MINNESOTA BOARD OF PHARMACY

Hemp Derived Products
Frequently Asked Questions
June 30, 2022

INTRODUCTION

This document provides answers to some of the questions that the Board of Pharmacy ("Board") has been receiving. It is in response to legislation that was enacted at the conclusion of the 2022 legislative session. ***Note, the Board cannot give advice on the manufacturing of such products, nor can it offer legal advice.*** *Individuals or companies involved in the manufacture, distribution, or sale of such products are encouraged to seek the advice of appropriate consultants and legal counsel.* Individuals or companies should also review the recently enacted updates to Minnesota Statutes Section 151.72. (Minn. Stats. §151.72).

Despite the updates enacted, other agencies retain the authority to regulate the growth or processing of hemp and the extraction of substances from hemp. The Board also does not regulate products that contain the portions of hemp that can be used in food because they are generally recognized as safe (for example, hemp seeds and hempseed oil). Those areas are under the jurisdiction of the Minnesota Department of Agriculture. Nor does the Board regulate the state's Medical Cannabis Program, which is under the jurisdiction of the Minnesota Department of Health.

Due to the Minnesota Pharmacy Practice and Wholesale Distribution Act, the Board has regulatory authority over drug products that are implicitly or explicitly intended for human or animal consumption. This includes the recently amended, Minn. Stats. §151.72. While the regulation of drugs remains under the Board's purview, the Board of Pharmacy strongly supports the legislation to create an Office of Cannabis Management to have authority over everything related to *Cannabis sativa.*

For the purposes of this document, "substances derived from hemp" means cannabinoids, including tetrahydrocannabinols (THC).

IMPORTANT ADVISORIES

Be advised that only products which meet ***all*** of the requirements of Minn. Stats. §151.72 are legal to sell under Minnesota law. Depending on the substances involved, products that do not meet all

of the requirements of that section may be misbranded or adulterated. It is a misdemeanor-level crime to sell misbranded or adulterated products. (See Minn. Stats. §151.29 and 151.30). Products that do not meet all the requirements may also be **schedule 1 controlled substances**, depending on the substance and quantity involved. It can be a felony-level crime to sell or possess controlled substances. (See Minn. Stats. §152.02 – 152.025).

Products containing substances derived from hemp that are manufactured within Minnesota must meet all of the requirements of Minn. Stats. §151.72, even if they are intended for sale outside of Minnesota. Manufacturers, wholesalers, and retailers located within Minnesota should not ship, sell, or deliver products into another state where the product would be prohibited by that state's law.

Any products containing substances derived from hemp that are shipped into Minnesota from outside of the state must meet the requirements of Minn. Stats. §151.72.

Any hemp used to derive cannabinoids that are used to manufacture products must meet the requirements of Minn. Stats. Chapter 18K and Minn. Rules Chapter 1565.

Finally, even if products fully meet all of the requirements under Minn. Stats. §151.72, they may still be illegal to sell under federal law administered by the United States Food and Drug Administration. (FDA). The FDA has provided information about the legality of substances derived from hemp on a FAQ Web page.

PRODUCT QUESTIONS

Q: What types of products does Minn. Stats. §151.72 apply to?

A: It applies to two types of products. First, it applies to any ***nonintoxicating cannabinoid*** product intended for human or animal consumption by any route of administration, that is ***not*** an edible cannabinoid. Examples include, *but are not limited to* tablets, capsules, solutions, tinctures, or other products meant for oral administration/ingestion; creams, lotions, ointments, salves, or other products meant for topical administration; products meant to be inhaled, smoked, vaped, sprayed into nostrils, or insufflated (sniffed); and hemp flowers and buds. Note, in addition to other requirements, these products must not contain more than 0.3% tetrahydrocannabinol.

The second type of products are ***edible cannabinoids***, which are defined in section 151.72 as products that are intended to be eaten or consumed as a beverage by humans, ***contain a cannabinoid in combination with food ingredients, and are not drugs.*** Note, in addition to other requirements, an edible cannabinoid product must not contain more than five milligrams of any tetrahydrocannabinol in a single serving, or more than a total of 50 milligrams of any tetrahydrocannabinol per package. Furthermore, to be considered an edible cannabinoid, ***no***

claim can be made or implied that the product can prevent, treat, or cure a disease, or alter the structure or function of a human or animal body.

Q: Can products that contain substances derived from hemp also contain over-the-counter (non-prescription) drugs?

A: FDA has warned companies that such products would be unapproved new drugs, making them illegal to sell under federal law.

Q: Can products that contain substances derived from hemp be sold as dietary supplements?

A: Only if FDA allows them to be sold as dietary supplements. Unlike the federal Food, Drug, & Cosmetic Act, the statutes under the jurisdiction of the Board do not separately recognize dietary supplements. Under state law, a product that is intended to alter the structure or function of human or animal bodies falls under the legal definition of a drug. However, the Board has deferred to federal law and the FDA in this area. If the FDA considers a product to be a legal dietary supplement, the Board does not consider it to be a drug. The FDA has indicated that certain substances derived from hemp cannot be sold as dietary supplements.

Q: Do the food ingredients used to make edible cannabinoids have to meet the requirements for food manufacturing that are administered by the Minnesota Department of Agriculture?

A: Yes. Food ingredients that will be combined with substances derived from hemp, to make an edible cannabinoid product, must meet requirements for food manufacturing. Prior to being combined with substances derived from hemp, food ingredients fall under the definition of "food" found in Minn. Stats. §34A.01, subd. 4 and are under the jurisdiction of the Minnesota Department of Agriculture. Additional information can be found at the Minnesota Department of Agriculture Manufactured Food Regulations page.

Q: Can an edible cannabinoid product be made by applying an extracted or concentrated hemp-derived cannabinoid to a commercially available candy or snack food item?

A: No. That is expressly forbidden by section 151.72.

Q: Can edible cannabinoids be produced under Minnesota's Cottage Food Exemption?

A: No. The Cottage Food Exemption is an exemption from food licensing and applies to food. Edible cannabinoids are explicitly excluded from the definition of food products found in Minn. Stats. §34A.01, subd. 4.

Q: Can products that contain substances derived from hemp be added to foods or beverages by restaurants, bars or other businesses that prepare food and beverages for onsite or take away consumption?

A: No. Minn. Stats. §151.72 only allows for the sale of manufactured and packaged products that contain substances derived from hemp. It does not allow for food service or further food preparation activities using products which contain substances derived from hemp.

Q: Can substances derived from hemp be included as an ingredient in packaged alcohol beverages?

A: Prior to licensing in Minnesota, alcoholic beverages must adhere to the federal requirements under the U.S Dept of Treasury Alcohol, Tobacco, Tax and Trade Bureau (TTB), which require the

submission and approval of the formulation and brand labels. A link is provided below from the TTB. https://www.ttb.gov/formulation/hemp-policy#:~:text=You%20are%20prohibited%20from%20using,Ale%20brewed%20with%20hemp%20seeds)

Q: What are the quantity limits of tetrahydrocannabinols that can be placed in edible cannabinoid products?

A: Edible cannabinoid products can contain no more than a total of 5 milligrams of tetrahydrocannabinols per dose and no more than a total of 50mg of tetrahydrocannabinols per package. **(See below for additional information).** If an edible cannabinoid product is intended for more than a single use or contains multiple servings, each serving must be indicated by scoring, wrapping, or other indicators designating the individual serving size.

Q: Are there restrictions on what types of tetrahydrocannabinols can be used in edible cannabinoids?

A: Section 151.72 does not specify particular tetrahydrocannabinols. However, the total amount of all tetrahydrocannabinols contained in a product must not exceed 5mg per dose or 50mg per package.

Q: Can an edible cannabinoid contain more than one type of tetrahydrocannabinol?

A: Yes, but the total amount of ***all*** tetrahydrocannabinols contained in an edible cannabinoid product cannot exceed 5mg per dose and 50 mg per package. (For example, a product cannot contain 5mg of delta-9 THC and 5mg of delta-8 THC).

Q: **For products which are not edible cannabinoids, what quantity or percentage limits apply to products that contain substances derived from hemp?**

A: The total amount of ***all*** tetrahydrocannabinols contained in such products cannot exceed 0.3%. (For example, a product cannot contain 0.3% of delta-9 THC and 0.3% of delta-8 THC). Examples of other types of products that are subject to the 0.3% limit include, but are not limited to, creams, lotions, ointments, salves, or other products meant for topical administration; products meant to be inhaled, smoked, vaped, sprayed into nostrils, or insufflated (sniffed); and hemp flowers and buds.

LICENSING AND PRODUCT APPROVAL

Q: **Do I have to get a license from the Board to manufacture, distribute, or engage in the retail sale of products that contain substances derived from hemp?**

A: No. Manufacturers, distributors, and sellers of products that contain substances derived from hemp are not licensed by the Board of Pharmacy. (The exception consists of FDA-registered manufacturers of drug products approved for medical use by the FDA, such as Marinol or Epidiolex.)

Q: **Does the Board test or approve products that contain substances derived from hemp, prior to their sale in Minnesota?**

A: The Board does not test or approve such products prior to their sale, but the products must meet all of the requirements of Minn. Stats. §151.72. Be advised, products that do not meet all of the requirements of that section may be misbranded or adulterated. It is a misdemeanor-level crime to sell misbranded or adulterated products. (See Minn. Stats. §151.29 and 151.30). Products that do not meet all the requirements may also be **schedule 1 controlled substances**, depending on the substance and quantity involved. It can be a felony-level crime to sell or possess controlled substances. (See Minn. Stats. §152.02 – 152.025).

Q: **Has the Board issued any rules concerning products that contain substances derived from hemp?**

A: No.

Q: **Will the Board allow products to deviate from any of the requirements found in Minn. Stats. §151.72?**

A: No. The recent updates to §151.72 do not grant the Board or any other agency authority to grant waivers to its requirements.

TESTING

Q: Do the testing requirements found in Minn. Stats. §151.72 apply to the hemp from which cannabinoids and tetrahydrocannabinols are derived, or to the finished product that will be sold to the consumer?

A: They apply to the finished product that will be sold to the consumer. A manufacturer of a product regulated under Minn. Stats. §151.72 must submit representative samples of products to an independent, accredited laboratory in order to certify that the product complies with requirements in that section.

Q: Do test results have to be submitted to the Board?

A: No, but upon the request of the board, the manufacturer of the product must provide the board with the results of the testing required under Minn. Stats. §151.72.

Q: Does the Board have a list of approved testing laboratories?

A: No. It is the responsibility of the manufacturer to identify an independent, accredited laboratory in order to certify that the product complies with the standards adopted by the board.

Q: How is the term "trace amounts" defined?

A: Minn. Stats. 151.72 does not define this term.

PACKAGING AND LABELING

Q: What are the packaging and labeling requirements for products that contain substances derived from hemp?

A: Those requirements are defined in Minn. Stats. §151.72.

Q: Does the Board approve packaging and labeling?

A: Packaging and labeling does not need to be proactively approved by the Board but must be compliant with the requirements of Minn. Stats. §151.72.

CONSUMER PROTECTIONS

Q: What can I do if I know of a local retailer who is selling products that contain cannabinoid to individuals under the age of 21?

A: Since it is a crime to sell such products to individuals under 21, this can be reported to local law enforcement agencies.

Q: How would I report an adverse reaction to a product containing a cannabinoid?

A: You can report an adverse reaction to the U.S. Food and Drug Administration using the FDA MedWatch form for consumers. The form can be found at: https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting