Edible Cannabis Product Exemptions (COMAR 10.62.37.21)

The Maryland Medical Cannabis Commission voted unanimously to adopt the following resolution and recommendations on January 27, 2022.

Background

The Commission's authorizing statutes require the Commission to allow licensed processors to produce edible cannabis products, which are defined as "any medical cannabis product intended for human consumption by oral ingestion, in whole or in part." Health-General Article, 13-3301(h)(1). The law also establishes an exemption to this definition for an "Other dosage form that is recognized by the United States Pharmacopeia, the national formulary, or the Food and Drug Administration *and is approved by the Commission*."

In developing the medical cannabis edibles regulations, the Commission made approval of an edible cannabis product exemption contingent, in part, on the licensee seeking the exemption demonstrating it was certified by an accredited third-party certification body "in an alternative pharmaceutical or dietary supplement certification approved by the Commission." The regulations do not specify the type of pharmaceutical or dietary supplement certification required, but current Good Manufacturing Practices (cGMP) certification is the standard that the U.S. Food and Drug Administration adopted to ensure safe and effective food, drugs, dietary supplements, and medical devices. In addition, cGMP certifications in drug or dietary supplement manufacturing were discussed while drafting the edible cannabis product exemption regulations and in public meetings as potentially meeting this regulatory requirement. This is because the edible cannabis regulations had the same primary focus as FDAs cGMP regulations: the safe and sanitary receipt, storage, manufacture, transport, use, and disposal of products.

Ad Hoc Committee on Edible Cannabis Product Exemptions

According to COMAR 10.62.37.21, each product for which a licensee seeks an edible cannabis product exemption may only be reviewed and approved by the Commission. This means only a quorum of the full Commission membership in a meeting open to the public may consider product exemption requests.

The Ad Hoc Committee on Edible Cannabis Product Exemptions was formed on December 16, 2021, with the express purpose of making formal recommendations to the full Commission on how it should apply COMAR 10.62.37.21. Specifically the Ad Hoc Committee was asked to make recommendations on (1) the type of "alternative pharmaceutical or dietary supplement certifications" the Commission should consider approving as outlined in COMAR 10.62.37.21C.(4), and (2) any additional requirements the Commission should consider when evaluating submissions made pursuant to 10.62.37.21, in order to comply with Health-General

Article 13-3309(j), which requires the Commission to adopt and enforce regulations governing edible cannabis products that "ensure the safety of minors."

In developing its recommendations, the Ad Hoc Committee and Commission staff reviewed the Commission's authorizing statutes and regulations, in particular Health-General Article, 13-3309 and COMAR 10.62.37, the Code of Federal Regulations and guidance materials developed by the U.S. Food and Drug Administration regarding Current Good Manufacturing Practices for dietary supplements and drugs, and requirements in other jurisdictions, and consulted with relevant accreditation and certification bodies. Based on this review and deliberation with Commission staff, the Ad Hoc Committee proposes the following recommendations:

Ad Hoc Committee Recommendations

First, the Ad Hoc Committee recommends that, in accordance with COMAR 10.62.37.21C.(4), the full Commission consider approving a product for exemption if a licensed processor submits a valid certification in Current Good Manufacturing Practices (cGMP) that complies with 21 CFR Part 111 (dietary supplements) or 21 CFR 210 (drugs) from a third-party certification body accredited to certify for cGMP under these parts.

In support of such a submission, a licensed processor must:

1. Demonstrate that the third-party certification body:
    a. Is accredited to certify for cGMP that complies with 21 CFR Part 111 or 21 CFR Part 210; and
    b. Performed a facility audit of the licensed processor's facility using an audit checklist within the scope of accreditation that complies with 21 CFR Part 111 or 21 CFR Part 210; and
2. Submit the audit checklist for cGMP 21 CFR 111 or 21 CFR 210, facility score, the audit checklist score scale, and a corrective plan to remediate any deficiencies identified during the audit to the MMCC for review and approval. The Commission may issue a conditional approval, pending remediation of the deficiencies identified in the corrective action plan.

Second, whereas flavored, orally ingested cannabis products present significant health and safety risks, particularly to young children, as demonstrated by recent increases in poison control calls and emergency department visits related to edible cannabis products nationwide and in Maryland, the Ad Hoc Committee recommends that in order to "ensure the safety of minors" as required under Health-General 13-3309, the Commission not approve any product that exceeds 40 mg THC per serving – the current maximum for products on the market. In addition, as further outlined under the third recommendation below, the Committee recommends the Commission adopt amendments to COMAR 10.62.37.21 that establish a THC limit of 25 mg per serving.

Third, based on a review of products currently on the market, the Ad Hoc Committee recommends that the Commission consider clarifying the packaging and labeling requirements for all cannabis products, and product requirements for exempt products through regulatory amendments. In particular, the Committee recommends that the Commission authorize staff to draft amendments proposing the following changes:

1. Eliminate certain legal warnings that are currently required to appear on packaging that are otherwise addressed in the patient application and/or attestation;
2. Establish a larger minimum font or size for certain health and safety warnings to increase visibility;
3. Clarify the statements and warnings that must be displayed directly on the packaging, as opposed to any subsequent product labeling placed on the packaging;
4. Require the universal symbol to be displayed on the front of all packaging;
5. Require each product sold in solid dosage form to contain a marking or imprint that identifies the product manufacturer and amount of THC contained in each serving;
6. Require an icon/label on all packaging that conveys the product is not safe for children; and
7. Establish express product, packaging, and labeling standards for any product seeking exemption under COMAR 10.62.37.21, including a THC limit of 25 mg per serving and 100 mg per package.

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Tiffany D. Randolph, Esq., Acting Chair