EXHIBIT
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From: jsonick@gmail.com [jsonick@gmail.com] On Behalf Of Jason Nickerson [jason@greenbeltmgmt.com]
Sent: Friday, April 26, 2013 4:27 PM
To: Rubenstein, William; Berner, Gary; Nahas, Elisa
Subject: Additional Comments

Commissioner, on behalf of the Greenbelt Management team I am submitting some additional comments regarding the testing and branding portions of the regs. We appreciate the opportunity to contribute our thoughts and thank you in advance for our consideration.

Regards,

Jason Nickerson
President
Greenbelt Management LLC

Michelle Sexton ND
Research Faculty, Bastyr University
San Diego, CA

April 26, 2013

To Whom it may Concern:

I was asked to prepare this response to the proposed Connecticut regulations on medical Cannabis use by Greenbelt Management. I was approached because of my background in the chemical analysis of plant constituents, my research background in the pharmacology of cannabinoids, and my involvement in the quality control of Cannabis in Washington State. I have attached my CV so that my qualifications can be further reviewed. I am a Naturopathic Doctor, licensed in two states and have been certified as an herbalist since 1991.

This varied background has given me a uniques perspective on the use of Cannabis as a botanical medicine. I have been the chair of the scientific advisory bord for Americans for Safe Access, as well as a current member of the Board of Directors. I have no stake in this industry, but I do have a stake in the health and safety of the general public, and the application of the existing GMP standards to the production and use of Cannabis. There is a need to bring this plant, it's agricultural practices, analysis, and labeling up to the standard of other botanical medicines. There are existing frameworks for these regulations and would encourage the State of Connecticut to tap into these guidelines in an effort to not re-invent the wheel. The State of Washington, for whom I am serving as a consultant, is on thrack to create a model regulatory standard, heavily drawing upon the existing industry, as well as the resources that guide the rest of the botanical industry at large.

Please let me know if I can be helpful in putting you in touch with any of the organization or individuals who could further assist you in this process.

Regards,

Michelle Sexton ND

medicine, but not the safety profile. This recommendation is not in-line with any standard currently in place for any other botanical.

(8) A pass/fail rating based on the laboratory's microbiological and chemical residue analysis.

Chemical exposure should first be an issue for growing conditions and monitoring at that level of the grower. The need to test for chemical residue can be easily done using head-space sampling with GC/MS. The effort to minimize pesticide, miticide, mycotoxin exposure should first occur at the growing level, and if these compound have been used, the requisite testing is needed. Even our food is not subjected to this level of scrutiny, and by definition, botanical medicines are "food". We should work to minimized mycotoxin production in "the field". If the plant material is going to be combusted (smoked or vaporized) very few microbiological threats are there to warrant blanket testing.

Brand Registration

Each marijuana product shall be assigned a brand name and registered with the department (for $1000) with a profile of all active ingredients including:

1) THC
2) THCA
3) CBD
4) CBDA
5) Any other active ingredient that constitutes at least 1% of the marijuana batch used in the product.

I do not believe this is necessary for product safety. Labeling for each 'batch' should be acceptable. This is an unprecedented requirement for botanical medicine where nowhere near this level of scrutiny is imposed.

No two marijuana products shall be labeled with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient within a range of 97% to 103%.

19 x 0.97 = 18.43; 19 x 1.03= 19.57 (This is 0.6% allowable variance)

This means that if we tested Durban Poison (batch #1) and it came out with 19% active THC and 8% CBD and then tested Durban Poison (batch #2) and it came out with 17% THC and 8%CBD – it would have to be re-branded. This would result in the producer assigning a name that would not convey certain information to the patient about terpene profiles which are similar even when a potency range exists.

Although strain names are common identifiers in cannabis production, the name itself does not convey information about the safety or potency of the product. Identity, purity, quality are the most important factors for patients and can be verified at source of production through inspection and by chemical analysis by an independent laboratory.

Guidance on Residual Solvents in Extracts (adopted October 2010, revised July 2011) **Top of Page**

AHPA recommends that herbal extracts marketed in the U.S. limit any contained residual solvents to the levels established by the current International Conference on Harmonization's (ICH's) document, Impurities: Guideline for Residual Solvents, except that this guidance does not apply to the ICH limit of 50 mg per day for the class 3 solvent ethanol when it is present in liquid extracts formulated to contain ethanol, or for the class 3 solvent acetic acid when it is present in liquid extracts formulated to contain acetic acid or vinegar.

With regard to this guidance, solvents identified in the cited ICH document as class 1 solvents (benzene;* carbon tetrachloride;* 1,2-dichloroethane;* 1,1-dichloroethene; and 1,1,1-trichloroethane), which are considered by ICH as unacceptably toxic or an environmental hazard, are not appropriate for use, and should not be used, in the manufacture of herbal extracts.

With regard to this guidance, solvents identified in the cited ICH document as class 2 solvents, which are considered by ICH to be inherently toxic, are listed in the table below with the ICH recommended upper limits for Permissible Daily Exposures (PDE) and concentration limits given in ppm assuming a 10 gram daily dose.

Class 2 Solvent	*PDE (mg/day)*	*limit (ppm)*
Acetonitrile	4.1	410
Chlorobenzene	3.6	360
Chloroform*	0.6	60
Cyclohexane	38.8	3880
1,2-Dichloroethene	18.7	1870
Dichloromethane*	6.0	600
1,2-Dimethoxyethane	1.0	100
N,N-Dimethylacetamide*	10.9	1090
N,N-Dimethylformamide	8.8	880
1,4-Dioxane*	3.8	380
2-Ethoxyethanol	1.6	160
Ethyleneglycol	6.2	620
Formamide	2.2	220
Hexane	2.9	290
Methanol	30.0	3000
2-Methoxyethanol	0.5	50
Methylbutyl ketone*	0.5	50
Methylcyclohexane	11.8	1180
N-Methylpyrrolidone*	5.3	530
Nitromethane	0.5	50
Pyridine*	2.0	200
Sulfolane	1.6	160
Tetrahydrofuran	7.2	720
Tetralin	1.0	100
Toluene*	8.9	890
1,1,2-Trichloroethene	0.8	80
Xylene	21.7	2170

Guidance on Extract Labeling[1] (adopted March 2010) Top of Page

Any non-liquid herbal extract that discloses a quantitative extraction ratio stated as a ratio of two numbers represents the first number as the weight of starting plant material and the second

(a) (i) for dried, unprocessed herbs for use as ingredients in dietary supplements, and (ii) for herbal supplements in solid form consisting of dried, unprocessed herbs:

- Total aerobic plate count: 10^7 colony forming units/gram
- Total yeasts and molds: 10^5 colony forming units/gram
- Total coliforms: 10^4 colony forming units/gram
- Salmonella spp.: not detected in 10 grams
- Escherichia coli: not detected in 10 grams
- Total aflatoxins ($B_1 + B_2 + G_1 + G_2$): 20 μg/kg (ppb)
- Aflatoxin B_1: 5 μg/kg (ppb)

For purposes of this guidance the following definitions apply:

- "Dried unprocessed herb" *means* an herb or other botanical that is dehydrated from its fresh state and that has not been subjected to any further processing other than cleaning, grading, or size reduction (e.g., cutting or powdering).
- "Dietary supplement" *has the same meaning as* described in 21 U.S.C. 321 (ff). For purposes of this guidance a dietary supplement is a product in finished form ready for consumer use.
- "Herbal supplement" *means* a dietary supplement, as described in 21 U.S.C. 321 (ff), that contains one or more herbal ingredients (i.e., an herb or other botanical, or a concentrate, extract, or combination of an herb or other botanical). An herbal supplement may or may not contain additional non-herbal dietary ingredients (e.g., vitamins, minerals, amino acids, etc.) or excipients.
- "Botanical extract" *means* the complex, multi-component mixture obtained after using a solvent to dissolve components of an herbal or other botanical biomass. Botanical extracts may be in dry, liquid or semi-solid form. Excipients may be added to botanical extracts for various technical purposes (e.g., to adjust concentration; enhance stability; limit microbial growth; or improve drying, flow or other manufacturing characteristics). Botanical extracts are not the same as expressed juices, pure chemicals isolated from an herb, or synthetically modified plant constituents (though it should be noted that some chemical modifications might occur as the natural consequence of the extraction process).
- "Powdered extract" means a botanical extract that has been dried into a powder.
- "Soft (a.k.a. pilular, semi-solid, or solid) extract" means a botanical extract having a consistency of a thick liquid or paste.

In addition, for purposes of this guidance the following limitations and conditions apply:

- This guidance is not intended to suggest that manufacturers should establish specifications for any or all of the identified microbiological characteristics or mycotoxins in any specific herbal ingredient or supplement, but is rather intended to provide guidance for limits in the event any such specifications are set. This guidance is not, in fact, applicable for some herbal ingredients and supplements. In addition, it may not be relevant to test any specific herbal ingredient or supplement to determine the level of any or all of the microbiological characteristics or mycotoxins identified in this guidance.
- In determining whether *Salmonella* spp. and *E. coli* are not detected, the sample size may vary depending on the method used.
- Depending on the analytical methods used to detect *Salmonella* spp. or *E. coli*, failure to detect a microorganism may be reported as "absent," "not detected," "negative," or "less than" the detection limit.

Michelle Sexton

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• 2631 Wightman St, San Diego, CA 920104

EDUCATION

2008-11	POSTDOCTORAL FELLOWSHIP, UNIVERSITY OF WASHINGTON
2008	N.D. Naturopathic Medicine, Bastyr University, Seattle Washington
2003	B.S. Texas Tech University, Lubbock Texas. Cum Laude
1997	Certified Herbalist, Sage Mountain Herbal Center, Vermont
1993	Certified Professional Midwife, North American Registry of Midwives

EXPERIENCE:

2008-2012	Private Clinical Practice
2011-2012	Owner, Phytalytics LLC phytochemical analysis company
2011-present	Native Roots Consulting LLC
2011-2013	Bastyr University Research Institute, Assistant Research Scientist
2008-2011	Individual fellowship (F-32:NIH/NCCAM) University of Washington, Seattle, WA
2004-2006:	Research Scientist, Vanderbilt University, Department of Chemistry
2005	Pre-doctoral T-32 Research Fellow, Bastyr University
2004	Pre-doctoral T-32 Research Fellow, Bastyr University
2003	Undergraduate Researcher, Texas Tech University, Department of Chemistry
2001-2002	Undergraduate Researcher, Texas Tech University, College of Agric. Sci.
1993-2003	Private Midwifery Practice, primary obstetric/gynecology care
1988-2002 :	ICEA certified childbirth educator

PROFESSIONAL MEMBERSHIPS:

American Association of Naturopathic Physicians
Washington Association of Naturopathic Physicians
North American Registry of Midwives
International Cannabinoid Research Society
International Association for Cannabinoid Medicine
Society for Orthomolecular Medicine

Teaching Experience:

2012	Adjunct Faculty, Bastyr University
2011-12	Faculty, Bastyr University Research Institute
2011	Designed and co-taught a reproductive biology class for graduating seniors in the Department of Biology at University of Washington (Howard Hughes Medical Institute, Future Faculty Fellow)
2011	Facilitator, Mind Body Medicine Class, University of Washington
2010	Guest lecturer, Bastyr University, Herbal Sciences Program
2008	Teaching Assistant, Botanical Medicine, University of Washington
2003	Teaching Assistant, Horticulture, Texas Tech University
1990-1993	Certified Childbirth Educator, Texas Tech Health Sciences Center
1990-2000	Home-based Alternative Education of my (5) children

peripheral benzodiazepine receptor targeted agent for in vitro imaging and screening". Bioconjug Chem. 2006 May-Jun;17(3):735-40. 16704212

Mingfeng Bai, Michelle Sexton, Nephi Stella, and Darryl J. Bornhop "MBC94, A Conjugable ligand for cannabiod CB2 Receptor Imaging" (accepted Bioconjugate Chemistry) 18444670

Sexton M, Woodruff G, Cudaback E, Kreitzer FR, Xu C, Lin YH, Moeller T, Bai M, Manning HC, Bornhop D, Stella N. "Binding of NIR-conPK and NIR6T to astrocytomas and microglial cells: evidence for a protein related to TSPO. PLoS One Dec 18, 4(12) e8271

Sexton M, Woodruff G, Horne EA, Lin YH, Muccioli GG, Bai M, Stern E, Bornhop DJ, Stella N. NIR-mbc94, a fluorescent ligand that binds to endogenous CB2 receptors and is amenable to high-throughput screening. Chem Biol. 2011 May27, 18(5): 563-8.

Sexton, M, Sylvestroni, A, Stella, N. Differential migratory properties of monocytes isolated from human subjects naïve and non-naïve to Cannabis. Inflammopharmacology 2012, April 11.

OTHER EXPERIENCE

Owner, Phytalytics LLC 2011-2012

I designed and implemented analytical platforms for the quality control of medical *Cannabis* in Washington State using HTPLC, HPLC and GCMS. Procedures for the sampling of plant samples, topicals, extractions, infusions, concentrates and edibles were developed and data was collected on strains, chemical ratios and contaminants. This data has been presented at an international conference on cannabinoids.

Owner, Native Roots Consulting 2011-2013

I provide consulting services for product development and analytical platforms to the medical Cannabis industry.

Postdoctoral fellow University of Washington 2008-2011

I designed, wrote and was awarded my individual fellowship grant (F32) from the National Institutes of Health (NCCAM). My appointment was in the Departments of Pharmacology and Psychiatry and Behavioral Medicine. In this position, I was an independent researcher and administered my own grant, acted as the study coordinator for a pilot study in Multiple Sclerosis, looking at novel immune markers. I was responsible for all of the Human Subjects responsibilities, recruiting, screening patients, interviewing patients, drawing blood and conducting three assays on serum and blood cells. In this position I gave numerous journal clubs, talks to undergraduates, supervised and trained students in laboratory techniques, assay development and experimental design. I measured cell migration, cytokines in serum using bead array and endocannabinoinds with UPLC/MSMS.

Research Scientist University of Washington 2006-2008

We labeled cannabinoid receptor two (CB2), a marker of neuro-inflammation, with MBC94, synthesized in Dr. Bornhop's lab at Vanderbilt University. My previously developed assay was employed to determine the specificity and binding properties of this molecularly-targeted imaging agent, and then screen live microglia cells

Undergraduate researcher Texas Tech University, Department of Chemistry. 2002-2003

I assessed the Peripheral Benzodiazepine Receptor (PBR) expression in human, ex-vivo glioblastoma tissue using a molecularly-targeted lanthanide chelate. Labeling of this reliable marker of neuroinflammatioin with the dye and subsequent fluorescence microscopy revealed that a higher stage of disease correlated with increased labeling with the dye. (abstract and poster As a Research Assistant to Dr. Bornhop I assisted in the preparation of proposals (NIH, NSF, DOD) during my employment.

Developed an analytical platform for phytochemical analysis of native Echinacea sp. to West Texas using HPLC. 2002

Independent laboratory research, Bastyr University 2003

In collaboration with Dr. Gowsala Sivam. I performed HPLC quantification of ellagic acid in fresh organic raspberries. Results showed that fresh raspberry has a relatively high amount of ellagic acid, a potent nutritional anti-oxidant. (unpublished)