PROPOSED REGULATION

OF THE DEPARTMENT OF HEALTH

AND HUMAN SERVICES

LCB File No. R035-22

March 30, 2022

EXPLANATION – Matter in ***italics*** is new; matter in brackets [~~omitted material~~] is material to be omitted.

AUTHORITY: §§ 1-8, NRS 439.532, as amended by section 2 of Senate Bill No. 114, chapter 163, Statutes of Nevada 2021, at page 728.

A REGULATION relating to hemp; prescribing requirements concerning the testing and labeling of certain commodities or products containing hemp or cannabidiol that are intended for human consumption in this State; specifying when such a commodity or product is deemed to be adulterated; providing for the submission and investigation of complaints concerning such products; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law prohibits the sale or offer for sale of commodities or products containing hemp which are intended for human consumption or certain other commodities and products that purport to contain cannabidiol unless the commodities or products have been: (1) tested by an independent testing laboratory; and (2) labeled. Existing law requires the Department of Health and Human Services to adopt regulations: (1) requiring the testing and labeling of such commodities and products; and (2) identifying contaminants of certain such commodities or products which are foods and prescribe tolerances for such contaminants. (NRS 439.532, as amended by section 2 of Senate Bill No. 114, chapter 163, Statutes of Nevada 2021, at page 728) **Section 3** of this regulation defines the term "hemp product" to refer to those commodities and products containing hemp or cannabidiol that are regulated under existing law as described. **Section 6** of this regulation prohibits the sale or offer for sale of a hemp product that: (1) is not approved by the United States Food and Drug Administration or generally recognized as being safe for human consumption; (2) has not been tested by an independent testing laboratory; or (3) is not processed or labeled in accordance with state and federal law and regulations. **Section 7** of this regulation requires certain testing of hemp products.

Existing law prohibits: (1) the manufacture, sale or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated; and (2) the adulteration of any food, drug, device or cosmetic. (NRS 585.520) **Section 6** specifies when a hemp product is deemed to be adulterated.

Section 8 of this regulation authorizes a consumer or public agency to submit a complaint concerning a hemp product that is processed, sold or offered for sale in this State to: (1) the local

health authority, if the hemp product is a food or dietary supplement; or (2) the Commissioner of Food and Drugs, if the hemp product is a drug or cosmetic. **Section 8** also: (1) provides for the investigation of the complaint; and (2) requires the health authority or Commissioner, as applicable, to take certain actions if the complaint is substantiated.

Section 1. Chapter 439 of NAC is hereby amended by adding thereto the provisions set forth as sections 2 to 8, inclusive, of this regulation.

Sec. 2. ***As used in sections 2 to 8, inclusive, of this regulation, unless the context otherwise requires, the words and terms defined in sections 3, 4 and 5 of this regulation have the meanings ascribed to them in those sections.***

Sec. 3. ***"Hemp product" means a commodity or product containing hemp which is intended for human consumption or any other commodity or product that purports to contain cannabidiol with a THC concentration that does not exceed the maximum THC concentration established by federal law.***

Sec. 4. ***"Process" means to manufacture, store for distribution, package or repackage a hemp product.***

Sec. 5. ***"Processor" means a person or entity who processes a hemp product.***

Sec. 6. ***1. Unless federal law or regulation otherwise requires, a person shall not sell or offer for sale a hemp product that is processed in this State unless the hemp product:***

(a) Has been determined by the United States Food and Drug Administration to be safe or generally recognized as safe for use as an ingredient in food intended for human consumption;

(b) Has been tested by an independent testing laboratory in accordance with section 7 of this regulation;

(c) Is processed in accordance with all applicable federal and state laws and regulations, including, without limitation, any applicable provisions of Title 21 of the Code of Federal Regulations; and

(d) Is labeled in accordance with all applicable federal and state laws and regulations, including, without limitation, any applicable provisions of Title 21 of the Code of Federal Regulations and chapters 446 and 585 of NRS.

2. A hemp product shall be deemed to be adulterated for the purposes of chapter 585 of NRS if:

(a) The THC concentration of the hemp product exceeds the maximum THC concentration established by federal law for hemp;

(b) A pesticide which occurs on the list of pesticides published by the State Department of Agriculture pursuant to NRS 586.550 or is approved for use by the United States Environmental Protection Agency is present in the hemp product at a level which exceeds the level specified by the State Department of Agriculture or Environmental Protection Agency, as applicable;

(c) A pesticide which does not occur on the list of pesticides published by the State Department of Agriculture pursuant to NRS 586.550 or is not approved for use by the United States Environmental Protection Agency is present in the hemp product; or

(d) The hemp product meets any other condition for adulteration prescribed by federal or state law or regulations.

Sec. 7. *1. A hemp product that is processed, sold or offered for sale in this State must be tested by an independent testing laboratory certified by the Cannabis Compliance Board pursuant to NRS 678B.290 in the same manner as an equivalent marijuana product is*

required by the regulations adopted pursuant to NRS 678B.290 to be tested. In addition to any other test required by that section, the testing must include, without limitation, an analysis of:

(a) The THC content of the hemp product on a dry weight basis; and

(b) The content of any other cannabinoid or terpenoid that is listed in the ingredients of the product or on the product labeling.

2. Except as otherwise provided in this section, the homogeneity of the THC content of a hemp product must be verified by testing multiple samples from a single production run. If the THC content of a production run of a hemp product has been verified by an independent testing laboratory pursuant to this section and the recipe of the product has not been changed, the homogeneity of the THC content of an additional production run of the product may be verified by testing a single unit or serving from the production run.

3. The processor of a hemp product shall:

(a) Retain the final certificate of analysis containing the results of the testing of the product required by this section for at least 2 years after the date on which the product is sold; and

(b) Provide the certificate of analysis to the Division upon request.

4. As used in this section:

(a) "Cannabinoid" means THC, tetrahydrocannabinolic acid, cannabidiol or cannabidiolic acid.

(b) "Terpenoid" means alpha-bisabolol, alpha-humulene, alpha-pinene, alpha-terpinolene, beta-caryophyllene, beta-myrcene, caryophyllene oxide, limonene or linalool.

Sec. 8. *1. A consumer or a public agency may submit to:*

(a) The health authority a complaint alleging that a hemp product that is a food or dietary supplement and is processed, sold or offered for sale in this State does not meet a requirement prescribed by section 6 of this regulation or is adulterated as described in that section.

(b) The Commissioner a complaint alleging that a hemp product that is a drug or cosmetic and is processed, sold or offered for sale in this State does not meet a requirement prescribed by section 6 of this regulation or is adulterated as described in that section.

2. The health authority or Commissioner, as applicable, shall investigate a complaint submitted pursuant to subsection 1 to the extent it deems appropriate. An investigation may include, without limitation, requiring the testing of the product in accordance with recognized laboratory standards for testing of the applicable type of hemp product approved by the health authority or Commissioner, as applicable. The processor of the product is responsible for the cost of the testing and may perform the testing itself or cause the testing to be performed by a third party. The processor or third party, whomever performs the test, shall notify the health authority or Commissioner, as applicable, of the results of the testing not later than 24 hours after the completion of the testing.

3. If a complaint is substantiated, the health authority or Commissioner, as applicable, may:

(a) Require the processor of the hemp product that is the subject of the complaint to pay the cost of the investigation; and

(b) Take any action authorized under the applicable provisions of chapter 446 or 585 of NRS.

4. As used in this section:

(a) "Commissioner" means the Commissioner of Food and Drugs appointed pursuant to NRS 439.135.

(b) "Cosmetic" has the meaning ascribed to it in NRS 585.060.

(c) "Dietary supplement" means any product, other than tobacco, intended to supplement the diet that:

(1) Contains one or more of the following dietary ingredients:

(I) A vitamin;

(II) A mineral;

(III) An herb or other botanical;

(IV) An amino acid;

(V) A dietary substance for use by humans to supplement the diet by increasing the total dietary intake; or

(VI) A concentrate, metabolite, constituent, extract or combination of any ingredient described in sub-subparagraphs (I) to (V), inclusive;

(2) Is intended for ingestion in the form of a tablet, capsule, powder, softgel, gel capsule or liquid or, if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet; and

(3) Is required to be labeled as a dietary supplement in accordance with 21 C.F.R. § 101.36.

(d) "Drug" has the meaning ascribed to it in NRS 585.080.

(e) "Food" has the meaning ascribed to it in NRS 585.100.

(f) "Health authority" has the meaning ascribed to it in NRS 446.050.