

Item 11 - Rcv'd 2/27/18
WRITTEN COMM. - CREIGHTON

To whom it may concern:

I am part of a group of entrepreneurs that are currently considering starting up a cannabis manufacturing facility in Southern California and we would like to start our business in Chula Vista. My background is I have my Ph.D. in organic chemistry from UCSD and have been in the pharmaceutical industry for 18 years now. My specialty is large scale chemical manufacturing focusing on production of pharmaceutical active ingredients. I have set up and managed two successful labs in San Diego. My experience provides me with a unique perspective as someone that has dealt with City, State, County and Federal regulations around the safe production pharmaceuticals and fine chemicals. My partner is currently the Vice President of Production for Upsher-Smith, a large US manufacturer of generic drugs for humans.

Before I go any further I just want to say that having to come up with this ordinance has to be very challenging. The conflict between the State of California's voters and the federal government does not facilitate a smooth rollout for establishing city rules around this industry. I applaud the City and the authors for their hard work and thought that was put into crafting this ordinance.

It is our view that when considering manufacturing of fine chemicals for human consumption, whether it is pharmaceuticals, nutraceuticals or cosmetics there one critical issue. The critical issue is SAFETY. This issue is divided into two components: 1. Making sure the final product is safe for the customer and 2. Making sure the operation of the facility is safe.

Consumer Safety (GMP)

Assurance for a safe product for human consumption is addressed by something called a Good Manufacturing Practice (GMP) system. This is an integrated quality assurance system established by the manufacturer under the guidelines provided by the FDA. The rules are established. A deep understanding of how to implement a chemical GMP program is needed to assure manufacturers are producing a safe product for the consumer. Our founders have over 40 years of combined experience in establishing and implementing a GMP safety system.

Operational Safety (EH&S)

Operations of a chemical manufacturing facility requires a deep understanding of chemical safety. Establishing controls for safe operations requires an understanding of Federal, State, County and City Environmental Health and Safety (EH&S) laws, OSHA, dealing with the Department of Transportation, establishing a hazardous materials business plan, compliance with the city and county fire codes, proper disposal of hazardous materials through a licensed company, Compliance with the San Diego County Water Authority, understanding material safety. Handling and storing chemicals properly. All this to make sure a company is protecting the city as well as its employees. Again, our founders have over 40 years combined experience in dealing with operational safety for pharmaceutical manufacturing.

The current draft of the ORDINANCE OF THE CITY OF CHULA VISTA ADDING CHAPTER 5.19.050.ii.B OF THE CHULA VISTA MUNICIPAL CODE TO REGULATE COMMERCIAL CANNABIS.

Reads.

(B) a minimum of thirty-six (36) consecutive months as an owner with an aggregate ownership of 30% or more in a lawful alcohol or pharmaceutical business licensed and regulated by a state or the federal government. The 36 months of experience demonstrated must be of a type substantially similar to that allowed by the City License for which the applicant is applying;

The language currently proposed would prohibit our company and others like us from operating in Chula Vista.

I would like to dissect the language.

1. It seems unlikely that someone in the alcohol manufacturing business has a strong command of the safety around refining chemicals including THC, CBD etc. and all of the GMP and EH&S issues around this space. A bar, liquor store, or even a brewery are very different businesses than a chemical refinery.
2. There are very limited professionals that have hands on experience in chemical manufacturing on scale that have owned 30% of a given pharmaceutical company. Even the CEO's of Merck, Pfizer and Eli Lilly do not own that percentage of these companies. What about successful biotech entrepreneurs in La Jolla? If they are doing it right the venture capitalists are funding their endeavor and diluting the entrepreneurs far below 30% ownership. The more successful the company the faster they are funded by the VC the faster the entrepreneurs are diluted. The 30% ownership for three years criterion doesn't really make sense. Is the ordinance written to attract entrepreneurs that continually struggle to get funding?

There is a pool of professionals in the metro area that have worked for and managed companies that have significant chemical manufacturing experience. Again, the probability that they owned a 30% share of the company approaches zero. Therefore with the current language is locking out the very entrepreneurs I would think Chula Vista would like to own and operate in the area of refining and manufacturing of cannabis related products.

Let's take a step back. We all recognize that there needs to be a threshold of entry to assure safe manufacturing in Chula Vista which produces safe products for your constituents. We recommend the criteria needs to be founded in

1. Having the cash on hand to set up and operate safely (which is included in the ordinance) as well as
2. Having the expertise around safe chemical manufacturing.

Therefore I recommend the following clause used for 5.19.050.ii.B:

(B) a minimum of thirty-six (36) consecutive months as an owner/senior manager/senior executive affiliated with the fine chemical manufacturing industry (pharmaceutical/nutraceutical/cosmetic). The applicant(s) must have experience in the areas of chemical safety, environmental safety (EH&S), quality assurance and good manufacturing practices (GMP) in line with federal and state guidelines.

Again, I applaud the city for their hard work on trying to create a business environment that would attract serious entrepreneurs. I think the language could use a little refining, if you will allow the pun. It is our hope that the ordinance focuses on expertise for the delivery of safe products under a safe manufacturing system for your constituents and the City of Chula Vista. I am very happy to discuss further if you have any questions or concerns.

Kind regards,

Christopher Creighton, Ph.D.

