

**As Introduced**

**135th General Assembly**

**Regular Session**

**2023-2024**

**H. B. No. 495**

**Representatives Carruthers, Sweeney**

**Cosponsors: Representatives Grim, Brennan, Brent, Robb Blasdel, Russo,  
Dell'Aquila**

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**A BILL**

To amend sections 3715.01, 3715.025, 3715.99, and 1  
3717.01 and to enact section 3715.522 of the 2  
Revised Code to prohibit the sale of cosmetics 3  
tested on animals except under certain specified 4  
circumstances. 5

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

**Section 1.** That sections 3715.01, 3715.025, 3715.99, and 6  
3717.01 be amended and section 3715.522 of the Revised Code be 7  
enacted to read as follows: 8

**Sec. 3715.01.** (A) As used in this chapter: 9

(1) "Person" means an individual, partnership, 10  
corporation, or association. 11

(2) "Food" means: 12

(a) Articles used for food or drink for humans or animals; 13

(b) Chewing gum; 14

(c) Articles used for components of any such articles. 15

(3) "Drug" means:	16
(a) Articles recognized in the United States pharmacopoeia and national formulary, or any supplement to them;	17 18
(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;	19 20 21
(c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals;	22 23 24
(d) Articles intended for use as a component of any of the foregoing articles, other than devices or their components, parts, or accessories.	25 26 27
(4) "Device," except when used in division (B)(1) of this section and in division (A)(10) of section 3715.52, division (F) of section 3715.60, division (A)(5) of section 3715.64, and division (C) of section 3715.67 of the Revised Code, means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:	28 29 30 31 32 33 34
(a) Recognized in the United States pharmacopoeia and national formulary, or any supplement to them;	35 36
(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or animals;	37 38 39
(c) Intended to affect the structure or any function of the body of humans or animals, and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or animals and is not dependent upon	40 41 42 43

being metabolized for the achievement of any of its principal 44  
intended purposes. 45

(5) "Cosmetic" means: 46

(a) Articles intended to be rubbed, poured, sprinkled, or 47  
sprayed on, introduced into, or otherwise applied to the human 48  
body or any part thereof for cleansing, beautifying, promoting 49  
attractiveness, or altering the appearance; 50

(b) Articles intended for use as a component of any such 51  
article, except that "cosmetic" does not include soap. 52

(6) "Cosmetic ingredient" means a chemical or mixture used 53  
as a component in the manufacture of a cosmetic product, as 54  
described in 21 C.F.R. 700.3(e). 55

(7) "Cosmetic product" means a finished cosmetic, the 56  
manufacture of which has been completed. 57

(8) "Cosmetic animal testing" means the internal or 58  
external application or exposure of any cosmetic product or 59  
cosmetic ingredient to the skin, eyes, or any other organ or 60  
extremity of a live, nonhuman vertebrate for the purpose of 61  
evaluating the safety or efficacy of a cosmetic product or a 62  
cosmetic ingredient or nonfunctional constituent for use in a 63  
cosmetic product. 64

(9) "Cosmetic manufacturer" means any person whose name 65  
appears on the label of a cosmetic product pursuant to the 66  
requirements of 21 C.F.R. 701.12. 67

(10) "Cosmetic supplier" means any person that provides, 68  
directly or through a third party, a cosmetic ingredient used by 69  
a cosmetic manufacturer in the formulation of a cosmetic 70  
product. 71

(11) "Nonfunctional constituent" means any incidental ingredient, as defined in 21 C.F.R. 701.3. 72  
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(12) "Label" means a display of written, printed, or graphic matter upon the immediate container, exclusive of package liners, of any article. 74  
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Any word, statement, or other information required by this chapter to appear on the label must appear on the outside container or wrapper, if any, of the retail package of the article, or the label must be easily legible through the outside container or wrapper. 77  
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~~(7)~~(13) "Labeling" means all labels and other written, printed, or graphic matter: 82  
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- (a) Upon an article or any of its containers or wrappers; 84
- (b) Accompanying such article. 85

~~(8)~~(14) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics. 86  
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~~(9)~~(15) "New drug" means: 91

(a) Any drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof; 92  
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(b) Any drug the composition of which is such that the drug, as a result of investigation to determine its safety for use under such conditions, has become so recognized, but that 97  
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has not, other than in an investigation, been used to a material 100  
extent or for a material time under such conditions. 101

~~(10)~~ (16) "Contaminated with filth" applies to any food, 102  
drug, device, or cosmetic that has not been protected as far as 103  
may be necessary by all reasonable means from dust, dirt, and 104  
all foreign or injurious substances. 105

~~(11)~~ (17) "Honey" means the nectar and saccharine 106  
exudation of plants that has been gathered, modified, and stored 107  
in a honeycomb by honeybees. 108

~~(12)~~ (18) "Finished dosage form" means the form of a drug 109  
that is, or is intended to be, dispensed or administered to 110  
humans or animals and requires no further manufacturing or 111  
processing other than packaging, reconstituting, or labeling. 112

~~(13)(a)~~ (19)(a) "Manufacture" means the planting, 113  
cultivating, harvesting, processing, making, preparing, or 114  
otherwise engaging in any part of the production of a drug by 115  
propagating, compounding, converting, or processing, either 116  
directly or indirectly by extracting from substances of natural 117  
origin, or independently by means of chemical synthesis, or by a 118  
combination of extraction and chemical synthesis, and includes 119  
the following: 120

(i) Any packaging or repackaging of the drug or labeling 121  
or relabeling of its container, the promotion and marketing of 122  
the drug, and other activities incident to production; 123

(ii) The preparation and promotion of commercially 124  
available products from bulk compounds for resale by pharmacies, 125  
licensed health professionals authorized to prescribe drugs, or 126  
other persons. 127

(b) "Manufacture" does not include the preparation, 128

compounding, packaging, or labeling of a drug by a pharmacist as	129
an incident to either of the following:	130
(i) Dispensing a drug in the usual course of professional	131
practice;	132
(ii) Providing a licensed health professional authorized	133
to prescribe drugs with a drug for the purpose of administering	134
to patients or for using the drug in treating patients in the	135
professional's office.	136
<del>(14)</del> <u>(20)</u> "Dangerous drug" has the same meaning as in	137
section 4729.01 of the Revised Code.	138
<del>(15)</del> <u>(21)</u> "Generically equivalent drug" means a drug that	139
contains identical amounts of the identical active ingredients,	140
but not necessarily containing the same inactive ingredients,	141
that meets the identical compendial or other applicable standard	142
of identity, strength, quality, and purity, including potency,	143
and where applicable, content uniformity, disintegration times,	144
or dissolution rates, as the prescribed brand name drug and the	145
manufacturer or distributor holds, if applicable, either an	146
approved new drug application or an approved abbreviated new	147
drug application unless other approval by law or from the	148
federal food and drug administration is required.	149
No drug shall be considered a generically equivalent drug	150
for the purposes of this chapter if it has been listed by the	151
federal food and drug administration as having proven	152
bioequivalence problems.	153
<del>(16)</del> <u>(22)</u> "Licensed health professional authorized to	154
prescribe drugs" and "prescriber" have the same meanings as in	155
section 4729.01 of the Revised Code.	156
<del>(17)</del> <u>(23)</u> "Home" means the primary residence occupied by	157

the residence's owner, on the condition that the residence 158  
contains only one stove or oven used for cooking, which may be a 159  
double oven, designed for common residence usage and not for 160  
commercial usage, and that the stove or oven be operated in an 161  
ordinary kitchen within the residence. 162

~~(18)~~ (24) "Potentially hazardous food" means a food that 163  
is natural or synthetic, to which any of the following apply: 164

(a) It has a pH level greater than 4.6 when measured at 165  
seventy-five degrees fahrenheit or twenty-four degrees celsius. 166

(b) It has a water activity value greater than 0.85. 167

(c) It requires temperature control because it is in a 168  
form capable of supporting the rapid and progressive growth of 169  
infectious or toxigenic microorganisms, the growth and toxin 170  
production of clostridium botulinum, or in the case of raw 171  
shell eggs, the growth of salmonella enteritidis. 172

~~(19)~~ (25) "Cottage food production operation" means a 173  
person who, in the person's home, produces food items that are 174  
not potentially hazardous foods, including bakery products, 175  
jams, jellies, candy, fruit butter, and similar products 176  
specified in rules adopted pursuant to section 3715.025 of the 177  
Revised Code. 178

~~(20)~~ (26) "Biological product" means, except as provided 179  
in section 3715.011 of the Revised Code, a drug that is a 180  
biological product, as defined on ~~the effective date of this~~ 181  
~~amendment~~ March 21, 2017, in subsection (i) of section 351 of 182  
the "Public Health Service Act," 42 U.S.C. 262(i). 183

~~(21)~~ (27) "Interchangeable biological product" means, 184  
except as provided in section 3715.011 of the Revised Code, both 185  
of the following: 186

(a) A biological product that, on ~~the effective date of~~ 187  
~~this amendment~~ March 21, 2017, has been determined by the United 188  
States food and drug administration to meet the standards for 189  
interchangeability set forth in subsection (k) of section 351 of 190  
the "Public Health Service Act," 42 U.S.C. 262(k), as amended, 191  
and has been licensed under that subsection; 192

(b) A biological product that, prior to ~~the effective date~~ 193  
~~of this amendment~~ March 21, 2017, was determined by the United 194  
States food and drug administration to be therapeutically 195  
equivalent as set forth in its publication titled "Approved Drug 196  
Products with Therapeutic Equivalence Evaluations." 197

(B) For the purposes of sections 3715.52 to 3715.72 of the 198  
Revised Code: 199

(1) If an article is alleged to be misbranded because the 200  
labeling is misleading, or if an advertisement is alleged to be 201  
false because it is misleading, then in determining whether the 202  
labeling or advertisement is misleading, there shall be taken 203  
into account, among other things, not only representations made 204  
or suggested by statement, word, design, device, sound, or in 205  
any combination thereof, but also the extent to which the 206  
labeling or advertisement fails to reveal facts material in the 207  
light of such representations or material with respect to 208  
consequence which may result from the use of the article to 209  
which the labeling or advertisement relates under the conditions 210  
of use prescribed in the labeling or advertisement thereof or 211  
under such conditions of use as are customary or usual. 212

(2) The provisions regarding the selling of food, drugs, 213  
devices, or cosmetics include the manufacture, production, 214  
processing, packing, exposure, offer, possession, and holding of 215  
any such article for sale; and the sale, dispensing, and giving 216



of any such article, and the supplying or applying of any such 217  
articles in the conduct of any food, drug, or cosmetic 218  
establishment. The provisions do not prohibit a licensed health 219  
professional authorized to prescribe drugs from administering or 220  
personally furnishing a drug or device to a patient. 221

(3) The representation of a drug, in its labeling or 222  
advertisement, as an antiseptic is a representation that it is a 223  
germicide, except in the case of a drug purporting to be, or 224  
represented as, an antiseptic for inhibitory use as a wet 225  
dressing, ointment, dusting powder, or other use that involves 226  
prolonged contact with the body. 227

(4) Whenever jurisdiction is vested in the director of 228  
agriculture or the state board of pharmacy, the jurisdiction of 229  
the board shall be limited to the sale, offering for sale, 230  
giving away, delivery, or dispensing in any manner of drugs at 231  
the wholesale and retail levels or to the consumer and shall be 232  
exclusive in the case of such sale, offering for sale, giving 233  
away, delivery, or dispensing in any manner of drugs at the 234  
wholesale and retail levels or to the consumer in any place 235  
where prescriptions are dispensed or compounded. 236

(5) To assist in effectuating the provisions of those 237  
sections, the director of agriculture or state board of pharmacy 238  
may request assistance or data from any government or private 239  
agency or individual. 240

**Sec. 3715.025.** (A) A cottage food production operation 241  
shall not process acidified foods, low acid canned foods, or 242  
potentially hazardous foods. 243

(B) The director of agriculture shall adopt rules in 244  
accordance with Chapter 119. of the Revised Code specifying the 245

food items a cottage food production operation may produce that 246  
are in addition to the food items identified by name in division 247  
~~(A) (19)~~ (A) (25) of section 3715.01 of the Revised Code. The 248  
director shall not adopt rules that permit a cottage food 249  
production operation to produce any food that is a potentially 250  
hazardous food. 251

Sec. 3715.522. (A) Subject to division (B) of this 252  
section, no cosmetic manufacturer shall knowingly sell, offer 253  
for sale, or deliver at retail or to a consumer, a cosmetic 254  
product developed or manufactured using cosmetic animal testing 255  
that was conducted or contracted for by the cosmetic 256  
manufacturer, or any cosmetic supplier of the cosmetic 257  
manufacturer. 258

(B) Division (A) of this section does not apply to any of 259  
the following: 260

(1) Animal testing conducted outside of the United States 261  
in order to comply with a requirement of a foreign regulatory 262  
authority, provided that no evidence derived from such testing 263  
was relied upon by the cosmetic manufacturer or cosmetic 264  
supplier to substantiate the safety of the cosmetic product 265  
sold, offered, or delivered in this state; 266

(2) Animal testing conducted for any cosmetic or cosmetic 267  
ingredient subject to regulation under Chapter V of the "Federal 268  
Food, Drug, and Cosmetic Act," 21 U.S.C. 351, et seq.; 269

(3) Animal testing conducted for an ingredient intended to 270  
be used in a product other than a cosmetic and conducted 271  
pursuant to a requirement of the department of agriculture, 272  
state board of pharmacy, or a federal, state, or foreign 273  
regulatory authority, provided that no evidence derived from 274

such testing was relied upon to substantiate the safety of the 275  
cosmetic product sold, offered, or delivered in this state, 276  
unless all of the following apply: 277

(a) There is no non-animal method or strategy recognized 278  
by the department of agriculture, state board of pharmacy, a 279  
federal agency, or the organization for economic co-operation 280  
and development for the relevant safety endpoints for the 281  
cosmetic ingredient; 282

(b) There is documented evidence that animal testing was 283  
conducted with the intent to use the ingredient in a product 284  
other than a cosmetic; 285

(c) The ingredient has been used in a product other than 286  
cosmetics at least twelve months before the cosmetic 287  
manufacturer or cosmetic supplier relied on the results of 288  
animal testing. 289

(4) Animal testing requested, required, or conducted by 290  
the department of agriculture, state board of pharmacy, or a 291  
federal or state regulatory authority, if all of the following 292  
apply: 293

(a) There is no non-animal method or strategy recognized 294  
by the department of agriculture, state board of pharmacy, a 295  
federal agency, or the organization for economic co-operation 296  
and development for the relevant safety endpoints for the 297  
cosmetic ingredient or nonfunctional constituent; 298

(b) There is a reasonable probability that the ingredient 299  
or nonfunctional constituent poses a specific and serious 300  
adverse human health risk and the need to conduct an animal test 301  
is justified and supported by a detailed research protocol 302  
proposed as the basis for the evaluation of the cosmetic 303

ingredient or nonfunctional constituent; 304

(c) The cosmetic ingredient is widely used and cannot be 305  
replaced by another cosmetic ingredient capable of performing a 306  
similar function. 307

(5) A cosmetic, if the cosmetic in its final form was 308  
tested on animals before the effective date of this enactment, 309  
even if the cosmetic is manufactured on or after that date, 310  
provided that no new animal testing in violation of this section 311  
is conducted on the cosmetic by, or on behalf of, the cosmetic 312  
manufacturer; 313

(6) A cosmetic ingredient, if the cosmetic ingredient was 314  
tested on animals before the effective date of this enactment, 315  
even if the cosmetic ingredient is manufactured on or after that 316  
date, provided that no new animal testing in violation of this 317  
section is conducted on the cosmetic ingredient by, or on behalf 318  
of, the cosmetic manufacturer; 319

(7) A cosmetic manufacturer or cosmetic supplier 320  
reviewing, assessing, or retaining evidence from animal testing. 321

(C) No county, township, or municipal corporation, 322  
including a county that has adopted a charter under Ohio 323  
Constitution, Article X, Section 3, and a township that adopts a 324  
limited home rule government, shall prohibit or enforce a 325  
prohibition relating to cosmetic animal testing other than the 326  
prohibitions set forth in this section or identical 327  
prohibitions, which may be adopted by ordinance or resolution of 328  
the board of county commissioners, board of township trustees, 329  
or legislative authority of the municipal corporation. 330

**Sec. 3715.99.** (A) Whoever violates section 3715.13 or 331  
3715.38 of the Revised Code is guilty of a minor misdemeanor. 332

(B) Whoever violates section 3715.22, 3715.25, or 3715.27 333  
of the Revised Code is guilty of a misdemeanor of the fourth 334  
degree. 335

(C) Whoever violates section 3715.23 or 3715.34 of the 336  
Revised Code is guilty of a misdemeanor of the second degree. 337

(D) Whoever violates section 3715.52 or 3715.65 of the 338  
Revised Code is guilty of a misdemeanor of the fourth degree on 339  
a first offense; on each subsequent offense, the person is 340  
guilty of a misdemeanor of the second degree. 341

(E) Whoever violates section 3715.521 of the Revised Code 342  
is guilty of a minor misdemeanor. A violation of that section 343  
occurs on a daily basis, not according to the number of times 344  
per day that an expired drug, baby food, or infant formula is 345  
sold, offered for sale, or delivered at retail or to the 346  
consumer. Each day of violation is a separate offense. 347

(F) The director of agriculture or the director's designee 348  
shall impose a civil penalty, in accordance with Chapter 119. of 349  
the Revised Code, not exceeding five thousand dollars on whoever 350  
violates section 3715.522 of the Revised Code. The director 351  
shall impose an additional penalty of one thousand dollars for 352  
each day the violation continues. The director shall deposit the 353  
penalty to the credit of the cosmetic animal testing prevention 354  
fund, which is hereby created in the state treasury. All money 355  
in the fund shall be used to offset the costs incurred by the 356  
department of agriculture in enforcing section 3715.522 of the 357  
Revised Code. 358

**Sec. 3717.01.** As used in this chapter: 359

(A) "Ohio uniform food safety code" means the food safety 360  
and related standards adopted under section 3717.05 of the 361

Revised Code.	362
(B) "Food" means any raw, cooked, or processed edible substance used or intended for use in whole or in part for human consumption. "Food" includes ice, water or any other beverage, food ingredients, and chewing gum.	363 364 365 366
(C) "Retail food establishment" means a premises or part of a premises where food is stored, processed, prepared, manufactured, or otherwise held or handled for retail sale. Except when expressly provided otherwise, "retail food establishment" includes a mobile retail food establishment, seasonal retail food establishment, and temporary retail food establishment.	367 368 369 370 371 372 373
As used in this division:	374
(1) "Retail" means the sale of food to a person who is the ultimate consumer.	375 376
(2) "Prepared" means any action that affects a food, including receiving and maintaining it at the temperature at which it was received.	377 378 379
(D) "Seasonal retail food establishment" means a retail food establishment, other than a mobile retail food establishment, that is operated for not more than six months in a licensing period.	380 381 382 383
(E) "Temporary retail food establishment" means a retail food establishment that is operated at an event for not more than five consecutive days, except when operated for more than five consecutive days pursuant to division (E)(2) of section 3717.23 of the Revised Code.	384 385 386 387 388
(F) "Food service operation" means a place, location,	389

site, or separate area where food intended to be served in 390  
individual portions is prepared or served for a charge or 391  
required donation. As used in this division, "served" means a 392  
response made to an order for one or more individual portions of 393  
food in a form that is edible without washing, cooking, or 394  
additional preparation and "prepared" means any action that 395  
affects a food other than receiving or maintaining it at the 396  
temperature at which it was received. 397

Except when expressly provided otherwise, "food service 398  
operation" includes a catering food service operation, food 399  
delivery sales operation, mobile food service operation, 400  
seasonal food service operation, temporary food service 401  
operation, and vending machine location. 402

(G) "Catering food service operation" means a food service 403  
operation where food is prepared for serving at a function or 404  
event held at an off-premises site, for a charge determined on a 405  
per-function or per-event basis. 406

(H) "Food delivery sales operation" means a food service 407  
operation from which individual portions of food are ordered by 408  
a customer, prepared at another food service operation or a 409  
retail food establishment, and delivered to the customer by a 410  
person other than an employee of the food service operation or 411  
retail food establishment that prepared the food. 412

(I) "Mobile food service operation" means a food service 413  
operation that is operated from a movable vehicle, portable 414  
structure, or watercraft and that routinely changes location, 415  
except that if the operation remains at any one location for 416  
more than forty consecutive days, the operation is no longer a 417  
mobile food service operation. "Mobile food service operation" 418  
includes a food service operation that does not remain at any 419

one location for more than forty consecutive days and serves, in 420  
a manner consistent with division (F) of this section, only 421  
frozen desserts; beverages, nuts, popcorn, candy, or similar 422  
confections; bakery products identified in section 911.01 of the 423  
Revised Code; or any combination of those items. 424

(J) "Seasonal food service operation" means a food service 425  
operation, other than a mobile food service operation, that is 426  
operated for not more than six months in a licensing period. 427

(K) "Temporary food service operation" means a food 428  
service operation that is operated at an event for not more than 429  
five consecutive days, except when operated for more than five 430  
consecutive days pursuant to division (E) (2) of section 3717.43 431  
of the Revised Code. 432

(L) "Vending machine location" means an area or room where 433  
one or more vending machines are installed and operated, except 434  
that if the machines within an area are separated by more than 435  
one hundred fifty feet, each area separated by that distance 436  
constitutes a separate vending machine location. As used in this 437  
division, "vending machine" means a self-service device that 438  
automatically dispenses on the insertion of currency, tokens, or 439  
similar means a predetermined unit serving of food, either in 440  
bulk or in package, without having to be replenished after each 441  
use. 442

(M) "Board of health" means a board of health of a city or 443  
general health district or the authority having the duties of a 444  
board of health under section 3709.05 of the Revised Code. 445

(N) "Government entity" means this state, a political 446  
subdivision of this state, another state, or a political 447  
subdivision or other local government body of another state. 448



- (O) "Licensor" means one of the following: 449
- (1) A board of health approved under section 3717.11 of 450  
the Revised Code; 451
- (2) The director of agriculture acting pursuant to section 452  
3717.11 of the Revised Code with respect to the licensing of 453  
retail food establishments; 454
- (3) The director of health acting pursuant to section 455  
3717.11 of the Revised Code with respect to the licensing of 456  
food service operations. 457
- (P) "Licensing period" means the first day of March to the 458  
last day of February of the next succeeding year. 459
- (Q) "Mobile retail food establishment" means a retail food 460  
establishment that is operated from a movable vehicle or other 461  
portable structure, and that routinely changes location, except 462  
that if the establishment operates from any one location for 463  
more than forty consecutive days, the establishment is no longer 464  
a mobile retail food establishment. 465
- (R) "Unprocessed," when used with respect to fruits and 466  
vegetables, means that the fruits and vegetables are not 467  
processed beyond merely rough trimming and rinsing. 468
- (S) "Cottage food production operation" has the same 469  
meaning as in ~~division (A) (19) of~~ section 3715.01 of the Revised 470  
Code. 471
- Section 2.** That existing sections 3715.01, 3715.025, 472  
3715.99, and 3717.01 of the Revised Code are hereby repealed. 473