

From: [Sharon Sibbald](#)
To: [Calder, John P \(CED\)](#)
Subject: Re: Palmer's local option
Date: Wednesday, January 06, 2016 1:00:22 PM
Attachments: [Draft of Letter.docx](#)
Importance: High

Oh, right. Sorry.

On Wednesday, January 6, 2016 11:33 AM, "Calder, John P (CED)" <john.calder@alaska.gov> wrote:

Thank you Ms. Sibbald, but I'm unable to view your attachment. We cannot view .pages documents. Can you send it as MS Word document or .pdf?

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

From: Sharon Sibbald [mailto:sharon_sibbald@yahoo.com]
Sent: Wednesday, January 06, 2016 10:59 AM
To: Calder, John P (CED)
Subject: Re: Palmer's local option
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: [Sharon Sibbald](#)
To: [Calder, John P \(CED\)](#)
Subject: Re: Palmer's local option
Date: Friday, January 08, 2016 9:52:17 AM
Attachments: [Draft in Word.docx](#)
Importance: High

Hello Mr. Calder,

I haven't heard from you, so I thought I'd send the .doc copy again in case you didn't receive it. My original question to you was whether or not the 10 mile boundary applies to Palmer, but I don't see how it can't when I read the MCB's draft of the new regulations. I guess my question to you now is where can I send this letter to greatest effect? Am I too late to do anything? Is my only recourse to hire a lawyer?

Thank you in advance for any assistance whatsoever that you might be able to provide.

Sharon

On Wednesday, January 6, 2016 11:33 AM, "Calder, John P (CED)" <john.calder@alaska.gov> wrote:

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To: Marijuana, CED ABC (CED sponsored)
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Thanks!
Sharon Sibbald
sharon_sibbald@yahoo.com
907 350-1872



November 25, 2015

Office of the Lieutenant Governor
P.O. Box 110001
Juneau, AK 99811

VIA EMAIL: byron.mallott@alaska.gov

Re: Residency Requirements for Marijuana Businesses

Dear Mr. Mallott:

I am writing because, unfortunately, it appears that the Marijuana Control Board is getting poor advice about their ability to restrict the ability of non-Alaskans to enter the marijuana business in Alaska.

Without going into a full legal analysis, the US Constitution generally prevents the State from restricting travel between States. Tying the ability to open a marijuana business to the PFD is very unlikely to be sustained by the Courts.

This attempt to illegally restrict eligibility has several damaging effects. First, it discourages those with capital from considering opening a business in Alaska. In a time of challenging budgets, this is especially troublesome.

Second, these restrictions will be challenged in Court. These battles will cost the State money. These are not battles that need to be waged. Enacting blatantly unconstitutional regulations is not smart public policy.

I urge you to obtain independent legal advice on this issue. I am confident that you will be told that what the Board is proposing is unconstitutional. Any objective legal analysis should reach this conclusion. While it may 'feel good' to attempt to exclude those from Outside, Alaska's attempts at doing so have been repeatedly rejected by the Courts.

I realize this is an unusual letter but I urge you to carefully examine any such proposals that are submitted to you by the Marijuana Control Board. From both a business and a legal standpoint, these proposals are troublesome.

Sincerely,



Benjamin T. Adams
Attorney at Law, Alaska Bar Number 0606030

c. Marijuana Control Board, via john.calder@alaska.gov

From: [Ginger Smith](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Board Chair Ex Parte?
Date: Wednesday, January 27, 2016 10:57:54 PM

To Whom It May Concern:

I've been following the Marijuana Control Board meetings and regulations process quite closely, and while doing a Google search, I came upon this article in a San Francisco newspaper:

<http://m.sfgate.com/news/article/Pot-testing-rules-difficult-to-meet-for-island-6786754.php>

I have copied the full article at the end of this email.

One sentence in particular caught my attention:

"Aaron Bean, a Sitka resident who hopes to open marijuana cultivation and retail businesses, helped Schulte draft the amendment."

While listening to the many board meetings over the past year, I've heard the Marijuana Control Board members receive training during multiple meetings regarding ethics, board etiquette, and the regulations process. It's my understanding that ex parte conversations by board members are prohibited during the regulations drafting process.

A potential marijuana license applicant helping the Marijuana Control Board Chair draft an amendment to the proposed regulations sure seems to meet the definition of ex parte to me. I understand from this article and others that the particular amendment mentioned ended up being taken out in the version signed by the lieutenant governor, but one could assume that if Mr. Schulte had assistance from a potential industry member with drafting one amendment, that he probably had assistance with drafting others.

I, as a parent, voting citizen of Alaska, and concerned member of the public, am alarmed that the board chair is making back-door collaborations with the "industry" regarding potential changes to the regulations. What's the point of the public comment process if the board chair is going to have a secret meeting to draft amendments?

Although it has seemed at times like the industry board members have run the show, I've been relatively impressed by what I've heard during the meetings and read throughout the regulations drafting, and I appreciated hearing multiple and differing perspectives from the board members about potential regulations. I would, however, question Mr. Schulte's integrity, ethics, and/or competence as the board chair of a regulated and highly controversial new industry. It seems like the others involved want this thing to be done well, to be done honestly, and to be done fairly. If Mr. Schulte can't play by the rules, then he sure shouldn't be writing them.

Sincerely,

Ginger Smith

KETCHIKAN, Alaska (AP) — Lt. Gov. [Byron Mallott](#) has turned down a proposed change to marijuana regulations that would have made it easier for southeast and rural Alaska communities to comply with testing requirements.

Mallott signed testing regulations drafted by the [Alaska Marijuana Control Board](#) on Friday. The rules were approved without a provision that would have allowed alternative testing requirements for communities off the road system, The Ketchikan Daily News reported (<http://bit.ly/1QBHUzX>).

The Nov. 20 amendment stated that "when geographic location and transportation limitations make it unfeasible for a manufacturing facility to transport testing samples to a lab, an applicant for licensure may propose alternative means of testing to meet the requirements of this code."

[Bruce Schulte](#), chairman of the control board and the head of the [Alaska Marijuana Industry Association](#) board, had pushed for the amendment. He said the [Alaska Department of Law](#) rejected the change because it was too board.

As the state moves closer to accepting marijuana license applications, there remains a challenge for island communities with access to testing facilities. State rules require marijuana to be tested before businesses can sell it, and federal law prohibits air and water transportation of cannabis.

Information provided to the Marijuana Control Board indicates that testing equipment can carry six-figure price tags, which may put a testing facility out of reach for the smaller communities.

Aaron Bean, a Sitka resident who hopes to open marijuana cultivation and retail businesses, helped Schulte draft the amendment.

"There's no real realistic way to assume we would be a big enough market to support a \$500,000 to \$700,000 lab," Bean said. "... Not only that, but the state is requiring a doctorate with two years of lab experience, and there's just not a lot of those folks running around who would want to do that."

Bean said he plans to keep pushing for an amendment that would allow an alternative testing plan for island communities.

"I think that there's a lot of things (in the Department of Law review) that make sense from their side," Bean said. "We can make this work. I'm confident."

Information from: Ketchikan (Alaska) Daily News, <http://www.ketchikandailynews.com>

From: [Mark](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Analytical testing methods for MCB
Date: Tuesday, January 26, 2016 10:42:52 AM

I spoke with Naomi yesterday about several questions I have concerning the proposed analysis of marijuana under the auspices of the MCB, and she suggested that I frame these in an e-mail.

In no particular order, they are:

Is there a proposed approved analytical method for said testing?

One possible ready answer to this is to use the UNODC (United Nations Office on Drugs and Crime) method ST/NAR/40, ISBN 978-92-1-148242-3.

This would be a credible and recognized method widely accepted by most authorities.

Will the State of Alaska be performing any QC testing internally, and (if so) where?
Corollary - will there be a charge for this service?

Are there security requirements for an analytical lab's storage of samples?

For disposal of waste such as used solvents and excess samples (such as those that have exceeded their holding times)?

Is there a contact point person for marijuana analysis for the MCB?

There are several more points I'd like to clear up, but these will suffice for now.

Regards,

Mark Stowell
S & W Analytical
903-787-9087

Stowellmark@aol.comn

From: [Aaron](#)
To: [Franklin, Cynthia A \(CED\)](#)
Cc: sarah.oats@alaska.gov; [Calder, John P \(CED\)](#)
Subject: Agenda item request
Date: Saturday, November 21, 2015 1:31:09 PM
Importance: High

Aaron Bean
215 Peterson Ave.
Sitka, Alaska 99835

11-21-2015

Marijuana Control Board
C/O Cynthia Franklin
550 W 7th Ave Suite 1600
Anchorage, Alaska 99501

Director Franklin,

At your last meeting motions were made and the board approved to reduce the residency requirement threshold from, Alaska's permanent fund dividend requirements, to Alaska's voter registration requirements.

The amended regulation does not make sense for true Alaskans. I say 'true' Alaskans because, with this amendment the board inadvertently opened to flood gates to any US citizen in the entire continental untied states to open a marijuana establishment with nothing more than a click of a mouse.

Unless it was the board intentions to disenfranchise Alaskans I respectfully, and strongly, urge the board to consider at their next scheduled meeting to make motions to reverse its actions taken on residency requirements during its November 20th meeting. This could be accomplished by adding a simple agenda item.

I'd also like to note the states initial drafted residency requirement made perfect sense, not only for Alaskans, but as you mentioned during your comment it also works better for the timeline of ballot measure 2 implementation. Thank you for your consideration, and please let me know if you need any further justification or information.

Sincerely,

Aaron Bean
(907) 738-8923

From: [Aaron](#)
To: [Calder, John P. \(CED\)](#)
Cc: [Aaron](#); [Jana Weltzin](#); [Akhnr1023@gmail.com](#); [Robin Koutchak](#); [reuben.yerkes@cityofsitka.org](#); [shannon_haugland@yahoo.com](#); [Franklin, Cynthia A \(CED\)](#); [catvanveen@gmail.com](#); [Eric Vanveen](#)
Subject: Agenda item request
Date: Wednesday, January 27, 2016 7:13:12 AM
Attachments: [MCB Comment Law Review.pdf](#)
[ATT00001.htm](#)

Hi John,
Please forward my attached letter to the board. My letter includes a agenda item request, and a suggested amendment addressing the department of laws concerns with alternative testing.
Thanks,
Aaron Bean

From: [Gordon Epperly](#)
Subject: Advertisement of "Marijuana" is a Federal Crime
Date: Monday, December 21, 2015 7:28:00 PM
Attachments: [Email \(Remember Blind Copy\)1.jpg](#)
[Signature \(2\).jpg](#)
[Federal Register - Ryan Haight Online Pharmacy Consumer Protection Act of 2008.pdf](#)
[AP - Postal Service says mailing marijuana ads is unlawful \(12-18-15\).pdf](#)
Importance: High

From: "Gordon Epperly" <enter7740@14th-amendment.com>
To:
Cc: governor@alaska.gov; chris.peloso@alaska.gov; james.chennault@alaska.gov;
richard.pomeroy@usdoj.gov; christine.dollerhide@usdoj.gov;
david.urrea@usdoj.gov; deborah.simpson@usdoj.gov; kathey.virgin@usdoj.gov;
usaak.ecf@usdoj.gov
Sent: 12/21/2015 7:04:33 PM
Subject: Advertisement of "Marijuana" is a Federal Crime



Hello Everyone

On December 18, 2015, the "Associated Press" published an "Article" in the Newspapers of our Nation reporting that the "U.S. Postal Service" has ruled that mailing of advertisement regarding the sale, use, or distribution of "Marijuana" is unlawful under the laws of "The United States of America." That "Article" is attached to this message as a PDF file.

What is not addressed in this "Article" of the "Associated Press" is the "Federal Law" that prohibits the advertisement of "Marijuana" over the

Internet. Attached to this message is a PDF file of the "Federal Register" addressing the "Ryan Haight Online Pharmacy Consumer Protection Act of 2008" which liberal reading of the law extends to the prohibition of any employee of a government "Agency" or "Municipal Corporation" of a "State" from promoting "Marijuana" over the Internet. Please keep this in mind when implementing "City and Borough Ordinances" and "State Regulations" to implement the "Marijuana Ballot Initiative" law of 2014.

Title 21 United States Code (Federal Control Substance Act)

21 USC 843(c) Advertisement

(1) It shall be unlawful for any person to place in any newspaper, magazine, handbill, or other publications, any written advertisement knowing that it has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule \1\ I controlled substance. As used in this section the term "advertisement" includes, in addition to its ordinary meaning, such advertisements as those for a catalog of Schedule \1\ I controlled substances and any similar written advertisement that has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule \1\ I controlled substance. The term "advertisement" does not include material which merely advocates

the use of a similar material, which advocates a position or practice, and does not attempt to propose or facilitate an actual transaction in a Schedule \1\ I controlled substance.

\1\ So in original. Probably should not be capitalized.

(2)(A) It shall be unlawful for any person to knowingly or intentionally use the Internet, or cause the Internet to be used, to advertise the sale of, or to offer to sell, distribute, or dispense, a controlled substance where such sale, distribution, or dispensing is not authorized by this subchapter or by the Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.].

(B) Examples of activities that violate subparagraph (A) include, but are not limited to, knowingly or intentionally causing the placement on the Internet of an advertisement that refers to or directs prospective buyers to Internet sellers of controlled substances who are not registered with a modification under section 823(f) of this title.

(C) Subparagraph (A) does not apply to material that either—

(i) merely advertises the distribution of controlled substances by nonpractitioners to the extent authorized by their registration under this subchapter; or

(ii) merely advocates the use of a controlled substance or includes pricing information without attempting to facilitate an actual transaction involving a controlled substance.

21 USC 843

(d) Penalties

(1) Except as provided in paragraph (2), any person who violates this section shall be sentenced to a term of imprisonment of not more than 4 years, a fine under title 18, or both; except that if any person commits such a violation after one or more prior convictions of him for violation of this section, or for a felony under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 8 years, a fine under title 18, or both.

Respectfully Submitted



Gordon Warren Epperly

From: [Anna Marley](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Cc: [John Burns](#)
Subject: Application Forms
Date: Thursday, January 28, 2016 12:14:29 PM

Ms. Franklin:

After reviewing the Public Notice of the Marijuana Control Board Meeting on February 11th, the January 25th Press Release, and having visited the FAQ site as directed by the Board's voicemail message, I am confused as to when applications for licensing will be available. The meeting Notice states that the Board will consider the agenda for approval of forms and updated timeline for licensing, the Press Release states that the Board will spend the next 6-months finalizing application forms; and the answer to FAQ ("What is the timeline for implementation?" and "Is the Board keeping a list of interested businesses?") states that the Board will start accepting applications by February 24th and will act on those applications within 90 days.

We represent a Fairbanks business that is interested in applying for a marijuana cultivator and/or retail license. We would appreciate your advising us when the applications will be available and, if already available, where we can obtain them.

Thank you,

Anna

Anna M. Marley

**Legal Assistant
Burns & Associates, PC
100 Cushman Street, Suite 311
Fairbanks, Alaska 99701
Telephone: 907-452-1666; Facsimile: 907-456-5055**

Law Office of Burns & Associates - Confidential Attorney-Client Communication

This e-mail and any files transmitted with it are confidential and intended solely for the use of the individual or entity to whom they are addressed. If you have received this e-mail in error, please notify Anna, immediately at (907) 452-1666. Please note that any views or opinions presented in this e-mail are solely those of the author and do not necessarily represent those of the firm. Finally, the recipient should check this e-mail and any attachments for the presence of viruses. The firm accepts no liability for any damage caused by any virus transmitted by this e-mail.

From: [Kenneth Jones](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Applications
Date: Sunday, November 22, 2015 10:38:29 AM

When might a person actually start filling out forms applying for a Distribution license and a dispensary license?
Thank you for your time and assistance Kenny Jones

Sent from my iPad

From: mwyeth@gci.net
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Biglake
Date: Monday, January 04, 2016 10:29:52 PM

To whom it may concern.

I have interest in a grow operation on some acreage in big lake but as of now the Borough hasn't defined any land use or given any guidance! If they fail to act by the deadline does the state regulations cover the establishment of the new business?

Best regards.
Matt Wyeth

From: [joe.gil](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: A Bad Crop
Date: Thursday, January 21, 2016 5:51:08 AM

theoretical: I grow all this pot.....it doesn't turn out so good.....I have bales of it that I can't sell.....do I get taxed on this?....or is the tax determined for what I can sell it for....

Thanks.....Joe Gil port protection alaska

From: forestwelton84@gmail.com
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Fwd: FOREST W. ~License & associated. (Fairbanks) THANKS!
Date: Wednesday, January 20, 2016 12:10:20 PM

Oops misspelled email on first send....thanks.

Begin forwarded message:

From: "forestwelton84@gmail.com" <forestwelton84@gmail.com>
Date: January 20, 2016 at 12:04:33 PM AKST
To: maraijuana@alaska.gov, cynthia.franklin@alaska.gov
Subject: FOREST W. ~License & associated. (Fairbanks) THANKS!

Hello,

I am interested in having a business associated to marijuana although I'm not sure precisely what the best approach is. I thought it would be a wise move to apply for licenses for a dispensary AND/OR factory AND/OR delivery service. If there is only a small number of licenses given out for Fairbanks and I set up a business/ invest massive amounts of money and then am not awarded a license for the reason of "none are remaining for this area" then it would be devastating financially.

If I apply for a license (or multiple) and am approved then I can keep one (if I'm awarded one) and build a business within the parameters the state has set.

So....I guess the questions are as follows....

- 1.Can I apply for more then one license?
- 2.Must I have a LLC. and or a physical business set up first... or just proposed location which can change on approval from the board.
3. What number of license in each associated category are awarded for an area like Fairbanks?
- 4.Will there be additional licenses given for say....60mi Elliot Hwy (random mi. number) if someone bought land way outside of the city limits to start a factory?
5. Any additional blunt/ straight forward info you would be willing to send my way...Please feel free to be ~very~ straight forward.

I need the cut and dry version so I can make a decision on if this is something for me to invest in or not!?!?

Thanks for your time!!!!

~Forest

From: [Clifford Fitka](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Fwd: Marijuana Laws
Date: Friday, January 22, 2016 1:37:55 PM

Sent from my iPhone

Begin forwarded message:

From: Clifford Fitka <ccfitka@gmail.com>
Date: January 15, 2016 at 9:53:00 AM AKST
To: Representative.Benjamin.Nageak@akleg.gov
Subject: Fwd: Marijuana Laws

Sent from my iPhone

Begin forwarded message:

From: Clifford Fitka <ccfitka@gmail.com>
Date: January 15, 2016 at 3:11:31 AM AKST
To: Representative.Neal.Foster@akleg.gov
Subject: Fwd: Marijuana Laws

Sent from my iPhone

Begin forwarded message:

From: Clifford Fitka <ccfitka@gmail.com>
Date: January 15, 2016 at 2:34:17 AM AKST
To: Senator.Donny.Olson@akleg.gov
Subject: Fwd: Marijuana Laws

Sent from my iPhone

Begin forwarded message:

From: Clifford Fitka <ccfitka@gmail.com>
Date: January 15, 2016 at 12:42:22 AM
AKST
To: governor@alaska.gov
Subject: Fwd: Marijuana Laws

Sent from my iPhone

Begin forwarded message:

From: Clifford Fitka
<ccfitka@gmail.com>
Date: January 14, 2016 at
11:24:46 PM AKST
To: grace.jang@alaska.gov
Subject: Marijuana Laws

Just read the article you have on the rules of the new marijuana laws. Question: If marijuana can only be sold after it has been tested for the levels and other factors, how does a business in the marijuana industry located in "Bush" Alaska, wether it is growing, manufacturing, or sale get tested since it cannot be flown in to a lab to do so? Granted that this eliminates the possibility of such entrepreneurs from receiving income from sales to the urban side of Alaska; such business in rural communities could benefit in producing a municipal & state taxable micro economic infrastructure to create some form of boost to the stagnant rural economy. As of now that the law is written, without some remedy to this paradoxical hiccup, the law excludes "Bush" Alaska from fully participating in these new opportunities to economic

development.

From: [Clifford Fitka](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Fwd: Testing
Date: Friday, January 22, 2016 1:39:41 PM

Sent from my iPhone

Begin forwarded message:

From: Clifford Fitka <ccfitka@gmail.com>
Date: January 17, 2016 at 9:24:19 PM AKST
To: Paul.Labolle@akleg.gov
Subject: Testing

Thank you for your response. This is the only reply so far.

I understand the federal issue situation, however, this can be resolved at the state level if certain aspects of the unique situation of most villages off the interconnected road system.

I googled the kits, and they are available in kits. I think it could be feasible, if communities off the interconnecting road systems were allowed an exemption to testing facilities and usage of home testing kits. This however most likely would need an amendment because the law requires more than the testing. The multiple compounds, molds, insecticides, and various other things to be tested for would make it out of reach for aspiring entrepreneurs in "road locked" bush AK. Their needs to be something done to clarify and remedy this for the bush.

From: [Clifford Fitka](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Fwd: Watetways
Date: Friday, January 22, 2016 1:39:12 PM

Sent from my iPhone

Begin forwarded message:

From: Clifford Fitka <ccfitka@gmail.com>
Date: January 19, 2016 at 4:17:55 PM AKST
To: Paul Labolle <paul.labolle@akleg.gov>
Subject: Watetways

Does transportation exclusion of marijuana on federal level have a loophole in anilca waterway section?

From: [joe.gil](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: license application
Date: Wednesday, January 20, 2016 3:10:27 PM

I need a license application for limited cultivation and a retail store sales.....what are the requirements to be a testing facility? Will I be able to transport pot to Juneau on a private carrier from Prince of Wales Island - Ketchikan? Can I buy product in Washington state to sell in Alaska? When can I start growing for the summer tourist season? I have already looked through the final regs and need more specific clarification ; I appreciate your assistance , thank you , Joe Gil Point Baker Alaska 99927 907 617-8604

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: [Charles Lester](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Local option
Date: Thursday, January 21, 2016 11:36:46 AM

MCB,

If a locality elects to opt out of commercial marijuana, is the state going to make a 10 mile barrier from the locality that opted out? Or will an unorganized Borough be able to apply for commercial marijuana businesses without the consent of the locality that opted out? In other words will the locality control what goes on outside of its borders? Thank you.

Charles Lester

From: [Charles Lester](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Local option
Date: Thursday, January 21, 2016 11:43:20 AM

Is there a 10 mile barrier if a municipality opts out of commercial marijuana? Meaning will this 10 mile barrier extend out into a unorganized Borough? Thank you

Charles Lester

From: [Joey Zuray](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Date: Friday, January 22, 2016 9:49:15 PM

Hello my name is Joey Zuray. I am from Tanana Alaska and I am very interested in the booming marijuana industry. I have a question about the best way to get my own growing and selling marijuana legally. And starting my own store. And would the village council be able to keep you from starting your own store?
Sent from my iPhone

From: [T.K](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Marijuana Cultivation Facilities (3 AAC 306.400 - 3 AAC 306.480)
Date: Wednesday, January 20, 2016 1:16:18 PM

Good afternoon,

Can a marijuana cultivation facility be constructed within a connex that meets local zoning?

Thanks for your time and effort.

Sincerely,

Tony Kuse

From: [Jimmy Blaze](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: questions
Date: Thursday, January 21, 2016 1:05:56 PM

Good morning ,

I'm searching for clarification of "Cultivation" in the context of a limited marijuana cultivation facility license to a person operating a marijuana cultivation facility with fewer than 500 square feet under cultivation?

Does that mean all Plants? Flowering? Vegetative?

Can that mean only Plants in the flowering stage

Does it include Non Flowering Plants?

Can drying and curing be accomplished on the same property but outside of the 500SQFT?

Can two different licenses occupy the same location?

Is there a link for definitions used in the Regulations?

thank you for your time

jimmy

Jimmy Blaze
Action Sports Athlete
Cell 907.947.0164
jimmy@jimmyblaze.com
www.jimmyblaze.com

From: [Duane Barrett](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Re: Standard Cultivation facility operating plan format?
Date: Friday, January 22, 2016 11:45:01 AM

I have a very involved operating plan, including all aspects of regulations, it is all in paper form, I need to know what format the MCB would like to receive my operating plan with the application.

Kind regards
Garth vaughan

I have a very involved operating plan, including all aspects of regulations, it is all in paper form, I need to know what format the MCB would like to receive my operating plan with the application.

Kind regards
Garth vaughan

From: [Chris Moniz](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Request to unsubscribe from emails
Date: Wednesday, January 20, 2016 1:52:19 PM

Hello,

I no longer want to receive the PSUMInfo email notifications regarding this issue. Can someone please remove my email address from the list?

Thank you,

-Chris Moniz

From: [Mark](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Analytical testing methods for MCB
Date: Tuesday, January 26, 2016 10:42:52 AM

I spoke with Naomi yesterday about several questions I have concerning the proposed analysis of marijuana under the auspices of the MCB, and she suggested that I frame these in an e-mail.

In no particular order, they are:

Is there a proposed approved analytical method for said testing?

One possible ready answer to this is to use the UNODC (United Nations Office on Drugs and Crime) method ST/NAR/40, ISBN 978-92-1-148242-3.

This would be a credible and recognized method widely accepted by most authorities.

Will the State of Alaska be performing any QC testing internally, and (if so) where?
Corollary - will there be a charge for this service?

Are there security requirements for an analytical lab's storage of samples?

For disposal of waste such as used solvents and excess samples (such as those that have exceeded their holding times)?

Is there a contact point person for marijuana analysis for the MCB?

There are several more points I'd like to clear up, but these will suffice for now.

Regards,

Mark Stowell
S & W Analytical
903-787-9087

Stowellmark@aol.comn

From: [Anna Marley](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Cc: [John Burns](#)
Subject: Application Forms
Date: Thursday, January 28, 2016 12:14:29 PM

Ms. Franklin:

After reviewing the Public Notice of the Marijuana Control Board Meeting on February 11th, the January 25th Press Release, and having visited the FAQ site as directed by the Board's voicemail message, I am confused as to when applications for licensing will be available. The meeting Notice states that the Board will consider the agenda for approval of forms and updated timeline for licensing, the Press Release states that the Board will spend the next 6-months finalizing application forms; and the answer to FAQ ("What is the timeline for implementation?" and "Is the Board keeping a list of interested businesses?") states that the Board will start accepting applications by February 24th and will act on those applications within 90 days.

We represent a Fairbanks business that is interested in applying for a marijuana cultivator and/or retail license. We would appreciate your advising us when the applications will be available and, if already available, where we can obtain them.

Thank you,

Anna

Anna M. Marley

**Legal Assistant
Burns & Associates, PC
100 Cushman Street, Suite 311
Fairbanks, Alaska 99701
Telephone: 907-452-1666; Facsimile: 907-456-5055**

Law Office of Burns & Associates - Confidential Attorney-Client Communication

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From: [Jon C](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Cultivation Facility License Prior To Construction
Date: Friday, January 29, 2016 5:13:44 AM

To Whom It May Concern:

Will I be able to apply for a marijuana cultivation facility license for an undeveloped piece of land assuming blue prints for construction are provided and all other application requirements are met?

Thank you,

Jonathan Cortez
(907) 862-5309

From: [jerad brown](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Cultivation facility rules
Date: Thursday, January 28, 2016 12:13:04 PM

Does a cannabis cultivation facility have to be privately owned or can it have a bank lien on it? In other words, can I buy a warehouse through a bank by financing it, then use that warehouse to grow?

Thank you

From: [Johnston, Naomi A \(CED\)](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: FW: Contact us - Website
Date: Monday, February 01, 2016 8:14:55 AM

From: Maxcell Graves [mailto:graves@acsalaska.net]
Sent: Monday, February 01, 2016 8:03 AM
To: Johnston, Naomi A (CED)
Subject: Contact us - Website

To Ms. Johnston:

I would like to know when the Marijuana Handlers permit will be available and the cost?

Thanks,

Max Graves

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: [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: 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: [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: [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: [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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A regulated communication can either be in the form of a written opinion or some other communication that is not an opinion. The preceding communication is a written communication that is not an opinion. Accordingly, it cannot, by itself, be relied upon to avoid, and assure protection from, tax penalties associated with it in any way. Such assurances, if possible, can only be obtained by securing an opinion letter. Should you wish to explore the option of receiving an opinion letter relating to the matter described above, or any other matter, please contact us so that we may discuss it with you.

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: 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

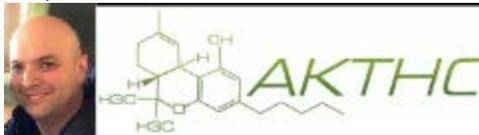
Each person whose name appears on the label as handling agricultural or vegetable seed subject to this chapter shall keep for two years a complete record of each lot of agricultural or vegetable seed handled, and shall keep for two years a file sample of each lot of seed after final disposition of the 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: [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: [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

From: [Treyvon Milner](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Restrictions Inquiry
Date: Tuesday, January 26, 2016 6:50:20 PM

Hello,

I have a few questions regarding the regulations and restrictions around the cannabis industry.
Industry

- 1). Under 3 AAC 306.405. Standard marijuana cultivation facility: privileges and prohibited, the terms "prepare" and "package" are loosely defined and I was wondering if rolling a marijuana cigarette qualifies as preparation and/or packaging and can be then further packaged for re-sale by a marijuana retail store or if it is considered a marijuana product?
- 2). Where would I find the regulations and restrictions regarding vertical integration and the operations of Marijuana Cultivation Facilities and Marijuana Retail stores under one company.
- 3). Is there an ideal place to print out copies of the Municipality Rules/Regulations and MOA business zoning maps surrounding marijuana and if so, where would it be?

And finally,

- 4). Has any decision been reached as to how much the fees will be for each individual license and how much sales tax will be?

Thank you for your time and consideration,
Trey M.

Cheers

From: [zells](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: store question II
Date: Tuesday, January 26, 2016 11:42:13 AM

Hi,

I just sent an email about opening a glass/tee shirt shop before the marijuana becomes available. I should clarify that further by saying this is using the SAME building. So glass first and adding marijuana later in the same building.

Thanks Again
Peter Zell

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

From: [zells](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: store question
Date: Tuesday, January 26, 2016 10:57:14 AM

Hello,

As I am waiting for my license approval from the State, can I open the store as a glass and tee shirt store with no marijuana on the premises?

Thank You
Peter Zell

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

From: [Joseph Robinson](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Zoning Question
Date: Tuesday, January 26, 2016 1:42:48 PM

I am interested in leasing a property which is located in a B3 zone, however, this particular premises is located just next to an R3 zoned area. Are there any restrictions- such as the 500-foot rule for schools, churches etc., along the borders of R3 zoned properties?

Thank You for your assistance,

Sincerely,

Joe Robinson

From: [Ginger Smith](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Board Chair Ex Parte?
Date: Wednesday, January 27, 2016 10:57:54 PM

To Whom It May Concern:

I've been following the Marijuana Control Board meetings and regulations process quite closely, and while doing a Google search, I came upon this article in a San Francisco newspaper:

<http://m.sfgate.com/news/article/Pot-testing-rules-difficult-to-meet-for-island-6786754.php>

I have copied the full article at the end of this email.

One sentence in particular caught my attention:

"Aaron Bean, a Sitka resident who hopes to open marijuana cultivation and retail businesses, helped Schulte draft the amendment."

While listening to the many board meetings over the past year, I've heard the Marijuana Control Board members receive training during multiple meetings regarding ethics, board etiquette, and the regulations process. It's my understanding that ex parte conversations by board members are prohibited during the regulations drafting process.

A potential marijuana license applicant helping the Marijuana Control Board Chair draft an amendment to the proposed regulations sure seems to meet the definition of ex parte to me. I understand from this article and others that the particular amendment mentioned ended up being taken out in the version signed by the lieutenant governor, but one could assume that if Mr. Schulte had assistance from a potential industry member with drafting one amendment, that he probably had assistance with drafting others.

I, as a parent, voting citizen of Alaska, and concerned member of the public, am alarmed that the board chair is making back-door collaborations with the "industry" regarding potential changes to the regulations. What's the point of the public comment process if the board chair is going to have a secret meeting to draft amendments?

Although it has seemed at times like the industry board members have run the show, I've been relatively impressed by what I've heard during the meetings and read throughout the regulations drafting, and I appreciated hearing multiple and differing perspectives from the board members about potential regulations. I would, however, question Mr. Schulte's integrity, ethics, and/or competence as the board chair of a regulated and highly controversial new industry. It seems like the others involved want this thing to be done well, to be done honestly, and to be done fairly. If Mr. Schulte can't play by the rules, then he sure shouldn't be writing them.

Sincerely,

Ginger Smith

KETCHIKAN, Alaska (AP) — Lt. Gov. [Byron Mallott](#) has turned down a proposed change to marijuana regulations that would have made it easier for southeast and rural Alaska communities to comply with testing requirements.

Mallott signed testing regulations drafted by the [Alaska Marijuana Control Board](#) on Friday. The rules were approved without a provision that would have allowed alternative testing requirements for communities off the road system, The Ketchikan Daily News reported (<http://bit.ly/1QBHUzX>).

The Nov. 20 amendment stated that "when geographic location and transportation limitations make it unfeasible for a manufacturing facility to transport testing samples to a lab, an applicant for licensure may propose alternative means of testing to meet the requirements of this code."

[Bruce Schulte](#), chairman of the control board and the head of the [Alaska Marijuana Industry Association](#) board, had pushed for the amendment. He said the [Alaska Department of Law](#) rejected the change because it was too board.

As the state moves closer to accepting marijuana license applications, there remains a challenge for island communities with access to testing facilities. State rules require marijuana to be tested before businesses can sell it, and federal law prohibits air and water transportation of cannabis.

Information provided to the Marijuana Control Board indicates that testing equipment can carry six-figure price tags, which may put a testing facility out of reach for the smaller communities.

Aaron Bean, a Sitka resident who hopes to open marijuana cultivation and retail businesses, helped Schulte draft the amendment.

"There's no real realistic way to assume we would be a big enough market to support a \$500,000 to \$700,000 lab," Bean said. "... Not only that, but the state is requiring a doctorate with two years of lab experience, and there's just not a lot of those folks running around who would want to do that."

Bean said he plans to keep pushing for an amendment that would allow an alternative testing plan for island communities.

"I think that there's a lot of things (in the Department of Law review) that make sense from their side," Bean said. "We can make this work. I'm confident."

Information from: Ketchikan (Alaska) Daily News, <http://www.ketchikandailynews.com>

From: [Dani Phelps](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Business licence
Date: Tuesday, January 19, 2016 10:07:25 PM

What type of business license do I apply for if I apply for a commercial marijuana grow?
Would it be agricultural business license? And is it different for a dispensary?

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: [TIMOTHY JOHNSON](#)
To: [Calder, John P. \(CED\)](#)
Subject: Comments on Draft Articles 1-9
Date: Saturday, November 21, 2015 9:42:26 AM
Importance: High

Mr. Calder,

Please consider the following comments before adopting state rules on marijuana regs:

Public notice -3 AAC 306.025 Application Procedure

The advertising requirement alerts those of criminal intent to the exact location of a licensed cultivation site. The requirement could result in physical harm and loss of property to the licensed establishment. Should an incident occur, the authorities requiring such notice may be held criminally and civilly liable. In layman's terms, advertising the location of a legal grow shouts to would-be thieves, Hey, here's the exact location of thousands of dollars worth of product! Come an' get it! I understand the intent of the requirement, but posting is sufficient and advertising the exact location is absurd.

Video surveillance 3 AAC 306.720

The cost of 40 days of storage is prohibitive. 40 days is also unnecessarily long. This is a huge disincentive to small businesses. Please reduce the number of days of storage.

Thank you for your consideration of these comments. Please send a response if possible.

Mr. Johnson

From: [April Neumann](#)
To: [Calder, John P. \(CED\)](#)
Subject: Comments on Draft Set 2
Date: Saturday, January 09, 2016 10:01:16 AM
Importance: High

Hello, thank you for your time. My comment to you is about public use. If you do not provide a way for public use you have failed to implement part of the initiative. It seems that it is being avoided or perhaps you don't have enough time or your just trying to keep it illegal. By the way, while we wait for you to regulate this to death, people are still being arrested for something that is now legal. It doesn't matter how illegal you try to make it, it's still legal.

Sent from my iPad

From: [Cheryl Bowie](#)
To: [Calder, John P. \(CED\)](#)
Subject: Community Based Paper
Date: Monday, December 07, 2015 10:50:49 AM
Importance: High

I sent this out on Facebook

This last year I have traveled to DC for AASLD and Caring Ambassadors.

During the process of participating in my Fellowship as a Liver Disease Ambassador for Caring Ambassadors so many of our communities have or are facing the legalisation of marijuana (Cannabis) I wanted to review new health statistics in the states that have gone full commercial development of Cannabis.

Things I am interested in longterm are

- 1) Reducing cancer deaths through cannabis
- 2) Reviewing treatment completion of patients using cannabis vs those who do not.
- 3) Affects of Cannabis on the liver
- 4) Harm Reduction through Cannabis and longterm outcomes of people using cannabis as a replacement drug in the area of illicit drug use.
- 5) Using cannabinoids via BHO and RSO as detox agents for heroin addicts and the success or failure of that.
- 6) Updated demographic information in each state
- 7) The number of Misdemeanor charges of possession of illicit drugs in states that have legalized Cannabis
- 8) Review broadly what cannabis is being studied for:
- 9) Disease transmission rates, what's risen or fallen. Could this help reduce HIV, HEP C and other communicable diseases
- 10) Identify educational material for people interested in consuming cannabis responsibly.

I'm putting together a presentation for Fellows of Caring Ambassadors called

Desire vs Fact: How is Cannabis changing our communities?

If you are a fellow with Caring Ambassadors please reach out to me if you want to assist or provide data for your state.

This is huge I'm so excited. Caring Ambassadors will allow us to provide and complete a presentation. I have reached out to different cannabis experts, one of which is Doug Fine, he wrote the book "Too High to Fail". Its about Cannabis Economics. He is willing to assist Caring Ambassadors just on their merit but I was wondering if Alaska would like to sponsor an event up here in which he could also be a wonderful resource for our new industry.

I am not sure what all of it looks like quite yet and if I could get funding on some level or a sponsor to help get this together that would be awesome because its bigger than anticipated.

Please forward to the board for informational purposes.

Sincerely,

Cheryl Bowie
907-903-6513

From: [Jon C](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Cultivation Facility License Prior To Construction
Date: Friday, January 29, 2016 5:13:44 AM

To Whom It May Concern:

Will I be able to apply for a marijuana cultivation facility license for an undeveloped piece of land assuming blue prints for construction are provided and all other application requirements are met?

Thank you,

Jonathan Cortez
(907) 862-5309

From: [jerad brown](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Cultivation facility rules
Date: Thursday, January 28, 2016 12:13:04 PM

Does a cannabis cultivation facility have to be privately owned or can it have a bank lien on it? In other words, can I buy a warehouse through a bank by financing it, then use that warehouse to grow?

Thank you

From: [lawrence wood](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: current marijuana regulations needing clarification
Date: Wednesday, January 06, 2016 10:08:57 AM

Good day and thanks for all your hard work.

There are 2 issues the board should attempt to clarify regarding personal cannabis and its relationship to the forthcoming commercial institution.

First, as one more interested in growing and processing my own cannabis, there is no good or legal way of obtaining clones or seeds as cultivation facilities are prohibited from selling directly to the public. As there are no seed banks up here and the care of clones may be cost prohibitive, retail shops aren't likely to sell either. Please consider allowing the public to purchase clones directly from growers.

Second, plants per residence needs to be clarified. As I read the law, the right to grow 6 plants belongs to individual Alaskans, not Alaskan households. I assume therefore that in my home which I own jointly with my spouse, each of us can grow 6 plants, total of 12. If my adult son and my brother live with us, they also have the right to grow 6 plants each with my permission. Now there are 24 plants growing in my home. At what point does this "appear" to be a commercial operation. A question posed on the FAQs section of the website alluded to "the legal limit for the residence" set forth in AS 17.38.020. Unless I have an incomplete copy, I can find no mention of such a residential limitation other than requiring permission of the property owner. I have read the 2 references provided. They appear neither helpful nor contributory. But then I'm not an attorney. I'm a private citizen wishing to obey the law. Please clarify this for those of us without legal degrees!

Thank you for your time.
LW



U.S. Department of Justice

Office of the Deputy Attorney General

The Deputy Attorney General

Washington, D.C. 20530

February 14, 2014

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: James M. Cole 
Deputy Attorney General

SUBJECT: Guidance Regarding Marijuana Related Financial Crimes

On August 29, 2013, the Department issued guidance (August 29 guidance) to federal prosecutors concerning marijuana enforcement under the Controlled Substances Act (CSA). The August 29 guidance reiterated the Department's commitment to enforcing the CSA consistent with Congress' determination that marijuana is a dangerous drug that serves as a significant source of revenue to large-scale criminal enterprises, gangs, and cartels. In furtherance of that commitment, the August 29 guidance instructed Department attorneys and law enforcement to focus on the following eight priorities in enforcing the CSA against marijuana-related conduct:

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;
- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession or use on federal property.

Under the August 29 guidance, whether marijuana-related conduct implicates one or more of these enforcement priorities should be the primary question in considering prosecution

under the CSA. Although the August 29 guidance was issued in response to recent marijuana legalization initiatives in certain states, it applies to all Department marijuana enforcement nationwide. The guidance, however, did not specifically address what, if any, impact it would have on certain financial crimes for which marijuana-related conduct is a predicate.

The provisions of the money laundering statutes, the unlicensed money remitter statute, and the Bank Secrecy Act (BSA) remain in effect with respect to marijuana-related conduct. Financial transactions involving proceeds generated by marijuana-related conduct can form the basis for prosecution under the money laundering statutes (18 U.S.C. §§ 1956 and 1957), the unlicensed money transmitter statute (18 U.S.C. § 1960), and the BSA. Sections 1956 and 1957 of Title 18 make it a criminal offense to engage in certain financial and monetary transactions with the proceeds of a “specified unlawful activity,” including proceeds from marijuana-related violations of the CSA. Transactions by or through a money transmitting business involving funds “derived from” marijuana-related conduct can also serve as a predicate for prosecution under 18 U.S.C. § 1960. Additionally, financial institutions that conduct transactions with money generated by marijuana-related conduct could face criminal liability under the BSA for, among other things, failing to identify or report financial transactions that involved the proceeds of marijuana-related violations of the CSA. *See, e.g.*, 31 U.S.C. § 5318(g). Notably for these purposes, prosecution under these offenses based on transactions involving marijuana proceeds does not require an underlying marijuana-related conviction under federal or state law.

As noted in the August 29 guidance, the Department is committed to using its limited investigative and prosecutorial resources to address the most significant marijuana-related cases in an effective and consistent way. Investigations and prosecutions of the offenses enumerated above based upon marijuana-related activity should be subject to the same consideration and prioritization. Therefore, in determining whether to charge individuals or institutions with any of these offenses based on marijuana-related violations of the CSA, prosecutors should apply the eight enforcement priorities described in the August 29 guidance and reiterated above.¹ For example, if a financial institution or individual provides banking services to a marijuana-related business knowing that the business is diverting marijuana from a state where marijuana sales are regulated to ones where such sales are illegal under state law, or is being used by a criminal organization to conduct financial transactions for its criminal goals, such as the concealment of funds derived from other illegal activity or the use of marijuana proceeds to support other illegal activity, prosecution for violations of 18 U.S.C. §§ 1956, 1957, 1960 or the BSA might be appropriate. Similarly, if the financial institution or individual is willfully blind to such activity by, for example, failing to conduct appropriate due diligence of the customers’ activities, such prosecution might be appropriate. Conversely, if a financial institution or individual offers

¹ The Department of the Treasury’s Financial Crimes Enforcement Network (FinCEN) is issuing concurrent guidance to clarify BSA expectations for financial institutions seeking to provide services to marijuana-related businesses. The FinCEN guidance addresses the filing of Suspicious Activity Reports (SAR) with respect to marijuana-related businesses, and in particular the importance of considering the eight federal enforcement priorities mentioned above, as well as state law. As discussed in FinCEN’s guidance, a financial institution providing financial services to a marijuana-related business that it reasonably believes, based on its customer due diligence, does not implicate one of the federal enforcement priorities or violate state law, would file a “Marijuana Limited” SAR, which would include streamlined information. Conversely, a financial institution filing a SAR on a marijuana-related business it reasonably believes, based on its customer due diligence, implicates one of the federal priorities or violates state law, would be label the SAR “Marijuana Priority,” and the content of the SAR would include comprehensive details in accordance with existing regulations and guidance.

services to a marijuana-related business whose activities do not implicate any of the eight priority factors, prosecution for these offenses may not be appropriate.

The August 29 guidance rested on the expectation that states that have enacted laws authorizing marijuana-related conduct will implement clear, strong and effective regulatory and enforcement systems in order to minimize the threat posed to federal enforcement priorities. Consequently, financial institutions and individuals choosing to service marijuana-related businesses that are not compliant with such state regulatory and enforcement systems, or that operate in states lacking a clear and robust regulatory scheme, are more likely to risk entanglement with conduct that implicates the eight federal enforcement priorities.² In addition, because financial institutions are in a position to facilitate transactions by marijuana-related businesses that could implicate one or more of the priority factors, financial institutions must continue to apply appropriate risk-based anti-money laundering policies, procedures, and controls sufficient to address the risks posed by these customers, including by conducting customer due diligence designed to identify conduct that relates to any of the eight priority factors. Moreover, as the Department's and FinCEN's guidance are designed to complement each other, it is essential that financial institutions adhere to FinCEN's guidance.³ Prosecutors should continue to review marijuana-related prosecutions on a case-by-case basis and weigh all available information and evidence in determining whether particular conduct falls within the identified priorities.

As with the Department's previous statements on this subject, this memorandum is intended solely as a guide to the exercise of investigative and prosecutorial discretion. This memorandum does not alter in any way the Department's authority to enforce federal law, including federal laws relating to marijuana, regardless of state law. Neither the guidance herein nor any state or local law provides a legal defense to a violation of federal law, including any civil or criminal violation of the CSA, the money laundering and unlicensed money transmitter statutes, or the BSA, including the obligation of financial institutions to conduct customer due diligence. Even in jurisdictions with strong and effective regulatory systems, evidence that particular conduct of a person or entity threatens federal priorities will subject that person or entity to federal enforcement action, based on the circumstances. This memorandum is not intended, does not, and may not be relied upon to create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal. It applies prospectively to the exercise of prosecutorial discretion in future cases and does not provide defendants or subjects of enforcement action with a basis for reconsideration of any pending civil action or criminal prosecution. Finally, nothing herein precludes investigation or prosecution, even in the absence of any one of the factors listed above, in particular circumstances where investigation and prosecution otherwise serves an important federal interest.

² For example, financial institutions should recognize that a marijuana-related business operating in a state that has not legalized marijuana would likely result in the proceeds going to a criminal organization.

³ Under FinCEN's guidance, for instance, a marijuana-related business that is not appropriately licensed or is operating in violation of state law presents red flags that would justify the filing of a Marijuana Priority SAR.

From: [Jake Staser](#)
To: [Calder, John P. \(CED\)](#)
Subject: Database of Local Ordinances
Date: Wednesday, January 20, 2016 11:54:38 AM
Importance: High

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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In October, Palmer decided to ban commercial marijuana businesses within the city limits by a vote of 374 to 318. Around the same time, the Marijuana Control Board was drafting regulations, one of which states that if a municipality bans commercial pot businesses, they're also banned within 10 miles of that municipality. This is a great disappointment for me, as I had hoped to get a cultivation license, and I live just about a mile north of Palmer's boundary.

I know that the Marijuana Control Board is basing that 10 mile zone on local option statutes in Title 4 and the revisions in Senate Bill 99, but in both texts and all of their other assorted incarnations, the stated reason for these local options is to control problem drinking in rural areas—the kind of drinking that often leads to violence, suicide and other legal and social problems that plague some rural communities.

I don't believe that the 10 mile boundary around Palmer is legally justified for several reasons. First, the situation with alcohol in villages is very much different than marijuana in Palmer. Before statehood, Alaskan villages could exercise a local option to ban alcohol possession under authority of the Indian Reorganization Act of 1936, but after statehood, villages found those bans unenforceable because there were no state laws against importation or possession. By the 80s, Alaska Natives living in villages were dying from homicide, suicide and accident five times more frequently than the national rate and in most of these deaths, alcohol was involved. With the 1980s revisions of Title 4, rural communities were once again able to use the local option as a way to control alcohol and its associated problems. However, there's no credible evidence that marijuana is the cause of violence or suicide, so the Marijuana Control Board had no justification for the enforcement of a local option. Also Senate Bill 99 suggests changes to Title 4 that include free samples of beer, wine, and distilled spirits so that the popular brewpubs in urban areas can sell their wares—that's sort of the opposite of a local option to ban alcohol sales but underscores the fact that the local option in Title 4 refers to rural jurisdictions.

One other proposed revision in Senate Bill 99 is to repeal local option #4—the option that bans the sale and importation of alcohol but not possession. The stated intent is that if possession isn't banned, enforcement is compromised because anyone can claim to have "found" the alcohol and not be involved in the other prohibited activities. Because of the language of AS 17.38, Palmer could not ban the possession of marijuana. Palmer will likely face the same types of enforcement problems as alcohol in the villages but for no good reason, costing the city and the state much needed revenue for enforcement personnel, court costs and so on.

Village local options since the 80s have included a zone of five miles around communities that vote to ban alcohol in order to make enforcement easier. The stated intent of the proposed increase to 10 miles in Senate Bill 99 is for the same reason. A buffer zone of 5 to 10 miles makes sense in a village setting where limited funds and a shortage of personnel make enforcement difficult, but that ban won't serve the same purpose with marijuana in and around Palmer. Palmer has no shortage of police and is easily accessible by road, making the 10 mile zone burdensome and unjustified.

The explicitly stated intent of Title 4 and Senate Bill 99 local options is to address the "increase in alcohol-related problems and deaths" in rural Alaska. Since marijuana doesn't cause those types of problems, I believe that the MCB's 10 mile zone around Palmer is an unwarranted case of extraterritorial jurisdiction. AS 20.35.020 deals with extraterritorial jurisdiction in Alaska. The statute states that it's permissible only under specific circumstances, none of which applies to

commercial businesses. I don't see any other way to view it—this is an infringement of AS 20.35.020.

And what about ballot box representation? I wasn't allowed to vote in Palmer's election and yet their very narrow voter ban applies a huge burden on the rest of us within that ten mile boundary. Ten miles actually extends all the way into Wasilla. I know that since Wasilla is its own town, it's not subject to Palmer's laws, but where will the various government agencies draw the line between them? Right on Wasilla's city limits? The way the regulation is written, it sounds like the ban extends 10 miles from every jagged point in the Palmer's boundary. What an enforcement nightmare! The ban also extends to most of the good agricultural land in Alaska which seems crazy to me. I know that other people besides myself are/were planning to cultivate marijuana in the ground and what better ground than that in the Palmer valley? This regulation will keep farmers forever struggling to make it here instead of growing what could be for once a profitable operation. I've been cultivating my land, bringing in compost, working it with a pitchfork and shovel, amending with organic materials, and so on to grow flowers for greenhouses and weddings, etc. and believe me, there's isn't much money in it, especially considering that during the summer, I work between 12 and 16 hours per day. But for two years now, I'm been preparing for a future in the commercial cultivation of marijuana. Farming has always been marginal in Alaska, but this could mean much better incomes for people who've been trying to eek a living out of the land here for years.

Also, Palmer's ballot and its complete initiative to ban commercial pot businesses never said one word about a 10 mile boundary. I think many of those voters would have voted differently if they'd known about it because they understand that Palmer was established by farmers and it still has the greatest number of farmers in Alaska. Many of those voters recognize that farming needs an economic boost if it hopes to survive.

Additionally, the majority of Palmer's voters voted for recreational marijuana in the general election. I understand that many of those voters didn't turn out for the more recent election but it seems to me that the intent of the general election vote is being circumvented by this more recent election.

I hope to hear from you about this issue and also hope that you can provide some help to remove the 10 mile zone from the draft copy of the new laws before they take effect.

Thank you for your time.

Sincerely,
Sharon Sibbald
PO Box 1682
Palmer, AK 99645
907 350-1872
sharon_sibbald@yahoo.com

From: [Bob Morgan](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Draft Rule Interpretation Question [IWOV-MS1.FID447781]
Date: Monday, January 11, 2016 9:43:24 AM

To Whom It May Concern:

I had an interpretation question about Final Regulations as adopted and amended by the Marijuana Control Board.

Administrative rule 3 AAC 306.435(a): "Clones or cuttings must be limited to 50 or fewer plants and identified by a batch tracking number."

The definition in draft rule 3 AAC 306.990(b)(9): "'clones' or 'cuttings' means small starter plants (A) shorter than eight inches tall; and (B) used to propagate marijuana plants;"

As the administrative rules are still awaiting approval by the Governor's Office and Department of Law, I am seeking clarification on the following questions:

- 1) Is a licensee limited to 50 or fewer total clones or cuttings for the entire facility?
- 2) Conversely, is this language implying a single clone ("clone A") may only be used for a single batch of up to 50 plants, "clone B" may be used for a separate batch of up to 50 plants, and so on?
- 3) Is there a limit on the number of "mother plants" per facility?
- 4) If seeds are used, is there a limit to the number of seeds and seedlings shorter than eight inches tall at any given time?

Thank you for your assistance,

-Bob Morgan

(312) 521-2474

rmorgan@muchshelist.com

Bob Morgan

Much Shelist, P.C.

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Chicago, IL 60606

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From: [Sam Friedman](#)
To: [Calder, John P. \(CED\)](#)
Subject: Fairbanks News-Miner inquiry
Date: Monday, November 23, 2015 3:55:21 PM
Importance: High

Hi John,

I'm reporting on the opening of a new marijuana club here in Fairbanks. It's called The Higher Calling ([facebook.com/THCFairbanks/?fref=ts](https://www.facebook.com/THCFairbanks/?fref=ts)).

I'd like to know if this kind of business is legal under ACB regulations. The owner's understanding is that it is, especially after changes made at Friday's board meeting.

- 1) Is that also your understanding?
- 2) Does the ACB have a similar stance Pot Luck Events? A similar business down in Anchorage?

Cheers,
Sam

--

Sam Friedman

Outdoors editor

Fairbanks Daily News-Miner

p: 907-459-7545

sfriedman@newsminer.com

@FDNMoutdoors

www.newsminer.com

From: [cliff rider](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Felony conviction and permitting?
Date: Monday, January 04, 2016 9:33:07 PM

Greetings, I have a felony conviction (DUI) that is more than 5 years old, am I eligible to apply for a permit? I have read the regulations and it appears that as of now I am not eligible with any felony convictions-ever, I know that initially in the creation of the regulations they had the 5 year limit in place, did they revise it or am I reading it wrong?

Thanks

From: [Rex Powers](#)
To: [Calder, John P \(CED\)](#); [Franklin, Cynthia A \(CED\)](#)
Subject: FOCUS STANDARDS
Date: Thursday, December 03, 2015 10:24:27 PM
Attachments: [State Summary.pages](#)
Importance: High

John, Good evening.

Thank you again for taking time to accept my call this afternoon.

I wanted to get off a short response and follow up to the call....I have attached a overview summary of FOCUS and a very simple "perspective" of how we see standards as the foundation for establishing a compliance driven Cannabis Program for any state or municipality.

After 18 months of structured development the standards are complete and we are beginning our pilot program next week. We anticipate full ANSI accreditation by Q2 2016 and have started connecting with a number of states to explore timelines and budgets for implementation.

Please review this short document as well as our web site and feel free to reach back out at your convenience as I am sure you or your staff will have questions that we are happy and anxious to answer.

Just as a side note...FOCUS is a non profit 501C3 and we are the only organization in the world that is established for the sole and exclusive purpose of developing Quality/Safety Standards for the legal cannabis industry.. FOCUS IS NOT a trade or membership organization...nor are we a "advocacy" group.

Best wishes and we look forward to learning how we can assist you in building a SAFE, sustainable and standards driven cannabis economy for ALASKA!

Rex

--

Rex Powers
President & CEO
Foundation of Cannabis Unified Standards
602-692-9470

www.focusstandards.org

Our mission:

To protect public health, consumer safety, and promote integrity within the cannabis industry.

FOCUS IS A 501c3 NON PROFIT ORGANIZATION

THE FOCUS MISSION:To protect public health, consumer safety, and promote integrity within the cannabis industry.



From: [Jody Tow](#)
To: [Calder, John P. \(CED\)](#)
Subject: FW: ABC Board Website Question
Date: Friday, January 15, 2016 3:11:53 PM
Importance: High

Good afternoon,

I have some questions below that I emailed Ms. Franklin about on Monday but am still awaiting a response. Could you please forward these questions to the appropriate person that can answer them for me? I appreciate it.

Thank you,

Jody Tow
Finance Director
Petersburg Borough
P 907.772.4425|F 907.772.3759
jtow@petersburgak.gov

From: Jody Tow
Sent: Monday, January 11, 2016 1:29 PM
To: 'cynthia.franklin@alaska.gov'
Subject: ABC Board Website Question

Good Afternoon,

I enjoyed your presentation on the new State marijuana regulations at the AGFOA conference that was held in Anchorage last fall. As the Petersburg Borough forms its' own ordinance on the topic I had a couple of questions that I have been asked that I don't know the answer to.

1. Can the Borough form an excise tax on marijuana similar to tobacco?
2. Can you clarify what you said at the meeting about medical marijuana? Am I correct that having a medical marijuana card does not entitle a sales tax exemption similar to a medical drug prescription?
3. Is it possible to get a medical prescription from a doctor for medical marijuana that is different from having a "medical marijuana card" that could be considered tax exempt?

Thanks for your help on this, I am sure that you are extremely busy.

Thanks again,

Jody Tow
Finance Director
Petersburg Borough
P 907.772.4425|F 907.772.3759
jtow@petersburgak.gov

From: bob_bradley
To: [Calder, John P. \(CED\)](mailto:Calder, John P. (CED))
Subject: Fw: Changing -AGAIN- the Residency requirements for applying for ANY Marijuana license.
Date: Wednesday, November 25, 2015 6:50:14 PM
Importance: High

--- On Tue, 11/24/15, bob_bradley <bob_bradley2003@yahoo.com> wrote:

> From: bob_bradley <bob_bradley2003@yahoo.com>
> Subject: Changing -AGAIN- the Residency requirements for applying for ANY Marijuana license.
> To: PSUMInfo@alaska.gov, "governor@gov.state.ak.us" <governor@gov.state.ak.us>, "newstips@alaskadispatch.com" <newstips@alaskadispatch.com>
> Date: Tuesday, November 24, 2015, 3:33 AM
> I read several day's ago that the board had
> ,by a 3/5 vote, changed the residency requirement from
> Permanent Fund to ALL other form's of Alaska Residency.
> This , then ALLOWED me TO QUALIFY for application
> purposes, as I've NOT applied for a PFD in at least a
> decade, as I have been absent from Alaska, more than 180
> day's, due to RETIREMENT in Thailand. Why, NOT
> retain real property in Alaska, Why NOT visit every 3/6
> month's, etc., yet maintain my VOTING RIGHTS in Alaska,
> hold a valid driver's License, etc.. Because my
> combined income is \$1,600.00 per month = SSI & State
> Retirement (though GREAT Medical Insurance). The
> answer is clearly, I do NOT receive enough money to live
> & OR to provide for my Thai wife.... we once had a
> Green Card, which would have allowed her to Clean toilets,
> as any decent immigrant is allowed & then mandated to
> not be absent from America, because the privilege of
> American work in such fields is necessary , we won't
> (Americans)do it & that's why you're granted a
> Green Card === Anyway, 6 years ago, at the birth of
> our oldest grand son, Kow-pun, we decided to return the card
> because we were needed to take care of the child- 2 times
> for 4-6 month's each - those pesky- Fucking Family
> Values, thus we couldn't return, as required , with NO
> more than a 6 month's absence. This summer my wife
> and I returned , again, to Anchorage ; compelled to mooch
> off FRIENDS, until, through letters of recommendation, we
> were allowed to RENT an apartment on Govt. Hill - \$695.00
> per month. Because I'm such a GREAT fucking Human
> Being, I applied for 50+ job's - I'm 71. As U
> know it's against the law to discriminate based on AGE =
> so the employer, just does NOT respond, that breaks - NO
> LAW. I was lucky, I got a job at a Hamburger FrANCHISE
> & AT A LOCAL Whisky store..... worked BOTH
> job's @ \$10.00 an hour - LUCKY. My relevant
> background is this : I served my state, in the
> legislature, much like a Fucking Marine, I caused to
> be written, caused it to be passed and caused the Governor
> to allow it to become= Law, the decriminalization of
> Marijuana & PROBABLY gave COVER to the state

> Supreme Court in their Raven decision, which they decided -
> 1 week after the passage of the above bill..... I
> additionally read the press comments by an A.G. Female per
> the issue of the Residency change == how FUCKING dare
> she make those editorial - personal opinion- comment's
> & how dare the Executive Director of the Pot &
> Whisky Office - a Quasi-Fucking, Judicial Office & Body,
> make Her editorialized comments. Why do I want to
> apply for a Marijuana License --- To Make Money!!!
> What's the relavent shit here, after my state
> service I opened a business, it was successful, I SOLD it,
> Opened another, it was successful, I Sold It, again I
> operated another business, successful, I Sold It.. etc ===
> ALL " Mom & Pop ' types - NEVER big time
> - NEVER BANKRUPT!!.. Now you want to go back on
> RECONSIDERATION and change the reg per Residency to the PFD
> standard, AGAIN, EXCLUDING ME... With NO public
> comment, but ALLOWED, written- how fucking tasteful.
> If you change that timid 3rd Vote - through AG.s or
> state employees , not withstanding the 5 member board - U
> will DAMAGE ME and my Family - my wife and I would operate
> the store by ourselves , we would ,eventually buy a LITTLE
> place so we could return regularly to my AMERICAN / Alaskan
> home , which I've called home and VOTED since
> 1960/64..... bucks made would go to MY/OUR grand
> kids===== what U thought, that I wanted to control the
> world of WEED/ to Franchise the fucking Universe? I
> NOW ask U to NOT change / reconsider the VOTE, I ask the
> Governor, who I just met in the elevator, on my way to your-
> Whisky/Pot office to intervene & I ask ALL Alaskan's
> of Good Morals & Cheer - even the Press to STOP this
> excessively restrictive threat..... further, If Weed
> is to Alcohol via the VOTE & the STATED INTENTION on the
> Ballot - Plain ENGLISH..... are the Requirements of a
> whiskey license, the requirements of the Permanent Fund
> Dividend OR are they otherwise??! === Bob
> Bradley...553-58-1198, adl:
> 0161241

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

From: Alaska Glass Gardens Alaska Green Cross [mailto:akgreenglaciers@gmail.com]
Sent: Tuesday, February 02, 2016 2:58 PM
Subject: Fwd: Compliance Tools for the Cannabis Industry

As You might know I am the mother of a 18 yr old who nwas killed in Down Town Anchorage over a Gram of marijuana, so I hope You will take that in to consideration when I say that this is hands down the best way to keep the industry workers number 1 Safe and number 2 Honest. Happy to answer any questions you may have please call me in regards to a visit to our Dimond location

One Love

----- Forwarded message -----

From: **Mikey Margolin** <Mikey@c4eversystems.com>
Date: Tue, Feb 2, 2016 at 1:05 PM
Subject: Compliance Tools for the Cannabis Industry
To: Alaska Glass Gardens Alaska Green Cross <akgreenglaciers@gmail.com>

Hello Adele,

This email is to inform you and the State of Alaska of the compliance, transparency and safety of our system for the cannabis industry. Our robust and easy to use solution has been designed by former DEA agents, federal regulators and bank executives.

The combined forces of C4EverSystems and Kind Financial have made significant improvement in the cannabis tracking, accounting and banking area. We have worked closely with banking professionals in conjunction with federal authorities to ensure all FinCEN's, "BSA Exceptions Regarding Marijuana Related-Businesses" (FIN-2014-G001) and Deputy Attorney James M. Cole's Memo, "Guidance Regarding Marijuana Enforcement" guidelines have been addressed and properly monitored.

Kind Financial's Seed-To-Sale tracking system, Agrisoft, was developed in response to state

regulations that control the cultivation, storage, transportation, sale, transfer, processing, testing, record-keeping, and destruction of cannabis. This system was guided by COO Matt Cook the author of Colorado's successful medical marijuana statute. Mr. Cook is former Senior Director of Enforcement for the Colorado Department of Revenue and has now been consulting a variety of different states and countries with the kiosk payment solution. C4Ever provides public facing kiosk to dispensaries that are fully integrated with the Agrisoft system. Since 2006, The C4Ever technology has processed over \$500 million in transactions for highly regulated government entities such as jails, prisons, police departments, courthouses and municipalities. This technology is now available to the cannabis industry.

Payment kiosks ensure that no cash changes hands with dispensary staff but, instead, is collected in an ATM-like kiosk that makes correct change, checks for counterfeit bills, and eliminates theft and errors. Customers either place and pay for their order at the kiosk then take a payment receipt to the counter for fulfillment or; work with dispensary personnel to place their order then directed to the kiosk to make their payment before fulfillment. All payments collected during a business day at dispensaries are accounted for in real time in the point-of-sale system for each dispensary and can be automatically uploaded to the State tracking system to prevent any black market sales. A current audit of sales may be taken at any time. At the end of the day, the kiosk produces a receipt accounting for all sales. The State, and/or bank, personnel will have visibility to these reports and a system login to facilitate auditing. The State will know exactly how much tax revenue was generated per account.

Payment kiosks in dispensaries, processors, and cultivation centers will ensure that every sale is accounted for and every dollar is collected and cannot be diverted illegitimately. The kiosk can take a picture of each person ensuring that each transaction is a sale to an individual qualified customer, not a bulk sale in disguise. The banks will be able to know the customer's customer for every deposit accepted.

Here is a [LINK](#) to download an additional presentation regarding our solution. Please let me know if you have any questions.

We look forward to working with you and developing a safe and successful cannabis program for the state of Alaska.

Thank you,

Mikey

Michael Anthony Tuccelli-Margolin
V.P. Operations



C4EverSystems
Cash Management

O: [844.424.3837](tel:844.424.3837)

C: [702.591.0818](tel:702.591.0818)

mikey@C4EverSystems.com

www.C4EverSystems.com

[Click Here](#) to learn about our products

From: [Johnston, Naomi A \(CED\)](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: FW: Contact us - Website
Date: Monday, February 01, 2016 8:14:55 AM

From: Maxcell Graves [mailto:graves@acsalaska.net]
Sent: Monday, February 01, 2016 8:03 AM
To: Johnston, Naomi A (CED)
Subject: Contact us - Website

To Ms. Johnston:

I would like to know when the Marijuana Handlers permit will be available and the cost?

Thanks,

Max Graves

From: [bob bradley](#)
To: [Calder, John P. \(CED\)](#)
Subject: Fw: December 1, 2015 Marijuana Meeting
Date: Wednesday, November 25, 2015 4:44:37 PM
Importance: High

On Thursday, November 26, 2015 8:38 AM, bob bradley <bob_bradley2003@yahoo.com> wrote:

On Thursday, November 26, 2015 7:00 AM, "Andrews, Maxine R (CED)" <maxine.andrews@alaska.gov> wrote:

Pursuant to Alaska Statutes, 17.38.083, the Marijuana Control Board is holding a meeting on December 1, 2015 in Anchorage, Alaska. At the meeting the Marijuana Control Board will discuss and may amend residency requirements in Article 1 of adopted regulations relating to licensing of marijuana establishments in 3 AAC 306.010 *et. seq.* No public testimony will be taken during this meeting.

The meeting will be located at 3601 C St (The Frontier Building), Room 880, Anchorage, Alaska. Some board members, the director, and counsel will appear telephonically. The public call in number for the meeting is [1-800-315-6338](tel:1-800-315-6338); code 69173#. The meeting will begin at 10:00 a.m.

The State of Alaska Department of Commerce, Community, and Economic Development complies with Title II of the Americans With Disabilities Act of 1990 and the Rehabilitation Act of 1973. Individuals with disabilities who may need auxiliary aids or services or special modifications to participate in this public meeting should contact John Calder by email at john.calder@alaska.gov to make any necessary arrangements.

Maxine Andrews

Business Registration Examiner | Dept. of Commerce and Economic Development | Alcohol and Marijuana Control Office
550 W. 7th Ave. Ste. 1600 Anchorage, AK 99501 | 907.269.0358 | fax 907.334.2285



Please consider the environment before printing this e-mail.

Less paper is better for us and our environment.

From: [Samaniego, Joe P. \(CED\)](#)
To: [Calder, John P. \(CED\)](#)
Cc: [Franklin, Cynthia A. \(CED\)](#)
Subject: FW: General Question
Date: Monday, December 07, 2015 1:30:50 PM
Importance: High

Joe Samaniego

Administrative Assistant I

907-269-0352 · joe.samaniego@alaska.gov

Alcohol & Marijuana Control Office

Department of Commerce, Community, & Economic Development

550 West 7th Avenue, Suite 1600

Anchorage, AK 99501-3569



Please consider the environment before printing this e-mail. Less paper is better for us and our environment.

From: Smokin AK Fine Cigars [<mailto:anchorpointsmokin@outlook.com>]
Sent: Monday, December 07, 2015 1:08 PM
To: Samaniego, Joe P (CED)
Subject: General Question

Good Day Mr. Samaniego

As a member of the Chamber of Commerce many individuals come to me for questions and answers dealing with issues concerning the State and its regulations. The marijuana board has set regulations for dealing with the sales of marijuana throughout the state. As per 3 AAC 306.010. license restrictions many towns such as Homer, Anchor Point, and Ninilchik for example have a church is located what seems to be within 300' feet within each other. Thus not giving the struggling local economy the opportunity to provide jobs, revenue and town improvements with such restrictions. My answer for the majority of the questions posed to me by individuals asking, agrees with are the restrictions on Schools and Youth Originations and correctional facilities but fall extremely short in support of the idea of the restrictions dealing with Churches. Will any waivers be granted provide that the local churches have no objection to the sales in their perspective towns if the store falls within the 500' foot mark?

Very Respectfully

John Cox

From: kenneth reese [mailto:rvk458@hotmail.com]

Sent: Wednesday, January 27, 2016 12:52 PM

To: Franklin, Cynthia A (CED)

Subject: Re: Marijuana legalization

I take it objections and ideas are over. The state is on too rules and regulations. This state can not answer the question I have. They are important and meaning full. I am a registered voter. Also a unjust convicted felon. In 2013 I was charged with growing pot with the intended purpose to distribute. I was the last person to be incarcerated in the State of Alaska for this crime. I was sentenced to 6 months flat time. I served 28 days in lemon Creek. the remainder in the halfway house. Under the new FBI back ground check policy for convicted felons. I take it I would not be eligible to apply for commercial growers license. correct? All this marijuana laws do not make any practical since. Because the State already convicted me for a crime that should never been a crime to begin with. I truly feel the commercialization of pot in Alaska will not work like it has, lets say like in Colorado. You see every state is different and unique. this Federal B>S is just that. Alaska could have been and still could be a leader in this field of legal Marijuana. You see By the time 26 or 27 states are on board, the federal government will be forced once again {not the first time in history it happened with alcohol after the end of prohibition.} to re recognize the STATES individual rights to govern its own citizens. That is how 50 states with 50 different alcohol laws came to be. but with Alaska we could have been the first state with 50 different pot laws that benefit each local community its the way they saw was best. the bill that passed basically gave each community in Alaska a blank slate to write there own laws on pot that they felt would best benefit the community that they live in. But not one could come up with anything? what did the voters or the state expect to happen? I personally was hoping that would have or still could happen. All the regulation are over kill for the state of Alaska and make no financial or business since. I do not know it all or claim too. but I do know a lot about this industry. I believe I know the best way to reduce the amount of pot that enters our state. I also believe my ideas are the fairest for the state of Alaska and its citizens. I know you are a busy person, but I am asking you to please listen to what I have to say. This is all for now, but you will keep hearing from me. I trust hope and pray you are open minded and educated enough to realize it might just be benefit to me and the State and the citizen of Alaska, to take a little of yours ours and the states time to listen to what I am saying? for all I know public input is over What your still working on the

rules and regulations? Does the State not to get it write the first time? I can explain why this is not going to work in the state of Alaska if you would listen to me. I believe it was you that said while you were here in Ketchikan, "

One thing I have found out the people who some pot are very passionate about it!! Well not only am I passionate about pot, I am also passionate about being a American, voicing my opinion and very passion about helping the State get This right lets not blow it. I look forward to corresponding with you more on this subject. Sincerely Kenneth G. Reese P.S I apolige for my writing skills, but if you need documented certified proof of my credentials, I do have them, certified and documented by the GREAT STATE OF ALASKA

From: Franklin, Cynthia A (CED) <cynthia.franklin@alaska.gov>
Sent: Wednesday, January 27, 2016 10:02 AM
To: kenneth reese
Subject: RE: Marijuana legalization

Hi Kenneth,

For marijuana questions you can use marijuana@alaska.gov. Thanks,

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

From: kenneth reese [<mailto:rvk458@hotmail.com>]
Sent: Wednesday, January 27, 2016 9:26 AM
To: Franklin, Cynthia A (CED)
Subject: Marijuana legalization

Dear Cynthia Franklin , My mane is Kenneth G. Reese, I have been a commercial marijuana grower in Ketchikan for over 30 years. I feel I have some valuable insight on the commercial marijuana business. I grew and attempted to sell it for 30 years. I feel you could benefit from the knowledge I have to share. I am not even sure I have the right e-mail address? So please reply if you receive ,this e-mail. Thank you ,sincerely Kenneth g. Reese

From: Dinegar, Harriet C (LAW)
Sent: Tuesday, February 02, 2016 4:34 PM
To: Franklin, Cynthia A (CED)
Subject: FW: Marijuana Establishment 500 Ft Setback Provision

Just to be certain you have this --

From: Korting, Nancy A (LAW) **On Behalf Of** General, Attorney (LAW sponsored)
Sent: Thursday, January 07, 2016 2:11 PM
To: Dinegar, Harriet C (LAW); Schroeder, Kaci K (LAW)
Subject: FW: Marijuana Establishment 500 Ft Setback Provision

From: Debra Thompson [<mailto:dthompson@petersburgak.gov>]
Sent: Thursday, January 07, 2016 2:08 PM
To: General, Attorney (LAW sponsored); Franklin, Cynthia A (CED)
Cc: 'sen.bert.stedman@akleg.gov'; 'rep.jonathan.kreiss-tomkins@akleg.gov'
Subject: Marijuana Establishment 500 Ft Setback Provision

Attorney General Richards, ABC Board Director Franklin, and Marijuana Control Board Members,

Please find attached a letter from the Petersburg Borough, Petersburg Resolution #2016-02, Map A and Map B, all regarding the 500 foot setback provision for licensed marijuana establishments.

Ms. Franklin, please share these attachments with the Marijuana Control Board members as well.

If you have any questions, please feel free to contact me.

*Thank you,
Debbie*

--

Debra K. Thompson
Borough Clerk

Petersburg Borough
907-772-4519 ext 23



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

From: Franklin, Cynthia A (CED)
Sent: Friday, January 29, 2016 11:11 AM
To: 'Jim Chumbley'
Subject: RE: marijuana licensing guidelines

Hi Jim,

Sounds like you are talking about being a landlord to marijuana businesses. You do not need a license for that as long as you are not conducting activities yourself that only licensees can conduct, such as growing and selling marijuana. The licensee has to prove that they have the right to occupy the property where the premises will be located. They either do that with a lease or proof of ownership.

You should read the rules so that you know the type of access that will be required by our enforcement officers for any licensed marijuana establishment to be in compliance. They must let our officers in to inspect and investigate. You can find the rules here: <https://www.commerce.alaska.gov/web/Portals/9/pub/DisclaimerFinalRegs12.1.15.pdf> Articles 3 and 4 are specific to the license types you mentioned, but Articles 1, 7 and 9 apply to all license types.

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

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

From: Jim Chumbley [<mailto:jimchumbley@gmail.com>]
Sent: Friday, January 29, 2016 10:23 AM
To: Franklin, Cynthia A (CED)
Cc: Richard L. Gingras
Subject: marijuana licensing guidelines

Hi Cynthia,

My name is Jim Chumbley.

With a partner we own a self storage facility in an industrial area of the Richardson Highway between Fairbanks and North Pole. The North Star Borough has designated this as an appropriate area for marijuana distribution, although I believe we have to apply for a conditional use permit from them.

We are interested in housing a marijuana store front and perhaps a growing operation in the storage units, but do not want to operate it ourselves. Have you developed any guidelines yet for non-owner licensing? Would we need a license or could we just rent to a licensee?

I did not see these types of questions answered in the FAQ section of your website.

My phone is 907-322-3373.

Thanks for your attention,

Jim

From: Nick Coltman [mailto:nick.coltman@anchoragepress.com]

Sent: Monday, February 01, 2016 1:25 PM

To: Franklin, Cynthia A (CED)

Subject: Marijuana Notices

Hi Cynthia,

We've had a fair amount of inquiries from parties interested in posting notice of their intent to open marijuana facilities. As I understand it, the application for such facilities isn't even available yet. So, are these people jumping the gun and wasting their money by placing such ads now? And, if not, have you developed a form, similar to the the liquor license forms, which we should use for these ads.

Thanks so much for your help!

Best Regards,

Nick

Nick Coltman

Publisher

Anchorage Publishing

540 E. 5th Avenue

Anchorage, AK 99501

PH: 907-561-7737

FX: 907-561-7777

From: Hudson, David R (DOH) [mailto:david.hudson@doh.wa.gov]
Sent: Monday, February 01, 2016 10:28 AM
To: Franklin, Cynthia A (CED)
Cc: Penner, Brian K (HSS)
Subject: FW: Marijuana Question

Hi Cynthia,

Since Brian is out today, I'm hoping you can help me with this question below. Thanks in advance.

From: Hudson, David R (DOH)
Sent: Monday, February 01, 2016 7:25 AM
To: 'brian.penner@alaska.gov'
Subject: Marijuana Question

Hi Brian,

Can you help me with this question? Is it legal in AK for MJ producers/processors to provide MJ retailers with branded promotional items? Thanks

David Hudson
Section Manager, Community-Based Prevention
Office of Healthy Communities
PO Box 47848
310 Israel Rd., SE
Tumwater, WA 98501
360 236-3665
david.hudson@doh.wa.gov
Cell: (503) 382-7177

Office Hours: Monday – Thursday: 7:00-4:30
Friday: 7:00-11:00

From: Franklin, Cynthia A (CED)
Sent: Wednesday, January 27, 2016 12:12 PM
To: 'Michelle Niland'
Subject: RE: Marijuana questions

Michelle,

Which community are you from? Who is your local government? Are you a local government official? I only ask because we have set up a special email box for questions from local governments.

Most of the answers to your questions just require you to read the regulations. You can read them on our website here:

1. See 3 AAC 306.025(b) and (d). Lots of notice is required.
2. See same sections as in #1. Your local government can also institute its own comment period.
3. See Article 5.
4. Zoning is completely the province of the local government except for 3 AAC 306.010(a). See also 306.010(c).

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

From: Michelle Niland [<mailto:michelleniland@yahoo.com>]
Sent: Tuesday, January 26, 2016 5:30 PM
To: Franklin, Cynthia A (CED)
Subject: Re: Marijuana questions

Thank you. Hopefully passing along the answers will lighten your load a bit.

Michelle

On Tuesday, January 26, 2016 6:46 AM, "Franklin, Cynthia A (CED)" <cynthia.franklin@alaska.gov> wrote:

I will get you answers today. We have been completely slammed with questions.

CF

On Jan 25, 2016, at 8:59 PM, Michelle Niland <michelleniland@yahoo.com> wrote:

Hi Cynthia,

I haven't heard back from you. Any chance some of my questions could be addressed since we have a community council meeting in 2 days and this topic will come up?

I am getting texts and emails from concerned local residents. I mentioned to several of them that I had reached out to you. Perhaps I should just give out your contact info at the meeting and let them try directly?

Just to refresh, some of my original questions are:

1. How would the public be notified or find out when an application for grow or dispensary is filed so they can have the chance to comment.
2. How much time for comment period will the public be guaranteed on each application?
3. What sort of regulation will the state impose on manufacturing facilities? Local rumor is they aren't being addressed by local planning commission, so may provide a loophole for neighborhood producers.
4. What can people do if they don't want grow or distribution happening in their residential neighborhoods?

Thanks,
Michelle

From: [Franklin, Cynthia A \(CED\)](#)
To: [Hamburg, Glen R \(CED\)](#); [Calder, John P \(CED\)](#); [Enghirst, Abigail L \(CED\)](#); [Samaniego, Joe P \(CED\)](#)
Subject: FW: Media question-Marijuana rules
Date: Wednesday, January 27, 2016 10:56:37 AM
Attachments: [image001.png](#)
Importance: High

FYI

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

From: Franklin, Cynthia A (CED)
Sent: Wednesday, January 27, 2016 10:56 AM
To: 'Bohrer, Becky'
Cc: Fowler, Micaela R (CED)
Subject: RE: Media question-Marijuana rules

Hi Becky,

We do not. The regulations originally required local governments to report to us at least when they opt out, but the department of law removed that regulation from an early draft on the grounds that only the legislature can order local governments to report things to the state. So local governments are under no obligation to report anything to us relating to marijuana developments. We learn the same way as the general public, by reading it in the paper.

We are currently working with the Division of Community and Regional Affairs to see if they have the resources to begin keeping a list based on voluntary reporting by local governments. If and when that pans out, you will see notification of that development and a link on our website.

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

From: Bohrер, Becky [<mailto:bbohrer@ap.org>]
Sent: Wednesday, January 27, 2016 9:45 AM
To: Franklin, Cynthia A (CED)
Subject: Media question-Marijuana rules

Ms. Franklin,

Does the Marijuana Control Board have a list of various actions taken by municipalities and communities with regard to marijuana rules?

If so, could you direct me to where I can find that, or provide a copy?

Thank you, and sincerely,
Becky Bohrер



Becky Bohrer

The Associated Press, Juneau, Alaska

Office: 907-586-1515

Cell: 907-229-0371

Twitter: <http://twitter.com/beckybohrerap>

From: Dinegar, Harriet C (LAW)
Sent: Tuesday, February 02, 2016 4:35 PM
To: Franklin, Cynthia A (CED)
Subject: FW: Proposed resolution to reconsider marijuana set backs

This should complete what you have from Sitka and P'brg.

From: Korting, Nancy A (LAW) **On Behalf Of** General, Attorney (LAW sponsored)
Sent: Wednesday, January 06, 2016 12:33 PM
To: Dinegar, Harriet C (LAW); Schroeder, Kaci K (LAW)
Subject: FW: Proposed resolution to reconsider marijuana set backs

As below?

From: Will Earnhart [<mailto:wearnhart@BHB.com>]
Sent: Wednesday, January 06, 2016 10:45 AM
To: Duerre, Ralph; Will Earnhart; Edwards, Brent; Ennis, Deitra; Evans, Joe; Ewers, Paul; Franklin, Cynthia; Gates, Dean; Michael Gatti; Graves, Cary; Greenberg, Bennett; Greenough, Marc; Groh, Clifford; Halloran, Sean; Hansell, Quincy; Hartle, John; Heikes, Trena; Hillhouse, Theresa; Johnson, Joyce; Jones, Paul; Kearse, Joanne; Kimbrell, Leila; Klepaski, Cynthia; Thomas Klinkner; Koutchak, Robin; Leduc, Elizabeth H (DOA); Levesque, Joe; Levesque, Shane; Amy Limeres; Longenbaugh, Leslie; Lyle, George; Marsh, Michael; McJannet, Scott; Mead, Amy; Meyen, Bradley E (LAW); Middleton, Tim; Moore, Jeff; Munson, Patrick; Newton, Laura; Orman, Christopher; Owens, Robert; Palmer, Robert; Parker, Doug; Patkotak, Ethel; Rasmussen, Linda; Reeves, Susan; Regnart, Glenda; Reilly, Patrick; Ritchie, Barbara; Ryman, Danielle; Seaver, Mitch; Sebens, Jane; Severin, Sam; Sherwood, Todd; Spiropoulos, Nick; Stearns, Krista; Stroble, Margaret; Teytelman, Yan; Thompson, Chuck; Thompson, Colette; Tilly, Cassandra; Travostino, Joan; Tucker, Julia; Voss, Ed; Weiss, Pam; Welch, Terry; Holly Wells; Wheeler, Dennis; Wilson, Zane; Wright, Sarah; General, Attorney (LAW sponsored); Falsey, William (Bill) D
Subject: FW: Proposed resolution to reconsider marijuana set backs

Robin has an update she has asked to share with the group. Thank you, Robin.

William A. Earnhart

Birch Horton Bittner & Cherot

1127 West 7th Ave | Anchorage AK 99501

Tel 907.263.7285 | Main 907.276.1550

wearnhart@bhb.com | www.birchhorton.com
[Bio](#) | [vCard](#)

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From: Robin Koutchak [<mailto:robin.koutchak@cityofsitka.org>]
Sent: Wednesday, January 06, 2016 9:10 AM
To: Will Earnhart
Cc: Reuben Yerkes
Subject: Proposed resolution to reconsider marijuana set backs

A couple updates from southeast.

The Sitka Marijuana Advisory Committee, which is also the designated LRA, drafted a resolution which will go before our assembly next week. It urges the State to reconsider and reduce the 500 ft. set back in the marijuana regs to 200 ft. for various reasons which are set forth in the resolution, such as our topography and population, tourist economy and comparison to the 200 ft. set back required for alcohol establishments as well as leaving the option open for local governments to decide for themselves the setback requirements in line with local zoning practices.

Again, our assembly has not acted on this yet but will hear it next Tuesday. The Petersburg clerk contacted our office after their council members read about the MACs proposed resolution in the newspaper and asked us to share it. With our permission they used it to fashion their own and it went before their council and was passed this week. They will be sending copies to the appropriate state agencies and their legislators. If any of you have client's that want to use it, you are welcome to contact me and I will forward you a copy of Petersburg's as well as ours as it stands right now.

Also, we have sent a letter of notice to the State Marijuana Control Board that we have a designated LRA in Sitka. That was passed by the Assembly in late November.

Robin K.

Robin L. Koutchak
City and Borough of Sitka Attorney
100 Lincoln Street, Room 302
Sitka, AK 99835
(907) 747-1879 direct

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any dissemination, distribution or copying of this communication is strictly prohibited. Did you read that? It may also be subject to Public Record requests if outside the scope of attorney-client privilege.

From: [James Brooks](#)
To: [Calder, John P. \(CED\)](#)
Subject: FW: Question on food inspections
Date: Wednesday, December 02, 2015 3:56:35 PM
Attachments: [image.jpg](#)
[image.jpg](#)
Importance: High

Mr. Calder, forwarding this question to you, since Ms. Franklin is out of the office.

--



----- Forwarded Message

From: James Brooks <james.k.brooks@juneauempire.com>
Date: Wed, 02 Dec 2015 15:54:56 -0900
To: "Franklin, Cynthia A (CED)" <cynthia.franklin@alaska.gov>
Conversation: Question on food inspections
Subject: Question on food inspections

Ms. Franklin:

Working on a story about food safety, engineering and other permits required of new marijuana businesses. Spoke at length with DEC's Kim Stryker and had some confusion about 306.520 (1):

Does it require folks opening a business to get a food safety permit /before/ applying for a manufacturing facility license? Ms. Stryker had been under the impression that folks would apply for a food permit /after/ getting a manufacturing license.

--



----- End of Forwarded Message

From: mike horwath [mailto:mbhorwath@hotmail.com]
Sent: Monday, February 01, 2016 11:07 AM
To: Franklin, Cynthia A (CED)
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: [Samaniego, Joe P. \(CED\)](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Cc: [Calder, John P. \(CED\)](#)
Subject: FW: surveillance
Date: Tuesday, January 19, 2016 8:02:55 AM
Importance: High

Joe Samaniego
Administrative Assistant I
907-269-0352 · joe.samaniego@alaska.gov
Alcohol & Marijuana Control Office
Department of Commerce, Community, & Economic Development
550 West 7th Avenue, Suite 1600
Anchorage, AK 99501-3569

Please consider the environment before printing this e-mail. Less paper is better for us and our environment.

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

From: zells [<mailto:zells@mtaonline.net>]
Sent: Monday, January 18, 2016 5:16 PM
To: Samaniego, Joe P (CED)
Subject: surveillance

Hello,

I would like clarification on this. On page 98 of the regs, it says "each point-of-sale area" must have a camera. Does that mean if I have six cash registers on one long counter, I must have one camera over each register for a total of six. Or does it mean you need to cover the area with two or three cameras like a bank?
By the way, you gave me marijuana@alaska.gov for these questions. Does not work. Any other place I can go?

Thanks
Peter Zell

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

From: j bass [mailto:jbassalaska@yahoo.com]

Sent: Sunday, January 31, 2016 10:44 AM

To: Franklin, Cynthia A (CED)

Subject: transportation of marijuana within city limits of wasilla

January 31, 2016

- 1) Can we transport personal use, plants and product on all public roadways as long as we do not exceed the legal limits of possession?
- 2) What state regulation allows for this?
- 3) Can a city ban the use of public roads for this transportation?
- 4) What regulation covers the transport of commercial product?

Thank you

Jan Bass

Wasilla

jbassalaska@yahoo.com

From: [Tobias Coughlin-Bogue](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Fwd: Article - Is Corporate Weed on Its Way to Washington State?
Date: Thursday, January 14, 2016 11:21:05 AM
Attachments: [image001.png](#)

Hello,

See below. I'm hoping someone can advise me on the relationship between the Alaska Cannabis Institute and the Marijuana Handler's Permit. I spoke with the ACI's founder on the phone, and he indicated to me that completion of one of his courses would immediately qualify students for the MHP, which seemed to be dependent on "authorization" from the ACPE. The information below leads me to question that assertion. I've taken my brief on the topic offline for now, pending further info. Hoping you can set me straight here.

Thank You,

Tobias

----- Forwarded message -----

From: **Kussart, Kierke A (ACPE)** <kierke.kussart@alaska.gov>
Date: Thu, Jan 14, 2016 at 11:36 AM
Subject: RE: Article - Is Corporate Weed on Its Way to Washington State?
To: Tobias Coughlin-Bogue <tcough@gmail.com>

Good morning, Tobias,

Thank you for your quick response to my email.

I do not have any information on if the classes offered by ACI do or do not qualify students for the Marijuana Handler's Permit. That area of Alaska law is under the Marijuana Control Board at the Department of Commerce, Community and Economic Development and I would direct you to them for information on their permitting requirements.

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

Regards,

**Kierke A Kussart
Institutional Authorization
Alaska Commission on Postsecondary Education**

[907-465-6741](tel:907-465-6741)
[907-465-5316](tel:907-465-5316) (fax)

From: Tobias Coughlin-Bogue [mailto:tcough@gmail.com]
Sent: Wednesday, January 13, 2016 6:05 PM
To: Kussart, Kierke A (ACPE)
Subject: Re: Article - Is Corporate Weed on Its Way to Washington State?

Kierke,

I just wanted to write and offer my apologies for the error. My editor should be making a correction shortly. I also wanted to let you know that I wrote that because I received a press release from ACI specifically using the word authorization, which might be something you want to sort out with them.

For my own information, could you clarify how the "authorized" vs "exempt from authorization" distinction affects what their classes can do. Their founder led me to understand that his students would be qualified for the Marijuana Handler's Permit upon completing the course, because the course was "authorized" as a qualifying course. Given that they are not authorized, but merely exempt from authorization, does their course still qualify students for the permit?

I very much appreciate you alerting us to the error, and hope this hasn't caused you any inconvenience.

Thanks,

Tobias Coughlin-Bogue

On Wed, Jan 13, 2016 at 6:18 PM, Kathleen Richards <krichards@thestranger.com> wrote:

Can you look into this and confirm we need to make a correction?

Begin forwarded message:

From: "Kussart, Kierke A (ACPE)" <kierke.kussart@alaska.gov>

Subject: Article - Is Corporate Weed on Its Way to Washington State?

Date: January 13, 2016 at 5:20:34 PM PST

To: "legaldepartment@thestranger.com" <legaldepartment@thestranger.com>

Cc: "editor@thestranger.com" <editor@thestranger.com>

Good afternoon,

The article "Is Corporate Weed on Its Way to Washington State?" found here:<http://www.thestranger.com/news/pot/2016/01/13/23413154/is-corporate-weed-on-its-way-to-washington-state> contains inaccurate information. The Alaska Commission on Postsecondary Education did not authorize the Alaska Cannabis Institute. The Alaska Cannabis Institute applied for Exemption from Institutional Authorization to offer short course of study. Based on the information provided in the application on the duration of the programs offered, it was determined that the Alaska Cannabis Institute is exempt from the authorization provisions of AS 14.48, as set out in 20 AAC 17.015(4). Exemption is not a form of approval; rather, it is confirmation that the institution is not subject to ACPE's oversight or approval.

To reiterate, the Alaska Cannabis Institute is not authorized or approved by the Alaska Commission on Postsecondary Education. The correct status is "exempt from authorization."

Please contact me with any questions.

Regards,



Kierke A Kussart
Institutional Authorization
Alaska Commission on Postsecondary Education

[907-465-6741](tel:907-465-6741)

[907-465-5316](tel:907-465-5316) (fax)

From: [Franklin, Cynthia A \(CED\)](#)
To: [Calder, John P \(CED\)](#); [Johnston, Naomi A \(CED\)](#)
Subject: Fwd: Cultivators License
Date: Thursday, January 28, 2016 11:55:17 AM
Importance: High

Sent from my iPhone

Begin forwarded message:

From: Bruce R Martin <brucermartin@gmail.com>
Date: January 28, 2016 at 9:02:01 AM AKST
To: "Franklin, Cynthia A (CED)" <cynthia.franklin@alaska.gov>
Subject: Re: Cultivators License

Good morning Cynthia,

I sent the attached email to your office about 10 days ago and have not received a reply.

Just following up in case it did not make it to you for some reason.

Thanks for the help.

Best Regards

Bruce

Sent from my iPhone

On Jan 18, 2016, at 4:10 PM, Bruce Martin <brucermartin@gmail.com> wrote:

Good afternoon Cynthia,

I am planning to start a cannabis cultivation business. A couple of questions as we plan and prepare.

- 1) The regs suggest that the required forms are available. I do not seem to find any link to them. Are they currently available or not until 2/24/16? I would like to have my application package ready to submit as soon as possible so that it is on the top of the stack so to speak.
- 2) I am located in the Seward area but outside of the city limits and in an area that has become for the most part lite industrial. Can the city of Seward, as they have opted out, influence the boards decision?

3) The regs note a requirement of a majority of residents within 1 mile to sign off on a petition. Is this 1 mile radius or traffic pattern, (road miles)? As I mentioned, my location is primarily a lite industrial area with a freight forwarding company, auto mechanic shop, boat storage, waste management shop, redi mix concrete company, metals recycling business, a company the remodels steel containers into portable man camp units, a seasonal horse back trail ride company and my shop/warehouse building located pretty much in the center of these businesses. 8-9 residences within 1/2 mile.

I currently have my business plan, financials and operations plans written and am working to remodel the warehouse space to comply with the regulations published. Have no criminal record and a strong business background.

Thank you for your time in answering these questions.

Bets Regards

Bruce Martin, Owner
Budding Alaska LLC

From: [Travis Fraser](#)
To: [Marijuana, CED ABC \(CED sponsored\)](#)
Subject: Fwd: Failure Notice
Date: Wednesday, January 06, 2016 12:40:05 PM

Sent from my iPhone

Begin forwarded message:

From: MAILER-DAEMON@yahoo.com
Date: January 6, 2016 at 11:52:43 AM AKST
To: travisfraser00@yahoo.com
Subject: Failure Notice

Sorry, we were unable to deliver your message to the following address.

<marijuana@alaska.com>:

Mail server for "alaska.com" unreachable for too long :

--- Below this line is a copy of the message.

Received: from [66.196.81.171] by nm34.bullet.mail.bf1.yahoo.com with NNFMP; 05 Jan 2016 20:50:48 -0000

Received: from [98.139.211.200] by tm17.bullet.mail.bf1.yahoo.com with NNFMP; 05 Jan 2016 20:50:48 -0000

Received: from [127.0.0.1] by smtp209.mail.bf1.yahoo.com with NNFMP; 05 Jan 2016 20:50:48 -0000

X-Yahoo-Newman-Id: 558170.81768.bm@smtp209.mail.bf1.yahoo.com

X-Yahoo-Newman-Property: ymail-3

X-YMail-OSG:

IPeV8XoVM1kDQtBPQamA2XjDK8RISZfXulYqiQYStgwPRLw
8MQuMxusePKkSC2Pib1vIRDPHX2TzdzDmXw8IFCk1Pc4IyGVuRMpmTKWiccu

2bawYAotePu_AxqfmczKovtcYCUQme5zfM6uOGDNCPoPJBpwV9ooEGiW9Sap

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cdFSAYKKOGIQEx70_IwQu8lJNXMLfIVYtvMY0Ph1vpEDQW6OO_ZEoOv97DkA

Gc3XWlJW3pXbHL4bE35kogTi6jn5D32Vgb_oB7WXEpPmSLKGjP3tGHQ8Omwp

3ddARott0r0FLXuIXBkHjE9wP0_hRvb3M4e9_Gdyz0f_kd1L.6hLv3..sLmN
e8NTA5nrwTfqYpipYMCpbzMZaqaJyQRhxWqG9TIGigpTBU3.WDrshq4bRChD

gRLj_bncXyMLq5pa83dsf5m3FRqY3oqFGXVbfbOxcwnqBNKL1Vt7_XLnxmYE

y0vt4n2amtCN9aIWqC4r1a.ltL6deiKmh4jB_5p70iLMI0izV1qrlr9kgBa
waQ--

X-Yahoo-SMTP: OrpYIpGswBBdZfxDjW3xhSL5Jf30TnUnj1nW

From: Travis Fraser <travisfraser00@yahoo.com>

Content-Type: multipart/alternative;
boundary=Apple-Mail-C01F0C1E-5DD9-416A-B6AD-DE30A0BD86D5
Content-Transfer-Encoding: 7bit
Mime-Version: 1.0 (1.0)
Subject: Fwd: Travis Fraser Buffer from cushman housing first
Message-Id: <8D43FAE2-505E-4C2D-A666-4A87A6B64DD9@yahoo.com>
Date: Tue, 5 Jan 2016 11:50:46 -0900
References: <AA40ADD8-8C0E-4E98-8647-6921A56C681B@yahoo.com>
To: marijuana@alaska.com
X-Mailer: iPhone Mail (13B143)
--Apple-Mail-C01F0C1E-5DD9-416A-B6AD-DE30A0BD86D5
Content-Type: text/plain;
charset=us-ascii
Content-Transfer-Encoding: quoted-printable
Sent from my iPhone
Begin forwarded message:

From: Travis Fraser <travisfraser00@yahoo.com>

Date: January 5, 2016 at 11:43:06 AM AKST

To: marijuana@AK.gov

Subject: Travis Fraser Buffer from cushman housing first=20

=20

The address is 1550 south cushman and according to Fairbanks
Burrough ,hou=

sing first wich is on opposite side of cushman address appears to be 1521 so=
uth cushman does not fall under their buffer requirements because it does no=
t house children. So I am wondering if the state sees that the same way or i=
f they may add buffers pertaining to this particular housing situation=20

=20

Sent from my iPhone

--Apple-Mail-C01F0C1E-5DD9-416A-B6AD-DE30A0BD86D5
Content-Type: text/html;
charset=utf-8
Content-Transfer-Encoding: quoted-printable
<html><head><meta http-equiv=3D"content-type" content=3D"text/html";
charset=3D=
utf-8"></head><body dir=3D"auto"><div>

Sent from my iPhone</div>
<div>=

Begin forwarded message:

</div><blockquote type=3D"cite">
<div>=
From: Travis Fraser <trav=

isfraser00@yahoo.com>
Date: January 5, 2016 at 11:43:06 AM A=KST
To: marijuana@AK.gov
Subject: Travis Fraser Buffer from cushman housing first

</div></blockquote><blockquote type="cite"><div>The address is 1=

550 south cushman and according to Fairbanks Burrough ,housing first wich is on opposite side of cushman address appears to be 1521 south cushman does not fall under their buffer requirements because it does not house children. So I am wondering if the state sees that the same way or if they may add buffers pertaining to this particular housing situation

Sent from my iPhone</div></blockquote></body></html>--Apple-Mail-C01F0C1E-5DD9-416A-B6AD-DE30A0BD86D5--

From: kenneth reese <rvk458@hotmail.com>
Date: January 27, 2016 at 1:36:33 PM AKST
To: "Franklin, Cynthia A (CED)" <cynthia.franklin@alaska.gov>
Subject: Re: Marijuana legalization

So you mean I have to talk to who? Dan Ortiz? could you please put me in touch with them or e-mail add for me? The politic stuff is new to me. I Am just now getting involved with our city council here on the topic. I do not not believe it is to late for the state to get right Its seems like the State and local goverments are starting to feel to much pressure from the voters. Slow down relax its ok, the pot heads or smokers really want this turn out fair and best for all the citizen of this great state. So please do not brush me off ,I will keep on until I die.

sincerely Kenneth G Reese P.S I look forward to meeting you on your next visit to Ketchikan sincerely Kenneth G. Reese

From: Franklin, Cynthia A (CED) <cynthia.franklin@alaska.gov>
Sent: Wednesday, January 27, 2016 1:16 PM
To: kenneth reese
Subject: RE: Marijuana legalization

Mr. Reese,

The prohibition on felons applying for a license within 5 years of conviction is statutory, not regulatory. Your issue is with our legislators, who amended the board bill from the floor to add the prohibition. It cannot be changed by regulation.

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

From: kenneth reese [<mailto:rvk458@hotmail.com>]
Sent: Wednesday, January 27, 2016 12:52 PM

To: Franklin, Cynthia A (CED)
Subject: Re: Marijuana legalization

I take it objections and ideas are over. The state is on too rules and regulations. This site can not answer the question I have. They are important and meaning full. I am a registered voter. Also a unjust convicted felon. In 2013 I was charged with growing pot with the intended purpose to distribute. I was the last person to be incarcerated in the State of Alaska for this crime. I was sentenced to 6 months flat time. I served 28 days in lemon Creek. the remainder in the halfway house. Under the new FBI back ground check policy for convicted felons. I take it I would not be eligible to apply for commercial growers license. correct? All this marijuana laws do not make any practical since. Because the State already convicted me for a crime that should never been a crime to begin with. I truly feel the commercialization of pot in Alaska will not work like it has, lets say like in Colorado. You see every state is different and unique. this Federal B>S is just that. Alaska could have been and still could be a leader in this field of legal Marijuana. You see By the time 26 or 27 states are on board, the federal government will be forced once again {not the first time in history it happened with alcohol after the end od prohibition.} to re recognize the STATES individual rights to govern its own citizens.

That is how 50 states with 50 different alcohol laws came to be. but with Alaska we could have been the first state with 50 different pot laws that benefit each local community its the way they saw was best. the bill that passed basically gave each community in Alaska a blank slate to write there own laws on pot that they felt would best benefit the community that they live in. But not one could come up with anything? what did the voters or the state expect to happen? I personally was hoping that would have or still could happen. All the regulation are over kill for the state of Alaska and make no financial or business since. I do not know it all or claim too. but I do know a lot about this industry. I believe I know the best way to reduce the amount of pot that enters our state. I also believe my ideas are the fairest for the state of Alaska and its citizens. I know you are a busy person, but I am asking you to please listen to what I have to say. This is all for now, but you will keep hearing from me. I trust hope and pray you are open minded and educated enough to realize it might just be benefit to me and the State and the citizen of Alaska, to take a little of yours ours and the states time to listen to what I am saying? for all I know public input is over What your still working on the rules and regulations? Does the State not to get it write the first time? I can explain why this is not going to work in the state of Alaska if you would listen to me. I believe it was you that said while you were here in

Ketchikan, "

One thing I have found out the people who some pot are very passionate about it!! Well not only am I passionate about pot, I am also passionate about being a American, voicing my opinion and very passion about helping the State get This right lets not blow it. I look forward to corresponding with you more on this subject. Sincerely Kenneth G. Reese P.S I apolige for my writing skills, but if you need documented certified proof of my credentials, I do have them, certified and documented by the GREAT STATE OF ALASKA

From: Franklin, Cynthia A (CED) <cynthia.franklin@alaska.gov>

Sent: Wednesday, January 27, 2016 10:02 AM

To: kenneth reese

Subject: RE: Marijuana legalization

Hi Kenneth,

For marijuana questions you can use marijuana@alaska.gov. Thanks,

Cynthia Franklin, Director

Alcoholic Beverage & Marijuana Control Boards

907-269-0351

From: kenneth reese [<mailto:rvk458@hotmail.com>]

Sent: Wednesday, January 27, 2016 9:26 AM

To: Franklin, Cynthia A (CED)

Subject: Marijuana legalization

Dear Cynthia Franklin , My mane is Kenneth G. Reese, I have been a commercial marijuana grower in Ketchikan for over 30 years. I feel I have some valuable insight on the commercial marijuana business. I grew and attempted to sell it for 30 years. I feel you could benefit from the knowledge I have to share. I am not even sure I have the right e-mail address? So please reply if you receive ,this e-mail. Thank you ,sincerely Kenneth g. Reese

From: [Gordon Epperly](#)
To: [General, Attorney \(LAW sponsored\)](#); [Alaska Governor Bill Walker \(GOV sponsored\)](#)
Subject: FYI - U.S. opposes marijuana challenge by Colorado's neighbors
Date: Tuesday, December 29, 2015 11:09:52 AM
Attachments: [logo - Lyle Denniston.jpg](#)
[U.S. Supreme Court--Brief for the United States as Amicus Curia.pdf](#)
Importance: High



[Lyle Denniston](#) Independent Contractor Reporter

Posted Thu, December 17th, 2015 9:05 am

U.S. opposes marijuana challenge by Colorado's neighbors

Citing a host of constitutional, legal and practical problems, the Obama administration [urged the Supreme Court](#) on Wednesday not to allow two states to [sue Colorado directly](#) in the Supreme Court over their claim of cross-border crime traced to their neighbor's regime of legal sales of marijuana.

Nebraska and Oklahoma do have the option, the administration argued, to try to challenge the Colorado program in lower courts — though it suggested that such an approach may have problems, too.

Under the Constitution, the Supreme Court has the authority to try, as an original trial court, controversies between states. It has great discretion to do so or not, and U.S. Solicitor General Donald B. Verrilli, Jr., noted that permission is seldom granted. Mainly, he argued, it is the right approach only when one state is the direct cause of harm to another.

Colorado, the Solicitor General contended, is not directly harming either Nebraska or Oklahoma, and any criminal activity inside those states is the result of actions by third parties, not instigated by Colorado's marijuana policy.

One year ago, the two states filed their plea to sue Colorado directly in the Supreme Court, contending that there is no other court where they could do so. They do not challenge Colorado's legalization of personal and medical use of marijuana, but they do object to the regime's manufacture, possession, and distribution of marijuana — in short, its commercial aspects.

Solicitor General Verrilli, asked by the Court for the federal government's views, outlined the federal policy against marijuana marketing, which has been relaxed so that it allows states to do as Colorado and Washington State have done in legalizing the availability of the drug in small quantities. That is the gap in federal enforcement that Colorado's neighbors have argued has led to marijuana buyers bringing the drug back across their borders.

In its brief, the federal government argued: “Where a state has alleged that another state permitted — but did not direct or approve — the injurious actions of other parties, this Court has declined to exercise original jurisdiction This Court has continued to enforce the

direct-injury requirement, which substantially overlaps with the Article III standing requirement that the injury be fairly traceable to the defendant's actions.”

The Nebraska-Oklahoma complaint does not meet that standard, the federal government contended. Their basic complaint is that the authorization of licensed marijuana production and distribution within Colorado “increases the likelihood that third parties will commit criminal offenses in Nebraska and Oklahoma.” Colorado has not directed or authorized anyone to carry marijuana across the state border, Verrilli said.

While the states have claimed that the Colorado program makes it easier for such transport, the federal government said, “that is a far less direct connection between state action and the alleged injury” that the Court had previously found in allowing original lawsuits between states.

Allowing this original case to go forward, Verrilli said, would open the way to many attempts by states to sue in the Supreme Court to try to compel other states to conform their laws to federal policies that do not demand such adherence. The government argued that a number of other technical legal problems would arise if states were free to try to police the conduct of other states.

The government implied that the neighboring states were exaggerating the problem of cross-border criminal activity, noting that the Colorado program only allows the purchase of one ounce or less of marijuana. Large-scale trafficking in marijuana is not likely, the government contended. Moreover, that type of distribution is the focus of direct federal law enforcement, Verrilli pointed out.

The Solicitor General also discounted the states' claim that the Supreme Court is the only tribunal where they could get relief from the Colorado marijuana scheme. He noted that non-state parties interested in enforcing laws against marijuana have already filed two suits in federal court in Washington, D.C.

While private parties are on both sides of those two lawsuits, Verrilli said Nebraska and Oklahoma could sue in their own names against an appropriate state official in Colorado. He conceded, though, that such a claim might encounter some of the same legal complications as their attempt to sue in the Supreme Court.

As a final point, Verrilli rejected Colorado's suggestion that, if the original case went forward, the federal government would have to be sued, too, because of federal drug policy and its relationship to Colorado's program. The neighbors' lawsuit would require no rulings on the rights or powers of the federal government, he argued.

The two states will get an opportunity to respond to the federal government's views before the Justices decide whether to allow the states' lawsuit to go forward. Colorado has already filed its opposition to the case.

Guidance for Industry

Botanical Drug Products

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
June 2004**

Chemistry

Guidance for Industry

Botanical Drug Products

Copies of this Guidance are available from:

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**U.S. Department of Health and Human Services
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Guidance for Industry¹ Botanical Drug Products

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance explains when a botanical drug may be marketed under an over-the-counter (OTC) drug monograph and when FDA regulations require approval for marketing of a new drug application (NDA), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 355(b). In addition, this document provides sponsors with guidance on submitting investigational new drug applications (INDs) for botanical drug products, including those botanical products (or *botanicals*) currently lawfully marketed as foods (including conventional foods and dietary supplements) in the United States.

This guidance also discusses several areas in which, because of the unique nature of botanicals, FDA finds it appropriate to apply regulatory policies that differ from those applied to synthetic, semisynthetic, or otherwise highly purified or chemically modified drugs (including antibiotics derived from microorganisms). This latter group of drug substances is referred to in this guidance as synthetic or highly purified drugs. Therefore, when the recommendations on a specific topic discussed in this guidance differ from those in other existing guidances (e.g., *Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances*, 1987),² this guidance takes precedence. In particular, this guidance states that applicants may submit reduced documentation of nonclinical (preclinical) safety and of chemistry, manufacturing, and controls (CMC) to support an IND for initial clinical studies of

¹This guidance has been prepared by working groups in the Medical Policy, Pharmacology and Toxicology, and Complex Drug Substances Coordinating Committees in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration (FDA).

² FDA has issued a draft guidance entitled *Drug Substance: Chemistry, Manufacturing, and Controls Information*, which, when finalized, will replace the 1987 guidance (see 69 FR 929, January 7, 2004).

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botanicals that have been legally marketed in the United States and/or a foreign country as dietary supplements without any known safety concerns.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Botanical products are finished, labeled products that contain vegetable matter as ingredients.³ A botanical product may be a food (including a dietary supplement), a drug (including a biological drug), a medical device (e.g., gutta-percha), or a cosmetic under the Act. An article is generally a food if it is used for food (21 U.S.C. 312(f)(1)). Whether an article is a drug, medical device, or cosmetic under the Act turns on its “intended use” (21 U.S.C. 312(g)(1)(B) and (C), (h)(2) and (3), (i)). “Intended use” is created by claims made by or on behalf of a manufacturer or distributor of the article to prospective purchasers, such as in advertising, labeling, or oral statements.

For the purposes of this document, the term *botanicals* includes plant materials, algae, macroscopic fungi, and combinations thereof. It does not include:

- Materials derived from genetically modified botanical species (i.e., by recombinant DNA technology or cloning).
- Fermentation products (i.e., products produced by fermentation of yeast, bacteria, and other microscopic organisms, including when plants are used as a substrate, and products produced by fermentation of plant cells), even if such products are previously approved for drug use or accepted for food use in the United States (e.g., antibiotics, amino acids, and vitamins).
- Highly purified substances (e.g., paclitaxel) or chemically modified substances (e.g., estrogens synthesized from yam extracts) derived from botanical sources.

This guidance addresses all botanical drug products (in all dosage forms) that are regulated under the Act, except those also regulated under section 351 of the Public Health Service Act (42 U.S.C. 262). Although this guidance does not address drugs that contain animals or animal parts (e.g., insects, annelids, shark cartilage) and/or minerals, either alone or in combination with botanicals, many scientific principles described in this guidance may also apply to those products. When a drug product contains botanical ingredients in combination with either (1) a synthetic or highly purified drug or (2) a biotechnology derived or other naturally derived drug, this guidance only applies to the botanical portion of the product.

³*Botanical product* and other terms used in this guidance are defined in the Glossary for use in this guidance only; these definitions may not be appropriate in other contexts.

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III. GENERAL REGULATORY APPROACHES

Many botanical products are used widely in the United States. Depending on its labeling and intended use, a botanical product can be a food, a dietary supplement, and/or a drug. Botanicals used for food and consumed primarily for their taste, aroma, or nutritive value (e.g., lettuce, herbs used as seasonings) are regulated as foods. Botanicals can also be dietary supplements if they are labeled as dietary supplements and otherwise meet the dietary supplement definition in section 201(ff) of the Act (21 U.S.C. 321(ff)).

If a botanical product is intended for use in diagnosing, mitigating, treating, or curing disease, it is a drug under section 201(g)(1)(B) of the Act and is subject to regulation as such. If a botanical product is intended to prevent disease, it is also a drug under section 201(g)(1)(B), except that a product that bears a health claim authorized in accordance with section 403(r) of the Act (21 U.S.C. 343(r)) is not a drug solely because its labeling contains such a claim. If the intended use of a botanical product is to affect the structure or function of the human body, it may be regulated either as a dietary supplement or as a drug, depending on the circumstances.

Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), an orally ingested product that meets the definition of a “dietary supplement” under section 201(ff) of the Act may be lawfully marketed with a statement that (1) claims a benefit related to a classical nutrient deficiency disease (and discloses the prevalence of the disease in the United States), (2) describes how the product is intended to affect the structure or function of the human body, (3) characterizes the documented mechanism by which the product acts to maintain such structure or function, or (4) describes general well-being from consumption of the product (section 403(r)(6)(A) of the Act).⁴ A dietary supplement statement of the type described above may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases (section 403(r)(6) of the Act).⁵

If a botanical product is intended to affect the structure or function of the body but does not meet the definition of a dietary supplement, or does not meet the requirements for making a structure/function claim under section 403(r)(6) of the Act, it is subject to regulation as a drug under section 201(g)(1)(C) of the Act. As noted above, a botanical product is subject to regulation as a drug under section 201(g)(1)(B) of the Act if it is intended for use in diagnosing, mitigating, treating, curing, or preventing disease (except for a product marketed with certain health claims authorized under section 403(r) of the Act). Under section 505(b) of the Act, a

⁴The manufacturer must have substantiation that such statement is truthful and not misleading (section 403(r)(6)(B) of the Act) and must notify FDA that the statement is being used no later than 30 days after the first marketing of the dietary supplement with the statement (section 403(r)(6) of the Act). In addition, the statement must be accompanied by the following disclaimer: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease” (section 403(r)(6)(C) of the Act). FDA regulations at 21 CFR 101.93(b)-(e) prescribe the required format and placement of the disclaimer in dietary supplement labeling.

⁵FDA regulations at § 101.93(g) define *disease* for purposes of this provision and set forth what types of statements FDA will consider to be claims to diagnose, mitigate, treat, cure, or prevent disease.

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drug must be marketed under an approved NDA⁶ unless the product is excluded from the definition of a new drug under section 201(p) of the Act. Certain products that FDA determines are generally recognized as safe and effective in accordance with section 201(p) may be marketed under FDA's OTC drug monograph system.

A. Marketing Under OTC Drug Monograph Versus Approved NDA

A botanical drug product may be marketed in the United States under (1) an OTC drug monograph or (2) an approved NDA or ANDA. A botanical product that has been marketed in the United States for a material time and to a material extent for a specific OTC drug indication may be eligible for inclusion in an OTC drug monograph codified in 21 CFR parts 331-358. The manufacturer would need to submit a petition in accordance with 21 CFR 10.30 to amend the monograph to add the botanical substance as a new active ingredient.

Under current regulations, if there is no marketing history in the United States or a foreign country for a botanical drug product,⁷ if available evidence of safety and effectiveness does not warrant inclusion of the product in an OTC drug monograph, or if the proposed indication would not be appropriate for nonprescription use, the manufacturer must submit an NDA to obtain FDA approval to market the product for the proposed use (sections 201(p) and 505 of the Act). An NDA for a botanical drug could seek approval for either prescription or OTC use, depending on the indication and characteristics of the product and whether it is safe for use outside of the supervision of a practitioner licensed by law to administer it. If existing information on the safety and effectiveness of a botanical drug product is insufficient to support an NDA, we recommend that new clinical studies be conducted to demonstrate safety and effectiveness.⁸

When a final OTC drug monograph is published for a specific use of a botanical drug, any person may market a product containing the same substance and for the same use, provided the labeling and other active ingredients (if present) are in accord with all relevant monographs and other applicable regulations. In contrast, when a product is approved under an NDA, the approval is specific to the drug product that is the subject of the application (the applicant's drug product), and the applicant may be eligible for

⁶Under section 505(j) of the Act, a botanical drug product may also be marketed as a generic drug under an abbreviated new drug application (ANDA). The *generic* version of the previously approved drug would have to be both pharmaceutically equivalent and bioequivalent to such drug. For information on the submission of ANDAs, see FDA regulations in 21 CFR parts 314 and 320 as well as Agency guidance documents.

⁷FDA has issued a final rule that establishes criteria and procedures by which conditions may become eligible for inclusion in the OTC drug monograph system (67 FR 3060, January 23, 2002). Among other things, the final rule addresses how FDA considers *foreign* marketing data in determining whether a drug has been used under particular conditions to a material extent and for a material time (as required under section 201(p) of the Act) to qualify for inclusion in an OTC drug monograph.

⁸See 21 CFR 312.20 (concerning requirement for an IND).

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marketing exclusivity for either 5 years (if it is a new chemical entity) or 3 years from the time of approval, even in the absence of patent protection. A new botanical drug (containing multiple chemical constituents) may qualify as a new chemical entity under § 314.108(a). If a product qualifies as a new chemical entity, during the period of exclusivity, FDA will not approve, or in some cases even review, certain competitor products unless the second sponsor conducts all studies necessary to demonstrate the safety and effectiveness of its product and submits a 505(b)(1) application. Therefore, if a person wishing to market a botanical drug product that is not included in an existing OTC drug monograph desires marketing exclusivity for the product, the person should seek approval of an NDA rather than petition the Agency to amend a monograph. Attachment A contains a schematic showing different regulatory approaches that can be taken for marketing botanical drug products in the United States, including OTC drug monograph and NDA procedures.

B. CMC Information for Botanical Drug Products

Botanical drug products have certain unique characteristics that should be taken into account in the application of FDA regulations and guidance. Botanical drugs are derived from vegetable matter and are usually prepared as complex mixtures. Their chemical constituents are not always well defined. In many cases, the active constituent in a botanical drug is not identified, nor is its biological activity well characterized. Therefore, the CMC documentation that should be provided for botanical drugs will often be different from that for synthetic or highly purified drugs, whose active constituents can be more readily chemically identified and quantified. For example, FDA would expect an NDA for a synthetic or highly purified drug to identify the active ingredient. However, it would not be essential for the sponsor of a botanical drug to identify the active constituents (although FDA recommends that this be done if feasible). Even if the sponsor were to eventually identify the active constituents in the NDA, the active constituents might not be identified during the IND stage.

Because of the complex nature of a typical botanical drug and the lack of knowledge of its active constituent(s), FDA may rely on a combination of tests and controls to ensure the identity, purity, quality, strength, potency, and consistency of botanical drugs. These tests and controls include (1) multiple tests for drug substance and drug product (e.g., spectroscopic and/or chromatographic fingerprints, chemical assay of characteristic markers, and biological assay), (2) raw material and process controls (e.g., strict quality controls for the botanical raw materials and adequate in-process controls), and (3) process validation (especially for the drug substance).

C. CMC and Toxicology Information to Support Initial Studies

Many botanical products are legally available in the United States as dietary supplements. Given the wide availability of such products outside of clinical trials, it is important to assess the effectiveness of such products. To support initial clinical trials, the nonclinical pharmacology and toxicology information that must be provided under 21 CFR 312.22(b) for legally available botanical products with no known safety issues (see

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section VI.A) may be markedly reduced compared to that expected for synthetic or highly purified new drugs that are not legally marketed and for which there is no prior human experience. In most cases, additional toxicology and CMC data will not be required for such initial trials.

D. Applicability of Combination Drug Regulations

Botanical drug products that are derived from a single part of a plant (e.g., leaves, stems, roots, or seeds), or from a single species of alga or macroscopic fungus (e.g., a mushroom), are not considered to be fixed-combination drugs within the meaning of 21 CFR 300.50 and 330.10(a)(4)(iv). Consequently, they do not have to meet the requirements for combination drugs, principally the need to demonstrate that each component or active ingredient makes a contribution to claimed effects.

Botanical drugs composed of multiple parts of a single species of plant, alga, or macroscopic fungus, or of parts from different species of plants algae, or macroscopic fungi, currently are subject to the combination drug requirements. However, FDA is considering revising its regulations to allow for the exemption of such botanical drugs from application of the combination drug requirements under certain circumstances.

IV. MARKETING A BOTANICAL DRUG UNDER AN OTC DRUG MONOGRAPH

A botanical product that has been marketed in the United States for a material time and to a material extent for a specific OTC indication may be eligible for consideration in the OTC drug monograph system. Currently, there are several botanical drugs, including cascara, psyllium, and senna, that are included in the OTC drug review. For a botanical drug substance to be included in an OTC drug monograph, there must be published data establishing general recognition of safety and effectiveness, usually including results of adequate and well-controlled clinical studies (see §§ 314.126(b) and 330.10). Requirements related to safety, effectiveness, and labeling for drugs to be included in an OTC drug monograph are set forth in 21 CFR part 330.

A request to amend an OTC drug monograph to include a botanical substance must be submitted by citizen petition in accordance with §§ 10.30 and 330.10(a)(12). There should be publicly available quality standards for such a botanical drug substance in the drug section (i.e., not in the National Formulary or other nondrug sections) of the *United States Pharmacopeia* (USP).⁹ In the absence of a USP drug monograph, the petitioner should include suitable quality standards for the botanical drug substance in its citizen petition and simultaneously propose adoption of those standards in the USP. Additional criteria and procedures by which a botanical drug substance may become eligible for inclusion in the OTC drug monograph system are set forth in § 330.14. FDA regulations on current good manufacturing practices (CGMPs) apply to all OTC drug monograph products, including any listed botanical drug products (see § 330.1(a)).

⁹However, a botanical drug's conformance to the standards of the USP or any other official compendium does not establish that the botanical is safe, effective, and not misbranded for its intended use as a drug.

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For further information on the OTC drug monograph approach to marketing a botanical drug product, sponsors are encouraged to contact CDER's Division of Over-the-Counter Drug Products (HFD-560).

V. MARKETING A BOTANICAL DRUG UNDER AN NDA

A botanical drug product that is not generally recognized as safe and effective for its therapeutic claims is considered a new drug under section 201(p) of the Act. Section 505(a) of the Act requires any person wishing to market a botanical drug product that is a new drug to obtain FDA approval of an NDA or ANDA for that product. According to section 505(d) of the Act and § 314.50, an NDA must contain substantial evidence of effectiveness derived from adequate and well-controlled clinical studies, evidence of safety, and adequate CMC information. The format of an NDA submission and the requirements for its various sections are set forth in part 314 and discussed in several CDER guidance documents.

VI. INDS FOR BOTANICAL DRUGS

If available information is insufficient to support an NDA for a botanical drug, the sponsor will need to develop further data. An IND is required under section 505(i) of the Act and 21 CFR part 312 (unless exempt under § 312.2(b)) when a botanical product is studied in the United States for a drug use (see section 201(g) of the Act), even if such study is intended solely for research purposes. Under § 312.22, an IND must contain sufficient information to demonstrate that the drug product is safe for testing in humans and that the clinical protocol is properly designed for its intended objectives.

A. IND Information for Different Categories of Botanicals

Under § 312.22(b), the amount of information that must be submitted in an IND for a particular drug product depends on, among other things, the novelty of the drug, the extent to which it has been studied previously, the drug product's known or suspected risks, and the developmental phase of the drug. Sections VII and VIII of this guidance describe the information that we recommend a sponsor provide in meeting the requirements in § 312.23 for an IND for initial (i.e., phase 1 and phase 2) clinical studies of a botanical drug. As noted above, for botanicals legally marketed under the DSHEA, there will often be very little new CMC or toxicological data needed to initiate such trials, as long as there are no known safety issues associated with the product and it is to be used at approximately the same doses as those currently or traditionally used or recommended. A botanical drug is considered to have a known safety issue when FDA has evidence that it produces serious and/or possibly life-threatening effects. Nonclinical evaluation to characterize toxicities may be appropriate for products with known safety issues. For example, nonclinical data may be appropriate to help establish safe doses and to determine ways to better monitor potential toxicities in humans. Such nonclinical studies may be needed early in development (see § 312.23(a)(8)).

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Properly conducted early clinical investigations, including controlled effectiveness trials in phase 2, will allow a determination of whether there is a clinical effect worth pursuing and will provide a more systematic evaluation of safety than previously available. If a botanical drug product shows promise of effectiveness in such early trials, the potential for wider use for particular purposes will create a need for greater assurance of product quality and consistency and for expanded (i.e., phase 3) clinical studies of safety and effectiveness (§ 312.22(b)). IND information appropriate for expanded clinical studies of botanical drugs is discussed in section IX.

Under § 312.22(b), the IND sponsor of a botanical product that has been previously marketed but *not* in the United States must provide sufficient additional information to assist FDA in determining the safety of the product for use in initial clinical studies (section VII). Such additional information is appropriate under that regulation because these products are not already marketed in the United States and evidence of safety should be provided before patients are exposed to them.

This guidance also addresses the type of information that should be provided under § 312.22 in INDs for initial studies on botanical products that have not been lawfully marketed anywhere or have known safety issues (section VIII). In contrast to botanical products that have been marketed in some form, considerably less information may be available on the safety of a new botanical product that has not been marketed anywhere as a food or dietary supplement and has not been tested as a drug in humans. Consequently, it is appropriate that, under § 312.22(b), sponsors of INDs for initial trials of botanical products that have not previously been lawfully marketed anywhere, or for which there are known safety issues, provide certain additional information to FDA.

The information to be provided in an IND for a botanical drug product is illustrated schematically in Attachment B and discussed in this section and sections VII-IX below. FDA encourages sponsors of INDs for initial studies of botanical drugs to seek input from CDER review divisions (organized based on the therapeutic classes of the drugs) to ensure that the appropriate information is submitted and that the clinical protocols are well designed. Many guidance documents specific to particular indications or dosage forms are also available from the respective review divisions.

FDA may place an IND for initial studies of a botanical drug on clinical hold (i.e., an order issued by the Agency to delay a proposed clinical study) if it finds that the IND does not contain sufficient information required under § 312.23 to assess the risk to subjects of the proposed studies (§ 312.42(b)(1)(iv)). However, the lack of any specific item of information listed in § 312.23 for a phase 1 study will not necessarily justify imposing a clinical hold. Possible grounds for a clinical hold are set forth in § 312.42(b) and discussed in CDER's guidance for industry on *Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products* (November 1995).

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B. Basic Format for INDs

The format and general requirements for IND submissions are stated in § 312.23 and discussed in several CDER guidance documents, including the phase 1 guidance referenced above. These requirements are summarized below, with guidance on the specific types of information that we recommend sponsors of botanical drug products provide to meet these requirements:

1. *Cover Sheet (see § 312.23(a)(1))*
2. *Table of Contents (see § 312.23(a)(2))*
3. *Introductory Statement and General Investigational Plan (see § 312.23(a)(3))*
4. *Investigator's Brochure (see § 312.23(a)(5))*
5. *Protocols (§ 312.23(a)(6))*

Section 312.23(a)(6) requires information on protocols for planned studies. In general, clinical evaluation of botanical drug products for safety and effectiveness does not differ significantly from evaluation of synthetic or highly purified drugs. For study results to be interpretable, clinical studies must be well designed and carefully executed (see § 314.126). A sponsor need not differentiate the clinical effects of each molecular entity in a botanical product derived from a single part of a plant (see section III.D, Applicability of Combination Drug Regulations). Even where the components of a combination product must be studied under § 300.50, initial controlled studies could be used to evaluate the entire combination product. For additional information on the clinical development of new drugs, see the CDER guidance *Format and Content of the Clinical and Statistical Sections of an Application* (July 1988) and other guidances related to the submission of applications involving specific drug classes and diseases.

Clinical studies of botanical products may pose special problems associated with the incorporation of traditional methodologies, such as selection of doses and addition of new botanical ingredients based on response, that will need to be resolved. In almost all cases, credible studies will be randomized, double blind, and placebo-controlled (or dose-response) (see § 314.126). Studies with only active controls may be appropriate when it is unethical to use a placebo, as would be the case in serious and life-threatening conditions for which there is established effective therapy. However, active studies pose special difficulties in interpretation and should be used only when a placebo cannot be used and there is good reason to expect the botanical treatment to be effective. With respect to serious illnesses for which there is established effective therapy, we generally encourage sponsors to use an “add-on” design for the initial trials: The botanical product would be compared to a placebo, each being added to the standard treatment. For symptomatic disorders where the use of a placebo poses no ethical problem, placebo-controlled trials should almost always be conducted because active control trials are particularly difficult to interpret in such situations. Having a concurrent active treatment

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group in addition to placebo control (e.g., a three-armed study) is advisable in certain cases (as in psychiatric trials) to verify the assay sensitivity of the study. The sponsor is encouraged to consult International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidance *E10 Choice of Control Group and Related Issues in Clinical Trials* (May 2000).

For botanical as well as for synthetic or highly purified drugs, absolute safety does not exist for any therapeutic intervention, and FDA must assess risks in light of potential clinical benefits (see § 312.22). For more comprehensive information on safety evaluations, see other CDER guidance documents. As is the case for synthetic or highly purified drugs, the best safety data on newly developed botanicals will be derived from controlled efficacy trials, but for chronic indications, long-term, open-label extensions also will be important. For chronic conditions, exposures of at least 6-12 months' duration are usually appropriate (see ICH guidance *E1A The Extent of Population Exposure to Assess Clinical Safety: For Drugs Intended for Long-term Treatment of Non-Life-Threatening Conditions* (March 1995)).

Section VII.E of this guidance provides recommendations on the protocol design of initial clinical trials for botanical products legally marketed under the DSHEA. Sections VIII.E and IX.E provide information on the design of initial clinical trials for nonmarketed botanical drug products and for expanded studies on all botanical drug products, respectively.

As with any clinical study, appropriate human research subject protections must be followed, including submission of the protocol to an institutional review board (IRB) and obtaining proper informed consent (see 21 CFR parts 56 and 50). Pursuant to § 50.25, the consent form should describe any procedures that are experimental along with a description of the risks, benefits, and alternatives of taking the product. We recommend that the consent form acknowledge any lack of additional chemical or toxicological characterization.

6. Chemistry, Manufacturing, and Controls (§ 312.23(a)(7))

The requirements for the content and format of the CMC section of an IND are stated in § 312.23(a)(7)(iv)(a)-(e). These regulations require documentation of the drug substance, drug product, placebo, labeling, and an environmental analysis.

Plant materials used in the production of botanical drug products often are not completely characterized and defined or are prone to contamination, deterioration, and variation in composition and properties. In many cases, the active constituent in a botanical drug is not identified, nor is its biological activity well characterized. Therefore, in contrast to the situation with synthetic or highly purified drug products, it may be difficult to ensure the quality of a botanical drug by controlling only the corresponding drug substance and drug product. To ensure that a botanical drug product used in clinical trials is of consistently good quality, and that sufficient information exists to meet the requirements

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of § 312.23(a)(7)(iv), the sponsor should have, in addition to final product testing, appropriate quality controls for the botanical raw materials. The manufacturing process should be well defined, with adequate in-process controls, especially for the drug substance.

As noted in section III.C, sponsors of initial clinical trials on botanical products that have been legally marketed as dietary supplements and that do not have safety issues can submit less CMC information than must be provided under §§ 312.22(b) and 312.23(a)(7)) for later studies or for studies on products not previously marketed. Section VII.B describes the CMC information that generally will be necessary under § 312.23(a)(7) for initial trials on previously marketed botanicals without safety issues.

To comply with §§ 312.22(b) and 312.23(a)(7), sponsors must submit additional CMC information for initial studies of nonmarketed botanical products and marketed botanicals with safety issues (see section VIII.B) and for expanded trials on all botanical products (see section IX.B). Additional guidance (not specific to botanical drugs) on the submission of CMC information in INDs and marketing applications can be found in other CDER guidance documents.

In the initial stage of clinical studies of a botanical drug, it is generally not necessary to identify the active constituents or other biological markers or to have a chemical identification and assay for a particular constituent or marker. Identification by spectroscopic and/or chromatographic fingerprinting and strength by dry weight (weight minus water or solvents) can be acceptable alternatives. Attributes for lot or batch release testing should be determined as the clinical study progresses, although appropriate acceptance criteria for batch release need not be established until later in phase 3 studies. Batch analyses on clinical batches should be submitted as they become available, to demonstrate batch-to-batch consistency and to help establish appropriate acceptance criteria for fingerprinting. Identification of active constituents is helpful in optimizing manufacturing procedures, ensuring batch consistency, and contributing to an understanding of the clinical effects of the botanical product. Therefore, when feasible, active constituents should be identified during phase 3 studies.

A single formulation (i.e., one in which the components or ingredients and composition of the drug substance and drug product are kept constant) and a single dosage form should be used throughout the different stages of the clinical trials unless this proves impossible. Screening of a number of sources/batches for product quality is recommended to ensure that the material used in initial trials will yield interpretable results that can be used to guide later development. Once a batch or source of acceptable quality is identified, sufficient quantities should be obtained to sustain the initial clinical trials. This is especially important if the sponsor does not have access to the manufacturing and controls information on the botanical drug substance and finished product. In addition, sufficient quantities of the botanical raw material and drug substance from the same batch should be retained for future chemical characterization and/or pharmacological/toxicological testing. It is also important to obtain the botanical drug product from a source willing to provide FDA with detailed manufacturing and

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controls information when needed, or as clinical evaluation of the product progresses. These factors are crucial if the sponsor intends to pursue FDA approval for a new drug application for the botanical product.

Consistency should be maintained when multiple batches are used in the nonclinical and clinical trials. It also is important that the material used in phase 1/2 trials be verified for its authenticity (see VIII.B.1 below). Samples from phase 1/2 studies should be retained for comparison with batches to be used in the phase 3 trials to ensure consistency. Bridging studies (clinical and/or nonclinical) should be performed if the use of batches with different characteristics in different phases cannot be avoided.

Botanical raw materials may sometimes be dispensed at clinics on an as needed or by prescription basis and subsequently prepared by patients themselves at home. We recommend avoiding these practices during clinical trials if at all possible because data related to such use may not be reliable because of variability in preparation by patients. When absolutely necessary, dispensing in such a manner may be considered for initial clinical studies. But as clinical trials are expanded, the botanical drug product should be produced in a controlled manner by an established manufacturer to ensure the validity and reliability of data.

If previously available nonclinical and/or clinical data are provided or referenced in the IND, a comparison should be made of the botanical drug products used in the referenced studies, the products to be used in the proposed trials, and (if appropriate) the products intended for marketing (including their corresponding botanical raw materials, drug substances, and formulations).

If a synthetic or highly purified drug or a biotechnology- or other naturally derived (non-botanical) drug is added to a botanical drug product, the CMC data for this added substance should be described or cross-referenced according to § 312.23(b) and guidances. Under § 312.23(a)(7), animal parts (e.g., insects, annelids, shark cartilage) or minerals that are combined with a botanical in a drug product, must be accompanied by additional manufacturing and controls information specific to these materials because they are part of the drug substance being studied.

CMC information on a botanical raw material, drug substance, and/or drug product may be submitted by the sponsor as part of the IND or by the manufacturer (if different from the sponsor) in a drug master file (DMF). A DMF is a submission from a manufacturer to FDA that may be used to provide confidential information on a human drug (§ 314.420(a)). The information contained in a DMF may be cross-referenced to support an IND or NDA and is reviewed and used by FDA only when authorized by the manufacturer. However, the sponsor relying on information in a DMF should have adequate acceptance testing (e.g., identification test, assay) before accepting the raw material, drug substance, or drug product received from the DMF holder for further processing or for use in humans directly.

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7. *Pharmacological and Toxicological Information (§ 312.23(a)(8))*

The content and format for pharmacological and toxicological information to be provided in an IND are described in § 312.23(a)(8). Nonclinical pharmacology and toxicology studies are useful in guiding early clinical studies and in predicting the potential toxicity of a new drug.

Ordinarily, less nonclinical information will be required to support the initial clinical trials of currently marketed orally ingested botanical products than is expected for synthetic or highly purified drugs. For a botanical product that is not currently lawfully marketed in the United States, but is administered orally and prepared, processed, and used according to methodologies for which there is prior human experience, sufficient information may be available to support initial clinical studies without standard nonclinical testing. However, for a botanical drug with a route of administration other than oral, additional pharmacology/toxicology information may be necessary before initial clinical studies.

After initial clinical studies, further pharmacology and toxicology studies of a botanical drug generally would be needed before later phases of clinical development and before approval for marketing. Sections VII.C, VIII.C, and IX.C provide details on the pharmacological and toxicological information that should be provided for clinical trials on botanical drugs.

8. *Previous Human Experience With the Product (§ 312.23(a)(9))*

Under § 312.23(a)(9), an IND sponsor must submit information about previous human experience with an investigational drug. Many botanical products have been marketed or tested in clinical studies (often involving few patients). When such studies have been conducted, data from the studies must be included in an IND for a botanical drug to assist FDA in its overall safety assessment. Sections VII.A, VIII.A, and IX.A of this guidance provide additional recommendations on the submission of information on previous human experience with a botanical product.

VII. INDs FOR PHASE 1 AND PHASE 2 CLINICAL STUDIES OF LAWFULLY MARKETED BOTANICAL PRODUCTS WITHOUT SAFETY CONCERNS

This section provides more detailed guidance on the submission of certain types of information for INDs for initial clinical studies on botanical products that have been lawfully marketed and that do not raise safety issues (for drugs with known safety concerns, see section VIII). This section also notes where additional information must be provided under § 312.22(b) when an IND is for a botanical product that has been marketed in one or more foreign countries but not the United States.

A. Description of Product and Documentation of Human Use

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1. Description of Botanicals Used (§ 312.23(a)(3)(i))

The following information should be provided for **each** of the botanical raw materials used as ingredients in a botanical drug product:

- Common or usual names of the plant, alga, or macroscopic fungus
- Synonyms (e.g., Latin, Greek, English, Spanish, Chinese)
- Name of variety, species, genus, and family, including the name of the botanist who first described the species or variety, if known
- Chemical class of the active constituent (the chemical constituent that is responsible for the claimed pharmacological activity or therapeutic effect) or characteristic marker (a chemical constituent used for identification and/or quality control purposes), if known

2. History of Use (§ 312.23(a)(3)(ii),(a)(9))

The sponsor should include information found in historical sources (e.g., books of medical practice in Ayurveda, traditional Chinese medicine, Unani, Sida) and scientific literature about the prior human use of the botanical product, and each of its ingredients, in traditional foods and drugs. Any literature submitted must be provided in English (and in its original language, if other than English) (§ 312.23(c)).

3. Current Marketed Use (§ 312.23(a)(3)(ii), (a)(9))

The sponsor must include information about the nature and extent of the current worldwide use of the botanical product, and each of its ingredients, in foods and drugs, including evidence concerning its marketing experience in the United States and/or foreign countries. For a foreign-marketed botanical product, the sponsor should provide data that verify its safe human use, including proof of the annual sales volume, an estimate of the size of the exposure population, and the rate of adverse effects.

B. Chemistry, Manufacturing, and Controls

Outlined below is the CMC information that we recommend you submit, in meeting the requirements of § 312.23(a)(7), in an IND to support a phase 1 or phase 2 clinical trial on a botanical product that is currently lawfully marketed without any known safety issues in the United States and/or a foreign country. Literature references and relevant official compendia or published standards should be provided whenever possible.

1. Botanical Raw Material (§ 312.23(a)(7)(i))

The information discussed in section VII.A.1 should be provided for all currently lawfully marketed products. It is important for the safe conduct of clinical trials to

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ensure the proper identity of botanical raw materials used in the trials. Since there is no history of U.S. experience for botanical raw materials marketed only outside the United States, a certificate of authenticity of the plant and plant parts should be provided for such materials. A trained professional who is competent to determine authenticity should sign this certificate. This information also should be provided, if available, for a botanical raw material marketed in the United States.

2. *Botanical Drug Substance (§ 312.23(a)(7)(iv)(a))*

The general method of preparation (e.g., pulverization, decoction, expression, aqueous extraction, or ethanolic extraction) must be provided under § 312.23(a)(7)(iv)(a). This is especially important where more than one process exists in the literature on which the safety of the botanical drug substance is based.

3. *Botanical Drug Product (§ 312.23(a)(7)(iv)(b))*

A botanical drug product is manufactured from a botanical drug substance by adding one or more excipients, mixing, blending, granulating, tableting, encapsulating, or performing other dosage-form-specific procedures, followed by packaging. When packaged without further processing, a botanical drug substance is considered the drug product. We recommend that the following information be provided for a botanical drug product:

- A qualitative description of the finished product, including the dosage form, route of administration, names of all ingredients (i.e., botanical drug substance and excipients), and a statement that the product is not adulterated with potent, toxic, or addictive botanical substances, synthetic or highly purified drugs, biotechnology-derived drugs, or other naturally derived drugs.
- The composition or quantitative description of the finished product (i.e., the quantity of the botanical drug substance and each excipient, if any) expressed in terms of amount per dosage unit. We recommend that sponsors provide this information in tabular form.

Example for a single-herb botanical drug product

Component	Amount per tablet	Amount per batch
Senna leaf extract (8:1 powdered aqueous extract)	250 mg	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 amount may also be expressed on the basis of amount of botanical raw material (e.g., weight of dried leaves).

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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

Example for a multi-herb botanical drug product:

Component	Amount per tablet	Amount per batch
A 5:1 powdered, aqueous extract from 1:1 mixture of <i>Forsythia suspensa</i> Vahl. flowers and <i>Lonicera japonica</i> Thunb. fruits	600 mg	24 kg
Excipient 1	100 mg	4.0 kg
Excipient 2	10 mg	0.4 kg

- The manufacturer's certificate of analysis for the study product or, if none is available, authorization to allow FDA to cross-reference the manufacturer's previous submission for the relevant CMC information. If this information is unavailable for a foreign-marketed product, the sponsor should perform quality testing on the product according to the recommendations listed under section VIII.B.3. In addition to those tests, heavy metal analysis, and an animal safety test (see below), if applicable, should be performed. The test methods and results should be provided in the IND. The study product should be from a single source and, where feasible, from a single batch. A product sample from the batch to be used in the clinical study should be retained for possible future testing by FDA and/or the sponsor.

4. *Animal Safety Test (§ 312.23(a)(8))*

An animal safety test (different from the rabbit pyrogen test, USP <151>) is an acute animal toxicity test applied only to injectable drug products. We recommend that this test be performed for crude extracts from natural sources, especially when the raw material, process, and final product cannot be fully characterized and controlled.

5. *Placebo (§ 312.23(a)(7)(iv)(c))*

The components of any placebo used must be described.

6. *Labeling (§ 312.23(a)(7)(iv)(d))*

The following labeling information must be provided:

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- A copy of the container label and the immediate outer carton label of the marketed product to be used in the clinical study.
- A mock or printed representation of the proposed container label that will be provided to the investigators in the proposed clinical study. It should contain the following information: protocol number; patient number; sponsor's name; product name or code number; strength and/or potency; recommended storage conditions; lot number; and (as required under § 312.6) the statement, "Caution: New drug -- Limited by Federal law to investigational use." In a placebo-controlled clinical trial, both the study drug and the placebo should be properly labeled to protect the integrity of the blinded study.

7. Environmental Assessment or Claim of Categorical Exclusion (§ 312.23(a)(7)(iv)(e))

A claim for categorical exclusion from the requirement for preparation of an environmental assessment (EA) ordinarily can be made for an IND (21 CFR 25.31(e)).

C. Pharmacology/Toxicology Information

1. All Marketed Botanical Products

Under § 312.23(a)(8), previous human experience and available animal toxicity data concerning the clinical formulation and the individual botanical ingredients within the formulation must be provided to support initial clinical trials (phase 1 and phase 2) of a botanical drug product for the proposed use. As noted in section VI.A, initial studies for botanical products with no known safety concerns and that have been marketed in the United States as dietary supplements may generally be conducted without further pharmacologic/toxicologic testing. Nevertheless, available information should be provided. A database search should be conducted, when feasible, to identify information relevant to the safety and effectiveness of the following:

- the final formulation of the intended commercial botanical drug product
- the individual botanical ingredients
- the known chemical constituents of the botanical ingredients.

Under § 312.23(a)(8)(ii), an integrated summary of available data from medical and toxicological databases (e.g., Medline, Toxline, TOMES, RTEC) must be submitted for review. Using the information gathered from this literature, the sponsor should address, as appropriate for the proposed study, the following issues concerning the botanical drug product:

- general toxicity
- target organs or systems of toxicity

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- teratogenic, carcinogenic, or mutagenic potential of any botanical ingredient in the product
- relationship of dosage and duration to toxic responses
- pharmacological activity.

2. Foreign-Marketed Botanical Products

For the reasons discussed in section VI, additional information must be provided in accordance with § 312.22(b) for a botanical product that has been previously marketed but not in the United States. In addition to the information listed above, the sponsor should provide data that support safe human use and should include the annual sales volume, an estimate of the size of the exposure population, and available data on the rate of adverse effects. The nature of nonclinical pharmacology/toxicology information needed before a sponsor conducts an initial clinical study will be determined on a case-by-case basis, depending on the indications, proposed dose, duration and size of study, and available data supporting safe human experience.

D. Bioavailability

Pharmacokinetic and pharmacodynamic information is helpful in the design and interpretation of clinical studies. Since botanical products often consist of more than one chemical constituent and the active constituents are often unknown, standard pharmacokinetic measurements to demonstrate systemic exposure to a product in animals and/or humans may be difficult to obtain. However, when feasible, sponsors are encouraged to monitor the blood levels of known active constituents, representative markers, or major chemical constituents in a botanical drug product (see section IX.D).

E. Clinical Considerations

The initial clinical trial for a botanical product currently marketed under the DSHEA will ordinarily be a well-controlled study capable of demonstrating effectiveness. Because the product is marketed and the dose that is thought to be appropriate and well tolerated is known, there should be little need for pilot or typical phase 1 studies, and uncontrolled observations are unlikely to be useful. Sponsors are therefore strongly encouraged to initiate more definitive trials early in the development program to determine whether a botanical product has efficacy for one or more claimed indications. Safety data should be collected during the trials. If there is doubt about the best dose of the product tested, a randomized, parallel, fixed-dose, dose-response study may be particularly useful as an initial trial.

Regarding the safety of the drug, a botanical preparation lawfully marketed in the United States will generally be considered acceptable for at least short-term (e.g., up to several months) use in clinical trials. For foreign-marketed botanical products, safety considerations will be based on available CMC, pharmacology, and toxicology information, as well as indications, proposed doses, duration and size of the study, and available data supporting safe human use.

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VIII. INDs FOR PHASE 1 AND PHASE 2 CLINICAL STUDIES FOR NONMARKETED BOTANICAL PRODUCTS AND PRODUCTS WITH KNOWN SAFETY CONCERNS

This section discusses the type of information that we recommend be provided in meeting the requirements for INDs for initial trials of botanicals that (1) have not previously been lawfully marketed in the United States or elsewhere or (2) that have been marketed and have known safety issues.

A. Description of Product and Documentation of Human Use

In addition to the information outlined in section VII.A.1-2, the following should be provided in accordance with the listed subsections of § 312.23 for each raw material contained in a botanical product not lawfully marketed in either the United States or other countries:

1. Description of Botanicals Used (§ 312.23(a)(3)(i))

- Morphological and anatomical description (including gender, if applicable) and a photograph of the plant or plant part, alga, or macroscopic fungus used
- Natural habitat and geographical distribution of the plant, alga, or macroscopic fungus
- Current sources of the plant, alga, or macroscopic fungus, including its geographical location and whether it is cultivated or harvested from the wild
- A statement indicating whether the species is any of the following:
 - Determined to be endangered or threatened under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora;
 - Entitled to special protection under some other Federal law or international treaty to which the United States is a party;
 - The critical habitat of a species that has been determined to be endangered or threatened

2. History of Use (If Any) (§ 312.23(a)(3)(ii), (a)(9))

- Method of preparation, processing, and formulation

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- Routes, schedules, and doses of administration
- Medical claims
- Contraindications and adverse events associated with use in humans and animals
- Traditional geographical areas and populations in which such use occurred
- A description of the similarities and/or differences between the traditional preparation and the proposed clinical formulation

3. Current Investigational Use (If Any) (§ 312.23(a)(3)(ii), (a)(9))

- Proposed therapeutic claim and dose regimen (mg/kg/dose and dose/day)
- All available information in the literature that addresses the proposed therapeutic claim, including both positive and negative studies

B. Chemistry, Manufacturing, and Controls

Outlined below is the CMC information that should be submitted, in meeting the requirements of § 312.23(a)(7), in an IND to support a phase 1 or phase 2 clinical trial using a botanical product that is not currently lawfully marketed in the United States or a foreign country, or for which there are known safety issues.

1. Botanical Raw Material (§ 312.23(a)(7)(i))

A botanical drug substance can be derived from one or more botanical raw materials. The following recommendations apply to each individual botanical raw material used.

The botanical raw material should be described as outlined in sections VII.A.1 and VIII.A.1. If the botanical raw material has no documented history of use, the IND sponsor should so indicate. The following information should be provided:

- Identification by trained personnel of the plant, plant parts, alga, or macroscopic fungus used, including organoleptic, macroscopic, and microscopic examination. The identification should be done against a voucher specimen (reference specimen). If more than one variety of a given species is used, each should be specified. A sample of the plant, plant parts, or other botanical materials should be retained and stored under appropriate conditions by the raw material supplier and botanical drug substance manufacturer for each batch. These samples will be used for verification of identity, if needed.
- A certificate of authenticity

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- A list of all grower(s) and/or supplier(s) (including names and addresses). The following items should be provided for each grower/supplier, if available:
 - Harvest location
 - Growth conditions
 - Stage of plant growth at harvest
 - Harvest time
 - Collection, washing, drying, and preservation procedures
 - Handling, transportation, and storage conditions

2. *Botanical Drug Substance (§ 312.23(a)(7)(iv)(a))*

The following information should be provided for all botanical drug substances, regardless of whether they are prepared from one or more botanical raw materials:

- A qualitative description of the drug substance, including the name, appearance, physical and chemical properties, active constituent (if known), biological activity (if known), and clinical indication (if known) of each botanical raw material. If the active constituent, biological activity, and/or clinical indication is unknown, the IND sponsor should clearly so state. In the case of a multi-herb substance, the sponsor should state whether the drug substance is prepared by combining individually processed botanical drug substances or by processing combined botanical raw materials.
- The quantitative description (strength) of the drug substance. Historically, the strength of a botanical drug substance is expressed simply as the absolute dry weight of the processed substance. The batch size and the yield of the process, relative to the botanical raw material, also should be indicated. Furthermore, where the active constituents or other chemical markers are known and measurable, the amount in which they are present in the botanical drug substance should be declared. For a multi-herb substance, its composition should be expressed in terms of the relative ratio of the individually processed botanical drug substances or of the botanical raw materials before processing, whichever is appropriate.
- The name and address of the drug substance manufacturer (processor).
- A description of the manufacturing process for the botanical drug substance. The description should include the quantity of botanical raw material, solvents, extraction and/or drying, and yield. 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

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- 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 the drug substance, 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. Examples of spectroscopic methods include ultraviolet, infrared, Fourier transformed infrared, and mass spectroscopy. Examples of chromatographic methods include high performance liquid chromatography (HPLC), HPLC with diode array detection, thin layer chromatography (TLC), 2-dimensional-TLC, and gas chromatography.
 - Chemical assay (i.e., assay) for active constituents or 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 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 (equivalent to botanical raw material)
 - Heavy metals
 - Microbial limits
 - Animal safety test, if applicable
 - A description of the container/closure in which the botanical drug substance is to be stored and/or shipped.
 - Available stability data on the drug substance. The sponsor should develop stability-indicating analytical methods and conduct stability studies as the IND progresses.

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- The container label, which should reflect the qualitative and quantitative description of the botanical drug substance, as discussed above, and recommended storage conditions. Examples of labeling for single-herb and multi-herb substances are shown below:

Single-herb substance:

- Expressed in terms of yield:
Senna, 10 kg, equivalent to 80 kg of dried leaves
or
Senna, 10 kg, 8:1 (w/w) powdered extract of dried leaves
- Expressed in terms of active constituents:
Senna, 10 kg extract, containing 2 kg of hydroxyanthracene glycosides (sennosides), calculated as sennoside B
- Expressed in terms of chemical markers:
Valerian, 10 kg extract, containing 0.1 kg valeric acid

Multi-herb substance:

- Prepared by combining individually processed botanical drug substances:
Lonicera japonica Thunb. and *Forsythia suspensa* Vahl., 6 kg, containing 3 kg of *Lonicera japonica* Thunb. 4:1 solid extract and 3 kg of *Forsythia suspensa* Vahl. 6:1 solid extract
- Prepared by processing combined botanical raw materials:
Lonicera japonica Thunb. and *Forsythia suspensa* Vahl., 6 kg, a 5:1 powdered extract prepared from 15 kg of *Lonicera japonica* Thunb. and 15 kg of *Forsythia suspensa* Vahl

3. *Botanical Drug Product (§ 312.23(a)(7)(iv)(b))*

The following information should be provided:

- A qualitative description of the finished product (see section VII.B.3.)
- The composition, or quantitative description, of the finished product (i.e., the name and quantity of the botanical drug substance and of each excipient (if any), expressed in terms of amount per dosage unit and amount per batch). This information should be provided in tabular form. A quantitative description of the drug substance should be provided as described in section VIII.B.2.