OFFICE OF THE SECRETARY OF STATE
TOBIAS READ
SECRETARY OF STATE

MICHAEL KAPLAN
DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 603
DEPARTMENT OF AGRICULTURE

FILED
11/26/2025 9:08 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Amending Animal Remedies, Pharmaceuticals, and Veterinary Biologicals Rules

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 12/31/2025 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Ryan Schulz
503-986-4760
rulemaking@oda.oregon.gov

635 Capitol St NE
Salem,OR 97301

Filed By:
Sunny Summers
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 12/16/2025
TIME: 10:00 AM - 11:00 AM
OFFICER: Sunny Summers

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 25254579628269
SPECIAL INSTRUCTIONS:
Meeting ID: 252 545 796 282 69
Passcode: LS36md76

+1 503-446-4951,,439928395#

NEED FOR THE RULE(S)

These rule changes are needed to clarify ambiguous rules/requirements that have created confusion among manufacturers over what products must be registered and how to register those products. Clarification was also needed regarding how civil penalties and other enforcement mechanisms may be applied to violations.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Oregon Revised Statutes chapter 596

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

These changes are not anticipated to affect racial equity in Oregon.

FISCAL AND ECONOMIC IMPACT:

These rules are not anticipated to have a fiscal impact beyond current requirements.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s):

a. These rules are anticipated to have a minimal impact on manufacturers of animal remedies, pharmaceuticals, and veterinary biologics.

(2) Effect on small businesses: (a) estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

a. Approximately 650 manufacturers are currently licensed under this program.

b. These rules are not expected to create any new reporting, recordkeeping or administrative activities beyond existing registration requirements.

c. These rules are anticipated to have a minimal cost to manufacturers of animal remedies, pharmaceuticals, and veterinary biologics.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

ODA consulted a Rules Advisory Committee in developing these rules. An invitation for self-nomination was sent to over 17,000 agency contacts, and all nominations were accepted for participation on the RAC.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:
603-012-0210, 603-012-0220, 603-012-0230, 603-012-0240, 603-012-0250

AMEND: 603-012-0210

RULE SUMMARY: Reorder and add additional definitions

CHANGES TO RULE:

603-012-0210
Definitions ¶

In addition to the definitions set forth in ORS 596.095, the following shall apply:¶
(1) "~~Product" means an animal remedy, pharmaceutical or veterinary biologic readily distinguishable from any other animal remedy, pharmaceutical or veterinary biologic by its content, brand name, trade name, manufacturer, use as specified in labeling, or other distinction, but not including size or quantity of packaging~~Animal remedy" means any product used to prevent, inhibit, cure, enhance, or protect the health or well-being of animals, but does not include food, surgical instruments, or accessories. A product will be deemed to be used to prevent, inhibit, cure, enhance, or protect the health or well-being of animals if it contains labeling indicating that it is intended for such use.¶
(2) "Autogenous biologic" means a product that meets the requirements in 9 CFR §113.113 (January 1, 2025

edition).¶
(3) "Feed" has the meaning given that term in ORS 633.006.¶
(4) "Food" means a nutritionally adequate feed for animals other than humans; by specific formula is compounded to be fed as the sole ration and is capable of maintaining life and/or promoting production without any additional substance being consumed except water or forage.¶
(25) "~~Animal remedy" means any product~~Labeling" means all labe~~led for veterinary/animal use to prevent, inhibit or cure or enhance or protect the health or well-being of animals, but does not include food, surgical instruments or accessories~~s and other written or graphic materials in print or electronic form,¶
(a) Upon a product or any of its containers for wrappers, or¶
(b) Accompanying or promoting such product.¶
(6) "Manufacturer" means any person whose name appears on the label of a veterinary product indicating that it is the manufacturer or had the product manufactured for them.¶
(~~3~~7) "Pharmaceutical" means drug products labeled for veterinary/animal use by the U.S. Food and Drug Administration.¶
(~~4~~8) "~~Veterinary biologic" means biological products licensed for veterinary/animal use by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service~~Product" means an item readily distinguishable from any other item by its content, brand name, trade name, manufacturer, use as specified in labeling, formulation, concentration, dosage form, or other distinction, but not including packaging size or quantity.¶
(~~5~~9) "~~Autogenous biologic" means a product derived from a source within the individual animal(s), or~~Repeat violation" means the same or similar violation by a person for which the Department has pursued an enforcement action, including alternative enforcement actions such as a letter of advisement, within the past five years, including a violation which ~~i~~ts ~~confines, upon which it is to be used.¶~~
~~(6) "Food" means materials that are intended to provide energy or other nutrients to an animal. A food can be converted into an animal remedy by virtue of the claims made on the labeling~~the subject of a pending appeal, but not including a violation addressed in an order that has been withdrawn or successfully appealed. Without limiting the foregoing, a person's failure to register a veterinary product after receiving a letter of advisement regarding nonregistration of a different veterinary product shall be considered a repeat violation. ¶
(10) "Veterinary biologic" means biological products licensed for veterinary/animal use by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service.¶
(11) "Veterinary client patient relationship" has the meaning given that term in OAR 875-005-0005¶
(12) "Veterinary product" means an animal remedy, pharmaceutical, or veterinary biologic.
Statutory/Other Authority: ORS 561.190
Statutes/Other Implemented: ORS 596.095

AMEND: 603-012-0220

RULE SUMMARY: Clarify wording of exemptions to match current requirements, moving current license-based exemption to definition of food in 603-012-0210 to match statute.

CHANGES TO RULE:

603-012-0220
Exemptions ¶

The following are exempt from the registration required by ORS 596.100:¶
(1) ~~Animal remed~~Veterinary ~~p~~Products compounded by or for Oregon licensed veterinarians for use in the course of their practice~~.¶~~
~~(2) Animal food if registered with the Department under ORS 633.015~~ under a Veterinary Client Patient Relationship.¶
(~~3~~2) ~~Dog and cat food licensed under ORS 619.031.¶~~
~~(4) Pesticides with an EPA number on their retail packaging~~ Pesticide products regulated under the Federal Insecticide, Fungicide, and Rodenticide Act.
Statutory/Other Authority: ORS 561.190, 596.105
Statutes/Other Implemented: ORS 561.190, 596.105

AMEND: 603-012-0230

RULE SUMMARY: Include explicit requirement to register products annually with information required as part of registration

CHANGES TO RULE:

603-012-0230
Registration and Fees ¶

(1) ~~The annual registration fee for each animal remedy, pharmaceutical or veterinary biologic product~~Each veterinary product, except autogenous biologics, manufactured, compounded, delivered, distributed, or exposed for sale in this state must be registered annually using a form provided by the department, and including the following information in addition to any other information requested by the Department:¶
(a) The complete product name as it appears in on the product labeling including, if applicable, the unique brand, formulation, and/or concentration of the product.¶
(b) Each Universal Product Code (UPC) displayed on labeling. If multiple UPCs are utilized by a single product, a description of distinguishing factors (distributor, package size, etc) between each UPC must also be included.¶
(2) The annual registration fee for each veterinary product except autogenous biologics is $100.¶
(~~2~~3) Each manufacturer of autogenous biologics ~~shall~~must register and pay a total of $100 annually for all autogenous biologic products formulated.
Statutory/Other Authority: ORS 561.190, 596.100
Statutes/Other Implemented: ORS 596.100

REPEAL: 603-012-0240

RULE SUMMARY: This rule is not needed the Department only has enforcement authority against a manufacturer.

CHANGES TO RULE:

~~603-012-0240~~
~~Enforcement~~
~~The following procedures will be followed when enforcement action is undertaken:¶~~
~~(1) Manufacturers will be notified when unregistered products are identified in the marketplace, and will be given 30 days in which to register the product.¶~~
~~(2) If products remain unregistered after the 30 days notice, the retail seller of the product will be notified that product is unregistered and requested to return it to their supplier.¶~~
~~(3) The product will not be eligible to be offered for sale until it is registered.¶~~
~~(4) Unless the retail seller refuses to remove the unregistered product from sale, all subsequent enforcement action will be taken against the manufacturer.~~
~~Statutory/Other Authority: ORS 561.190, 596.020, 596.100~~
~~Statutes/Other Implemented: ORS 596.020, 596.100~~

AMEND: 603-012-0250

RULE SUMMARY: Consolidate violation categories to only 2 categories. Clarify wording to apply only to manufacturer (matching statutory authority), clarify how repeat violations are handled.

CHANGES TO RULE:

603-012-0250
Enforcement Guidelines ¶

(1) The Department may use alternative enforcement actions in addition to, or instead of, assessing a civil penalty. Alternative enforcement actions may include~~,~~ but are not limited to: a letter of advisement; a notice of violation; a stop sale, use or removal; and license/registration revocation, suspension or denial.¶
(2) In addition to any other penalty provided by law, the Director may assess civil penalties for commission of acts prohibited by ORS 596.100. Civil penalties will be assessed in accordance with the magnitude of the violation. Prohibited acts are categorized by magnitude of violation as follows:¶
(a) Category ~~I (Major)~~1: In addition to taking any alternative enforcement action deemed necessary to protect the public interest, the Department will issue a civil penalty for a Category ~~I~~1 violation. Category ~~I~~1 violations include:¶
(A) Registering or attempting to register any product using fraudulent or deceptive practices in an effort to evade or attempt to evade the requirement of ORS 596.100 or rules adopted there-under;¶
(B) Submitting false or fraudulent applications, records, invoices or reports; and¶
(C) Making any false or misleading representation in connection with the sale, offer for sale, or distribution of an animal remedy, veterinary biologic or pharmaceutical.¶
(D) Impeding, obstructing, hindering or otherwise preventing or attempting to prevent the Department from performing its duties under ORS 596.100.¶
(b) Category ~~II (Moderate): Prior to issuing a civil penalty for a Category II violation, the Department will take written alternative enforcement action and may allow a specified amount of time to take corrective action. Failure to complete the required corrective action within the specified time period will result in the immediate issuance of~~2: Except for a repeat violation, for which the Department may immediately issue a civil penalty, prior to issuing a civil penalty. for a Category ~~II~~2 violation~~s include: making any false or misleading representation in connection with the sale, offer for sale, or distribution of an animal remedy, veterinary biologic or pharmaceutical.¶~~
~~(c) Category III (Minor): Prior to issuing a civil penalty for a Category III violation~~ against a manufacturer, the Department will take written alternative enforcement action and will allow a specified amount of time to take corrective action. Failure to complete the corrective action within the specified time period or repeat violations may result in the immediate issuance of a civil penalty. Category ~~III~~2 violations include:¶
(A) Selling, offering for sale, or distributing a~~n animal remedy, veterinary biologic or pharmaceutical~~ veterinary product that is not registered with the ~~State~~ Department ~~of Agricultu~~under ORS 596.100; and¶
(B) Failing, refusing, or neglecting to pay registration fees required under ORS 596.100; and¶
(~~B~~C) Failing, refusing, or neglecting to p~~ay~~rovide complete product registration ~~fee~~information as required under O~~RS 596.100~~AR 603-012-0230(1).¶
(3)(a) Maximum civil penalties are not to exceed the following:¶
(A) Category ~~–~~ 1¶
(i) First ~~V~~violation - ~~2~~$500,¶
(ii) Second ~~V~~violation - ~~3rd Violation.¶~~
~~Category I (Major) - $500 - $1,500 - $2,500.¶~~
~~Category II (Moderate) $250 - $750 - $2,500.¶~~
~~Category III (Minor) - $125 - $375~~$1,500, and¶
(iii) Third or subsequent violations - $2,500.¶
(B) Category 2¶
(i) First violation - $250,¶
(ii) Second violation - $750, and¶
(iii) Third or subsequent violations - $2,500.¶
(4b) ~~A civil penalty assessed under ORS 596.995 may be remitted or reduced upon such terms~~In determining whether a violation is first, second, or third violation, the Department will focus on the nature of the actions and not the specific product involved, and ~~conditions as the Dire~~may consider a subsequent failure to register a product or ~~of Agriculture deems proper and consistent with public health and safety.~~a subsequent sale of an unregistered product, even if a different product than involved in the earlier violation, a second or third violation. ¶
(~~4~~5) ~~A~~Notwithstanding sections (2) and (3) of this rule, any violation that arises from gross negligence or willful

misconduct and results in substantial harm to human health, animal health, or the environment may be subject to a civil penalty of not more than $2,500 for the initial violation or any subsequent violation. In the context of the acts prohibited in this section, "refusing" constitutes willful misconduct that is subject to a civil penalty of not more than $2,500 for the initial violation or any subsequent violation.
Statutory/Other Authority: ORS 561.190
Statutes/Other Implemented: ORS 596.100, 596.955