

HOUSE COMMITTEE OF REFERENCE AMENDMENT

Committee on Health & Insurance.

SB22-120 be amended as follows:

1 Amend reengrossed bill, page 2, line 8, strike "**Definitions.**" and
2 substitute "**Definitions - rules.**".

3 Page 2, after line 9 insert:

4 "(1) (a) "APPROVED KRATOM DELIVERY FORM" MEANS A FINISHED
5 KRATOM PRODUCT OR KRATOM EXTRACT MANUFACTURED IN CAPSULE,
6 TABLET, POWDER, LIQUID TINCTURE, TEA BAG, BEVERAGE, OR EDIBLE
7 FORM.

8 (b) "APPROVED KRATOM DELIVERY FORM" DOES NOT INCLUDE:
9 (I) ANY FORM THAT IS INTENDED TO BE USED BY COMBUSTION OR
10 VAPORIZATION;

11 (II) ANY FORM THAT IS INTENDED TO BE ADDED TO FOOD; OR

12 (III) ANY FORM THAT MIMICS A CANDY PRODUCT OR IS
13 MANUFACTURED, PACKAGED, OR ADVERTISED IN A WAY THAT APPEALS TO
14 CHILDREN, INCLUDING ANY KRATOM PRODUCT THAT IS IN THE DISTINCT
15 SHAPE OF FRUIT, STARS, CARTOON RENDERINGS, HUMANS, OR ANIMALS.

16 (2) "FOOD" HAS THE MEANING SET FORTH IN SECTION 25-4-1602."

17 Renumber succeeding subsections accordingly.

18 Page 2, lines 13 and 14, strike "AND CONCENTRATED IN ORDER TO
19 PROVIDE MORE STANDARDIZED DOSING." and substitute "THROUGH AN
20 EXTRACTION PROCESS SUBJECT TO THE UNITED STATES PHARMACOPEIA AS
21 APPROVED BY THE EXECUTIVE DIRECTOR BY RULE."

22 Page 3, line 4, after "MEANS" insert "THE FINISHED PRODUCT PACKAGED
23 FOR SALE TO A CONSUMER CONTAINING".

24 Page 3, lines 6 and 7, strike "A POWDER, CAPSULE, PILL, BEVERAGE, OR
25 SOME OTHER EDIBLE PRODUCT." and substitute "AN APPROVED KRATOM
26 DELIVERY FORM MEANT FOR HUMAN CONSUMPTION."

27 Page 3, line 14, strike "JULY 1, 2023," and substitute "JANUARY 1, 2024,".

28 Page 3, lines 24 and 25, strike "EXCEPT AS PROVIDED IN SUBSECTION (3)
29 OF THIS SECTION, EFFECTIVE JULY 1, 2023," and substitute "EFFECTIVE
30 JANUARY 1, 2024,".

31 Page 3, strike line 27 and substitute "REGISTER ALL KRATOM PRODUCTS
32 THAT THE KRATOM PROCESSOR INTENDS TO SELL, PREPARE, OR MAINTAIN

1 IN THE STATE AND PROVIDE THE INFORMATION REQUIRED BY THE
2 EXECUTIVE DIRECTOR BY RULE TO THE DEPARTMENT, INCLUDING:".

3 Page 4, lines 24 and 25, strike "A KRATOM PROCESSOR IS NOT REQUIRED
4 TO DISCLOSE ANY INFORMATION THAT IS A TRADE SECRET," and substitute
5 "THE DEPARTMENT SHALL MAINTAIN THE CONFIDENTIALITY OF REPORTS
6 AND OTHER INFORMATION OBTAINED FROM A KRATOM PROCESSOR THAT
7 ARE TRADE SECRETS,".

8 Page 5, after line 3 insert:

9 "(5) THE DEPARTMENT SHALL BEGIN ACCEPTING THE
10 REGISTRATIONS AND INFORMATION DESCRIBED IN SUBSECTIONS (1) AND
11 (2) OF THIS SECTION BY JULY 1, 2023."

12 Page 5, line 24, strike "AND" and substitute "OR".

13 Page 6, after line 23 insert:

14 "(3) THIS SECTION IS EFFECTIVE JANUARY 1, 2024."

15 Page 7, line 1, strike "(1)" and substitute: "(1) THE DEPARTMENT MAY
16 INSPECT AND INVESTIGATE PREMISES AT WHICH KRATOM PRODUCTS ARE
17 MANUFACTURED, PROCESSED, STORED, OR SOLD OR THE BOOKS AND
18 RECORDS THAT MUST BE MAINTAINED PURSUANT TO THIS ARTICLE 15 AND
19 THE RULES PROMULGATED PURSUANT TO THIS ARTICLE 15 FOR THE
20 PURPOSES OF DETERMINING COMPLIANCE WITH THIS ARTICLE 15 AND THE
21 RULES PROMULGATED PURSUANT TO THIS ARTICLE 15.

22 (2) (a)".

23 Page 7, line 5, strike "(2)" and substitute "(b)"

24 Page 7, line 6, strike "(1)" and substitute "(2)(a)".

25 Page 7, line 8, strike "(3)" and substitute "(c)".

26 Page 7, line 13, strike "THE" and substitute "NO LATER THAN JANUARY 1,
27 2024, THE".

28 Page 8, strike line 3 and substitute "PROCESSORS, INCLUDING THE
29 REGISTRATION REQUIREMENTS FOR RETAILERS AND RETAIL LOCATIONS IN
30 THE STATE.

31 (2) THE EXECUTIVE DIRECTOR MAY PROMULGATE RULES RELATING
32 TO:

33 (a) PROCEDURES AND REQUIREMENTS FOR THE REGISTRATION OF

1 KRATOM PROCESSORS AND RETAILERS AND FOR THE ISSUANCE, RENEWAL,
2 SUSPENSION, AND REVOCATION OF THE REGISTRATION OF KRATOM
3 PROCESSORS AND RETAILERS PURSUANT TO THIS ARTICLE 15, INCLUDING
4 SETTING APPROPRIATE REGISTRATION FEES THAT REFLECT THE
5 DEPARTMENT'S DIRECT AND INDIRECT COSTS TO ADMINISTER AND
6 IMPLEMENT THIS ARTICLE 15;

7 (b) PROCEDURES AND REQUIREMENTS CONSISTENT WITH THIS
8 ARTICLE 15 FOR KRATOM PRODUCT REGISTRATION, INCLUDING SETTING
9 APPROPRIATE REGISTRATION FEES THAT REFLECT THE DEPARTMENT'S
10 DIRECT AND INDIRECT COSTS TO ADMINISTER AND IMPLEMENT THIS
11 ARTICLE 15;

12 (c) ESTABLISHING REQUIREMENTS TO DETERMINE THE
13 COMPLIANCE OF KRATOM PROCESSORS AND RETAILERS WITH THIS ARTICLE
14 15, INCLUDING TESTING REQUIREMENTS AND PROTOCOLS TO ENSURE, AT
15 A MINIMUM, THAT KRATOM PRODUCTS PROCESSED AND SOLD BY KRATOM
16 PROCESSORS REGISTERED PURSUANT TO SECTION 44-15-103 DO NOT
17 CONTAIN PROHIBITED SUBSTANCES, ARE NOT ADULTERATED, AND ARE NOT
18 INJURIOUS TO HEALTH. THE TESTING REQUIREMENTS ESTABLISHED BY THE
19 EXECUTIVE DIRECTOR PURSUANT TO THIS SUBSECTION (2)(c) MAY INCLUDE
20 TESTING FOR CHEMICAL AND BIOLOGICAL CONTAMINANTS DEEMED TO BE
21 PUBLIC HEALTH HAZARDS AND TO THE EXTENT APPLICABLE SHOULD ALIGN
22 WITH THE UNITED STATES PHARMACOPEIA STANDARDS FOR DIETARY
23 SUPPLEMENTS;

24 (d) HEALTH AND SAFETY REGULATIONS AND STANDARDS FOR THE
25 MANUFACTURE OF KRATOM PRODUCTS;

26 (e) REQUIREMENTS FOR INSPECTIONS, INVESTIGATIONS,
27 INVENTORY EMBARGO, AND OTHER ACTIVITIES THAT MAY BE NECESSARY
28 TO DETERMINE COMPLIANCE WITH THIS ARTICLE 15;

29 (f) REQUIREMENTS RELATED TO BOOKS AND RECORDS A KRATOM
30 PROCESSOR MUST MAINTAIN AND MAKE AVAILABLE FOR INSPECTIONS
31 UPON THE REQUEST OF THE DEPARTMENT;

32 (g) REQUIREMENTS FOR THE MANUFACTURE, DISTRIBUTION, AND
33 SALE OF KRATOM PRODUCTS AND, IN ADDITION TO THE REQUIREMENTS OF
34 SECTION 44-15-104 (2), REQUIREMENTS FOR THE ENFORCEMENT OF THIS
35 ARTICLE 15, INCLUDING APPROPRIATE PENALTIES FOR VIOLATIONS OF THIS
36 ARTICLE 15 OR THE RULES PROMULGATED IN ACCORDANCE WITH THIS
37 ARTICLE 15; AND

38 (h) REQUIREMENTS AND PROCEDURES FOR ESTABLISHING AND
39 EXECUTING A RECALL PLAN AND REPORTING ADVERSE EVENTS IN
40 ACCORDANCE WITH SECTION 44-15-106, INCLUDING DEFINING AN ADVERSE
41 EVENT FOR THE PURPOSES OF SECTION 44-15-106."

42 Page 8, line 15, strike "In" and substitute "ON OR BEFORE JANUARY 1,
43 2024, IN".

1 Page 8, line 23, strike "THE" and substitute "ON OR BEFORE JANUARY 1,
2 2024, THE".

3 Page 8, line 27, strike "**Retailers.**" and substitute "**Restrictions -
4 retailers - kratom processors.**".

5 Page 9, after line 4 insert:

6 "(2) A KRATOM PROCESSOR OR RETAILER SHALL NOT:

7 (a) LABEL A KRATOM PRODUCT IN A MANNER INCONSISTENT WITH
8 THIS ARTICLE 15 OR THE RULES PROMULGATED PURSUANT TO THIS ARTICLE
9 15;

10 (b) ON AND AFTER JANUARY 1, 2024, DISTRIBUTE OR MARKET A
11 KRATOM PRODUCT THAT IS NOT REGISTERED WITH THE DEPARTMENT IN
12 ACCORDANCE WITH SECTION 44-15-103;

13 (c) PREPARE, DISTRIBUTE, OR OFFER FOR SALE:

14 (I) A KRATOM PRODUCT THAT VIOLATES THIS ARTICLE 15;

15 (II) A KRATOM PRODUCT THAT IS NOT IN AN APPROVED KRATOM
16 DELIVERY FORM;

17 (III) A KRATOM PRODUCT THAT IS POTENTIALLY HARMFUL TO A
18 CONSUMER; OR

19 (IV) A KRATOM PRODUCT ON WHICH THE LABEL INFERS OR
20 INDICATES THAT THE PRODUCT CAN PREVENT, CURE, TREAT, OR MITIGATE
21 A DISEASE OR CONDITION;

22 (d) IMPROPERLY SAMPLE OR TEST A KRATOM PRODUCT, FALSIFY A
23 CERTIFICATE OF ANALYSIS FOR A KRATOM PRODUCT, OR KNOWINGLY
24 SUBMIT A FALSIFIED CERTIFICATE OF ANALYSIS FOR A KRATOM PRODUCT;

25 (e) LABEL OR PROMOTE A KRATOM PRODUCT AS A DRUG; OR

26 (f) FAIL TO REGISTER WITH THE DEPARTMENT IN ACCORDANCE
27 WITH SECTION 44-15-103."

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