015 2:23:37 PM

Hello,

I have some questions regarding the current marijuana regulations for a cultivation/manufacturing facility:

- Does the proposed premises require that the building physically be built at the time of application if we own the land? (Referencing Article 1 3AAC 306.020) or are we able to provide the 'plans' for the proposed premise at the time of application?
- Are there restrictions for how close we can live to a cultivation facility? Can we live in the same building as a cultivation facility? For example a warehouse with an apartment attached or could we have a residential property on the same parcel of land?
- If we are required to have the building in place at the time of application would we need to have the security system already installed or just drawn on the plans?
- We are aware that online sales are prohibited; Does this impede us from taking orders online and completing the transaction on the licensed premises?

Thank you for taking the time to review these questions.

Cristopher Konopka

From: [Ben Adams](#)
To: [Mallott, Byron I \(GOV\)](#)
Cc: [Calder, John P \(CED\)](#)
Subject: Residency rules for Marijuana businesses
Date: Wednesday, November 25, 2015 2:53:20 PM
Attachments: [AdamsFietz Sharp 20151125 191324.pdf](#)
Importance: High

For your consideration.

Benjaman T. Adams
Attorney at Law

From: [Damani Williams](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Residency/Fees
Date: Thursday, January 28, 2016 8:42:45 AM

To Whom It may Concern,

I, respectfully request the specific information as follows:

State of Alaska Marijuana retail residency requirements, all actively known fees, and all valid laws passed in association with obtaining and complying with local and State of Alaska approved Marijuana retail licensing.

I thank you very much in advance for your time and attention in this matter.

Sincerely,

Damani Williams

CITY AND BOROUGH OF SITKA

RESOLUTION NO. 2016-01

A RESOLUTION OF THE CITY AND BOROUGH OF SITKA, REQUESTING THE STATE DEPARTMENT OF LAW REVISE THE 500 FOOT SET-BACK PROVISION IN 3 AAC 306.010.

WHEREAS, Ballot Measure No. 2, "An Act to Tax and Regulate the Production, Sale, and Use of Marijuana" passed with a majority of the voters in support; and

WHEREAS, due to geographic constraints dictated by local topography many municipalities have limited real-estate on which to develop; and

WHEREAS, a result of those limitations on developable real-estate is that municipalities are compelled to reconcile highly incongruous zoning and building uses in close proximity to each other; and

WHEREAS, the requirement for there to be a 500 foot space between any licensed marijuana establishment and a school, recreation or youth center, building where religious services are regularly conducted and a correctional facility limits the ability of an establishment to receive a license from the state; and

WHEREAS, such a requirement stands in direct contradiction to AS 17.38.090(a) thus making implementation of the law unreasonably impracticable; and,

WHEREAS, licensed liquor establishments operate under a 200 ft. setback, per AS 04.11.410(a),


NOW, THEREFORE, BE IT RESOLVED the Assembly of the City and Borough of Sitka, Alaska, requests that the Alaska State Department of Law recommend the set-back distance required between all marijuana establishments and any schools, recreation or youth centers, religious buildings and correctional facilities be a minimum of 200 ft. to be determined by local planning and zoning regulation.

PASSED, APPROVED, AND ADOPTED by the Assembly of the City and Borough of Sitka, Alaska on this 12th day of January, 2016.



Mim McConnell, Mayor

ATTEST:



Sara Peterson, CMC
Municipal Clerk