Exempted Edible Products

Summary

This proposal clarifies requirements for exempted edible products.

10.62.37 Edible Cannabis Products

.21 Medical Cannabis Products and Components Not Subject to This Chapter.

A. - C. (text unchanged)

D. An application submitted pursuant to §C(1) of this regulation shall include:

(1) Documentation demonstrating that the third-party certification body:

(a) Is accredited to certify for Good Manufacturing Practice 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 third-party certification body's scope of accreditation that complies with 21 CFR Part 111 or 21 CFR Part 210; and

(2) A completed:

(a) Audit checklist of the licensed processor's facility that complies with 21 CFR Part 111 or 21 CFR Part 210; and

(b) Corrective action plan to remediate any deficiencies identified during the audit.

E. Product Restrictions.

(1) A licensee seeking an exemption for a dosage form from Regulations .01—.19 shall:

(a) Only manufacture or distribute the dosage form in geometric shapes;

(b) Ensure each serving of the dosage form:

(i) Is physically separated;

(ii) Is individually wrapped; and

(iii) Contains a marking or imprint that identifies the licensee and amount of THC contained in each serving; and

(c) Comply with child-resistant packaging requirements established in 16 CFR §1700.

(2) A licensee seeking an exemption for a dosage form from Regulations .01—.19 may not manufacture a dosage form that exceeds:

(a) 25 milligrams THC per serving; and

(b) 100 milligrams THC per package.

(3) Liquid dosage forms.

(a) A licensee seeking an exemption for a dosage form from Regulations .01 -- .19 may not manufacture a liquid dosage form that:

(i) Contains coffee, tea, carbonated water, juice, or soda;

(ii) If single use, exceeds a volume of 60 mL; and

(iii) If multi-use, exceeds a volume of more than 250 mL

(b) A multi-use liquid dosage form may not be approved by the Commission unless the licensee submits product stability and homogeneity studies for a period of 12 months, in accordance with the Commission's current version of technical authority for medical cannabis testing.