**R66. Agriculture and Food, Specialized Products.**

**R66-51. Kratom Product Registration and Labeling.**

**R66-51-1. Authority and Purpose.**

(1) Pursuant to Section 4-45-107, this rule establishes the requirements for labeling and registration of kratom products.

**R66-51-2. Definitions.**

(1) "7-OH" means 7-hydroxymitragynine (CAS 174418-82-7).

(2) "Batch or lot" means a uniquely processed quantity identified by a specific date and the timeframe between two consecutive cleanups.

(3) "Certificate of Analysis" (COA) means a document produced by a testing laboratory listing the quantities of the various analytes for which testing was performed.

(4) "Finished product" means a reasonably homogenous kratom product in its final packaged form.

(5) "Label" means the display of any written, printed, or graphic matter upon the immediate container of a kratom product or a statement by or under the control of the kratom processor or distributor, which is directly related to the kratom product bearing the label.

(6) "Registrant" means a person who assumes responsibility for the compliance of the product registration.

(7) "Serving Size" means a specific amount of food, measured as an integer, that's used as a standard reference to help consumers make informed choices.

(8) "Third-party Laboratory" means a laboratory that has no direct interest in a processor or distributor of kratom products that can perform mandated testing utilizing validated methods.

(9) "Unapproved delivery form" means:

(a) any form that is combustible or intended to be used for vaporization; or

(b) any form that mimics a candy product or is manufactured, packaged, or advertised in a way that appeals to children.

**R66-51-3. Product Registration.**

(1) A registrant shall register any kratom product distributed, available for distribution, or that is intended to be offered for sale to an end consumer, including on the internet or social media platforms, annually with the department.

(2) The department shall require a separate registration fee for each kratom product unless:

(a) the label is identical;

(b) the product delivery form is identical; and

(c) the product ingredients are identical.

(3) A single registration may include products that contain the same kratom ingredients in the same kratom delivery form but in a different container or volume.

(4) To register a product, a registrant shall:

(a) apply on a form provided by the department; and

(b)(i) include a Certificate of Analysis (COA) for the kratom product from a third-party laboratory, based on tests performed within the previous six months.

(ii) The third-party laboratory shall have International Organization for Standardization (ISO) 17025:2017 accreditation from an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

(iii) A third-party laboratory may test a kratom product before obtaining ISO/IEC 17025:2017 accreditation, provided the third-party laboratory:

(A) adopts and follows minimum good laboratory practices which satisfy the OECD Principles of Good Laboratory Practice and Compliance Monitoring published by the Organization for Economic Co-operation and Development; and

(B) is currently in the process of becoming ISO/IEC 17025:2017 accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

(5) A non-refundable registration fee, as outlined in the fee schedule approved by the Legislature, shall be paid to the department with the submission of a registration application.

(6) The department shall deny or withdraw registration if:

(a) the kratom product violates Title 4, Chapter 45, Kratom Consumer Protection Act;

(b) there is any reasonable basis to suspect that the kratom product is unsafe or that ingredients violate state law;

(c) the kratom product is in a shape that is appealing to children; or

(d) the product contains a prohibited additive as outlined in Section R66-52-11.

(6) A new registration application is required for the following:

(a) a change in the kratom product ingredients or processes that materially alters the product;

(b) a change to the recommended usage; or

(c) a change of name for the product.

(7) Other changes may not require a new registration, but the registrant shall submit copies of each label change to the department as soon as they are effective.

(8) The registrant is responsible for the accuracy and completeness of information submitted.

(9) Kratom product registrations shall expire on June 30 of each year, and the department may not prorate these registrations.

(10) The department shall deny product registration if products:

(a) violate Chapter 4-45 Kratom Consumer Protection Act; or

(b) are in an unapproved delivery form.

**R66-51-4. Product Renewal.**

(1)(a) Beginning on May 1 of each year, a registrant shall renew a product registration by submitting payment of an annual renewal fee per kratom product on or before June 30.

(b) The department shall assess a late fee for a renewal of a kratom product registration submitted on or after July 1 and may not issue a renewal until paid.

(2) A kratom product that has been discontinued shall continue to be registered in the state until the product is no longer available for distribution.

**R66-51-5. Certificate of Analysis.**

(1) Testing shall be performed on finished products identified with a lot or batch number.

(2) At a minimum, the certificate of analysis for each batch of kratom product in its final form shall include the following test results:

(a) the contents of mitragynine and 7-hydroxymitragynine in the kratom product certifying compliance with this rule and Subsection 4-45-104(1);

(b) microbials;

(c) heavy metals;

(d) pesticides;

(e) solvents; and

(f) mycotoxins if requested by the department.

(3) The test results required in Section R66-51-5 shall be reported in accordance with the requirements for a kratom product in Rule R66-52, including the specified units of measure.

(4) The certificate of analysis shall also include the following information:

(a) the lot or batch identification number of the tested product;

(b) the date received;

(c) the date of testing completion;

(d) the method of analysis for each test conducted;

(e) proof that the certificate of analysis is connected to the product documented by:

(i) a photo of the kratom product that was tested; or

(ii) as determined by the department;

(f) the name of the kratom processor that manufactured the product; and

(g) the name and address of the laboratory that completed the testing.

(5) The lot or batch number on the certificate of analysis shall match the lot or batch number on the kratom product.

(6) An adverse or non-compliant test result shall be cause for denial of registration.

**R66-51-6. Label Requirements.**

(1) The label of a kratom product shall contain the following information, legibly displayed:

(a) product name or common name, on the front of the label;

(b) the suggested use of the product, including serving size and recommended daily intake;

(c) the amount of mitragynine and 7-hydroxymitragynine contained in the packaged kratom product;

(d) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

(e) identification of each kratom product by a unique batch or lot number, specifically linking each kratom product to a specific batch or lot manufactured by the kratom processor;

(f) manufacturer, packer, or distributor name and address; and

(g) the following statements:

(i) "this product has not been evaluated by the Food and Drug Administration" or an equivalent statement; and

(ii) "this product is not intended to diagnose, treat, cure, or prevent any disease" or an equivalent statement.

(2) If there is not sufficient room on the kratom product label, the kratom product may include a scannable bar code, QR code, or web address linked to a document containing any additional required information.

(3) A kratom product shall meet the standards of any applicable state laws and regulations relating to the labeling of food, including Chapter 4-5, Utah Wholesome Food Act.

(4) A kratom product label may not:

(a) contain claims that the product is intended to diagnose, treat, cure, or prevent any health condition or disease on the label or labeling unless the product has been registered with the FDA;

(b) have any likeness bearing resemblance to a cartoon character or fictional character;

(c) appear to imitate a food or other product that is typically marketed toward or that is appealing to children; or

(d) contain statements that remove responsibility or liability for the use of the product.

(5) A registrant misbrands a kratom product if:

(a) its label is false or misleading in any way; or

(b) it fails to conform to any requirement specified in this section.

**R66-51-7. Product Appearance and Flavor.**

(1) A kratom processor may not produce a kratom product that is designed to mimic a candy product.

(2) A kratom processor may not produce a product that includes a candy-like flavor or another flavor that appeals to children.

(3) A kratom processor may not shape a kratom product in any way that appeals to children.

(4) A kratom product shall be packaged in child-resistant packaging.

**R66-51-8. Inspection and Testing.**

(1) The department shall conduct a randomized inspection of kratom products distributed or available for distribution in the state for compliance with this rule.

(2) The department shall periodically sample, analyze, and test a kratom product distributed within the state for compliance with registration and labeling requirements and the certificate of analysis.

(a) Each department sample shall include at least ten grams of kratom product.

(b) The department may test a kratom product for any substance listed in Rule R66-52 as well as for any substance the department deems necessary.

(c) A kratom product that is found to contain a prohibited substance shall be considered adulterated in violation of this rule.

(3) The department may conduct an inspection of kratom products distributed or available for distribution for any reason the department deems necessary.

(4) The sample taken by the department shall be the official sample.

(5) Upon request, a kratom processor shall provide documentation certifying that any batch of kratom raw materials acquired pursuant to a compliant specification purchase that is used to process or manufacture a kratom product is compliant with Section R66-51-5.

**R66-51-9. Violation.**

(1) Each improperly labeled kratom product shall be a separate violation of this rule.

(2) Kratom products not meeting the labeling requirements shall be considered misbranded.

(3) Kratom products shall be considered falsely advertised if they do not meet the labeling requirements of this rule.

(4) It is a violation to distribute or market a kratom product that is not registered with the department.

(5) It is a violation to distribute or market a kratom product that contains 7-OH at greater than 2% of the alkaloid composition.

(6) It is a violation to distribute or market a kratom product that has not been tested as required by Rule R66-52.

(7) It is a violation to distribute or market a kratom product that is marketed toward or is appealing to children.

(8) It is a violation to submit a fraudulent COA to the department.

**KEY: kratom, kratom processor, product registration, labeling**

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