# FENNEMORE.

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# ELECTRONIC MAIL

NEVADA CANNABIS COMPLIANCE BOARD 555 E. Washington Avenue, Suite 4100 Las Vegas, Nevada 89101 Electronic Mail: CCBmeetings@ccb.nv.gov

> Re: <u>WORKSHOP ON REGULATION 12.065</u>; Supplemental Comments of Ziel Equipment, Sales & Services, Inc.

Dear Sir or Madam:

We represent Ziel Equipment, Sales & Services, Inc. ("<u>Ziel</u>" or the "<u>Company</u>"). The purpose of this letter is to provide the Company's supplemental comments on Regulation 12.065, which amplify the previous comments Ziel submitted on January 4, 2021 and respond to the discussion at the Nevada Cannabis Compliance Board's ("<u>CCB</u>") workshop on January 19, 2021 (the "<u>Workshop</u>").

#### **IDENTITY AND INTEREST OF THE COMMENTER**

Ziel is a leading developer of Radio Frequency ("**RF**") equipment for the reduction of microbial pathogens. The food and cannabis industries across North America, Europe, South America, and Australia utilize RF technology to safely remediate products intended for human consumption or ingestion. Ziel's devices utilize *non-ionizing* radiation to pasteurize products like almonds, cashews, macadamias, sesame and chia. This technology has been adapted for the cannabis industry to successfully remediate bacterial and fungal pathogens. These devices help cannabis licensees ensure that they are providing a safe product that meets the highest quality standards. Moreover, Ziel's technology allows licensees to satisfy these standards through a method that is compatible with the requirements for organic certification.

#### **SUPPLEMENTAL COMMENTS**

Ziel appreciates the thoughtful discussion led by Dr. Young during the Workshop and concurs with Dr. Young's observation that changes to Regulation 12.065 are necessary. Ziel offers these supplemental comments to address some of the questions and issues raised by Dr. Young during the Workshop.

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### 1. Cannabis is not analogous to OTC medications

Federal law requires that food products treated with ionizing radiation like x-rays or gamma rays be labeled with the Radura symbol and include the statement "treated with radiation" or "treated by irradiation."<sup>1</sup> This labeling requirement promotes consumer awareness because "the ability to reliably differentiate between irradiated and non-irradiated foods or ingredients is in the interest of government agencies, food processors, and consumers."<sup>2</sup> The Food and Drug Administration ("<u>FDA</u>") has determined that this labeling requirement *does not* apply foods treated with non-ionizing radiation like RF.

During the Workshop, representatives of RAD Source Technologies, Inc. ("**RAD**")<sup>3</sup> argued that these FDA regulations are irrelevant to the cannabis industry because cannabis is not a "food." Instead, RAD suggested that the CCB look to FDA regulations governing over the counter ("**OTC**") medications, which do not require Radura labeling. While cannabis is not strictly a "food," cannabis is frequently ingested as food and is often labeled similarly to food products. For example, cannabis products are labeled with ingredients, common allergens, as well as information about whether the cannabis is "organic." Requiring labeling consistent with 21 C.F.R. § 179.26 continues this commonsense approach. OTC drugs, on the other hand, are subject to numerous federal safety and efficacy standards not applicable to either food or cannabis. While the FDA has lifted the Radura labeling requirements for OTC medications that meet these substantial requirements, it notably *did not* make that same determination for produce and other food items which are not subject to this same level of oversight.

# 2. Labeling with CFU measurements is burdensome and confusing for consumers

RAD also suggested during the workshop that the CCB implement a labeling requirement stating the "CFU"<sup>4</sup> count for the cannabis. First, this suggestion does not advance the purpose of Regulation 12.065, which is to inform consumers about the use of ionizing radiation on cannabis products.<sup>5</sup> Second, the measurement of colony forming units present per gram of product

<sup>&</sup>lt;sup>1</sup> See 21 C.F.R. § 179.26; see also FDA, Understanding Food Irradiation: What Industry Needs to Know, https://www.fda.gov/food/irradiation-food-packaging/understanding-food-irradiation-what-industry-needs-know.

<sup>&</sup>lt;sup>2</sup> Kim M. Morehouse and Vanee Komolprasert, *Irradiation of Food and Packaging*, ACS Symposium Series 875, Chapter 1 (2004) *available at* https://www.fda.gov/food/irradiation-food-packaging/overview-irradiation-food-and-packaging.

<sup>&</sup>lt;sup>3</sup> RAD manufactures equipment that treats cannabis with ionizing x-ray radiation.

<sup>&</sup>lt;sup>4</sup> CFU counts measure the amount of yeast or mold present.

<sup>&</sup>lt;sup>5</sup> The Radura label denotes the use of ionizing radiation; this label has never symbolized non-ionizing radiation. FDA, *Food Irradiation: What You Need to Know*, https://www.fda.gov/food/buy-store-serve-safe-food/food-irradiation-what-you-need-know.

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information is not typically included on food labels and this is not the type of information consumers can readily understand or interpret. For CFU information to be of use to cannabis users, the consumer would need to conduct independent research and determine the CFU totals they are comfortable consuming. Placing this burden on consumers undermines the entire purpose of the state's cannabis testing and regulatory system. Consumers should be able to rely on the CCB to establish safe parameters for cannabis products and know that products offered for sale to the public meet these safety requirements.

# 3. CCB labeling requirements should reflect established science

The FDA and other federal and state regulatory authorities have developed distinct regulatory requirements for the use of technology employing ionizing and non-ionizing radiation. These divergent requirements are rooted in the fundamental differences between ionizing and non-ionizing radiation, as well as the different risks associated each type of radiation. The CCB should utilize a similar approach: different cannabis treatment methods should be assessed individually and evaluated according to the unique risks associated with each process. RAD's claim that labeling cannabis treated with ionizing radiation unfairly applies to one company misunderstands the role of the CCB. The CCB's role is not to artificially construct a "level playing field" by ignoring clear scientific distinctions. Rather, the CCB is obligated to craft regulations that reflect scientific reality and allow consumers to make educated and informed decisions about their health.

For these reasons, the CCB should amend Regulation 12.065 to clarify that this labeling requirement applies to ionizing radiation. This change is consistent with federal law and promotes consumer education and choice. Please advise if you have any questions or require additional information.

Sincerely,

FENNEMORE CRAIG, P.C.

/s/ **Katherine Hoffman** Katherine L. Hoffman