As Passed by the House

134th General Assembly

Regular Session 2021-2022

H. B. No. 236

Representatives Fraizer, Lipps

Cosponsors: Representatives Lightbody, West, Click, Leland, Lepore-Hagan, Liston, Seitz, Smith, M.

A BILL

To amend sections 3719.41 and 4729.01 and to enact	1
sections 930.01, 930.02, 930.03, 930.04, 930.05,	2
930.06, 930.07, and 930.99 of the Revised Code	3
to regulate the processing, sale, and	4
distribution of kratom.	5

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3719.41 and 4729.01 be amended	6
and sections 930.01, 930.02, 930.03, 930.04, 930.05, 930.06,	7
930.07, and 930.99 of the Revised Code be enacted to read as	8
follows:	9
Sec. 930.01. As used in this chapter:	10
(A) "Kratom" means the plant mitragyna speciosa and any	11
part of that plant, including the seeds thereof and all	12
derivatives and extracts.	13
(B) "Kratom product" means any product that is made with	14
kratom. "Kratom product" includes dietary supplements or food	15
intended for human consumption.	16

(C) "Kratom processing license" means a license to process	17
kratom issued under this chapter.	18
(D) "Process" or "processing" means converting kratom into_	19
a kratom product.	20
Sec. 020 02 (A) The director of equivalence shall	21
Sec. 930.02. (A) The director of agriculture shall	
establish a program to monitor and regulate kratom processing	22
and the sale of kratom products in this state. Under the	23
program, the director shall issue kratom processing licenses in	24
accordance with rules adopted under section 930.03 of the	25
Revised Code.	26
(B) Any person that wishes to process kratom shall apply	27
for and obtain a kratom processing license from the director in	28
accordance with rules adopted under section 930.03 of the	29
Revised Code. Such licenses are valid for three years, unless	30
earlier suspended or revoked by the director.	31
(C) Subject to section 930.04 of the Revised Code, any	32
person may, without a kratom processing license, possess, buy,	33
<u>or sell kratom or kratom products.</u>	34
Sec. 930.03. The director of agriculture, in consultation	35
with the governor and attorney general, shall adopt rules in	36
accordance with Chapter 119. of the Revised Code establishing	37
standards and procedures for the regulation of kratom	38
processing. The rules shall include all of the following:	39
(A) The form of an application for a kratom processing	40
license and the information required to be included in each	41
license application;	42
(B) The amount of an initial application fee that an	43
applicant shall submit along with an application for a kratom	44
processing license, and the amount of an annual license fee that	45

a licensee shall submit for a kratom processing license. In	46
adopting rules under division (B) of this section, the director	47
shall ensure both of the following:	48
(1) That the amount of the application for and appual	49
(1) That the amount of the application fee and annual	-
license fee does not exceed an amount sufficient to cover the	50
costs incurred by the department of agriculture to administer	51
and enforce this chapter;	52
(2) That there is one uniform application fee and one	53
uniform annual license fee that applies to all applicants for a	54
kratom processing license.	55
(C) Requirements and procedures regarding standards of	56
financial responsibility for each applicant for a kratom	57
processing license;	58
	- 0
(D) Procedures and requirements for the issuance, renewal,	59
denial, suspension, and revocation of a kratom processing	60
license, including providing for a hearing under Chapter 119. of	61
the Revised Code with regard to such a denial, suspension, or	62
revocation;	63
(E) Grounds for the denial, suspension, and revocation of	64
a kratom processing license;	65
(F) A requirement that any person that materially	66
falsifies information in an application for a kratom processing	67
license is ineligible to receive the license;	68
(G) A procedure for testing kratom products for purposes	69
of determining compliance with this chapter and rules adopted	70
<u>under it;</u>	71
(H) Requirements and procedures for the issuance,	72
administration, and enforcement of corrective action plans	73

issued under section 930.05 of the Revised Code;	74
(I) A procedure for conducting annual inspections of, at a	75
minimum, a random sample of kratom processing license holders to	76
verify that kratom plants are not being processed in violation	77
of this chapter and rules adopted under it;	78
(J) A procedure for the effective disposal of all products	79
derived from plants processed in violation of this chapter and	80
rules adopted under it;	81
(K) Annual reporting requirements and procedures for	82
kratom processing license holders;	83
(L) Recordkeeping and documentation maintenance	84
requirements and procedures for kratom processing license	85
holders;	86
(M) Fees for the laboratory testing of plants and	87
products;	88
(N) Standards for the labeling of kratom products that	89
require a label to include, at a minimum, specific directions	90
necessary for the safe and effective use of a kratom product by	91
consumers and a recommended serving size;	92
(0) Procedures and requirements for the transportation and	93
distribution of kratom products;	94
(P) Any other requirements or procedures necessary to	95
administer and enforce this chapter.	96
Sec. 930.04. (A) As used in this section:	97
(1) "Controlled substance" has the same meaning as in	98
section 4729.01 of the Revised Code.	99
(2) "Drug" has the same meaning as in section 3719.01 of	100

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the Revised Code.	101
(B) No person shall process kratom without a kratom	102
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processing license issued by the director of agriculture under	103
this chapter.	104
(C) No person who holds a kratom processing license shall	105
violate this chapter or rules adopted under it.	106
(D) No person subject to a corrective action plan issued	107
by the director of agriculture under section 930.05 of the	108
Revised Code shall fail to comply with the plan.	109
(E) No person shall transport a kratom product in	110
violation of rules adopted under section 930.03 of the Revised	111
Code.	112
(F) No person shall distribute, sell, or expose for sale_	113
any of the following:	114
(1) A kratom product that is adulterated with a dangerous	115
non-kratom substance. A kratom product is adulterated with a	116
dangerous non-kratom substance if the kratom product is mixed or	117
packed with a non-kratom substance and that substance affects	118
the quality or strength of the kratom product to such a degree	119
as to render the kratom product injurious to a consumer.	120
(2) A kratom product that is contaminated with a dangerous	121
non-kratom substance. A kratom product is contaminated with a	122
dangerous non-kratom substance if the kratom product contains a	123
poisonous or otherwise deleterious non-kratom ingredient,	124
including, but not limited to, any drug or controlled substance.	125
(3) A kratom product containing a level of 7-	126
hydroxymitragynine in the alkaloid fraction that is greater than	127
two per cent of the overall alkaloid composition of the kratom	128

129 product. (4) A kratom product containing any synthetic alkaloids 130 including synthetic mitragynine, synthetic 7-hydroxymitragynine, 131 or any other synthetically derived compounds of the kratom 132 133 <u>plant.</u> (5) A kratom product that is not properly labeled in 134 accordance with rules adopted under section 930.03 of the 135 Revised Code. 136 (6) A kratom product with a label containing claims that 137 the kratom product is intended to diagnose, treat, cure, or 138 prevent any medical condition or disease. 139 Sec. 930.05. (A) The director of agriculture shall issue a 140 corrective action plan to any person that the director 141 determines has negligently violated section 930.04 of the 142 Revised Code. The director shall include in the corrective 143 action plan both of the following: 144 (1) A reasonable date by which the person shall correct 145 the violation; 146 147 (2) A requirement that the person report to the director regarding the person's compliance with the requirements of this 148 chapter, rules adopted under it, and the corrective action plan 149 for two calendar years immediately following the date of the 150 violation. 151 (B) If the director determines that a person negligently 152 violated section 930.04 of the Revised Code three or more times 153 in any five-year period, the director shall revoke the person's 154 kratom processing license, if any, and shall refuse to issue a 155 kratom processing license to that person for a period of five 156

years beginning on the date that the director determines that

the person committed the most recent violation.

(C) The director shall report a person who the director	159
determines has violated section 930.04 of the Revised Code with	160
a culpable mental state greater than negligence to the attorney	161
general and the applicable county prosecutor.	162
Sec. 930.06. There is hereby created in the state treasury	163
the kratom program fund. The fund shall consist of all fees	164
collected under rules adopted under section 930.03 of the	165
Revised Code; money appropriated to the fund; and any other	166
money received from gifts or federal grants. All investment	167
earnings of the fund shall be credited to the fund. The director	168
of agriculture shall use money in the fund to administer and	169
enforce this chapter and rules adopted under it.	170
Sec. 930.07. (A) The director of agriculture may enter at	171
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reasonable times upon any public or private property at which	172
kratom is being processed, distributed, or sold for the purpose	173
of determining compliance with this chapter and rules adopted	174
under it. The director may apply for and any judge of an	175

appropriate court of record may issue a search warrant, <u>necessary to achieve the purposes of this chapter within the court's territorial jurisdiction.</u>

(B) (1) If the director determines that emergency179conditions exist requiring immediate action necessary to protect180public health or safety or the environment, the director may181issue an order stating the existence of such conditions and182requiring specific actions be taken to mitigate those conditions183without providing prior notice or an adjudication hearing in184accordance with Chapter 119. of the Revised Code.185

(2) Any person to whom such an order is issued shall_

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immediately comply with that order, and may apply to the	187
director for an adjudication hearing. Upon receiving an	188
application for an adjudication hearing, the director shall hold	189
the hearing as soon as practicable and not later than thirty	190
days after receipt of the application. On the basis of the	191
hearing, the director shall continue the order in effect, revoke	192
<u>it, or modify it.</u>	193
(C) In addition to any other available remedies, the	194
director of agriculture, the attorney general, or a county	195
prosecutor may apply to a court of common pleas in the county	196
where any provision of section 930.04 of the Revised Code or an	197
order issued under division (B) of this section is being	198
violated for an injunction restraining any person from	199
continuing the violation.	200
Sec. 930.99. (A) Whoever recklessly violates section	201
930.04 of the Revised Code is guilty of the following:	202
(1) For a first offense, a minor misdemeanor;	203
(2) For each subsequent offense, a misdemeanor of the	204
fourth degree.	205
The court shall order an offender who is convicted of or	206
pleads guilty to a third or subsequent offense ineligible to	207
receive a kratom processing license under this chapter. The	208
court shall provide written notice of that order to the director	209
of agriculture. Upon receipt of the notice, the director shall	210
revoke any kratom processing license that the offender holds and	211
shall refuse to issue a kratom processing license to the	212
offender beginning on the date of the court order.	213
(B) The prosecuting attorney of the applicable county or	214
the attorney general may prosecute an action under this section.	215

H. B. No. 236 As Passed by the House

Sec. 3719.41. (A) For purposes of administration, 216 enforcement, and regulation of the manufacture, distribution, 217 dispensing, and possession of controlled substances, the state 218 board of pharmacy shall adopt rules in accordance with Chapter 219 119. of the Revised Code establishing schedule I, schedule II, 220 schedule III, schedule IV, and schedule V incorporating the five 221 schedules of controlled substances under the federal drug abuse 222 control laws. 223

The board may include in the schedules any compound, 224 mixture, preparation, or substance that was included in the 225 schedules immediately prior to March 22, 2020, as long as the 226 inclusion does not have the effect of providing less stringent 227 control of the compound, mixture, preparation, or substance than 228 is provided under the federal drug abuse control laws or 229 regulations adopted under those laws. 230

(B) Except as provided in section 3719.45 of the Revised Code, the board periodically shall update the schedules by rule adopted in accordance with Chapter 119. of the Revised Code to correspond to any change in the federal drug abuse control laws or regulations adopted under those laws, any addition, transfer, or removal by congress or the attorney general of the United States as described in section 3719.43 of the Revised Code, and any addition, transfer, or removal by the board by rule adopted under section 3719.44 of the Revised Code.

(C) Notwithstanding divisions (A) and (B) of this section, 240 the board shall not adopt rules including hemp-or, a hemp 241 product, kratom, or a kratom product in a schedule as a 242 controlled substance. 243

(D) As used in this section, "hemp": 244

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<u>(1) "Hemp"</u> and "hemp product" have the same meanings as in	245
section 928.01 of the Revised Code <u>;</u>	246
(2) "Kratom" and "kratom product" have the same meanings	247
as in section 930.01 of the Revised Code.	248
Sec. 4729.01. As used in this chapter:	249
(A) "Pharmacy," except when used in a context that refers	250
to the practice of pharmacy, means any area, room, rooms, place	251
of business, department, or portion of any of the foregoing	252
where the practice of pharmacy is conducted.	253
(B) "Practice of pharmacy" means providing pharmacist care	254
requiring specialized knowledge, judgment, and skill derived	255
from the principles of biological, chemical, behavioral, social,	256
pharmaceutical, and clinical sciences. As used in this division,	257
"pharmacist care" includes the following:	258
(1) Interpreting prescriptions;	259
(2) Dispensing drugs and drug therapy related devices;	260
(2) Dispensing drugs and drug therapy related devices;(3) Compounding drugs;	260 261
(3) Compounding drugs;	261
(3) Compounding drugs;(4) Counseling individuals with regard to their drug	261 262
(3) Compounding drugs;(4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and	261 262 263
(3) Compounding drugs;(4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and assisting in the selection of drugs and appliances for treatment	261 262 263 264
 (3) Compounding drugs; (4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and assisting in the selection of drugs and appliances for treatment of common diseases and injuries and providing instruction in the 	261 262 263 264 265
 (3) Compounding drugs; (4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and assisting in the selection of drugs and appliances for treatment of common diseases and injuries and providing instruction in the proper use of the drugs and appliances; 	261 262 263 264 265 266
 (3) Compounding drugs; (4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and assisting in the selection of drugs and appliances for treatment of common diseases and injuries and providing instruction in the proper use of the drugs and appliances; (5) Performing drug regimen reviews with individuals by 	261 262 263 264 265 266 267
 (3) Compounding drugs; (4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and assisting in the selection of drugs and appliances for treatment of common diseases and injuries and providing instruction in the proper use of the drugs and appliances; (5) Performing drug regimen reviews with individuals by discussing all of the drugs that the individual is taking and 	261 262 263 264 265 266 267 268

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pharmacist determines that an individual with a prescription has 272 a drug regimen that warrants additional discussion with the 273 prescriber; 274 (7) Advising an individual and the health care 275 professionals treating an individual with regard to the 276 individual's drug therapy; 277 (8) Acting pursuant to a consult agreement, if an 278 279 agreement has been established; (9) Engaging in the administration of immunizations to the 280 extent authorized by section 4729.41 of the Revised Code; 281 (10) Engaging in the administration of drugs to the extent 282 authorized by section 4729.45 of the Revised Code. 283 (C) "Compounding" means the preparation, mixing, 284 assembling, packaging, and labeling of one or more drugs in any 285 of the following circumstances: 286 (1) Pursuant to a prescription issued by a licensed health 287 professional authorized to prescribe drugs; 288 (2) Pursuant to the modification of a prescription made in 289 accordance with a consult agreement; 290 (3) As an incident to research, teaching activities, or 291 chemical analysis; 292 293 (4) In anticipation of orders for drugs pursuant to prescriptions, based on routine, regularly observed dispensing 294 patterns; 295 (5) Pursuant to a request made by a licensed health 296 professional authorized to prescribe drugs for a drug that is to 297 be used by the professional for the purpose of direct 298

administration to patients in the course of the professional's 299 practice, if all of the following apply: 300 (a) At the time the request is made, the drug is not 301 commercially available regardless of the reason that the drug is 302 not available, including the absence of a manufacturer for the 303 drug or the lack of a readily available supply of the drug from 304 a manufacturer. 305 (b) A limited quantity of the drug is compounded and 306 307 provided to the professional. (c) The drug is compounded and provided to the 308 professional as an occasional exception to the normal practice 309 of dispensing drugs pursuant to patient-specific prescriptions. 310 (D) "Consult agreement" means an agreement that has been 311 entered into under section 4729.39 of the Revised Code. 312 (E) "Drug" means: 313 (1) Any article recognized in the United States 314 pharmacopoeia and national formulary, or any supplement to them, 315 intended for use in the diagnosis, cure, mitigation, treatment, 316 or prevention of disease in humans or animals; 317 (2) Any other article intended for use in the diagnosis, 318 cure, mitigation, treatment, or prevention of disease in humans 319 or animals; 320 (3) Any article, other than food, intended to affect the 321 structure or any function of the body of humans or animals; 322 (4) Any article intended for use as a component of any 323 article specified in division (E)(1), (2), or (3) of this 324 section; but does not include devices or their components, 325 parts, or accessories. 326 "Drug" does not include "hemp" or a "hemp product" as 327 those terms are defined in section 928.01 of the Revised Code. 328 "Drug" does not include "kratom" or a "kratom product" as those 329 terms are defined in section 930.01 of the Revised Code. 330

- (F) "Dangerous drug" means any of the following: 331
- (1) Any drug to which either of the following applies: 332

(a) Under the "Federal Food, Drug, and Cosmetic Act," 52
Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is
required to bear a label containing the legend "Caution: Federal
law prohibits dispensing without prescription" or "Caution:
Federal law restricts this drug to use by or on the order of a
licensed veterinarian" or any similar restrictive statement, or
the drug may be dispensed only upon a prescription;

(b) Under Chapter 3715. or 3719. of the Revised Code, the340drug may be dispensed only upon a prescription.341

(2) Any drug that contains a schedule V controlled
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substance and that is exempt from Chapter 3719. of the Revised
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Code or to which that chapter does not apply;
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(3) Any drug intended for administration by injection into
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(4) Any drug that is a biological product, as defined in348section 3715.01 of the Revised Code.349

(G) "Federal drug abuse control laws" has the same meaningas in section 3719.01 of the Revised Code.351

(H) "Prescription" means all of the following: 352

(1) A written, electronic, or oral order for drugs or 353

combinations or mixtures of drugs to be used by a particular 354 individual or for treating a particular animal, issued by a 355 licensed health professional authorized to prescribe drugs; 356 (2) For purposes of sections 2925.61, 4723.484, 4730.434, 357 and 4731.94 of the Revised Code, a written, electronic, or oral 358 order for naloxone issued to and in the name of a family member, 359 friend, or other individual in a position to assist an 360 individual who there is reason to believe is at risk of 361 experiencing an opioid-related overdose. 362 (3) For purposes of section 4729.44 of the Revised Code, a 363 written, electronic, or oral order for naloxone issued to and in 364 the name of either of the following: 365 (a) An individual who there is reason to believe is at 366 risk of experiencing an opioid-related overdose; 367 (b) A family member, friend, or other individual in a 368 position to assist an individual who there is reason to believe 369 is at risk of experiencing an opioid-related overdose. 370 (4) For purposes of sections 4723.4810, 4729.282, 371 4730.432, and 4731.93 of the Revised Code, a written, 372 electronic, or oral order for a drug to treat chlamydia, 373 gonorrhea, or trichomoniasis issued to and in the name of a 374 patient who is not the intended user of the drug but is the 375 sexual partner of the intended user; 376 (5) For purposes of sections 3313.7110, 3313.7111, 377 3314.143, 3326.28, 3328.29, 4723.483, 4729.88, 4730.433, 378

4731.96, and 5101.76 of the Revised Code, a written, electronic,379or oral order for an epinephrine autoinjector issued to and in380the name of a school, school district, or camp;381

(6) For purposes of Chapter 3728. and sections 4723.483, 382

4729.88, 4730.433, and 4731.96 of the Revised Code, a written, 383 electronic, or oral order for an epinephrine autoinjector issued 384 to and in the name of a qualified entity, as defined in section 385 3728.01 of the Revised Code; 386

(7) For purposes of sections 3313.7115, 3313.7116,
3314.147, 3326.60, 3328.38, 4723.484, 4730.434, 4731.92, and
5101.78 of the Revised Code, a written, electronic, or oral
order for injectable or nasally administered glucagon in the
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name of a school, school district, or camp.

(I) "Licensed health professional authorized to prescribe 392
drugs" or "prescriber" means an individual who is authorized by 393
law to prescribe drugs or dangerous drugs or drug therapy 394
related devices in the course of the individual's professional 395
practice, including only the following: 396

(1) A dentist licensed under Chapter 4715. of the Revised397Code;398

(2) A clinical nurse specialist, certified nurse-midwife,
or certified nurse practitioner who holds a current, valid
license issued under Chapter 4723. of the Revised Code to
practice nursing as an advanced practice registered nurse;
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(3) A certified registered nurse anesthetist who holds a
(3) A certified registered nurse anesthetist who holds a
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current, valid license issued under Chapter 4723. of the Revised
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Code to practice nursing as an advanced practice registered
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nurse, but only to the extent of the nurse's authority under
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sections 4723.43 and 4723.434 of the Revised Code;
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(4) An optometrist licensed under Chapter 4725. of the
Revised Code to practice optometry under a therapeutic
pharmaceutical agents certificate;
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(5) A physician authorized under Chapter 4731. of the 411

medicine and surgery, or podiatric medicine and surgery;	413
(6) A physician assistant who holds a license to practice	414
as a physician assistant issued under Chapter 4730. of the	415
Revised Code, holds a valid prescriber number issued by the	416
state medical board, and has been granted physician-delegated	417
prescriptive authority;	418
(7) A veterinarian licensed under Chapter 4741. of the	419
Revised Code.	420
(J) "Sale" or "sell" includes any transaction made by any	421
person, whether as principal proprietor, agent, or employee, to	422
do or offer to do any of the following: deliver, distribute,	423
broker, exchange, gift or otherwise give away, or transfer,	424
whether the transfer is by passage of title, physical movement,	425
or both.	426
	420
(K) "Wholesale sale" and "sale at wholesale" mean any sale	427
(K) "Wholesale sale" and "sale at wholesale" mean any sale	427
(K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article	427 428
(K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.	427 428 429
(K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.(L) "Retail sale" and "sale at retail" mean any sale other	427 428 429 430
(K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.(L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale.	427 428 429 430 431
(K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.(L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale.(M) "Retail seller" means any person that sells any	427 428 429 430 431 432
 (K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser. (L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale. (M) "Retail seller" means any person that sells any dangerous drug to consumers without assuming control over and 	427 428 429 430 431 432 433
 (K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser. (L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale. (M) "Retail seller" means any person that sells any dangerous drug to consumers without assuming control over and responsibility for its administration. Mere advice or 	427 428 429 430 431 432 433 434
 (K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser. (L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale. (M) "Retail seller" means any person that sells any dangerous drug to consumers without assuming control over and responsibility for its administration. Mere advice or instructions regarding administration do not constitute control 	427 428 429 430 431 432 433 434 435

understandable manner, all of the following:

of dangerous drugs at wholesale.

(1) The proprietary name of the drug product; 440 (2) The established (generic) name of the drug product; 441 (3) The strength of the drug product if the product 442 contains a single active ingredient or if the drug product 443 contains more than one active ingredient and a relevant strength 444 can be associated with the product without indicating each 445 active ingredient. The established name and quantity of each 446 active ingredient are required if such a relevant strength 447 cannot be so associated with a drug product containing more than 448 449 one ingredient. 450 (4) The dosage form; (5) The price charged for a specific quantity of the drug 451 product. The stated price shall include all charges to the 452 consumer, including, but not limited to, the cost of the drug 453 product, professional fees, handling fees, if any, and a 454 statement identifying professional services routinely furnished 455 by the pharmacy. Any mailing fees and delivery fees may be 456 stated separately without repetition. The information shall not 457 be false or misleading. 458 (O) "Wholesale distributor of dangerous drugs" or 459 "wholesale distributor" means a person engaged in the sale of 460 dangerous drugs at wholesale and includes any agent or employee 461 of such a person authorized by the person to engage in the sale 462

(P) "Manufacturer of dangerous drugs" or "manufacturer"
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means a person, other than a pharmacist or prescriber, who
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manufactures dangerous drugs and who is engaged in the sale of
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those dangerous drugs.

(Q) "Terminal distributor of dangerous drugs" or "terminal 468

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distributor" means a person who is engaged in the sale of 469 dangerous drugs at retail, or any person, other than a 470 manufacturer, repackager, outsourcing facility, third-party 471 logistics provider, wholesale distributor, or pharmacist, who 472 has possession, custody, or control of dangerous drugs for any 473 purpose other than for that person's own use and consumption. 474 "Terminal distributor" includes pharmacies, hospitals, nursing 475 homes, and laboratories and all other persons who procure 476 dangerous drugs for sale or other distribution by or under the 477 supervision of a pharmacist, licensed health professional 478 authorized to prescribe drugs, or other person authorized by the 479 state board of pharmacy. 480

(R) "Promote to the public" means disseminating a
representation to the public in any manner or by any means,
other than by labeling, for the purpose of inducing, or that is
likely to induce, directly or indirectly, the purchase of a
dangerous drug at retail.

(S) "Person" includes any individual, partnership,
association, limited liability company, or corporation, the
state, any political subdivision of the state, and any district,
department, or agency of the state or its political
subdivisions.

(T) (1) "Animal shelter" means a facility operated by a
humane society or any society organized under Chapter 1717. of
the Revised Code or a dog pound operated pursuant to Chapter
955. of the Revised Code.

(2) "County dog warden" means a dog warden or deputy dog
warden appointed or employed under section 955.12 of the Revised
Code.

(U) "Food" has the same meaning as in section 3715.01 of 498 the Revised Code. 499 (V) "Pain management clinic" has the same meaning as in 500 section 4731.054 of the Revised Code. 501 (W) "Investigational drug or product" means a drug or 502 product that has successfully completed phase one of the United 503 States food and drug administration clinical trials and remains 504 under clinical trial, but has not been approved for general use 505 by the United States food and drug administration. 506 "Investigational drug or product" does not include controlled 507 substances in schedule I, as defined in section 3719.01 of the 508 Revised Code. 509 (X) "Product," when used in reference to an 510 investigational drug or product, means a biological product, 511 other than a drug, that is made from a natural human, animal, or 512 microorganism source and is intended to treat a disease or 513 medical condition. 514

(Y) "Third-party logistics provider" means a person that
provides or coordinates warehousing or other logistics services
pertaining to dangerous drugs including distribution, on behalf
of a manufacturer, wholesale distributor, or terminal
distributor of dangerous drugs, but does not take ownership of
the drugs or have responsibility to direct the sale or
disposition of the drugs.

(Z) "Repackager of dangerous drugs" or "repackager" means
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 a person that repacks and relabels dangerous drugs for sale or
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 distribution.

(AA) "Outsourcing facility" means a facility that is525engaged in the compounding and sale of sterile drugs and is526

registered as an outsourcing facility with the United States	527
food and drug administration.	528
(BB) "Laboratory" means a laboratory licensed under this	529
chapter as a terminal distributor of dangerous drugs and	530
entrusted to have custody of any of the following drugs and to	531
use the drugs for scientific and clinical purposes and for	532
purposes of instruction: dangerous drugs that are not controlled	533
substances, as defined in section 3719.01 of the Revised Code;	534
dangerous drugs that are controlled substances, as defined in	535
that section; and controlled substances in schedule I, as	536
defined in that section.	537
Section 2. That existing sections 3719.41 and 4729.01 of	538
the Revised Code are hereby repealed.	539
Section 3. Section 4729.01 of the Revised Code is	540
presented in this act as a composite of the section as amended	541
by H.B. 24, H.B. 197, H.B. 203, H.B. 231, H.B. 341, and S.B. 57,	542
all of the 133rd General Assembly. The General Assembly,	543
applying the principle stated in division (B) of section 1.52 of	544
the Revised Code that amendments are to be harmonized if	545
reasonably capable of simultaneous operation, finds that the	546
composite is the resulting version of the section in effect	547
prior to the effective date of the section as presented in this	548
act.	549