

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 1301:18-4-08

Rule Type: New

Rule Title/Tagline: Limitations on Cannabis Products.

Agency Name: Department of Commerce

Division: Division of Cannabis Control

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I. Rule Summary

1. **Is this a five year rule review?** No
 - A. **What is the rule's five year review date?**
2. **Is this rule the result of recent legislation?** No
3. **What statute is this rule being promulgated under?** 119.03
4. **What statute(s) grant rule writing authority?** 3780.03, 3796.03
5. **What statute(s) does the rule implement or amplify?** 3780.03, 3780.04, 3796.06, 3796.061
6. **Does the rule implement a federal law or rule in a manner that is more stringent or burdensome than the federal law or regulation requires?** No
 - A. **If so, what is the citation to the federal law or rule?** Not Applicable
7. **What are the reasons for proposing the rule?**

To establish requirements for cannabis products to be reviewed and approved prior to manufacture or distribution.

- 8. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.**

This rule requires that licensees comply with certain requirements for cannabis products. The restrictions in this rule ensure that all cannabis products are appropriate and limit exposure to minors and individuals not authorized to administer cannabis. Furthermore, licensees are required to seek and obtain approval prior to manufacturing a new product and register each product with the Division.

- 9. Does the rule incorporate material by reference? No**
- 10. If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.75, please explain the basis for the exemption and how an individual can find the referenced material.**

Not Applicable

- 11. If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

Not Applicable

II. Fiscal Analysis

- 12. Please estimate the increase / decrease in the agency's revenues or expenditures in the current biennium due to this rule.**

This will have no impact on revenues or expenditures.

N/A

Not Applicable.

- 13. What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?**

Although not established in this rule, the new product registration fee is \$100. Otherwise, the costs to comply with the rule are generally surrounding staff time to complete the required product registration submission. This will vary based on the complexity of the product and the volume of new products a licensee may propose.

- 14. Does the rule increase local government costs? (If yes, you must complete an RSFA Part B). No**

15. **Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C). No**
16. **If the rule imposes a regulation fee, explain how the fee directly relates to your agency's cost in regulating the individual or business.**

Not Applicable.

III. Common Sense Initiative (CSI) Questions

17. **Was this rule filed with the Common Sense Initiative Office? Yes**
18. **Does this rule have an adverse impact on business? Yes**
 - A. **Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business? No**
 - B. **Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms? No**
 - C. **Does this rule require specific expenditures or the report of information as a condition of compliance? Yes**

Yes. Licensees must report all information about their proposed product to the Division. Additionally, although not directly established in this rule, the new product registration fee is \$100.
 - D. **Is it likely that the rule will directly reduce the revenue or increase the expenses of the lines of business of which it will apply or applies? No**

IV. Regulatory Restriction Requirements under S.B. 9. Note: This section only applies to agencies described in R.C. 121.95(A).

19. **Are you adding a new or removing an existing regulatory restriction as defined in R.C. 121.95? Yes**
 - A. **How many new regulatory restrictions do you propose adding to this rule?**

1. (A) No licensee shall manufacture, process, or distribute, or cause to be created, used, or distributed, any cannabis product that is any of the following

B. How many existing regulatory restrictions do you propose removing from this rule? 0

C. If you are not removing existing regulatory restrictions from this rule, please list the rule number(s) from which you are removing restrictions.
2 Regulatory Restrictions from OAC 3796:3-3-01.

D. Please justify the adoption of the new regulatory restriction(s).
The restrictions in this rule ensure that all products are in accordance with health and safety standards prior to manufacture and ultimately sale to customers at a dispensary.