

603-012-0210 – Definitions

In addition to the definitions set forth in ORS 596.095, the following shall apply:

- (1) "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 man; 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.
- (5) "Labeling" means all labels 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.
- (6) "Pharmaceutical" means drug products labeled for veterinary/animal use by the U.S. Food and Drug Administration
- ~~(47)~~ "Product" means an animal remedy, pharmaceutical or veterinary biologic item readily distinguishable from any other animal remedy, pharmaceutical or veterinary biologic 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 of packaging.
- (8) "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a violation which is the subject of a pending appeal, but not including a violation addressed in an order that has been withdrawn or successfully appealed.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.
- (9) "Veterinary biologic" means biological products licensed for veterinary/animal use by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service.
- ~~(9)~~10 "Veterinary client patient relationship" has the meaning given that term in OAR 875-005-0005
- ~~(9)~~11 "Veterinary product" means an animal remedy, pharmaceutical, or veterinary biologic.

- ~~(2) "Animal remedy" means any product labeled 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.~~
- ~~(3) "Pharmaceutical" means drug products labeled for veterinary/animal use by the U.S. Food and Drug Administration.~~
- ~~(4) "Veterinary biologic" means biological products licensed for veterinary/animal use by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service.~~
- ~~(5) "Autogenous biologic" means a product derived from a source within the individual animal(s), or its 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.~~

Statutory/Other Authority: ORS 561.190
Statutes/Other Implemented: ORS 596.095

Existing Rule: <https://secure.sos.state.or.us/oard/view.action?ruleNumber=603-012-0210>

603-012-0220 – Exemptions

The following are exempt from the registration required by ORS 596.100:

- (1) ~~Animal remedy products~~ Veterinary Products compounded by Oregon licensed veterinarians for use in the course of their practice under a Veterinary Client Patient Relationship.
- (2) ~~Animal food if registered with the Department under ORS 633.015.~~
- (3) ~~Dog and cat food licensed under ORS 619.031.~~
- (4) ~~Pesticides~~ Pesticide products regulated under the Federal Insecticide, Fungicide, and Rodenticide Act with an EPA number on their retail packaging.

Statutory/Other Authority: ORS 561.190 & 596.105

Statutes/Other Implemented: ORS 561.190 & 596.105

Existing Rule: <https://secure.sos.state.or.us/oard/view.action?ruleNumber=603-012-0220>

603-012-0230

Fees**Registration and Fees**

- (1) 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.
- (42) The annual registration fee for each veterinary product except autogenous biologics ~~animal remedy, pharmaceutical or veterinary biologic product~~ is \$100.
- (23) Each manufacturer of autogenous biologics ~~shall~~ must register and pay a total of \$100 annually for all autogenous biologic products ~~products~~ formulated.

Statutory/Other Authority: ORS 561.190 & 596.100

Statutes/Other Implemented: ORS 596.100

Existing Rule: <https://secure.sos.state.or.us/oard/view.action?ruleNumber=603-012-0240>

603-012-0240

Enforcement for Unregistered Products

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 remains unregistered after the 30 days notice(), the Department will notify the retail seller of the product will be notified that product is unregistered and requested to return it to their supplier cannot be offered for sale until it is registered.~~
- (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 continues to offer the product from sale after the notice provided under section (2) of this rule, all subsequent enforcement action will be taken against the manufacturer. If the retail seller continues to offer the product for sale after the notice provided under section (2), the Department may, without additional written alternative enforcement action or additional time to take corrective action, and without limiting other remedies available against the retail seller or against the manufacturer or otherwise relating to the unregistered product, immediately assess a civil penalty against the retail seller.~~

Statutory/Other Authority: ORS 561.190, 596.020 & 596.100

Statutes/Other Implemented: ORS 596.020 & 596.100

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 1 I (Major)~~: 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 1 I~~ violation. ~~Category 1 I~~ 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 a civil penalty. Category II violations 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 2 III (Minor)~~: Except for a repeat violation, for which the Department may immediately issue a civil penalty, ~~Prior to issuing a civil penalty for a Category 2 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 2 III~~ violations include:
 - (A) Selling, offering for sale, or distributing ~~an animal remedy, veterinary biologic or pharmaceutical product~~ a veterinary product that is not registered with the ~~State Department of Agriculture~~ Department under ORS 596.100; and
 - (B) Failing, refusing, or neglecting to pay registration fees required under ORS 596.100; and-
 - (C) Failing, refusing, or neglecting to provide complete product registration information as required under OAR 603-012-0230(1).
- (3) (a) Maximum civil penalties are not to exceed the following:

Category — 1st Violation — 2nd Violation — 3rd Violation.

Category ~~1I (Major)~~ — \$500 — \$1,500 — \$2,500.

Category ~~2II (Moderate)~~ — \$250 — \$750 — \$2,500.

Category III (Minor) — \$125 — \$375 — \$2,500.

(b) 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 may consider a subsequent failure to register a product or a subsequent sale of an unregistered product, even if a different product than involved in the earlier violation, a second or third violation.

~~(4) A civil penalty assessed under ORS 596.995 may be remitted or reduced upon such terms and conditions as the Director of Agriculture deems proper and consistent with public health and safety.~~

~~(54)~~ Notwithstanding sections (2) and (3) of this rule, A 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 ~~then than~~ 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

Existing Rule: <https://secure.sos.state.or.us/oard/view.action?ruleNumber=603-012-0250>