BEFORE THE DEPARTMENT OF REVENUE
OF THE STATE OF MONTANA

In the matter of the adoption of New Rule I pertaining to marijuana and marijuana products packaging and labeling application and approval process	)))))	NOTICE OF ADOPTION

TO: All Concerned Persons

1. On February 25, 2022, the Department of Revenue (department) published MAR Notice No. 42-1048 pertaining to the public hearing on the proposed adoption of the above-stated rule (New Rule I) at page 274 of the 2022 Montana Administrative Register, Issue Number 4.

2. On March 22, 2022, the department held a public hearing to consider the proposed adoption of New Rule I. There were no commenters present to provide testimony or commentary in support of the rule. The following commenters appeared and provided oral testimony for informational purposes or in general opposition to New Rule I: Katrina Farnum, Garden Mother; Evan Kajander and Sarah Markman, Apogee Gardens; Geoffrey Erickson 1-Step Software Solutions; Kate Cholewa, Montana Cannabis Industry Association; Pepper Petersen, Montana Cannabis Guild; and Joanna Barney, Sacred Sun Farms. The department received written comments submitted by interested persons for informational purposes or in general opposition to New Rule I.

3. On April 29, 2022, the department published an amended notice of public hearing on the proposed adoption of New Rule I at page 594 of the 2022 Montana Administrative Register, Issue Number 8 (amended proposal notice). The amended proposal notice contained the department's amendments to the original proposal notice described in paragraph 1. The amendments attempted to resolve a majority of the commenters' issues or concerns which were provided to the department at the March 22, 2022 administrative rules hearing or during the initial public comment period.

4. No additional public hearing was held to consider the amended proposal notice. The department extended the comment period for the proposed rulemaking in accordance with 2-4-305, MCA, until May 6, 2022.

5. The department received additional written comments to the amended proposal notice submitted by interested persons regarding New Rule I.

6. The department has adopted New Rule I (42.39.320) as presented in the April 29, 2022 amended proposal notice.

7. The department has thoroughly considered all comments and testimony received from the public hearing, initial comment period, and extended comment period. A summary of the comments received and the department's responses are as follows:

COMMENT 1: Ms. Farnum commented that Garden Mother develops eighty-five distinct products (due to being vertically integrated for twelve years) and expressed concerns with the fees that potentially correspond to the number of packaging and labeling applications they will need to submit for approval.

Ms. Markman also made similar comments about the volume of labels for a vertically integrated licensee with many products.

Mr. Kajander appreciated the broader product categories and exit packaging. Mr. Kajander observes that the department may want to consider the addition of additional product subcategories from the ones listed in New Rule I, as proposed.

Other commenters expressed concern with the fee proposals expressed in the original proposal notice.

RESPONSE 1: At the March 22, 2022 rules hearing, the department provided clarification - applicable at the time - that the department sought label approvals for four product types: flower, ingestible products, non-ingestible products, and concentrates and extracts unless the licensee sold products in the medical market with increased THC content, which would require additional product label approvals.

New Rule I, as presented in the amended proposal notice and adopted, provides up to a maximum of eight total label applications - based on the applicant's sale of some or all of the adult-use or medical marijuana or marijuana product categories. As the department stated in the revised statement of reasonable necessity for the amended proposal notice, all current lawful marijuana or marijuana product types can be categorized as one of the listed types.

The department refers Ms. Farnum and all other commenters to the revised fee structure adopted in (15), which provides for zero fee application options and a maximum fee, all of which were provided and described in the amended proposal notice.

COMMENT 2: Ms. Farnum and Ms. Barney asked if the department was able to provide a guaranteed timeframe for the turnaround of its review and approval of label applications. Ms. Farnum's comments focus on her uncertainty of where to start because turnaround time for label manufacturers is six to eight weeks and with a volume of labels, any denial, rejection, or change - even if it is a very small change, could be very burdensome to meet the January 1, 2023 requirement. Ms. Farnum illustrated her concerns over application processing times through anecdotal examples of estimated industry need for product packages and labels subject to approval by the department.

Ms. Barney echoed Ms. Farnum's comments and emphasized that supply-side logistics have impacted vendor fulfillment of labels and packages.

Ms. Markman made similar comments to Ms. Farnum's relative to Apogee Gardens.

Mr. Petersen commented his concerns that application processing turnaround times under the original proposal, and amended proposal notice, will become punitive to applicants.

As a related comment, Colleen Powers, owner of Farm406, suggested the department include in the rule a provision that would state a procedural turnaround for the department, such as "The DOR will notify the applicant within 30 days. . . ." Ms. Powers also requested the department modify the timeline of ten days for an applicant to reapply when corrections or rejections are involved.

RESPONSE 2: The department cannot provide "guaranteed" timeframes for the review and approval of label applications because application processing and final approval is a fact-dependent analysis on a case-by-case basis. The department has also removed the 10-day period for application resubmission.

The department refers the commenters to Response 1 which the department believes greatly reduces label volume and approval logistics between the date of adoption of New Rule I, the amended application deadlines in New Rule I(20), and the final implementation of product packaging and labeling requirements in (23). The department will diligently pursue its regulatory obligations and encourages a proactive approach by applicants in the submission of all packaging and labeling applications. In the event of an unforeseen industry-wide complication that impacts the packaging and labeling requirements in (23), the department believes there is sufficient time to develop contingencies which it could propose to and resolve with industry to meet the requirements of statute and New Rule I.

COMMENT 3: Ms. Farnum and Ms. Barney provided commentary and asked about the definition of unique marijuana packaging and what would require a separate application. Ms. Farnum and Ms. Barney asked for more clarity in the terminology for packaging and labeling and their usage in New Rule I.

RESPONSE 3: Based on these comments, the department amended New Rule I(2) through (4) to clarify packaging and (6) through (10) to describe expanded product categories and to provide criteria for pre-approved template and custom label designs.

COMMENT 4: Ms. Barney requested the department provide a "reference guide" for packaging guidelines. She contends other states with legal cannabis, such as California, Colorado, Oregon, and Washington, all have one-page reference guides that include pictures or descriptions of what labels and packages look like and what is generally acceptable. Ms. Barney believes such a reference would be beneficial for regulatory consistency because she has, at times, received conflicting information from department personnel.

RESPONSE 4: The department thanks Ms. Barney for her comment and responds that it is developing a reference guide that will be accessible through the department's website to assist applicants with the packaging and labeling application process.

COMMENT 5: Mr. Kajander commented on the font size for packages and labels which requires legible font and lower case letter O must be at least 1/16th of an inch in height. He suggests the requirement be based in computer font size (i.e., eight-point or ten-point font) instead of fractional inches.

Mr. Erickson commented his opinion that the department should reduce the required font size on a label. He provided examples of packages and labels with current and his suggested font sizes, which he contends are still legible and are consistent with those of prescription drug labels issued by licensed pharmacies.

Ms. Cholewa provided similar commentary but added that combinations of font sizes could be possible to enhance label "warning messages" (i.e., impaired driving risks).

RESPONSE 5: While the department appreciates the commentary provided by Messrs. Kajander and Erickson and Ms. Cholewa, those requirements are specified under ARM 42.39.314, which is outside the scope of this current rulemaking. The department will take the recommendations under advisement for future amendment of ARM 42.39.314.

COMMENT 6: Mr. Erickson provided commentary about the department's proposed application review process. He opines that the initial process appears to be very time-consuming for the department because it would involve the review of each label submitted. This was a concern echoed by Mr. Petersen.

Mr. Erickson suggests the department adopt a "universal," preapproved label template, which the department could offer to applicants. An applicant would affirm its use of the template label - to be downloaded from the department - and the review process could be significantly streamlined and offered for little or no cost.

Mr. Petersen offered similar comments about universal labeling and that many applicants will be using labels provided by testing laboratories; a statement shared by other commenters. He suggested the department make allowances for both universal label types and requested the department streamline or automate the packaging and labeling approval process.

Similarly to Messrs. Erickson and Petersen, Ms. Powers commented her concern about the potential application processing bottleneck that could befall the department and believes existing statute and rule provide sufficient guidance, and packaging and labeling compliance could be enforced through department inspection and audit of licensees.

RESPONSE 6: The department has adopted into New Rule I a no-cost, preapproved label template option and provided the parameters for its use. The department concurs that use of a label template will expedite review and processing of packaging and labeling applications.

As to comments that packaging and labeling are often provided by testing laboratories and the use of those packages and labels should not be charged a fee, the department responds that the use of testing laboratories for generating labels is not universal. Some licensees that utilize testing laboratories to generate labels also include their unique logo, which would require department approval.

Regarding Ms. Powers' comments regarding sufficiency of existing authority and inspection and audit as the means to enforce packaging and labeling compliance, the department responds that while it agrees its inspection and audit functions can help ensure compliance, the packaging and labeling application and approval process is expressly required by 16-12-208(8), MCA.

COMMENT 7: Mr. Petersen commented extensively on the department's application fee structure and fiscal impact statement, as presented in the original proposal notice. Mr. Petersen contended the proposed fees amounted to a "green tax" and that the "fiscal note" in the original proposal notice was inadequate; the latter opinion was also shared by Ms. Barney.

Mr. Petersen commented that just because the legislature gave the department authority to set fees, the department should not set whatever fee it deems appropriate. Mr. Petersen also commented his opinion that, by loose calculation, the original proposed packaging and labeling fees could have a theoretical fiscal impact to industry of $2.5 to $4 million.

Mr. Petersen and Ms. Barney also question whether the application fees paid were based on a per-location or per-licensee basis.

RESPONSE 7: The department responds that it has adopted New Rule I as presented in the amended proposal notice and refers Mr. Petersen to it in response to a majority of his concerns. As for streamlining the application approval process, and providing zero cost application fee options, the department directs Mr. Petersen to the amended proposal notice and Response Nos. 1 through 4, and 6 (above).

As to the inadequacy of the department's "fiscal note," the department responds that the fiscal impact statement is not a fiscal note; the statement is required by 2-4-302, MCA, and met statutory requirements. The department also acknowledged in the statement that it could not accurately estimate total fiscal impact for the reasons stated, which is permitted by 2-4-302, MCA. However, with the adoption of the revised fee structures the department estimated minimum and maximum ranges of fiscal impact using necessary assumptions - a process which is often used in legislative fiscal notes - in an attempt to provide additional information and transparency about the fiscal impact of the application fees.

As for the establishment of fees, the legislature authorized the department to designate fees sufficient to administer and enforce the Montana Marijuana Regulation and Taxation Act (see 16-12-112(1)(q), MCA). New Rule I includes application fees that the department contends satisfies the needs and requirements of 16-12-112(1)(q), MCA. And certain fees were eliminated when the department's administration of the packaging and labeling application process was amended. The department acknowledges Mr. Petersen's continuing objection to fees which will likely be at odds with any department proposal regardless of its justification or merits.

Lastly, in response to Mr. Petersen's and Ms. Barney's comments about whether fees are paid per location or license, the department directs them to New Rule I(5) and (13) which confirm that applications (and corresponding fees) are based per licensee.

COMMENT 8: As stated in Comment 1, the department received several comments from interested persons opposing the application fees in New Rule I, both responsive to the original proposal and amended proposal notices. The comments can be generalized as general objection to fees which they state are excessive, will inflate the costs of product, and will lead customers to purchase through the illicit market.

Similarly, the department received comments from David Hiller, Yellowstone Buds, LLC, that industry needs time to catch up from implementation of the expanded market and he requests the department slow the implementation of new regulations - especially those that are fee-based - because of the burden placed on the industry.

RESPONSE 8: The department is sensitive to the concerns raised through these fees comments although they are somewhat speculative. The industry in Montana is not a new one, and the department has weighed legislative intent regarding fee structures (see Response 7) with the costs and benefits of the expanding marketplace and the need for administrative rules. The department believes the fees are appropriate, reasonable, and declines to change fee amounts from the revised fee amounts upon the adoption of New Rule I. As for administrative rules, the department agrees that only those rules that are necessary for the department to carry out its legislative mandate should be adopted and that is determinative when the department considers its rules proposals.

The department understands comments it received regarding marijuana and marijuana products testing costs but declines to respond as they are outside the scope of this rulemaking.

COMMENT 9: Mr. Petersen provided commentary during the March 22 public hearing regarding packaging and labeling for wholesalers. Mr. Petersen recognizes statutory packaging and labeling requirements are for product intended for ultimate sale to the consumer, but he asks for clarity in the rule for wholesalers who are packaging and labeling and then delivering the product to retail licensees who are the ones involved with the direct sale to consumers. Mr. Petersen contends marijuana or marijuana products for retail sale should only require one approval; if that is done by the wholesaler and that wholesaler supplies inventory to retailers, no additional application, fees, or department approval are necessary. The department can enforce packaging and labeling compliance through its inspectors.

Ms. Cholewa commented that the proposed required approval of the same product label at the wholesale and retail levels seems redundant at face value and does not appear to contribute to public safety or transparent function in that the same label may be subject to approval many times over, incurring the cost of submission but also the cost of staff time for both businesses and the department. Ms. Cholewa asks for elimination of this requirement or redirection to verification of label approvals on file at dispensaries carrying a wholesaler's products whose labels remain consistent between it and its retailers.

The department also received several comments from marijuana product wholesale representatives during the extended comment period for the amended proposal notice which can be generalized as supporting a "one approval" product

application process. The commenters contend the proposed process will be unduly burdensome on industry and the department alike with minimal benefit.

Similar to the general wholesale comments, the department received comments that oppose the non-transferability of packaging and labeling approvals, which the department has construed to mean to support the position that should a wholesaler apply for, and obtain, packaging and labeling approvals for all of its products, those approvals should be extended to a retail licensee that sells the product.

RESPONSE 9: The department appreciates the comments with respect to wholesale products. The department is unable to further amend New Rule I, upon adoption, to accommodate these concerns. Amending the rule to accommodate prepackaged wholesale product would require additional and extensive system rebuilds that would delay the implementation of the package and label review process which would, in turn, delay the department's ability to ensure licensee compliance with packaging and labeling requirements by January 1, 2023.

In addition, requiring a retail dispensary licensee to secure packaging and labeling approval before ultimate sale to consumer eliminates any uncertainty as to who is ultimately liable for non-compliant packaging and labeling.

COMMENT 10: The department received several comments that pertained to general operational concerns of the cannabis industry and the amount of administrative regulation promulgated by the department. Other comments raised issues that did not pertain to the proposed rulemaking.

RESPONSE 10: While the department appreciates the comments and suggestions, they are outside the scope of this specific rulemaking and the procedural constraints of the Montana Administrative Procedure Act. The department will consider all suggestions for inclusion in future rulemaking for the chapter.

/s/ Todd Olson	/s/ Brendan Beatty
Todd Olson	Brendan Beatty
Rule Reviewer	Director of Revenue

Certified to the Secretary of State May 31, 2022.