

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

<p>1. Type of Estimate and Analysis <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected</p>	<p>2. Date November 12, 2020</p>
<p>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable) CSB 2.75</p>	
<p>4. Subject Removing FDA approved cannabidiol from scheduling</p>	
<p>5. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S</p>	<p>6. Chapter 20, Stats. Appropriations Affected</p>
<p>7. Fiscal Effect of Implementing the Rule <input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget</p>	
<p>8. The Rule Will Impact the Following (Check All That Apply) <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses (if checked, complete Attachment A)</p>	
<p>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1). \$0</p>	
<p>10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	
<p>11. Policy Problem Addressed by the Rule On August 21, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register removing drug products approved by the U.S. Food and Drug Administration that contain cannabidiol derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols from schedule V. This rule removes FDA approved cannabidiol from the Wisconsin drug schedules and creates an exception within Schedule V.</p>	
<p>12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments. The rule was posted on the department's website for 14 days to solicit economic impact comments from businesses, business sectors, associations representing business, local governmental units, and individuals. No comments were received.</p>	
<p>13. Identify the Local Governmental Units that Participated in the Development of this EIA. None.</p>	
<p>14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred) No impact.</p>	
<p>15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule The benefit is for the federal and state controlled substances acts to be in conformity and alleviate confusion.</p>	
<p>16. Long Range Implications of Implementing the Rule The long range implication of implementing the rule will be to remove Food and Drug Administration approved cannabidiol from Schedule V.</p>	
<p>17. Compare With Approaches Being Used by Federal Government</p>	

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On June 5, 2020, the Department of Justice, Drug Enforcement Administration provided a letter to the Controlled Substances Board indicating that as a result of the Agricultural Improvement Act of 2018, the Federal Drug Administration approved drug product Epidiolex is no longer controlled under the federal Controlled Substances Act.

The Agricultural Improvement Act of 2018 defines the term “hemp” to “mean the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol (also known as Δ 9-THC) concentration of not more than 0.3 percent on a dry weight basis.” (7 U.S.C. § 1639o.). The Agricultural Improvement Act of 2018 also amended the Controlled Substances Act by excluding “hemp” from the definition of marijuana under 21 U.S.C. § 802 (16) and the listing of tetrahydrocannabinols under 21 U.S.C. § 812 (c).

The prescription drug product Epidiolex is a cannabis derivative with a Δ 9-THC concentration of not more than 0.3% on a dry weight basis. Therefore, as a result of the Department of Justice, Drug Enforcement Administration letter and the Agricultural Improvement Act, the drug product Epidiolex is no longer controlled under the federal Controlled Substances Act.

On August 21, 2020, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register removing drug products approved by the U.S. Food and Drug Administration that contain cannabidiol derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols from schedule V.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)
Illinois: Illinois does not schedule Food and Drug Administration approved cannabidiol.

Iowa: Iowa schedules Food and Drug Administration approved cannabidiol as Schedule V controlled substances.

Michigan: Michigan does not schedule Food and Drug Administration approved cannabidiol.

Minnesota: Minnesota does not schedule Food and Drug Administration approved cannabidiol.

19. Contact Name

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ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
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