Division of Cannabis Regulation
Guidance Document – 01.03.2024
Topic: Item Approval Process Efficiencies

On September 1, 2023, the Division of Cannabis Regulation (DCR) implemented the Item Approval process per 19 CSR 100-1.120(2). This process requires licensees to submit all marijuana product designs, packaging designs, and label designs to DCR for a compliance review with 19 CSR 100-1.120(1), prior to use. The Item Approval process is in place to ensure products and packaging are designed in a manner that protects public health.

In working through the Item Approval process and considering feedback from licensees, DCR has identified areas that will improve the process and allow DCR and licensees to gain efficiencies. For all final marijuana product, below are the efficiencies DCR is implementing **effective immediately**.

- Licensees are no longer required to submit child-resistant certifications, packaging specification sheets, packaging manufacturer's food grade statements or certifications of FDA compliance as part of the preapproval process. As this documentation is no longer required during the Item Approval process, it will not be reviewed for compliance. This is not variance or waiver of rule; Licensees are required to always maintain documentation for compliance verification.
- Licensees submitting a template-based item request no longer needs to resubmit die-lines, logos, and other documentation that is the same information submitted with the template that has been previously approved by DCR.
    - Licensees shall continue to denote the Template Item Approval Number and the difference between the template and item submitted on the Item Approval Application under the section regarding approved template items.
- Licensees shall provide all supplemental information such as Item Approval Application, die-lines, QR Code (if applicable), and logos by email to CannabisProductCompliance@health.mo.gov.
    - DCR will no longer provide box.com links to licensees unless needed due to file size.
    - *This includes licensees that have items currently submitted but have not received a box.com link from DCR*.

DCR's goal is to meet and exceed the 30-day and 60-day timeframes outlined within 19 CSR 100-1.120(2). Removing the necessity to send each applicant a box.com link will result in a noticeable reduction in the total review period. This change allows the product compliance staff to focus on reviewing item submissions, and licensees will not have to wait for a link to remit information. DCR anticipates the average review time will reduce by at least 10-15 days for single items while greater reductions will be realized for items based on an approved template.

These changes will significantly reduce the amount of information and time required for licensees to submit items for review, as compliance with certain rules will be conducted after this process. DCR continues to expect full compliance with 19 CSR 100-1.120 and will **not** allow temporary fixes on non-compliant packaging as has been allowed for in the past. Therefore, if a licensee fails to comply with rules that were attested to during the Item Approval process, DCR is prepared to initiate recalls, destruction orders, and other penalties as necessary in lieu of allowing a licensee to use non-compliant packaging while compliant packaging is ordered and distributed.

DCR will conduct back-end compliance reviews on packaging, labeling, and products to ensure compliance with 19 CSR 100-1.120. For example, with DCR removing the requirement to submit child-resistant certification through the Item Approval process, licensees are required to maintain documentation to demonstrate compliance with the requirement.

Additionally, licensees must understand that DCR reviews for compliance with 19 CSR 100-1 and is not verifying compliance with any other local, state, or federal regulations. It is a licensee's responsibility to ensure compliance with any other applicable regulations.

DCR encourages licensees preparing to submit multiple entries to reach out to the Product Compliance Team for questions regarding a compliant submission, as they may benefit from using template items. DCR prioritizes its review and approval of template items over reviewing and approving multiple similar items. Using template items allows a licensee to make necessary corrections to a single submission, rather than needing to make corrections on multiple similar items.

DCR will continue to review the Item Approval process for efficiencies and provide licensees additional resources to better understand the process and expectations. For questions or feedback regarding packaging, labeling, and product design; compliance; or the Item Approval process, please contact the Product Compliance Team by email at CannabisProductCompliance@health.mo.gov.

Licensees may find additional information on our website:
https://health.mo.gov/safety/cannabis/facility-comms-guidance.php.